COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

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Date: April 19, 2023

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

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

The proposed amendments:

- Add the following diseases/events to the list of reportable conditions in Appendix A: Blastomycosis, coccidioidomycosis, histoplasmosis, carbapenemase-producing organisms, invasive *E. coli* infections (Boulder County only), mpox (monkeypox), and RSV-associated hospitalizations (making it reportable statewide rather than the five-county Denver metropolitan area).
- Remove the following diseases/events from the list of reportable conditions in Appendix A: Catheter-associated urinary tract infections (CAUTI).
- Modify the following diseases/events on the list of reportable conditions in Appendix A: Carbapenem-resistant *Acinetobacter baumannii* (CRAB), *Candida auris*, chlamydia, COVID-19, Enterobacteriaceae, gonorrhea, *Mycobacterium* nontuberculosis, tick-borne relapsing fever, and syphilis.
- Bring clarity to end users of the rule by renumbering footnotes and aligning footnotes with proposed changes in Appendix A.
- Amend Regulation 1, 3, 4, and Appendix A to:
    - Clarify that sex assigned at birth is the data element that should be reported with each case, rather than sex.
    - Add sexual orientation and gender identity to the list of data elements that must be reported with each case.
    - Add pregnancy status to the list of data elements that must be reported with each case of syphilis and HIV.

    - Add the phone number of the responsible physician or other health care provider to the list of data elements that must be reported with each case.
- Amend Regulation 1 to:
    - Add data elements that must be reported for each hospitalized case report.
    - Clarify reporting requirements pertaining to health care-associated infections.
- Amend Regulation 2 to clarify that people in charge of institutes of higher education or their designee are considered disease reporters.
- Amend Regulation 4 to clarify that public and private laboratories must report all confirmed or suspected cases of active tuberculosis disease to the Department or county, district, or municipal public health agency within one working day.
- Amend Regulation 5 to add that public health investigations may be conducted in response to identified or potential reportable conditions, or to evaluate exposures to known causes of reportable conditions for the purposes of case identification and prevention.
- Amend Regulation 10 to update authorizing statute citation, add definitions for puncturing devices and reusable equipment, and clarify practices around infection prevention.
- Amend Regulation 11 to update the name of the Ryan White Comprehensive Acquired Immunodeficiency Syndrome (AIDS) Resources Emergency Act to Ryan White Comprehensive Human Immunodeficiency Virus (HIV) Resources Emergency Act, and add to operational standard D that all persons newly diagnosed with HIV will be assessed for linkage to care services.
- Amend Appendix B to add antimicrobial-resistant infections to the list of health care-associated infections (HAI), and add acute care hospitals, inpatient rehabilitation facilities, long-term acute care hospitals, and other hospitals to the list of health facility types.
- Incorporate gender neutral language throughout the regulation (i.e., removing his/her and him/her and replacing it with “person” or “their”).
- Make permanent the emergency rules put in place on February 15, 2023, which added COVID-19-associated hospitalizations to the list of reportable conditions. In response to the COVID-19 pandemic, public health order (PHO) 20-38 was issued on April 15, 2021. This order required all Colorado hospitals to report all hospitalized cases of COVID-19 to the Department. PHO 20-38 was rescinded on February 22, 2023. Emergency rulemaking was conducted on February 15, 2023 to update 6 CCR 1009-1 to include COVID-19-associated hospitalizations on the list of reportable conditions. Making this addition permanent in rule is necessary for the Department and local public health agencies to have the ability to continue to monitor the severity of COVID-19, hospitalization burden, overall trends, including trends in populations that have been disproportionately impacted by COVID-19, and conduct assessments of vaccine effectiveness.

Finally, the Department has proposed changes that are technical in nature and 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 COVID-19 pandemic, prepare for future potential surges of other pathogens, continue to bring clarity to the rule, and minimize potential confusion among end-users of the rule. The Department contacted a wide variety of stakeholders to solicit input on these proposed amendments. To date, no major factual or policy issues have been encountered.

Changes to rule language are highlighted, in ALL CAPS, or strikethrough where appropriate.

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 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, 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:

- Add the following diseases/events to the reportable list:
  - Three fungal infections: Blastomycosis, coccidioidomycosis, and histoplasmosis.
    - These fungal infections can cause outbreaks and are typically acquired from soil and other environmental exposures and often misdiagnosed.
    - The burden of disease related to these fungal pathogens in Colorado is
    - low based on prior analyses of hospital discharge data. However,
    - Centers for Disease Control and Prevention (CDC) believes climate
    - change is shifting the epidemiology, resulting in expansion of
    - geographical areas where these pathogens pose a public health risk.
    - Conducting disease surveillance for these pathogens will provide a
    - better understanding of the epidemiology in Colorado, how it may
    - change over time, and allow for public health to inform health care
    - providers of the risk in order to improve diagnosis and treatment. The
    - reporting timeframe for all three pathogens will be four days. CDPHE
    - anticipates performing surveillance and investigation activities for these pathogens in-house.

  - Carbapenemase-producing organisms:

    - Carbapenemases are resistance mechanisms (enzymes that cause high-level antibiotic resistance) that are transmissible between bacteria and associated with rapid spread, difficult-to-treat disease, and poor outcomes. Currently, carbapenem-resistant *Enterobacterales*, *Acinetobacter spp.*, and *Pseudomonas aeruginosa* are reportable conditions prioritized by CDC and CDPHE for prevention and response. Clinical laboratories submit isolates of these organisms to the CDPHE State Lab where they are tested for carbapenemases. The CDPHE Communicable Disease branch responds to contain their spread. Clinical laboratories are increasingly able to detect carbapenemases in the absence of clinical cultures using molecular methods, and carbapenemases are increasingly detected in new bacterial species. CDPHE proposes to add carbapenemase-producing organisms to Appendix A in order to better capture all organisms

that present this public health risk. Surveillance and investigation activities for these pathogens are performed by CDPHE.

- *Escherichia coli* (*E. coli*) invasive infections:
  - Invasive *E. coli* infections will only be reportable in Boulder County residents as part of a special surveillance project through CDC's Emerging Infections Program to better understand the epidemiology of these infections. The reporting timeframe will be 30 days. CDPHE will perform surveillance and investigation activities for this pathogen with contractual support from Boulder County Public Health. Invasive *E. coli* infections are different from Shiga toxin-producing *E. coli* and Enterobacterales extended-spectrum beta-lactamase (which are both currently reportable statewide).
- Mpox (monkeypox):
  - The outbreak of mpox that occurred in Colorado and nationwide in 2022 and subsequent ongoing community transmission demonstrated the need to have mpox as a specific reportable disease/event in order to detect cases and outbreaks and target vaccine efforts. There are ongoing public health actions, such as vaccination, that can be offered to populations at greatest risk in order to control the spread. The reporting timeframe will be four days. Currently, mpox is reportable under the smallpox disease/event condition, which lists orthopoxvirus as a reportable pathogen/organism. CDPHE expects requiring reporting of mpox separately to result in more timely case reporting, leading to more timely public health actions. CDPHE anticipates maintaining capacity to conduct case investigation activities in-house, with LPHAs opting in to conduct these activities in their jurisdiction, if they have capacity.
- RSV (respiratory syncytial virus)
  - Expand RSV-associated hospitalization reporting requirement to statewide (rather than the five-county Denver metro area), and add RSV-associated death for people younger than 18 years to better track and understand the seasonality, burden, and severity of RSV. The reporting timeframe for all RSV reports (hospitalizations and pediatric deaths) will be four days. The current RSV season is the earliest and most severe season for RSV-associated pediatric hospitalizations in Colorado, resulting in pediatric hospitalizations at unprecedented levels. Individual case investigation is not required for reported RSV-associated hospitalizations or pediatric deaths. Outbreaks in congregate settings are typically investigated by LPHAs. CDPHE anticipates maintaining capacity to summarize statewide RSV data on a weekly basis during the viral respiratory season.

- Remove the following diseases/event from the reportable list:
  - Catheter-associated urinary tract infection (CAUTI):
    - CAUTI reporting is now required under § 25-3-601-607, C.R.S. (Hospital-Acquired Infections Disclosure), so requiring reporting per this regulation is duplicative.

