COLORADO
Department of Public Health & Environment

To:	Members of the State Board of Health
From:	Rachel Herlihy, MD, MPH, Communicable Disease Branch Chief & State Epidemiologist ***RH***
Through:	Scott Bookman, Director, Division of Disease Control and Public Health Response (DCPHR) ***SB***
Date:	August 18, 2021
Subject:	Rulemaking Hearing concerning Proposed Amendments to 6 CCR 1009-1, Epidemic and Communicable Disease Control

Please find copies of the following documents: Statement of Basis and Purpose and Specific Statutory Authority, Regulatory Analysis, Stakeholder Engagement, and Proposed Amendments to 6 CCR 1009-1, Epidemic and Communicable Disease Control.

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

The proposed amendments:

- Address changes to reporting related to the ongoing COVID-19 pandemic. In particular, the proposed amendments add SARS-CoV-2 / COVID-19 as a reportable condition separate from severe or novel Coronavirus; rename "severe or novel coronavirus" to "Coronavirus - severe or novel"; add a footnote to clarify that all SARS-CoV-2 results for all test types are reportable, including positive, negative, and inconclusive test results, SARS-CoV-2 sequencing lineage, and mutation profile results; and add Multisystem Inflammatory Syndrome in Children (MIS-C) in people aged < 21 years as a reportable condition.
- Remove conditions from the list of reportable conditions, or modify the reporting time period in that list, as appropriate. Here the proposed amendments remove the reporting requirement for any Gram-negative bacteria resistant to colistin, and also lengthen the reporting time frame for *Mycobacterium*, nontuberculous (NTM) from 4 to 30 days.
- Bring clarity to end users of the rule. Here the proposed amendments clarify the organisms reportable per the reporting requirement for carbapenem-resistant *Acinetobacter baumannii* (CRAB), clarify the diagnostic criteria used to report hepatitis A to be consistent with the national case definition, and clarify that reporting is specific to electronic laboratory reporting (ELR) of positive interferon-gamma release assay (IGRA) reports for tuberculosis immune reactivity.
- Add phone number, email address, and preferred language to the list of information that must be reported with each case of any reportable disease or condition, and clarify that physical address is what should be reported.
- Amend Regulation 4 to shorten the reporting time frame from 7 calendar days to 4 calendar days when a healthcare worker, correctional facility worker, or detention facility worker has a positive tuberculin skin test (TST) result (defined as = or > 5 mm induration) or positive tuberculosis IGRA result if the worker has had prolonged or frequent face-to-face contact with an infectious tuberculosis case.
- Amend Regulation 5 to clarify that public health can review negative or inconclusive test results as part of the case investigation process and to add language that clarifies the types of information that must be made available to public health during an investigation.
- Amend Regulation 8 to require 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 a coronavirus that is novel or could cause severe human disease, including SARS-CoV-2, must report the facts to the Department or county, district, or municipal public health agency.

Finally, the Department has proposed changes that are technical in nature and are intended to clarify existing rule language and provide better alignment with statute without significant policy change.

In total, the proposed amendments are necessary to address challenges encountered during the ongoing COVID-19 pandemic, continue to bring clarity to the rule, and minimize potential confusion among end-users of the rule. The Department has contacted a wide variety of stakeholders to solicit input on these proposed amendments; any factual or policy issues are discussed below in the Stakeholder Engagement section.

Changes to the rule language appear in ALL CAPS or strikethrough, and are highlighted when added since the request for rulemaking hearing.

Statement of Basis and Purpose and Specific Statutory Authority

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

Basis and Purpose.

The Epidemic and Communicable Disease Control rule names the communicable diseases that are reportable to the Department and 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, including those issues related to COVID-19; and align this rule with current practice, including advances in surveillance techniques, prevention, diagnosis, and treatment of communicable diseases.

The proposed amendments:

- Address changes to reporting related to the ongoing COVID-19 pandemic. In particular, the proposed amendments:
  - Make SARS-CoV-2 / COVID-19 an individually reportable condition, separate and distinct from other severe or novel coronaviruses. This addition will keep other severe or novel coronavirus immediately reportable while making SARS-CoV-2 / COVID-19 positive, negative, and inconclusive results reportable within 1 working day. It is no longer necessary for a laboratory or other disease reporter to immediately report a case of COVID-19, but the Department does want any case of Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS), or other severe or novel coronavirus to be reported immediately so that necessary case investigation and disease control measures can promptly occur. We propose to list COVID-19 on the table twice (similar to what is done for hepatitis C): one line to indicate that positive results of any test type along with sequencing and lineage information are reportable, and one line to indicate that negative and inconclusive results of any test type are reportable. We believe that this listing over two lines will make these reporting expectations more clear for the end users of this rule.
  - Rename severe or novel coronavirus to "Coronavirus - severe or novel". This renaming of severe or novel coronavirus is needed to distinguish between SARS-CoV-2 / COVID-19 and other severe or novel coronaviruses as well as list the condition in an alphabetical way in the Appendix A table that is more understandable to end users of this rule; the reporting time frame for SARS-CoV-2 / COVID-19 will be one working day, while other severe or novel coronaviruses will keep the current requirement of immediately reportable.
  - Add a footnote that clarifies that all SARS-CoV-2 results for all test types are reportable, including: positive, negative, and inconclusive test results, SARS-CoV-2 sequencing lineage, and mutation profile results. This footnote language further aligns reporting requirements in Colorado with guidelines established by the U.S. Department of Health and Human Services. Each of these results are reportable to public health within one working day of the result; sequencing lineage and mutation profile results may not be available for days or weeks after a positive SARS-CoV-2 result. Results are to be reported through electronic laboratory reporting, or other electronic submission approved by CDPHE. These results allow for the department to better describe the SARS-CoV-2 pandemic and the impacts for state and local mitigation guidance in relation, but not limited to:
    - Percent positivity (the percentage of all COVID-19 tests that are run that are positive, which is an important indicator of the transmission levels of COVID-19 in a given community and in the state; during the pandemic, the goal is to remain under 5% positivity);
    - Variant mutation patterns (important information used to detect which variants -- including possible new variants -- may be circulating which could impact levels of disease in a community and in the state depending on the variant's transmissibility and protection conferred by vaccines); and
    - Currently circulating variants based on sequencing lineage data (as we learn more about the different variants of SARS-CoV-2 and how variants affect transmission and vaccine efficacy, it will be important to have timely sequencing data from clinical laboratories that are able to conduct this work).
  - Add Multisystem Inflammatory Syndrome in Children (MIS-C) as a reportable condition; this condition will be reportable in people under the age of 21 years, per the current Centers for Disease Control and Prevention (CDC) MIS-C case definition (https://www.cdc.gov/mis-c/hcp/). MIS-C is a serious condition where different body parts can become inflamed, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal

