COLORADO
Department of Public Health & Environment

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

To: Members of the State Board of Health

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

Through: Rachel Herlihy, DCEED Division Director RH

Date: July 1, 2015

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to Rules and Regulations Pertaining to Epidemic and Communicable Disease Control, 6 CCR 1009-1 for the rulemaking hearing to occur in September of 2015

The Colorado Department of Public Health and Environment (CDPHE) is proposing a number of updates, clarifications, and technical changes to the Rules and Regulations Pertaining to Epidemic and Communicable Disease Control. These changes are pursuant to Executive Order D 2012-002, which requires the Department to review its regulations to ensure that they are efficient, effective, and essential. Proposed changes are described below.

1) In order to more clearly and efficiently explain who must report conditions (laboratories and/or individuals) and the required timing of reporting (24 hours vs. 7 days), Regulations 1-3 will be reformatted and the three tables now in regulations will be combined.

2) To comply with CDC reporting requirements and be able to link multiple tests performed on the same specimen, an additional requirement for accession number to be included on all reported diseases with supporting laboratory results will be incorporated into Regulation 1.

3) Specific changes under the current Regulation 3 - Laboratory Reporting, are listed below.

    a. Addition of a requirement for clinical and reference laboratories to submit cultures or original clinical material for specific reportable conditions as listed in *Isolate submission to the state public health laboratory* at https://www.colorado.gov/pacific/cdphe/report-a-disease. Testing laboratories will submit bacterial culture isolates or patient clinical material that yields positive findings to the CDPHE Laboratory Services Division.

    Clinical material is defined as:
    (i) A culture isolate containing the infectious organism for which submission of material is required, or
    (ii) If an isolate is not available, material containing the infectious organism for which submission of material is required, in the following order of preference:
    (A) a patient specimen;
    (B) nucleic acid; or
    (C) other laboratory material.

The purpose of this regulatory change is to preserve public health's ability to detect outbreaks and effectively monitor trends in reportable disease in the setting of changing laboratory methods. The list of pathogens for which this will apply will be derived from existing submission guidance; CDPHE is not planning to expand the list for which submission is currently requested. Submission of isolates or clinical material is required in approximately 30 other states.

Submission of isolates and clinical material has long been voluntary in Colorado and submission rates have been very high. For example during 2013-2014, submission rates for reported cases of *Salmonella* and *Streptococcus pneumoniae* were 94% and 96%, respectively. Even for shiga toxin-producing *E. coli* (STEC), which is most frequently tested using culture-independent diagnostic testing (CIDT), submission rates were 94% in this time frame.

This regulation will codify existing practice. CDPHE has an existing courier service in place to transport material to the state public health laboratory. CDPHE will provide necessary transport material and guidance to clinical laboratories for submission of isolates or clinical material.

b. Deletion of methicillin-resistant *Staphylococcus aureus* (MRSA) from the "Conditions Reportable by all Laboratories." We propose deleting this condition in favor of shifting resources to other newly emerging drug resistant organisms, such as carbapenem-resistant *Pseudomonas*.

c. Change in the definition of carbapenem-resistant Enterobacteriaceae (CRE)to be consistent with a proposed national case definition.

d. Addition of carbapenem-resistant *Pseudomonas* – Report within 7 days (by laboratories).

e. Addition of Viral hemorrhagic fever – Report within 24 hours (by individuals or laboratories). Includes: Crimean-Congo hemorrhagic fever, Ebola virus disease, Lassa fever, Lujo fever, Marburg fever, Guanarito fever, Junin fever, Machupo fever, Sabia fever (reportable by individuals; the same-named viruses are reportable by laboratories).

f. Addition of Severe or Novel Coronavirus - Report within 24 hours (by individuals or laboratories)

Severe Acute Respiratory Syndrome (SARS) was previously reportable, but with the recognition of a second severe coronavirus (Middle East Respiratory Syndrome Coronavirus, or MERS-CoV) we propose a broader category that encompasses both conditions.

g. Change *Francisella tularensis* (Tularemia) from the seven day report category to the 24 hour report category.

Timely notification of public health allows for intervention in the areas of appropriate antibiotic choice (there are a limited number of antibiotics approved to treat this condition), and will facilitate quicker investigation and response. Investigation is indicated to prevent other exposures and to identify other cases with the same exposure. This bacterium is also highly infectious when grown in culture and laboratory-acquired infections have been documented. Earlier

reporting will allow for better management of potentially exposed laboratory workers.

4) Specific changes under the current Regulation 2 – Reporting by Individuals, are listed below.

   a. Addition of Acute flaccid myelitis (AFM) - Report within seven days (by individuals).

      AFM is a syndrome characterized by rapid onset of weakness in one or more limbs and distinct abnormalities of the spinal cord gray matter on magnetic resonance imaging (MRI). During the summer and fall of 2014, a cluster of 11 cases meeting the AFM case definition occurred in Colorado and 107 occurred in other US states. Interpreting the increase in reports of AFM in 2014 has been challenging in the absence of baseline incidence of AFM. Routine reporting of this condition is necessary to facilitate interpretation of apparent increases in this syndrome, to track Colorado trends and contribute to national trends, and to better define the etiologic agent. CDC has recently made funding available to all State health departments to support this surveillance, which will be carried out by CDPHE.

   b. Addition of viral hemorrhagic fever – Report within 24 hours (by individuals or laboratories). Includes: Crimean-Congo hemorrhagic fever, Ebola virus disease, Lassa fever, Lujo fever, Marburg fever, Guanarito fever, Junin fever, Machupo fever, Sabia fever (reportable by individuals; the same-named viruses are reportable by laboratories). See 3e. Rationale above.

   c. Addition of Severe or Novel Coronavirus - Report within 24 hours (by individuals or laboratories). See 3f. Rationale above.

   d. Change Tularemia (*Francisella tularenisis*) from a seven day report to a 24 hour report. See 3g. Rationale above.

5) Specific changes under Regulation 4F – Treatment and Control of Tuberculosis, are listed below.

