COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

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

Through: Tony Cappello, PhD, MPH DCEED Director TC

Date: April 1, 2019

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

---

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

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

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 new or changing communicable diseases; and align this rule with current practice, including advances in prevention, diagnosis, and treatment of communicable diseases.

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

- Negative (nonreactive) confirmatory assays for Hepatitis C virus (HCV) - reportable statewide;
- Respiratory syncytial virus (RSV)-associated hospitalizations - reportable in the 5-county metropolitan area;
- Nontuberculous mycobacteria (NTM) - reportable in the 5-county metropolitan area;
- Gram-negative bacteria resistant to colistin - reportable statewide;
- Updating the requirements for reporting of vancomycin-resistant Staphylococcus aureus to include isolates resistant or intermediate to vancomycin - reportable statewide;
- Updating the requirements and specimen submission for reporting of active tuberculosis (TB) disease to include laboratory reporting of positive nucleic acid amplification tests (NAATs) - reportable statewide;

- Requiring laboratories with electronic reporting capabilities to report all positive interferon gamma release assays (IGRAs) - a test for latent tuberculosis infection - reportable statewide;
- Expanding the reporting of carbapenem-resistant Acinetobacter baumannii (CRAB) currently reportable in the 5-county Denver metropolitan area for sterile sites and urine to statewide for all specimen sites; and
- Updating the language in Regulation 4 (I) to clarify that the list of healthcare providers required to notify public health prior to discharging a patient with active TB disease includes healthcare providers within jails, prisons, and other incarceration facilities.

The Department also proposes amendments to require submission of specimens or clinical material from laboratories statewide for the following reportable multi-drug resistant organisms:

- Carbapenem-resistant *Acinetobacter baumannii*
- Carbapenem-resistant Enterobacteriaceae
- Gram-negative bacteria resistant to colistin

In addition, the Department proposes technical changes throughout the rule that are intended to:

- Continue to bring clarity to the rule; and
- Minimize potential confusion among end-users of the rule.

The Department has contacted a wide variety of stakeholders to solicit input on these proposed amendments. The Department has heard concerns from a small number of stakeholders regarding an increased burden to them when the Department adds new reportable conditions or laboratory submission requirements. The Department believes that the proposed additions here are necessary to protect public health, respond to new or emerging issues, and improve the data available to the Department to monitor conditions of concern to public health. The Department remains committed to investigating alternative surveillance strategies, laboratory practices and technical solutions that may decrease burden.

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

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

Basis and Purpose.

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

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 new or changing communicable diseases; and align this rule with current practice, including advances in prevention, diagnosis, and treatment of communicable diseases. In addition to expanding the list of reportable conditions and specimen submission requirements, the Department proposes technical changes to the rule that are intended to:

- Continue to bring clarity to the rule; and
- Minimize potential confusion among end-users of the rule.

The Department also proposes non-substantive technical changes to use the same formatting for statutory citations and sub-paragraphs throughout the rule.

The following noteworthy changes to the rule are proposed:

1. The Department proposes making Hepatitis C virus (HCV) negative (nonreactive) confirmatory assays reportable by laboratories statewide. Hepatitis C is a liver infection caused by HCV and can range from a mild illness lasting a few weeks to a serious, lifelong illness. Hepatitis C infection is often described as "acute," meaning a new infection, or "chronic," meaning a lifelong infection. Current reporting of positive HCV test results (screening and confirmatory) is no longer adequate to perform hepatitis C surveillance in Colorado. Advances in hepatitis C treatment have resulted in a growing population of people who have been successfully cured of their chronic infection. This is a positive trend but it is difficult to account for cured individuals when measuring the overall burden of hepatitis C in Colorado. This has not only impacted hepatitis C surveillance but has also expanded public health's role in hepatitis C surveillance to include monitoring treatment rates and access to care. Reporting of negative confirmatory assays will allow the Department to 1) accurately classify the proportion of Coloradans who are currently infected with HCV, 2) estimate the proportion of patients cured of HCV annually, 3) estimate the number of Coloradans who have received treatment and been re-infected with HCV post-treatment, 4) identify providers and areas where screening, but not confirmatory testing, is performed to improve HCV care, and 5) determine linkage to HCV care and treatment and identify unmet healthcare needs. This proposed change is reflected in the Reportable Diseases Table in Appendix A. To distinguish between reporting

Hepatitis C virus (+ serum antibody titer and/or positive (+) confirmatory assays) that are reportable by laboratories and providers, and negative (–) confirmatory assay reporting that are reportable by laboratories, a second row was added to table.

2. The Department proposes making respiratory syncytial virus (RSV)-associated hospitalizations reportable in the 5-county Denver metropolitan area (Adams, Arapahoe, Denver, Douglas and Jefferson counties). RSV is the most common cause of hospital admission for respiratory illness in children in the US and a leading cause of admission for adults with respiratory illness. RSV is an under-recognized cause of respiratory illness but has been estimated to annually cause approximately 177,000 hospitalizations and 14,000 deaths among adults over 65, and 57,527 hospitalizations and 200 deaths among children less than 5 years. Routine surveillance is needed to more precisely measure the burden of disease in adults and children and support the development of prevention and treatment strategies. Numerous products to prevent RSV infections are in development that directly target infants, older children, or adults, or indirectly target infants though maternal immunization. RSV surveillance and population-based estimates of disease burden are needed to inform vaccination strategies and establish a baseline for future evaluation of vaccine impact. This proposed change is reflected in the Reportable Diseases Table in Appendix A.

3. The Department proposes to make nontuberculous mycobacteria (NTM) reportable by laboratories in the 5-county Denver metropolitan area (Adams, Arapahoe, Denver, Douglas, and Jefferson counties). Mycobacteria include a variety of species, including species causing tuberculosis and leprosy; the latter two conditions are not included in the category of NTM. NTM are a diverse group of bacteria, comprised of more than 180 species that are commonly found in the environment, including in soil and water. These bacteria can cause serious lung, skin, lymph node, or soft tissue infections, as well as more widespread disease in people who are immunocompromised. Scientific literature suggests that rates are increasing nationally. The Centers for Disease Control and Prevention (CDC) and the Council of State and Territorial Epidemiologists (CSTE) have made NTM surveillance and outbreak investigations a public health priority. The burden of NTM in Colorado is unknown; however, based on surveillance performed in other states, we estimate there are approximately 300 cases of NTM annually in the 5-county Denver metropolitan area. The primary purpose of surveillance is to monitor trends over time and detect outbreaks, which have been linked to healthcare facilities and community settings such as nail salons and tattoo parlors. Reporting will be by laboratory, preferably electronically via current systems to minimize burden. Funding through the CDC's Emerging Infections Program is limited, and available for the 5-county Denver metropolitan area; however, if successful this may serve as a pilot for expanding surveillance statewide in future years. This proposed change is reflected in the Reportable Diseases Table in Appendix A.