- Modify the following disease/event on the reportable list:
    - Clarify the organisms that are reportable per the existing reporting requirement for carbapenem-resistant *Acinetobacter baumannii* (CRAB). This pathogen can be resistant to nearly all antibiotics and cause serious infections in patients, especially those in intensive care units. Because CRAB includes a complex of bacterial species, CDPHE wants to clarify the language that all species within the complex should be reported in order to capture and track the changing epidemiology of this organism. This proposal clarifies and does not expand reporting requirements.
    - Change the reporting timeframe for animal bites by mammals not including dogs, cats, bats, skunks, foxes, raccoons, coyotes, or other wild carnivores to four days, rather than four hours. The reporting timeframe was inadvertently and incorrectly changed to four hours during the last revision and should be four days. The reporting timeframe for animal bites by dogs, cats, bats, skunks, foxes, raccoons, coyotes, or other wild carnivores remains at 24 hours.
    - Remove *Candida haemulonii* as a reportable pathogen/organism under *Candida auris* disease events. In the past, *C. auris* has been misidentified as *C. haemulonii*, but per the Council of State and Territorial Epidemiologists (CSTE), this is no longer an issue.
    - Clarify that chlamydia detected from any body site is reportable. Chlamydia can cause infections in different sites of the body, such as cervicitis, urethritis, proctitis, conjunctivitis, lymphadenopathy, and proctocolitis. In newborns, it can cause pneumonia. Adding this clarification will help ensure complete reporting of all chlamydial infections to public health so appropriate case follow-up can occur.
    - Modify COVID-19 reporting: The Department proposes the following amendments to COVID-19 reporting to 1) adjust to the ongoing surveillance needs of the pandemic response, and 2) align with laboratory data reporting guidance issued by the U.S. Department of Health and Human Services (HHS) in March and April 2022. In July and August 2022, CDPHE sent memos to laboratory reporters clarifying that COVID-19 reporting requirements should align with the HHS guidance (these memos can be found on this CDPHE webpage). The proposed changes formally incorporate this guidance into the rule.
        - As stated in the July and August 2022 memos, CDPHE will no longer require reporting of negative rapid **and** antigen SARS-CoV-2 negative test results. CDPHE is issuing this clarification as this applies to all rapid test types (including non-NAAT rapid molecular tests), as described in the HHS memo.
        - For positive test results: Nucleic acid amplification tests (NAAT) and rapid antigen tests will be reportable (rather than test results from any test type). NAAT tests detect genetic material and include reverse transcription polymerase chain reaction (RT-PCR) tests and isothermal amplification tests. The Department proposes that serology/antibody tests and any at-home test no longer be reportable. Clinical labs that perform lineage or sequencing will continue to report those results. This change will align Colorado's reporting requirements with CSTE case definitions for COVID-19 and CDC's expectations for case reporting by states to CDC.
        - For negative test results: NAAT tests will be reportable (rather than all negative or inconclusive results on any test type). The Department

proposes that negative rapid and antigen SARS-CoV-2 negative test results no longer be reported. This aligns with current HHS guidance for clinical laboratory and test reporting.

- The Department proposes that the reporting timeframe for all COVID-19 reports (positive, negative, and inconclusive results) be four days, rather than one working day. There is no longer an urgency to receive COVID-19 reports within one working day, and this change will align with the reporting timeframe of other viral respiratory pathogens.

- Permanently add COVID-19-associated hospitalizations as a reportable condition. Currently, most reporting of COVID-19-associated hospitalizations is done through the COVID Patient Hospital Surveillance (COPHS) system via an automated data extract, so the current burden on hospital staff is minimal. The proposed amendment would require reporting of COVID-19-associated hospitalizations within four days of the case's hospitalization. Currently, COPHS collects data about patients who were either admitted or under observation status for 24 hours or more and meet at least one of the following criteria:
  - Had an admission diagnosis of COVID-19, or
  - Had a discharge diagnosis of COVID-19, or
  - Received a positive COVID-19 diagnostic test (antigen, rapid molecular, or PCR) during the hospitalization or emergency department encounter immediately preceding the hospitalization.

  The proposed amendment will continue using this reporting criteria and the COPHS system, which may be adjusted over time as the pandemic progresses and other automated reporting mechanisms are implemented.

  Monitoring hospitalizations is important for detecting shifts in the severity of COVID-19, hospitalization burden, and overall trends, including trends in populations that have been disproportionately impacted by COVID-19 (health equity impact), and assists the Department in conducting assessments of vaccine effectiveness. Hospitalized case surveillance has been in this rule since 2004 for influenza and since 2018 for RSV. On an ongoing weekly basis, the Department analyzes influenza and RSV case hospitalization data and publishes this data on its website. This informs partners and the public about the magnitude and trends of illness and impacts on the hospital system and guides public health actions. Similar analyses are currently conducted and will be conducted in the future, for COVID-19-associated hospitalizations to inform partners and the public, and guide public health actions.

- Update the spelling of Enterbacteriaceae to Enterbacterales to align with current naming convention and clarify the organisms reportable per the reporting requirement for Enterobacterales.

- Change the reporting timeframe for Enterbacterales extended-spectrum beta-lactamase (ESBL) from four days to 30 days. ESBL data are collected to estimate burden of disease and risk factors, but do not trigger an immediate public health response. This change gives providers more time to comply with reporting requirements related to provision of medical records and aligns with the proposed timeline for reporting of invasive *E. coli* in Boulder County.

- Clarify that disseminated gonorrhea is reportable under the current gonorrhea reporting requirement. Disseminated gonorrhea is uncommon and typically occurs when untreated gonorrhea enters the bloodstream and spreads to distant sites in the body, leading to a variety of clinical manifestations, which can be severe. Public health can connect health care providers to consultation services to aid with clinical management and work with testing laboratories to obtain isolates for further characterization.

- Clarify that the pathogen/organism that causes leprosy (Hansen's Disease) is *Mycobacterium leprae*. Currently, this field is blank and we propose adding the organism for clarity and consistency.

- Clarify the organisms reportable per the current reporting requirement for *Mycobacterium* nontuberculosis (NTM). *M. gordonae* is removed from the list of reportable NTM because it is considered non-pathogenic in nearly all instances when it is isolated from a clinical culture. This species of NTM is also excluded from the CSTE case definition for the same reason.

- Combine streptococcal toxic shock syndrome and toxic shock syndrome (non-streptococcal) into one entry in Appendix A labeled as "toxic shock syndrome (Streptococcal and non-streptococcal)." This change is intended to make it more clear that both types of toxic shock syndrome are reportable.

- Clarify organisms reportable per the current reporting requirement for tick-borne relapsing fever. The current reporting requirement is for the bacterium that causes TBRF. *Borrelia hermsii* is most commonly seen in Colorado, but other species can be seen in other parts of the country. CDPHE has found that not all reporting agencies are aware that spirochetemia found on routine blood work is indicative of TBRF infection. We would like to add spirochetemia and clarify that any *Borrelia* species other than *B. burgdorferi* are reportable as potential causes of TBRF.

- Clarify that all associated results for syphilis are to be reported, including treponemal tests (EIA, CIA, CMIA, FTA-ABS, PCR, TP, TPA, TP-PA) and non-treponemal tests (RPR, VDRL, CSF quantitative titers).

- Renumber the footnotes and propose changes to footnotes to align with the proposed changes in Appendix A. These technical changes are intended to bring clarity or reduce confusion among end users of the rule.

The Department also proposes amendments to:

- Regulation 1, 3, 4, and Appendix A: Clarify that sex assigned at birth is the data element that should be reported with each case, rather than sex.

- Regulation 1, 3, 4, and Appendix A: Add sexual orientation and gender identity to the list of data elements that must be reported with each case. The Department proposes to collect this information in response to HB22-1157 - Utilization of Demographic Data by CDPHE, which requires CDPHE to collect certain public health data elements, including sexual orientation and gender identity, to assess health disparities and inequities. Neither HB22-1157 nor this proposed rule language require people to provide this information as a condition of receiving medical treatment. This proposal does require that when a reporting entity has sexual orientation and gender identity information available for someone, it must be reported with each case. Currently, the following patient information must be reported with each case report: Patient name, date of birth, sex

(proposing to change to sex assigned at birth), race, ethnicity, phone number, physical address, including city and county, email address, and preferred language. Adding sexual orientation and gender identity will also guide case follow-up activities that may be conducted by public health disease intervention staff.

- Disability is also a data element HB22-1157 requires CDPHE to collect. Once standards are developed about how and what disability data will be collected, CDPHE will incorporate those standards into this rule.

- Regulation 1, 3, 4, and Appendix A: Add pregnancy status to the list of data elements that must be reported with each case of syphilis and HIV. As of September 2022, Colorado's congenital syphilis case reports are 77% higher than they were for the same period in 2021. Case reports of HIV in people who are pregnant are rare. However, gathering this data upon the initial case report will increase the timeliness of public health interventions to connect the person who is pregnant to resources that can prevent transmission to the newborn.