   The proposed change regarding laboratory storage of tuberculosis culture material will better define the intent of the Regulation 4F and delete language that is not in current use.

6) In the process of reformatting regulations 1-3 to create the Reportable Diseases Table, several technical changes will be made to clarify and/or streamline existing regulations. These changes are specified in the *Statement of Basis and Purpose and Statutory Authority*.

7) Regulation 10, "Cleaning and Sterilization of Needles, Instruments, Probes, and Devises Used by Acupuncturists, Tattoo Artists, and Persons Performing Ear or Other Percutaneous Piercing" has been updated to align with current practice. Colorado statute requires the Executive Director to promulgate rules relating to the proper cleaning and sterilization of needles used in the practice of acupuncture and the sanitation of acupuncture offices. The current Regulation 10 will be repealed by the Board of Health as a review of the rule history indicates the Board of Health adopted the rule in error. The updated Regulation 10 will be adopted by the Executive Director, rather than the Board of Health, as per statute. The Department has opted

to use a single rulemaking packet so the Board of Health and stakeholders can easily track the revisions to this section. Communication with acupuncture stakeholders has occurred through other pathways.

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

Basis and Purpose.

1) In order to more clearly and efficiently explain who must report conditions (laboratories and/or individuals) and the required timing of reporting (24 hours vs. 7 days), Regulations 1-3 will be reformatted and the three tables now in regulations will be combined. The new requirement to submit cultures or original clinical material (see 3a. below) will be incorporated into the new table.

2) To comply with CDC reporting requirements and be able to link multiple tests performed on the same specimen, an additional requirement for accession number to be included on all reported diseases with supporting laboratory results will be incorporated into Regulation 1.

   Rationale: An acccession number is a unique ID assigned to a specimen by a testing laboratory. When received, this number serves as an additional safegard to ensure we are able to associate all tests performed with the appropriate specimen. There are instances where multiple specimens of the same type are collected from the same individual on the same day and sent to a lab for testing; without accession numbers we are unable to differentiate tests performed on each specimen when results are reported to CDPHE. The CDC requires the reporting of tests by specimen for certain groups of diseases. Obtaining the accession number is also important in determining and eliminating duplicate results received from multiple reporting sources. The inclusion of accession number in electronic laboratory reporting is standard practice.

3) Specific changes under the current Regulation 3 - Laboratory Reporting, are listed below.

   a. Addition of a requirement for clinical and reference laboratories to submit cultures or original clinical material for specific reportable conditions as listed in *Isolate submission to the state public health laboratory* at https://www.colorado.gov/pacific/cdphe/report-a-disease. Testing laboratories will submit bacterial culture isolates or patient clinical material that yields positive findings to the CDPHE Laboratory Services Division.

      Clinical material is defined as:
      (i) A culture isolate containing the infectious organism for which submission of material is required, or
      (ii) If an isolate is not available, material containing the infectious organism for which submission of material is required, in the following order of preference:
      (A) a patient specimen;
      (B) nucleic acid; or
      (C) other laboratory material.

      Rationale: The purpose of this regulatory change is to preserve public health's ability to detect outbreaks and effectively monitor trends in reportable disease in

the setting of changing laboratory methods. The list of pathogens for which this will apply will be derived from existing submission guidance; CDPHE is not planning to expand the list for which submission is currently requested. Submission of isolates or clinical material is required in at least 20 other states.

Test methodologies performed by clinical and reference laboratories for the detection of enteric bacterial pathogens such as *Salmonella* and Shiga toxin-producing *E. coli* (STEC) are rapidly changing. Several types of culture-independent diagnostic tests (CIDT) have recently been approved by the US Food and Drug Administration. Clinical laboratories in Colorado have begun to adopt these new methods for enteric disease testing and it is likely they will adopt these methods for other pathogen groups in the near future. While CIDT has many benefits, the tests do not yield isolates that can be submitted to the state public health laboratory. Current methods for outbreak detection depend on the use of isolates for subtyping (including serotyping, serogrouping, and pulsed-field gel electrophoresis [PFGE]). To maintain our very effective statewide surveillance system and continue to be able to detect outbreaks, it is crucial that clinical laboratories continue to submit culture isolates or clinical material that can be used for subtyping.

Submission of isolates and clinical material has long been voluntary in Colorado and submission rates have been very high. For example during 2013-2014, submission rates for reported cases of *Salmonella* and *Streptococcus pneumoniae* were 94% and 96%, respectively. Even for STEC, which is most frequently tested using CIDT, submission rates were 94% in this time frame.

This regulation will codify existing practice. CDPHE has an existing courier service in place to transport material to the state public health laboratory. CDPHE will provide necessary transport material and guidance to clinical laboratories for submission of isolates or clinical material.

b. Deletion of methicillin-resistant *Staphylococcus aureus* (MRSA) from the "Conditions Reportable by all Laboratories." (MRSA was reportable in the 5-county Denver metropolitan area.)

   Rationale: The addition of other conditions below, including an additional multidrug resistant organism (MDRO), carbapenem-resistant *Pseudomonas* species, necessitates examining other possible conditions for deletion. Federal funding previously available for MRSA is not currently available. We propose deleting this condition in favor of shifting resources to other newly emerging MDROs, such as carbapenem-resistant *Pseudomonas*. Additionally, MRSA data from 2013 to present is also available to the Department through Colorado reporting of healthcare-associated infections via the CDC National Healthcare Safety Network (NHSN) as per statute C.R.S. 25-3-601. Although this data uses slightly different parameters for reporting, Colorado will still be able to monitor MRSA data for trends.

c. Change in the definition of carbapenem-resistant Enterobacteriaceae (CRE)

   From: *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)

To: *Escherichia coli*, *Klebsiella* species, and *Enterobacter* species that are resistant to at least one carbapenem (including imipenem, meropenem, doripenem, or ertapenem); OR *Escherichia coli*, *Klebsiella* species, and *Enterobacter* species that test positive for production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA-48) demonstrated by a recognized test (e.g., polymerase chain reaction, metallo-ß-lactamase test, modified-Hodge test, Carba-NP)

