STATE OF COLORADO

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Dedicated :o protecting and improving the health and environment of the people of Colorado

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Colorado Department
of Public Health
and Environment

NOTICE OF PUBLIC RULE-MAKING HEARING
BEFORE THE COLORADO BOARD OF HEALTH

NOTICE is hereby given pursuant to the provisions of Section 24-4-103, C.R.S., that the Colorado Board of Health will conduct a public rule-making hearing on October 17, 2012 in the Sabin-Cleere Conference Room of the Colorado Department of Public Health and Environment, Bldg. A, First Floor, 4300 Cherry Creek Drive, South, Denver, CO 80246, to consider the promulgation of Rules and Regulations Pertaining to Epidemic and Communicable Disease Control, 6 CCR 1009-1, Regulations 1 and 3. The Board meeting commences in the morning. For the specific time this hearing is scheduled, please consult the meeting agenda on the Board's Web site at http://www.cdphe.state.co.us/op/bh/index.html on or after Friday, October 5, 2012, or call (303) 692-3464.

The purpose of this hearing is to receive public comments on proposed revisions to 6 CCR 1009-1, the Rules and Regulations Pertaining to Epidemic and Communicable Disease Control, Regulations 1 and 3. The proposed changes to the rules include the expansion of one new provider reportable condition from the Denver metropolitan area to the entire state in Regulation 1 and the addition of two new laboratory reportable conditions to Regulation 3.

Specifically, the rules are modified to expand healthcare-associated infections (HAIs) in the list of provider reportable conditions in Regulation 1 from the five-county Denver metropolitan area (Adams, Arapahoe, Denver, Douglas, Jefferson) to the state of Colorado. This condition was added in December 2010 for the purpose of facilitating applied public health projects as part of the Department's Emerging Infections Program cooperative agreement with the Centers for Disease Control and Prevention (CDC) in collaboration with facilities choosing to voluntarily participate in these projects. Colorado receives federal funding through the CDC Emerging Infections Program to participate in these HAI projects. By expanding this reportable condition from the Denver metropolitan area to the entire state, facilities across the state will be able to easily participate in these projects on a voluntary basis, thus providing valuable knowledge of HAIs statewide, including in rural and urban areas, and resulting in fewer requests to Denver metropolitan area facilities to participate in projects. To avoid placing a reporting burden on healthcare facilities, participation by facilities in these applied public health projects has been and will continue to be voluntary on a project by project basis. Facilities that choose not to participate in a project do not need to report anything new, and therefore, there will be no reporting burden on these facilities. The cooperation between the Department and facilities that do choose to participate will be facilitated by this rule.

The rules are also modified to add the following two conditions to the laboratory reportable conditions list in Regulation 3 – Laboratory Reporting:

1) 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);

and

2) 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

The proposed rules have been developed by the Disease Control and Environmental Epidemiology Division of the Colorado Department of Public Health and Environment pursuant to Section § 25-1-122(1) and § 25-1-108(1)(c)(I), C.R.S.

Copies of the proposed rules may be obtained by contacting the Colorado Department of Public Health and Environment, Disease Control and Environmental Epidemiology Division, DSI A3-3630, 4300 Cherry Creek Drive S., Denver, CO 80246, (303) 692-2491. The proposed amendments will also be available on the Board's Web site at http://www.cdphe.state.co.us/op/bh/index.html under "Notices of Upcoming Public Rulemaking Hearings and Draft Proposed Rules."

The Board encourages all interested persons to participate in the hearing by providing written data, views, or comments, or by making oral comments at the hearing. At the discretion of the Chair, oral testimony at the hearing may be limited to five minutes or less depending on the number of persons wishing to comment.

The Board requests submission of written materials no later than October 3, 2012 to allow the Board sufficient time to review the comments prior to the meeting. Persons wishing to submit written comments or views should submit them to:

Colorado Board of Health
ATTN: Jamie L. Thornton, Program Assistant
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South EDO-A5
Denver, Colorado 80246-1530
FAX: 303-691-7702, e-mail: Jamie.thornton@state.co.us

The proposed revisions to be considered at the hearing, together with the proposed statement of basis and purpose, specific statutory authority and regulatory analysis will be available for inspection at the above address by any person at least five working days prior to the hearing.

