

# REPORT OF THE STATE AUDITOR

**Communicable Disease Epidemiology Program Department of Public Health and Environment** 

Performance Audit July 2003

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July 29, 2003

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This report contains the results of a performance audit of the Communicable Disease Epidemiology Program. The audit was conducted pursuant to Section 2-3-103, C.R.S., which authorizes the State Auditor to conduct audits of all departments, institutions, and agencies of state government. The report presents our findings, conclusions, and recommendations, and the responses of the Department of Public Health and Environment.

#### TABLE OF CONTENTS

PAGE
REPORT SUMMARY
Recommendation Locator
DISEASE CONTROL AND ENVIRONMENTAL EPIDEMIOLOGY 7
FINDINGS AND RECOMMENDATIONS
CHAPTER 1. COMMUNICABLE DISEASE REPORTING
Colorado Electronic Disease Reporting System
Utilization of CEDRS
Timeliness of Disease Reports
CEDRS Completeness and Accuracy
Regulations
Enforcement of Reporting Requirements
CHAPTER 2. COMMUNICABLE DISEASE CONTROL OVERSIGHT 35
Follow-Up Investigations
Regional Epidemiologists
Records Retention
Performance Measures
Disease Statistics
APPENDICES
Appendix A
Appendix B



### STATE OF COLORADO OFFICE OF THE STATE AUDITOR

REPORT SUMMARY

JOANNE HILL, CPA State Auditor

# Communicable Disease Epidemiology Program Performance Audit August 2003

#### **Authority, Purpose, and Scope**

This performance audit was conducted under the authority of Section 2-3-103, C.R.S., which authorizes the Office of the State Auditor to conduct performance audits of all departments, institutions, and agencies of state government. The audit focused primarily on the Communicable Disease Epidemiology Program (the Program) within the Colorado Department of Public Health and Environment (the Department) and its activities related to communicable disease reporting, surveillance, and investigation and follow-up. The audit work, performed from January 2003 through July 2003, was conducted in accordance with generally accepted governmental auditing standards.

We acknowledge the assistance and cooperation extended by management and staff at the Department of Public Health and Environment as well as representatives from local health departments and county nursing services.

#### **Background**

The Department is statutorily charged with controlling epidemic and communicable diseases and protecting the public health. The Disease Control and Environmental Epidemiology Division (the Division or DCEED) is the agency within the Department assigned responsibility for carrying out this mandate. The Division maintains a disease-monitoring network with Colorado's health care providers and hospitals to identify the causes and modes of communicable disease transmission and to stop disease outbreaks. In addition, the Division investigates the incidence and prevalence of environmental and chronic diseases, and evaluates potential risks from environmental toxicologic exposures. Concerns about epidemics and communicable disease management have been elevated because of recent bioterrorism threats. As a result, federal funding for communicable disease control has increased significantly.

In 1999 the Division implemented a Web-based system known as the Colorado Electronic Disease Reporting System (CEDRS). CEDRS is the repository for communicable disease surveillance data in Colorado, with the exception of tuberculosis, sexually transmitted diseases, and HIV infections.

For more information on this report, contact the Office of the State Auditor at (303) 869-2800.

In Fiscal Year 2002 approximately 16,000 communicable disease case reports were entered into CEDRS. As part of the audit, we evaluated the contents of CEDRS. This review included a download of the CEDRS database for Calendar Years 1999 through 2002. Additionally, we conducted site visits to five local health departments and two county nursing services. As part of our site visits, we interviewed local health agency staff and conducted a case file review for diseases requiring follow-up investigations.

