



To: Members of the State Board of Health

From: Rachel Herlihy, MD, MPH, State Epidemiologist and Communicable Disease Branch Chief, Disease Control and Environmental Epidemiology Division (DCEED)

Through: Tony Cappello, PhD, DCEED Director (Approval initials of Division Director) **TC**

Date: March 1, 2018

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to 6 CCR 1009-1, Epidemic and Communicable Disease Control with a request for a rulemaking hearing to be set for May 16, 2018

Please find copies of the following documents: Statement of Basis and Purpose and Specific Statutory Authority, Regulatory Analysis, Stakeholder Engagement, and Proposed Amendments to 6 CCR 1009-1, Epidemic and Communicable Disease Control with a request for the Board of Health to set a rulemaking hearing to occur on May 16, 2018.

The Epidemic and Communicable Disease Control rule names the communicable diseases that are reportable to the Department and local public health agencies (LPHAs), in order to protect the public's health. The rule also details the manner in which these conditions must be reported and includes language about access to pertinent medical records.

The proposed amendments to update the list of reportable conditions to include:

- *Candida auris*;
- Catheter-associated urinary tract infections (CAUTIs) and methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia from certain health care facilities in Colorado via the National Healthcare Safety Network (NHSN);
- Additional species of carbapenem-resistant Enterobacteriaceae (CRE);
- Selected Extended-Spectrum Beta-Lactamase (ESBL)-producing Enterobacteriaceae (*Escherichia coli* and *Klebsiella* species) for a selected area (Boulder County); and
- Move Japanese encephalitis and Powassan virus disease under Arboviral Disease.

The Department proposes making outbreaks reportable by laboratories. Due to the increased use of molecular subtyping methods, laboratories may identify cases or clusters that are related and represent suspected outbreaks. Furthermore, the Department proposes language to clarify when an outpatient laboratory is required to report to the Department.

In addition, the Department proposes technical changes throughout the rule that are intended to align this rule language with language in 6 CCR 1009-7, Detection, Monitoring and Investigation of Environmental and Chronic Disease. The Department seeks alignment of these rules to bring clarity, consistency and completeness to end users as both rules have the same stakeholders.

The Department has contacted a wide variety of stakeholders to solicit input on these proposed amendments. To date, the Department has not received any feedback in opposition to the proposed additions or changes. The Department remains committed to engaging its stakeholders during this rulemaking period. In total, the proposed amendments align our rules with statute, continue to bring clarity to the rules and minimize potential confusion among end-users of the rules. Most changes appear in ALL CAPS and strikethroughs. Changes highlighted in yellow were only highlighted to ensure members can see punctuation changes and edits within the table.

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

Basis and Purpose.

The Epidemic and Communicable Disease Control rule names the communicable diseases that are reportable to the Department and LPHAs, in order to protect the public's health. The rule also details the manner in which these conditions must be reported and includes language about access to pertinent medical records.

In addition to expanding the list of reportable conditions, the Department proposes technical changes to the rule that are intended to:

- Align our rule with statute;
- Continue to bring clarity to the rule;
- Minimize potential confusion among end-users of the rule; and
- Simplify the language of the existing rule.

The following noteworthy changes to the rule are proposed:

- 1) The Department proposes making *Candida auris* (*C. auris*) reportable by laboratories and health care providers. *C. auris* is an emerging fungus that is resistant to multiple antifungal drugs and has caused outbreaks in several states and other countries. In some patients, *C. auris* can enter the bloodstream and spread throughout the body, causing serious invasive infections. Due to resistance to antifungals, it can be very difficult to treat and to control spread. Furthermore, *C. auris* can be difficult to identify with standard laboratory methods, resulting in misidentification. When not correctly identified as *C. auris*, it is most commonly misidentified as *Candida haemulonii* (*C. haemulonii*). Therefore, the Department proposes requiring reporting of all suspected *C. auris* as well as *C. haemulonii* within 1 working day. Isolates identified as *C. haemulonii* will be tested (likely at the regional laboratory or CDC laboratory) to determine if the isolate is *C. haemulonii* or *C. auris*. It is important to quickly identify *C. auris* so that healthcare facilities can take special precautions to stop its spread; a single case of *C. auris* could result in an outbreak in one or more healthcare facilities, necessitating a resource intensive response. If the isolate is identified as *C. haemulonii*, no public health action needs to be taken. This proposed change is reflected in the Reportable Diseases Table in Appendix A.
- 2) The federal Centers for Medicare and Medicaid Services (CMS) requires reporting of catheter-associated urinary tract infections (CAUTIs) and methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia by certain health care facilities in Colorado via the National Healthcare Safety Network (NHSN). The Department proposes the addition of CAUTI and MRSA bacteremia to the list of reportable conditions. The proposed addition will ensure the Department has access to these data in NHSN so that nationally reported rates can be confirmed, and disease control measures implemented. This proposed change would require these facilities to confer rights to the Department to access NHSN data for those conditions, and would include access to retrospective data. This proposed change would not require any additional reporting

from those facilities that are already reporting CAUTI and/or MRSA bacteremia to NHSN, nor would it require facilities not currently reporting to begin doing so. This proposed change is reflected in the Reportable Diseases Table in Appendix A.

- 3) In 2015, carbapenem-resistant Enterobacteriaceae (CRE), a group of bacteria with resistance to certain antibiotics that cause healthcare-associated infections, were added to the list of reportable conditions with reporting specifically required for three species of Enterobacteriaceae: *Escherichia coli*, *Klebsiella* species, and *Enterobacter* species. Since that time, additional species within the Enterobacteriaceae group have been identified by the CDC as having mechanisms that confer resistance to carbapenems. The Department proposes adding *Citrobacter* species, *Serratia* species, *Raoultella* species, *Providencia* species, *Proteus* species, *Morganella* species, and any carbapenemase-producing Enterobacteriaceae of CRE genus and species. Laboratories that report will be familiar with the tests that determine if a carbapenemase is present, and specific test types are listed within the definition in the rule itself. At the present time, few laboratories perform this testing, and would likely perform testing on the organisms listed within the definition, so the burden is expected to be extremely low for any carbapenemase-producing organism identified that is not listed here. This proposed change is reflected in the Reportable Diseases Table in Appendix A.
- 4) The Department proposes adding selected Extended-Spectrum Beta-Lactamase (ESBL)-producing Enterobacteriaceae (*Escherichia coli* and *Klebsiella* species) to the list of reportable conditions for a selected area (Boulder County). ESBL-producing Enterobacteriaceae are another group of antimicrobial-resistant bacteria that can cause healthcare-associated infections and infections in the community and are resistant to multiple antibiotics, making infections more difficult to treat. The current incidence of these infections is unknown in Colorado and nationally, but is expected to be high relative to other reportable antimicrobial-resistant pathogens (e.g., approximately 15 cases of CRE annually in Boulder county). This proposal follows a successful 2017 pilot project conducted in Boulder County that detected approximately 90 cases of ESBL and demonstrated the likely burden of disease; additional information on cases is still being collected. Based on data collected during this pilot project, the Department estimates 500 cases of ESBL will be reported in Boulder County annually. The Department is proposing a small catchment area due to resource limitations, but will work with CDC and other state partners looking at ESBL-producing Enterobacteriaceae to understand the epidemiology of this important condition. Using data from this sentinel catchment area plus data from NHSN, the Department can use limited resources to begin to understand the burden of this pathogen in Colorado. This proposed change is reflected in the Table in Appendix A.
- 5) The Department proposes making suspected outbreaks reportable by laboratories. Currently, outbreaks are reportable by health care providers only. Due to the increased use of molecular subtyping methods in clinical, commercial, and public health laboratories, these laboratories may identify cases or clusters that are related and represent suspected outbreaks. This proposed change gives laboratories the requested authority needed to report these clusters and facilitate earlier public health response to outbreaks. This proposed change is reflected in the Reportable Diseases Table in Appendix A.