organs. The cause of MIS-C is unknown; however, many children with MIS-C have tested positive for SARS-CoV-2 or have been around someone with COVID-19. Adding this condition to the reportable list allows public health to conduct surveillance for this new rare condition in order to learn more about risk factors, who is affected, how often it occurs, and how it might relate to different strains of SARS-CoV-2 that are circulating. CDC has asked states to collect information on reported MIS-C cases and share that information with CDC. As of July 16, 2021, CDPHE has learned of 100 confirmed MIS-C cases since the beginning of the pandemic.

- Remove conditions from the list of reportable conditions, or modify the reporting time period in that list, as appropriate.
  - The Department proposes removing the reporting requirement for any Gram-negative bacteria resistant to colistin or a minimum inhibitory concentration (MIC) of ≥4 mcg/ml to align requirements in this rule with the CDC reporting priorities.
  - The Department proposes the time period for reporting Mycobacterium, nontuberculous (NTM) be changed from 4 days to 30 days. The purpose of NTM surveillance is to understand the burden and epidemiology of NTM. Most NTM infections are acquired from the environment (e.g., soil and water), cause indolent infections, and are not transmitted from person-to-person. Therefore, there is no immediate public health response for the majority of cases. NTM can rarely cause outbreaks related to contaminated medical equipment or procedures, such as pedicures associated with contaminated water that would be immediately reportable as an outbreak and trigger a public health response.
- Bring clarity to end users of the rule.
  - The Department proposes to clarify the organisms reportable per the reporting requirement for carbapenem-resistant *Acinetobacter baumannii* (CRAB) by specifying A. baumannii complex includes A. baumannii, A. calcoaceticus, A. pittii, A. nosocommialis, or any combination of these species or with the word 'complex' added afterwards. This clarification is necessary to capture species within the Acinetobacter baumanii complex which may not be readily recognized as such by reporting laboratories. This will help prevent underreporting of this pathogen.
  - The Department proposes to clarify the diagnostic criteria used to report hepatitis A to be consistent with the national case definition by adding positive Nucleic Acid Amplification Tests (NAAT) and Polymerase Chain Reaction (PCR) positive results in addition to the current requirement of Immunoglobulin M (IgM) positive results. These testing methods are validated and may become more widely used in commercial laboratories. Adding these test results will lead to more complete reporting of the condition.
  - The Department proposes to clarify that reporting is specific to electronic laboratory reporting (ELR) of positive interferon-gamma release assay (IGRA) for tuberculosis immune reactivity. This is a technical change to clarify that only laboratory positive IGRAs are reportable by ELR and not all latent tuberculosis infections (LTBI) as implied by the current version of Appendix A.
- The Department proposes that phone number, email address, and preferred language be added to the list of information that must be reported with each case of any reportable condition. These proposed changes are noted throughout the rule. The Department is proposing collection of this additional information to aid in follow-up case investigation. The Department's response to COVID-19 illustrated the need to have accurate phone numbers and email addresses so we can promptly reach cases and share information. Already required to be reported with each case is patient's name, date of birth, sex, race, ethnicity, and address (including city and county). We believe that adding preferred language will expedite public health follow-up processes as public health staff will be aware of possible needs for interpretation and translation services. This will also help public health staff prepare for a more culturally appropriate follow-up process and contribute to health equity efforts.
- The Department proposes to update language in Regulation 4 to shorten the reporting time frame from 7 calendar days to 4 calendar days when a healthcare worker, correctional facility worker, or detention facility worker has a positive tuberculin skin test (TST) result (defined as = or > 5 mm in duration) or positive tuberculosis interferon gamma release assay (IGRA) result if the worker has had prolonged or frequent face-to-face contact with an infectious tuberculosis case. This change is to align reporting time requirements that changed 7-day reportables to 4-day reportables several years ago.
- The Department proposes to update language in Regulation 5 to clarify the types of information and records that should be made available to public health during an investigation (paragraph H). Through the process of investigating thousands of COVID-19 outbreaks, as well as historically in non-COVID outbreaks, public health has come across barriers in accessing information and records needed from a variety of settings in a timely manner in order to implement prompt disease control measures. Clarifying the language around which information and records public health may need during an investigation in the regulation will provide clarity to public and private

entities involved in the investigation as well as provide clarity to local public health agencies on the type of records and information they can request. We propose adding the following information to paragraph H: listing examples of types of records public health may need access to, including but not limited to current and former employee/student rosters and contact information, schedules (such as work or school schedules), health and medical information, job duties and descriptions, and patron or client contact information. We also added supplies to the list of items within the place of employment that we may need to collect information about during the course of an investigation.

- The Department proposes to update language in Regulation 8 to require 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 a coronavirus that is novel or could cause severe human disease, including SARS-CoV-2, must report the facts to the Department or county, district, or municipal public health agency. This addition is to assure that coronaviruses of human health concern in the veterinary setting are reported to the public health so that control actions can be initiated when necessary.

