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To: Members of the Colorado State Board of Health

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Date: November 20, 2024

Subject: 2024 Board of Health Rulemaking: 6 CCR 1009-1: Epidemic and Communicable Disease Control

The Division of Disease Control and Public Health Response within the Colorado Department of Public Health and Environment is requesting that the Board of Health revise 6 Colorado Code of Regulations (CCR) 1009-1, Epidemic and Communicable Disease Control.

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

Proposed changes to the rules include:

- Adding the following diseases/events to the reportable list in Appendix A:
 - Amebae, free-living
 - Bioterrorism agent or incident (currently reportable in rule narrative)
 - Chagas disease
 - Congenital cytomegalovirus (CMV) if <1 year of age
 - *Cronobacter* invasive infections if <1 year of age
 - Glanders
 - Hepatitis D
 - Influenza and RSV positive molecular and rapid antigen test results, as well as lineage or sequencing results
 - Influenza - novel (currently reportable in rule narrative)
 - Melioidosis
- Modifying reporting practices for certain diseases/events on the reportable list in Appendix A:
 - Animal bites



COLORADO

**Department of Public
Health & Environment**

- *Candida auris*
- Carbapenemase-producing organisms
- *Clostridium difficile* infection
- COVID-19
- Enterobacterales, carbapenem-resistant (CRE)
- Enterobacterales, extended-spectrum beta-lactamase (ESBL)
- *Escherichia coli* invasive infections
- Healthcare-associated infections
- Hepatitis A, B, C, and other viral hepatitis
- Legionellosis
- Mpox
- Outbreaks
- Syphilis
- Viral hemorrhagic fever
- Amending several current rules and regulations:
 - Add language to clarify existing requirements.
 - Add additional reportable characteristics and data elements such as the name of the owner of a dog or cat involved in a bite incident and location of bite in a wild animal biting incident.
 - Add pregnancy status to the list of data elements that must be reported with each case of hepatitis B and hepatitis C.
 - Clarify that laboratory reporters must ensure disease reporting occurs outside of specimen submission to the CDPHE Laboratory.
 - Add that a county, district, or municipal public health agency that learns of a reportable disease, epidemic, or communicable disease exposure in a different local jurisdiction must notify the local jurisdiction in a timely manner
 - Clarify that health care providers within all correctional and health care facilities must notify public health when suspected and confirmed active tuberculosis disease patients are discharged to ensure continuity of care.
 - Add novel influenza viruses to the list of reportable diseases that 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 public health.
- Adding a new regulation (Regulation 12 - Congenital Syphilis) in response to [Public Health Order 24-01](#) and [House Bill 24-1456](#) that describes requirements for offering syphilis testing to anyone who is pregnant, including during the third trimester of the pregnancy.
- Technical changes intended to clarify existing rule language and better align with statute without significant policy change.

In total, the proposed amendments are necessary to reflect the current epidemiology and surveillance practices of several infectious diseases in Colorado, prepare for future pathogen surges, clarify the rule, and minimize potential confusion among end-users of the rule.



COLORADO

**Department of Public
Health & Environment**

CDPHE staff carried out a wide-ranging stakeholder process, notifying more than 2,100 individuals and organizations about this rulemaking and proposed changes via email. Staff presented the proposed changes at a regularly scheduled LPHA communicable disease stakeholder meeting and an LPHA directors meeting, with approximately 200 attendees between the two. CDPHE also held an open public webinar, “Public Listening Session for Epidemic and Communicable Disease Control,” with 84 attendees. At these meetings, the Department requested suggestions, concerns, and questions about the proposed changes. The Department also took written feedback via an online Google form and email. After the request for rulemaking, the Department continued to collect feedback via form and email.



COLORADO
Department of Public
Health & Environment

**STATEMENT OF BASIS AND PURPOSE AND SPECIFIC STATUTORY AUTHORITY
for
6 CCR 1009-1: Epidemic and Communicable Disease Control**

Background

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

The intent of the proposed amendments is to update the list of reportable conditions to better allow the Department to respond to emerging issues and align this rule with current practice, including advances in surveillance techniques, prevention, diagnosis, and treatment of communicable diseases.

Statutory authority

Authority for these rules lies within several statutes, as follows:

- §25-1-122, C.R.S. gives the State Board of Health authority to require reporting of occurrences of diseases and conditions to public health.
- §25-1.5-102, C.R.S. requires the State Board of Health to determine, by rule and regulation, those epidemic and communicable diseases and conditions that are dangerous to the public health.
- §§25-4-501 and 25-4-502, C.R.S. describes the risk and outlines the reportability for tuberculosis.
- §25-4-201, C.R.S. requires the State Board of Health to promulgate rules concerning prenatal testing standards for syphilis, including frequency of testing.

Summary of changes

The proposed rule changes focus on the list of reportable diseases, conditions, and related events (Appendix A of the rule set):

- Adding the following diseases/events to the reportable list:
 - **Amebae, free-living:** The Department proposes to add *Acanthamoeba* species (excluding keratitis), *Balamuthia mandrillaris*, and *Naegleria fowleri* as reportable diseases under "Amebae, free-living". These ameba species are free-living (meaning the organisms live independently and do not require a human or animal host to survive) in soil and water and can cause rare but serious illnesses in humans. Climate change may increase the risk that these



COLORADO

Department of Public Health & Environment

organisms pose to humans (especially for [N. fowleri](#), which national

epidemiology in Colorado and how it may change over time. It will allow public health agencies to inform health care providers of the risk, improving diagnosis and treatment and informing interventions such as public education. Both laboratories and providers will be required to report infections from all specimen sources within four days. Submission of clinical material to the CDPHE Public Health Laboratory will be required. CDPHE anticipates performing surveillance and investigation activities for these rare pathogens in-house in collaboration with impacted local public health agencies, if the local public health agencies have response capacity.

- **Bioterrorism agent or incident:** Currently, Regulation 1 (Reportable Diseases, Conditions, and Related Events) of this rule states that health care providers, hospitals, emergency departments, clinics, health care centers, and laboratories must immediately report the occurrence of a single case or cluster of any unusual disease or manifestation of illness which may be caused by or related to a bioterrorism agent or incident. CDPHE proposes to add this reporting requirement to Appendix A for clarity, but is not proposing changes to the reporting requirements themselves.
- **Chagas disease:** Add Chagas disease, a life-threatening but treatable infection caused by the parasite *Trypanosoma cruzi*, as a reportable disease. The parasite usually spreads to humans through contact with triatomine insects (also called kissing bugs). A particular species of triatomine insects ([Triatoma](#)

Triatomine insects feed on blood from people and other animals. *Trypanosoma cruzi* parasites are found in the feces of the insect and can enter a human through the bite wound. Chagas disease is most common in rural areas of Mexico and Central and South America. Conducting disease surveillance will provide a better understanding of the risk of transmission between triatomine insects and people in Colorado and will inform disease control actions. Both laboratories and providers will be required to report infections from all specimen sources within four days. Submission of clinical material to the CDPHE Public Health Laboratory will be upon request. CDPHE anticipates performing surveillance and investigation activities for this rare disease in-house in collaboration with impacted local public health agencies, if the local public health agencies have response capacity.

- **Congenital cytomegalovirus (cCMV) if <1 year of age:** Add reporting of all positive cCMV test results and negative cCMV test results on urine specimens when they occur in people younger than 1 year of age. Negative results on



COLORADO

**Department of Public
Health & Environment**

causes mild or no symptoms in children and adults. People who are pregnant and infected with CMV can pass the virus to their developing baby, which has the potential to cause severe health consequences and permanent disability for newborns. [According to the CDC](#) and the [National CMV Foundation](#), about one

cCMV will have birth defects or other long-term health problems, like hearing loss, vision impairment, developmental [REDACTED]

conduct disease surveillance to describe the epidemiology of the infection in Colorado and identify at-risk populations. A [public health surveillance case definition exists for cCMV](#). We are requesting negative test result reporting to assist public health in determining if a patient meets the laboratory criteria [REDACTED]

[REDACTED] positive results

all specimen sources within four days. Laboratories capable of reporting electronically will be required to report negative results from urine specimens within four days. Submission of clinical material to the CDPHE Public Health Laboratory will be upon request. CDPHE anticipates performing surveillance activities for this pathogen in-house with no added workload for local public health agencies. Based on [surveillance conducted in other states for cCMV](#), we anticipate less than 50 cases reported in Colorado each year.

- ***Cronobacter* invasive infections if <1 year of age:** Add *Cronobacter* species (including *C. sakazakii* and *C. malonaticus*) as reportable diseases when they cause invasive infections in people less than 1 year of age. This bacteria is ubiquitous in the environment and can live in dry foods like powdered infant formula (PIF). While human infections are rare, *Cronobacter* can cause serious illness and death in young infants, infants born prematurely, and infants with weakened immune systems. [Centers for Disease Control and Prevention](#) estimates two to four cases of severe infection occur in infants annually nationwide. Outbreaks associated with PIF have been reported [in the U.S.](#) and [other countries](#). Conducting disease surveillance for this pathogen in infants will allow for better understanding of the disease epidemiology and how it may change over time. Improved surveillance enables better cluster and outbreak detection, which can lead to identification of contaminated PIF and subsequent product recalls that can protect against future exposures. *Cronobacter* invasive infections among infants became a nationally notifiable condition in 2023 and has a [public health surveillance case definition](#). Both laboratories and providers will be required to report infections from all specimen sources within four days. Submission of clinical material to the CDPHE Public Health Laboratory will be required. CDPHE anticipates performing surveillance and investigation activities for these rare pathogens in-house in collaboration with impacted local public health agencies, if the local public health agencies have response capacity.



COLORADO

Department of Public Health & Environment

- **Glanders:** Add glanders, an infection caused by the bacteria *Burkholderia mallei*, as a reportable disease. Glanders mostly occurs in animals but can infect humans and cause skin, mucous membrane, pulmonary, and bloodstream infections. Glanders is on the [CDC list of potential bioterrorism agents](#) as a category A agent, which means that it could be weaponized and easily transmitted from person to person, resulting in a major public health impact and high mortality rates. While any suspected bioterrorism situation is already reportable per Regulation 1, specifically listing glanders in Appendix A will make it more apparent that cases need to be reported to public health in a timely manner. It will also allow public health agencies to conduct more complete disease surveillance to better understand the epidemiology of the pathogen, especially because there are occasional reports of infection in laboratory workers and people who work with animals. Both laboratories and providers will be required to report infections from all specimen sources within one working day. Submission of clinical material to the CDPHE Public Health Laboratory will be upon request. CDPHE anticipates performing surveillance and investigation activities for this pathogen in-house in collaboration with impacted local public health agencies, if the local public health agencies have response capacity.
- **Hepatitis D:** Add hepatitis D, a liver infection caused by the [hepatitis D virus](#) (HDV) that can cause severe liver damage and death, as a reportable disease. HDV infections are believed to be rare in the U.S., but under-identified due to limited testing and reporting practices. Conducting disease surveillance for HDV will improve Colorado's ability to understand the burden of HDV infections; determine which populations are disproportionately affected; assess testing practices and disease outcomes; and assist in finding unreported cases of hepatitis B virus infection as HDV can only infect people who are also infected with hepatitis B virus. A new standardized case definition for public health surveillance of HDV was recently approved by the Council of State and Territorial Epidemiologists and will be effective in 2025. While not a nationally notifiable condition, HDV is currently reportable in 31 U.S. states/territories. Both laboratories and providers will be required to report infections from all specimen sources within four days. Submission of clinical material to the CDPHE Public Health Laboratory will be upon request. CDPHE anticipates performing surveillance and investigation activities for HDV in-house.
- **Influenza and RSV:** Add influenza and RSV positive molecular and rapid antigen test results, as well as lineage or sequencing results, as reportable conditions, but only for laboratories that perform electronic laboratory reporting (i.e., provider reporting is not required). Influenza- and RSV-associated hospitalizations and pediatric deaths are already reportable, and they are important components of tracking viral respiratory disease burden and severity in the state. Sometimes patients hospitalized with influenza or RSV are tested at health care facilities or laboratories that are not connected to the facility where they are hospitalized, which makes linking a positive test result to an associated hospitalization challenging. Similarly, finding test results for



COLORADO

Department of Public Health & Environment

reported influenza- and RSV-associated pediatric deaths can be challenging. Collecting all positive influenza and RSV test results through electronic laboratory reporting will improve public health agencies' ability to link test results to hospitalized patients and pediatric deaths. In addition, monitoring positive influenza and RSV results can be an early indicator of the start of viral respiratory disease season or detect aberrations in disease occurrence. Both of these conditions will contain a reference to footnote 10 following Appendix A that provides details on reporting requirements. Only laboratories that are able to report via electronic laboratory reporting will be required to report infections from all specimen sources within four days. Submission of clinical material to the CDPHE Public Health Laboratory will be upon request. CDPHE anticipates performing surveillance activities for these test results in-house with no added workload for local public health agencies.