#### **Key Findings**

#### **Communicable Disease Reporting**

- The Department has not optimized the use of the Colorado Electronic Disease Reporting System. We found a significant number of public health entities and others do not access CEDRS on a routine basis, either to report data directly or to use as a tool for disease surveillance. Although Board of Health regulations require the reporting of certain communicable diseases, regulations do not specify the method of reporting. According to the Department's Centers for Disease Control and Prevention (CDC) bioterrorism grant, one of the purposes of the program is to develop a system to "rapidly detect a terrorist event through a highly functioning, mandatory, reportable disease surveillance system as evidenced by ongoing timely and complete reporting by providers and laboratories...." CEDRS is an integral component of the State's disease surveillance "system." To ensure that this and other Departmental mandates for disease control and prevention are accomplished, the Department should take steps to optimize the use of CEDRS.
- A significant number of communicable diseases are not being reported within the required 24-hour and 7-day time frames. About one-third of the 24-hour reportable disease cases we reviewed were entered into CEDRS beyond the 24-hour time requirement. Additionally, 61 percent of hepatitis C and about 18 percent of 7-day reportable disease cases (excluding hepatitis C) were reported or entered into CEDRS beyond the 7-day requirement. Timely reporting through CEDRS is important because local health agencies rely on the system to notify them of disease occurrences, and follow-up investigations typically are not conducted until cases are reported in CEDRS.
- Disease data contained in CEDRS in Calendar Year 2002 were not always complete. Statutes and Department regulations require certain information be reported for all communicable diseases. While we found that most information is reported, other required information such as race and ethnicity often are not reported.
- According to statute, the Department has the power and duty to enforce Colorado's public health laws and the standards, orders, rules, and regulations established, issued, or adopted by the Board. Statutes impose criminal penalties upon responsible parties for failure to

report required public health information to the Department. Department management and staff were unaware of these penalties. The Department should communicate the mandatory nature of specific reporting requirements and inform entities and individuals of the potential penalties for failure to comply. If voluntary compliance is not reached and/or repeated violations are identified, appropriate steps toward enforcement should be taken.

#### **Communicable Disease Control Oversight**

- Follow-up investigations are not occurring in all cases. Follow-up investigations are conducted to determine the source and prevent the spread of disease, and to educate the patient about how the disease was acquired and how to prevent further spread. There are no comprehensive standards or guidelines for the local public health agencies to apply in conducting communicable disease follow-up investigations. As a result, inconsistencies, confusion, and conflicting practices surround this important component of the State's communicable disease control program.
- The roles and responsibilities of the regional epidemiologists are unclear. The Department employs five regional epidemiologists who are physically assigned to various geographic regions and specific local health agencies throughout the State. We spoke with all of the Department's regional epidemiologists and found they have an inconsistent view of their roles within the State's communicable disease control system. There also are gaps in services and the potential for duplication of job duties, particularly with the addition of 13 bioterrorism epidemiologists located throughout the State. The Department should ensure the cost-effective use of resources in controlling and preventing communicable diseases and epidemics by addressing these gaps and inconsistencies.

#### RECOMMENDATION LOCATOR

Rec. No.	Page No.	Recommendation Summary	Agency Addressed	Agency Response	Implementation Date
1	18	Optimize the use and usefulness of CEDRS by (a) determining and addressing the reasons users do not fully utilize the system, (b) expanding access to other users including commerical laboratories, (c) assessing the usefulness and accessibility of the system with users on a regular basis, and (d) providing ongoing training to users.	Department of Public Health and Environment	Agree	<ul> <li>a.) Implemented and ongoing</li> <li>b.) Implemented and ongoing</li> <li>c.) Implemented and onging</li> <li>d.) Implemented and ongoing</li> </ul>
2	24	Ensure timely reporting and entry of information into CEDRS by (a) following standard practice for one-day data entry, (b) developing a review process to identify untimely disease reports, and (c) working with local health agencies and reporting entities to create an action plan to address untimely disease reports.	Department of Public Health and Environment	Agree	<ul><li>a.) Implemented</li><li>b.) Implemented and ongoing</li><li>c.) February 2004</li></ul>
3	29	Increase efforts to ensure completeness and accuracy of information in CEDRS by systematically reviewing data entered directly by reporting entities or indirectly by Division staff.	Department of Public Health and Environment	Agree	Implemented and ongoing
4	32	Ensure practices are consistent with Board of Health regulations for communicable diseases by (a) reviewing existing rules and regulations and proposing appropriate regulatory changes, and (b) ensuring printed materials and other information are consistent with Board of Health rules and regulations.	Department of Public Health and Environment	Agree	<ul><li>a.) Implemented and ongoing</li><li>b.) January 2004</li></ul>
5	34	Ensure compliance with statutory and regulatory communicable disease reporting requirements by informing public health and other health care agencies and individuals about the mandatory nature of requirements and the possible penalties for noncompliance, and by undertaking enforcement actions, when appropriate.	Department of Public Health and Environment	Partially Agree	Implemented and ongoing