Dated this 23 day of August 2012.

Christopher E. Urbina, MD, MPH
Executive Director/Chief Medical Officer

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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,
Regulations 1 and 3

May 16, 2012

Basis and Purpose. The Board of Health is authorized to designate certain communicable conditions reportable to state and local health departments. The list of reportable diseases is reviewed annually and is updated as necessary and appropriate to be current with the communicable diseases and surveillance methods that require responses by state or local public health agencies in Colorado.

The proposed changes include the expansion of one new provider reportable condition from the Denver metropolitan area to the entire state in Regulation 1 and the addition of two new laboratory reportable conditions to Regulation 3. More detailed discussion of these proposed changes is as follows:

1) Change to Regulation 1: Healthcare-Associated Infections

The rules are modified to expand healthcare-associated infections (HAIs) in the list of provider reportable conditions in Regulation 1 from the five-county Denver metropolitan area (Adams, Arapahoe, Denver, Douglas, Jefferson) to the state of Colorado. This condition was added in December 2010 for the purpose of facilitating applied public health projects as part of the Department's Emerging Infections Program cooperative agreement with the Centers for Disease Control and Prevention (CDC) in collaboration with facilities choosing to voluntarily participate in these projects. Currently there is a need to expand this condition statewide to facilitate the participation of healthcare facilities statewide in these voluntary projects.

HAIs are among the leading causes of preventable deaths in the United States, accounting for an estimated 1.7 million infections and 99,000 associated deaths in 2002. In addition to the substantial human suffering caused by healthcare-associated infections, the financial burden attributable to HAIs is estimated to be $28 to $33 billion in excess healthcare costs each year. Only certain HAIs are currently reportable in Colorado under § 25-3-601, C.R.S. for the purposes of reporting risk-adjusted HAI rates by individual health facility. HAIs reportable under this statute include certain surgical site infections (after coronary artery bypass grafts, hysterectomies, hernia repairs, breast procedures, colon procedures, and hip and knee replacements), and certain central line-associated bloodstream infections (in intensive care units, rehabilitation hospitals, and those associated with outpatient dialysis). However, this is only a subset of all HAIs; surgical site infections and bloodstream infections account for 31% of all HAIs, and currently only a subset of those are reportable.

By making HAIs a reportable condition in December 2010 under the Rules and Regulations Pertaining to Epidemic and Communicable Disease Control, Colorado has been able to collaborate with CDC and a federal CDC-funded network of states with the purpose of performing applied public health projects designed to investigate the epidemiology of HAIs, including prevalence and risk factors. Colorado receives federal funding through the CDC Emerging Infections Program to participate in these HAI projects. By expanding this reportable condition from the Denver metropolitan area to the entire state, facilities across the state will be able to easily participate in these projects on a voluntary basis, thus providing valuable knowledge of HAIs statewide, including in rural and urban areas, and resulting in fewer requests to Denver metropolitan area facilities to participate in projects.

To avoid placing a reporting burden on healthcare facilities, participation by facilities in these applied public health projects has been and will continue to be voluntary on a project by project basis. Facilities that choose not to participate in a project do not need to report anything new, and therefore, there will be no reporting burden on these facilities. Facilities that do choose to participate in a project shall make records available for review by the Department upon request within a reasonable timeframe, and this will be acceptable and considered good faith reporting.

This change can be found on page 3, lines 5-6 of the proposed rule.

