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

Through: Tony Cappello, PhD, DCEED Director ***TC***

Date: May 1, 2018

Subject: **Rulemaking Hearing** - Proposed Amendments to 6 CCR 1009-1, Epidemic and Communicable Disease Control

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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.

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.

During the request for rulemaking, the Board asked the department to consider the clearest way to refer to *Candida auris* in the Reportable Diseases Table in Appendix A. Since the

request for rulemaking, staff have studied this request and concluded that listing "*Candida auris*" in the first column is the most appropriate way to refer to this condition as it is consistent with the preferred case definition developed by the Council for State and Territorial Epidemiologists[1] and used by the Centers for Disease Control and Prevention[2].

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. 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. The changes highlighted in yellow for the request for rulemaking presentation continue to appear in yellow so members can see punctuation changes and edits within the table. New language added since the request for rulemaking is also highlighted in yellow.

[1] Council of State and Territorial Epidemiologists. Standardized case definition for Candida auris causing clinical infection and colonization in people. Atlanta, GA: Council of State and Territorial Epidemiologists; 2017. http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/2017PS/2017PSFinal/17-ID-03.pdf

[2] Centers for Disease Control and Prevention. National Notifiable Diseases Surveillance System (NNDSS). *Candida auris* 2018 Case Definition. https://wwwn.cdc.gov/nndss/conditions/candida-auris/case-definition/2018/ Accessed April 26, 2018.

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 confirmed 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. This proposal follows a 2017 pilot project conducted in Boulder County that detected approximately 90 cases of ESBL and demonstrated the likely burden of disease and feasibility of data reporting; additional information on cases is still being collected. Boulder County has been supportive of the pilot, and plans are in place to provide additional funding support to Boulder County to continue surveillance beyond the pilot. 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 correct 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, 25-1-108 (c) (I), 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.

__X___ No

Does this rulemaking incorporate materials by reference?

_____ Yes ___ URL or ___ Sent to State Publications Library

__X___ No

Does this rulemaking create or modify fines or fees?

_____ Yes

___X__ No

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

_X_ 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. Setting up systems in laboratories for reporting will help alleviate some of the burden of reporting. Additionally, the Department is conducting an evaluation of electronic reporting of antibiotic resistant infections, with the goal of obtaining these reports electronically, which will decrease the burden further.

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.

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

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

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

XX The proposed revisions implement stakeholder feedback.

XX 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

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)
_X_ 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.[3] 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

[3] https://www.cdc.gov/mmwr/preview/mmwrhtml/00001665.htm

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)*. 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 Department's outreach to stakeholders has been ongoing with open communication among all stakeholder groups. The Department conducted direct outreach to specific stakeholders (LPHAs, Infection Preventionists, Clinical Laboratories, the Colorado Hospital Association, and the Colorado Medical Society). Additionally, the Department shared communication about the proposed rule changes to a broader audience through the weekly "Hot Topics" e-newsletter. Several stakeholders have asked clarifying questions, but no opposition feedback was received.

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.

_X___ 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. 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:_____ _____

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Disease Control and Environmental Epidemiology Division

EPIDEMIC AND COMMUNICABLE DISEASE CONTROL

6 CCR 1009-1

Adopted by the Board of Health on_____, 2018. Effective _____, 2018.

Regulation 1. Reportable Diseases

For the purpose of these regulations, the diseases named in the Reportable Diseases Table (Appendix A) are declared to be potentially dangerous to ~~the~~ public health and shall be reportable in accordance with ~~the provisions of~~ these regulations. IN ADDITION, ANY LANGUAGE SPECIFYING "(THE) DEPARTMENT" REFERS TO THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT.

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, ANIMAL TO PERSON 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 DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~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.

Manner of Reporting

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

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 DEPARTMENT, LABORATORY SERVICES DIVISION ~~CDPHE State Laboratory~~.

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 D~~d~~epartment OR FEDERAL AGENCIES 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, cases of diseases shall be reported by the physician or other health care provider and by other persons either treating or having knowledge of a reportable disease, including, but not limited to coroners, persons in charge of hospitals or other institutions licensed by the ~~Colorado~~ Department ~~of Public Health and Environment~~, (or their designees), persons in charge of schools (including school nursing staff), licensed day care centers, or any other person providing testing and/or counseling to a person with a sexually transmitted infection.