Finally, the Department has proposed changes that are technical in nature and are intended to clarify existing rule language and provide better alignment with statute without significant policy change. Within this subset of changes, the Department proposes a renumbering of the footnotes. This proposal will allow for all footnotes to appear in order on the table in Appendix A. Additionally, the Department is proposing to rename the table in Appendix A to "Reportable Disease, Condition, and Related Event Table". The current table is named "Reportable Disease Table", and the proposed change captures the contents of the table more accurately, as diseases, conditions, and events/syndromes (such as acute flaccid myelitis and hemolytic uremic syndrome) are included in the table. These changes are intended to bring clarity to the rule and reduce confusion among end users of the rule.

Specific Statutory Authority.
Statutes that require or authorize rulemaking:
Sections 25-1-108(1)(c), 25-1.5-102, 25-1-122, and 25-4-511(1), C.R.S.

Is this rulemaking due to a change in state statute?	
_____ Yes, the bill number is _____. Rules are _____ authorized _____ required.	
__X__ No	
Does this rulemaking include proposed rule language that incorporates materials by reference?	
_____ Yes	Url:
__X__ No	
Does this rulemaking include proposed rule language to create or modify fines or fees?	
_____ Yes	
__X__ No	
Does this proposed rule language create (or increase) a state mandate on local government?	
__X__ 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.	

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

Regulatory Analysis

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

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

Group of persons/entities Affected by the Proposed Rule	Size of the Group	Relationship to the Proposed Rule
Infection control providers, clinical laboratory personnel, hospitals, healthcare providers and electronic lab senders from throughout the state as well as any out of state lab that conducts testing on Colorado residents.	1000	C/B
Professional organizations including the Colorado Medical Society and the Colorado Hospital Association and the general public.	?	S
Local public health agencies (LPHAs), the Department, entities required to report, and the general public will benefit from the proposed changes to the rule that clarify the reporting requirements and/or update the reporting requirements to match the latest diagnostic technology or current practice standards making timelier, more complete, and actionable data available.	>100	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, please use this relationship categorization key:

C = individuals/entities that implement or apply the rule.

S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.

B = the individuals that 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:

The proposed changes include additions to the list of reportable conditions necessitated by changes in conditions of public health concern. These changes will require some additional laboratory or healthcare provider staff time to report. Local public health agencies (LPHAs), schools, and government-run health care facilities do have a duty to report conditions listed in Appendix A; however, the bulk of reporting occurs by non-governmental clinical laboratories. For the laboratories for which the burden of submission will increase, CDPHE staff will work with them to minimize the burden when possible. It is not anticipated that the proposed changes will increase local public health costs and improved reporting may increase timely investigation. However, state and local investigation costs will continue to be incurred.

Please describe any anticipated financial costs or benefits to these individuals/entities.

C = As described above, laboratories and healthcare providers that do not report electronically will experience increased workloads, resulting in increased personnel costs. However, with approximately 90% of reportable test results being received electronically, this increased cost will only be experienced by a small subset of healthcare providers and laboratories. Additionally, laboratories and healthcare providers that report electronically could experience minor costs associated with the one-time programming change to add or modify reportable conditions.

S = None.

B = Reduced risk of infection.

Non-economic outcomes

Summarize the anticipated favorable and non-favorable 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:

C = Healthcare providers, laboratories, and hospital infection preventionists are the primary reporters of conditions included in the Reportable Disease Table in Appendix A. 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; all of which the Department expects will result in improved customer experience.

B = Laboratories will have minimal additional reporting and submission requirements based on the current version of the regulation. Laboratories and the healthcare facilities they serve will receive the results of testing performed by the state laboratory on 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.

Unfavorable non-economic outcomes:

C = The addition of reportable conditions and laboratory submission requirements increases the reporting burden on laboratories and providers. To minimize the burden, the Department favors electronic reporting whenever possible. At this time, all large commercial and hospital laboratories report electronically or are in the process of on-boarding. Approximately 90% of reportable test results are received electronically. 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 (current elements included in the regulation are patient's name, date of birth, sex, race, address, ethnicity, name and address of responsible health care provider, name of disease or condition, and laboratory information; new proposed elements are phone number, email address, and preferred language). 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 to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

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

   The costs to the agency for managing the proposed additional COVID-19 reports will be covered by federal cooperative agreement and grant funding (mostly funding from the Centers for Disease Control and Prevention -- Emerging Infections Program [EIP] funding and Epidemiology and Laboratory Capacity [ELC] funding, which are funding sources that CDPHE has been receiving for over 20 years). CDPHE has received EIP and ELC funding to support receiving COVID-19 case reports through at least July 2023, and we anticipate that after that time we will be able to absorb COVID-19 reporting into our typical federal funding sources. Any other costs to the Department will be minimal and can be absorbed. There is no anticipated effect on state revenues.

   Anticipated CDPHE Revenues: N/A

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

   Anticipated Revenues for another state agency: N/A

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

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

_X_	Comply with a statutory mandate to promulgate rules.
_X_	Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
_X_	Maintain alignment with other states or national standards.
___	Implement a Regulatory Efficiency Review (rule review) result
_X_	Improve public and environmental health practice.

_X_ Implement stakeholder feedback.
Advance the following CDPHE Strategic Plan priorities (select all that apply):
1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO2e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO2e per year by June 30, 2020 and to 113.144 million metric tons of CO2e by June 30, 2023. ___ Contributes to the blueprint for pollution reduction ___ Reduces carbon dioxide from transportation ___ Reduces methane emissions from oil and gas industry ___ Reduces carbon dioxide emissions from electricity sector
2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023. ___ Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the oil and gas industry. ___ Supports local agencies and COGCC in oil and gas regulations. ___ Reduces VOC and NOx emissions from non-oil and gas contributors
3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023. ___ Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes. ___ Increases physical activity by promoting local and state policies to improve active transportation and access to recreation. ___ Increases the reach of the National Diabetes Prevention Program and Diabetes Self-Management Education and Support by collaborating with the Department of Health Care Policy and Financing.
4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by June 30, 2023. ___ Ensures access to breastfeeding-friendly environments.
5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023. ___ Performs targeted programming to increase immunization rates. ___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).
6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023. ___ Creates a roadmap to address suicide in Colorado. ___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate. ___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries. ___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.
7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020. ___ Conducts a gap assessment. ___ Updates existing plans to address identified gaps. ___ Develops and conducts various exercises to close gaps.
8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023. ___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident. ___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment. ___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or

incident response plan.
9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023. ___ Implements the CDPHE Digital Transformation Plan. ___ Optimizes processes prior to digitizing them. ___ Improves data dissemination and interoperability methods and timeliness.
10. Reduce CDPHE's Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023. ___ Reduces emissions from employee commuting ___ Reduces emissions from CDPHE operations
11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023. ___ Used a budget equity assessment
_X_ Advance CDPHE Division-level strategic priorities