- **Influenza - novel:** Currently, Regulation 1 in this rule states that reporters must report cases of a newly recognized entity, including novel influenza. CDPHE proposes to add this reporting requirement in Appendix A for clarity, especially in light of the ongoing highly pathogenic avian influenza outbreak caused by influenza A(H5N1), but is not proposing changes to the reporting requirements themselves.
- **Melioidosis:** Add melioidosis, an infection caused by the bacteria *Burkholderia pseudomallei*, as a reportable disease. The bacteria is found in soil and water mainly in tropical climates and can infect humans and animals. Diagnosis is challenging, as the infection can affect one or multiple body systems. It is unlikely that the bacteria is found naturally in the environment in Colorado. However, in recent years, [outbreaks](#) of the illness have occurred in people who have had contact with contaminated products made in areas where the bacteria is present. Melioidosis is on the [CDC list of potential bioterrorism agents](#) as a category A agent, became a nationally notifiable condition in 2022, and has a [public health surveillance case definition](#). While any suspected bioterrorism situation is already reportable per Regulation 1 in the rule, specifically listing melioidosis in Appendix A will make it more apparent that cases need to be reported to public health in a timely manner. This will allow public health to conduct more complete disease surveillance to better understand the epidemiology of the pathogen and promptly identify clusters and outbreaks of illness that could be indicative of intentional or common source exposures. Both laboratories and providers will be required to report infections from all specimen sources within one working day. Submission of clinical material to the CDPHE Public Health Laboratory will be upon request. CDPHE anticipates performing surveillance and investigation activities for this pathogen in-house in collaboration with impacted local public health agencies, if the local public health agencies have response capacity.
- Modifying the following disease/event on the reportable list:
 - **Animal bites:** Change to “Animal bites and exposures” to clarify that bites by certain animals are reportable (dogs, cats, bats, skunks, foxes, raccoons,



COLORADO

**Department of Public
Health & Environment**

coyotes, or other wild carnivores), as well as any bat exposures. Bat bites may not be readily apparent. Public health and animal control officers can assess bat exposure situations to determine if an exposed individual would benefit from rabies post-exposure prophylaxis.

- ***Candida auris***: Change the time frame for reporting from immediately to one working day. While a suspected or confirmed case of *C. auris* requires prompt public health investigation, cases identified on non-typical workdays (e.g., weekends or holidays) can be reported on the next workday and does not require immediate, emergent response.
- **Carbapenemase-producing organisms**: Change the time frame for reporting from four days to one working day. Prompter reporting will allow for more timely initiation of public health investigations to prevent spread of these drug-resistant organisms.
- ***Clostridium difficile* infection**: Change to *Clostridioides difficile* to align with [current naming convention](#). In addition, add a footnote to Appendix A describing that any positive test must be reported, including positive results from multi-step algorithms and cultures, regardless of where the test falls within the algorithm.
- **COVID-19**: Now that the COVID-19 public health emergency has ended, changes in COVID-19 reporting are proposed to make COVID-19 surveillance more similar to other viral respiratory pathogens, like RSV and influenza. We propose to continue to require reporting of positive SARS-CoV-2 molecular and rapid antigen test results, as well as lineage or sequencing results; however, this requirement will only apply to laboratories that perform electronic laboratory reporting (i.e., provider reporting is not required). These changes will allow for more efficient identification of COVID-19-associated hospitalizations and deaths and allow for continued monitoring of positive test burden and new and circulating variants. Changes are proposed to footnote 10 following Appendix A to provide details on COVID-19 reporting requirements.

| Current COVID-19 reporting requirements | Proposed COVID-19 reporting requirements |
|---|--|
| SARS-CoV-2 positive nucleic acid amplification test and rapid antigen tests and COVID-19 lineage or sequencing by both laboratories and providers | SARS-CoV-2 positive molecular and rapid antigen tests and lineage or sequencing results by laboratories capable of electronic laboratory reporting |
| SARS-CoV-2 negative or inconclusive result on any nucleic acid amplification test | Remove negative or inconclusive nucleic acid amplification test result reporting |
| COVID-19-associated hospitalizations | Remains the same |
| N/A | Add COVID-19-associated deaths, all ages, to be reported by providers within four days |



COLORADO

**Department of Public
Health & Environment**

- **Enterobacterales, carbapenem-resistant (CRE); Enterobacterales, extended-spectrum beta-lactamase (ESBL); and *Escherichia coli* invasive infections:** Change references to *Escherichia coli* in these three reportable conditions to *Escherichia* species to capture and require reporting of all bacteria within the genus. The associated footnotes that appear after Appendix A will also be updated to reflect these proposed changes. In recent years, additional *Escherichia* species (such as *Escherichia albertii*) have demonstrated resistance to commonly used antibiotics. As part of CDC's Emerging Infections Program (EIP), the Department conducts surveillance for these organisms to determine the incidence of disease, trends over time, risk factors, and resistance mechanisms. Expanding surveillance to all *Escherichia* species will allow the Department to continue contributing to EIP projects around *Escherichia* resistance.
- **Healthcare-associated infections:** Change the reporting time frame from four days to thirty days for health care facilities that are voluntarily participating in applied public health projects. These voluntary projects are often conducted retrospectively and, thus, do not require timely reporting.
- **Viral hepatitis:** Several changes are proposed around reporting requirements for different forms of viral hepatitis. Reporting requirements are already in place for hepatitis A, B, C, and other forms of viral hepatitis. The addition of reporting hepatitis D virus is described above.
 - **Hepatitis A, B, C, and hepatitis, other viral:** Add the requirement to report select liver function test (LFT) results (alanine transaminase (ALT), aspartate aminotransferase (AST), and total bilirubin) when reporting hepatitis A, B, C, and hepatitis (other viral) positive test results. We are requesting the LFT results that were performed at or closest to the time of the positive hepatitis A, B, C or other viral hepatitis positive test result. This addition will assist public health agencies in determining if cases meet [public health surveillance case definitions](#).
 - **Hepatitis B:** Add the requirement to report negative test results for hepatitis B virus (HBV), including negative hepatitis B surface antigen tests, hepatitis B virus DNA detection tests, and/or negative confirmatory assays. Requiring reporting of negative test results will help public health agencies determine false-positive results, monitor patients through their infection and recovery, and help identify patients that would benefit from connection to resources. Only laboratories that are able to report via electronic reporting will be required to report negative results from all specimen sources within four days. Submission of clinical material to the CDPHE Public Health Laboratory will be upon request. CDPHE anticipates continuing to perform surveillance and investigation activities for HBV in-house.
 - **Hepatitis B in children <3 years of age:** The [recommendation for children exposed to hepatitis B perinatally](#) is to receive hepatitis B immune globulin and hepatitis B vaccine at birth and to complete the



COLORADO

Department of Public Health & Environment

hepatitis B vaccine series by 6 months of age. After the hepatitis B vaccine series is complete, it is necessary to check for infection and immunity by using the hepatitis B surface antigen and the hepatitis B surface antibody laboratory tests. Testing is done no sooner than 9 months of age and a minimum of 30 days after vaccine series completion. Public health case management may continue up to age 2 for children with incomplete hepatitis B vaccination series and/or who are missing post-vaccination serology testing. Only laboratories will be required to report results (positive, negative, and inconclusive hepatitis B surface antigen [HBsAg] and antibody to hepatitis B surface antigen [anti-HBs] test results) from all specimen sources within four days. Submission of clinical material to the CDPHE Public Health Laboratory will be upon request. CDPHE performs surveillance and investigation activities for perinatal hepatitis B in-house, so there is no added workload for LPHAs.

- **Hepatitis C:** Add negative hepatitis C virus (HCV) antibody tests in the “Pathogen/Organism” column as reportable. Currently, only negative hepatitis C confirmatory assay results are reportable. Reporting of negative/non-reactive HCV antibody tests will allow for improved ascertainment of case exposure timelines and identification of acute HCV cases. Only laboratories that are able to report via electronic laboratory reporting will be required to report negative results from all specimen sources within four days.
- **Legionellosis:** Add that submission of respiratory specimens to the CDPHE Public Health Laboratory is required. Submission of respiratory specimens will allow the Department to perform confirmatory testing, typing, and sequencing, which are helpful for confirming infections and linking human infections to positive environmental samples. Footnote 25 is proposed to clarify that submission of urine specimens (such as urine samples collected for *Legionella* urine antigen tests) are not needed.
- **Mpox:** Change the reporting time frame from four days to one working day. Clade I mpox is emerging in several different countries and causing outbreaks. Clade I mpox can result in more severe illness than clade II mpox, which has been circulating in the U.S. since 2022. Shortening the reporting time frame will allow public health to more quickly assess if a reported case has a travel history or exposure history that is concerning for clade I mpox and allow public health to identify contacts and offer post-exposure prophylaxis to prevent or lessen the severity of illness.
- **Outbreaks:** Currently, Regulation 1 in this rule states that reporters must report any unusual illness or an outbreak or epidemic of illnesses that may be a risk to the public and which may affect large numbers of persons. These include illnesses transmitted through food, through water, from animal to person, or from person to person. In Appendix A, in the “Outbreaks” row, we propose to add animals, vectors, and environmental contamination to the description of outbreaks that need to be reported to public health. We also



COLORADO

**Department of Public
Health & Environment**

- propose to add that any pathogen causing an outbreak is reportable to align with Regulation 1 and to add clarity around outbreak reporting requirements.
- **Syphilis:** Add reporting of negative laboratory testing results for syphilis to aid public health agencies in determining compliance with the new testing requirements for pregnant persons outlined in the new proposed Regulation 12 (Congenital Syphilis), described below. Reporting of positive syphilis results is already required in the rules. Only laboratories that can report via electronic laboratory reporting will be required to report negative test results from all specimen sources within one working day. Submission of clinical material by the testing laboratory to the CDPHE Public Health Laboratory will be upon CDPHE's request. CDPHE anticipates continuing to perform surveillance and investigation activities for this pathogen in-house with no added workload for local public health agencies.
 - **Viral hemorrhagic fever:** Add Rift Valley fever to the list of viral pathogens that cause viral hemorrhagic fever and are reportable to public health. A new standardized case definition for public health surveillance of Rift Valley fever was recently approved by the Council of State and Territorial Epidemiologists and will be effective in 2025. Rift Valley fever and other viruses that cause viral hemorrhagic fever are extremely rare in the U.S., but they do require prompt reporting and public health response to protect health care workers, laboratorians, and the public. All reports of viral hemorrhagic fever, including Rift Valley fever, are immediately reportable to public health.

The Department also proposes amendments to:

- **Regulation 1 (Reportable Diseases, Conditions, and Related Events):**
 - Add a sentence to clarify that the diseases, conditions, and related events in Appendix A pertain to those diagnosed or detected in humans, with the exception of those outlined in Regulation 8 (Reporting of Diseases Among Animals and Waiver Process for Rabies Inoculation).
 - Add illnesses transmitted by vectors to people to the list of illnesses or outbreaks that are reportable to public health, along with illnesses transmitted through food, water, animal to person, and person to person.
 - Clarify that the name and location information of the owner of a dog or cat involved in an animal bite must be reported, if known, by the health care provider. This allows public health officials and animal control officers to follow up with animal owners to assess the risk of rabies transmission.
 - Clarify that health care providers must report the location information of wild animal bites by bats, skunks, foxes, raccoons, coyotes, and other wild carnivores, if known. In addition, add non-bite bat exposures as reportable (as described above in changes proposed in Appendix A). This information aids public health officials, animal control officers, and wildlife officials in assessing the risk of rabies transmission.