- 6) The Department proposes to remove Japanese encephalitis and Powassan virus disease as individually listed reportable conditions and instead group them with Arboviral Disease. Laboratories run tests for these as a group and call the test an arboviral antibody panel. Because these tests are run in a group and not individually reportable by physicians, the proposed changes will make reporting easier for laboratories." This proposed change is reflected in the Reportable Diseases Table in Appendix A.
- 7) In 2017, candidemia, a bloodstream infection caused by yeast, was made reportable. To ensure resources are available to support reporting, only laboratories that serve residents of the five county Denver metropolitan area (Adams, Arapahoe, Denver, Douglas, and Jefferson) are required to report. A footnote clarifying the reporting area has been added. This proposed change is reflected in the Reportable Disease Table in Appendix A.
- 8) The Department proposes removal of footnote 12 for Group A streptococci and Group B streptococci. This is a technical change. Because these conditions are only reportable for residents of the five county Denver metropolitan area, it is unnecessary to also specify the area for submission of clinical material. The footnote was replaced to clarify that submission of clinical material is only required from residents of the five county Denver metropolitan area.. These changes align reporting for these conditions with other Active Bacterial Core (ABC) surveillance in the Emerging Infections Program (EIP). EIP ABCs is a CDC-funded active population-based laboratory surveillance network that operates in 10 states. Colorado's participation in ABCs is limited to the five county Denver metropolitan area. This proposed change is reflected in the Reportable Conditions Table in Appendix A.
- 9) The Department proposes to change the reporting parameters for Hemolytic Uremic Syndrome (HUS) from children less than or equal to 18 years of age to children less than 18 years of age. This proposed change will align reporting with other reportable pediatric conditions. This proposed change is reflected in the Reportable Diseases Table in Appendix A.
- 10) The Department proposes to remove ertapenem from the list of carbapenem antibiotics listed in footnote 5 associated with *Acinetobacter baumannii* carbapenem-resistant (CRAB). *Acinetobacter baumannii* is intrinsically resistant to ertapenem and it should not be used to indicate the presence of carbapenem resistance. This proposed change is reflected in the Reportable Diseases Table in Appendix A.
- 11) The Department proposes to add language in Regulation 3 - Laboratory Reporting, to clarify that outpatient clinics performing on-site laboratory testing are required to meet laboratory reporting requirements. Outpatient clinics are now performing laboratory testing with automated multiplex polymerase chain reaction (PCR) systems, equipment previously limited to hospital or commercial laboratories. The proposed language ensures consistency across Colorado laboratories.
- 12) The Department proposes to change language in Regulation 4 - Treatment and Control of Tuberculosis so that the reporting timeframe for Tuberculosis cases is changed from "24 hours" to "1 working day". This proposed change brings the text of the rule into alignment with the reporting timeframe listed in Appendix A. In addition, the Department proposes new language in Part F to better align this section of the rule

with current practice. Both of these proposed changes are technical in nature and do not represent a change in policy.

- 13) The remainder of the proposed changes corrects grammatical errors, align citation and formatting within the rule, update terms to align with statute or current name usage. These changes improve alignment with language in 6 CCR 1009-7, Detection, Monitoring and Investigation of Environmental and Chronic Disease. The Department seeks alignment of these rules to bring clarity, consistency and completeness to end users as both rules have the same stakeholders.

Specific Statutory Authority.

Statutes that require or authorize rulemaking: Sections 25-1.5-102 and 25-1-122, C.R.S.

Is this rulemaking due to a change in state statute?

Yes, the bill number is _____. Rules are authorized required.
 No

Does this rulemaking incorporate materials by reference?

Yes URL or Sent to State Publications Library
 No

Does this rulemaking create or modify fines or fees?

Yes
 No

Does the proposed rule create (or increase) a state mandate on local government?

No. This rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed. Though the rule does not contain a state mandate, the rule may apply to a local government if the local government has opted to perform an activity, or local government may be engaged as a stakeholder because the rule is important to other local government activities.

The Department works in partnership with county, district and municipal public health agencies. These entities may receive additional information or more timely information for the purposes of a disease control investigation in their community; however, there is no state mandate on local government within the rule.

No. This rulemaking reduces or eliminates a state mandate on local government.

Yes. This rule includes a new state mandate or increases the level of service required to comply with an existing state mandate, and local government will not be reimbursed for the costs associated with the new mandate or increase in service.

The state mandate is categorized as:

Necessitated by federal law, state law, or a court order
 Caused by the State's participation in an optional federal program

Imposed by the sole discretion of a Department

Other: _____

Has an elected official or other representatives of local governments disagreed with this categorization of the mandate? Yes No

If yes, please explain why there is disagreement in the categorization.

Please elaborate as to why a rule that contains a state mandate on local government is necessary.

REGULATORY ANALYSIS
for Amendments to
6 CCR 1009-1, Epidemic and Communicable Disease Control

1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.
 - A. Identify each group of individuals/entities that rely on the rule to maintain their own businesses, agencies or operation, and the size of the group:

Infection control and clinical laboratory personnel at approximately 90 clinical laboratories (including three outpatient laboratories) and approximately 100 hospitals, health care providers throughout the state, and personnel at 53 county, district or municipal public health agencies (LPHAs).
 - B. Identify each group of individuals/entities interested in the outcomes the rule and those identified in #1.A achieve, and if applicable, the size of the group:

LPHAs, community-based or advocacy organizations such as Parents of Kids with Infectious Diseases (PKIDS), professional organizations such as the Colorado Medical Society or Colorado Association of Local Public Health Officials (CALPHO), federal agencies such as CDC, and the general public.
 - C. Identify each group of individuals/entities that benefit from, may be harmed by or at-risk because of the rule, and if applicable, the size of the group:

LPHAs, the Department, entities required to report, and the general public will benefit from the proposed changes to the rule. The benefit of these changes include clearer, updated rules that are more easily interpreted and, therefore, ensures more complete reporting of diseases of public health importance. Each of these proposed changes will provide better and/or timelier data to the Department and LPHAs. These agencies, in turn, will be able to use this data to detect, prevent, and treat communicable disease in communities across Colorado, benefitting the general public. Specifically, the proposed additions to the rule relate to healthcare-associated infections, therefore, Coloradans experiencing health problems and accessing health care services may experience the greatest benefit.
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.
 - A. For those that rely on the rule to maintain their own businesses, agencies or operations:

Favorable non-economic outcomes: Most of the proposed changes to this rule will result in clarification for consistent interpretation by end-users of the rule, practice shifts to increase efficiency by end-users of the rule, more consistent formatting and proper cross-references within the rule; all of which the Department expects will result in improved customer experience. For example, outpatient clinics performing

on-site laboratory testing have not been reporting. As the Department has identified these outpatient laboratories, the Department has notified them of the laboratory reporting requirements. Clarifying within this rule that outpatient clinics performing on-site laboratory testing are also required to meet laboratory reporting requirements will ensure consistency across Colorado laboratories.

Unfavorable non-economic outcomes: The proposed changes include additions of healthcare-associated infections to the list of reportable conditions necessitated by changes in conditions of public health concern. These changes will require some additional laboratory or health care provider staff time to report. *C. auris* is expected to be rare and additional pathogens are expected to add little burden to overall CRE reporting. ESBL will add approximately 500 reports for laboratories serving Boulder County, and the Department will assist laboratories in their efforts to set up systems to report data; isolates will not be requested. The majority of reporters utilize electronic reporting and thus, this should be a one-time programming change.

B. For those that are affected by or interested in the outcomes the rule and those identified in #1.A achieve.

Favorable non-economic outcomes: Those who live, work and play in Colorado rely on the Department to collect timely information on communicable diseases of public health concern. Proposed changes to this rule optimize the data collected so that the Department can take reasonable actions to protect and inform the public, thereby preventing the occurrence of additional cases of communicable diseases and potential outbreaks. Health care providers, laboratories, and hospital infection preventionists are the primary reporters of conditions included in the Reportable Disease Table in Appendix A. Changing the rule to bring clarity and consistency will allow them to more accurately and completely provide necessary information to the Department.

Unfavorable non-economic outcomes: N/A

Any anticipated financial costs monitored by these individuals/entities? N/A

Any anticipated financial benefits monitored by these individuals/entities? N/A

C. For those that benefit from, are harmed by or are at risk because of the rule, the services provided by individuals identified in #1.A, and if applicable, the stakeholders or partners identified in #1.B.

This rule names the communicable diseases that are reportable to the Department and LPHAs, in order to protect the public's health. By proposing updates to this rule that continue to align our rule with statute, continue to bring clarity to the rule, add new conditions of public health concern, and minimize potential confusion among end-users of the rules, the Department expects the data it receives will be more timely, consistent, and complete. Improved data collection will facilitate the Department's and LPHA's actions to protect the public's health.

Financial costs to these individuals/entities: N/A

Financial benefits to or cost avoidance for these individuals/entities: N/A

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.

A. Anticipated CDPHE personal services, operating costs or other expenditures:

The costs to the agency for managing reports of the proposed additional healthcare associated infections will be covered by federal grant funding. Any other costs to the Department will be minimal and can be absorbed. There is no anticipated effect on state revenues.

B. Anticipated personal services, operating costs or other expenditures by another state agency: N/A

Anticipated Revenues for another state agency: N/A

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

Check mark all that apply:

Inaction is not an option because the statute requires rules be promulgated.