Rationale: Based on a study done by CDC and Emerging Infections Program (EIP) sites, the new proposed definition more specifically identifies CRE likely to be carbapenemase-producers, which are of particular interest to public health due to the organisms' ability to transfer resistance genes to other organisms. This definition will be proposed at the annual Council of State and Territorial Epidemiologists (CSTE) meeting in June, and it is anticipated that this definition will be adopted nationally. Adopting the CRE definition used nation-wide will allow for consistency among states reporting CRE, and comparability of Colorado cases with other jurisdictions.

d. Addition of carbapenem-resistant *Pseudomonas* – Report within 7 days (by laboratories). Defintion: *Pseudomonas* species that are resistant to at least one of the following carbapenems: imipenem, meropenem, or doripenem; OR *Pseudomonas* species that test positive for production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA)

   Rationale: *Pseudomonas* is intrinsically nonsusceptible to many commonly used antimicrobials and can acquire resistance to other antimicrobials through chromosomal mutations and horizontal transfer of mobile genetic elements. Although the percentage of multidrug resistant *P. aeruginosa* observed in recent years has been relatively consistent, reports of carbapenemase-producing Pseudomonas are increasing. The prevalence of Pseudomonas in Colorado is currently unknown (although the burden is expected to be low) and is of interest to public health to prevent transmission by assisting health care facilities in implementing infection control measures.

e. Addition of Viral hemorrhagic fever – Report within 24 hours (by individuals or laboratories). Includes: Crimean-Congo hemorrhagic fever, Ebola virus disease, Lassa fever, Lujo fever, Marburg fever, Guanarito fever, Junin fever, Machupo fever, Sabia fever (reportable by individuals; the same-named viruses are reportable by laboratories).

   Rationale: Recent events in West Africa have made clear that Ebola virus may be a threat in the United States, and that prolonged, large outbreaks are possible. Ebola virus is just one of a group of viral hemorrhagic fever viruses; though all are exceedingly rare, the conditions are all considered to be reportable conditions at the national level and should be added to the Colorado reportable condition requirements as a group.

f. Addition of Severe or Novel Coronavirus - Report within 24 hours (by individuals or laboratories)

Rationale: Severe Acute Respiratory Syndrome (SARS) was previously reportable, but with the recognition of a second severe coronavirus (Middle East Respiratory Syndrome Coronavirus, or MERS-CoV) we propose a broader category that encompasses both conditions. Thus far two cases of MERS have been identified in the US, both infected in Saudi Arabia. Person to person spread of these severe coronaviruses is possible among close contact and in health care settings.

g. Change *Francisella tularensis* (Tularemia) from the seven day report category to the 24 hour report category.

Rational: Timely notification of public health allows for intervention in the areas of appropriate antibiotic choice (there are a limited number of antibiotics approved to treat this condition), and will facilitate quicker investigation and response. Investigation is indicated to prevent other exposures and to identify other cases with the same exposure. This bacterium is also highly infectious when grown in culture and laboratory-acquired infections have been documented. Earlier reporting will allow for better management of potentially exposed laboratory workers.

4) Specific changes under the current Regulation 2 – Reporting by Individuals, are listed below.

a. Addition of Acute flaccid myelitis (AFM) - Report within seven days (by individuals).

Definition: A person with onset of acute focal limb weakness, and a magnetic resonance image showing a spinal cord lesion largely restricted to gray matter, and spanning one or more spinal segments OR cerebrospinal fluid (CSF) with pleocytosis (CSF white blood cell count >5 cells/mm3); CSF protein may or may not be elevated. This definition was accepted at the annual Council of State and Territorial Epidemiologists meeting in June 2015, and is the standard definition to be used nationally.

Rationale: AFM is a syndrome characterized by rapid onset of weakness in one or more limbs and distinct abnormalities of the spinal cord gray matter on magnetic resonance imaging (MRI). During the summer and fall of 2014, a cluster of 11 cases meeting the AFM case definition occurred in Colorado and 107 occurred in other US states. Interpreting the increase in reports of AFM in 2014 has been challenging in the absence of baseline incidence of AFM. Routine reporting of this condition is necessary to facilitate interpretation of apparent increases in this syndrome, to track Colorado trends and contribute to national trends, and to better define the etiologic agent. CDC has recently made funding available to all State health departments to support this surveillance, which will be carried out by CDPHE.

b. Addition of viral hemorrhagic fever – Report within 24 hours (by individuals or laboratories). Includes: Crimean-Congo hemorrhagic fever, Ebola virus disease, Lassa fever, Lujo fever, Marburg fever, Guanarito fever, Junin fever, Machupo fever, Sabia fever (reportable by individuals; the same-named viruses are reportable by laboratories). See 3e. Rationale above.

c. Addition of Severe or Novel Coronavirus - Report within 24 hours (by individuals or laboratories). See 3f. Rationale above.

d. Change Tularemia (*Francisella tularenisis*) from a seven day report to a 24 hour report. See 3g. Rationale above.

5) Specific changes under Regulation 4F – Treatment and Control of Tuberculosis, are listed below.

From: 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.

To: When a laboratory performs a culture that is positive for *Mycobacterium tuberculosis*, the laboratory shall store the isolate until it receives a request from the state or local health department for the isolate. In lieu of such storage, the laboratory may fulfill this requirement by submitting the isolate to the state public health laboratory.

Rationale: This change will better define the intent of the Regulation 4F and delete language that is not in current use. There is no clinical purpose for the state or local health department to notify a laboratory when a patient with a positive *Mycobacterium tuberculosis* culture has completed a course of therapy, therefore this portion of the regulation should be deleted. CDPHE obtains isolates that are culture positive for *Mycobacterium tuberculosis* for genotyping purposes, which has assisted in tuberculosis control within the state and contributed to confirming or ruling out epidemiologically linked case clusters. CDC has established a national program for that purpose.