Regulation 3. Laboratory Reporting

Where Reporter = 'L' in the Appendix A, Reportable Diseases Table, cases of diseases shall be reported with the information required in Regulation 1 by the laboratory, OR BY AN OUTPATIENT CLINIC THAT PERFORMS LABORATORY TESTING ON SITE, whether or not associated with a hospital. The following laboratories shall also report: 1) out-of-state laboratories that maintain an office or collection facility in Colorado or arrange for collection of specimens in Colorado; and 2) in-state laboratories that send specimens to out-of-state referral laboratories. The case shall be reported by a laboratory when a result diagnostic of or highly correlated with clinical illness is found. 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 DEPARTMENT, ~~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. Laboratories should make an effort to report all test results electronically, whenever possible.

Regulation 4. Treatment and Control of Tuberculosis

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

A. All confirmed or suspected cases of active tuberculosis disease, regardless of whether confirmed by laboratory tests, shall be reported to the DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~state or local health agency~~ within 1 WORKING DAY ~~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 calendar days the following tuberculin skin test (TST) or Interferon-Gamma Release Assay (IGRA) result if it occurs in a health care worker, correctional facility worker, or detention facility worker:~~-~~ a positive TST (defined as = OR > 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 1 WORKING DAY ~~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 DEPARTMENT, ~~CDPHE~~ LABORATORY SERVICES DIVISION ~~State Public Health Laboratory~~, or for facilities located in Boulder, Broomfield, Denver, Adams, Douglas, Arapahoe, and Jefferson counties, to the Denver Public Health laboratory. The reporting requirement is not fulfilled if the laboratory submits an isolate from a culture to either of the public health laboratories or if the laboratory delays sending the sputum specimen for more than 2 calendar days after collection of the specimen.

F. When a laboratory performs a culture that is positive for *Mycobacterium tuberculosis*, the laboratory shall SUBMIT A SAMPLE OF THE ISOLATE ~~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 DEPARTMENT, LABORATORY SERVICES DIVISION ~~state public health laboratory~~ NO LATER THAN ONE WORKING DAY AFTER THE OBSERVATION OF POSITIVE FINDINGS.

G. The DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~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 DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~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 multi~~ple~~ drug-~~-~~resistant tuberculosis (MDR-TB), it is necessary and appropriate and good medical practice that persons with active tuberculosis disease receive directly observed treatment for their disease. All ~~medical~~ HEALTH CARE 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).

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 ~~d~~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.

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

(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 COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~local health agency~~. The results of screening shall be given in writing to the person screened. Any person who is found to have latent TUBERCULOSIS ~~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 DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCIES ~~State Health Department or the local health agency~~ from developing voluntary screening programs, from investigating and screening contacts of suspected or confirmed cases of tuberculosis in a contagious form, or from responding to potential outbreaks of tuberculosis in a community.

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

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

A. ~~(a)~~ R~~r~~eview of pertinent, relevant medical records by authorized personnel, if necessary to confirm the diagnosis; to investigate causes; to identify other cases related to the outbreak or the reported communicable disease in a region, community, or workplace; to determine if a patient with a reportable disease has received adequate treatment to render him/her non-infectious or a person exposed to a case has received prophylaxis, if appropriate. Such review of records may occur without patient consent and shall be conducted at reasonable times and with such notice as is reasonable under the circumstances. Where feasible, facilities are encouraged to provide remote electronic access to authorized health department staff for this purpose;

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

C. ~~(c)~~ M~~m~~edical examination and testing of persons with the explicit consent of such persons;

D. ~~(d)~~ O~~o~~btaining from public or private businesses or institutions THE LISTS OF PERSONS WITH A SIMILAR OR COMMON POTENTIAL EXPOSURE TO A REPORTED CASE; ~~the identities and locating information of persons, travelers, passengers, or transportation crews with a similar or~~

~~common potential exposure to the infectious agent as a reported case~~; such exposure may be current or have occurred in the past;

E. ~~(e)~~ ~~I~~interviewing or administering questionnaire surveys confidentially to any resident of a community or any agent, owner, operator, employer, employee OF A PUBLIC OR PRIVATE BUSINESS OR INSTITUTION, ~~or client of a public or private business or institution~~, that is either epidemiologically associated with A REPORTED CASE ~~the outbreak or with the reported communicable disease case~~ or has had a similar exposure as a reported case;