The proposed revisions are necessary to comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.

The proposed revisions appropriately maintain alignment with other states or national standards.

The proposed revisions implement a Regulatory Efficiency Review (rule review) result, or improve public and environmental health practice .

The proposed revisions implement stakeholder feedback.

The proposed revisions advance the following CDPHE Strategic Plan priorities:

Goal 1, Implement public health and environmental priorities Goal 2, Increase Efficiency, Effectiveness and Elegance Goal 3, Improve Employee Engagement Goal 4, Promote health equity and environmental justice Goal 5, Prepare and respond to emerging issues, and Comply with statutory mandates and funding obligations
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Strategies to support these goals:

Substance Abuse (Goal 1)

Mental Health (Goal 1, 2, 3 and 4)

Obesity (Goal 1)

Immunization (Goal 1)

Air Quality (Goal 1)

Water Quality (Goal 1)

Data collection and dissemination (Goal 1, 2, 3, 4 and 5)

Implements quality improvement or a quality improvement project (Goal 1, 2, 3 and 5)

- ___ Employee Engagement (career growth, recognition, worksite wellness) (Goal 1, 2 and 3)
- ___ Incorporate health equity and environmental justice into decision-making (Goal 1, 3 and 4)
- _X_ Establish infrastructure to detect, prepare and respond to emerging issues (Goal 1, 2, 3, 4, and 5)

___ Other favorable and unfavorable consequences of inaction:

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

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. The specific revisions proposed in this rulemaking were developed in conjunction with stakeholder input. Reporting cases of communicable disease is important in the planning and evaluation of disease prevention and control programs, in the assurance of appropriate medical therapy, and in the detection of outbreaks.¹ The proposed revisions provide the most benefit for the least amount of cost, are the minimum necessary or are the most feasible manner to achieve compliance with statute and protect the public's health.

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

Few alternative methods for achieving the purpose of the proposed rules were considered because the statute refers to rulemaking and the rule utilizes the widely accepted and proven public health methodology of epidemiologic surveillance and laboratory investigation. The proposed clarifications to the rule are in direct response to stakeholder feedback or demonstrated interpretation challenges, and are intended to decrease their effort in reporting. Proposed changes were also crafted to allow LPHAs to target their resources. The proposed healthcare-associated infection additions do not require local resources for investigation, though some LPHAs may choose to partner with the Department when cases of these new conditions occur in their jurisdiction. In the case of CAUTIs and MRSA, reporting via NHSN was chosen over typical case reporting methods to utilize existing infrastructure and minimize reporting burden on infection preventionists.

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.

- *C. auris* is an emerging fungal infection that is resistant to multiple antifungal drugs and has caused outbreaks in several states and other countries. In some patients, *C. auris* can enter the bloodstream and spread throughout the body, causing serious invasive infections; due to resistance to antifungals, it can be very difficult to treat and control spread. Urgent public health action is needed with the health care facilities in which it is identified to prevent transmission to other patients. There have been 215 cases identified in the US as of January 31, 2018, in 10 states with the majority of cases identified in New York. Colorado has not identified any cases of *C. auris* to date. When not correctly identified as *C. auris*, it is most commonly misidentified as *Candida haemulonii* (*C. haemulonii*).

¹ <https://www.cdc.gov/mmwr/preview/mmwrhtml/00001665.htm>

Colorado has not identified any cases of *C. haemulonii* to date, though the Department is unlikely to know about any cases as this fungal infection has not been reportable to the Department. Therefore, the Department proposes reporting of all suspected *C. auris* as well as *C. haemulonii* within 1 working day because it is important to quickly identify *C. auris* so that healthcare facilities can take special precautions to stop its spread. Isolates identified as *C. haemulonii* will be tested (likely at the regional laboratory or CDC laboratory) to determine if the isolate is *C. haemulonii* vs. *C. auris*. If the isolate is identified as *C. haemulonii*, no public health action needs to be taken.

- The selection of additional genera and species of Enterobacteriaceae to be added to the definition of CRE was determined in consultation with CDC. These organisms were identified by CDC as having carbapenemases in other states in the U.S. It is unknown the volume of CRE among these organisms in Colorado, but based on CDC data these organisms much less commonly are resistant to carbapenems and, therefore, the additional volume of cases is expected to be low.
- A pilot with selected laboratories is underway in Boulder County to determine the volume of ESBL cases. During October to December 2017, about 90 cases were reported to the Department by four participating laboratories. Since an additional four laboratories are expected to serve Boulder County residents (for a total of eight main laboratories), we estimate approximately 500 ESBL cases per year for this surveillance.
- In 2015, 464 cases of CAUTI were reported in Colorado facilities, per NHSN data provided by CDC. This same data indicate that certain facilities (long-term acute care facilities) have a higher than expected rate of CAUTIs, indicating that prevention may be indicated. Since facilities already report this data into NHSN for CMS, there is no additional burden to healthcare facilities for data collection.
- The number of cases of health care facility onset MRSA bacteremia reported into NHSN during 2013-2016 was between 378 and 431, per year, based on data within the NHSN system. Rates during this same period have been increasing, indicating that public health action may be needed. Since certain health care facilities already report this data into NHSN for CMS, there is no additional burden to health care facilities for data collection.

STAKEHOLDER ENGAGEMENT
for Amendments to
6 CCR 1009-1, Epidemic and Communicable Disease Control

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:

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

Colorado health care providers, Colorado hospital infection preventionists and lab directors, LPHAs, Colorado Regional Epidemiologists, Association for Professionals in Infection Control (APIC), Colorado reference lab contacts, Colorado Chapter of the American Society for Clinical Laboratory Science, Colorado Hospital Association, Colorado Medical Society, currently identified Colorado out-patient clinics performing on-site laboratory testing, the Department's Division of Environmental Health and Sustainability and the Department's Health Facilities and Emergency Medical Services Division.

Targeted outreach conducted:

- On 1/17/18, proposed changes were described to Colorado Regional Epidemiologists and other LPHA staff on a conference call with opportunity for discussion and questions.
- On 1/19/18, proposed changes were presented in person to APIC members at their monthly meeting with opportunity for discussion and questions. A requested follow-up email summarizing the proposed changes was sent to APIC on 1/22/18.
- On 1/31/18, proposed changes were presented in person to the members of the Colorado Chapter of the American Society for Clinical Laboratory Science with opportunity for discussion and questions.
- In February, emails summarizing the proposed changes and requesting feedback were sent to the Colorado Hospital Association, the Colorado Medical Society, clinical laboratory directors in the state, and via our "Hot Topics" distribution list which includes physicians, infection preventionists, laboratorians, and local public health staff.

Stakeholder Group Notification

The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

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

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

The Department has shared proposed changes and requested feedback from stakeholders through conference calls, in-person meetings, and written communication. These discussions led to greater understanding of the reporting processes. While the Department will continue to engage stakeholders throughout the development of the proposed rules, to date, there have been no major factual or policy issues encountered.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

Overall, after considering the benefits, risks and costs, the proposed rule:

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.	Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.	Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce.
	Improves access to food and healthy food options.	Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
X	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.	Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.
	Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.	Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.
X	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.	Ensures a competent public and environmental health workforce or health care workforce.
	Other: _____ _____	Other: _____ _____

1 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

2
3 **Disease Control and Environmental Epidemiology Division**

4
5 **EPIDEMIC AND COMMUNICABLE DISEASE CONTROL**

6
7 **6 CCR 1009-1**

8
9
10 **Adopted by the Board of Health on _____, 2018. Effective _____, 2018.**

11
12 **Regulation 1. Reportable Diseases**

13
14 For the purpose of these regulations, the diseases named in the Reportable Diseases Table (Appendix A)
15 are declared to be potentially dangerous to the public health and shall be reportable in accordance with
16 the provisions of these regulations.

17
18 The Colorado Board of Health also requires the reporting of any unusual illness, or outbreak, or epidemic
19 of illnesses, which may be of public concern whether or not known to be, or suspected of being,
20 communicable. Such illnesses, outbreaks, or epidemics include, but are not limited to: 1) those which
21 may be a risk to the public and which may affect large numbers of persons such as illnesses transmitted
22 through food, water, ANIMAL TO PERSON or from person to person; 2) cases of a newly recognized
23 entity, including novel influenza; 3) those related to a health care setting or contaminated medical devices
24 or products; and 4) those related to environmental contamination by any infectious agent or toxic product
25 of such an agent.