6) In the process of reformatting regulations 1-3 to create the Reportable Diseases Table, the following technical changes will be made to clarify and/or streamline existing regulations:

a. Giardiasis and hepatitis A, B and C – Requirement in List B of Regulation 1 will be changed to drop the stipulation that reporting be based on physician diagnosis whether or not supporting laboratory data are available.

b. Delete sentence from regulation 3 that reads "Test results indicating acute infection or chronic infectiousness for any of the following should be reported." Information about which tests should be reported is specified for each disease so this sentence is not necessary.

c. Group outbreaks – Description in table will be changed to read "Outbreaks including food poisoning - known or suspected of all types including those transmitted from food, water, person-to-person, and related to a health care setting" to be more consistent with descriptive language in Regulation 1 that reads, "…Such illnesses, outbreaks, or epidemics include, but are not limited to: 1) 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) cases of a newly recognized entity, including novel influenza; 3) those

related to a health care setting or contaminated medical devices or products; and 4) those related to environmental contamination by any infectious agent or toxic product of such an agent." Additionally, "group outbreaks" has been changed to "outbreaks."

d. Mumps – Changed to specify that reporting of mumps virus is for acute infection only.

e. Q fever and smallpox – The laboratory reporting section will be changed to include the pathogen rather than disease name for each. Q fever will be changed to "*Coxiella burnetii*" and smallpox will be change to "Variola virus (Orthopox virus)."

f. Rocky Mountain Spotted Fever – Diagnosis has been changed to the more correct terminology of "Spotted fever rickettsiosis."

g. A footnote has been added to the table to explain the definition of 'normally sterile site'

h. Footnote language has been added to clarify the requirement that reporting, when limited by specific counties, refers to *residents* of those counties.

i. Streptococcal Toxic Shock Syndrome was added as a separate condition. Previously this condition was included under 'Toxic Shock Syndrome' and/or invasive Group A Streptococci. Now it is more clearly specified as a separate entry in the table.

j. "(CRE)" has been added to "Enterobacteriaceae, carbapenem-resistant" for clarification.

k. "Any site" has been deleted from "Staphylococcus aureus, Vancomycin-resistant (any site)" since the specimen source is now a separate column in the table.

l. In the previous version, "West Nile virus and other Arboviral diseases" are reportable. The 'other' diseases are listed in a footnote. In this version each of the conditions and the pathogen causing the condition is spelled out within the table for clarification.

m. In the previous version, some conditions were to be reported if 'suspected' and another group of conditions were to be reported 'based on the physician's diagnosis, whether or not supporting laboratory data are available'. These two concepts have been combined to 'Report shall be based on the diagnosis or suspected diagnosis of the attending physician or other health care provider, whether or not supporting laboratory data are available'.

n. In the previous version, the Regulation specified that Laboratories must report with 'the information required in Regulation 1', but the same requirement was not required of Individuals. In this version the same language is used for both reporters.

o. Regulation 3 has been revised to improve readability.

p. Regulation 4 has been revised to update current methods of assessing latent tuberculosis infection (tuberculin skin testing or use of interferon-gamma release assays).

7) Regulation 10, "Cleaning and Sterilization of Needles, Instruments, Probes, and Devises Used by Acupuncturists, Tattoo Artists, and Persons Performing Ear or Other Percutaneous Piercing" has been updated to align with current practice. Colorado statute requires the Executive Director to promulgate rules relating to the proper cleaning and sterilization of needles used in the practice of acupuncture and the sanitation of acupuncture offices. The current Regulation 10 will be repealed by the Board of Health as a review of the rule history indicates the Board of Health adopted the rule in error. The updated Regulation 10 will be adopted by the Executive Director, rather than the Board of Health, as per statute. The Department has opted to use a single rulemaking packet so the Board of Health and stakeholders can easily track the revisions to this section. Communication with acupuncture stakeholders has occurred through other pathways.

Specific Statutory Authority.
The Board of Health rules are promulgated pursuant to the following statutes:

C.R.S. 25-1.5-102 Epidemic and communicable diseases – powers and duties of department.

C.R.S. 25-1-122 Named reporting of certain diseases and conditions – access to medical records – confidentiality of reports and records.

C.R.S. 25-4-502 Tuberculosis to be reported.

The Executive Director rules are promulgated pursuant to the following statute:

C.R.S. 12-29.5-111 Acupuncturists- powers and duties of the executive director of the department of public health and environment.

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
6 CCR 1009-1
Rules and Regulations Pertaining to Epidemic and Communicable Disease Control

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

Classes of persons affected by the proposed rule changes include 1) clinical laboratory personnel; 2) personnel at hospitals responsible for reporting, such as infection preventionists; 3) health care providers; 4) local public health personnel; and 5) the general public.

Clinical laboratory personnel will bear some cost of the changes to laboratory reporting, and will benefit from the deletion of methicillin-resistant *Staphylococcus aureus* (MRSA) from the "Conditions Reportable by all Laboratories."

Health care providers and other reporters will bear a cost related to new reporting for acute flaccid myelitis.

All users will benefit from the improved clarity and efficiency of having almost all of the information needed to report conditions in one updated table. Users will also benefit from technical changes that improve the accuracy and modernization of the rule.

The benefit of the rule accrues to the general public who may be at risk of illness. By maintaining the ability of public health officials to obtain isolates or clinical material, we are able to: 1) identify outbreaks, their cause, and implement prevention measures; 2) set priorities and monitor trends to determine if control measures are effective; and 3) contribute to vaccine development based on serogroup data for specific pathogens. The general public at risk for tularemia will also benefit due to more prompt, appropriate treatment and prevention.

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.

Clinical laboratory personnel

For clinical laboratory personnel, the requirement for clinical and reference laboratories to submit cultures or original clinical material for specific reportable conditions will codify existing practice and the burden to laboratories will be minimized. Current submission rates are > 90% and CDPHE has an existing courier service in place to transport material to the state public health laboratory. CDPHE will also provide necessary transport material and guidance to clinical laboratories for submission of isolates or clinical material.