COLORADO

**Department of Public
Health & Environment**

- Clarify that methicillin-resistant *Staphylococcus aureus* (MRSA) bloodstream infections are listed as reportable in Appendix A because they are not reportable in § 25-3-601 et seq., C.R.S. (which is the statute that specifies that healthcare-associated infections are reportable through the National Healthcare Safety Network).
 - Clarify that public health projects around healthcare-associated infections are related to infections listed in Appendix A and Appendix B of the rule.
 - Add a definition for gender identity, which has been a data element required to be reported for sexually transmitted infections for a number of years. We are proposing to use the CDC gender identity definition used for surveillance purposes, which is defined as an individual's personal sense of being male, female, or transgender.
 - Reorder several existing sentences in the "Manner of Reporting" section for better readability and organization.
- **Regulation 2 (Reporting by Individuals):**
 - Clarify that when the reporter is listed as "P" in Appendix A, they must report known or suspected cases of diseases and outbreaks.
- **Regulation 3 (Laboratory Reporting):**
 - Clarify that all specimens sent to the CDPHE Public Health Laboratory must be accompanied by a test order, and specimen submission to the CDPHE Public Health Laboratory does not constitute disease reporting (i.e., laboratory reporters must ensure disease reporting occurs outside of specimen submission).
- **Regulation 4 (Treatment and Control of Tuberculosis):**
 - Section A: Clarify that physicians need to report the suspected or confirmed affected body part when reporting a suspected or confirmed tuberculosis case(s). Add a definition for "suspected cases of active tuberculosis disease" to provide clarity.
 - Section H: Clarify that health care providers within all correctional and health care facilities must notify public health when a suspected and confirmed active tuberculosis disease patient is discharged to ensure continuity of care.
- **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):**
 - Move the sentence that addresses "reasonable efforts shall be made by the Department or county, district, or municipal public health agencies to consult with the responsible physician, other health care providers, or the medical facility caring for the patient prior to any further follow-up by the Department or county, district, or municipal public health agencies" that is currently in Regulation 9 (Confidentiality) to this regulation because this action is part of



COLORADO

**Department of Public
Health & Environment**

the investigation process.

- **Regulation 6 (Information Sharing):**
 - Add that a county, district, or municipal public health agency that learns of a reportable disease, epidemic, or communicable disease exposure in a different local jurisdiction must notify the local jurisdiction in a timely manner. Utilizing the statewide disease reporting system (EpiTrax) for this notification fulfills the requirement.
 - Clarify that CDPHE can utilize the statewide disease reporting system (EpiTrax) to fulfill the county, district, or municipal public health agency notification requirement when CDPHE learns of a case of a reportable disease within the local agency's jurisdiction.
- **Regulation 8 (Reporting of Diseases Among Animals and Waiver Process for Rabies Inoculation):**
 - Section A: Due to the current and ongoing widespread influenza A(H5N1) outbreak in wild and domestic animals, add novel influenza viruses to the list of reportable diseases that 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 public health.
- **Regulation 9 (Confidentiality):**
 - See proposed change described in Regulation 5 above.
- **Regulation 12 (Congenital Syphilis):**
 - In response to [Public Health Order 24-01](#) and [House Bill 24-1456](#), add a new regulation that describes requirements for all health care facilities and providers to offer syphilis testing to anyone who is pregnant, unless a documented syphilis test has already occurred that meets the requirements or the person declines testing. Testing will be required during the first trimester of pregnancy or at the patient's initial prenatal visit, during the third trimester of pregnancy, at the time of delivery, and when there is a fetal death after 20 weeks' gestation. House Bill 24-1456 requires the State Board of Health, on or before January 1, 2025, to promulgate rules concerning prenatal testing standards for syphilis, including the frequency of testing. At least every three years, the Department is required to review the rules for alignment with national prenatal testing recommendations for sexually transmitted infections and the Department's infection control duties. At least 17 other states require syphilis testing later in pregnancy.
- **Regulation 2 and Appendix A footnotes:**
 - Change "licensed day care center" to "licensed child care center" when referring to entities that must report cases to public health, in order to use language that is consistent with how these entities are referred to in other



COLORADO

**Department of Public
Health & Environment**

rules (e.g., 6 C.C.R. 1010-7, Rules and Regulations Governing the Health and Sanitation of Child Care Facilities in the State of Colorado).

- **Regulation 1, 3, and Appendix A footnotes:**
 - Add pregnancy status to the list of data elements that must be reported with each case of hepatitis B and hepatitis C. Gathering this data upon the initial case report will improve the ability to identify perinatal cases and increase the timeliness of public health interventions to connect the person who is pregnant to resources that can prevent transmission to the newborn.

Specific Statutory Authority:

Sections §25-1-108(1)(c), 25-1.5-102, 25-1-122, 25-4-502, 25-4-511(1), 25-4-201, C.R.S.

Is this rulemaking due to a change in state statute?

☒ Yes Rules are ☐ authorized ☒ required.

[Note: Only §25-4-201, C.R.S. has changed (due to House Bill 24-1456) to require the State Board of Health to promulgate rules concerning prenatal testing standards for syphilis, including frequency of testing]

☐ No

Does this rulemaking include proposed rule language that incorporates materials by reference?

☐ Yes ☐ URL ☒ No

Does this rulemaking include proposed rule language to create or modify fines or fees?

☐ Yes ☒ No

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

☐ Yes ☒ No.

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed;
- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or;
- The proposed rule reduces or eliminates a state mandate on local government.



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REGULATORY ANALYSIS
For
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.

| Group of persons/entities affected by the proposed rule | Size of the group | Relationship to the proposed rule C/S/B |
|---|-------------------|--|
| Infection prevention practitioners, clinical laboratory personnel, hospitals, and electronic lab reporters from throughout the state, as well as any out-of-state labs that conduct testing on Colorado residents | ~700 | C/B |
| Health care providers | 100,000 | C/B |
| Schools, licensed day care centers, institutions of higher education, coroners, persons providing testing and/or counseling to a person with a sexually transmitted infection | ~2,000 | C/B |
| Local public health agencies (LPHAs) | ~55 | C/B |
| CDPHE staff | ~200 | C/B |
| General public of Colorado | ~5.9 million | B |

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, use this relationship categorization key:

- C = Individuals/entities who implement or apply the rule.
- S = Individuals/entities who do not implement or apply the rule but are interested in others applying the rule.



COLORADO

**Department of Public
Health & Environment**

- B = Individuals who are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by, or be at risk because of the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

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.

Economic outcomes

Summarize the financial costs and benefits, include a description of costs that must be incurred, costs that may be incurred, any Department measures taken to reduce or eliminate these costs, any financial benefits.

Individuals/entities who implement the rule (C) and individuals who are ultimately served (B):

- The proposed changes include additions and modifications to the list of reportable conditions and data elements required for certain case reports necessitated by changes in conditions of public health concern. These changes will require some additional laboratory, health care provider (especially infection prevention practitioners), and/or data manager staff time to modify or set up reporting systems, but the time and costs associated with these changes are expected to be minor. Local public health agencies, coroners, schools, licensed day care centers, institutions of higher education, people providing testing and/or counseling to a person with a sexually transmitted infection, and government-run health care facilities have a duty to report diseases and conditions listed in Appendix A. However, the bulk of reporting occurs by clinical laboratories and is triggered by positive laboratory testing results. To minimize the reporting and cost burden, the Department favors electronic reporting whenever possible. At this time, all large commercial and hospital laboratories report electronically. More than 90% of reportable test results are received electronically.
- For laboratories whose burden of reporting and specimen and/or isolate submission will increase, CDPHE staff will work with them to minimize the burden, when possible, and only request specimens and/or isolate submission when additional work-up will be performed by a public health laboratory.
- CDPHE anticipates conducting surveillance and investigation activities for the proposed additions to Appendix A and has capacity to do so. The proposed additions may increase LPHA costs if there is an outbreak caused by the disease or condition in the LPHA jurisdiction that the LPHA investigates. Outbreaks of the proposed additions are rare, so the impact should be minimal. The Department and LPHAs will benefit from



COLORADO

Department of Public Health & Environment

the proposed changes to the rule that clarify and update the reporting requirements to be in line with the latest diagnostic technology and practice standards. The proposed changes will make disease surveillance data more precise and actionable by public health, as well as provide actionable data for disease reporters. Costs for disease surveillance and investigation activities at the Department and at LPHAs will continue to be incurred.

- Regarding the proposed addition of Regulation 12 (Congenital Syphilis), which require all health care facilities and providers to offer syphilis testing to anyone who is pregnant, unless a documented syphilis test has already occurred that meets the requirements or the patient declines testing, potential costs of these efforts have been estimated. During the 2024 legislative process which amended the statute requiring syphilis testing during pregnancy, analysts at the Colorado Department of Health Care Policy and Financing estimated the cost of care covered by Medicaid for a baby born with syphilis is approximately \$30,000 in the baby's first year of life. Colorado has experienced a 900% increase in congenital syphilis cases since 2017, based on 2023 provisional data. From January 1 to July 31, 2024, there have been 45 reported congenital syphilis cases, including six stillbirths and two fetal deaths. A Medicaid cost analysis estimates that increased testing costs associated with universal third trimester pregnancy screening offsets potential congenital treatment costs, even if future rates of cases increase slowly.

Non-economic outcomes

Summarize the anticipated favorable and unfavorable non-economic outcomes (short-term and long-term), and, if known, the likelihood of the outcomes for each affected class of persons by the relationship category.

Favorable non-economic outcomes:

Individuals/entities who implement the rule (C) and individuals who are ultimately served (B):

- Laboratories and health care providers (primarily infection prevention practitioners) are the primary reporters of conditions included in Appendix A. Schools, licensed day care centers, and institutes of higher education are also reporters, but tend to report outbreaks rather than individual cases. Many 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, updated language to reflect best practices and new diagnostic technology, and more consistent formatting. The Department expects all of these changes will result in improved customer experience, data quality, and health outcomes, as well as a better understanding of public health communicable disease issues affecting Colorado. The Department and many LPHAs analyze and report surveillance data to partners and the public who may use the data for planning, public health interventions, and decision-making.



COLORADO

**Department of Public
Health & Environment**

- Laboratories will have minimal additional reporting and submission requirements based on the current version of the regulation. Laboratories and the health care facilities they serve will receive the results of testing performed by the State Public Health Laboratory on specimens and isolates that are submitted. These results can be used to inform patient treatment and facility infection prevention efforts, resulting in decreased spread of these organisms.
- The general public will benefit from better surveillance data, investigation processes, and interventions for diseases and conditions that may impact their health.

Unfavorable non-economic outcomes:

Individuals/entities who implement the rule (C) and individuals who are ultimately served (B):

- The Department provides technical support to all laboratories interested in electronic reporting. With electronic reporting in place, the burden of reporting involves a one-time programming change to add or modify reportable conditions. The Department understands that disease reporters may not currently have access to all of the data elements listed in these regulations (pregnancy status is proposed to be added to the list of data elements that must be reported with each case of hepatitis B and hepatitis C). The Department will continue to work with disease reporters to enable them to collect and report each data element as they become accessible.

3. The probable costs to the agency and any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

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

The costs to the agency for managing the proposed additional disease reports and laboratory submissions will be covered by CDC cooperative agreement funding, specifically the Emerging Infections Program (EIP), Epidemiology and Laboratory Capacity (ELC), and Tuberculosis Elimination and Laboratory funding, as well as several CDC sexually transmitted infections, HIV, and viral hepatitis cooperative agreements, which are funding sources that CDPHE has been receiving for more than 20 years.