The updated draft version of the Disease Control and Public Health Response strategic plan contains goals, activities, and metrics around tracking and investigating COVID-19. For example, there are activities around detecting and investigating COVID-19 outbreaks through surveillance data, and analyzing surveillance data to track deaths, hospital admissions, and case interview success rates.

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include: N/A

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

   Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. The specific revisions proposed in this rulemaking were developed in conjunction with stakeholders. Reporting cases of communicable disease is important in the planning and evaluation of disease prevention and control programs, in the assurance of appropriate medical therapy, and in the detection of outbreaks.[1] The 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. As previously described, the Department favors less burdensome 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 statute refers to rulemaking and this rule utilizes the widely accepted and proven public health methodology of epidemiologic surveillance and laboratory investigation.

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

   The following data and references informed the Department's proposed rulemaking:

- New CDC performance measures around COVID-19 and MIS-C surveillance, case investigation and contact tracing, and tracking emerging strains via lineage and genomic sequencing analysis. These activities will also help Colorado track the incidence of COVID-19 over time, monitor population groups most affected, monitor vaccine effectiveness, and inform future mitigation actions.
- The Council for State and Territorial Epidemiologists (CSTE) interim position statement on COVID-19 and MIS-C.
- CDC guidance on carbapenem-resistant Acinetobacter species for which to conduct surveillance.
- CDC guidance on deprioritizing reporting and surveillance activities for gram-negative bacteria resistant to colistin
- The CSTE position statement and case definition for hepatitis A.

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

Stakeholder Engagement

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

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

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

Colorado healthcare providers, Colorado hospital infection preventionists and lab directors (including microbiology lab contacts), Local Public Health Agencies (LPHAs) (directors and communicable disease contacts), Colorado Regional Epidemiologists, Association for Professionals in Infection Control (APIC), Colorado reference lab contacts, Colorado Medical Society, the Department's Office of Emergency Preparedness and Response, the Department's Health Facilities and Emergency Medical Services Division, Colorado Department of Agriculture State Veterinarian's Office, Colorado Veterinary Medical Association, Colorado State University Veterinary Diagnostic Lab, Colorado Parks and Wildlife Veterinary Staff, as well as representatives for coroners and Emergency Medical Services.

Targeted outreach conducted:

- Emails sent to the above contacts on May 5, May 6, May 11, July 2 and July 5, 2021.
- Discussion on statewide LPHA calls on April 29 and May 6, 2021.
- Discussion on regional epidemiologist call on May 5, 2021.

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

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

__X__ Yes. This is selected for the rulemaking to document that timely division notification occurred.

Since the request, the Department has received comments regarding the addition of reporting phone number, email address and preferred language for each reportable disease/condition. While support for the idea has been expressed, at least one comment has pointed out that these additional data elements create an increased burden on disease reporters. Disease reporters may need to undertake programming changes to create data fields to capture these new data elements, at a cost. Additionally, the collection of identifying data points may not always take place by the disease reporters and it may be outside of their ability to request the new data elements. The Department understands that it may take a period of time for disease reporters to come into full compliance with these new requirements and is committed to working with disease reporters to ensure that all reasonable steps, within the disease reporters control, are being taken to collect the new data elements, without creating an undue burden.

The Department remains committed to continued communication with stakeholders throughout the rulemaking period and during implementation of these proposed amendments.

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

Overall, after considering the benefits, risks and costs, the proposed rule (Select all that apply.):

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.		Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.

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

Department of Public Health and Environment

Disease Control and Environmental Epidemiology Division
Epidemic and Communicable Disease Control
6 CCR 1009-1

Regulation 1. Reportable Diseases, CONDITIONS, AND RELATED EVENTS

For the purpose of these regulations, the diseases, CONDITIONS, AND RELATED EVENTS named in the Reportable Diseases, CONDITION, AND RELATED EVENT Table (Appendix A) are declared to be potentially dangerous to public health and shall be reportable in accordance with these regulations. In addition, any language specifying "(the) Department" refers to the Colorado Department of Public Health and Environment.

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

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

Manner of Reporting

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

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

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

The Department shall develop systems and forms for reporting for physicians, other 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.

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

All specimens shall be accompanied by the following information: (a) Patient's name, date of birth, sex, race, ethnicity, PHONE NUMBER, PHYSICAL address (INCLUDING CITY AND COUNTY), EMAIL ADDRESS, AND PREFERRED LANGUAGE (b) Name and address of responsible physician or other health care provider (c) Name of disease or condition (d) Laboratory information - test name, collection date and specimen type. Laboratories should make an effort to report all test results electronically, whenever possible.

Regulation 4. Treatment and Control of Tuberculosis

The emergence of multiple drug-resistant tuberculosis in this country and state dictates a coherent and consistent strategy in order to protect the public health from this grave threat. The underlying principles of disease control expressed in the following rules are as follows: use of the most rapid and modern diagnostic methods by laboratories, rapid reporting, full patient compliance with medical treatment, and prevention of spread of tuberculosis in 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 1 working day by physicians, healthcare providers, hospitals, other similar private or public institutions, or any other person providing treatment to the confirmed or suspected case. The reports shall include the following information: the patient's name, date of birth, sex, race, ethnicity, PHONE NUMBER, PHYSICAL address (including city and county), EMAIL ADDRESS, PREFERRED LANGUAGE, name and address of the reporting physician or agency; and such other information as is needed to locate the patient for follow-up. If reported by a physician, the physician shall also give the evidence upon which the diagnosis of tuberculosis was made, the part of the body affected, and the stage of disease.