Other requirements of laboratories (report with accession number, change in the definition of carbapenem-resistant Enterobacteriaceae [CRE], and the addition of carbapenem-resistant *Pseudomonas*, viral hemorrhagic fever, and severe or novel coronavirus) represent minor changes in report processing, which is becoming a largely electronic process. The burden of reporting new cases of carbapenem-resistant

Pseudomonas is anticipated to be very low. In addition, reporting of viral hemorrhagic fever and severe or novel coronavirus are currently reportable as unusual illnesses.

The change in reporting of *Francisella tularensis* (Tularemia) from the seven day report category to the 24 hour report category may result in a need for manual reporting to meet the 24 hour requirement. However, this is a relatively uncommon pathogen - the 5-year average from 2009-2013 was 2.0 cases/year.

The deletion of MRSA from the reportable conditions list will decrease the reporting burden for laboratories in the Denver metropolitan area. MRSA data from 2013 to present is also available to the Department through Colorado reporting of healthcare-associated infections via the CDC National Healthcare Safety Network (NHSN) as per statute C.R.S. 25-3-601. Although this data uses slightly different parameters for reporting, Colorado will still be able to monitor MRSA data for trends.

Personnel at hospitals responsible for reporting and health care providers

Personnel at hospitals responsible for reporting and health care providers will bear some cost of reporting clinical information (testing and symptoms) about acute flaccid myelitis cases. The outbreak in 2014 that prompted this reporting resulted in 11 Colorado cases, but we expect fewer cases in future years.

The reporting of viral hemorrhagic fever and severe or novel coronavirus are currently reportable as unusual illnesses, so this change only serves to clarify current reporting requirements. These conditions are very rare.

The change in reporting of *Francisella tularensis* (tularemia) from the seven-day report category to the 24-hour report category may result in a need for manual reporting to meet the 24-hour requirement. However, this is a relatively uncommon pathogen. The 5-year average from 2009-2013 was 2.0 cases/year. The general public at risk for tularemia will benefit due to more prompt, appropriate treatment and prevention.

Health care facilities and providers will benefit from the addition of carbapenem-resistant *Pseudomonas* by receiving consultation from the Department for each new case to assist them in implementing appropriate infection control measures and preventing transmission within their facility and between facilities. The general public will also benefit through the increased public health knowledge of an additional multidrug-resistant organism in their communities.

Changes under Regulation 4F – Treatment and Control of Tuberculosis, codify current process, making the regulation clearer for all stakeholders. These changes do not result in additional cost.

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.

We expect the change requiring submission of cultures or original clinical material for specific reportable conditions to result in some cost to the Colorado Department of Public Health and Environment Laboratory, though the exact amount is difficult to estimate. A rough estimate, based on 1000 samples, would be about $17,000. This is the maximum we expect to incur, but does not account for two factors: the rate of culture-independent testing uptake and the

number of laboratories who will continue to perform culture. Federal grant funds can be utilized to cover much of this cost.

The addition of acute flaccid myelitis to the reportable conditions list will also result in some cost to the Department, but these costs will be covered by federal funding.

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 (MRSA) and more complete reporting. There may be some cost to laboratories to change the process of reporting to include the accession number, change in CRE definition, and add carbapenem-resistant *Pseudomonas*, viral hemorrhagic fever, and severe or novel coronavirus. These costs are not quantifiable, but are thought to be small. There may also be a cost for health care providers to report newly reportable conditions (viral hemorrhagic fevers, MERS-CoV, acute flaccid myelitis) though these conditions are unusual conditions that should have been reported under the requirement to report outbreaks or unusual conditions.

Inaction would result in continued reporting of MRSA for little public health gain, lack of clarity in the rules, lack of ability to compare Colorado data to other states and national data, and lack of information about newly emerging entities of acute flaccid myelitis and carbapenem-resistant *Pseudomonas*.

Should laboratories stop submitting isolates/clinical material to the state public health laboratory, outbreaks will not be detected until they are far larger, and some will not be detected at all. This puts the public at risk of increased illness.

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.

Regarding the requirement to submit clinical material, approximately 30 other states currently have this requirement (personal communication, Kirsten Larson, Association of Public Health Laboratories) and this procedure is recommended by the Association of Public Health Laboratories ('Meet with State Board of Health or other governing entity to determine if regulations need to be revised or updated to include mandatory submission of clinical material and/or isolates for reportable diseases' – APHL CIDT Fact Sheet, February 2015).

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

No alternative methods for achieving the purpose of the proposed rules were considered because the rules utilize the widely accepted, proven public health methodology of surveillance and laboratory investigation.

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.

See quantified estimates above. In addition, between 2009 and 2013, the average number of cases of MRSA per year was 420, declining each year through 2013. The number of carbapenem-resistant *Pseudomonas* cases per year is anticipated to be significantly lower than MRSA cases, effectively decreasing burden on laboratories for reporting for multi-drug resistant organisms with the deletion of MRSA and the addition of carbapenem-resistant *Pseudomonas*.

STAKEHOLDER COMMENTS

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

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

Colorado hospital infection preventionists and lab directors, Colorado Hospital Association staff, Colorado local public health directors, and local public health communicable disease staff were all given the opportunity to comment or suggest changes to the proposed rules.

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

On 4/27/15 a memo was sent to all infection preventionists at Colorado acute care hospitals, all Lab Directors at acute care hospitals, communicable disease contacts at each local health contacts, and all local public health directors.

On 5/12/15 a second memo was sent to the same stakeholders with updated changes and a 'strike changes' version of rule. Based on this outreach, an infection preventionist suggested that we update Regulation 4, Treatment and Control of Tuberculosis, to include current methods of assessing latent tuberculosis infection (tuberculin skin testing or use of interferon-gamma release assays instead of 'ppd' or 'tuberculosis skin test'). This was done.

On 5/15/15 Dr. Miller attended the Colorado Association of Local Public Health Officers to present changes to the rule and take comments on the proposal. There were no suggested changes.