Anticipated CDPHE Revenues: N/A

Anticipated personal services, operating costs, or other expenditures by another state agency:

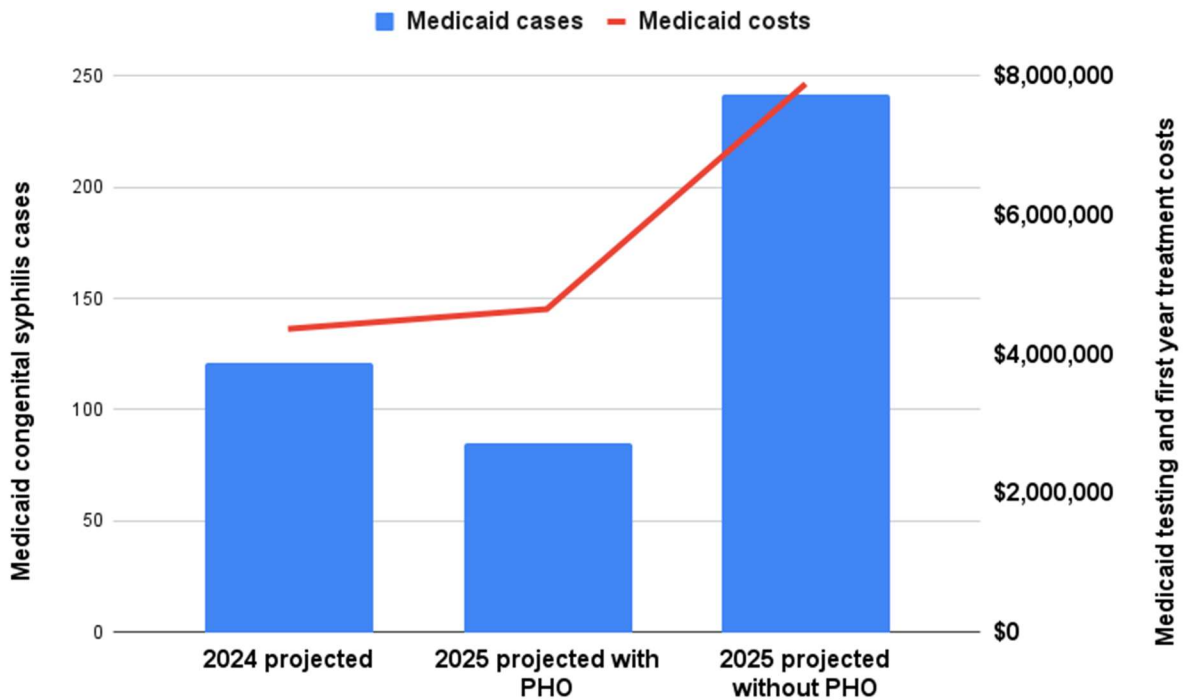
Colorado's Medicaid Program analyzed costs associated with caring for congenital syphilis Medicaid cases with and without implementation of pregnancy testing requirements. They



COLORADO

Department of Public Health & Environment

found that projected costs increased slightly in 2025 with the new requirements, and increased significantly without the new requirements. Long term, it is estimated that pregnancy testing requirements will result in cost savings but it will be delayed until case rates slow or decline. The Medicaid cost per test is currently \$41.91. The first year of treatment cost for a congenital syphilis case is approximately \$30,000 during the baby's first year of life. In the chart and table below, PHO stands for public health order, which is how the syphilis testing requirements are currently enforced until they are established in rule.



| | 2024 projected | 2025 projected with PHO | 2025 projected without PHO |
|--------------------------|----------------|-------------------------|----------------------------|
| Projected Medicaid cases | 121 | 85 (30% decrease) | 242 (100% increase) |
| First trimester testing | \$721,270 | \$721,270 | \$721,270 |
| Third trimester testing | \$94,079 | \$721,270 | \$94,079 |
| Delivery testing | \$0 | \$721,270 | \$0 |



COLORADO **Department of Public Health & Environment**

| | | | |
|-----------------------------|--------------------|--------------------|--------------------|
| 1st year of life treatment* | \$3,547,231 | \$2,483,062 | \$7,073,418 |
| Total cost | \$4,362,580 | \$4,646,873 | \$7,888,767 |

*Treatment costs are conservative because it only accounts for first year costs. Lifetime costs are likely substantially higher and would demonstrate greater cost-effectiveness and cost savings. Longer term costs of congenital syphilis are not available from the Colorado Department of Health Care Policy and Finance or the medical literature.

Anticipated revenues for another state agency: N/A

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

Along with the costs and benefits discussed above, the proposed revisions:

- ☒ **Comply with a statutory mandate to promulgate rules.**
- ☒ **Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.**
- ☒ **Maintain alignment with other states or national standards.**
- ☐ **Implement a Regulatory Efficiency Review (rule review) result**
- ☒ **Improve public and environmental health practice.**
- ☒ **Implement stakeholder feedback.**
- ☒ **Advance the following CDPHE Strategic Plan priorities:**

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, 5)**
- ☒ **Implement quality improvement/a quality improvement project (Goal 1, 2, 3, 5)**
- ☐ **Employee Engagement (Goal 1, 2, 3)**
- ☒ **Decisions incorporate health equity and environmental justice (Goal 1, 3, 4)**
- ☒ **Detect, prepare, and respond to emerging issues (Goal 1, 2, 3, 4, 5)**
- ☒ **Advance CDPHE Division-level strategic priorities.**

- 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 stakeholders. Reporting cases of communicable diseases and conditions are 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. The benefits, risks, and costs of these proposed revisions were compared to the costs and benefits of other options. The proposed revisions provide the most benefit for the lowest cost, are the minimum necessary, or are the most feasible manner to achieve compliance with statute. The Department favors electronic laboratory reporting, whenever possible.

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 applicable statutes refer to rulemaking, and this rule utilizes the widely accepted and proven public health methodology of epidemiologic and laboratory surveillance and investigation.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

- CDC. About Cytomegalovirus. (<https://www.cdc.gov/cytomegalovirus/about/index.html>).
- CDC. Bioterrorism Agents/Diseases. (<https://emergency.cdc.gov/agent/agentlist-category.asp>).
- CDC. Cronobacter Outbreak Linked to Powdered Infant Formula. (<https://www.cdc.gov/cronobacter/outbreaks/source-date/index.html>).
- CDC. Surveillance Case Definitions for Current and Historical Conditions. (<https://ndc.services.cdc.gov/>).
- CDPHE. Public Health Order 24-01 - Declaring a Congenital Syphilis Epidemic and Expanding Testing Opportunities. (<https://drive.google.com/file/d/1yxs95JPtTnrrqzex168EBKi5600nIE3p/view>).
- Colorado General Assembly. HB24-1456 - Increase Syphilis Testing During Pregnancy. (<https://leg.colorado.gov/bills/hb24-1456>).
- Colorado State University (CSU). Conenose Bugs ("Kissing Bugs") and Insects of Similar Appearance in Colorado. (<https://extension.colostate.edu/topic-areas/insects/conenose-bugs-kissing-bugs-and-insects-of-similar-appearance-in-colorado-5-624/>).
- Editorial. *C. difficile* - A Rose by Any Other Name. Lancet - Infectious Diseases 2019;19:149. [Describes the naming convention for *C. difficile*].
- Gee, J, et al. Multistate Outbreak of Melioidosis Associated with Imported Aromatherapy Spray. N Engl J Med 2022;386:861-868. [Describes an outbreak of



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Department of Public Health & Environment

meliodosis in the U.S. associated with an aromatherapy room spray that contained ingredients imported from other countries].

- Gharpure R, et al. Geographic Range of Recreational Water-Associated Primary Amebic Meningoencephalitis, United States, 1978-2018. *Emerg Infect Dis* 2021;27(1):271-274. [Presents data supporting the northward expansion of *Naegleria fowleri* exposures associated with lakes, ponds, reservoirs, rivers, streams, and outdoor aquatic venues in the U.S.].
- Heilmann A, et al. Impact of Climate Change on Amoeba and the Bacteria they Host. *J Assoc Med Microbiol Infect Dis Can* 2024;9(1):1-5. [Summarizes the role warming temperatures may play in expanding the geographical range of some free-living amoeba, especially *Naegleria fowleri*].
- Henry M, and Fouladkhah A. Outbreak History, Biofilm Formation, and Preventive Measures for Control of *Cronobacter sakazakii* in Infant Formula and Infant Care Settings. *Microorganisms* 2019;7(3):77. [Describes several outbreaks of *Cronobacter sakazakii* in the U.S. and internationally associated with powdered infant formula].
- National CMV Foundation. (<https://www.nationalcmv.org/>).
- National Institutes of Health (NIH). Hepatitis D. (<https://www.niddk.nih.gov/health-information/liver-disease/viral-hepatitis/hepatitis-d#common-d>).
- Raines K, et al. Congenital Cytomegalovirus Surveillance in the United States. *Birth Defects Res.* 2023;115(1):11-20. [Summarizes current public health surveillance practices for cCMV].
- Schillie S, et al. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. *MMWR Recommendations and Reports* 2018;67(1):1-31. [Describes current best practices around preventing hepatitis B, including practices around perinatal hepatitis B].

STAKEHOLDER ENGAGEMENT
for
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.

CDPHE contacted several stakeholders in preparation for this request for rulemaking hearing. Between July 2 and July 30, 2024, CDPHE solicited feedback from the stakeholders listed below. These groups were emailed a memo describing the proposed amendments to the rule and a strikethrough version of the rule.

Pre-request stakeholder engagement included:

- One virtual public listening session on July 18, 2024, from 10 a.m. - noon with 84 attendees, including approximately 16 LPHAs and 10 health care organizations
- Presentations during two regularly scheduled communicable disease meetings, with approximately 200 people present across both meetings
- An online form for stakeholders to provide feedback

After the Board of Health granted the request for rulemaking, the full stakeholder group was notified via email that they could continue to provide written feedback via Google form or email. One individual provided feedback in the Google form, and one individual provided feedback via email. One comment was submitted directly to the Board of Health. CDPHE staff members reached out to these stakeholders individually to help clear misunderstandings about the proposed changes and to explain the reasoning behind the changes.

Whenever possible, CDPHE staff members with existing relationships and partnerships contacted those stakeholders directly. Stakeholder groups who CDPHE engaged with about the proposed rules include:

- Professional associations
 - Colorado Medical Society
 - American Academy of Pediatrics Colorado
 - Colorado Association of Local Public Health Officials (CALPHO)
 - Association for Professionals in Infection Control (APIC) Colorado chapter
 - Colorado Hospital Association
 - Colorado Veterinary Medical Association
 - Colorado Coroners Association
- Professionals
 - Colorado hospital infection preventionists
 - Colorado healthcare providers



COLORADO

Department of Public Health & Environment

- Long-term care facility staff
- School nurses
- Child care nurse consultants
- Contacts in higher education
- Other agencies
 - Local public health agencies (240 distinct contacts, including directors and communicable disease staff)
 - Colorado Department of Agriculture
 - Colorado Parks and Wildlife veterinary staff
- Laboratories
 - Colorado State University Veterinary Diagnostic Lab
 - Laboratory disease reporters (approximately 245)
- Partners of CDPHE's Office of STI/HIV and Viral Hepatitis (approximately 1,300 contacts)
 - Viral Hepatitis Task Force and Viral Hepatitis Elimination Coalition (approximately 190 individuals)
 - HIV support and advocacy organizations
 - Community-based organizations
 - Medical professionals
 - Community members
 - Staff at Colorado syringe access programs (140 individuals)
- CDPHE staff
 - Department's Health Facilities and Emergency Medical Services Division
 - Department's Office of Emergency Preparedness and Response
 - Department's Immunization Branch
 - State Public Health Laboratory

Summary of pre-request stakeholder feedback

| Feedback mechanism | Attendance/participation estimates | Number of individuals providing feedback |
|--------------------|------------------------------------|--|
| Standing meetings | 200 | 0 |
| Listening session | 84 | 4 |
| Feedback form | N/A | 3 |
| Email | N/A | 0 |

Formal stakeholder engagement (post-request)



| Feedback mechanism | Attendance/participation estimates | Number of individuals providing feedback |
|--|------------------------------------|--|
| Feedback form | N/A | 1 |
| Email | N/A | 1 |
| Written comments sent to the Board of Health | N/A | 1 |

Stakeholder concerns

Below are some of the stakeholder concerns with the proposed rules and CDPHE's justifications.

- **One laboratory stakeholder expressed that liver function tests reporting for hepatitis A, B, and C cases may be an additional reporting burden for labs.** Given the relative simplicity and low burden of electronic laboratory reporting systems, the Department does not believe this will be a significant burden on reporters. CDPHE is conducting some targeted outreach to laboratories that report a high number of hepatitis A, B, and C cases to collect more information on how reporting of LFTs will work to determine if there is an unrecognized burden placed on laboratories. Outreach thus far has indicated that at least one large clinical laboratory will be able to add this reporting element relatively quickly and easily. We also clarified in the rule that the only needed LFT results are the ones performed at or closest to the time of the positive hepatitis A, B, or C test.
- **One health care provider/hospital partner asked for clarification on LFT reporting and if those results need to be reported independently of hepatitis A, B, and C results.** Clarification was made to the proposed rule changes to reflect that results of LFTs performed at or closest to the time of positive hepatitis A, B, and C tests are reportable. The Department does not expect all LFT results that are ever run for any case of hepatitis A, B and C to be reported.
- **One hospital system shared multiple pieces of feedback:**
 - Feedback on adding cCMV if <1 year of age to the reportable list since this condition since CMV is a common virus found in people of all ages, and questions on if this is reportable in other states. We replied to this stakeholder with information on why we would like to make cCMV reportable, and a list of states where it is currently reportable (at least 10 states, including Nebraska, Utah, and Iowa).
 - Feedback on adding influenza and RSV positive molecular and rapid antigen test results, as well as lineage or sequencing results, as reportable conditions



COLORADO

Department of Public Health & Environment

since some laboratories are not able to report electronically. We replied to this stakeholder with information that more than 90% of disease reporting in Colorado comes in through electronic laboratory reporting, so we believe we will be capturing the majority of positive test results.