B. Physicians, healthcare providers, and healthcare facilities shall report within 4 ~~7~~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 1 working day any result diagnostic of or highly correlated with active tuberculosis disease, including culture positive and nucleic acid amplification tests (NAAT) positives for Mycobacterium tuberculosis and sputum smears positive for acid fast bacilli, and shall report the results of tests for antimicrobial susceptibility performed on positive cultures for tuberculosis.

D. Results must be reported by the laboratory which performs the test, but an in-state laboratory which sends specimens to an out-of-state referral laboratory is also responsible for reporting the results.

E. When a laboratory performs a culture that is positive for Mycobacterium tuberculosis, the laboratory shall submit a sample of the isolate to the Department, 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 tuberculosis (MDR-TB), it is necessary, appropriate and good medical practice for persons with active tuberculosis disease to receive directly observed therapy (DOT) 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 Denver Public Health. DOT is not required for patients with extrapulmonary tuberculosis disease provided that the presence of pulmonary tuberculosis has been investigated and excluded. In applicable situations, a variance shall be granted in accordance with § 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 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 jails, prisons, and other incarceration facilities and hospitals and healthcare facilities providing inpatient treatment to persons with active tuberculosis disease shall notify the Department or county, district, or municipal public health agency of their intent to discharge a patient and involve the Department or county, district, or municipal public health agency in the discharge planning process prior to discharging the patient from the facility. 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 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 TB 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 TB disease. 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 compatible with tuberculosis in the infectious stages, the 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 reportable conditions and shall be considered official duties of the 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 him/her non-infectious or a person exposed to a case has received prophylaxis, if appropriate. Such review of records may occur without patient consent and shall be conducted at reasonable times and with such notice as is reasonable under the circumstances. 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; and

K. Review of previously conducted environmental or product sampling data that may be related to the cause of the outbreak or reportable disease.

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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, 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:

(1) The animal to be exempted has a medical condition defined as "a disease, illness, or other pathological state" for which, in the opinion of the exempting veterinarian, a rabies inoculation is contraindicated;

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

(3) The veterinarian completes and signs the veterinary section of the Exemption from Rabies Vaccination form provided by the Department;

(4) The animal owner signs the informed consent section of the Exemption from Rabies Vaccination form;

(5) The veterinarian maintains the signed exemption as part of the animal's medical record and provides a copy to the owner;

(6) The exemption issued is limited to the anticipated duration of the animal's medical condition that precludes inoculation; and

(7) The veterinarian provides a copy of the exemption form to the Department or county, district, or municipal public health agency 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 his/her designee(s) may review Exemption from Rabies Vaccination forms and examine the veterinary records pertaining to the medical condition to determine if the medical condition legitimately contraindicates rabies inoculation. If appropriate, the executive director or his/her designee(s) may refer the case to the Board of Veterinary Medicine.

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226 Appendix A. Reportable Diseases, CONDITION, AND RELATED EVENT Table

Disease/Event	Pathogen/Organism	Time*	Reporter[1]	Specimen Source(s)[2]	Send Clinical Material[3]
Acinetobacter baumannii, carbapenem-resistant (CRAB)[4]	Carbapenem-resistant *Acinetobacter baumannii* (including *Acinetobacter baumannii* complex and, *Acinetobacter baumannii-calcoaceticus complex, ACINETOBACTER. PITTII, ACINETOBACTER. NOSOCOMIALIS, OR ANY COMBINATION OF THESE SPECIES OR WITH THE WORD 'COMPLEX' ADDED AFTERWARDS)*	4 days	L	All	Required
Acute flaccid myelitis		4 days	P		Upon request
Animal bites by dogs, cats, bats, skunks, foxes, raccoons, coyotes, or other wild carnivores [5,7]5,6		24 hrs	P		Not applicable
Animal bites by mammals not listed above[65]		4 hrs	P		Not applicable
Anthrax[65]	*Bacillus anthracis*	Immed	L & P	All	Required
Arboviral Disease	Eastern equine encephalitis, Japanese encephalitis, LaCrosse encephalitis virus, California encephalitis serogroup, Powassan virus, St. Louis encephalitis virus and Western equine encephalitis virus	4 days	L	All	Upon request
Botulism[65]	*Clostridium botulinum*	Immed	L & P	All	Upon request
Brucellosis[6]	*Brucella* species	4 days	L & P	All	Required
Campylobacteriosis	*Campylobacter* species	4 days	L & P	All	Upon request
Candida auris[47]	*Candida auris, Candida haemulonii*	Immed	L & P	All	Required
Candidemia[4-8- Metro]	*Candida* species	30 days	L	Blood	Upon request
Catheter-associated urinary tract infection (CAUTI)[9]	Any	Per CMS[9]	P	Urine	Not applicable
Chancroid	*Haemophilus ducreyi*	4 days	L & P	All	Upon request
Chikungunya	Chikungunya virus	4 days	L	All	Upon request
Chlamydia	*Chlamydia trachomatis*	4 days	L & P	All	Upon request
Cholera[65]	*Vibrio cholerae*	Immed	L & P	All	Required
CJD and other transmissible spongiform encephalopathies (TSEs)[65]		4 days	P	All	Upon request
Clostridium difficile infection[4-8- Metro]	*Clostridium difficile*	30 days	L	All	Upon request
Colorado tick fever	Colorado tick fever virus	4 days	L	All	Upon request
COVID-19[10]	• SARS-COV-2 (POSITIVE RESULT ON ANY TEST TYPE) • COVID-19 LINEAGE OR SEQUENCING	1 WORKING DAY	L & P	ALL	UPON REQUEST
COVID-19[10]	SARS-COV-2 (NEGATIVE OR INCONCLUSIVE RESULT ON ANY TEST TYPE)	1 WORKING DAY	L & P	ALL	UPON REQUEST
CORONAVIRUS – SEVERE OR NOVEL	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS (SARS-COV-2), MIDDLE EAST RESPIRATORY SYNDROME CORONAVIRUS, (MERS-COV) OR OTHER SEVERE OR NOVEL CORONAVIRUS	IMMED	L & P	ALL	UPON REQUEST
Cryptosporidiosis	*Cryptosporidium* species	4 days	L & P	All	Upon request
Cyclosporiasis	*Cyclospora* species	4 days	L & P	All	Upon request