Two stakeholder meetings were held to receive comments about the proposal for submission of clinical material. Notice about the meetings were sent to Colorado hospital infection preventionists and lab directors, Colorado Hospital Association staff, Colorado local public health directors, and local public health communicable disease staff.

Stakeholder meeting #1, held 6/5/15
- No attendees in person
- 2 attendees on the phone, no comments

Stakeholder meeting #2, held 6/12/15
- No attendees in person
- 1 attendee on the phone, no comments

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.

None.

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 HEEJ 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 the Reportable Diseases Table~~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) 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) cases of a newly recognized entity, including novel influenza; 3) those related to a health care setting or contaminated medical devices or products; and 4) 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, foxes, raccoons, coyotes, 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~~

~~List B - Require Report Within 7 Days~~

~~Bites by mammals not included in List A~~	~~Leprosy~~
~~Brucellosis*~~	~~Listeriosis~~
~~Campylobacteriosis~~	~~Lyme Disease~~

~~Chancroid~~	~~Lymphogranuloma venereum~~
~~Chlamydia Trachomatis~~	~~Malaria*~~
~~Cryptosporidiosis~~	
~~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*~~
~~Legionellosis*~~	~~Varicella*~~

~~* 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. In addition, all laboratory information reported shall include specimen accession number. For animal bites by dogs, cats, bats, skunks, foxes, raccoons, coyotes, and other wild carnivores, the name and locating information of the owner of the biting animal shall be reported, if known, by the health care provider. For healthcare-associated infections, except as provided in § 25-3-601, C.R.S., facilities choosing to voluntarily participate in applied public health projects on a project by project basis shall make medical records available for review by the Department upon request within a reasonable time frame.

See Appendix A, Reportable Diseases Table and Footnotes to determine time frame for reporting (from diagnosis or test result), who shall report, the reporting area, whether laboratory information is required for a report, and whether an isolate or clinical material must be sent to the State Laboratory. ~~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

Where Reporter = 'P' in the Appendix A Reportable Diseases Table, c~~C~~ases 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

Where Reporter = 'L' in the Appendix A Reportable Diseases Table, cases of diseases~~Cases of diseases listed in Regulation 1~~ shall ~~also~~ be reported with the information required in Regulation 1 by the laborator~~ies~~y that performs the test, whether or not associated with a hospital. The following laboratories shall also report: ~~, and by~~1) out of state laboratories that maintain an office or collection facility in Colorado or arrange for collection of specimens in Colorado; and 2) ~~. 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 laboratories~~y~~ ~~which~~that send~~s~~ specimens to ~~an~~ out-of-state ~~laboratory~~ referral laboratories~~y is also responsible for reporting results~~. ~~T~~The ~~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).

For organisms so noted in Appendix A, Reportable Diseases Table, testing laboratories shall routinely submit bacterial culture isolates or patient clinical material that yields positive findings to the CDPHE Laboratory Services Division. Clinical material is defined as: (i) A culture isolate containing the infectious organism for which submission of material is required, or (ii) If an isolate is not available, material containing the infectious organism for which submission of material is required, in the following order of preference: (A) a patient specimen; (B) nucleic acid; or (C) other laboratory material.

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

~~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~~	~~Rickettsia species~~
~~Clostridium botulinum~~	~~Rubella (acute infection)~~
~~Corynebacterium diphtheriae~~	~~Severe Acute Respiratory Syndrome (SARS)~~
~~Cryptosporidium species~~	
~~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)~~	~~West Nile virus (acute infection) and other Arboviral diseases++~~
~~Mumps~~	~~Yersinia pestis~~
~~Mycobacterium tuberculosis, including antimicrobial sensitivity~~	~~Yersinia, non-pestis +~~

~~test results and positive AFB sputum smears.~~	

~~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~~ tuberculin skin test (TST) or Interferon-Gamma Release Assay (IGRA) result if it occurs in a health care worker, correctional facility worker, or detention facility worker: a positive ~~ppd~~ TST (defined as = 5 mm induration) or positive IGRA test (based on manufacturer's interpretation criteria) if the worker has had prolonged or frequent face-to-face contact with an infectious tuberculosis case.

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 a request~~notification~~ from the state or local health department ~~that the patient has completed a full and appropriate course of treatment for active tuberculosis disease~~for the isolate. 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~~ TST~~skin test~~ and/or IGRA 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~~ TST ~~skin test~~ and IGRA 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~~ TST ~~skin test~~or IGRA test and clinical evaluation. If free of signs and symptoms of tuberculosis, subsequent testing would be dependent on the results of the ~~TB~~ TST~~skin test~~ or IGRA 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 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, plague, tularemia, 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. Use of Sterile~~Cleaning and Sterilization of~~ Needles, and Cleaning and Disinfection of Other Instruments, Probes, and Devi~~c~~ses Used by ~~Acupuncturists, Tattoo Artists, and Persons Performing Ear or Other Percutaneous Piercing~~Practitioners of Acupuncture and Adjunctive Therapies

This regulation is promulgated pursuant to ~~CRS 25-1-107(1)(A) and~~Section C.R.S. 12-29.5-111 which state~~s~~ 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 surfaces (e.g., tables, counters, ~~and~~ chairs) used in connection with ~~these~~ procedures involving equipment items shall be ~~constructed of a material which is easily cleaned and capable of being sanitized with a chemical germicide~~ cleaned and

disinfected with a disinfectant registered by the U.S. Environmental Protection Agency for use in health care settings according to labeled instructions. Equipment items shall be defined as any needle, instrument, probe, or device utilized by practitioners of acupuncture that punctures the skin or enters tissue of any patient/client.

Prior to and after each treatment of acupuncture ~~and each application of tattoo or ear/percutaneous piercing~~, the ~~applicator~~ practitioner shall perform hand hygiene by either washing his/her hands ~~at a sink with both hot and cold running water and with soap having bactericidal qualities~~ or using an alcohol-based hand sanitizer.