- Regulation 1, 3, 4, and Appendix A: Add phone number of the responsible physician or other health care provider (in addition to name and address) to the list of data elements that must be reported with each case.

- Regulation 1: Add data elements that must be reported for each hospitalized case report (e.g., currently reportable for influenza statewide and RSV in the five-county Denver metro area, and COVID-19 statewide per the February 15, 2023, emergency rulemaking hearing). The Department proposes to collect hospital admission date(s) and name of facility where 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.

- Regulation 1: The Department proposes several clarifications within this regulation to 1) specify that reporting requirements for health care-associated infections (HAIs) are provided in § 25-3-601-607, C.R.S. and reported to the National Health care Safety Network (NHSN), 2) highlight that select HAIs not covered by this statute are listed in Appendix A of this regulation and also reported to NHSN, and 3) to further clarify that facilities reporting outbreaks of HAIs shall make medical records available for review by the Department upon request and within a reasonable timeframe. These clarifications are needed to minimize confusion that may arise if certain HAIs are reportable under one regulatory mechanism but not the other (e.g., an HAI may be reportable under § 25-3-601-607, C.R.S but not under 6 CCR 1009-1, or vice versa).

- Regulation 2: Add language to clarify that people in charge of institutes of higher education or their designee are considered disease reporters. These facilities often have congregate living settings which can be at higher risk of disease transmission and outbreaks where public health disease control interventions can be helpful.

- Regulation 4: Clarify that public and private laboratories must report all confirmed or suspected cases of active tuberculosis disease to the Department or county, district, or municipal public health agency within one working day. The Department proposes other changes in Regulation 4 that are technical in nature, provide clarity, and further align with the remaining regulations within this rule.

- Regulation 5: Add that public health investigations may be conducted in response to identified or potential reportable conditions, or to evaluate exposures to known causes of reportable conditions for the purposes of case identification and prevention (e.g., if environmental or product testing finds a reportable pathogen in water or a certain environment or product, public health can investigate to determine if there are human

illnesses associated with the environmental findings).

- Regulation 10: The proposed changes in this section update the authorizing statute citation; adds definitions for puncturing devices and reusable equipment; and clarifies practices around needle use, reusable equipment, cleaning and disinfecting, disposal, who can perform certain activities, and handwashing practices. Language in this section was reordered to improve readability for the end user of the rule.

- Regulation 11: Changes made in this section update the name of the Ryan White Comprehensive AIDS Resources Emergency Act to Ryan White Comprehensive Human Immunodeficiency Virus Resources Emergency Act, and add to operational standard D that all persons newly diagnosed with HIV will be assessed for linkage to care services.

- Appendix B: Added antimicrobial-resistant infections to the list of HAIs, and added acute care hospitals, inpatient rehabilitation facilities, long-term acute care hospitals, and other hospitals to the list of health facility types. The suggested edits clarify the definition of HAI in the appendix and align it with generally accepted definitions of what constitutes a health care facility (e.g., an acute care hospital was not listed as a facility type) or HAI (e.g., antimicrobial resistant infections acquired in a hospital).

- Throughout the rule: Incorporate gender neutral language throughout the regulation (i.e., removing his/her and him/her and replacing it with “person” or “their”).

Finally, the Department has proposed changes that are technical in nature and 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. This change is 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 incorporate 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 the 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 Select category: C/CLG/S/B
Infection control providers, clinical laboratory personnel, hospitals, health care providers, and electronic lab report senders from throughout the state, as well as any out-of-state lab that conducts testing on Colorado residents.	1,000	C/B
Professional, trade, community, and advocacy organizations, including the Colorado Medical Society, Acupuncture Society, Colorado Hospital Association, Colorado chapter of the Association for Professionals in Infection Control and Epidemiology, Colorado Association of Local Public Health Officials, and the general public.	1,000	S
Schools, licensed day care centers, institutions of higher education.	2,000	C/B
Local public health agencies (LPHAs), the Department, entities required to report, and the general public.	>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, use this relationship categorization key:

C = Individuals/entities that implement or apply the rule.
CLG = Local governments that must implement the rule in order to remain in compliance with the law.
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

C/B: The proposed changes include additions and modifications to the list of reportable conditions and data elements required for each case report necessitated by changes in conditions of public health concern. These changes will require some additional laboratory, health care provider, and/or data manager staff time to report. Local public health agencies (LPHAs), coroners, schools, licensed day care centers, persons providing testing and/or counseling to a person with a sexually transmitted infection, and government-run health care facilities have a duty to report conditions listed in Appendix A. However, the bulk of reporting occurs by non-governmental clinical laboratories. To minimize the burden, the Department favors electronic reporting whenever possible. At this time, all large commercial and hospital laboratories report electronically. Approximately 90% of reportable test results are received electronically. Some reporters could experience minor costs associated with the one-time programming change to add or modify reportable conditions to their electronic reporting feed. For the laboratories for which the burden of reporting and specimen/isolate submission will increase, CDPHE staff will work with them to minimize the burden when possible.

Reporting of RSV and COVID 19-associated hospitalizations statewide may increase the workload of infection prevention and data management staff at hospitals. Currently, reporting of hospitalized COVID-19 cases is done via the COVID Patient Hospital Surveillance (COPHS) system, where most hospitals have built automated data extracts from electronic medical records and transmit the resulting CSV files to a CDPHE REDCap database. However, efforts are underway at the Department to offer automated hospitalized case reporting for influenza, RSV, and COVID-19 through a process called electronic case reporting (eCR). Health care organizations and hospital groups are onboarding in Colorado to send eCR data to CDPHE, which will reduce the burden on hospitals to perform this reporting directly. There are some limitations to this program, such as only large hospital organizations with certain vendors for their electronic health record will be able to utilize eCR, but CDPHE hopes to see a large increase in reporting organizations over the coming year. This proposed change will necessitate continued resources at the Department to enter and review the case reports, analyze the data, and create reports for internal and external partners and the public. Currently, the Department receives federal funds to support this effort. LPHAs may choose to do their own analyses of the data collected around COVID-19-associated hospitalizations.

The Department proposes adding institutions of higher education to this list of reporters. However, health clinics at institutions of higher education are already required to report cases and outbreaks, so the burden will be minimal and more focused on reporting outbreaks. The proposed addition of several diseases/events may increase LPHA costs if there is an outbreak caused by the disease/event in the LPHA jurisdiction that the LPHA investigates. However, CDPHE anticipates conducting surveillance and investigation

activities for the proposed additions, and outbreaks of the proposed additions are rare, so the impact should be minimal. The Department and LPHAs will benefit from 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 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.

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.

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/B = Health care providers, laboratories, and hospital infection preventionists are the primary reporters of conditions included in the Reportable Disease Table in Appendix A. Schools and licensed child care centers 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, all of which the Department expects 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.

Hospitals (likely infection prevention staff) are the primary reporters of COVID-19-associated hospitalizations. However, most hospitals have automated this reporting through the COPHS system, described above. The reporting process may be helpful for hospitals to track the burden of COVID-19 on their system/facility. Since COVID-19-associated hospitalizations have been reportable by public health order since early in the pandemic, hospitals have historic data that can be compared to current data to assess trends in COVID-19-associated hospitalizations. The Department also analyzes and reports on this data, which can inform hospitals, LPHAs, and other entities who may use the data for planning and decision-making.

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 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 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 (new proposed elements clarify that sex assigned at birth is the data element that should be reported with each case, rather than sex; sexual orientation and gender identity are proposed to be added to the list of data elements that must be reported with each case when the reporter has the information; and pregnancy status is proposed to be added to the list of data elements that must be reported with each case of syphilis and HIV). The Department will continue to work with disease reporters to enable them to collect and report each data element as they become accessible.

Reporting of COVID-19-associated hospitalizations can be a reporting burden on hospitals. To minimize this burden, CDPHE is taking steps to offer more automated surveillance for hospitalized cases through a process called eCR, described above. Health care organizations and hospital groups are onboarding in Colorado to send eCR data to CDPHE, which will reduce the burden on hospitals to perform this reporting directly. There are some limitations to this program, but CDPHE hopes to see a large increase in reporting organizations over the coming year.

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 disease reports and laboratory submissions will be covered by CDC Emerging Infections Program (EIP) funding and Epidemiology and Laboratory Capacity (ELC) funding, and several CDC sexually transmitted infections/HIV grants, which are funding sources that CDPHE has been receiving for more than 20 years. The cost to the Department for managing the addition of COVID-19-associated hospitalizations to the list of reportable conditions in the rule will be covered by EIP and ELC funding. The Department has received funding from these sources specifically for COVID-19 surveillance activities. However, this amount of funding will be reduced or eliminated by July 2024. We anticipate that after that time, the Department will be able to absorb COVID-19-associated hospitalizations 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: NA

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

      Anticipated Revenues for another state agency: NA

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.