- Feedback on adding reporting of negative hepatitis B test results due to reporting burden on providers. We replied to this stakeholder that only laboratories that can report electronically will be required to report negative test results to public health.
- Feedback on adding reporting of negative testing results for syphilis and questions about the reporting time frame. We replied to this stakeholder that the addition of negative test result reporting will be the same as for positive test result reporting (one working day), and it will only be reportable by laboratories that can report electronically.
- **Two LPHA partners asked for additional clarity on when public health agencies need to be notified after a suspected tuberculosis patient has been discharged from the hospital or other setting.** The CDPHE Tuberculosis Program would prefer to not add timelines for when a hospital or other entity (such as a correctional facility) must notify public health of patient discharge at this time, as timelines are going to differ based on the type of facility and the patient's situation. We would prefer to change the language at this time and monitor compliance with the new language to determine if strict timelines would be feasible.
- **One LPHA partner found a discrepancy in the proposed rule language around syphilis negative result reporting and the memo the Department created to describe the proposed changes.** In the memo, the Department incorrectly stated that negative syphilis reporting would be performed by both laboratories and health care providers, when the proposed change is that only laboratories capable of reporting via electronic laboratory reporting will report. This error was fixed in the memo.
- **A rural medical center submitted objections to the Board of Health, stating that the additional reporting of positive molecular and rapid antigen test results for influenza and RSV cases, as well as lineage or sequencing results, would be a burden for their laboratory.** Department staff reached out to the commenter and clarified that this additional reporting burden only applies to laboratories that have the ability to perform electronic laboratory reporting. We offered to have their laboratory consult with our electronic laboratory reporting staff.
- **A state-run health care facility expressed concerns about the overall burden of disease reporting and its desire to transmit disease reports electronically.** This facility was connected with the CDPHE Electronic and Disease Reporting branch to explore electronic laboratory reporting options with the intent of making overall reporting to CDPHE easier and more efficient.



COLORADO

**Department of Public
Health & Environment**

- A large commercial clinical laboratory provided feedback on requiring reporting of pregnancy status for hepatitis B and C cases (a proposed amendment), requiring reporting of gender identity for sexually transmitted infections (an existing requirement), and requiring reporting of liver function test results for hepatitis A, B, and C cases (a proposed amendment). The laboratory expressed concerns about the amount of time it will take to implement reporting of pregnancy status due to coordination and training efforts that need to occur between different teams and concerns that providers that order tests do not routinely provide this information with each test order. The laboratory requested that CDPHE delay implementation until at least July 1, 2025. The laboratory shared similar concerns about reporting of gender identity for sexually transmitted infections, which has been a requirement in the rule for many years.

Department staff reached out to the laboratory to clarify that the Department understands that disease reporters, especially laboratories, may not currently have access to certain data elements required for each disease/condition report. The Department will work with reporters to collect data elements over time as they become available. The Department is working on other initiatives to collect disease reporting data elements, such as electronic case reporting using medical records, which will reduce the burden on laboratories to report this information in the future. For each disease report, laboratory reporters are required to provide information on the ordering or responsible health care provider, so public health can follow up with those providers or conduct medical record review to collect missing data elements.

Regarding the concerns around reporting of liver function test results, the laboratory stated that hepatitis A, B, and C test results and liver function test results are not always linked together in laboratory information systems, which may result in the laboratory reporting all liver function test results. They requested that CDPHE allow for additional time for laboratories to implement this requirement. Department staff reached out to the laboratory to clarify that laboratories will not be penalized if they do not have access to liver function test results, if liver function tests were not conducted, or if the laboratory is unable to distinguish liver function test results that were performed at or closest to the time of the positive viral hepatitis test result. Hepatitis A, B, C, and other viral hepatitis is also reportable by providers, and public health is often in contact with providers (or reviews medical records) to ascertain these results if they are not available at the testing laboratory.

1 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

2 **Division of Disease Control and Public Health Response**

3 **EPIDEMIC AND COMMUNICABLE DISEASE CONTROL**

4 **6 CCR 1009-1**

6 **Regulation 1. Reportable Diseases, Conditions, and Related Events**

7 For the purpose of these regulations, the diseases, conditions, and related events named in the
8 Reportable Diseases, Conditions, and Related Events Table (Appendix A) are declared to be potentially
9 dangerous to public health and shall be reportable in accordance with these regulations. In addition, any
10 language specifying “(the) Department” refers to the Colorado Department of Public Health and
11 Environment. **The diseases, conditions, and related events named in Appendix A and throughout this rule**
12 **pertain to those diagnosed or detected in humans, with the exception of those outlined in Regulation 8 -**
13 **Reporting of Diseases Among Animals and Waiver Process for Rabies Inoculation.**

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

22 The occurrence of a single case of any unusual disease or manifestation of illness which the healthcare
23 provider determines or suspects may be caused by or related to a bioterrorist agent or incident must be
24 reported immediately by telephone to the Department or county, district, or municipal public health
25 agency by the healthcare provider and the hospital, emergency department, clinic, healthcare center, and
26 laboratory in which the person is examined, tested, and/or treated. The same immediate reporting is
27 required for any unusual cluster of illnesses that may be caused by or related to a bioterrorist agent or
28 incident. Bioterrorist agents **that cause illness** include, but are not limited to, anthrax, plague, smallpox,
29 tularemia, botulism, viral hemorrhagic fever and brucellosis.

31 **Manner of Reporting**

32 All cases are to be reported with patient's name, date of birth, sex assigned at birth, race, ethnicity, phone
33 number, physical address (including city and county), email address, preferred language and name and
34 address and phone number of responsible physician or other healthcare provider; and such other
35 information as is needed to locate the patient for follow up. **All laboratory information reported shall**
36 **include specimen accession number.** The patient's pregnancy status shall be reported for cases of
37 syphilis, ~~and~~ HIV, hepatitis B, and hepatitis C. The patient's relevant treatment **and gender identity** shall
38 be reported for sexually transmitted infections. **Gender identity is defined as an individual's personal**
39 **sense of being male, female, or transgender.** For reports from a publicly funded anonymous testing site,
40 as provided in § 25-4-411, C.R.S., the patient's name and address are not required.

41 When hospitalization is a criteria for reporting (e.g., a hospitalized patient with a positive test result for
42 COVID-19, influenza, or RSV), the report shall provide hospital admission date(s) and the name of the

facility where the patient is hospitalized. When requested by the department, the report shall also include discharge date(s), ventilator and intensive care unit (ICU) use, and other fields as needed. ~~Reports on hospitalized patients may be made part of a report by the hospital as a whole instead of reports from individual providers. In addition, all laboratory information reported shall include specimen accession number.~~

For animal bites by ~~owned dogs, and cats, the name and locating information of the owner of the biting animal shall be reported, if known, by the healthcare provider.~~ For bites by bats, skunks, foxes, raccoons, coyotes, and other wild carnivores, ~~as well as non-bite bat exposures, the name and locating information of the owner of the biting animal or the location information of the wild animal shall be reported, if known,~~ by the healthcare provider.

Reporting requirements for healthcare-associated infections are provided by § 25-3-601 et seq., C.R.S. and are reported to the National Healthcare Safety Network (NHSN). ~~Methicillin-resistant Staphylococcus aureus (MRSA) bloodstream infections Select healthcare-associated infections not covered by, § 25-3-601, C.R.S., are listed below in 6 CCR 1009-1 Appendix A because they are not covered by § 25-3-601, C.R.S., and reporting requirements are satisfied by reporting also reported to NHSN.~~ Facilities reporting outbreaks of healthcare-associated infections, and those choosing to voluntarily participate in applied public health projects ~~related to healthcare-associated infections as indicated in Appendix A and Healthcare-Associated Infections (Appendix B), 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.~~

See Appendix A, ~~Reportable Diseases, Condition, and Related Event Table and Footnotes~~ to determine time frames 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, ~~State Public Health Laboratory Services Division.~~

~~Reports on hospitalized patients may be made part of a report by the hospital as a whole instead of reports from individual providers.~~

The Department shall develop systems and forms for reporting for physicians, other healthcare providers and hospitals. When hospitals and laboratories transmit disease reports electronically using systems and protocols developed by the Department 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,~~ known or suspected cases and outbreaks of diseases shall be reported by the physician or other healthcare 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 Department (or their designees), persons in charge of schools (including school nursing staff), licensed ~~childday~~ care centers, persons in charge of institutions of higher education or their designee, 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, Condition, and Related Event 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, Condition, and Related Event Table~~, testing laboratories shall routinely submit bacterial culture isolates or patient clinical material that yields positive findings to the Department, ~~State Public Health Laboratory Services Division~~. Clinical material is defined as: (i) ~~a~~ ~~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 ~~a test order with~~ the following information: (a) Patient's name, date of birth, sex assigned at birth, race, ethnicity, phone number, physical address (including city and county), email address, and preferred language; pregnancy status shall be reported for cases of syphilis, ~~HIV, hepatitis B and hepatitis CHIV~~ (b) Name and address and phone number of responsible physician or other healthcare provider (c) Name of disease or condition (d) Laboratory information - test name, collection date, ~~specimen accession number~~, and specimen type. Laboratories should make an effort to report all test results ~~and patient information~~ electronically, whenever possible, ~~as specimen submission to the Department, State Public Health Laboratory does not constitute disease reporting.~~

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 healthcare settings. The tuberculosis statute (§ 25-4-501, et seq., C.R.S.) 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 within ~~one~~⁴ working day by physicians, healthcare providers, hospitals, private and public laboratories, 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 assigned at birth, race, ethnicity, phone number, physical address (including city and county), email address, preferred language, name and address, and phone number of the reporting physician or other healthcare provider 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 ~~or why tuberculosis is being considered, the suspected or confirmed affected body part of the body affected, and whether it is confirmed or suspected tuberculosis disease. the stage of disease. For the purposes of this reporting requirement, "suspected" is defined as anyone being considered for tuberculosis disease as part of the differential diagnosis, leading to the ordering and performing of any tuberculosis testing.~~

B. Physicians, healthcare providers, and healthcare facilities shall report within ~~four~~⁴ calendar days the following tuberculin skin test (TST) or Interferon-Gamma Release Assay (IGRA) result if it occurs in a healthcare 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 ~~one~~⁴ working day any result diagnostic of or highly correlated with active tuberculosis disease, including cultures ~~s-positive~~ and nucleic acid amplification tests (NAAT)

positives for *Mycobacterium tuberculosis* (MTB) or similar confirmatory testing, and sputum smears positive for acid-fast bacilli. Laboratories, and shall report the results of tests for antimicrobial susceptibility performed on positive cultures for tuberculosis.

- D. Results must be reported by the laboratory that 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. When a laboratory performs a culture that is positive for *Mycobacterium tuberculosis*, the laboratory shall submit a sample of the isolate to the Department, State Public Health Laboratory Services Division no later than one working day after the observation of positive findings.
- F. The Department or county, district, or municipal public health agency 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 antimicrobial susceptibility test results are finalized. The Department or county, district, or municipal public health agency shall provide the laboratory and hospital the results of its evaluation, including comparison of the laboratory indices to norms for other similar laboratories.
- G. The Board of Health determines that to prevent the emergence of multi-drug-resistant multi-drug-resistant tuberculosis (MDR-TB), it is necessary, appropriate, and standard good medical practice for persons with active tuberculosis disease to receive directly observed therapy (DOT) throughout the treatment for their disease. All healthcare providers and healthcare organizations are required to provide DOT 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 Department or tuberculosis clinic at the Public Health Institute at Denver Health. DOT is highly recommended as it remains standard practice, but is not required by legislation for patients with extrapulmonary tuberculosis disease, provided that the presence of pulmonary tuberculosis has been thoroughly investigated and excluded, including microscopy testing. In applicable situations, a variance shall be granted in accordance with § 25-4-506(3), C.R.S.