~~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.~~

Needles and other equipment items that puncture the skin or enters the tissues of any patient/client should be disposable single-use items that are appropriately discarded immediately after use in an appropriate sharps container, and should never be used on more than one patient. Equipment items that are vehicles for needles and other puncturing devices should either be disposable, single-use items (preferred), or thoroughly cleaned and disinfected between each patient use according to the manufacturers' instructions. If there are no manufacturers' instructions for how to clean and disinfect the device, the device should not be used on more than one patient. When lancet devices (used to quickly puncture the skin with a needle) are used, they should be single-use, disposable devices, and should never be shared between patients.~~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. Reportable Diseases Table

Disease/Event	Pathogen/Organism	Time	Reporter[1]	Specimen Source(s)[2]	Send Clinical Material[3]	Limited Reporting area[4]
Acinetobacter baumannii, carbapenem-resistant (CRAB)[5]	Carbapenem-resistant *Acinetobacter baumannii* (including *Acinetobacter baumannii* complex and *Acinetobacter baumannii-calcoaceticus* complex)	30 days	L	Sterile sites, urine		Metro
Acute flaccid myelitis		**7 days**	**P**			
Animal bites by dogs, cats, bats, skunks, foxes, raccoons, coyotes, or other wild carnivores[6,7]		24 hours	P			
Animal bites by mammals not listed above[6]		7 days	P			
Anthrax[6]	*Bacillus anthracis*	24 hours	L & P	All	Required	
Botulism[6]	*Clostridium botulinum*	24 hours	L & P	All		
Brucellosis[6]	*Brucella* species	7 days	L & P	All	Required	
California/LaCrosse serogroup virus diseases	LaCrosse encephalitis virus, California encephalitis serogroup virus, etc.	7 days	L	All		
Campylobacteriosis	*Campylobacter* species	7 days	L & P	All		
Chancroid	*Haemophilus ducreyi*	7 days	L & P	All		
Chikungunya	Chikungunya virus	7 days	L	All		
Chlamydia	*Chlamydia trachomatis*	7 days	L & P	All		
Cholera[6]	*Vibrio cholerae*	24 hours	L & P	All	Required	
CJD and other transmissible spongiform encephalopathies (TSEs)[6]		7 days	P			
Clostridium difficile infection	*Clostridium difficile*	30 days	L	All	Requested[8]	Metro
Colorado tick fever	Colorado tick fever virus	7 days	L	All		
Cryptosporidiosis	*Cryptosporidium* species	7 days	L & P	All		
Cyclosporiasis	*Cyclospora* species	7 days	L & P	All	Required	
Dengue	Dengue virus	7 days	L	All		
Diphtheria[6]	*Corynebacterium diphtheriae*	24 hours	L & P	All	Required	
Eastern equine encephalitis	Eastern equine encephalitis virus	7 days	L	All		
Encephalitis[6]		7 days	P	All		
Enterobacteriaceae, carbapenem-resistant (CRE)[9]	Carbapenem-resistant *Escherichia coli*, *Klebsiella* species, *Enterobacter* species	7 days	L	All	Requested[10]	
Escherichia coli O157:H7 and Shiga toxin-producing Escherichia coli[11]	Shiga toxin-producing *Escherichia coli*[11]	7 days	L & P	All	Required	
Giardiasis[6]	*Giardia lamblia*	7 days	L & P	All		
Gonorrhea, any site	*Neisseria gonorrhoeae*	7 days	L & P	All		
Group A streptococci[12]	*Streptococcus pyogenes*	7 days	L	Sterile only	Required[13]	Metro
Group B streptococci	*Streptococcus agalactiae*	7 days	L	Sterile only	Required[13]	Metro
Haemophilus influenzae ~~(invasive disease)~~[6]	*Haemophilus influenzae*	24 hours	L & P	Sterile only	Required	
Hantavirus disease[6]	Hantavirus	7 days	L & P	All		
Healthcare-associated infections[14]		7 days	P			
Hemolytic uremic syndrome if ≤ 18 years[6]		7 days	P			
Hepatitis A[6]	Hepatitis A virus (+IgM	24	L & P	All		

Disease/Event	Pathogen/Organism	Time	Reporter[1]	Specimen Source(s)[2]	Send Clinical Material[3]	Limited Reporting area[4]
	anti-HAV)	hours				
Hepatitis B[6]	Hepatitis B virus (+HBsAg, +IgM anti-HBc, +HBeAg, or +HBV DNA)	7 days	L & P	All	-	-
Hepatitis C[6]	Hepatitis C virus (+ serum antibody titer, including signal to cut-off ratio, or more specific + tests)	7 days	L & P	All	-	-
Hepatitis, other viral	-	7 days	P	-	-	-
Influenza-associated death if < 18 years	-	7 days	P	-	-	-
Influenza-associated hospitalization	-	7 days	P	-	-	-
Japanese encephalitis	Japanese Encephalitis virus	7 days	L	All	-	-
Legionellosis[6]	*Legionella* species	7 days	L & P	All	-	-
Leprosy (Hansen's Disease)	-	7 days	P	-	-	-
Listeriosis	*Listeria monocytogenes*	7 days	L & P	All	Required	-
Lyme disease	*Borrelia burgdorferi*	7 days	L & P	All	-	-
Lymphogranuloma venereum (LGV)	*Chlamydia trachomatis*	7 days	L & P	All	-	-
Malaria[6]	*Plasmodium* species	7 days	L & P	All	-	-
Measles (rubeola)[6]	Measles virus	24 hours	L & P	All	-	-
Meningococcal Disease ~~(invasive disease)~~[6]	*Neisseria meningitidis* or gram-negative *diplococci*	24 hours	L & P	Sterile only	Required	-
Mumps[6]	Mumps virus (acute infection)	7 days	L & P	All	-	-
~~Group~~Outbreaks ~~including food poisoning~~ - known or suspected of all types including those transmitted from food, water, person-to-person, and related to a health care setting[6]	-	24 hours	P	-	-	-
Pertussis (whooping cough)[6]	*Bordatella pertussis*	24 hours	L & P	All	Requested[8]	-
Plague[6]	*Yersinia pestis*	24 hours	L & P	All	Required	-
Poliomyelitis[6]	Poliovirus	24 hours	L & P	All	-	-
Powassan virus disease	Powassan virus	7 days	L	All	-	-
Pseudomonas, carbapenem-resistant[15]	*Pseudomonas* species	7 days	L	All	Requested[8]	-
Psittacosis	*Chlamydia psittaci*	7 days	L & P	All	-	-
Q fever[6]	~~Q fever~~ *Coxiella burnetii*	7 days	L & P	All	-	-
Rabies: human (suspected)[6]	Rabies virus (Lyssavirus)	24 hours	L & P	All	-	-
~~Rocky Mountain Spotted Fever~~ Spotted fever rickettsiosis	*Rickettsia* species	7 days	L & P	All	-	-
Rubella (acute infection)	Rubella virus	24 hours	L & P	All	-	-
Rubella, congenital[6]	Rubella virus	7 days	L & P	All	-	-
Salmonellosis	*Salmonella* species	7 days	L & P	All	Required	-
Severe or novel coronavirus ~~Acute Respiratory Syndrome (SARS)~~[6]	Severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV)	24 hours	L & P	All	-	-
Shigellosis	*Shigella* species	7 days	L & P	All	Required	-
Smallpox[6]	~~Smallpox~~ Variola virus (Orthopox virus)	24 hours	L & P	All	-	-