___ 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 and 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.

These proposed amendments align with the DCPHR 2022-2023 Strategic Plan priorities #2: Incorporate the learnings of the COVID response across all DCPHR work streams, and #3: Continue and increase focus on equity/IDEA (Inclusion, Diversity, Equity, and Accessibility) across all DCPHR lines of work. The Department learned the value of collecting, analyzing, and reporting on COVID-19-associated hospitalizations during the pandemic, as it informs public health actions. The value of this data has also been demonstrated historically with existing influenza and RSV requirements around reporting hospitalized cases. In addition, demographic characteristics of each reported hospitalized case allow for analyses to detect populations that are disproportionately affected by COVID-19, so public health resources and interventions can be directed to appropriate groups.

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: NA

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 specific revisions proposed around COVID-19-associated hospitalizations were developed in alignment with the requirements of PHO 20-38 prior to its termination.

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 less burdensome electronic laboratory reporting, whenever possible.

6. Alternative rules or alternatives to rulemaking considered and why rejected.

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

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 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.

For COVID-19-associated hospitalizations, the Department used existing data being reported throughout the COVID-19 pandemic. This data provided situational awareness and a common operating picture for local, regional, and state public health and medical services during a crisis event such as the COVID-19 pandemic. Monitoring hospitalizations is important for detecting shifts in severity of illness, hospitalization burden, overall trends, including trends in populations who have been disproportionately impacted by COVID-19, and conducting assessments of vaccine effectiveness. The way the Department is analyzing and sharing this data with partners can be found on CDPHE's COVID-19 website, which updates weekly. As the pandemic response evolves, it is likely that COVID-19-associated hospitalization data sharing will become more similar to how the Department shares influenza and RSV data.

Other data considered includes:

- CDC. 2019 AR Threats Report. (https://www.cdc.gov/drugresistance/biggest-threats.html).
- CDC. Health care-Associated Infections - Community Interface (HAIC). Multi-site Gram Negative Surveillance Initiative. (https://www.cdc.gov/hai/eip/mugsi.html).
- WHO. Antimicrobial resistance. (https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance)
- Infectious Diseases Society of America (IDSA). Antimicrobial resistance. (https://www.idsociety.org/public-health/antimicrobial-resistance/antimicrobial-resistance/).
- CDC. Acinetobacter in Health care Settings. (https://www.cdc.gov/hai/organisms/acinetobacter.html).
- Gadre A, Enbiale W, Andersen LK, Coates SJ. The effects of climate change on fungal diseases with cutaneous manifestations: A report from the International Society of Dermatology Climate Change Committee. The Journal of Climate Change and Health 2022;6:100156. (https://www.sciencedirect.com/science/article/pii/S2667278222000451) [Provides an overview of the effects of climate change on fungal infections, including blastomycosis, coccidioidomycosis, and histoplasmosis.]
- The Council of State and Territorial Epidemiologists (CSTE). Position statement 19-ID-02: Standardized Surveillance Case Definition for Blastomycosis. 2019. (https://www.cste.org/page/PositionStatements).
- The Council of State and Territorial Epidemiologists (CSTE). Position statement 22-ID-05: Update to the Standardized Case Definition and National Notification for Candida auris. 2022. (https://www.cste.org/page/PositionStatements).
- CDC. *Candida auris*. (https://www.cdc.gov/fungal/candida-auris/index.html).
- The Council of State and Territorial Epidemiologists (CSTE). Position statement 22-ID-07:Update to the Standardized Surveillance Case Definition and National

Notification for Coccidioidomycosis. 2022. (https://www.cste.org/page/PositionStatements).
- CDC. Valley fever maps. (https://www.cdc.gov/fungal/diseases/coccidioidomycosis/maps.html).
- The Council of State and Territorial Epidemiologists (CSTE). Position statement 22-ID-04: Change in Case Definition from Carbapenemase-Producing Carbapenem-Resistant Enterobacteriaceae (CP-CRE) to Carbapenemase-Producing Organisms (CPO). 2022. (https://www.cste.org/page/PositionStatements).
- CDC.Carbapenem-resistant Enterobacterales (CRE). (https://www.cdc.gov/hai/organisms/cre/index.html).
- CDC. ESBL-producing Enterobacterales in Health care Settings. (https://www.cdc.gov/hai/organisms/ESBL.html).
- Magill SS, et al. Changes in Prevalence of Health Care–Associated Infections in U.S. Hospitals. N Engl J Med 2018;379:1732-44. [Indicates that *E. coli* is one of the most common health care-acquired infections based on a prevalence survey. Provides support for population-based surveillance for invasive *E. coli* infections].
- CDC. Histoplasmosis maps. (https://www.cdc.gov/fungal/diseases/histoplasmosis/maps.html).
- The Council of State and Territorial Epidemiologists (CSTE). Position statement 17-ID-07: Standardized Case Definition for Extrapulmonary Nontuberculous Mycobacteria Infections - Revised. 2017. (https://www.cste.org/page/PositionStatements).
- CDC. Health care-Associated Infections - Community Interface (HAIC). Nontuberculous mycobacteria. (https://www.cdc.gov/hai/eip/ntm.html).
- CDC. CDC's Core Infection Prevention and Control Practices for Safe Health care Delivery in All Settings. (https://www.cdc.gov/infectioncontrol/guidelines/core-practices/index.html). [Injection and medication safety guidelines apply to acupuncture settings].
- From January through September 2022, Colorado's congenital syphilis case reports were 77% higher than they were for the same period in 2021. Additionally, CDPHE reports that diagnoses of syphilis among women of reproductive age has steadily increased in Colorado over the last 5 years. https://cdphe.colorado.gov/syphilis-and-pregnancy
- Carlson JM, Tannis A, Woodworth KR, et al. Substance Use Among Persons with Syphilis During Pregnancy — Arizona and Georgia, 2018–2021. MMWR Morb Mortal Wkly Rep 2023;72:63–67. DOI: http://dx.doi.org/10.15585/mmwr.mm7203a3
- Colorado General Assembly. HB 22-1157 - Utilization of Demographic Data by Colorado Department of Public Health and Environment - Concerning the utilization of demographic health data by the department of public health and environment to address health inequities, and, in connection therewith, making an appropriation. https://leg.colorado.gov/bills/hb22-1157
- CDPHE. Colorado Flu and RSV Report. https://leg.colorado.gov/bills/hb22-1157

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
CDPHE invited the following people and/or entities to provide input in the development of these proposed rules:

Colorado health care providers, Colorado hospital infection preventionists, lab directors and laboratorians (including microbiology lab contacts and CDPHE's laboratory staff), local public health agencies (LPHAs) (directors and communicable disease contacts), Association for Professionals in Infection Control (APIC) Colorado chapter, Colorado Association of Local Public Health Officials (CALPHO), electronic laboratory reporters, Colorado Medical Society, Colorado Hospital Association, the Department's Office of Emergency Preparedness and Response, the Department's Health Facilities and Emergency Medical Services Division, the Department's State Public Health Laboratory, Colorado Department of Agriculture, State Veterinarian's Office, Colorado Veterinary Medical Association, Colorado State University Veterinary Diagnostic Lab, Colorado Parks and Wildlife Veterinary Staff, Colorado Coroners Association, school nurses, child care nurse consultants, higher education contacts, the State's Office of STI/HIV and Viral Hepatitis, The Center on Colfax, One Colorado, Gill Foundation, the Department's Immunization Branch, and the Acupuncture Association of Colorado.

Between December 27, 2022, and January 18, 2023, CDPHE solicited stakeholder feedback from the entities listed above via email, where a memo describing the proposed amendments to the rule and a strikethrough version of the rule were included as attachments. Stakeholders were asked to provide feedback in an online survey form. Of the nearly 30 distinct stakeholder groups, the groups comprising the most people were the nearly 400 LPHA staff and approximately 3,200 electronic lab reporters (this number of electronic lab reporters increased greatly during the COVID-19 pandemic but is beginning to decline as the pandemic response turns into an endemic response). Whenever possible, CDPHE staff members with existing relationships and partnerships with a stakeholder were asked to forward on the memo and strikethrough version of the rule.