4. The Department proposes expanding carbapenem-resistant *Acinetobacter baumannii* (CRAB) currently reportable in the 5-county Denver metropolitan area for sterile sites and urine to statewide for all specimen sites. The Department proposes requiring specimen submission for CRAB so that these isolates can be tested to determine if unusual mechanisms of resistance are present (carbapenemases) that would require additional public health action. Carbapenem-resistant organisms continue to be a public health priority, particularly in

healthcare settings, since they are difficult to treat, can be transmitted person-to-person even if no infection is apparent, and because public health has a role in providing recommendations for the prevention of transmission. Limited CRAB surveillance has been useful to understand burden, provide infection prevention recommendations to healthcare facilities, and detect one outbreak to date. However, since not all cases of CRAB are reportable, we are limited in our ability to detect outbreaks and provide infection prevention recommendations to decrease transmission for all cases. The burden of this reportable condition is very low and based on our experience with surveillance in the 5-county Denver metropolitan area, we have sufficient resources to conduct statewide surveillance. Since surveillance began in 2013, 34 cases of CRAB have been reported, for an average of 6 per year; CRAB is rare in Colorado. After speaking with laboratories currently conducting surveillance for CRAB, we anticipate cases increasing to approximately 25-35 cases per year following expansion to the entire state and all specimen types. Additionally, the Department proposes shortening the time for reporting from 30 days to 4 days, and requiring the submission of isolates. This change will allow the Department to identify outbreaks, confirm outbreaks with isolate testing, and provide infection prevention recommendations in a timely manner. Currently, isolates that are non-susceptible (intermediate or resistant) to carbapenems are reportable. To align with the current national case definition, the Department proposes dropping the requirement for intermediate susceptibility and only requiring reporting and submission of resistant isolates. These proposed changes are reflected in the Reportable Diseases Table in Appendix A.

5. The Department proposes to make Gram-negative bacteria resistant to colistin reportable by laboratories statewide and to require submission of isolates. Colistin is an antibiotic that is typically used to treat very resistant infections with Gram-negative bacteria, and often is a last-resort antibiotic. Colistin resistance may indicate the presence of an emerging mechanism of antibiotic resistance, called *mcr*. Similar to carbapenem-resistant Enterobacteriaceae (CRE) and CRAB, colistin-resistant organisms can be transmitted between patients and are difficult to treat. Public health can intervene to provide infection prevention recommendations to decrease the transmission of organisms harboring *mcr* and prevent outbreaks. No cases of colistin resistance with *mcr* have yet been detected in Colorado. Colistin resistance is rare, and the burden of reporting is expected to be low. Additionally, organisms with intrinsic resistance to colistin (*Proteus* spp., *Serratia* spp., *Providencia* spp., *Morganella* spp., *Neisseria* spp., *Brucella* spp., *Burkholderia* spp.) are exempt from reporting. This proposed change is reflected in the Reportable Diseases Table in Appendix A.

6. The Department proposes to clarify reporting for vancomycin-resistant *Staphylococcus aureus* (VRSA) to include vancomycin-intermediate *Staphylococcus aureus* (VISA). VRSA has been reportable since 1996 and Colorado has never had a case. However, VRSA remains a public health concern because vancomycin is a key antibiotic used to treat many serious bacterial infections. Continued VRSA surveillance is needed to ensure early detection and containment. This change is proposed in response to a national recommendation that VISA isolates be considered suspect VRSA cases and have confirmatory testing done at state public health labs and CDC. To rule out VRSA, the Department proposes that laboratories report and submit VISA (e.g., suspected VRSA) isolates in addition to VRSA. Antibiotic susceptibility is measured by determining the level of the antibiotic (minimum inhibitory concentration or MIC) that

prevents growth of the organism. There are defined, quantitative antibiotic levels at which an organism is considered susceptible, intermediate, or resistant. VRSA is defined as an isolate of *S. aureus* with a MIC of ≥16 µg/ml; VISA is defined as an isolate of *S. aureus* with an MIC of 4-8 µg/ml. CDC guidance specifies that *S. aureus* isolates with an MIC ≥4 µg/ml (which includes VISA and VRSA) should have the MIC value confirmed by confirmatory tests at the state laboratory and CDC. This proposed change is reflected in the Reportable Diseases Table in Appendix A.

7. The Department proposes modification of isolate submissions for carbapenem-resistant Enterobacteriaceae (CRE). Isolates of CRE, reportable statewide, are currently listed in the regulations as "requested." The Department proposes modification of isolates be changed to "required." By requiring submission of all CRE isolates, the state laboratory will test all submitted isolates for specific mechanisms of carbapenem-resistance that require additional public health recommendations for infection control to prevent transmission. Requiring all isolates will allow for the identification of all carbapenemase-producing CRE. Most laboratories currently submit isolates, so the added burden is expected to be low for most laboratories. This proposed change is reflected in the Reportable Diseases Table in Appendix A.

8. The Department proposes two changes to the reporting for tuberculosis. The first change is an administrative update to align reporting of active tuberculosis disease (TB) with current practice. The second change (see #9) is a new laboratory reporting requirement that is a precursor to reporting of latent tuberculosis infection (LTBI). TB is a potentially serious infectious disease that mainly affects the lungs. Caused by bacteria, TB is spread through the air from infected people and can be fatal if not treated. The Department proposes amending the requirements for reporting of active TB to include laboratory reporting of positive nucleic acid amplification tests (NAATs). NAATs are a newer testing option for active TB but have gained widespread use with their demonstrated utility in reliably and rapidly identifying active TB disease, a one (1) working-day reportable condition. Thus, this proposed addition of positive NAAT results aligns rule language with current practice and with the current national case definition, which includes patients with positive NAAT results. This proposed change is reflected in the Reportable Diseases Table in Appendix A. A portion of the language found in current Regulation 4 (E) was relocated within the table in Appendix A, and in Table footnote 18.

9. The Department proposes requiring laboratories with electronic reporting capabilities statewide to report all positive interferon gamma release assays (IGRAs). IGRA tests detect tuberculosis infection, including latent infections. Someone has LTBI if they are infected with the TB bacteria but do not have signs of active TB disease and do not feel ill. However, they can develop active TB disease in the future. Currently, the Department has very little information regarding people with TB infection, but an estimated 75-80 percent of all cases of TB disease originate from untreated or incompletely-treated cases of latent TB infection. The Department believes that eventually making LTBI reportable will improve surveillance of TB throughout the state. However, making LTBI a reportable condition is not feasible at this time due to the burden this would create among clinicians, who currently depend largely on non-laboratory based skin testing. As IGRA becomes the standard of care and replaces skin testing,

we expect that it will become feasible to propose LTBI as a reportable condition in the near future. What is feasible now, as a first step toward making LTBI reportable, is to collect IGRA results that are electronically available. Information that we gather with IGRA reporting as an interim measure will help us estimate the burden of LTBI in Colorado, plan for future comprehensive LTBI reporting, and explore reporting systems and follow-up strategies. This proposed reporting requirement also supports the recently published 2018 Technical Instructions for Civil Surgeons[1] that requires the use of IGRAs for TB testing of all immigration status adjustment applicants. This proposed change is reflected in the Reportable Diseases Table in Appendix A.