#### RECOMMENDATION LOCATOR

Rec. No.	Page No.	Recommendation Summary	Agency Addressed	Agency Response	Implementation Date
6	39	Ensure statutory responsibilities for investigating communicable diseases are fulfilled by (a) identifying and communicating to local health agencies those reportable diseases and conditions that do or do not require follow-up, (b) providing training to local health agencies, (c) developing and providing guidelines to local health agencies for conducting and documenting follow-up investigations, and (d) monitoring the follow-up conducted by local health agencies to ensure investigations are adequate and complete.	Department of Public Health and Environment	Agree	<ul> <li>a.) November 2003</li> <li>b.) Implemented and ongoing</li> <li>c.) Implemented and ongoing</li> <li>d.) Implemented and ongoing</li> </ul>
7	43	Ensure the effectiveness and usefulness of the five regional epidemiologists by identifying and clearly defining programmatic functions and geographical jurisdictions.	Department of Public Health and Environment	Agree	Implemented and ongoing
8	45	Adopt and disseminate comprehensive communicable disease record retention policies to local public health agencies, and ensure these policies are approved in accordance with Section 24-80-102.7, C.R.S.	Department of Public Health and Environment	Agree	November 2003
9	46	Review the performance measures reported to the Joint Budget Committee in its annual budget request and adopt measures of efficiency and effectiveness related to its mission of controlling and preventing the spread of communicable diseases through investigations and/or follow-up.	Department of Public Health and Environment	Agree	July 2004
10	48	Improve the accuracy and reliability of disease statistics by ensuring staff comply with Board of Health regulations and follow CEDRS data entry review procedures.	Department of Public Health and Environment	Agree	February 2004

# Disease Control and Environmental Epidemiology

#### **Background**

Among its statutory powers and duties, the Colorado Department of Public Health and Environment (the Department) is charged with controlling epidemic and communicable diseases and protecting the public health. Statutes define communicable diseases as:

...illnesses due to a specific infectious agent or its toxic products that arise through transmission of that agent or its products from an infected person, animal, or reservoir to a susceptible host, either directly or indirectly through an intermediate plant or animal host, vector, or inanimate environment.

Epidemic diseases are statutorily defined as communicable or noncommunicable illnesses or conditions "in excess of normal expectancy, compared to the usual frequency of the illness or condition in the same area, among the specified population, at the same season of the year." Concerns about epidemics and communicable disease management have been elevated because of recent bioterrorism threats. As a result, federal funding for communicable disease control has increased significantly.

The Disease Control and Environmental Epidemiology Division (the Division or DCEED) is the agency within the Department assigned responsibility for carrying out the Department's mission with regard to controlling and preventing epidemic and communicable diseases. The Division maintains a disease-monitoring network with Colorado's health care providers and hospitals to identify the causes and modes of communicable disease transmission and to stop disease outbreaks. In addition, the Division investigates the incidence and prevalence of environmental and chronic diseases, and evaluates potential risks from environmental toxicologic exposures. In Fiscal Year 2003 the General Assembly appropriated about \$23 million to the Division, more than \$19 million of which were federal funds. Also during Fiscal Year 2003, the Division employed 127 FTE.

#### Communicable Disease Epidemiology Program

The Communicable Disease Epidemiology Program (the Program) resides within the Disease Control and Environmental Epidemiology Division. In Fiscal Year 2002 the Program received approximately \$2 million. The majority of the Program's funding derives from federal sources, such as those from the Centers for Disease Control and Prevention's (CDC) categorical and cooperative agreements. In Fiscal Year 2002 approximately 5 percent, or \$97,000, of the Program's funding came from the General Fund. The Program currently has 15.6 FTE.