Disease/Event	Pathogen/Organism	Time	Reporter[1]	Specimen Source(s)[2]	Send Clinical Material[3]	Limited Reporting area[4]
St. Louis encephalitis	St. Louis encephalitis virus	7 days	L	All	-	-
~~*Staphylococcus aureus*: Methicillin-resistant (MRSA)~~	~~Methicillin-resistant *Staphylococcus aureus*~~	~~30 days~~	~~L~~	~~Sterile only~~	-	~~Metro~~
Staphylococcus aureus, Vancomycin-resistant ~~(any site)~~	Vancomycin-resistant *Staphylococcus aureus*	7 days	L	All	Required	-
Streptococcal toxic shock syndrome	*Streptococcus pyogenes*	7 days	P	All	Required[13]	-
Streptococcus pneumoniae ~~Invasive Disease~~	*Streptococcus pneumoniae*	7 days	L	Sterile only	Required[13]	-
Syphilis (1°, 2°, or early latent)[6]	*Treponema pallidum*	24 hours	L & P	All	-	-
Tetanus[6]	*Clostridium tetani*	7 days	P	All	-	-
Tick-borne relapsing fever[6]	*Borrelia* species	7 days	L & P	All	-	-
Toxic shock syndrome (non-streptococcal)	-	7 days	P	-	-	-
Trichinosis[6]	*Trichinella* species	7 days	P	All	-	-
Tuberculosis disease (active)[6]	*Mycobacterium tuberculosis*[16]	24 hours	L & P	All	See Reg 4F	-
Tularemia[6]	*Francisella tularensis*	24 hours	L & P	All	Required	-
Typhoid fever[6]	*Salmonella* Typhi	24 hours	L & P	All	Required	-
Varicella (chicken pox)[6]	Varicella virus	7 days	L & P	All	-	-
Vibriosis	*Vibrio* species, non-cholera	7 days	L	All	Required	-
Viral hemorrhagic fever	Crimean-Congo hemorrhagic virus, Ebola virus , Lassa fever virus, Lujo virus, Marburg virus, Guanarito virus, Junin virus, Machupo virus, Sabia virus	24 hours	L & P	All	Required	-
West Nile virus (acute infection, IgM+)	West Nile virus	7 days	L	All	-	-
Western equine encephalitis	Western equine encephalitis virus	7 days	L	All	-	-
Yellow fever	Yellow fever virus	7 days	L	All	-	-
Yersiniosis	*Yersinia* non-*pestis* species	7 days	L	All	Required	Seven

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

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

2 Specimen sources: A condition is reportable when the pathogen is isolated or detected from any specimen source unless where otherwise indicated. A normally "sterile site" is defined as blood, CSF, pleural fluid (includes chest fluid, thoracocententesis fluid), peritoneal fluid (includes abdominal fluid, ascites), pericardial fluid, bone (includes bone

marrow), joint or synovial fluid, needle aspirate or culture of any specific joint, internal body sites (sterilely obtained from biopsy/tissue/abscess/aspirate/fluid/swab from lymph node, brain, heart, liver, spleen, vitreous fluid, kidney, pancreas, vascular tissue, or ovary). Skin and skin abcesses are not considered sterile sites.

3 Testing laboratories shall routinely submit bacterial culture isolates or patient clinical material that yields positive findings to the CDPHE Laboratory Services Division. Clinical material is defined as:

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

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

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

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

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

8 Clinical material is requested from selected laboratories located in the the seven-county Denver Metropolitan Area (Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas, and Jefferson Counties).

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

10 Selected clinical material is requested from laboratories located in the seven-county Denver Metropolitan Area (Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas, and Jefferson Counties) from residents of the Metro Area (Adams, Arapahoe, Denver, Douglas and Jefferson counties).

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

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

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

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

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

16 **Including (+) AFB sputum smear**

Appendix ~~A~~B. Healthcare-Associated Infections

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

Healthcare-associated infections include:

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

Health facility types include:

- Ambulatory surgical centers

Birth centers

Convalescent centers

Dialysis treatment clinics/End-stage renal disease facilities

Hospices

Hospitals (general, psychiatric, rehabilitation, maternity, and long-term care)

Long-term care facilities

Outpatient clinics (community clinics; community clinics with emergency centers; rural health clinics; outpatient rehabilitation facilities; outpatient physical therapy, occupational therapy or speech pathology services; and private physician offices)

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.

Regulations 1 – 3, 5, 9 eff. 10/15/2014.