10. The Department proposes to update language in Regulation 4(I) to improve continuity of care and uninterrupted treatment of patients with active TB disease. Regulation 4(I) currently requires hospitals and healthcare facilities to notify public health prior to discharging a patient with active TB disease. The Department proposes clarifying the language to ensure physicians and healthcare providers serving patients held within jails, prisons and other correctional or detention facilities notify local public health officials when inmates with active TB are discharged to a community setting. These changes are proposed to ensure adequate follow-up and coordination among healthcare providers and public health so that continuity of care and directly observed therapy (DOT) standards are met. Releasing TB patients without these measures jeopardizes the individual's health and puts the public at risk of exposure to TB.

11. The language proposed to be deleted in 4(E) is intended to clarify that the Department requires a positive mycobacterium tuberculosis (MTB) culture be sent to the state laboratory for further drug-susceptibility testing, not a sputum specimen. The proposed deletions in 4(K)(2) and (3) are intended to remove language that is out of date, or no longer relevant or required.

12. In Appendix A, the "Send Clinical Material" column of the table was updated because blanks in the table were subject to misinterpretation. The column now identifies when clinical material is required, required upon request, not required or not applicable, to ensure laboratories and providers understand when to retain and when to submit clinical material.

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.

Statutes that inform or direct the rule content: Sections 25-4-502 C.R.S.

Is this rulemaking due to a change in state statute?

_____ Yes, the bill number is _____. Rules are ___ authorized ___ required.

__X___ No

[1] https://www.cdc.gov/immigrantrefugeehealth/exams/ti/civil/technical-instructions-civil-surgeons.html

Does this rulemaking incorporate materials by reference?

_____ Yes ___ URL or ___ Sent to State Publications Library

__X___ No

Does this rulemaking create or modify fines or fees?

_____ Yes

__X___ No

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

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

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

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

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

   A. Identify each group of individuals/entities that rely on the rule to maintain their own businesses, agencies or operation, and the size of the group:

      Infection control and clinical laboratory personnel at approximately 90 clinical laboratories (including three outpatient laboratories) and approximately 100 hospitals, healthcare providers throughout the state, personnel at 53 county, district or municipal public health agencies (LPHAs), the Department's subcontracted community-based organizations that perform HCV blood draws, personnel at local US Immigration and Customs Enforcement, Department of Corrections, the Colorado Jail Association and private providers who treat TB patients and serve on the Department's Tuberculosis Elimination Workgroup.

   B. Identify each group of individuals/entities interested in the outcomes the rule and those identified in #1.A achieve, and if applicable, the size of the group:

      Community-based or advocacy organizations such as Parents of Kids with Infectious Diseases (PKIDS), professional organizations such as the Colorado Medical Society or Colorado Association of Local Public Health Officials (CALPHO), federal agencies such as CDC, the Colorado HIV Alliance, the Colorado Viral Hepatitis Task Force, and the general public.

   C. Identify each group of individuals/entities that benefit from, may be harmed by or at-risk because of the rule, and if applicable, the size of the group:

      LPHAs, the Department, entities required to report, and the general public will benefit from the proposed changes to the rule. Many of the proposed changes will allow the Department to collect data on and respond to emerging public health issues and allow for a more complete reporting of diseases of public health importance. LPHAs, the Department, and entities required to report, will benefit from the proposed changes to the rule that clarify the reporting requirements and/or update the reporting requirements to match the latest diagnostic technology or current practice standards making timelier, more complete, and actionable data available.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

   A. Identify each group of individuals/entities that rely on the rule to maintain their own businesses, agencies or operation, and the size of the group:

Favorable non-economic outcomes: Healthcare providers, laboratories, and hospital infection preventionists are the primary reporters of conditions included in the Reportable Disease Table in Appendix A. Many of the proposed changes to this rule will result in clarification for consistent interpretation by end-users of the rule, practice shifts to increase efficiency by end-users of the rule, updated language to reflect best practices and new diagnostic technology, and more consistent formatting; all of which the Department expects will result in improved customer experience.

Although laboratories will have additional reporting and submission requirements for antimicrobial resistant infections, all laboratories and the healthcare facilities they serve will receive the results of testing performed by the state laboratory on isolates (including CRE, CRAB, and Gram-negative organisms resistant to colistin) that can and should be used inform facility infection prevention efforts resulting in decreased spread of these organisms. Early detection of infections due to antimicrobial resistant organisms and NTM via routine surveillance will halt the spread of disease and prevent outbreaks.

Unfavorable non-economic outcomes: The addition of reportable conditions and laboratory submission requirements increases the reporting burden on laboratories and providers. To minimize the burden, the Department favors electronic reporting whenever possible. At this time, all large commercial and hospital laboratories report electronically or are in the process of on-boarding. Approximately 90% of reportable test results are received electronically. The Department provides technical support to all laboratories interested in electronic reporting. With electronic reporting in place, the burden of reporting involves a one-time programming change to add or modify reportable conditions. With the exception of RSV, all proposed new reportable conditions are reportable through electronic laboratory systems. For RSV, the Department is working with the Colorado Regional Health Information Organization (CORHIO), to develop electronic case reporting technology that would minimize the burden of reporting by hospital infection preventionists.

Economic outcomes: The proposed changes include additions of healthcare-associated infections to the list of reportable conditions necessitated by changes in conditions of public health concern. These changes will require some additional laboratory or healthcare provider staff time to report. Modification of vancomycin-resistant *S. aureus* is expected to add very little burden as the condition is rare, as are colistin-resistant Gram negative bacteria. The addition of additional specimen sites and expansion statewide of the already reportable CRAB is also expected to be low-burden to laboratories across the state. NTM will add approximately 300 reports for laboratories serving the 5-county Denver metropolitan area, but the burden will be minimized by the use of electronic laboratory reporting; isolates will not be requested except in the case of an outbreak, which is rare. The requirement of isolates for CRE might add additional burden for some laboratories that currently submit only some isolates; 5-county Denver metropolitan area laboratories already do so, and many laboratories outside of the Denver metropolitan area do not have a high burden of CRE. For the laboratories for which the burden of submission will increase, CDPHE staff will work with them to minimize burden when possible. It is not anticipated that the proposed changes will increase local public health costs and improved reporting

may increase timely investigation. However, state and local investigation costs will continue to be incurred.