Dengue	Dengue virus	4 days	L	All	Upon request
Diphtheria[65]	*Corynebacterium diphtheriae*	Immed	L & P	All	Required
Encephalitis[65]		4 days	P	All	Upon request
Enterobacteriaceae, carbapenem-resistant (CRE)[11]	Carbapenem-resistant *Escherichia coli*, *Klebsiella* species, *Enterobacter* species *Citrobacter* species, *Serratia* species, *Raoultella* species, *Providencia* species, *Proteus* species, *Morganella* species, and any carbapenemase-producing Enterobacteriaceae of any genus and species	4 days	L	All	Required
Enterobacteriaceae, extended- spectrum beta-lactamase (ESBL)~~[4-8-Boulder, 12]~~	*Escherichia coli* and *Klebsiella* species	4 days	L	All	Upon request
Escherichia coli O157:H7 and Shiga toxin-producing Escherichia coli[13]	Shiga toxin-producing *Escherichia coli*[13]	4 days	L & P	All	Required
Giardiasis	*Giardia lamblia*	4 days	L & P	All	Upon request
Gonorrhea, any site	*Neisseria gonorrhoeae*	4 days	L & P	All	Upon request
~~Gram negative bacteria resistant to colistin###~~	~~Gram negative bacteria (excludes *Proteus, Providencia, Morganella, Serratia, Burkholderia, Neisseria, Chromobacterium, Edwardsiella, and Brucella)*~~	~~4 days~~	~~L~~	~~All~~	~~Required~~
Group A streptococci[14,~~4-8- Metro~~]	*Streptococcus pyogenes*	4 days	L	Sterile only	Required
Group B streptococci[~~4-8- Metro~~]	*Streptococcus agalactiae*	30 days	L	Sterile only	Required
Haemophilus influenzae	*Haemophilus influenzae*	1 working day	L & P	Sterile only	Required
Hantavirus disease[65]	Hantavirus	4 days	L & P	All	Upon request
Healthcare-associated infections[165]		4 days	P		Not applicable
Hemolytic uremic syndrome if <18 years[65]		4 days	P		Upon request
Hepatitis A[65]	Hepatitis A virus (+IgM anti-HAV, +PCR or +NAAT),	1 working day	L & P	All	Upon request
Hepatitis B	Hepatitis B virus (+HBsAg, +IgM anti- HBc, +HBeAg, or +HBV DNA)	4 days	L & P	All	Upon request
Hepatitis C[#16]	Hepatitis C virus (+ serum antibody titer and/or + confirmatory assays)	4 days	L & P	All	Upon request
Hepatitis C[#16]	Hepatitis C virus (- confirmatory assays)	4 days	L	All	Upon request
Hepatitis, other viral		4 days	P		Upon request
Human immunodeficiency virus (HIV)/ acquired immunodeficiency syndrome (AIDS)	• Human immunodeficiency virus • CD4 counts (any value) • HIV viral load (any value) • HIV GENOTYPE	4 days	• L & P • L & P • L & P • L	All	Upon request
Influenza-associated death if <18 years		4 days	P		Upon request
Influenza-associated hospitalization	Influenza Virus	4 days	L & P	All	Upon request
Legionellosis	*Legionella* species	4 days	L & P	All	Upon request
Leprosy (Hansen's Disease)		4 days	P		Upon request
Listeriosis	*Listeria monocytogenes*	4 days	L & P	All	Required
Lyme disease	*Borrelia burgdorferi*	4 days	L & P	All	Upon request

Lymphogranuloma venereum (LGV)	*Chlamydia trachomatis*	4 days	L & P	All	Upon request
Malaria [65]	*Plasmodium* species	4 days	L & P	All	Upon request
Measles (rubeola)[65]	Measles virus	Immed	L & P	All	Upon request
Meningococcal Disease[65]	*Neisseria meningitidis* or gram-negative *diplococci*	Immed	L & P	Sterile only	Required
Methicillin-Resistant *Staphylococcus aureus* (MRSA) bacteremia[9]	Methicillin-Resistant *Staphylococcus aureus* (MRSA)	Per CMS[9]	P	Blood	Not applicable
MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (MIS-C) IF <21 YEARS		4 DAYS	P		UPON REQUEST
Mumps[65]	Mumps virus (acute infection)	4 days	L & P	All	Upon request
Mycobacterium, nontuberculous (NTM)[4-8-Metro]	*Mycobacterium* species (except *tuberculosis* complex and *leprae*)	30 4 days	L	All	Upon request
Outbreaks - known or suspected of all types - including those transmitted from food, water, person-to-person, and related to a healthcare setting[65]		Immed	L & P		Upon request
Pertussis (whooping cough)[65]	*Bordatella pertussis*	1 working day	L & P	All	Upon request
Plague[65]	*Yersinia pestis*	Immed	L & P	All	Required
Poliomyelitis[65]	Poliovirus	Immed	L & P	All	Upon request
Pseudomonas, carbapenem- resistant[17]	*Pseudomonas aeruginosa*	4 days	L	All	Upon request
Psittacosis	*Chlamydia psittaci*	4 days	L & P	All	Upon request
Q fever[65]	*Coxiella burnetii*	4 days	L & P	All	Upon request
Rabies: human (suspected)[65]	Rabies virus (Lyssavirus)	Immed	L & P	All	Upon request
Respiratory Syncytial Virus-associated hospitalizations[4-8- Metro]	Respiratory SYNCYTIAL ~~Synctial~~ Virus	4 DAYS	L & P	All	Upon request
Rickettsiosis	*Rickettsia* species, including Rocky Mtn spotted fever and typhus groups	4 days	L & P	All	Upon request
Rubella (acute infection)[65]	Rubella virus	1 working day	L & P	All	Upon request
Rubella (congenital)[65]	Rubella virus	4 days	L & P	All	Upon request
Salmonellosis	*Salmonella* species	4 days	L & P	All	Required
~~Severe or novel coronavirus~~	~~Severe acute respiratory syndrome coronavirus (SARS CoV), Middle East respiratory syndrome coronavirus (MERS-CoV)~~	~~Immed~~	~~L&P~~	~~All~~	~~Upon request~~
Shigellosis	*Shigella* species	4 days	L & P	All	Required
Smallpox[65]	Variola virus (Orthopox virus)	Immed	L & P	All	Upon request
Staphylococcus aureus, Vancomycin-non-susceptible[## 18]	Vancomycin non-susceptible *Staphylococcus aureus*	4 days	L	All	Required
Streptococcal toxic shock syndrome[19]	*Streptococcus pyogenes*	4 days	P	All	Required[16]
Streptococcus pneumoniae[19]	*Streptococcus pneumoniae*	4 days	L	Sterile only	Required[15]
Syphilis[65]	*Treponema pallidum*	1 working day	L & P	All	Upon request
Tetanus[65]	*Clostridium tetani*	4 days	P	All	Upon request