2) Change to Regulation 3: Addition of selected carbapenem-non-susceptible *Enterobacteriaceae* and carbapenem-non-susceptible *Acinetobacter* to the laboratory reportable conditions list

The rules are modified to add the following two conditions to the laboratory reportable conditions list in Regulation 3 – Laboratory Reporting:

1) *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)

   And

2) *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

Organisms that are not susceptible to the antibiotic class called carbapenems, including

carbapenem-non-susceptible *Enterobacteriaceae* (CRE) and *Acinetobacter baumannii* (CRAB), are emerging and represent a serious threat to public health. There are extremely limited treatment options available for these organisms, there is the potential for widespread transmission (including in the community), and there is an associated high mortality in infected patients. Since carbapenems are often the best option to treat these organisms, very few antimicrobials are currently available to treat organisms that are resistant to carbapenems, and additional broad-spectrum antimicrobial agents are estimated to be years away from approval. Treatment issues have been compounded recently by the emergence of isolates that are resistant to all antimicrobials; no treatment options currently exist for these organisms. The fact that *Enterobacteriaceae* are a common cause of infections in both healthcare and community settings suggests that treatment challenges might become even more complicated if CRE organisms move from healthcare settings, where they currently are primarily found, to outpatient settings. However, knowledge of the distribution and implementing interventions to decrease spread can prevent the continued transmission of these organisms.

CRE have disseminated widely throughout the United States since being first reported in 2001. Despite the spread of CRE, the current U.S. distribution of CRE appears to be heterogeneous; these organisms are commonly isolated from patients in some parts of the U.S, but they are not regularly found in patients from other regions. Even in areas where CRE are found they may be more common in some healthcare settings, such as long-term acute care, than they are in others. Among *Acinetobacter*, multidrug resistance has become an important problem, and in 2009, 66% of *Acinetobacter* were nonsusceptible to at least one carbapenem (CRAB). The regional and overall distribution of CRE and CRAB in Colorado is currently unknown.

In January 2012, the Department received federal funding through the CDC Emerging Infections Program to track both CRE and CRAB. Current CDC guidance recommends public health departments take initiative to understand the prevalence of CRE in their jurisdictions, increase awareness among healthcare facilities about the public health importance of CRE, recommended prevention measures, emphasize the importance of timely recognition of any CRE colonized- or infected-patients, and implement regional and facility-based interventions designed to stop the transmission of these organisms. Since *Enterobacteriaceae* is a family of many bacteria, CDC recommends focusing on the most frequently seen bacteria within the family: *Escherichia coli*, *Klebsiella* species, and *Enterobacter* species.

The Department plans to use CRE data statewide and CRAB data in the 5-county Denver metropolitan area to collect state-wide and regional incidence and rates, detect increases and outbreaks of these organisms, and provide timely information back to facilities. Additionally, receiving reports of CRE and CRAB cases will allow the Department to provide directed education and recommendations to facilities across the healthcare spectrum that are experiencing their first cases of CRE and CRAB to prevent transmission of these organisms.

These changes can be found on page 5, lines 11-19 of the proposed rule.

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3) Change to Regulation 3: Formatting

During the course of these changes, a formatting error was detected in Regulation 3. These changes were corrected.

This change can be found on page 5, lines 20-21 of the proposed rule.

Specific Statutory Authority. These rules are promulgated pursuant to the following statutes: C.R.S. § 25-1-122(1) and C.R.S. § 25-1-108(1)(c)(I).

Major Factual and Policy Issues Encountered. Not applicable.

Alternative Rules Considered and Why Rejected. 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.

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 include, but are not limited to, 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 or be outbreaks of a bioterrorist agent or of a newly recognized entity; such outbreaks or epidemics shall include but are not limited to those related to contaminated medical devices or products or suspected to be 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	Active Tuberculosis

invasive disease caused by Haemophilus influenzae	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 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 ~~located in the Denver Metropolitan Area (Adams, Arapahoe, Denver, Douglas, and Jefferson Counties)~~ 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; 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's diagnosis, whether or not supporting laboratory data are available. All other diseases in list B shall be reported only when the physician'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 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; 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
Chlamydia psittaci	Relapsing Fever (Borrelia species)
Chlamydia trachomatis	Rocky Mountain Spotted Fever
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)
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.

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;

(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 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.