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

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

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

Favorable non-economic outcomes:
Those who live, work and play in Colorado rely on the Department to collect timely information on communicable diseases of public health concern. Proposed changes to this rule optimize the data collected so that the Department can take reasonable actions to protect and inform the public, thereby preventing the occurrence of additional cases of communicable diseases and potential outbreaks. As previously described, surveillance data on RSV that is collected in Colorado will directly contribute to the development of new national RSV vaccination recommendations. Future at-risk children and adults will be protected from the morbidity and mortality associated with RSV infections. Clarifying the language around coordination of care for patients with TB disease will protect those patients from treatment failure and society from the development of resistant TB organisms.

Unfavorable non-economic outcomes: N/A

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

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

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

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

several of the proposed additions relate to antibiotic-resistant healthcare-associated infections. Better detection of these organisms will enable critical public health action to limit the spread of these organisms in a facility and potentially reduce related morbidity and mortality, thereby benefiting Coloradans experiencing health problems and accessing healthcare services.

Financial costs to these individuals/entities: N/A

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

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

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

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

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

Anticipated Revenues for another state agency: N/A

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

Check mark all that apply:

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

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

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

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

XX The proposed revisions implement stakeholder feedback.

XX The proposed revisions advance the following CDPHE Strategic Plan priorities:

Goal 1, Implement public health and environmental priorities Goal 2, Increase Efficiency, Effectiveness and Elegance

Goal 3, Improve Employee Engagement Goal 4, Promote health equity and environmental justice Goal 5, Prepare and respond to emerging issues, and Comply with statutory mandates and funding obligations

Strategies to support these goals:

___ Substance Abuse (Goal 1)
___ Mental Health (Goal 1, 2, 3 and 4)
___ Obesity (Goal 1)
___ Immunization (Goal 1)
___ Air Quality (Goal 1)
___ Water Quality (Goal 1)
XX Data collection and dissemination (Goal 1, 2, 3, 4 and 5)
___ Implements quality improvement or a quality improvement project (Goal 1, 2, 3 and 5)
___ Employee Engagement (career growth, recognition, worksite wellness) (Goal 1, 2 and 3)
___ Incorporate health equity and environmental justice into decision-making (Goal 1, 3 and 4)
XX Establish infrastructure to detect, prepare and respond to emerging issues (Goal 1, 2, 3, 4, and 5)

___ Other favorable and unfavorable consequences of inaction:

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

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. The specific revisions proposed in this rulemaking were developed in conjunction with 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.[2] The benefits, risks and costs of these proposed revisions were compared to the costs and benefits of other options. The proposed revisions provide the most benefit for the lowest cost, are the minimum necessary or are the most feasible manner to achieve compliance with statute. As previously described, the Department favors less burdensome electronic laboratory reporting, whenever possible.

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

Few alternative methods for achieving the purpose of the proposed rules were considered because the statute refers to rulemaking and this rule utilizes the widely accepted and proven public health methodology of epidemiologic surveillance and laboratory investigation.

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

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

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

   - According to the CDC, Hepatitis C Virus (HCV) infection becomes chronic in approximately 75-85% of cases, meaning that 15-25% of individuals will self-resolve the virus without treatment. This cohort is unaccounted for in current disease reporting. Additionally, CDC states that over 90% of HCV-infected persons can be cured of HCV infection regardless of genotype with 8-12 weeks of oral therapy. The treated cohort is another population that is not accurately reflected by current disease reporting.[3] Reporting of HCV negative RNA test results is needed to more accurately describe disease burden of HCV in the context of curative treatment and self-resolution of infection.

     Additionally, the decision to propose reporting of HCV negative RNA test results is modeled after other states' laws, including Washington State, where this change has helped the state to better understand the epidemiology of HCV and the burden of morbidity from chronic infection.

   - According to CDC, Respiratory Syncytial Virus (RSV) is the most common cause of hospital admission for respiratory illness in children in the US and a leading cause of admission for adults with respiratory illness. Nationally, RSV has been estimated to cause approximately 177,000 hospitalizations and 14,000 deaths in older adults and 57,527 hospitalizations among children less than 5 years[4]. RSV surveillance and population-based estimates of disease burden are needed to inform vaccine strategies and establish a baseline for future evaluation of vaccine impact.

   - In 2017, the Council of State and Territorial Epidemiologists (CSTE) approved a position statement[5] creating a "Standardized Case Definition for Extrapulmonary Nontuberculous Mycobacteria [NTM] Infections" in order to assist states in establishing NTM surveillance for the purpose of identifying and stopping outbreaks. Based on published reports and discussions with several other states where NTM is reportable, as well as with one Colorado laboratory, we estimate that there will be approximately 300 reports of NTM in the 5-county Denver metropolitan area per year (range 94-368 cases/year).

   - Colistin is considered a last-resort antibiotic because it can be used to treat patients with infections that have already developed resistance to other antibiotics. CDC is actively searching for and identifying the *mcr* colistin resistance mechanism in bacteria in the U.S. So far it has been identified in 21 states but not yet in Colorado.[6] A Colorado surveillance system for colistin resistance and *mcr* would allow for early detection and containment.

[3] https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm
[4] https://www.cdc.gov/rsv/research/us-surveillance.html
[5] https://cdn.ymaws.com/www.cste.org/resource/resmgr/2017PS/2017PSFinal/CDC_OID_Response_to_17CC01_a.pdf
[6] https://www.cdc.gov/drugresistance/biggest-threats/tracking/mcr.html

- The Department has very little information regarding people with TB infection, but an estimated 75-80 percent of all cases of TB disease originate from untreated or incompletely-treated cases of latent TB infection.[7] Information that we gather with IGRA reporting as an interim measure will help us estimate the burden of LTBI in Colorado, plan for future comprehensive LTBI reporting, explore reporting systems and follow-up strategies and supports multiple goals and activities in Colorado's TB elimination Plan.[8] Specifically, these goals are:
    - Goal 1: Find and engage individuals and populations at-risk for TB infection
        - Use data-driven epidemiological profiles and surveillance systems to identify those most at-risk for progressing from TB infection to TB disease.
    - Goal 2: Test those at-risk for TB infection and progression to TB disease so individuals know their status
        - Evaluate those with positive tests to diagnose and/or exclude active or inactive TB.
        - Recommend treatment based upon the risk of progression to active TB disease.
    - Goal 3: Ensure completion of treatment of those diagnosed with TB infection
        - Utilize efficacious short-course therapies when appropriate to achieve treatment completion for TB infection.

[7] P A LoBue, J H Mermin, Latent Tuberculosis Infection: The Final Frontier in TB Elimination in the U.S. Lancet Infect Dis 2017 Published Online May 8, 2017 http://dx.doi.org/10.1016/ S1473-3099(17)30248-7

[8] https://drive.google.com/open?id=0B2o0IwpCuPw7MlpSVlVxd2JGQ2M

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

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

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

Colorado healthcare providers, Colorado hospital infection preventionists and lab directors, LPHAs, Colorado Regional Epidemiologists, Association for Professionals in Infection Control (APIC), Colorado reference lab contacts, Colorado Chapter of the American Society for Clinical Laboratory Science, Colorado Hospital Association, Colorado Medical Society, the Department's Office of Emergency Preparedness, the Department's Health Facilities and Emergency Medical Services Division, the Department's Laboratory Services Division, private healthcare providers who participate in the Department's TB elimination workgroup, the Colorado Department of Corrections, and the Immigration and Customs Enforcement Regional Coordinator.