Healthcare providers and healthcare organizations shall report to the Department or county, district, or municipal public health agency within seven 7 calendar days the name of any patient on DOT who has missed one dose. When requested by healthcare providers and healthcare organizations, the county, district, or municipal public health agency will ensure the provision of DOT to outpatients with active tuberculosis disease and this shall fulfill the requirement for the healthcare providers and healthcare organizations.

- H. All healthcare providers within all correctional and healthcare facilities jails, prisons, and other incarceration facilities and hospitals and healthcare facilities providing inpatient testing or treatment to persons with suspected and confirmed active tuberculosis disease shall notify and include the Department or county, district, or municipal public health agency when they begin their of their intent to discharge planning process a patient and involve the Department or county, district, or municipal public health agency in the transition discharge-planning process prior to discharging the patient from the facility to ensure a safe and appropriate discharge plan is in place for the safety of the patient and the community. Public health will be involved in the discharge planning to ensure continuity of care, safe discharge for the patient and community, appropriate medication regimen, arrangement of home visits, and directly observed therapy. The intention of the notification and involvement in discharge planning is to discuss the treatment plan

~~for the patient and to assure adequate follow-up and coordination among healthcare providers and public health so that continuity of care and the DOT standard are met.~~

I. All licensed hospitals and nursing home facilities shall maintain a registry of the TST and/or IGRA test results of healthcare 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 § 25-4-508, C.R.S., authorized personnel of the Department may inspect and have access to such a register in the course of an investigation intended to identify sources and contacts of a case of active tuberculosis disease and to control tuberculosis.

J.

- (1) With respect to tuberculosis treatment and control, the chief medical officer of a county, district, or municipal public health agency must be a physician licensed to practice medicine in the State of Colorado. The chief medical officer of a county, district, or municipal public health agency may design a program, consistent with good medical practice, of required screening for latent tuberculosis 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 are at increased risk of tuberculosis (TB) infection or tuberculosisTB disease or 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 to rule out tuberculosisTB disease if either test result is positive. If free of signs and symptoms of tuberculosis disease, subsequent testing would be dependent on the results of the TST or IGRA test.
- (2) If an individual has signs and symptoms consistent with tuberculosis in the infectious stages, the ~~state or local~~ chief medical 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. The results of the screening shall be given in writing to the person screened. Any person who is found to have latent tuberculosis 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.
- (3) Locally required screening programs shall be evaluated and reviewed by the local board of health every three years.
- (4) Nothing in this rule shall prohibit the Department or county, district, or municipal public health agencies 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 identified or potential reportable conditions and shall be considered official duties of the Department or county, district, or municipal public health agencies. Investigations may be conducted to evaluate exposures to known causes of reportable conditions for purposes of case identification and prevention. ~~Reasonable efforts shall be made by the Department or county, district, or municipal public health agencies to consult with the responsible physician, other healthcare providers, or the medical facility caring for the patient prior to any further follow-up by Department or county, district, or municipal public health agencies.~~ Such investigations may include, but are not limited to:

- A. Review of pertinent, relevant medical records by authorized personnel, if necessary to confirm the diagnosis; to investigate causes; to identify other cases related to the outbreak or the reported communicable disease in a region, community, or workplace; to determine if a patient with a reportable disease has received adequate treatment to render the person 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. Such review of records may include negative or inconclusive laboratory results. Where feasible, facilities are encouraged to provide remote electronic access to authorized health department staff for this purpose.
- B. Performing follow-up interview(s) with the case or persons knowledgeable about the case to collect information pertinent and relevant to the cause(s) of or risk factors for the reportable condition.
- C. Medical examination and testing of persons with the explicit consent of such persons.
- D. Obtaining from public or private businesses or institutions the lists of persons with a similar or common potential exposure to a reported case; such exposure may be current or have occurred in the past.
- E. Interviewing or administering questionnaire surveys confidentially to any resident of a community or any agent, owner, operator, employer, employee of a public or private business or institution, that is either epidemiologically associated with a reported case or has had a similar exposure as a reported case.
- F. Collecting and analyzing samples or measurements of items that may be related to the cause of the outbreak or reportable disease.
- G. Taking 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. 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 (including but not limited to current and former employee/student rosters and contact information, schedules, health and medical information, job duties and descriptions, and patron or client contact information), and materials and supplies 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.
- 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 learns of a case of a reportable disease or an epidemic or communicable disease exposure potentially threatening to public health, it shall notify the

Department ~~or the local jurisdiction in which the case resides~~ in a timely manner, usually within the timeframe for reporting in Regulation 1 ~~and Appendix A. Utilizing the statewide disease reporting system developed and in use by the Department and county, district, and municipal public health agencies fulfills the notification requirement.~~

The Department shall, in turn, notify the appropriate county, district, or municipal public health agency in a timely manner, usually within the timeframe for reporting in Regulation 1 ~~and Appendix A, whenever it learns of a case of a reportable disease or ~~it learns~~ of an epidemic or communicable disease exposure potentially threatening to public health in the local agency's jurisdiction. Utilizing the statewide disease reporting system developed and in use by the Department and county, district, and municipal public health agencies fulfills the notification requirement.~~

These requirements shall not apply if the Department and 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 shall be restricted to information necessary for the treatment, control, investigation, and prevention of epidemic and communicable diseases dangerous to public health.

Regulation 7. Food Handling and Infected Persons

No person, while infected with a disease in a communicable form ~~that 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 Department.

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 public health such as rabies, anthrax, plague, tularemia, encephalitis, bovine spongiform encephalopathy, coronaviruses that cause novel or severe human disease, including SARS-CoV-2, ~~novel influenza viruses~~, etc., shall promptly report the facts to the Department or county, district, or municipal public health agency.

B. Pursuant to § 25-4-607 (2), C.R.S., 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:

- (5) 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;
- (6) A valid veterinary-client-patient relationship, as defined under § 12-64-103 (15.5), C.R.S., has been established between the veterinarian, owner and animal to be exempted from rabies inoculation;

- (7) The veterinarian completes and signs the veterinary section of the Exemption from Rabies Vaccination form provided by the Department;
- (8) The animal owner signs the informed consent section of the Exemption from Rabies Vaccination form;
- (9) The veterinarian maintains the signed exemption as part of the animal's medical record and provides a copy to the owner;
- (10) The exemption issued is limited to the anticipated duration of the animal's medical condition that precludes inoculation; and
- (11) The veterinarian provides a copy of the exemption form to the Department or county, district, or municipal public health agency 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 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 their designee(s) may review Exemption from Rabies Vaccination forms and examine the veterinary records pertaining to the medical condition to determine if the medical condition legitimately contraindicates rabies inoculation. If appropriate, the executive director or their designee(s) may refer the case to the 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 in compliance with these regulations shall be confidential information subject to §§ 25-1-122(4) and 25-4-406(1), C.R.S. ~~Reasonable efforts shall be made by the Department to consult with the responsible physician, other healthcare providers, or the medical facility caring for the patient prior to any further follow-up by Department or county, district, or municipal 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 § 12-200-1115, C.R.S., which states the Department shall promulgate rules relating to the proper use of sterile 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, etc.) used in connection with procedures shall be cleaned and disinfected with a disinfectant registered by the U.S. Environmental Protection Agency (EPA) that is approved for use in healthcare settings. Cleaning and disinfection shall occur following each use and according to the disinfectant manufacturer label instructions.

Puncturing devices shall be defined as any needle, instrument, probe, or other devices utilized by practitioners of acupuncture, or adjunctive therapies, that punctures the skin or enters tissue of any patient/client. Needles and other puncturing devices shall be sterile and 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/client. The Food and Drug Administration (FDA) requires that sterile needles be used and always labeled for single patient use.

Equipment shall be defined as any item utilized by practitioners of acupuncture, or adjunctive therapies, that serve as vehicles for needles or other puncturing devices. These items do not puncture the skin or enter the tissue. Equipment shall either be disposable, single-use items (preferred), or thoroughly cleaned and disinfected between each patient/client use according to the manufacturers' instructions. If there are no manufacturers' instructions for how to clean and disinfect the equipment, the equipment shall not be used on more than one patient and disposed of properly.

Acupuncture and adjunctive therapies where sterile needles and puncturing devices are used shall only be performed by licensed practitioners. Prior to and after each treatment of acupuncture, the practitioner shall perform hand hygiene by either washing their hands with soap and water or using an alcohol-based hand sanitizer.

Regulation 11. Sexually Transmitted Infections

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

Information concerning testing, treatment, causes, or the prevention of sexually transmitted infections (STIs) shall be shared, to the minimum extent necessary to achieve the public health purpose, between the appropriate county, district, or municipal public health agency, contracted agency, Ryan White Comprehensive Human Immunodeficiency Virus (HIV) Resources Emergency Act-funded agency, other health agency or person providing direct services related to STIs and the Department, as provided by § 25-4-406(1)(b), C.R.S.

With respect to Regulation 5, investigations related to STIs 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 STIs. The Department shall destroy personal identifying information of all persons with CD4 or viral load results if the investigation subsequent to the report finds no evidence of a STI.

Section 25-4-411 (1)(a), C.R.S., requires the Department to conduct an anonymous counseling and testing program for persons considered to be at high risk for the acquisition of 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 Department 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 Department.

B. All persons performing partner services will have completed courses concerning introduction to STI interviewing and partner notification, and other related courses as specified by the Department.

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 and assessed for linkage to care 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 STI prevention providers developed by the Department. 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 Department.
- F. In accordance with § 25-4-404(2), C.R.S., the Department shall create and maintain guidelines, subject to approval by the Board of Health, concerning the public health procedures described in §§ 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.

Regulation 12. Congenital Syphilis

All healthcare facilities and providers including but not limited to, hospitals, urgent care clinics, community health clinics, freestanding emergency departments, medical offices, correctional facilities, and licensed medical professionals that medically evaluate and treat anyone who is pregnant for any reason shall take all necessary steps to offer syphilis testing using a standardized algorithm for all patients in their care who are pregnant, unless a documented syphilis test has already occurred that meets the requirement or the patient declines testing, in each circumstance that follows:

- A. During the first trimester of pregnancy or at the patient's initial prenatal visit.
- B. During the third trimester of pregnancy (between 28 - 32 weeks gestational age or up to 32 weeks gestational age).
- C. At the time of delivery.
- D. When there is a fetal death after 20 weeks' gestation.

469
470

Appendix A. Reportable Diseases, Conditions, and Related Events Table

| Disease/Event | Pathogen/Organism | Time* | Reporter ¹ | Specimen Source(s) ² | Send Clinical Material ³ |
|---|---|-------------------------|-----------------------|---------------------------------|-------------------------------------|
| <i>Acinetobacter baumannii</i> , carbapenem-resistant (CRAB) ⁴ | Carbapenem-resistant <i>Acinetobacter baumannii</i> (species in the <i>A. baumannii</i> complex, e.g., <i>A. baumannii</i> , <i>A. calcoaceticus</i> , <i>A. lactucae</i> , <i>A. nosocomialis</i> , <i>A. pittii</i> , <i>A. seifertii</i> , etc.) | 4 days | L | All | Required |
| Acute flaccid myelitis | | 4 days | P | | Upon request |
| Amebae, free-living | <i>Acanthamoeba</i> spp. (excluding keratitis), <i>Balamuthia mandrillaris</i> , <i>Naegleria fowleri</i> | 4 days | L & P | All | Required |
| Animal bites and exposures ^{5,6} : Bites: by dogs, cats, bats, skunks, foxes, raccoons, coyotes, or other wild carnivores Exposures: any bat exposure ^{5,6} | | 24 hrs | P | | Not applicable |
| Animal bites by mammals not listed above ⁵ | | 4 days | P | | Not applicable |
| Anthrax ⁵ | <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 | Upon request |
| Bioterrorism agent or incident, known or suspected | Any pathogen | Immed | L & P | All | Required |
| Blastomycosis | <i>Blastomyces</i> species | 4 days | L & P | All | Upon request |
| Botulism ⁵ | <i>Clostridium botulinum</i> | Immed | L & P | All | Upon request |
| Brucellosis ⁵ | <i>Brucella</i> species | 4 days | L & P | All | Required |
| Campylobacteriosis | <i>Campylobacter</i> species | 4 days | L & P | All | Upon request |
| <i>Candida auris</i> ⁷ | <i>Candida auris</i> | 1 working day Immed | L & P | All | Required |
| Candidemia ^{8-Metro} | <i>Candida</i> species | 30 days | L | Blood | Upon request |
| Carbapenemase-producing organisms ⁹ | Positive phenotypic test for carbapenemase production or detection of a carbapenemase gene | 1 working day 4-days | L | All | Required |
| Chagas disease | <i>Trypanosoma cruzi</i> | 4 days | L & P | All | Upon request |
| Chancroid | <i>Haemophilus ducreyi</i> | 4 days | L & P | All | Upon request |
| Chikungunya | Chikungunya virus | 4 days | L | All | Upon request |
| Chlamydia, any site | <i>Chlamydia trachomatis</i> | 4 days | L & P | All | Upon request |
| Cholera ⁵ | <i>Vibrio cholerae</i> | Immed | L & P | All | Required |
| Creutzfeld-Jakob Disease (CJD) and other transmissible spongiform encephalopathies (TSEs) ⁵ | | 4 days | P | All | Upon request |
| <i>Clostridioides difficile</i> infection ^{8-Metro 10} | <i>Clostridioides difficile</i> | 30 days | L | All | Upon request |
| Coccidioidomycosis | <i>Coccidioides</i> species | 4 days | L & P | All | Upon request |
| Colorado tick fever | Colorado tick fever virus | 4 days | L | All | Upon request |