26
27 The occurrence of a single case of any unusual disease or manifestation of illness which the health care
28 provider determines or suspects may be caused by or related to a bioterrorist agent or incident must be
29 reported immediately by telephone to the DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL
30 PUBLIC HEALTH AGENCY ~~state or local health department~~ by the health care provider and the hospital,
31 emergency department, clinic, health care center, and laboratory in which the person is examined, tested,
32 and/or treated. The same immediate reporting is required for any unusual cluster of illnesses that may be
33 caused by or related to a bioterrorist agent or incident. Bioterrorist agents include, but are not limited to,
34 anthrax, plague, smallpox, tularemia, botulism, viral hemorrhagic fever and brucellosis.

35
36 **Manner of Reporting**

37
38 All cases are to be reported with patient's name, date of birth, sex, race, ethnicity, and address (including
39 city and county) and name and address of responsible physician or other health care provider; and such
40 other information as is needed to locate the patient for follow up. In addition, all laboratory information
41 reported shall include specimen accession number. For animal bites by dogs, cats, bats, skunks, foxes,
42 raccoons, coyotes, and other wild carnivores, the name and locating information of the owner of the biting
43 animal shall be reported, if known, by the health care provider. For healthcare-associated infections,
44 except as provided in § 25-3-601, C.R.S., facilities choosing to voluntarily participate in applied public
45 health projects on a project by project basis shall make medical records available for review by the
46 Department upon request within a reasonable time frame. In addition, for sexually transmitted infections,
47 the patient's sex at birth, gender identity and relevant treatment shall be reported. For reports from a
48 publically funded anonymous testing site, as provided in §25-4-411, C.R.S, the patient's name and
49 address are not required.

50
51 See Appendix A, Reportable Diseases Table and Footnotes to determine time frame for reporting (from
52 diagnosis or test result), who shall report, the reporting area, whether laboratory information is required
53 for a report, and whether an isolate or clinical material must be sent to the DEPARTMENT,
54 LABORATORY SERVICES DIVISION ~~CDPHE State Laboratory~~.

55
56 Reports on hospitalized patients may be made part of a report by the hospital as a whole.

57
58 The Department shall develop systems and forms for reporting for physicians, other health care providers
59 and hospitals. When hospitals and laboratories transmit disease reports electronically using systems and
60 protocols developed by the Department OR FEDERAL AGENCIES that ensure protection of
61 confidentiality, such reporting is acceptable and is considered good faith reporting.

62
63 **Regulation 2. Reporting by Individuals**

64
65 Where Reporter = 'P' in the Appendix A, Reportable Diseases Table, cases of diseases shall be reported
66 by the physician or other health care provider and by other persons either treating or having knowledge of
67 a reportable disease, including, but not limited to coroners, persons in charge of hospitals or other
68 institutions licensed by the Colorado Department of Public Health and Environment, (or their designees),
69 persons in charge of schools (including school nursing staff), licensed day care centers, or any other
70 person providing testing and/or counseling to a person with a sexually transmitted infection.

71
72 **Regulation 3. Laboratory Reporting**

73
74 Where Reporter = 'L' in the Appendix A, Reportable Diseases Table, cases of diseases shall be reported
75 with the information required in Regulation 1 by the laboratory, OR BY AN OUTPATIENT CLINIC THAT
76 PERFORMS LABORATORY TESTING ON SITE, whether or not associated with a hospital. The following
77 laboratories shall also report: 1) out-of-state laboratories that maintain an office or collection facility in
78 Colorado or arrange for collection of specimens in Colorado; and 2) in-state laboratories that send
79 specimens to out-of-state referral laboratories. The case shall be reported by a laboratory when a result
80 diagnostic of or highly correlated with clinical illness is found. Laboratory assays which demonstrate only
81 immunity should not be reported (for example, a single elevated rubella antibody titer obtained during
82 routine prenatal screening should not be reported).

83
84 For organisms so noted in Appendix A, Reportable Diseases Table, testing laboratories shall routinely
85 submit bacterial culture isolates or patient clinical material that yields positive findings to the
86 DEPARTMENT, CDPHE Laboratory Services Division. Clinical material is defined as: (i) A culture isolate
87 containing the infectious organism for which submission of material is required, or (ii) If an isolate is not
88 available, material containing the infectious organism for which submission of material is required, in the
89 following order of preference: (A) a patient specimen; (B) nucleic acid; or (C) other laboratory material.

90
91 All specimens shall be accompanied by the following information: (a) Patient's name, date of birth, sex,
92 race, ethnicity, and address (b) Name and address of responsible physician or other health care provider
93 (c) Name of disease or condition (d) Laboratory information - test name, collection date and specimen
94 type. Laboratories should make an effort to report all test results electronically, whenever possible.

95
96 **Regulation 4. Treatment and Control of Tuberculosis**

97
98 The emergence of multiple drug-resistant tuberculosis in this country and state dictates a coherent and
99 consistent strategy in order to protect the public health from this grave threat. The underlying principles of
100 disease control expressed in the following rules are as follows: use of the most rapid and modern
101 diagnostic methods by laboratories, rapid reporting, full patient compliance with medical treatment, and
102 prevention of spread of tuberculosis in health care settings. The tuberculosis statute (C.R.S. 25-4-501 et
103 seq.) covers subject matters not included in these regulations.

104
105 A. All confirmed or suspected cases of active tuberculosis disease, regardless of whether confirmed
106 by laboratory tests, shall be reported to the DEPARTMENT OR COUNTY, DISTRICT, OR
107 MUNICIPAL PUBLIC HEALTH AGENCY ~~state or local health agency~~ within 1 WORKING DAY 24
108 hours by physicians, health care providers, hospitals, other similar private or public institutions, or
109 any other person providing treatment to the confirmed or suspected case. The reports shall
110 include the following information: the patient's name, date of birth, sex, race, ethnicity, address

- 111 (including city and county), name and address of the reporting physician or agency; and such
112 other information as is needed to locate the patient for follow-up. If reported by a physician, the
113 physician shall also give the evidence upon which the diagnosis of tuberculosis was made, the
114 part of the body affected, and the stage of disease.
115
- 116 B. Physicians, health care providers, and health care facilities shall report within 7 calendar days the
117 following tuberculin skin test (TST) or Interferon-Gamma Release Assay (IGRA) result if it occurs
118 in a health care worker, correctional facility worker, or detention facility worker; ~~a~~ a positive TST
119 (defined as = 5 mm in duration) or positive IGRA test (based on manufacturer's interpretation
120 criteria) if the worker has had prolonged or frequent face-to-face contact with an infectious
121 tuberculosis case.
122
- 123 C. Laboratories shall report within 1 WORKING DAY ~~24 hours~~ any result diagnostic of or highly
124 correlated with active tuberculosis disease, including cultures positive for *Mycobacterium*
125 *tuberculosis* and sputum smears positive for acid fast bacilli, and shall report the results of tests
126 for antimicrobial susceptibility performed on positive cultures for tuberculosis.
127
- 128 D. Results must be reported by the laboratory which performs the test, but an in-state laboratory
129 which sends specimens to an out-of-state referral laboratory is also responsible for reporting the
130 results.
131
- 132 E. A laboratory may fulfill its requirement to report (in parts C and D of this regulation) by submitting
133 a sputum specimen from the patient to either the DEPARTMENT, ~~CDPHE~~ LABORATORY
134 SERVICES DIVISION ~~State Public Health Laboratory~~, or for facilities located in Boulder,
135 Broomfield, Denver, Adams, Douglas, Arapahoe, and Jefferson counties, to the Denver Public
136 Health laboratory. The reporting requirement is not fulfilled if the laboratory submits an isolate
137 from a culture to either of the public health laboratories or if the laboratory delays sending the
138 sputum specimen for more than 2 calendar days after collection of the specimen.
139
- 140 F. When a laboratory performs a culture that is positive for *Mycobacterium tuberculosis*, the
141 laboratory shall ~~SUBMIT A SAMPLE OF THE ISOLATE~~ ~~store the isolate until it receives a~~
142 ~~request from the state or local health department for the isolate. In lieu of such storage, the~~
143 ~~laboratory may fulfill this requirement by submitting the isolate to the DEPARTMENT,~~
144 ~~LABORATORY SERVICES DIVISION state public health laboratory~~ NO LATER THAN ONE
145 WORKING DAY AFTER THE OBSERVATION OF POSITIVE FINDINGS.
146
- 147 G. The DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~state~~
148 ~~or local health department~~ is authorized to perform evaluations of the timeliness of laboratory
149 diagnostic processes. The data collected in an evaluation may include the mean, median, and
150 range for the following indices: the length of time from specimen collection to isolation; the length
151 of time from isolation of an organism to identification of the organism as *Mycobacterium*
152 *tuberculosis*; and the length of time from isolation until susceptibility test results are finalized. The
153 DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~state or~~
154 ~~local health department~~ shall provide the laboratory and hospital the results of its evaluation,
155 including comparison of the laboratory indices to norms for other similar laboratories
156
- 157 H. The Board of Health determines that to prevent the emergence of multiple drug-~~r~~resistant
158 tuberculosis, it is necessary and appropriate and good medical practice that persons with active
159 tuberculosis disease receive directly observed treatment for their disease. All ~~medical~~-HEALTH
160 CARE providers and health care organizations are required to provide directly observed therapy
161 for patients with active tuberculosis disease for the full course of therapy, unless a variance for a
162 particular patient from this requirement is approved by the tuberculosis control program of the
163 ~~State Department of Public Health and Environment~~ or Denver Public Health. Directly observed
164 therapy is not required for patients with extrapulmonary tuberculosis disease provided that the
165 presence of pulmonary tuberculosis has been investigated and excluded. In applicable situations,
166 a variance shall be granted in accordance with C.R.S. 25-4-506(3).