Targeted outreach conducted:

- Emails sent to the above contacts on 12/21/2018, 12/27/2018, 1/14/2019, and 1/17/2019.
- Webinars on Wednesday, January 9, 2019 and Monday, January 14, 2019 to discuss proposed changes.
- In-person meeting with the Mile High Chapter of the Association for Professionals in Infection Control and Epidemiology (APIC) on 1/18/2019. APIC Mile High Colorado is a professional association of Infection Preventionists in Colorado, a key stakeholder group.

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

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

_X___ Yes.

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

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

The Department has heard concerns from a small number of stakeholders regarding an increased burden to them when the Department adds new reportable conditions or laboratory submission requirements. The Department believes that the proposed addition of reportable conditions is necessary to protect public health, respond to new or emerging issues, and improve the data available to the Department. Furthermore, the advent and expansion of electronic laboratory reporting means that when the Department does propose a new reportable condition, laboratories that report electronically make a one-time programming change to accommodate the new condition, but the ongoing burden of reporting is minimal. The majority of labs already report electronically. Currently, approximately 90% of reportable test results are received electronically. With the exception of RSV, all proposed new reportable conditions are reportable through electronic laboratory systems. For RSV, the Department is working with CORHIO to develop electronic case reporting technology that would minimize the burden of reporting by hospital Infection Preventionists. The requirement of isolate submission for CRE might add additional burden for some laboratories that currently submit only some isolates; however, 5-county Denver metropolitan area laboratories already do so, and many laboratories outside of the Denver metropolitan area do not have a high burden of CRE. For the laboratories for which the burden of submission will increase, CDPHE staff will work with them to minimize burden when possible.

The Department incorporated early stakeholder feedback regarding HCV and LTBI to modify the proposed reporting methods required, and to further clarify the proposed use of the data so that the burden on stakeholders could be decreased. As previously described, the Department favors less burdensome electronic laboratory reporting and, thus, has proposed electronic laboratory reporting in place of provider reporting, wherever possible. Because electronic laboratory reporting is not possible for RSV, the Department is exploring other electronic solutions.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking. Overall, after considering the benefits, risks and costs, the proposed rule:

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.	X	Reduces or eliminates healthcare costs, improves access to healthcare 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,		Reduces occupational hazards; improves an individual's ability to secure or

	community services, built environment, safe physical spaces or transportation.		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.		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 healthcare workforce.
	Other:_____ _____		Other:_____ _____

~~Strikethrough~~ text indicates text that is proposed to be deleted.
TEXT IN ALL CAPS or highlighted in yellow indicates proposed new text.

++

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Disease Control and Environmental Epidemiology Division

EPIDEMIC AND COMMUNICABLE DISEASE CONTROL

6 CCR 1009-1

_____

Adopted by the Board of Health on _____. Effective _____.

Regulation 1. Reportable Diseases

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

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

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

Manner of Reporting

All cases are to be reported with patient's name, date of birth, sex, race, ethnicity, and address (including city and county) and name and address of responsible physician or other healthcare provider; and such other information as is needed to locate the patient for follow up. In addition, all laboratory information reported shall include specimen accession number. For animal bites by dogs, cats, bats, skunks, foxes, raccoons, coyotes, and other wild carnivores, the name and locating information of the owner of the biting animal shall be reported, if known, by the healthcare provider. For healthcare-associated infections, except as provided in § 25-3-601, C.R.S., facilities choosing to voluntarily participate in applied public health projects on a project by project basis shall make medical

records available for review by the Department upon request within a reasonable time frame. In addition, for sexually transmitted infections, the patient's sex at birth, gender identity and relevant treatment shall be reported. For reports from a ~~publically~~ 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 Table and Footnotes to determine time frame for reporting (from diagnosis or test result), who shall report, the reporting area, whether laboratory information is required for a report, and whether an isolate or clinical material must be sent to the Department, Laboratory Services Division.

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

The Department shall develop systems and forms for reporting for physicians, other healthcare providers and hospitals. When hospitals and laboratories transmit disease reports electronically using systems and protocols developed by the Department or Federal agencies that ensure protection of confidentiality, such reporting is acceptable and is considered good faith reporting.

...

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 (~~C.R.S.~~ § 25-4-501, et seq., C.R.S.) covers subject matters not included in these regulations.

A. All confirmed or suspected cases of active tuberculosis disease, regardless of whether confirmed by laboratory tests, shall be reported to the Department or county, district, or municipal public health agency within 1 working day by physicians, healthcare providers, hospitals, other similar private or public institutions, or any other person providing treatment to the confirmed or suspected case. The reports shall include the following information: the patient's name, date of birth, sex, race, ethnicity, address (including city and county), name and address of the reporting physician or agency; and such other information as is needed to locate the patient for follow-up. If reported by a physician, the physician shall also give the evidence upon which the diagnosis of tuberculosis was made, the part of the body affected, and the stage of disease.

B. Physicians, healthcare providers, and healthcare facilities shall report within 7 calendar days the following tuberculin skin test (TST) or Interferon-Gamma Release Assay (IGRA) result if it occurs in a healthcare worker, correctional facility worker, or detention facility worker; a positive TST (defined as = or > 5 mm induration) or positive IGRA test (based on manufacturer's interpretation criteria) if the worker has had prolonged or frequent face-to-face contact with an infectious tuberculosis case.

C. Laboratories shall report within 1 working day any result diagnostic of or highly correlated with active tuberculosis disease, including culture positive AND NUCLEIC ACID AMPLIFICATION TESTS (NAAT) POSITIVES for *Mycobacterium tuberculosis* and sputum smears positive for acid fast bacilli, and shall report the results of tests for antimicrobial susceptibility performed on positive cultures for tuberculosis.

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

E. ~~A laboratory may fulfill its requirement to report (in parts C and D of this regulation) by submitting a sputum specimen from the patient to either the Department, Laboratory Services Division, or for facilities located in Boulder, Broomfield, Denver, Adams, Douglas, Arapahoe, and Jefferson counties, to the Denver Public Health laboratory. The reporting requirement is not fulfilled if the laboratory submits an isolate from a culture to either of the public health laboratories or if the laboratory delays sending the sputum specimen for more than 2 calendar days after collection of the specimen.~~

F. When a laboratory performs a culture that is positive for *Mycobacterium tuberculosis*, the laboratory shall submit a sample of the isolate to the Department, Laboratory Services Division no later than one working day after the observation of positive findings.