A second round of stakeholder feedback was conducted between March 8, 2023, and March 22, 2023, to the same entities listed above. Stakeholders were contacted via email, where an updated memo and strikethrough version of the rule were included as attachments. Stakeholders were asked to provide feedback in an online survey form.

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

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

_X___ Yes.

Summarize major factual and policy issues encountered and the stakeholder feedback received. If there is a lack of consensus regarding the proposed rule, also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

Twenty comments were received during this first round of stakeholder feedback. Below is a summary of the feedback received and how the Department responded to stakeholders' suggestions, questions, and concerns:

- Feedback that resulted in the Department modifying the proposed amendments:
  - An LPHA stakeholder suggested that *Mycobacterium leprae* be added to the pathogen/organism column of Appendix A: Reportable Diseases, Condition, and Related Event Table to be consistent with how other diseases and their pathogens appear. This change was made.
  - An LPHA stakeholder suggested that "species" be listed in the pathogen/organism column of Appendix A: Reportable Diseases, Condition, and Related Event Table, rather than "fungus" as originally proposed (i.e., list blastomyces "species," coccidioides "species," and histoplasma "species" in the "pathogen/organism" column). Additional species of these fungal pathogens continue to be discovered and characterized so listing "species" will make it more clear that all species are reportable. This change was made.
  - An LPHA stakeholder suggested that streptococcal toxic shock syndrome and toxic shock syndrome (non-streptococcal) be combined into one entry in Appendix A: Reportable Diseases, Condition, and Related Event Table, and labeled as toxic shock syndrome (Streptococcal and non-streptococcal). *Streptococcus pyogenes* and non-streptococcal bacteria are listed in the pathogen/organism field on this line, and a reference to Footnote 20 was added for clarity around the need for clinical laboratories to submit *Streptococcus pyogenes* isolates from patients with streptococcal toxic shock syndrome who reside in the five-county Denver metropolitan area. This change was made.
  - An LPHA stakeholder suggested adding physician/health care provider phone number to the list of data elements to be reported for each case in Regulation 1, 3, 4, and Appendix A (along with the current requirements for responsible physician/health care provider name and address data elements).
  - In response to a CDPHE staff member's comment, "animal bites by mammals not listed above" will correctly list 4 days instead of 4 hrs in the "time" column on Appendix A: Reportable Diseases, Condition, and Related Event Table.
  - A long term care facility health care provider questioned why "lower respiratory tract infections other than pneumonia" was listed on Appendix B: Health care-Associated Infections. The Department subject matter expert reviewed this feedback and determined that this should be removed as it is unlikely that public health investigations would be conducted for lower respiratory tract infections other than pneumonia (such as bronchitis).
  - A hospital expressed concern over requiring discharge date, ICU, and ventilator status for influenza- and RSV-associated hospitalizations. The hospital wondered if it would be required to manually update these data elements, which change over the course of someone's hospitalization. Another hospital expressed a similar concern around manually reporting RSV-associated hospitalization information. In response, the Department noted that the purpose of this requirement is for the continuation of COVID-19-associated

hospitalizations (which is addressed in an emergency rulemaking hearing being held on February 15, 2023) and the implementation of more widespread electronic case reporting in the future. The Department also explained that it is considering adding RSV- and influenza-associated hospitalizations to the COVID Patient Hospitalization Surveillance (COPHS) reporting system, which would further facilitate the automated collection of hospitalization information. Language in the rule was updated as follows (additions are in bold, and deletions appear as strikethrough text):

WHEN HOSPITALIZATION IS A CRITERIA FOR REPORTING (E.G., A HOSPITALIZED PATIENT WITH A POSITIVE TEST RESULT FOR INFLUENZA OR RSV), THE REPORT SHALL PROVIDE **HOSPITAL ADMISSION DATE(S) AND NAME OF FACILITY WHERE HOSPITALIZED. WHEN REQUESTED BY THE DEPARTMENT THE REPORT SHALL ALSO INCLUDE** ~~ADDITIONAL DATA, INCLUDING BUT NOT LIMITED TO: HOSPITAL ADMISSION DATE(S),~~ DISCHARGE DATE(S), ~~NAME OF FACILITY WHERE HOSPITALIZED, AND~~ VENTILATOR AND INTENSIVE CARE UNIT (ICU) USE, **AND OTHER FIELDS AS NEEDED.** ~~WHEN REQUESTED BY THE DEPARTMENT.~~

- Other feedback received by the Department:
  - Several LPHA stakeholders were concerned about the addition of reportable conditions creating more work for their agencies. The Department responded by explaining that labs and health care providers, not LPHAs, are responsible for diagnosing and reporting the vast majority of diseases/conditions. Also, CDPHE anticipates maintaining capacity for conducting surveillance and investigation activities for the proposed additions to Appendix A. Outbreaks of these proposed conditions could place additional burden on LPHAs to assist in the investigation in their jurisdiction. However, all outbreaks of any cause have been reportable for decades, so this is not a new addition or expectation, and LPHAs typically have an interest in responding to disease outbreaks in their jurisdiction. No further changes were made to the rule in response to these comments.
  - An LPHA stakeholder suggested adding additional data elements to the list of information reported for each case, including current and permanent address, social determinants of health data elements, and disease risk factor data. It was determined that these data elements are often not readily available to disease reporters, and are often collected as part of the public health investigation process, so no modifications to the proposed amendments were made.
  - An LPHA stakeholder suggested adding Chagas Disease to the list of reportable conditions since the vector has been found in parts of western Colorado. The Department will consider this request for future rulemaking once an analysis of the vector distribution and disease burden can be performed.
  - A hospital expressed concern about expanding RSV-associated hospitalization reporting statewide, and that current surveillance in the five-county Denver metropolitan catchment area was sufficient. The Department responded by noting that the Denver metropolitan area covers 50 percent of the state's population, and that stakeholders across the state want to have more awareness of the RSV activity in their jurisdiction as evidenced by an abundance of feedback received during the current RSV season from a variety of LPHA and other external partners. It was also noted that in 2019, when RSV hospitalizations were first made reportable but only in the Denver metropolitan area as part of CDC's Emerging Infections Program (EIP), the State Board of

Health emphasized the importance of making RSV hospitalizations reportable statewide in the near future to better capture the burden statewide and have the ability to detect differences in urban and rural populations. With the shift to COVID-19 endemicity and the possible availability of RSV vaccines and updated prophylaxis recommendations in the coming months/years, dedicating more resources to the surveillance of RSV across Colorado is a priority for the Department.

- A stakeholder representing a school/licensed child care facility expressed concern about the burden disease reporting places on these facilities, lack of compensation to facilities to perform reporting duties, and concerns that this may contribute to people not working in these facilities. The Department responded by noting that this rule is not associated with any funding, schools and licensed child care facilities have been included as reporters in this rule for many years, and recognizing that most schools and child care facilities do not serve as health care providers, but do have nurses and health consultants who often have knowledge of, and respond to, illness and disease issues among children, attendees, and staff that are within the purview of the rule. This is especially the case with outbreaks given the congregate nature of these settings. The Department goal of having school and child care facilities report disease is to ensure that potentially severe diseases and outbreaks can be responded to by the facility and public health to prevent further transmission.
- An LPHA stakeholder expressed appreciation for the proposed changes to gender neutral terminology and the addition of the new reportable conditions and better definition of some existing reportable conditions.

- Feedback around adding sexual orientation (SO) and gender identity (GI) to the list of data elements reported for each case:
  - A stakeholder representing a school/licensed child care facility expressed concern over the proposal to add these data elements to the rule, given that the population this stakeholder works with (children) often do not have this data available. The Department responded by providing the link to HB 22-1157 which requires this reporting, explaining the goals of collecting these data elements, and explaining that some disease reporters will not have access to these data elements and there is no penalty for not reporting these elements if they are unknown or not available. A stakeholder from a clinical laboratory shared similar concerns around clinical laboratories not having access to these data elements. The Department responded similarly in terms of there being no penalty for not reporting these elements if they are unknown or not available.
  - A stakeholder representing a clinical laboratory expressed concern around adding these data elements to the rule, as clinical laboratories often do not have this information for specimens that are tested, have no way of obtaining this information, potential lack of standardization around how these data elements are captured and categorized, and how the data will be stored and used by public health. The Department responded by providing a link to HB 22-1157 which requires this reporting, outlining how the Department is working on standardization around collecting, categorizing, and protecting the data; and acknowledging that the Department understands that some disease reporters, especially clinical laboratories, may not currently have access to these data elements.
  - A stakeholder from CDPHE shared concerns about collecting these data elements and if that data might be made available during legal processes that could result in discrimination and/or harm against certain groups of people that public health is ultimately trying to help. This stakeholder also has

concerns that people could avoid getting medical care if health care providers ask SOGI-related questions. All disease reporting data is held in strict confidence on secure databases, all public health staff who have access to this data are required to sign confidentiality agreements, and data release policies exist at CDPHE to control the amount of data that is shared publicly based on population size and types of data. These policies will be updated to include details on SOGI data if the proposed amendment passes. Personal health information and personally identifiable information collected through disease reporting and subsequent case follow-up activities is never shared in a public way. This stakeholder was provided information on the HB 22-1157.