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HEALTH CARE ~~Medical~~ providers and health care organizations shall report to the DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~state health department or local public health agency~~ within 7 calendar days the name of any patient on directly observed therapy who has missed one dose. When requested by HEALTH CARE ~~medical~~ providers and health care organizations, the DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~state health department or local public health agency~~ shall provide directly observed treatment to outpatients with active tuberculosis disease and this shall fulfill the requirement for the HEALTH CARE ~~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 DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~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 TST 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 TST and IGRA test results as confidential medical information. Pursuant to C.R.S. 25-4-508, authorized personnel of the ~~ed~~ ~~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 COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~local health agency~~ must be a physician licensed to practice medicine in the State of Colorado. The chief medical ~~health~~ officer of a COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~local health agency~~ may design a program, consistent with good medical practice, of required screening for latent TUBERCULOSIS ~~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 TST or IGRA test and clinical evaluation. If free of signs and symptoms of tuberculosis, subsequent testing would be dependent on the results of the TST or IGRA test.

 - (2) The chief medical ~~health~~ officer of a COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~local public 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 COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~local public health agency~~ should provide at least 30 calendar days notice to potentially affected persons, groups, and businesses prior to consideration of the proposed program by the local board of health.

- 223
224 (3) Except as provided in subparagraph 6 of this paragraph K, no program approved by a
225 local board of health shall be implemented without the approval of the ~~State Board of~~
226 Health. Within 30 calendar days of a program having been approved by a local board of
227 health, the COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~local~~
228 ~~public health agency~~ shall submit a copy of the proposed program to the ~~State Board of~~
229 Health. When considering a proposed COUNTY, DISTRICT, OR MUNICIPAL PUBLIC
230 HEALTH AGENCY ~~local public health agency~~ program, the ~~State Board of~~ Health shall
231 provide notice to all parties on its mailing list at least 20 calendar days prior to the
232 hearing.
233
- 234 (4) If an individual has signs and symptoms compatible with tuberculosis in the infectious
235 stages, the chief medical ~~health~~ officer may require examination pursuant to 25-4-506,
236 C.R.S. The screening may be performed by an institution, organization, or agency acting
237 at the direction of the COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~local~~
238 ~~health agency~~. The results of screening shall be given in writing to the person
239 screened. Any person who is found to have latent TUBERCULOSIS ~~TB~~ infection without
240 evidence of active disease shall be counseled and offered appropriate treatment by the
241 agency performing the screening, but the person is not required to take such treatment.
242
- 243 (5) Locally required screening programs shall be evaluated and reviewed by the local board
244 of health every three years.
245
- 246 (6) Nothing in this rule shall prohibit the DEPARTMENT OR COUNTY, DISTRICT, OR
247 MUNICIPAL PUBLIC HEALTH AGENCIES ~~State Health Department or the local health~~
248 ~~agency~~ from developing voluntary screening programs, from investigating and screening
249 contacts of suspected or confirmed cases of tuberculosis in a contagious form, or from
250 responding to potential outbreaks of tuberculosis in a community.
251

252 **Regulation 5. Investigations to Confirm the Diagnosis, Treatment, and Causes of Epidemic and**
253 **Communicable Diseases and to Determine Appropriate Methods of Epidemic and**
254 **Communicable Disease Control**
255

256 Investigations may be conducted to confirm the diagnosis, treatment, and causes of reportable conditions
257 and shall be considered official duties of the DEPARTMENT AND COUNTY, DISTRICT, OR MUNICIPAL
258 PUBLIC HEALTH AGENCIES ~~health department or health agency~~. Such investigations may include, but
259 are not limited to:
260

- 261 A. ~~(a)~~ Rreview of pertinent, relevant medical records by authorized personnel, if necessary to confirm
262 the diagnosis; to investigate causes; to identify other cases related to the outbreak or the reported
263 communicable disease in a region, community, or workplace; to determine if a patient with a
264 reportable disease has received adequate treatment to render him/her non-infectious or a person
265 exposed to a case has received prophylaxis, if appropriate. Such review of records may occur
266 without patient consent and shall be conducted at reasonable times and with such notice as is
267 reasonable under the circumstances. Where feasible, facilities are encouraged to provide remote
268 electronic access to authorized health department staff for this purpose;
269
- 270 B. ~~(b)~~ Pperforming follow-up interview(s) with the case or persons knowledgeable about the case to
271 collect information pertinent and relevant to the cause(s) of or risk factors for the reportable
272 condition;
273
- 274 C. ~~(c)~~ Mmedical examination and testing of persons with the explicit consent of such persons;
275
- 276 D. ~~(d)~~ Oobtaining from public or private businesses or institutions THE LISTS OF PERSONS WITH A
277 SIMILAR OR COMMON POTENTIAL EXPOSURE TO A REPORTED CASE; ~~the identities and~~
278 ~~locating information of persons, travelers, passengers, or transportation crews with a similar or~~

- 279 ~~common potential exposure to the infectious agent as a reported case~~; such exposure may be
 280 current or have occurred in the past;
 281
- 282 E. ~~(e)~~ Interviewing or administering questionnaire surveys confidentially to any resident of a community
 283 or any agent, owner, operator, employer, employee OF A PUBLIC OR PRIVATE BUSINESS OR
 284 INSTITUTION, ~~or client of a public or private business or institution~~, that is either
 285 epidemiologically associated with A REPORTED CASE ~~the outbreak or with the reported~~
 286 ~~communicable disease case~~ or has had a similar exposure as a reported case;
 287
- 288 F. ~~(f)~~ ~~Collecting environmental samples of substances or measurements of physical agents that may~~
 289 ~~be related to the cause of an outbreak or reportable communicable disease~~; COLLECTING AND
 290 ANALYZING SAMPLES OR MEASUREMENTS OF ITEMS THAT MAY BE RELATED TO THE
 291 CAUSE OF THE OUTBREAK OR REPORTABLE DISEASE;
 292
- 293 G. ~~(g)~~ Taking photographs OR VIDEOS related to the purpose of the investigation; If the
 294 photographs/VIDEOS are taken in a business, the employer shall have the opportunity to review
 295 the photographs/VIDEOS taken or obtained for the purpose of identifying those which contain or
 296 might reveal a trade secret;
 297
- 298 H. ~~(h)~~ ~~Entering a place of employment for the purpose of conducting investigations of those processes,~~
 299 ~~conditions, structures, machines, apparatus, devices, equipment, records, and materials within~~
 300 ~~the place of employment which are relevant, pertinent, and necessary to the investigation of the~~
 301 ~~outbreak or reportable communicable disease~~; ENTERING A PUBLIC OR PRIVATE ENTITY,
 302 SUCH AS A BUSINESS OR SCHOOL, FOR THE PURPOSE OF CONDUCTING
 303 INVESTIGATIONS OF THOSE PROCESSES, CONDITIONS, STRUCTURES, MACHINES,
 304 APPARATUS, DEVICES, EQUIPMENT, RECORDS, AND MATERIALS WITHIN THE PLACE OF
 305 EMPLOYMENT WHICH ARE RELEVANT, PERTINENT, AND NECESSARY TO THE
 306 INVESTIGATION; such investigations shall be conducted during regular working hours or at other
 307 reasonable times and with such notice as is reasonable under the circumstances.
 308
- 309 I. REVIEW OF WORKERS' COMPENSATION CLAIMS;
 310
- 311 J. REVIEW OF TOXIC TORT OR PRODUCT LIABILITY CLAIMS FILED WITH STATE OR
 312 FEDERAL COURTS WITHIN THE STATE; AND
 313
- 314 K. REVIEW OF PREVIOUSLY CONDUCTED ENVIRONMENTAL OR PRODUCT SAMPLING
 315 DATA THAT MAY BE RELATED TO THE CAUSE OF THE OUTBREAK OR REPORTABLE
 316 DISEASE.
 317