G. 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.

H. The Board of Health determines that to prevent the emergence of multi drug-resistant tuberculosis (MDR-TB), it is necessary~~, and~~ appropriate and good medical practice ~~that~~ FOR persons with active tuberculosis disease TO receive directly observed THERAPY ~~treatment~~ (DOT) for their disease. All healthcare providers and healthcare organizations are required to provide ~~directly observed therapy~~ DOT for patients with active tuberculosis disease for the full course of therapy, unless a variance for a particular patient from this requirement is approved by the tuberculosis control program of the Department or Denver Public Health. DOT ~~irectly observed therapy~~ is not required for patients with extrapulmonary tuberculosis disease provided that the presence of pulmonary tuberculosis has been investigated and excluded. In applicable situations, a variance shall be granted in accordance with ~~C.R.S.~~ § 25-4-506(3), C.R.S.

Healthcare providers and healthcare organizations shall report to the Department or county, district, or municipal public health agency within 7 calendar days the name of any patient on DOT who has missed one dose. When requested by healthcare providers and healthcare organizations, ~~the Department or~~ the county, district, or municipal public health agency WILL ENSURE THE PROVISION OF ~~shall provide~~ DOT ~~directly observed treatment~~ to outpatients with active tuberculosis disease and this shall fulfill the requirement for the healthcare providers and healthcare organizations.

I. All HEALTHCARE PROVIDERS WITHIN JAILS, PRISONS, AND OTHER INCARCERATION FACILITIES AND hospitals and healthcare facilities providing ~~in-patient~~ INPATIENT treatment to persons with active tuberculosis disease shall notify the Department or county, district, or municipal public health agency ~~immediately after plans are made~~ OF THEIR INTENT TO DISCHARGE A PATIENT AND INVOLVE THE DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY IN THE DISCHARGE PLANNING PROCESS PRIOR to DISCHARGING ~~discharge~~ the patient from the facility. The INTENTION OF THE notification AND INVOLVEMENT IN DISCHARGE PLANNING is ~~intended~~ to discuss the treatment plan for

the patient and to assure adequate follow-up and coordination among HEALTHCARE providers AND PUBLIC HEALTH so that ~~the~~ CONTINUITY OF CARE AND THE DOT standard ~~of directly observed treatment is~~ ARE met.

J. All licensed hospitals and nursing home facilities shall maintain a REGISTRY ~~register~~ of the TST and/or IGRA test results of healthcare workers in their facility, including physicians and physician extenders who are not employees of the facility but provide care to or have face-to-face contact with patients in the facility. The facility shall maintain such TST and IGRA test results as confidential medical information. Pursuant to ~~C.R.S.~~ § 25-4-508, C.R.S., authorized personnel of the Department may inspect and have access to such register in the course of an investigation intended to identify sources and contacts of a case of active tuberculosis disease and to control tuberculosis.

K. (1) With respect to tuberculosis treatment and control, the chief medical officer of a county, district, or municipal public health agency must be a physician licensed to practice medicine in the State of Colorado. The chief medical officer of a county, district, or municipal public health agency may design a program, consistent with good medical practice, of required screening for latent tuberculosis infection. The objective of the program must be to target persons who are at high risk of such infection based on recent local, state, national, or international epidemiologic data concerning the incidence of and risk factors for tuberculosis. The programs shall be limited to screening persons who ARE AT INCREASED RISK OF TUBERCULOSIS (TB) INFECTION OR TB DISEASE OR WHO participate in activities or who work in occupations and job categories that have a reasonably large proportion of persons at increased risk of tuberculosis. The programs should be designed so that the initial step in screening is the determination of whether a person has recognized risk factors for tuberculosis and if yes, then said person should undergo a TST or IGRA test and clinical evaluation TO RULE OUT TB DISEASE. If free of signs and symptoms of tuberculosis DISEASE, subsequent testing would be dependent on the results of the TST or IGRA test.

~~(2) The chief medical officer of a county, district, or municipal public health agency, with the prior approval of the local board of health and pursuant to the requirements of subparagraph 3 of this paragraph K, may require screening be performed for a particular group or population that has been identified as high risk based on the criteria set forth in this paragraph K, but each individual shall be informed of his or her right to be exempt from the screening because of medical or religious reasons. The county, district, or municipal public health agency should provide at least 30 calendar days notice to potentially affected persons, groups, and businesses prior to consideration of the proposed program by the local board of health.~~

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

(2~~-4~~) If an individual has signs and symptoms compatible with tuberculosis in the infectious stages, the chief medical officer may require examination pursuant to § 25-4-506, C.R.S. The screening may be performed by an institution, organization, or agency acting at the direction of the county, district, or municipal public health agency. The results of the screening shall be given in writing to the person screened. Any person who is found to

have latent tuberculosis infection without evidence of active disease shall be counseled and offered appropriate treatment by the agency performing the screening, but the person is not required to take such treatment.

(3~~5~~) Locally required screening programs shall be evaluated and reviewed by the local board of health every three years.

(4~~6~~) Nothing in this rule shall prohibit the Department or county, district, or municipal public health agencies from developing voluntary screening programs, from investigating and screening contacts of suspected or confirmed cases of tuberculosis in a contagious form, or from responding to potential outbreaks of tuberculosis in a community.

…

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

*****

B. Pursuant to ~~C.R.S.~~ § 25-4-607 (2), C.R.S., a veterinarian licensed in Colorado may issue a written waiver, as provided in this section, exempting an animal from a rabies vaccination order if the veterinarian, in his or her professional opinion, determines the rabies inoculation is contraindicated due to the animal's medical condition. The terms "waiver" and "exemption" as used in this section are interchangeable. A veterinarian may issue a waiver if:

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

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

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

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

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

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

(7~~.~~) The veterinarian provides a copy of the exemption form to the Department or county, district, or municipal public health agency or animal control agency, when requested.

*****

Regulation 9. Confidentiality

All personal medical records and reports held or viewed by the Department or county, district, or municipal public health agency in compliance with these regulations shall be confidential information subject to ~~C.R.S.~~ §§ 25-1-122(4) and ~~C.R.S.~~ 25-4-406(1), C.R.S. Reasonable efforts shall be made by

the Department to consult with the responsible physician, other healthcare providerS, or THE medical facility caring for the patient prior to any further follow-up by Department or county, district, or municipal public health agencies. This information is to be used by the public health agencies as source material for necessary disease control efforts and the development of prevention programs.

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

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

~~*****~~

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

With respect to Regulation 5, investigations related to sexually transmitted infections will be limited to the information necessary to confirm the diagnosis, treatment, source of infection, and identification of measures that may be used to prevent additional sexually transmitted infections. The Department shall destroy personal identifying information o~~f~~n all persons with CD4 or viral load results if the investigation subsequent to the report finds no evidence of a sexually transmitted infection.