For the second round of stakeholder engagement, CDPHE received four different responses. Below is a summary of those responses and how the Department responded to stakeholders' suggestions, questions, and concerns:

- One comment from an inpatient rehabilitation facility asked why hospital personnel, not just laboratories, must report these conditions. The Department responded with information around how disease reporting is conducted and why hospital personnel may need to report (i.e., not all reportable conditions are diagnosed by laboratory tests, so providers need to report; some conditions require prompt public health response, so providers need to report suspect cases before laboratory tests are performed; and providers often detect outbreaks that lab testing will not necessarily detect).
- Similar to feedback received in the first round of stakeholder engagement, an individual from a hospital expressed concern about laboratory personnel obtaining information on sexual orientation. The Department responded by acknowledging that it is difficult for labs to obtain this information since it may not be included in lab test orders or in the medical record, and patients may feel uncomfortable sharing this information in a clinical setting.
- A local community health center asked whether reporting of positive serologies would be required for blastomycosis, coccidioidomycosis, and histoplasmosis. The Department responded, clarifying that any test result from any test type that indicates possible infection with these fungal pathogens would be reportable.
- A health care provider expressed concern over the requirement to add the phone number of the responsible physician or other health care provider (in addition to name and address) to the list of data elements that must be reported with each case. The Department responded with information on how this data element is used by public health agencies conducting case follow-up activities, and that labs are not penalized for not providing this data element if they do not have access to it.

The Department is appreciative of the comments and suggestions received from its many stakeholders.

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.	X	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.	X	Ensures a competent public and environmental health workforce or health care workforce.
	Other:_____ _____		Other:_____ _____

COLORADO
Department of Public Health & Environment

TWENTY FIFTH AMENDED PUBLIC HEALTH ORDER 20-38
LIMITED COVID-19 HOSPITAL REPORTING
January 1, 2023

PURPOSE OF THE ORDER

I am issuing this Public Health Order (PHO or Order) in response to the existence of thousands of confirmed and presumptive cases of Coronavirus disease 2019 (COVID-19) and related deaths across the State of Colorado. This Order supersedes PHO 20-36 COVID-19 Dial and PHO 20-29 Voluntary and Elective Surgeries and Procedures, and outlines reporting requirements for hospitals.

FINDINGS

1. On March 10, 2020, Governor Jared Polis verbally declared a disaster emergency regarding COVID-19 in Colorado, and on March 11, 2020 Governor Polis issued **Executive Order D 2020 003**, memorializing the disaster declaration. The Governor's verbal declaration of a disaster emergency is now memorialized in **Executive Order D 2021 122**, as amended and extended by **D 2021 124, D 2021 125, D 2021 129, D 2021 132, D 2021 136, D 2021 139, D 2021 141, D 2022 003, D 2022 010, D 2022 013, D 2022 017, D 2022 020, D 2022 028, D 2022 035, D 2022 037, D 2022 044, and D 2022 045**. Since that time, the Governor has taken numerous steps to implement measures to mitigate the spread of disease within Colorado, and has further required that several public health orders be issued to implement his orders.

2. As of January 1, 2022, there have been 1,732,055 Coloradans diagnosed with COVID-19, 73,937 have been hospitalized and 14,535 Coloradans have died from COVID-19. There are 306 individuals currently hospitalized due to COVID-19, and 836 hospital beds remain unoccupied across the state. At this time, 90% of Colorado's intensive care beds are occupied and 90% of medical/surgical beds are occupied.

3. CDPHE continues to monitor COVID-19 cases, and in part relies on hospital reporting of cases as well as hospital capacity and resource availability to determine whether any additional measures need to be taken or additional resources are needed to further mitigate disease spread. Individuals are encouraged to get vaccinated and boosted to protect their own health and the health of their communities, as well as reduce their risk of hospitalization for COVID-19.

4. The following additional public health orders remain in effect:

   a. PHO 20-20 Requirements For Colorado Skilled Nursing Facilities, Assisted Living Residences, Intermediate Care Facilities, And Group Homes For COVID-19 Prevention And Response;
   b. PHO 21-01 Vaccine Access And Data Reporting For COVID-19; and
   c. PHO 22-01 Access to Testing and Treatment for COVID-19.

INTENT

This Order includes hospital reporting requirements regarding bed capacity to provide the State with critical information to assess the status of the COVID-19 pandemic relative to the statewide capacity to provide necessary medical care and services to Coloradans.

ORDER

This Order superseded and replaced Public Health Orders 20-29 and 20-36, as amended, on April 16, 2021.

I. COVID-19 RESTRICTIONS

A. Repealed.

B. Repealed.

C. SCHOOLS

1. In accordance with existing law, **Schools** shall report all COVID-19 cases and outbreaks to public health, and work with their local public health agencies and CDPHE, as applicable, regarding COVID-19 case investigations, which includes following all quarantine, isolation, investigation, and any other disease mitigation strategies deemed necessary by the public health agency.

D. Repealed.

E. Repealed.

F. Repealed.

Twenty Fifth Amended PHO 20-38 Limited COVID-19 Reporting
January 1, 2023

II. HOSPITAL FACILITY REPORTING

A. COVID-19 Case Reporting. All Colorado hospitals shall report to CDPHE in a form and format determined by CDPHE, certain information for confirmed (positive laboratory test) cases of COVID-19, including but not limited to:

1. race and ethnicity;
2. numbers of suspected and confirmed cases who are hospitalized, who are hospitalized and using a ventilator, or who are in the emergency department waiting for an inpatient bed;
3. REPEALED;
4. deaths due to COVID-19;
5. medical equipment and supply information, including but not limited to acute care bed, med/surgical bed, and intensive care unit (ICU) bed capacity and occupancy, and
6. COVID-19 vaccination status, including primary, additional and booster doses, and age.

Reporting by hospitals shall be done in CDPHE's EMResource reporting system twice per week on Tuesday and Friday by 10:00 a.m., or as otherwise required by this Order. Reporting via the COVID Patient Hospital Surveillance system (COPHS) shall continue as instructed by CDPHE.

B. Hospital Bed Capacity Reporting. All Colorado hospitals shall report to CDPHE the following in EMResource twice per week on Tuesday and Friday, by 10:00 a.m.:

1. The daily maximum number of adult and pediatric beds that are currently or can be made available within 24 hours for patients in need of ICU level care; and
2. The daily maximum number of all staffed acute care beds, including ICU beds, available for patients in need of non-ICU hospitalization.
3. The daily maximum number of all adult and pediatric med/surgical beds, available for patients in need of non-ICU hospitalization.

III. Repealed.

IV. Repealed.

V. ENFORCEMENT

This Order will be enforced by all appropriate legal means. Local authorities are encouraged to determine the best course of action to encourage maximum compliance. Failure to comply with

this order could result in penalties, including jail time, and fines, and may also be subject to discipline on a professional license based upon the applicable practice act.

VI. SEVERABILITY

If any provision of this Order or the application thereof to any person or circumstance is held to be invalid, the remainder of the Order, including the application of such part or provision to other persons or circumstances, shall not be affected and shall continue in full force and effect. To this end, the provisions of this Order are severable.

VII. DURATION

This Order shall become effective on Sunday, January 1, 2022 and will expire at 12:01 AM on January 31, 2023 unless extended, rescinded, superseded, or amended in writing.