318 **Regulation 6. Information Sharing**
 319

320 Whenever a COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~local public health~~
 321 ~~agency~~ learns of a case of a reportable disease or an epidemic or communicable disease exposure
 322 potentially threatening TO ~~the~~ public health, it shall notify the ~~State~~ Department of Health in a timely
 323 manner, usually within the timeframe for reporting in Regulation 1.
 324

325 The ~~State~~ Department of Health shall, in turn, notify the appropriate COUNTY, DISTRICT, OR
 326 MUNICIPAL PUBLIC HEALTH AGENCY ~~local health department or agency~~ in a timely manner, usually
 327 within the timeframe for reporting in Regulation 1, whenever it learns of a case of a reportable disease or
 328 it learns of an epidemic or communicable disease exposure potentially threatening TO ~~the~~ public health.
 329

330 These requirements shall not apply if the ~~State~~ DEPARTMENT and ~~local~~ COUNTY, DISTRICT, OR
 331 MUNICIPAL PUBLIC health agencies mutually agree not to share information on reported cases.
 332

333 Sharing of medical information on persons with reportable diseases between authorized personnel of
 334 THE DEPARTMENT AND COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCIES ~~state~~

335 ~~and local health departments~~ shall be restricted to information necessary for the treatment, control,
336 investigation, and prevention of epidemic and communicable diseases dangerous to ~~the~~ public health.

337
338 **Regulation 7. Food Handling and Infected Persons**

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

346
347 **Regulation 8. Reporting of Diseases Among Animals and Waiver Process for Rabies Inoculation**

- 348
349 A. Every veterinarian, livestock owner, veterinary diagnostic laboratory director, or other person
350 having the care of, or knowledge of, the existence of animals having or suspected of having any
351 disease which may endanger ~~the~~ public health such as rabies, anthrax, plague, tularemia,
352 encephalitis, bovine spongiform encephalopathy, etc., shall promptly report the facts to the
353 DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~local~~
354 ~~health department or health agency or the State Department of Health~~.
- 355
356 B. Pursuant to C.R.S. § 25-4-607 (2), a veterinarian licensed in Colorado may issue a written waiver,
357 as provided in this section, exempting an animal from a rabies vaccination order if the
358 veterinarian, in his or her professional opinion, determines the rabies inoculation is
359 contraindicated due to the animal's medical condition. The terms "waiver" and "exemption" as
360 used in this section are interchangeable. A veterinarian may issue a waiver if:
- 361
362 1. The animal to be exempted has a medical condition defined as "a disease, illness, or
363 other pathological state" for which, in the opinion of the exempting veterinarian, a rabies
364 inoculation is contraindicated;
 - 365
366 2. A valid veterinary-client-patient relationship, as defined under C.R.S. § 12-64-103 (15.5),
367 has been established between the veterinarian, owner and animal to be exempted from
368 rabies inoculation;
 - 369
370 3. The veterinarian completes and signs the veterinary section of the Exemption from
371 Rabies Vaccination form provided by the Department;
 - 372
373 4. The animal owner signs the informed consent section of the Exemption from Rabies
374 Vaccination form;
 - 375
376 5. The veterinarian maintains the signed exemption as part of the animal's medical record
377 and provides a copy to the owner;
 - 378
379 6. The exemption issued is limited to the anticipated duration of the animal's medical
380 condition that precludes inoculation; and
 - 381
382 7. The veterinarian provides a copy of the exemption form to the Department OR COUNTY,
383 DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY, ~~the local health department~~ or
384 animal control agency, when requested.
- 385
386 C. A waiver may not exceed a period of three years from the date of issuance. If the medical
387 condition persists beyond a three year period and, in the professional opinion of a veterinarian
388 licensed in ~~the State of~~ Colorado, the exemption continues to be appropriate, a new waiver may
389 be issued.

- 391 D. Upon receiving a complaint regarding the validity of a rabies inoculation exemption, the executive
392 director or his/her designee(s) may review Exemption from Rabies Vaccination forms and
393 examine the veterinary records pertaining to the medical condition to determine if the medical
394 condition legitimately contraindicates rabies inoculation. If appropriate, the executive director or
395 his/her designee(s) may refer the case to the ~~State~~ Board of Veterinary Medicine.

396 **Regulation 9. Confidentiality**

397
398
399 All personal medical records and reports held or viewed by the DEPARTMENT OR COUNTY, DISTRICT,
400 OR MUNICIPAL PUBLIC HEALTH AGENCY ~~state health department or local public health agency~~ in
401 compliance with these regulations shall be confidential information subject to C.R.S. 25-1-122(4) and
402 ~~AND~~ C.R.S. 25-4-406(1). Reasonable efforts shall be made by the ~~d~~Department to consult with the
403 responsible physician, other health care provider, or medical facility caring for the patient prior to any
404 further follow-up by THE DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH
405 AGENCIES ~~state health department or local public health agencies~~. THIS INFORMATION IS TO BE
406 USED BY THE PUBLIC HEALTH AGENCIES AS SOURCE MATERIAL FOR NECESSARY DISEASE
407 CONTROL EFFORTS AND THE DEVELOPMENT OF PREVENTION PROGRAMS.

408 409 **Regulation 10. Use of Sterile Needles, and Cleaning and Disinfection of Other Instruments, Probes,** 410 **and Devices Used by Practitioners of Acupuncture and Adjunctive Therapies (promulgated by the** 411 **Executive Director)**

412
413 This regulation is promulgated pursuant to ~~C.R.S.~~ Section 12-29.5-111, **C.R.S.**, which states ~~that~~ the
414 Department shall promulgate rules relating to the proper cleaning and sterilization of needles used in the
415 practice of acupuncture and the sanitation of acupuncture offices.

416
417 All parts of the premises of an acupuncture establishment shall be kept in a clean, sanitary, neat, and
418 orderly condition at all times. All surfaces (e.g., tables, counters, chairs) used in connection with
419 procedures involving equipment items shall be cleaned and disinfected with a disinfectant registered by
420 the U.S. Environmental Protection Agency for use in health care settings according to labeled
421 instructions. Equipment ~~items~~ shall be defined as any needle, instrument, probe, or device utilized by
422 practitioners of acupuncture that punctures the skin or enters tissue of any patient/client.

423
424 Prior to and after each treatment of acupuncture, the practitioner shall perform hand hygiene by either
425 washing his/her hands with soap and water or using an alcohol-based hand sanitizer.

426
427 Needles and other equipment items that puncture the skin or enter the tissues of any patient/client shall
428 be disposable single-use items that are appropriately discarded immediately after use in an appropriate
429 sharps container, and shall never be used on more than one patient. Equipment ~~items~~ that are vehicles
430 for needles and other puncturing devices shall either be disposable, single-use items (preferred), or
431 thoroughly cleaned and disinfected between each patient use according to the manufacturers'
432 instructions. If there are no manufacturers' instructions for how to clean and disinfect the device, the
433 device shall not be used on more than one patient.

434 435 436 **Regulation 11. Sexually Transmitted Infections**

437
438 The ~~Colorado~~ Board of Health recognizes that non-sexual transmission may occur for some ~~of these~~
439 infections, and ~~that~~ in individual cases, based on clinical and epidemiologic information, the responsible
440 physician or other health care provider may conclude the patient's infection was not sexually acquired.

441
442 Information concerning testing, treatment, causes, or the prevention of sexually transmitted infections
443 shall be shared, to the minimum extent necessary to achieve the public health purpose, between the
444 appropriate COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~local public health~~
445 ~~agency~~, contracted agency, Ryan White-funded agency, other health agency or person providing direct

446 services related to sexually transmitted infection and the ~~state Department of health~~, as provided by
447 ~~C.R.S. SECTION 25-4-406(1)(b)~~, **C.R.S.**

448
449 With respect to Regulation 5, investigations related to sexually transmitted infections will be limited to the
450 information necessary to confirm the diagnosis, treatment, source of infection, and identification of
451 measures that may be used to prevent additional sexually transmitted infections.

452
453 The ~~d~~Department shall destroy personal identifying information on all persons with CD4 or viral load
454 results if THE investigation subsequent to the report finds no evidence of a sexually transmitted infection.