F. ~~(f)~~ ~~Collecting environmental samples of substances or measurements of physical agents that may be related to the cause of an outbreak or reportable communicable disease;~~ COLLECTING AND ANALYZING SAMPLES OR MEASUREMENTS OF ITEMS THAT MAY BE RELATED TO THE CAUSE OF THE OUTBREAK OR REPORTABLE DISEASE;

G. ~~(g)~~ T~~t~~aking photographs OR VIDEOS related to the purpose of the investigation; If the photographs/VIDEOS are taken in a business, the employer shall have the opportunity to review the photographs/VIDEOS taken or obtained for the purpose of identifying those which contain or might reveal a trade secret;

H. ~~(h)~~ ~~Entering a place of employment for the purpose of conducting investigations of those processes, conditions, structures, machines, apparatus, devices, equipment, records, and materials within the place of employment which are relevant, pertinent, and necessary to the investigation of the outbreak or reportable communicable disease~~; ENTERING A PUBLIC OR PRIVATE ENTITY, SUCH AS A BUSINESS OR SCHOOL, FOR THE PURPOSE OF CONDUCTING INVESTIGATIONS OF THOSE PROCESSES, CONDITIONS, STRUCTURES, MACHINES, APPARATUS, DEVICES, EQUIPMENT, RECORDS, AND MATERIALS WITHIN THE PLACE OF EMPLOYMENT WHICH ARE RELEVANT, PERTINENT, AND NECESSARY TO THE INVESTIGATION; such investigations shall be conducted during regular working hours or at other reasonable times and with such notice as is reasonable under the circumstances.

I. REVIEW OF WORKERS' COMPENSATION CLAIMS;

J. REVIEW OF TOXIC TORT OR PRODUCT LIABILITY CLAIMS FILED WITH STATE OR FEDERAL COURTS WITHIN THE STATE; AND

K. REVIEW OF PREVIOUSLY CONDUCTED ENVIRONMENTAL OR PRODUCT SAMPLING DATA THAT MAY BE RELATED TO THE CAUSE OF THE OUTBREAK OR REPORTABLE DISEASE.

Regulation 6. Information Sharing

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

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

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

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

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

Regulation 7. Food Handling and Infected Persons

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

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

A. Every veterinarian, livestock owner, veterinary diagnostic laboratory director, or other person having the care of, or knowledge of, the existence of animals having or suspected of having any disease which may endanger ~~the~~ public health such as rabies, anthrax, plague, tularemia, encephalitis, bovine spongi~~e~~form encephalopathy, etc., shall promptly report the facts to the DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY ~~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 OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY, ~~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. I~~i~~f appropriate, the executive director or his/her designee(s) may refer the case to the S~~tate~~ Board of Veterinary Medicine.

Regulation 9. Confidentiality

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

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

This regulation is promulgated pursuant to ~~C.R.S.~~ Section 12-29.5-111, C.R.S., which states ~~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.

All parts of the premises of an acupuncture establishment shall be kept in a clean, sanitary, neat, and orderly condition at all times. All surfaces (e.g., tables, counters, chairs) used in connection with procedures involving equipment items shall be 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, the practitioner shall perform hand hygiene by either washing his/her hands with soap and water or using an alcohol-based hand sanitizer.

Needles and other equipment items that puncture the skin or enter the tissues of any patient/client shall be disposable single-use items that are appropriately discarded immediately after use in an appropriate sharps container, and shall never be used on more than one patient. Equipment ~~items~~ that are vehicles for needles and other puncturing devices shall 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 shall not be used on more than one patient.

Regulation 11. Sexually Transmitted Infections

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

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

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

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

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

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

Operational Standards

A. All persons providing HIV testing and counseling at a publicly funded HIV testing and counseling project in a non health-care setting will have completed an HIV testing and counseling course approved by the ~~state d~~Department ~~of health~~.

B. All persons performing partner services will have completed courses concerning introduction to sexually transmitted disease interviewing and partner notification, and other related courses as specified by the ~~state d~~Department ~~of health~~.

C. Of all HIV tests performed at a publicly funded HIV testing and counseling project, 99% of those persons testing HIV positive will receive test results and appropriate post-test counseling related to those test results. Publicly funded HIV testing sites shall make a good faith effort to inform all persons of their test results and shall provide pertinent HIV prevention counseling and referrals.