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|--|---|----------------------|---------------------|--------------|---------------------|
| COVID-19 ¹¹⁹ | <ul style="list-style-type: none"> SARS-CoV-2 (positive molecular NAAT and rapid antigen tests) COVID-19 IL lineage or sequencing results | 4 days | L- (ELR only) & P | All | Upon request |
| COVID-19¹⁴⁰ | SARS-CoV-2 (negative or inconclusive result on any NAAT test) | 4 days | L & P | All | Upon request |
| COVID-19-associated deaths, all ages | SARS-CoV-2 | 4 days | P | | Upon request |
| COVID-19-associated hospitalization | SARS-CoV-2 | 4 days | L & P | All | Upon request |
| Coronavirus – severe or novel | Severe Acute Respiratory Syndrome coronavirus (SARS-CoV), Middle East Respiratory Syndrome coronavirus, (MERS-CoV) or other severe or novel coronavirus other than SARS-CoV-2 | Immed | L & P | All | Upon request |
| Cronobacter invasive infections if <1 year of age | Cronobacter species (including <i>C. sakazakii</i>, <i>C. malonaticus</i>) | 4 days | L & P | All | Required |
| Cryptosporidiosis | <i>Cryptosporidium</i> species | 4 days | L & P | All | Upon request |
| Cyclosporiasis | <i>Cyclospora</i> species | 4 days | L & P | All | Upon request |
| Congenital cytomegalovirus (CMV) if <1 year of age | Cytomegalovirus (positive results) | 4 days | L & P | All | Upon request |
| Congenital cytomegalovirus (CMV) if <1 year of age | CMV DNA by NAAT or culture (negative results) | 4 days | L (ELR only) | Urine | Upon request |
| Dengue | Dengue virus | 4 days | L | All | Upon request |
| Diphtheria ⁵ | <i>Corynebacterium diphtheriae</i> | Immed | L & P | All | Required |
| Encephalitis ⁵ | | 4 days | P | All | Upon request |
| Enterobacterales, carbapenem-resistant (CRE) ¹²⁴ | Carbapenem-resistant Enterobacterales including, but not limited to, <i>Escherichia coli</i> species, <i>Klebsiella</i> species, <i>Enterobacter</i> species, <i>Citrobacter</i> species, <i>Serratia</i> species, <i>Raoultella</i> species, <i>Providencia</i> species, <i>Proteus</i> species, <i>Morganella</i> species | 4 days | L | All | Required |
| Enterobacterales, extended-spectrum beta-lactamase (ESBL) ^{8-Boulder,132} | <i>Escherichia coli</i> species and <i>Klebsiella</i> species. <i>Raoultella</i> species | 30 days | L | All | Upon request |
| <i>Escherichia coli</i> species, <i>coli</i> invasive infections ^{8-BoulderBoulder} | <i>Escherichia coli</i> species | 30 days | L | Sterile only | Upon request |
| <i>Escherichia coli</i> O157:H7 and Shiga toxin-producing <i>Escherichia coli</i> | Shiga toxin-producing <i>Escherichia coli</i> ¹⁴³ | 4 days | L & P | All | Required |
| Giardiasis | <i>Giardia lamblia</i> | 4 days | L & P | All | Upon request |
| Glanders | <i>Burkholderia mallei</i> | 1 working day | L & P | All | Upon request |
| Gonorrhea, any site, including disseminated gonorrhea ³ | <i>Neisseria gonorrhoeae</i> | 4 days | L & P | All | Upon request |
| Group A streptococci ^{15-4,8-Metro} | <i>Streptococcus pyogenes</i> | 4 days | L | Sterile only | Required |
| Group B streptococci ^{8-Metro} | <i>Streptococcus agalactiae</i> | 30 days | L | Sterile only | Required |
| <i>Haemophilus influenza</i> | <i>Haemophilus influenzae</i> | 1 working day | L & P | Sterile only | Required |
| Hantavirus disease ⁵ | Hantavirus | 4 days | L & P | All | Upon request |
| Healthcare-associated infections ¹⁶⁵ | | 30-4 days | P | | Not applicable |
| Hemolytic uremic syndrome if <18 years of age ⁵ | | 4 days | P | | Upon request |

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|--|--|---------------|--|-----|--|
| Hepatitis A ⁵ | <ul style="list-style-type: none"> Hepatitis A virus (+IgM anti-HAV, +PCR or +NAAT) Liver function test values for AST, ALT, and total bilirubin that were performed at or closest to the time of the positive hepatitis A result | 1 working day | L & P | All | Upon request |
| Hepatitis B | <ul style="list-style-type: none"> Hepatitis B virus (+HBsAg, +IgM anti-HBc, +HBeAg, or +HBV DNA) Liver function test values for AST, ALT, and total bilirubin that were performed at or closest to the time of the positive hepatitis B result | 4 days | L & P | All | Upon request |
| Hepatitis B | Hepatitis B virus (negative HBsAg, negative HBV DNA, and/or negative confirmatory assays) | 4 days | L (ELR only) | All | Upon request |
| Hepatitis B in children <3 years of age | HBsAg and anti-HBs positive, negative, and inconclusive lab results | 4 days | L | All | Upon request |
| Hepatitis C ¹⁷⁶ | <ul style="list-style-type: none"> Hepatitis C virus (+ serum antibody titer and/or + confirmatory assays) Liver function test values for AST, ALT, and total bilirubin that were performed at or closest to the time of the positive hepatitis C result | 4 days | L & P | All | Upon request |
| Hepatitis C ¹⁷⁶ | Hepatitis C virus (negative HCV antibody, negative confirmatory assays) | 4 days | L (ELR only) | All | Upon request |
| Hepatitis D | Hepatitis D virus (+anti-HDV IgM, +anti-HDV total, +HDAg, +HDV DNA, or +HDV RNA) | 4 days | L & P | All | Upon request |
| Hepatitis, other viral | <ul style="list-style-type: none"> Positive results Liver function test values for AST, ALT, and total bilirubin | 4 days | P | | Upon request |
| Histoplasmosis | <i>Histoplasma</i> species | 4 days | L & P | All | Upon request |
| 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) HIV genotype | 4 days | <ul style="list-style-type: none"> L & P L & P L & P L | All | Upon request |
| Influenza ¹¹ | <ul style="list-style-type: none"> Influenza virus (positive molecular and rapid antigen tests) Lineage or sequencing results | 4 days | L (ELR only) | All | Upon request |
| Influenza-associated death if <18 years of age | Influenza virus | 4 days | P | All | Upon request |
| Influenza-associated hospitalization | Influenza virus | 4 days | L & P | All | Upon request |
| Influenza – novel | Influenza virus | Immed | L & P | All | Upon request |
| Legionellosis ¹⁸ | <i>Legionella</i> species | 4 days | L & P | All | Required for all respiratory specimens Upon request |
| Leprosy (Hansen's Disease) | <i>Mycobacterium leprae</i> | 4 days | P | All | Upon request |
| Listeriosis | <i>Listeria monocytogenes</i> | 4 days | L & P | All | Required |
| Lyme disease | <i>Borrelia burgdorferi</i> | 4 days | L & P | All | Upon request |
| Lymphogranuloma venereum (LGV) | <i>Chlamydia trachomatis</i> | 4 days | L & P | All | Upon request |
| Malaria ⁵ | <i>Plasmodium</i> species | 4 days | L & P | All | Upon request |
| Measles (rubeola) ⁵ | Measles virus | Immed | L & P | All | Upon request |

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|---|---|-----------------------|--------------|--------------|----------------|
| Melioidosis | <i>Burkholderia pseudomallei</i> | 1 working day | L & P | All | Upon request |
| Meningococcal disease ⁵ | <i>Neisseria meningitidis</i> or gram-negative diplococci | Immed | L & P | Sterile only | Required |
| Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) bacteremia ¹⁹⁷ | Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) | Per CMS ¹⁷ | P | Blood | Not applicable |
| Mpox (monkeypox) | Mpox virus (orthopox virus) | 1 working day 4 days | L & P | All | Upon request |
| Multisystem Inflammatory Syndrome in Children (MIS-C) if <21 years | | 4 days | P | | Upon request |
| Mumps ⁵ | Mumps virus (acute infection) | 4 days | L & P | All | Upon request |
| <i>Mycobacterium</i> , nontuberculous (NTM) ^{8-Metro} | <i>Mycobacterium</i> species (except <i>tuberculosis</i> complex, <i>M. leprae</i> , and <i>M. goodii</i>) | 30 days | L | All | Upon request |
| Outbreaks - known or suspected of all types - including those transmitted from food, water, animals, vectors, environmental contamination, person-to-person, and related to a healthcare setting ⁵ | Any pathogen | Immed | L & P | | Upon request |
| Pertussis (whooping cough) ⁵ | <i>Bordetella pertussis</i> | 1 working day | L & P | All | Upon request |
| Plague ⁵ | <i>Yersinia pestis</i> | Immed | L & P | All | Required |
| Poliomyelitis ⁵ | Poliovirus | Immed | L & P | All | Upon request |
| <i>Pseudomonas</i> , carbapenem-resistant ²⁰⁻⁴⁸ | <i>Pseudomonas aeruginosa</i> | 4 days | L | All | Upon request |
| Psittacosis | <i>Chlamydia psittaci</i> | 4 days | L & P | All | Upon request |
| Q fever ⁵ | <i>Coxiella burnetii</i> | 4 days | L & P | All | Upon request |
| Rabies: human (suspected) ⁵ | Rabies virus (Lyssavirus) | Immed | L & P | All | Upon request |
| Respiratory syncytial virus (RSV) ¹¹ | <ul style="list-style-type: none"> Respiratory syncytial virus (positive molecular and rapid antigen tests) Lineage or sequencing results | 4 days | L (ELR only) | All | Upon request |
| Respiratory syncytial virus (RSV)-associated death if <18 years | Respiratory syncytial virus | 4 days | P | All | Upon request |
| Respiratory Syncytial Virus (RSV)-associated hospitalizations | Respiratory Syncytial Virus | 4 days | L & P | All | Upon request |
| Rickettsiosis | <i>Rickettsia</i> species, including Rocky Mountain spotted fever and typhus groups | 4 days | L & P | All | Upon request |
| Rubella (acute infection) ⁵ | Rubella virus | 1 working day | L & P | All | Upon request |
| Rubella (congenital) ⁵ | Rubella virus | 4 days | L & P | All | Upon request |
| Salmonellosis | <i>Salmonella</i> species | 4 days | L & P | All | Required |
| Shigellosis | <i>Shigella</i> species | 4 days | L & P | All | Required |
| Smallpox ⁵ | Variola virus (Orthopox virus) | Immed | L & P | All | Upon request |
| <i>Staphylococcus aureus</i> , Vancomycin-non-susceptible ^{21 49} | Vancomycin non-susceptible <i>Staphylococcus aureus</i> | 4 days | L | All | Required |
| <i>Streptococcus pneumoniae</i> ²²⁹ | <i>Streptococcus pneumoniae</i> | 4 days | L | Sterile only | Required |
| Syphilis ^{5, 234} | <i>Treponema pallidum</i> (positive results) | 1 working day | L & P | All | Upon request |