455
456 **C.R.S. SECTION 25-4-411 (1)(a)**, **C.R.S.** requires the ~~state d~~Department of health to conduct an
457 anonymous counseling and testing program for persons considered to be at high risk for infection with
458 human immunodeficiency virus (HIV). The provision of confidential counseling and testing for HIV is the
459 preferred screening service for detection of HIV infection. Local boards of health who provide HIV
460 counseling and testing through a contractual agreement with the ~~state d~~Department of health shall
461 consider the need for an anonymous HIV testing option in their jurisdiction, upon petition. The
462 consideration of this option must provide an opportunity for public comment in a public forum, including
463 anonymous testimony presented in writing or through an organization. Local boards of health electing to
464 provide confidential HIV testing with an anonymous option must do so in conjunction with publicly funded
465 HIV testing and counseling projects.

466 467 Operational Standards

- 468
469 A. All persons providing HIV testing and counseling at a publicly funded HIV testing and counseling
470 project in a non health-care setting will have completed an HIV testing and counseling course
471 approved by the state department of health.
472
473 B. All persons performing partner services will have completed courses concerning introduction to
474 sexually transmitted disease interviewing and partner notification, and other related courses as
475 specified by the ~~state d~~Department of health.
476
477 C. Of all HIV tests performed at a publicly funded HIV testing and counseling project, 99% of those
478 persons testing HIV positive will receive test results and appropriate post-test counseling related
479 to those test results. Publicly funded HIV testing sites shall make a good faith effort to inform all
480 persons of their test results and shall provide pertinent HIV prevention counseling and referrals.
481
482 D. All persons newly diagnosed with HIV will be referred for partner services. A minimum of 75% of
483 those offered partner services will receive an interview and appropriate referrals. Partner services
484 standards will be determined by the best practices guidance and code of conduct standards for
485 sexually transmitted infection prevention providers developed by the ~~state d~~Department of health.
486 These standards shall be made publicly accessible.
487
488 E. Operational and evaluation standards for HIV testing and counseling sites will be determined by
489 the best practices guidance developed by the ~~state d~~Department of health.
490
491 F. In accordance with ~~C.R.S. SECTION 25-4-404(2)~~, C.R.S., the DEPARTMENT ~~state department of~~
492 ~~health~~ shall create and maintain guidelines, subject to approval by the ~~state B~~oard of Hhealth,
493 concerning the public health procedures described in ~~C.R.S. SECTIONS 25-4-412 and 25-4-413~~,
494 **C.R.S.** These guidelines will include code of conduct standards for the delivery of partner
495 services and clients' rights, responsibilities and protections.
496

Appendix A. Reportable Disease Table

Disease/Event	Pathogen/Organism	Time*	Reporter ¹	Specimen Source(s) ²	Send Clinical Material ³
<i>Acinetobacter baumannii</i> , carbapenem-resistant (CRAB) ^{5, 4-Metro}	Carbapenem-resistant <i>Acinetobacter baumannii</i> (including <i>Acinetobacter baumannii</i> complex and <i>Acinetobacter baumannii-calcoaceticus</i> complex)	30 days	L	Sterile sites, urine	
Acute flaccid myelitis		4 days	P		
Animal bites by dogs, cats, bats, skunks, foxes, raccoons, coyotes, or other wild carnivores ^{6,7}		24 hrs	P		
Animal bites by mammals not listed above ⁵		4 days	P		
Anthrax ⁶	<i>Bacillus anthracis</i>	Immed	L & P	All	Required
Arboviral Disease	Eastern equine encephalitis, JAPANESE ENCEPHALITIS , LaCrosse encephalitis virus, California encephalitis serogroup, POWASSAN VIRUS , St. Louis encephalitis virus and Western equine encephalitis virus	4 days	L	All	
Botulism ⁶	<i>Clostridium botulinum</i>	Immed	L & P	All	
Brucellosis ⁶	<i>Brucella</i> species	4 days	L & P	All	Required
Campylobacteriosis	<i>Campylobacter</i> species	4 days	L & P	All	
CANDIDA AURIS⁸	CANDIDA AURIS, CANDIDA HAEMULONII	1 Working Day	L & P	ALL	Required
Candidemia ^{4-Metro}	<i>Candida</i> species	30 days	L	Blood	Requested
CATHETER-ASSOCIATED URINARY TRACT INFECTION (CAUTI)^{##}	ANY	PER CMS^{##}	P	URINE	
Chancroid	<i>Haemophilus ducreyi</i>	4 days	L & P	All	
Chikungunya	Chikungunya virus	4 days	L	All	
Chlamydia	<i>Chlamydia trachomatis</i>	4 days	L & P	All	
Cholera ⁶	<i>Vibrio cholerae</i>	Immed	L & P	All	Required
CJD and other transmissible spongiform encephalopathies (TSEs) ⁶		4 days	P		
<i>Clostridium difficile</i> infection ^{4-Metro}	<i>Clostridium difficile</i>	30 days	L	All	Requested ⁸
Colorado tick fever	Colorado tick fever virus	4 days	L	All	

Cryptosporidiosis	<i>Cryptosporidium</i> species	4 days	L & P	All	
Cyclosporiasis	<i>Cyclospora</i> species	4 days	L & P	All	
Dengue	Dengue virus	4 days	L	All	
Diphtheria ⁶	<i>Corynebacterium diphtheriae</i>	Immed	L & P	All	Required
Encephalitis ⁶		4 days	P	All	
Enterobacteriaceae, carbapenem-resistant (CRE) ⁹	Carbapenem-resistant <i>Escherichia coli</i> , <i>Klebsiella</i> species, <i>Enterobacter</i> species CITROBACTER SPECIES, SERRATIA SPECIES, RAOULTELLA SPECIES, PROVIDENCIA SPECIES, PROTEUS SPECIES, MORGANELLA SPECIES, AND ANY CARBAPENEMASE-PRODUCING ENTEROBACTERIACEAE OF ANY GENUS AND SPECIES	4 days	L	All	Requested ⁸
ENTEROBACTERIACEAE, EXTENDED-SPECTRUM BETA-LACTAMASE (ESBL)^{###, 4-BOULDER}	ESCHERICHIA COLI AND KLEBSIELLA SPECIES	4 DAYS	L	All	
Escherichia coli O157:H7 and Shiga toxin-producing Escherichia coli ¹⁰	Shiga toxin-producing <i>Escherichia coli</i> ¹⁰	4 days	L & P	All	Required
Giardiasis	<i>Giardia lamblia</i>	4 days	L & P	All	
Gonorrhea, any site	<i>Neisseria gonorrhoeae</i>	4 days	L & P	All	
Group A streptococci ^{11, 4-Metro}	<i>Streptococcus pyogenes</i>	4 days	L	Sterile only	Required ¹²
Group B streptococci ^{4-Metro}	<i>Streptococcus agalactiae</i>	30 days	L	Sterile only	Required ¹²
<i>Haemophilus influenzae</i>	<i>Haemophilus influenzae</i>	1 working day	L & P	Sterile only	Required
Hantavirus disease ⁶	Hantavirus	4 days	L & P	All	
Healthcare-associated infections ¹³		4 days	P		
Hemolytic uremic syndrome if \leq 18 years ⁶		4 days	P		
Hepatitis A ⁶	Hepatitis A virus (+IgM anti-HAV)	1 working day	L & P	All	
Hepatitis B	Hepatitis B virus (+HBsAg, +IgM anti-HBc, +HBeAg, or +HBV DNA)	4 days	L & P	All	
Hepatitis C	Hepatitis C virus (+ serum antibody titer, including signal to cut-off ratio, or more specific + tests)	4 days	L & P	All	
Hepatitis, other viral		4 days	P		

Human immunodeficiency virus (HIV)/ acquired immunodeficiency syndrome (AIDS)	<ul style="list-style-type: none"> • Human immunodeficiency virus • CD4 counts (any value) • HIV viral load (any value) • <i>HIV genotype</i> 	4 days	<ul style="list-style-type: none"> • L & P • L & P • L & P • L 	All	
Influenza-associated death if < 18 years		4 days	P		
Influenza-associated hospitalization		4 days	P		
Japanese Encephalitis	Japanese Encephalitis virus	4 days	L	All	
Legionellosis	<i>Legionella</i> species	4 days	L & P	All	
Leprosy (Hansen's Disease)		4 days	P		
Listeriosis	<i>Listeria monocytogenes</i>	4 days	L & P	All	Required
Lyme disease	<i>Borrelia burgdorferi</i>	4 days	L & P	All	
Lymphogranuloma venereum (LGV)	<i>Chlamydia trachomatis</i>	4 days	L & P	All	
Malaria ⁶	<i>Plasmodium</i> species	4 days	L & P	All	
Measles (rubeola) ⁶	Measles virus	Immed	L & P	All	
Meningococcal Disease ⁶	<i>Neisseria meningitidis</i> or gram-negative <i>diplococci</i>	Immed	L & P	Sterile only	Required
METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) BACTEREMIA^{##}	METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA)	PER CMS^{##}	P	BLOOD	
Mumps ⁶	Mumps virus (acute infection)	4 days	L & P	All	
Outbreaks - known or suspected of all types, ⁶ including those transmitted from food, water, person-to-person, and related to a health care setting ⁶		Immed	L & P		
Pertussis (whooping cough) ⁶	<i>Bordetella pertussis</i>	1 working day	L & P	All	Requested ⁸
Plague ⁶	<i>Yersinia pestis</i>	Immed	L & P	All	Required
Poliomyelitis ⁶	Poliovirus	Immed	L & P	All	
Powassan virus disease	Powassan virus	4 days	L	All	
Pseudomonas, carbapenem- resistant ¹⁴	<i>Pseudomonas aeruginosa</i>	4 days	L	All	Requested ⁸
Psittacosis	<i>Chlamydia psittaci</i>	4 days	L & P	All	