D. All persons newly diagnosed with HIV will be referred for partner services. A minimum of 75% of those offered partner services will receive an interview and appropriate referrals. Partner services standards will be determined by the best practices guidance and code of conduct standards for sexually transmitted infection prevention providers developed by the ~~state d~~Department ~~of health~~. These standards shall be made publicly accessible.

E. Operational and evaluation standards for HIV testing and counseling sites will be determined by the best practices guidance developed by the ~~state d~~Department ~~of health~~.

F. In accordance with ~~C.R.S~~ SECTION 25-4-404(2), C.R.S., the DEPARTMENT ~~state department of health~~ shall create and maintain guidelines, subject to approval by the ~~state~~ B~~b~~oard of H~~h~~ealth, concerning the public health procedures described in ~~C.R.S~~ SECTIONS 25-4-412 and 25-4-413, C.R.S. These guidelines will include code of conduct standards for the delivery of partner services and clients' rights, responsibilities and protections.

Appendix A. Reportable Disease Table

Disease/Event	Pathogen/Organism	Time*	Reporter[1]	Specimen Source(s)[2]	Send Clinical Material[3]
Acinetobacter baumannii, carbapenem-resistant (CRAB)[5, 4-Metro]	Carbapenem-resistant *Acinetobacter baumannii* (including *Acinetobacter baumannii* complex and *Acinetobacter baumannii-calcoaceticus* complex)	30 days	L	Sterile sites, urine	
Acute flaccid myelitis		4 days	P		
Animal bites by dogs, cats, bats, skunks, foxes, raccoons, coyotes, or other wild carnivores [6,7]		24 hrs	P		
Animal bites by mammals not listed above[6]		4 days	P		
Anthrax[6]	*Bacillus anthracis*	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]	*Clostridium botulinum*	Immed	L & P	All	
Brucellosis[6]	*Brucella* species	4 days	L & P	All	Required
Campylobacteriosis	*Campylobacter* species	4 days	L & P	All	
CANDIDA AURIS[8]	*CANDIDA AURIS, CANDIDA HAEMULONII*	IMMED	L & P	ALL	Required
Candidemia[4-Metro]	*Candida* species	30 days	L	Blood	Requested
CATHETER-ASSOCIATED URINARY TRACT INFECTION (CAUTI)[9]	ANY	PER CMS[9]	P	URINE	
Chancroid	*Haemophilus ducreyi*	4 days	L & P	All	
Chikungunya	Chikungunya virus	4 days	L	All	
Chlamydia	*Chlamydia trachomatis*	4 days	L & P	All	
Cholera[6]	*Vibrio cholerae*	Immed	L & P	All	Required
CJD and other transmissible spongiform encephalopathies (TSEs)[6]		4 days	P		
Clostridium difficile infection [4-Metro]	*Clostridium difficile*	30 days	L	All	Requested[10]
Colorado tick fever	Colorado tick fever virus	4 days	L	All	