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|---|--|---------------|--------------|-----|--------------|
| Syphilis ^{5, 23} | <i>Treponema pallidum</i> (negative results) | 1 working day | L (ELR only) | All | Upon request |
| Tetanus ⁵ | <i>Clostridium tetani</i> | 4 days | P | All | Upon request |
| Tick-borne relapsing fever ⁵ | <i>Borrelia</i> species and spirochetemia except <i>burgdorferi</i> species | 4 days | L & P | All | Upon request |
| Toxic shock syndrome ²²⁹ (streptococcal and non-streptococcal) | <i>Streptococcus pyogenes</i> and non-streptococcal bacteria | 4 days | P | All | Upon request |
| Trichinosis ⁵ | <i>Trichinella</i> species | 4 days | P | All | Upon request |
| Tuberculosis disease (active) ⁵ | <i>Mycobacterium tuberculosis</i> ²⁴² | 1 working day | L & P | All | Required |
| Tuberculosis immune reactivity indicated by a positive interferon gamma release assay test (IGRA) | <i>Mycobacterium tuberculosis</i> ²⁵³ | 4 days | L (ELR only) | All | Not Required |
| Tularemia ⁵ | <i>Francisella tularensis</i> | 1 working day | L & P | All | Required |
| Typhoid fever ⁵ | <i>Salmonella</i> Typhi | 1 working day | L & P | All | Required |
| Varicella (chicken pox) ⁵ | Varicella virus | 4 days | L & P | All | Upon request |
| 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, Guanarito virus, Junin virus, Machupo virus, Sabia virus, Rift Valley fever | Immed | L & P | All | Required |
| West Nile virus (acute infection) | West Nile virus | 4 days | L | All | Upon request |
| Yellow fever | Yellow fever virus | 4 days | L | All | Upon request |
| Yersiniosis ^{8-Seven} | <i>Yersinia non-pestis</i> species | 4 days | L | All | Required |
| Zika virus | Zika virus | 4 days | L | All | Upon request |

All cases are to be reported with patient's name, date of birth, sex assigned at birth, race, ethnicity, phone number, physical address (including city and county), email address, preferred language and name and address and phone number of responsible physician or other healthcare provider; and such other information as is needed in order to locate the patient for follow up. The patient's pregnancy status shall be reported for cases of syphilis, HIV, hepatitis B and hepatitis CHIV. 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.

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 or arrange for collection of specimens in Colorado; and by in-state laboratories which send specimens to an out-of- state laboratory referral laboratory), P = healthcare 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 (or their designees), persons in charge of schools (including nursing staff) and licensed **child 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 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, ~~State Public Health Laboratory Services Division~~. The isolate or clinical material shall be received at the Department, ~~State Public Health 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 assigned at birth, race, ethnicity, phone number, physical address (including city and county), email address, and preferred language; pregnancy status shall be reported for cases of syphilis, HIV, hepatitis B, and ~~hepatitis CHIV~~ (b) Name and address and phone number of responsible physician or other healthcare provider; (c) Name of disease or condition; and (d) Laboratory information - test name, collection date, ~~specimen accession number~~, and specimen type.

4 *Acinetobacter baumannii* (including species in the *A. baumannii* complex, e.g., *A. baumannii*, *A. calcoaceticus*, *A. lactucae*, *A. nosocomialis*, *A. pittii*, *A. seifertii*, etc.) that are resistant to at least one carbapenem (including imipenem, meropenem, or doripenem).

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

6 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 healthcare provider or reporter.

7 *Candida auris* identified, or any suspected *Candida auris*. Clinical material may not be available for screening tests.

8 Condition reportable only among residents of a specific catchment area.

8-MetroETRO Condition reportable only among residents of Denver Metropolitan Area (Adams, Arapahoe, Denver, Douglas, and Jefferson Counties)

8-SevenEVEN Condition reportable only among residents of seven-county Denver Metropolitan Area (Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas, and Jefferson counties)

8-BoulderOULDER Condition only reportable among residents of Boulder county

9 Clinical or screening test positive for a carbapenemase using a phenotypic, molecular test, or next generation sequencing. Common carbapenemase genes include: blaKPC, blaNDM, blaVIM, blaIMP, blaOXA-48, but other carbapenemase genes include but are not limited to: blaSIM, blaGIM, blaSPM, other OXA genes, etc. Phenotypic testing methods include but are not limited to: metallo-β-lactamase test, modified Hodge test, Carba NP, carbapenem inactivation method (CIM), modified carbapenem inactivation method (MCIM), EDTA-modified carbapenem inactivation method (ECIM), or immunochromatography tests (ICT). Molecular tests for carbapenemase genes include but are not limited to: Xpert Carba-R, VERIGENE, Streck ARM-D, Cepheid, validated laboratory-developed NAAT, etc. Clinical material may not be available for screening tests.

| | | |
|-----|------|--|
| 535 | 10 | Any positive tests shall be reported. All positive results from multi-step algorithms (including non- |
| 536 | | toxin detecting tests such as antigen tests (e.g., glutamate dehydrogenase or GDH, and cultures, |
| 537 | | etc.) shall also be reported, regardless of where the test falls within the algorithm. |
| 538 | 110 | All positive SARS-CoV-2 results for all test types including molecular tests, antigen tests, and |
| 539 | | sequencing lineage or mutation profile results except serology/antibody testing and at-home |
| 540 | | antigen tests are reportable. Positives will be reported by laboratories capable of electronic |
| 541 | | laboratory reporting (ELR) and only reported by ELR. Serology/antibody testing and at-home |
| 542 | | antigen tests are not reportable. Any individual as defined in Regulation 2, entity or facility that |
| 543 | | collects, performs, or tests for SARS-CoV-2 on specimens in Colorado is responsible for reporting |
| 544 | | all positive SARS-CoV-2 test results. SARS-CoV-2 sequencing lineage and mutation profile |
| 545 | | results, when performed, shall also be reported. For any NAAT or molecular SARS-CoV-2 tests |
| 546 | | conducted by CLIA-certified labs, negative and inconclusive results are also reportable. All |
| 547 | | entities required to report SARS-CoV-2 test result information shall report through CDPHE's |
| 548 | | electronic laboratory reporting (ELR) platform. Reporting entities can report directly to CDPHE |
| 549 | | ELR or through CDC PRIME ReportStream application, or other CDPHE-approved third party. |
| 550 | 124 | Enterobacterales including, but not limited to, <i>Escherichia</i> species <i>coli</i> , <i>Klebsiella</i> species, |
| 551 | | <i>Enterobacter</i> species, <i>Citrobacter</i> species, <i>Serratia</i> species, and <i>Raoultella</i> species that are |
| 552 | | resistant to at least one carbapenem (including imipenem, meropenem, doripenem, or |
| 553 | | ertapenem); or <i>Providencia</i> species, <i>Proteus</i> species, <i>Morganella</i> species that are resistant to at |
| 554 | | least one carbapenem (including meropenem, doripenem, or ertapenem); but not including |
| 555 | | imipenem); or Enterobacterales of any genus and species that test positive for production of |
| 556 | | carbapenemase (e.g., KPC, NDM, VIM, IMP, OXA-48, others). |
| 557 | 132 | <i>Escherichia</i> species, <i>coli</i> and <i>Klebsiella</i> species, or <i>Raoultella</i> species resistant to at least one |
| 558 | | extended-spectrum cephalosporin (ceftazidime, cefotaxime or ceftriaxone) or <i>Escherichia</i> |
| 559 | | species, <i>coli</i>, and <i>Klebsiella</i> species, or <i>Raoultella</i> species that test positive for production of an |
| 560 | | extended-spectrum beta-lactamase (ESBL) demonstrated by a recognized test (e.g., broth |
| 561 | | microdilution, disk diffusion). |
| 562 | 143 | This includes any Shiga toxin test or O157 antigen test that is positive, even if no culture is |
| 563 | | performed. If the laboratory does not have the capacity to perform H (flagellar) antigen tests, then |
| 564 | | <i>Escherichia coli</i> O157 should be reported. |
| 565 | 15-4 | If group A streptococci is isolated from a wound or surgical tissue/specimen and is accompanied |
| 566 | | by necrotizing fasciitis or streptococcal toxic shock syndrome, the case shall be reported and the |
| 567 | | isolate shall be submitted. |
| 568 | 165 | Reportable only by facilities that are voluntarily participating in applied public health projects. |
| 569 | | Appendix B includes a definition of healthcare-associated infections, a list of included infections, |
| 570 | | and a list of included health facility types. |
| 571 | 176 | All associated results, including negative (nonreactive) and positive (reactive) HCV confirmatory |
| 572 | | assays from persons who have been diagnosed with or who have laboratory evidence of HCV |
| 573 | | infection are reportable (e.g., antigen or nucleic acid amplification for HCV RNA [including |
| 574 | | qualitative, quantitative or genotype testing]). Negative HCV test results will be reported by |
| 575 | | laboratories capable of electronic laboratory reporting (ELR) and only reported by ELR. |
| 576 | 18 | Submission of urine specimens is not required. If respiratory samples are available on patients |
| 577 | | positive for legionellosis by urine antigen test, submit a respiratory sample. |
| 578 | 197 | Reporting requirement is fulfilled through the Department's access to the National Healthcare |
| 579 | | Safety Network (NHSN) for those healthcare facilities that are required to report methicillin- |

580 resistant *Staphylococcus aureus* (MRSA) bacteremia to the Centers for Medicare & Medicaid
581 services (CMS). In these instances these healthcare facilities shall confer rights to the
582 Department to access the NHSN data for these conditions.

583 ~~2048~~ *Pseudomonas aeruginosa* resistant to at least one of the following carbapenems: imipenem,
584 meropenem, or doripenem; OR *P. aeruginosa* that tests positive for production of a
585 carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA, others).

586 ~~2149~~ *Staphylococcus aureus* that are non-susceptible to vancomycin, which include isolates with
587 minimum inhibitory concentration (MIC) of ≥ 4 mcg/ml.

588 ~~220~~ Clinical material shall be submitted from laboratories when the material is from residents of the 5-
589 county metro area (Adams, Arapahoe, Denver, Douglas and Jefferson counties). For Toxic Shock
590 Syndrome, submission of *Streptococcus pyogenes* isolates from residents of the 5-county metro
591 area is required.

592 ~~234~~ All associated results for syphilis shall be reported **for positive syphilis test findings** including
593 treponemal tests (Enzyme Immunoassay [EIA], Chemoluminescence Assay [CIA], Fluorescent
594 Treponemal Antibody Absorption [FTA-ABS], Polymerase Chain Reaction [PCR], Multiplex Flow
595 Immunoassay [MFI], *Treponema pallidum* Particle Agglutination [TP-PA], *Treponema pallidum*
596 Antibody [TPA]) and Non-treponemal Tests (Rapid Plasma Reagin [RPR], Venereal Disease
597 Research Laboratory [VDRL], Cerebrospinal Fluid [CSF] Quantitative Titers). **Negative syphilis**
598 **test results will be reported by laboratories capable of electronic laboratory reporting (ELR) and**
599 **only reported by ELR.**

600 ~~242~~ Including (+) AFB sputum smear, culture (regardless of specimen site) and nucleic acid
601 amplification tests (NAAT). See regulation 4f.

602 ~~253~~ All positive interferon gamma release assays (IGRAs) will be reported by labs capable of
603 electronic laboratory reporting (ELR), and only reported by ELR.
604

605 **Appendix B. Healthcare-Associated Infections**

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

609 Examples of healthcare-associated infections include:

- 610 Bloodstream infections
- 611 Bone and joint infections
- 612 Cardiovascular system infections
- 613 Central nervous system infections
- 614 Eye, ear, nose, throat, or mouth infections
- 615 Gastrointestinal system infections
- 616 Pneumonia
- 617 Reproductive tract infections
- 618 Skin and soft tissue infections
- 619 Surgical site infections
- 620 Systemic infections
- 621 Urinary tract infections
- 622 Antimicrobial resistant infections

623

624 Health facility types include:

- 625 Acute care hospitals
- 626 Ambulatory surgical centers
- 627 Birth centers
- 628 Convalescent centers
- 629 Dialysis treatment clinics/end-stage renal disease facilities
- 630 Hospices
- 631 Hospitals
- 632 Inpatient rehabilitation facilities

- 633 Long-term acute care hospitals
- 634 Long-term care facilities
- 635 Other hospitals (e.g., Psychiatric, Maternity, Speciality)
- 636 Outpatient clinics (community clinics; community clinics with emergency centers; rural health clinics;
- 637 outpatient rehabilitation facilities; outpatient physical therapy, occupational therapy or speech pathology
- 638 services; and private physician offices)