Q fever ⁶	<i>Coxiella burnetii</i>	4 days	L & P	All	
Rabies: human (suspected) ⁶	Rabies virus (Lyssavirus)	Immed	L & P	All	
Rickettsiosis	<i>Rickettsia</i> species, including Rocky Mtn spotted fever and typhus groups	4 days	L & P	All	
Rubella (acute infection) ⁶	Rubella virus	1 working day	L & P	All	
Rubella (congenital) ⁶	Rubella virus	4 days	L & P	All	
Salmonellosis	<i>Salmonella</i> species	4 days	L & P	All	Required
Severe or novel coronavirus	Severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV)	Immed	L & P	All	
Shigellosis	<i>Shigella</i> species	4 days	L & P	All	Required
Smallpox ⁶	Variola virus (Orthopox virus)	Immed	L & P	All	
<i>Staphylococcus aureus</i> , Vancomycin-resistant	Vancomycin-resistant <i>Staphylococcus aureus</i>	4 days	L	All	Required
Streptococcal toxic shock syndrome	<i>Streptococcus pyogenes</i>	4 days	P	All	Required ¹²
<i>Streptococcus pneumoniae</i>	<i>Streptococcus pneumoniae</i>	4 days	L	Sterile only	Required ¹²
Syphilis ⁶	<i>Treponema pallidum</i>	1 working day	L & P	All	
Tetanus ⁶	<i>Clostridium tetani</i>	4 days	P	All	
Tick-borne relapsing fever ⁶	<i>Borrelia</i> species	4 days	L & P	All	
Toxic shock syndrome (non-streptococcal)		4 days	P		
Trichinosis ⁶	<i>Trichinella</i> species	4 days	P	All	
Tuberculosis disease (active) ⁶	<i>Mycobacterium tuberculosis</i> ¹⁵	1 working day	L & P	All	See Reg 4F
Tularemia ⁶	<i>Francisella tularensis</i>	1 working day	L & P	All	Required
Typhoid fever ⁶	<i>Salmonella</i> Typhi	1 working day	L & P	All	Required
Varicella (chicken pox) ⁶	Varicella virus	4 days	L & P	All	
Vibriosis	<i>Vibrio</i> species, non-cholera	4 days	L	All	Required

Viral hemorrhagic fever	Crimean-Congo hemorrhagic virus, Ebola virus, Lassa fever virus, Lujo virus, Marburg virus, Guaranito virus, Junin virus, Machupo virus, Sabia virus	Immed	L & P	All	Required
West Nile virus (acute infection, IgM+)	West Nile virus	4 days	L	All	
Yellow fever	Yellow fever virus	4 days	L	All	
Yersiniosis ^{4-Seven}	<i>Yersinia non-pestis</i> species	4 days	L	All	Required
Zika virus	Zika virus	4 days	L	All	

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

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

CANDIDA AURIS IDENTIFIED, OR ANY SUSPECTED *CANDIDA AURIS* (E.G., *CANDIDA HAEMULONII* IDENTIFIED BY A LABORATORY INSTRUMENT NOT EQUIPPED TO DETECT *CANDIDA AURIS*).

REPORTING REQUIREMENT IS FULFILLED THROUGH DEPARTMENT ACCESS TO THE NATIONAL HEALTHCARE SAFETY NETWORK (NHSN) FOR THOSE HEALTH CARE FACILITIES THAT ARE REQUIRED TO REPORT CATHETER-ASSOCIATED URINARY TRACT INFECTION (CAUTI) AND/OR METHICILLIN-RESISTANT *STAPHYLOCOCCUS AUREUS* (MRSA) BACTEREMIA TO THE CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS). IN THESE INSTANCES THESE HEALTH CARE FACILITIES SHALL CONFER RIGHTS TO THE DEPARTMENT TO ACCESS THE NHSN DATA FOR THESE CONDITIONS.

ESCHERICHIA COLI AND *KLEBSIELLA* SPECIES RESISTANT TO AT LEAST ONE EXTENDED-SPECTRUM CEPHALOSPORIN (CEFTAZIDIME, CEFOTAXIME OR CEFTRIAXONE) OR *ESCHERICHIA COLI* AND *KLEBSIELLA* SPECIES THAT TEST POSITIVE FOR PRODUCTION OF AN EXTENDED-SPECTRUM BETA-LACTAMASE (ESBL) DEMONSTRATED BY A RECOGNIZED TEST (E.G., BROTH MICRODILUTION, DISK DIFFUSION).

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 THE DEPARTMENT -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, CEREBROSPINAL FLUID (CSF), pleural fluid (includes chest fluid, thoracentesis 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 abscesses are not considered sterile sites.

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

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

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

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

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

4-BOULDER CONDITION REPORTABLE ONLY AMONG RESIDENTS OF BOULDER COUNTY.

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

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

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

- 8 Clinical material is requested from selected laboratories.

- 9 *Escherichia coli*, *Klebsiella* species, ~~and Enterobacter species~~, *CITROBACTER* SPECIES, *SERRATIA* SPECIES, AND *RAOULTELLA* SPECIES that are resistant to at least one carbapenem (including imipenem, meropenem, doripenem, or ertapenem); or ~~*Escherichia coli*, *Klebsiella* species, and Enterobacter species~~ *PROVIDENCIA* SPECIES, *PROTEUS* SPECIES, *MORGANELLA* SPECIES THAT ARE RESISTANT TO AT LEAST ONE CARBAPENEM (INCLUDING MEROPENEM, DORIPENEM, OR ERTAPENEM; BUT NOT INCLUDING IMIPENEM); OR ENTEROBACTERIACEAE OF ANY GENUS AND SPECIES that test positive for production of carbapenemase (i.e. E.G., KPC, NDM, VIM, IMP, OXA-48) demonstrated by a recognized test (e.g., MODIFIED CARBAPENEM INACTIVATION METHOD [MCIM], polymerase chain reaction [PCR], NUCLEIC ACID AMPLIFICATION TEST [NAAT], metallo-beta-lactamase test, modified-Hodge test [MHT], Carba-NP).

- 10 This includes any shiga-toxin test or O157 antigen test that is positive, even if no culture is performed. If the laboratory does not have the capacity to perform H (flagellar) antigen tests, then *Escherichia coli* O157 should be reported.
- 11 If Group A streptococci is isolated from a wound or surgical tissue/specimen and is accompanied by necrotizing fasciitis or streptococcal toxic shock syndrome, the case shall be reported and the isolate shall be submitted.
- 12 ~~Clinical material shall be submitted from laboratories located in the seven-county Denver Metropolitan Area (Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas, and Jefferson Counties) when the material is from residents of the Metro Area (Adams, Arapahoe, Denver, Douglas and Jefferson counties).~~ CLINICAL MATERIAL SHALL BE SUBMITTED FROM LABORATORIES WHEN THE MATERIAL IS FROM RESIDENTS OF THE FIVE-COUNTY METRO AREA (ADAMS, ARAPAHOE, DENVER, DOUGLAS AND JEFFERSON COUNTIES).
- 13 Reportable only by facilities that are voluntarily participating in applied public health projects. Appendix B includes a definition of healthcare-associated infections, a list of included infections, and a list of included health facility types.
- 14 *Pseudomonas aeruginosa* resistant to at least one of the following carbapenems: imipenem, meropenem, or doripenem; OR *Pseudomonas aeruginosa* that tests positive for production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA).
- 15 Including (+) AFB sputum smear.

Appendix B. Healthcare-Associated Infections

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

Healthcare-associated infections include:

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

Health facility types include:

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