Jill Hunsaker Ryan, MPH
Executive Director

January 1, 2023
Date

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Department of Public Health and Environment

~~**Disease Control and Environmental Epidemiology Division**~~ **DIVISION OF DISEASE CONTROL AND PUBLIC HEALTH RESPONSE**

Epidemic and Communicable Disease Control
6 CCR 1009-1

Regulation 1. Reportable Diseases, Conditions, and Related Events

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Manner of Reporting

All cases are to be reported with patient's name, date of birth, sex ASSIGNED AT BIRTH, SEXUAL ORIENTATION, GENDER IDENTITY, 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 to locate the patient for follow up. THE PATIENT'S PREGNANCY STATUS SHALL BE REPORTED FOR CASES OF SYPHILIS AND HIV. THE PATIENT'S RELEVANT TREATMENT SHALL BE REPORTED FOR SEXUALLY TRANSMITTED INFECTIONS. 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. WHEN HOSPITALIZATION IS A CRITERIA FOR REPORTING (E.G., A HOSPITALIZED PATIENT WITH A POSITIVE TEST RESULT FOR 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. 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. 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). SELECT ~~For~~ healthcare-associated infections NOT COVERED BY, ~~except as provided in~~ §25-3-601, C.R.S., ARE LISTED BELOW IN 6 CCR 1009-1 APPENDIX A AND ALSO REPORTED TO NHSN. Facilities REPORTING OUTBREAKS OF HEALTHCARE-ASSOCIATED INFECTIONS AND THOSE 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 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, cases 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 day 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

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All specimens shall be accompanied by the following information: (a) Patient's name, date of birth, sex ASSIGNED AT BIRTH, SEXUAL ORIENTATION, GENDER IDENTITY, race, ethnicity, phone number, physical address (including city and county), email address, and preferred language; PREGNANCY STATUS SHALL BE REPORTED FOR CASES OF SYPHILIS AND HIV (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 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, 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, SEXUAL ORIENTATION, GENDER IDENTITY, 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, 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 (MTB)* and sputum smears positive for acid fast bacilli, and shall report the results of tests for antimicrobial susceptibility performed on positive cultures for tuberculosis.

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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) 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 ~~Denver~~ Public Health INSTITUTE AT DENVER 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.

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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 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 ~~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.

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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. 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 ~~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

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D. Upon receiving a complaint regarding the validity of a rabies inoculation exemption, the executive director or THEIR ~~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 THEIR ~~his/her~~ designee(s) may refer the case to the Board of Veterinary Medicine.

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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 ~~12-29.5-111~~, C.R.S., which states the Department shall promulgate rules relating to the proper USE ~~cleaning and sterilization~~ 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) used in connection with procedures involving equipment items shall be cleaned and disinfected with a disinfectant registered by the U.S. Environmental Protection Agency for use in health care settings according to labeled instructions. Equipment shall be defined as any needle, instrument, probe, or device utilized by practitioners of acupuncture that punctures the skin or enters tissue of any patient/client.~~

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

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

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) ~~AIDS~~ Resources Emergency Act-funded agency, other health agency or person providing direct services related to ~~sexually transmitted infections~~ STIS and the Department, as provided by § 25-4-406(1)(b), C.R.S.

With respect to Regulation 5, investigations related to ~~sexually transmitted infections~~ 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 ~~sexually transmitted infections~~ 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 ~~sexually transmitted infection~~ STIS.

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 ~~infection with~~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 ~~sexually transmitted disease~~ 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 ~~sexually transmitted infection~~ 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.

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* (SPECIES IN THE ~~including~~ ~~*A. cinetobacter baumannii*~~ complex, E.G., ~~and~~ *A. BAUMANII, A. CALCOACETICUS, A. LACTUCAE, A. NOSOCOMIALIS, A. PITTII, A. SEIFERTII,* ETC.)~~*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 [5,6]		24 hrs	P		Not applicable
Animal bites by mammals not listed above[5]		4 DAYS ~~hrs~~	P		Not applicable
Anthrax[5]	*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
BLASTOMYCOSIS	*BLASTOMYCES* SPECIES	4 DAYS	L & P	ALL	UPON REQUEST
Botulism[5]	*Clostridium botulinum*	Immed	L & P	All	Upon request
Brucellosis[5]	*Brucella* species	4 days	L & P	All	Required
Campylobacteriosis	*Campylobacter* species	4 days	L & P	All	Upon request
Candida auris[7]	*Candida auris*~~, Candida haemulonii~~	Immed	L & P	All	Required
Candidemia[8-Metro]	*Candida* species	30 days	L	Blood	Upon request
CARBAPENEMASE-PRODUCING ORGANISMS[9]	POSITIVE PHENOTYPIC TEST FOR CARBAPENEMASE PRODUCTION OR DETECTION OF A CARBAPENEMASE GENE	4 DAYS	L	ALL	REQUIRED
~~Catheter-associated urinary tract infection (CAUTI)~~	~~Any~~	~~Per CMS~~	~~P~~	~~Urine~~	~~Not applicable~~
Chancroid	*Haemophilus ducreyi*	4 days	L & P	All	Upon request

Chikungunya	Chikungunya virus	4 days	L	All	Upon request
Chlamydia, ANY SITE	*Chlamydia trachomatis*	4 days	L & P	All	Upon request
Cholera[5]	*Vibrio cholerae*	Immed	L & P	All	Required
CJD and other transmissible spongiform encephalopathies (TSEs)[5]		4 days	P	All	Upon request
Clostridium difficile infection[8-Metro]	*Clostridium difficile*	30 days	L	All	Upon request
COCCIDIOIDOMYCOSIS	*COCCIDIOIDES* SPECIES	4 DAYS	L & P	ALL	UPON REQUEST
Colorado tick fever	Colorado tick fever virus	4 days	L	All	Upon request
COVID-19[10]	• SARS-CoV-2 (POSITIVE NAAT AND RAPID ANTIGEN TESTS ~~positive result on any test type~~) • COVID-19 lineage or sequencing	~~1 working~~ 4 days	L & P	All	Upon request
COVID-19[10]	SARS-CoV-2 (negative or inconclusive result on any NAAT test ~~type~~)	~~1 working~~ 4 days	L & P	All	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
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[5]	*Corynebacterium diphtheriae*	Immed	L & P	All	Required
Encephalitis[5]		4 days	P	All	Upon request
EnterobacterALES~~iaccae~~, carbapenem-resistant (CRE)[11]	Carbapenem-resistant ENTEROBACTERALES INCLUDING, BUT NOT LIMITED TO, *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
EnterobacterALES~~iaccae~~, extended-spectrum beta-lactamase (ESBL)[8-Boulder,12]	*Escherichia coli* and *Klebsiella* species	4 30 days	L	All	Upon request
ESCHERICHIA COLI INVASIVE INFECTIONS[8-BOULDER]	*ESCHERICHIA COLI*	30 4 DAYS	L	STERILE ONLY	UPON REQUEST
Escherichia coli O157:H7 and Shiga toxin-producing *Escherichia coli*	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, INCLUDING DISSEMINATED GONORRHEA[3]	*Neisseria gonorrhoeae*	4 days	L & P	All	Upon request
Group A streptococci[14,8-Metro]	*Streptococcus pyogenes*	4 days	L	Sterile only	Required
Group B streptococci[8-Metro]	*Streptococcus agalactiae*	30 days	L	Sterile only	Required
Haemophilus influenzae	*Haemophilus influenzae*	1 working day	L & P	Sterile only	Required

Hantavirus disease[5]	Hantavirus	4 days	L & P	All	Upon request
Healthcare-associated infections[15]		4 days	P		Not applicable
Hemolytic uremic syndrome if <18 years[5]		4 days	P		Upon request
Hepatitis A[5]	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
HISTOPLASMOSIS	*HISTOPLASMA* SPECIES	4 DAYS	L & P	ALL	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)	*MYCOBACTERIUM LEPRAE*	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[5]	*Plasmodium* species	4 days	L & P	All	Upon request
Measles (rubeola)[5]	Measles virus	Immed	L & P	All	Upon request
Meningococcal disease[5]	*Neisseria meningitidis* or gram-negative *diplococci*	Immed	L & P	Sterile only	Required
Methicillin-Resistant *Staphylococcus aureus* (MRSA) bacteremia[17 ~~9~~]	Methicillin-Resistant *Staphylococcus aureus* (MRSA)	Per CMS[17 ~~9~~]	P	Blood	Not applicable
MPOX (MONKEYPOX)	MPOX VIRUS (ORTHOPOX VIRUS)	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
Mycobacterium, nontuberculous (NTM)[8-Metro]	*Mycobacterium* species (except *tuberculosis* complex,~~and~~ *M. leprae*, AND *M. GORDONAE*)	30 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[5]		Immed	L & P		Upon request