Tick-borne relapsing fever[65]	*Borrelia* species	4 days	L & P	All	Upon request
Toxic shock syndrome (non-streptococcal)		4 days	P		Upon request
Trichinosis[65]	*Trichinella* species	4 days	P	All	Upon request
Tuberculosis disease (active)[65]	*Mycobacterium tuberculosis*[11,20]	1 working day	L & P	All	Required
~~Tuberculosis infection (LTBI)~~ TUBERCULOSIS IMMUNE REACTIVITY INDICATED BY A POSITIVE INTERFERON GAMMA RELEASE ASSAY TEST (IGRA)	*Mycobacterium ~~T~~tuberculosis*[11,21]	4 days	L	All	Not Required
Tularemia[65]	*Francisella tularensis*	1 working day	L & P	All	Required
Typhoid fever[65]	*Salmonella* Typhi	1 working day	L & P	All	Required
Varicella (chicken pox)[65]	Varicella virus	4 days	L & P	All	Upon request
Vibriosis	*Vibrio* species, non-cholera	4 days	L	All	Required
Viral hemorrhagic fever	Crimean-Congo hemorrhagic virus, Ebola virus, Lassa fever virus, Lujo virus, Marburg virus, Guanarito virus,Junin virus, Machupo virus, Sabia virus	Immed	L & P	All	Required
West Nile virus (acute infection, ~~IgM+~~)	West Nile virus	4 days	L	All	Upon request
Yellow fever	Yellow fever virus	4 days	L	All	Upon request
Yersiniosis[4,8-Seven]	*Yersinia* non-*pestis* 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, race, ethnicity, PHONE NUMBER, PHYSICAL address (including city and county), EMAIL ADDRESS, PREFERRED LANGUAGE and name and address of responsible physician or other healthcare provider; and such other information as is needed in order to locate the patient for follow up. In addition, all laboratory information reported shall include specimen accession number.

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

1 Reporter: The party responsible for reporting is indicated by one of the following: L = Laboratory (whether or not associated with a hospital; by out-of-state laboratories that maintain an office or collection facility in Colorado; and by in-state laboratories which send specimens to an out-of- state laboratory referral laboratory), P = 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 day care centers), L & P = Both.

2 Specimen sources: A condition is reportable when the pathogen is isolated or detected from any specimen source unless where otherwise indicated. A normally "sterile site" is defined as blood, cerebrospinal fluid (CSF), pleural fluid (includes chest fluid, thoracentesis fluid), peritoneal fluid (includes abdominal fluid, ascites), pericardial fluid, bone (includes bone marrow), joint or synovial fluid, needle aspirate or culture of any specific joint, internal body sites (sterilely obtained from biopsy/tissue/abscess/ aspirate/fluid/swab from lymph node, brain, heart, liver, spleen, vitreous fluid, kidney, pancreas, vascular tissue, or ovary). Skin and skin abscesses are not considered sterile sites.

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

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

~~4 Condition reportable only among residents of a specific catchment area.~~

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

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

~~4-Boulder Condition only reportable among residents of Boulder County~~

4 ~~5~~ *Acinetobacter baumannii* (including *Acinetobacter baumannii* complex, and *Acinetobacter baumannii-calcoaceticus* complex, ACINETOBACTER PITTII, ACINETOBACTER NOSOCOMIALIS, OR ANY COMBINATION OF THESE SPECIES OR WITH THE WORD 'COMPLEX' ADDED AFTERWARDS) that are resistant to at least one carbapenem (including imipenem, meropenem, or doripenem)

5 ~~6~~ 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 ~~7~~ For animal bites by dogs, cats, bats, skunks, foxes, raccoons, coyotes, and other wild carnivores, the name and locating information of the owner of the biting animal shall be reported, if known, by the healthcare provider OR r~~R~~eporter.

7 ~~8~~ *Candida auris* identified, or any suspected Candida auris (e.g., *Candida haemulonii* identified by a laboratory instrument not equipped to detect *Candida auris*).

8 CONDITION REPORTABLE ONLY AMONG RESIDENTS OF A SPECIFIC CATCHMENT AREA.

8-METRO CONDITION REPORTABLE ONLY AMONG RESIDENTS OF DENVER METROPOLITAN AREA (ADAMS, ARAPAHOE, DENVER, DOUGLAS, AND JEFFERSON COUNTIES)

8-SEVEN CONDITION REPORTABLE ONLY AMONG RESIDENTS OF SEVEN-COUNTY DENVER METROPOLITAN AREA (ADAMS, ARAPAHOE, BOULDER, BROOMFIELD, DENVER, DOUGLAS, AND JEFFERSON COUNTIES)

8-BOULDER CONDITION ONLY REPORTABLE AMONG RESIDENTS OF BOULDER COUNTY

9 Reporting requirement is fulfilled through the Department's access to the National Healthcare Safety Network (NHSN) for those healthcare facilities that are required to report catheter- associated urinary tract infection (CAUTI) and/or methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia to the Centers for Medicare & Medicaid services (CMS). In these instances these healthcare facilities shall confer rights to the Department to access the NHSN data for these conditions.