Cryptosporidiosis	*Cryptosporidium* species	4 days	L & P	All	
Cyclosporiasis	*Cyclospora* species	4 days	L & P	All	
Dengue	Dengue virus	4 days	L	All	
Diphtheria[6]	*Corynebacterium diphtheriae*	Immed	L & P	All	Required
Encephalitis[6]		4 days	P	All	
Enterobacteriaceae, carbapenem-resistant (CRE)[11]	Carbapenem-resistant *Escherichia coli*, *Klebsiella* species, *Enterobacter* 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[10]
ENTEROBACTERIACEAE, EXTENDED-SPECTRUM BETA-LACTAMASE (ESBL)[12]. 4-BOULDER	*ESCHERICHIA COLI* AND *KLEBSIELLA* SPECIES	4 DAYS	L	All	
Escherichia coli O157:H7 and Shiga toxin-producing Escherichia coli[13]	Shiga toxin-producing *Escherichia coli*[13]	4 days	L & P	All	Required
Giardiasis	*Giardia lamblia*	4 days	L & P	All	
Gonorrhea, any site	*Neisseria gonorrhoeae*	4 days	L & P	All	
Group A streptococci[14]. 4-Metro	*Streptococcus pyogenes*	4 days	L	Sterile only	Required[12]
Group B streptococci 4-Metro	*Streptococcus agalactiae*	30 days	L	Sterile only	Required[12]
Haemophilus influenzae	*Haemophilus influenzae*	1 working day	L & P	Sterile only	Required
Hantavirus disease[6]	Hantavirus	4 days	L & P	All	
Healthcare-associated infections[16]		4 days	P		
Hemolytic uremic syndrome if ≦< 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)	• Human immunodeficiency virus • CD4 counts (any value) • HIV viral load (any value) • *HIV genotype*	4 days	• L & P • L & P • L & P • L	All	
Influenza-associated death if < -18 years		4 days	P		
Influenza-associated hospitalization		4 days	P		
~~Japanese Encephalitis~~	~~*Japanese Encephalitis virus*~~	~~4 days~~	~~L~~	~~All~~	
Legionellosis	*Legionella* species	4 days	L & P	All	
Leprosy (Hansen's Disease)		4 days	P		
Listeriosis	*Listeria monocytogenes*	4 days	L & P	All	Required
Lyme disease	*Borrelia burgdorferi*	4 days	L & P	All	
Lymphogranuloma venereum (LGV)	*Chlamydia trachomatis*	4 days	L & P	All	
Malaria[6]	*Plasmodium* species	4 days	L & P	All	
Measles (rubeola)[6]	Measles virus	Immed	L & P	All	
Meningococcal Disease[6]	*Neisseria meningitidis* or gram-negative *diplococci*	Immed	L & P	Sterile only	Required
METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) BACTEREMIA[9]	METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA)	PER CMS[9]	P	BLOOD	
Mumps[6]	Mumps virus (acute infection)	4 days	L & P	All	
Outbreaks - known or suspected of all types- including those transmitted from food, water, person-to-person, and related to a health care setting[6]		Immed	L & P		
Pertussis (whooping cough)[6]	*Bordatella pertussis*	1 working day	L & P	All	Requested[10]
Plague[6]	*Yersinia pestis*	Immed	L & P	All	Required
Poliomyelitis[6]	Poliovirus	Immed	L & P	All	
~~Powassan virus disease~~	~~*Powassan virus*~~	~~4 days~~	~~L~~	~~All~~	
Pseudomonas, carbapenem-resistant[17]	*Pseudomonas aeruginosa*	4 days	L	All	Requested[10]
Psittacosis	*Chlamydia psittaci*	4 days	L & P	All	

Q fever[6]	*Coxiella burnetii*	4 days	L & P	All	
Rabies: human (suspected)[6]	Rabies virus (Lyssavirus)	Immed	L & P	All	
Rickettsiosis	*Rickettsia* 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	*Salmonella* 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	*Shigella* species	4 days	L & P	All	Required
Smallpox[6]	Variola virus (Orthopox virus)	Immed	L & P	All	
Staphylococcus aureus, Vancomycin-resistant	Vancomycin-resistant *Staphylococcus aureus*	4 days	L	All	Required
Streptococcal toxic shock syndrome	*Streptococcus pyogenes*	4 days	P	All	Required[15]
Streptococcus pneumoniae	*Streptococcus pneumoniae*	4 days	L	Sterile only	Required[15]
Syphilis[6]	*Treponema pallidum*	1 working day	L & P	All	
Tetanus[6]	*Clostridium tetani*	4 days	P	All	
Tick-borne relapsing fever[6]	*Borrelia* species	4 days	L & P	All	
Toxic shock syndrome (non-streptococcal)		4 days	P		
Trichinosis[6]	*Trichinella* species	4 days	P	All	
Tuberculosis disease (active)[6]	*Mycobacterium tuberculosis*[18]	1 working day	L & P	All	See Reg 4F
Tularemia[6]	*Francisella tularensis*	1 working day	L & P	All	Required
Typhoid fever[6]	*Salmonella* Typhi	1 working day	L & P	All	Required
Varicella (chicken pox)[6]	Varicella virus	4 days	L & P	All	
Vibriosis	*Vibrio* species, non-cholera	4 days	L	All	Required

Viral hemorrhagic fever	Crimean-Congo hemorrhagic virus, Ebola virus , Lassa fever virus, Lujo virus, Marburg virus, Guanarito virus, Junin virus, Machupo virus, Sabia virus	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]	*Yersinia* non-*pestis* 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.

[Editorial Comment - not for Final Publication - Please note that footnotes 8-18 have been renumbered]

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

9 REPORTING REQUIREMENT IS FULFILLED THROUGH THE DEPARTMENT'S 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.

10 Clinical material is requested from selected laboratories.

11 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).

12 *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).

13 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.

14 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.

15 ~~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).

16 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.

17 *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).

18 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