~~Section~~§ 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 infection with human immunodeficiency virus (HIV). The provision of confidential counseling and testing for HIV is the preferred screening service for detection of HIV infection. Local boards of health who provide HIV counseling and testing through a contractual agreement with the 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

*****

F. In accordance with § ~~Section~~ 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 ~~Sections~~ §§ 25-4-412 and 25-4-413, C.R.S. These guidelines will include code of conduct standards for the delivery of partner services and clients' rights, responsibilities and protections.

256
257

Appendix A. Reportable Disease Table

Disease/Event	Pathogen/Organism	Time*	Reporter[1]	Specimen Source(s)[2]	Send Clinical Material[3]
Acinetobacter baumannii, carbapenem-resistant (CRAB)~~[4-Metro, 5]~~	Carbapenem-resistant *Acinetobacter baumannii* (including *Acinetobacter baumannii* complex and *Acinetobacter baumannii-calcoaceticus* complex)	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 [6,7]		24 hrs	P		NOT APPLICABLE
Animal bites by mammals not listed above[6]		4 days	P		NOT APPLICABLE
Anthrax[6]	*Bacillus anthracis*	Immed	L & P	All	Required
Arboviral Disease	Eastern equine encephalitis, Japanese encephalitis, LaCrosse encephalitis virus, California encephalitis serogroup, Powassan virus, St. Louis encephalitis virus and Western equine encephalitis virus	4 days	L	All	UPON REQUEST
Botulism[6]	*Clostridium botulinum*	Immed	L & P	All	UPON REQUEST
Brucellosis[6]	*Brucella* species	4 days	L & P	All	Required
Campylobacteriosis	*Campylobacter* species	4 days	L & P	All	UPON REQUEST
Candida auris[8]	*Candida auris, Candida haemulonii*	Immed	L & P	All	Required
Candidemia[4-Metro]	*Candida* species	30 days	L	Blood	UPON REQUEST
Catheter-associated urinary tract infection (CAUTI)[9]	Any	Per CMS[9]	P	Urine	NOT APPLICABLE
Chancroid	*Haemophilus ducreyi*	4 days	L & P	All	UPON REQUEST
Chikungunya	Chikungunya virus	4 days	L	All	UPON REQUEST
Chlamydia	*Chlamydia trachomatis*	4 days	L & P	All	UPON REQUEST
Cholera[6]	*Vibrio cholerae*	Immed	L & P	All	Required
CJD and other transmissible spongiform encephalopathies (TSEs)[6]		4 days	P		UPON REQUEST
Clostridium difficile infection[4-Metro]	*Clostridium difficile*	30 days	L	All	UPON REQUEST
Colorado tick fever	Colorado tick fever virus	4 days	L	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[6]	*Corynebacterium diphtheriae*	Immed	L & P	All	Required
Encephalitis[6]		4 days	P	All	UPON REQUEST
Enterobacteriaceae, carbapenem-resistant (CRE)[11]	Carbapenem-resistant *Escherichia coli*, *Klebsiella* species, *Enterobacter* species *Citrobacter* species, *Serratia* species, *Raoultella* species, *Providencia* species, *Proteus* species, *Morganella* species, and any carbapenemase-producing Enterobacteriaceae of any genus and species	4 days	L	All	~~Requested~~ REQUIRED
Enterobacteriaceae, extended-spectrum beta-lactamase (~~E~~BSBL)[4-Boulder, 12]	*Escherichia coli* and *Klebsiella* species	4 days	L	All	UPON REQUEST
Escherichia coli O157:H7 and Shiga toxin-producing Escherichia coli[13]	Shiga toxin-producing *Escherichia coli*[13]	4 days	L & P	All	Required
Giardiasis	*Giardia lamblia*	4 days	L & P	All	UPON REQUEST
Gonorrhea, any site	*Neisseria gonorrhoeae*	4 days	L & P	All	UPON REQUEST
GRAM-NEGATIVE BACTERIA RESISTANT TO COLISTIN[###]	GRAM-NEGATIVE BACTERIA (EXCLUDES *PROTEUS*, *PROVIDENCIA*, *MORGANELLA*, *SERRATIA, BURKHOLDERIA, NEISSERIA, CHROMOBACTERIUM, EDWARDSIELLA,* AND *BRUCELLA*)	4 DAYS	L	ALL	REQUIRED
Group A streptococci[14, 4-Metro]	*Streptococcus pyogenes*	4 days	L	Sterile only	Required
Group B streptococci [4-Metro]	*Streptococcus agalactiae*	30 days	L	Sterile only	Required
Haemophilus influenzae	*Haemophilus influenzae*	1 working day	L & P	Sterile only	Required
Hantavirus disease[6]	Hantavirus	4 days	L & P	All	UPON REQUEST
Healthcare-associated infections[16]		4 days	P		NOT APPLICABLE
Hemolytic uremic syndrome if < 18 years[6]		4 days	P		UPON REQUEST
Hepatitis A[6]	Hepatitis A virus (+IgM anti-HAV)	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[#]	Hepatitis C virus (+ serum antibody titer ~~including signal to cut-off ratio, or more specific + tests~~ AND/OR + CONFIRMATORY ASSAYS)	4 days	L & P	All	UPON REQUEST
Hepatitis C[#]	Hepatitis C virus (- CONFIRMATORY ASSAYS)	4 days	L	All	UPON REQUEST
Hepatitis, other viral		4 days	P		UPON REQUEST

Human immunodeficiency virus (HIV)/ acquired immunodeficiency syndrome (AIDS)	• Human immunodeficiency virus • CD4 counts (any value) • HIV viral load (any value) • *HIV genotype*	4 days	• L & P • L & P • L & P • L	All	UPON REQUEST
Influenza-associated death if < 18 years		4 days	P		UPON REQUEST
Influenza-associated hospitalization	INFLUENZA VIRUS	4 days	L & P	All	UPON REQUEST
Legionellosis	*Legionella* species	4 days	L & P	All	UPON REQUEST
Leprosy (Hansen's Disease)		4 days	P		UPON REQUEST
Listeriosis	*Listeria monocytogenes*	4 days	L & P	All	Required
Lyme disease	*Borrelia burgdorferi*	4 days	L & P	All	UPON REQUEST
Lymphogranuloma venereum (LGV)	*Chlamydia trachomatis*	4 days	L & P	All	UPON REQUEST
Malaria[6]	*Plasmodium* species	4 days	L & P	All	UPON REQUEST
Measles (rubeola)[6]	Measles virus	Immed	L & P	All	UPON REQUEST
Meningococcal Disease[6]	*Neisseria meningitidis* or gram-negative *diplococci*	Immed	L & P	Sterile only	Required
Methicillin-Resistant *Staphylococcus aureus* (MRSA) bacteremia[9]	Methicillin-Resistant *Staphylococcus aureus* (MRSA)	Per CMS[9]	P	Blood	NOT APPLICABLE
Mumps[6]	Mumps virus (acute infection)	4 days	L & P	All	UPON REQUEST
MYCOBACTERIUM, NONTUBERCULOUS (NTM)[4-METRO]	*MYCOBACTERIUM* SPECIES (EXCEPT *TUBERCULOSIS* COMPLEX AND *LEPRAE*)	4 DAYS	L	ALL	UPON REQUEST
Outbreaks - known or suspected of all types - including those transmitted from food, water, person-to-person, and related to a healthcare setting[6]		Immed	L & P		UPON REQUEST
Pertussis (whooping cough)[6]	*Bordatella pertussis*	1 working day	L & P	All	UPON REQUEST ~~REQUESTED~~[10]
Plague[6]	*Yersinia pestis*	Immed	L & P	All	Required
Poliomyelitis[6]	Poliovirus	Immed	L & P	All	UPON REQUEST
Pseudomonas, carbapenem-resistant[17]	*Pseudomonas aeruginosa*	4 days	L	All	UPON REQUEST ~~REQUESTED~~[10]
Psittacosis	*Chlamydia psittaci*	4 days	L & P	All	UPON REQUEST
Q fever[6]	*Coxiella burnetii*	4 days	L & P	All	UPON REQUEST
Rabies: human (suspected)[6]	Rabies virus (Lyssavirus)	Immed	L & P	All	UPON REQUEST