Pertussis (whooping cough)[5]	*Bordatella pertussis*	1 working day	L & P	All	Upon request
Plague[5]	*Yersinia pestis*	Immed	L & P	All	Required
Poliomyelitis[5]	Poliovirus	Immed	L & P	All	Upon request
Pseudomonas, carbapenem-resistant[18] ~~17~~	*Pseudomonas aeruginosa*	4 days	L	All	Upon request
Psittacosis	*Chlamydia psittaci*	4 days	L & P	All	Upon request
Q fever[5]	*Coxiella burnetii*	4 days	L & P	All	Upon request
Rabies: human (suspected)[5]	Rabies virus (Lyssavirus)	Immed	L & P	All	Upon request
RESPIRATORY SYNCYTIAL VIRUS-ASSOCIATED DEATH IF <18 YEARS	RESPIRATORY SYNCYTIAL VIRUS	4 DAYS	P		UPON REQUEST
Respiratory Syncytial Virus-associated hospitalizations~~[8 Metro]~~	Respiratory Syncytial Virus	4 days	L & P	All	Upon request
Rickettsiosis	*Rickettsia* 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	*Salmonella* species	4 days	L & P	All	Required
Shigellosis	*Shigella* species	4 days	L & P	All	Required
Smallpox[5]	Variola virus (Orthopox virus)	Immed	L & P	All	Upon request
Staphylococcus aureus, Vancomycin-non-susceptible[19] ~~18~~	Vancomycin non-susceptible *Staphylococcus aureus*	4 days	L	All	Required
~~Streptococcal toxic shock syndrome[20] 19~~	~~*Streptococcus pyogenes*~~	~~4 days~~	~~P~~	~~All~~	~~Required~~
Streptococcus pneumoniae[20] ~~19~~	*Streptococcus pneumoniae*	4 days	L	Sterile only	Required
Syphilis[5, 21]	*Treponema pallidum*	1 working day	L & P	All	Upon request
Tetanus[5]	*Clostridium tetani*	4 days	P	All	Upon request
Tick-borne relapsing fever[5]	*Borrelia* species AND SPIROCHETEMIA EXCEPT *BURGDORFERI* SPECIES	4 days	L & P	All	Upon request
Toxic shock syndrome[20] (STREPTOCOCCAL AND non-streptococcal)	*STREPTOCOCCUS PYOGENES AND NON-STREPTOCOCCAL BACTERIA*	4 days	P	ALL	Upon request
Trichinosis[5]	*Trichinella* species	4 days	P	All	Upon request
Tuberculosis disease (active)[5]	*Mycobacterium tuberculosis* ~~20~~[22]	1 working day	L & P	All	Required
Tuberculosis immune reactivity indicated by a positive interferon gamma release assay test (IGRA)	*Mycobacterium tuberculosis*[23] ~~21~~	4 days	L	All	Not Required
Tularemia[5]	*Francisella tularensis*	1 working day	L & P	All	Required
Typhoid fever[5]	*Salmonella* Typhi	1 working day	L & P	All	Required
Varicella (chicken pox)[5]	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)	West Nile virus	4 days	L	All	Upon request
Yellow fever	Yellow fever virus	4 days	L	All	Upon request
Yersiniosis[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 ASSIGNED AT BIRTH, SEXUAL ORIENTATION, GENDER IDENTITY, 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 AND HIV. 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 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 ASSIGNED AT BIRTH, SEXUAL ORIENTATION, GENDER IDENTITY, race, ethnicity, phone number, PHYSICAL ADDRESS (INCLUDING CITY AND COUNTY), email address, AND preferred language ~~and physical address~~; PREGNANCY STATUS SHALL BE REPORTED FOR CASES OF SYPHILIS AND HIV (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 and specimen type.

4 *Acinetobacter baumannii* (including SPECIES IN THE *A. BAUMANNII* COMPLEX, E.G., *A. BAUMANII, A. CALCOACETICUS, A. LACTUCAE, A. NOSOCOMIALIS, A. PITTII, A. SEIFERTII,* ETC.*)~~*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 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* ~~(e.g., *Candida haemulonii* identified by a laboratory instrument not equipped to detect *Candida auris*)~~. CLINICAL MATERIAL MAY NOT BE AVAILABLE FOR SCREENING TESTS.

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 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-B-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.

10 All POSITIVE SARS-CoV-2 results for all test types EXCEPT SEROLOGY/ANTIBODY TESTING AND AT-HOME ANTIGEN TESTS are reportable. Any individual as defined in Regulation 2, entity or facility that collects, performs, or tests for SARS-CoV-2~~-2~~ on specimens in Colorado is responsible for reporting all positive SARS-COV-2 TEST RESULTS. ~~negative and inconclusive SARS-CoV-2 test results and~~ SARS-CoV-2 sequencing lineage and mutation profile results, WHEN PERFORMED, SHALL ALSO BE REPORTED. FOR ANY NAAT OR MOLECULAR SARS-COV-2 TESTS CONDUCTED BY CLIA-CERTIFIED LABS, NEGATIVE AND INCONCLUSIVE RESULTS ARE ALSO REPORTABLE. ~~to public health within one working day of the result.~~ All entities required to report SARS-COV-2 ~~COVID-19~~ test result information shall report through CDPHE's electronic laboratory reporting (ELR) platform. REPORTING ENTITIES CAN REPORT DIRECTLY TO CDPHE ELR OR ~~For entities that cannot report through the ELR platform, electronic submission of the information required shall occur through HL7 or~~ THROUGH CDC PRIME'S REPORTSTREAM APPLICATION ~~CDPHE-approved flat file format via secure file transfer protocol (FTP), via the CDPHE web-based reporting portal~~, or other CDPHE-approved THIRD PARTY ~~method~~.

11 ENTEROBACTERALES INCLUDING, BUT NOT LIMITED TO, *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 EnterobacterALES~~iaceae~~ of any genus and species that test positive for production of carbapenemase (e.g., KPC, NDM, VIM, IMP, OXA-48, OTHERS). ~~demonstrated by a recognized test (e.g., modified carbapenem inactivation method [mCIM], polymerase chain reaction [PCR], nucleic acid amplification test [NAAT], metallo-beta-lactamase test, modified-hodge test [MHT], carba-NP).~~

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

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

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

15 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 ~~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.

18 ~~17~~ *Pseudomonas aeruginosa* resistant to at least one of the following carbapenems: imipenem, meropenem, or doripenem; OR *P.~~seudomonas~~ aeruginosa* that tests positive for production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA, OTHERS).

19 ~~18~~ *Staphylococcus aureus* that are non-susceptible to vancomycin, which include isolates with minimum inhibitory concentration (MIC) of ≥4 mcg/ml.

20 ~~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). FOR TOXIC SHOCK SYNDROME, SUBMISSION OF STREPTOCOCCUS PYOGENES ISOLATES FROM RESIDENTS OF THE 5-COUNTY METRO AREA IS REQUIRED.

21 ALL ASSOCIATED RESULTS FOR SYPHILIS SHALL BE REPORTED INCLUDING TREPONEMAL TESTS (ENZYME IMMUNOASSAY [EIA], CHEMOLUMINESCENCE ASSAY [CIA], FLUORESCENT TREPONEMAL ANTIBODY ABSORPTION [FTA-ABS], POLYMERASE CHAIN REACTION [PCR], MULTIPLEX FLOW IMMUNOASSAY [MFI], *TREPONEMA PALLIDUM* PARTICLE AGGLUTINATION [TP-PA], *TREPONEMA PALLIDUM* ANTIBODY [TPA]) AND NON-TREPONEMAL TESTS (RAPID PLASMA REAGIN [RPR],

VENEREAL DISEASE RESEARCH LABORATORY [VDRL], CEREBROSPINAL FLUID [CSF] QUANTITATIVE TITERS).

22 ~~20~~ Including (+) AFB sputum smear, culture (regardless of specimen site) and nucleic acid amplification tests (NAAT). See regulation 4f.

23 ~~21~~ All positive interferon gamma release assays (IGRAs) will be reported by labs capable of electronic laboratory reporting (ELR), and only reported by ELR.

Appendix B. Healthcare-Associated Infections

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

EXAMPLES OF healthcare-associated infections include:

Bloodstream infections

Bone and joint infections

Cardiovascular system infections

Central nervous system infections

Eye, ear, nose, throat, or mouth infections

Gastrointestinal system infections

~~Lower respiratory tract infections other than pneumonia~~

Pneumonia

Reproductive tract infections

Skin and soft tissue infections

Surgical site infections

Systemic infections

Urinary tract infections

ANTIMICROBIAL RESISTANT INFECTIONS

Health facility types include:

ACUTE CARE HOSPITALS

Ambulatory surgical centers

Birth centers

Convalescent centers

Dialysis treatment clinics/end-stage renal disease facilities

Hospices

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

INPATIENT REHABILITATION FACILITIES

LONG-TERM ACUTE CARE HOSPITALS

Long-term care facilities

OTHER HOSPITALS (E.G., PSYCHIATRIC, MATERNITY, SPECIALITY)

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

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