10 ALL SARS-COV-2 RESULTS FOR ALL TEST TYPES ARE REPORTABLE. ANY INDIVIDUAL AS DEFINED IN REGULATION 2, ENTITY OR FACILITY THAT COLLECTS, PERFORMS, OR TESTS FOR SARS-COV-2 ON SPECIMENS IN COLORADO IS RESPONSIBLE FOR REPORTING ALL POSITIVE, NEGATIVE AND INCONCLUSIVE SARS-COV-2 TEST RESULTS AND SARS-COV-2 SEQUENCING LINEAGE AND MUTATION PROFILE RESULTS TO PUBLIC HEALTH WITHIN ONE WORKING DAY OF THE RESULT. ALL ENTITIES REQUIRED TO REPORT COVID-19 TEST RESULT INFORMATION SHALL REPORT THROUGH CDPHE'S ELECTRONIC LABORATORY REPORTING (ELR) PLATFORM. FOR ENTITIES THAT CANNOT REPORT THROUGH THE ELR PLATFORM, ELECTRONIC SUBMISSION OF THE INFORMATION REQUIRED SHALL OCCUR THROUGH HL7 OR CDPHE-APPROVED FLAT FILE FORMAT VIA SECURE FILE TRANSFER PROTOCOL (FTP), VIA THE CDPHE WEB-BASED REPORTING PORTAL, OR OTHER CDPHE-APPROVED METHOD.

11 *Escherichia coli*, *Klebsiella* species, *Enterobacter* species, *Citrobacter* species, *Serratia* species, and *Raoultella* species that are resistant to at least one carbapenem (including imipenem, meropenem, doripenem, or ertapenem); or *Providencia* species, *Proteus* species, *Morganella* species that are resistant to at least one carbapenem (including meropenem, doripenem, or ertapenem); but not including imipenem); or Enterobacteriaceae of any genus and species that test positive for production of carbapenemase (e.g., KPC,

NDM, VIM, IMP, OXA-48) demonstrated by a recognized test (e.g., modified carbapenem inactivation method [mCIM], polymerase chain reaction [PCR], nucleic acid amplification test [NAAT], metallo-beta-lactamase test, modified-hodge test [MHT], carba-NP).

12 *Escherichia coli* and *Klebsiella* species resistant to at least one extended-spectrum cephalosporin (ceftazidime, cefotaxime or ceftriaxone) or *Escherichia coli* and *Klebsiella* species that test positive for production of an extended-spectrum beta-lactamase (ESBL) demonstrated by a recognized test (e.g., broth microdilution, disk diffusion).

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

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

~~15 Clinical material shall be submitted from laboratories when the material is from residents of the 5-county metro area (Adams, Arapahoe, Denver, Douglas and Jefferson counties).~~

15 ~~16~~ Reportable only by facilities that are voluntarily participating in applied public health projects. Appendix B includes a definition of healthcare-associated infections, a list of included infections, and a list of included health facility types.

16 ALL ASSOCIATED RESULTS, INCLUDING NEGATIVE (NONREACTIVE) AND POSITIVE (REACTIVE) HCV CONFIRMATORY ASSAYS FROM PERSONS WHO HAVE BEEN DIAGNOSED WITH OR WHO HAVE LABORATORY EVIDENCE OF HCV INFECTION ARE REPORTABLE (E.G., ANTIGEN OR NUCLEIC ACID AMPLIFICATION FOR HCV RNA [INCLUDING QUALITATIVE, QUANTITATIVE OR GENOTYPE TESTING]).

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

~~18 Including (+) AFB sputum smear, culture (regardless of specimen site) and nucleic acid amplification tests (NAAT). See regulation 4 F.~~

18 *STAPHYLOCOCCUS AUREUS* THAT ARE NON-SUSCEPTIBLE TO VANCOMYCIN, WHICH INCLUDE ISOLATES WITH MINIMUM INHIBITORY CONCENTRATION (MIC) OF ≥4 MCG/ML.

19 CLINICAL MATERIAL SHALL BE SUBMITTED FROM LABORATORIES WHEN THE MATERIAL IS FROM RESIDENTS OF THE 5- COUNTY METRO AREA (ADAMS, ARAPAHOE, DENVER, DOUGLAS AND JEFFERSON COUNTIES).

20 INCLUDING (+) AFB SPUTUM SMEAR, CULTURE (REGARDLESS OF SPECIMEN SITE) AND NUCLEIC ACID AMPLIFICATION TESTS (NAAT). SEE REGULATION 4 F.

21 ALL POSITIVE INTERFERON GAMMA RELEASE ASSAYS (IGRAS) WILL BE REPORTED BY LABS CAPABLE OF ELECTRONIC LABORATORY REPORTING (ELR), AND ONLY REPORTED BY ELR.

~~19 All positive Interferon Gamma Release Assays (IGRAs) will be reported by lab.~~

~~# All associated results, including negative (nonreactive) and positive (reactive) HCV confirmatory assays from persons who have been diagnosed with or who have laboratory evidence of HCV infection are reportable (e.g., antigen or nucleic acid amplification for HCV RNA [including qualitative, quantitative or genotype testing]).~~

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

~~### Any Gram-negative bacteria (excludes *Proteus*, *Providencia*, *Morganella*, *Serratia*, *Burkholderia*, *Neisseria*, *Chromobacterium*, Edwardsiella, and *Brucella*) resistant to colistin or a minimum inhibitory concentration (MIC) of ≥4 mcg/ml.~~

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