RESPIRATORY SYNCYTIAL VIRUS-ASSOCIATED HOSPITALIZATIONS[4-METRO]	RESPIRATORY SYNCYTIAL VIRUS	4 DAYS	L & P	ALL	UPON REQUEST
Rickettsiosis	*Rickettsia* species, including Rocky Mtn spotted fever and typhus groups	4 days	L & P	All	UPON REQUEST
Rubella (acute infection)[6]	Rubella virus	1 working day	L & P	All	UPON REQUEST
Rubella (congenital)[6]	Rubella virus	4 days	L & P	All	UPON REQUEST
Salmonellosis	*Salmonella* species	4 days	L & P	All	Required
Severe or novel coronavirus	Severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV)	Immed	L & P	All	UPON REQUEST
Shigellosis	*Shigella* species	4 days	L & P	All	Required
Smallpox[6]	Variola virus (Orthopox virus)	Immed	L & P	All	UPON REQUEST
Staphylococcus aureus, Vancomycin-~~resistant~~ NON-SUSCEPTIBLE[##]	Vancomycin-~~resistant~~ NON-SUSCEPTIBLE *Staphylococcus aureus*	4 days	L	All	Required
Streptococcal toxic shock syndrome	*Streptococcus pyogenes*	4 days	P	All	Required[15]
Streptococcus pneumoniae	*Streptococcus pneumoniae*	4 days	L	Sterile only	Required[15]
Syphilis[6]	*Treponema pallidum*	1 working day	L & P	All	UPON REQUEST
Tetanus[6]	*Clostridium tetani*	4 days	P	All	UPON REQUEST
Tick-borne relapsing fever[6]	*Borrelia* species	4 days	L & P	All	UPON REQUEST
Toxic shock syndrome (non-streptococcal)		4 days	P		UPON REQUEST
Trichinosis[6]	*Trichinella* species	4 days	P	All	UPON REQUEST
Tuberculosis disease (active)[6]	*Mycobacterium tuberculosis*[18]	1 working day	L & P	All	REQUIRED
TUBERCULOSIS INFECTION (LTBI)	*MYCOBACTERIUM TUBERCULOSIS*[19]	4 DAYS	L	ALL	NOT REQUIRED
Tularemia[6]	*Francisella tularensis*	1 working day	L & P	All	Required
Typhoid fever[6]	*Salmonella* Typhi	1 working day	L & P	All	Required
Varicella (chicken pox)[6]	Varicella virus	4 days	L & P	All	UPON REQUEST
Vibriosis	*Vibrio* species, non-cholera	4 days	L	All	Required
Viral hemorrhagic fever	Crimean-Congo hemorrhagic virus, Ebola virus , Lassa fever virus, Lujo virus, Marburg virus, Guanarito virus, Junin virus, Machupo virus, Sabia virus	Immed	L & P	All	Required

West Nile virus (acute infection, IgM+)	West Nile virus	4 days	L	All	UPON REQUEST
Yellow fever	Yellow fever virus	4 days	L	All	UPON REQUEST
Yersiniosis[4-Seven]	*Yersinia* non-*pestis* species	4 days	L	All	Required
Zika virus	Zika virus	4 days	L	All	UPON REQUEST

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

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

1 Reporter: The party responsible for reporting is indicated by one of the following: L = Laboratory (whether or not associated with a hospital; by out-of-state laboratories that maintain an office or collection facility in Colorado; and by in-state laboratories which send specimens to an out-of-state laboratory referral laboratory), P = healthcare provider or other person knowing of or suspecting a case (including but not limited to coroners, persons in charge of hospitals or other institutions licensed by the Department (or their designees), persons in charge of schools (including nursing staff) and licensed day care centers), L & P = Both.

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

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

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

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

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

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

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

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

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

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

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

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

10 ~~Clinical material is requested from selected laboratories.~~ [Footnote reserved.]

11 *Escherichia coli, Klebsiella* species, *Enterobacter* species, *Citrobacter* species, *Serratia* species, and *Raoultella* species that are resistant to at least one carbapenem (including imipenem, meropenem, doripenem, or ertapenem); or *Providencia* species, *Proteus* species, *Morganella* species that are resistant to at least one carbapenem (including meropenem, doripenem, or ertapenem); but not including imipenem); or Enterobacteriaceae of any genus and species that test positive for production of carbapenemase (e.g., KPC, NDM, VIM, IMP, OXA-48) demonstrated by a recognized test (e.g., modified carbapenem inactivation method [mCIM], polymerase chain reaction [PCR], nucleic acid amplification test [NAAT], metallo-beta-lactamase test, modified-hodge test [MHT], carba-NP).

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

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

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

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

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

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

18 Including (+) AFB sputum smear, CULTURE (REGARDLESS OF SPECIMEN SITE) AND NUCLEIC ACID AMPLIFICATION TESTS (NAAT). SEE REGULATION 4 F.

19. ALL POSITIVE INTERFERON GAMMA RELEASE ASSAYS (IGRAS) WILL BE REPORTED BY LAB.

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

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

ANY GRAM-NEGATIVE BACTERIA (EXCEPT PROTEUS, PROVIDENCIA, MORGANELLA, SERRATIA, BURKHOLDERIA, NEISSERIA, CHROMOBACTERIUM, EDWARDSIELLA, AND BRUCELLA) RESISTANT TO COLISTIN OR A MINIMUM INHIBITORY CONCENTRATION (MIC) OF ≥4 MCG/ML.

Appendix B. Healthcare-Associated Infections

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

Healthcare-associated infections include:

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

Health facility types include:

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