Communicable diseases include foodborne, respiratory, waterborne, invasive bacterial, antibiotic resistant, vaccine-preventable, and animal-related diseases. To help carry out its responsibilities for controlling these diseases, the Program administers the Colorado Electronic Disease Reporting System (CEDRS) and conducts special studies to evaluate disease prevention activities to determine risk factors for communicable diseases. There is some overlap between the Program and other sections within the Division, such as the STD/HIV and Bioterrorism Response Sections. For example, CEDRS is one of the mechanisms used for reporting and tracking communicable diseases that fall within these sections.

It is important to note that the Department, including the Communicable Disease Epidemiology Program, is governed by statutes and regulations protecting the confidentiality of communicable disease patient information.

#### Statewide Communicable Disease Control System

In addition to the Program, a number of other entities are integrally involved in the State's overall communicable disease control system. The Program regularly interacts and/or partners with these entities. They include:

Centers for Disease Control and Prevention - The Centers for Disease Control and Prevention (the CDC) is an agency of the federal Department of Health and Human Services. The CDC is recognized as the leading federal agency for protecting the health and safety of citizens, at home and abroad. The CDC partners with national, state, and local organizations to detect, control, prevent, and respond to infectious diseases and their spread. The agency comprises various organizational components such as the National Centers for Environmental Health, Infectious Disease, HIV, STD, and TB Prevention, and the Epidemiology Program Office. The CDC does not have administrative authority over the Department. However, the Department receives funds from the CDC for which it must comply with CDC requirements.

- C State Board of Health (the Board) By statute, the State Board of Health is to designate, through rule and regulation, "those epidemic and communicable diseases and conditions that are dangerous to public health." The Board is authorized to require reports, without patient consent, relating to designated diseases and is charged with setting the manner, time period, and form in which the reports are to be made. Reporting requirements set by the Board are discussed in detail in Chapter 1 of the audit report.
- C Local Health Departments Currently there are 15 local health departments that serve 25 counties across the State. The Department does not have administrative authority over county, district, and regional health departments. However, these entities are subject to all statutes and Board regulations related to epidemic and communicable diseases. Statutes also give these public health agencies the power and duty to administer and enforce the laws pertaining to public health and the orders, rules, regulations, and standards of the State Board of Health. Local health departments also have the authority to investigate and control the causes of epidemic and communicable diseases.
- C Public Health Nursing Services There are 38 public health nursing services serving 39 counties across the State. These entities provide public health services to rural counties that do not have an organized local health department. Public Health Nursing Services are subject to statutes and Board regulations related to reporting epidemic and communicable diseases.
- C Hospitals, physicians, and public and private laboratories These entities also are subject to statutes and Board regulations related to reporting epidemic and communicable diseases.

#### **Health Alert Network**

The Health Alert Network (HAN) is the integrated information and communication system created in partnership with the CDC and national, state, and local health organizations. The CDC and the U.S. Department of Health and Human Services regularly use this network to disseminate information about important or urgent health information such as Severe Acute Respiratory Syndrome (SARS), West Nile virus, and monkeypox infections to the Department as well as to other states' health departments. Currently, monkeypox and SARS are not specifically designated as reportable diseases in Board regulations. In turn, Department staff notify hospitals, laboratories, emergency rooms, and health agencies via the State's internal Health Alert Network. Division documents state that many local health departments pass these notifications through their county networks, bringing the total notifications in

Colorado to more than 5,000 entities. Local health agency personnel we contacted told us that Colorado's HAN has been a very effective means of rapidly disseminating information. The HAN differs from CEDRS in that it is primarily a communications system and CEDRS is a disease reporting and surveillance system.

#### **Bioterrorism**

Since 1999 the Department has received funding from the CDC to prepare the public health community to plan for and respond to the consequences of bioterrorism. Following the events of September 11, 2001, and subsequent bioterrorism threats, the nation has been on higher alert than was previously the case. In response to increased concerns, the Department received a total of almost \$14.6 million for Fiscal Year 2003 from a CDC Public Health Preparedness and Response for Bioterrorism Grant. The Department partners with many other state and local agencies, such as the Departments of Local Affairs, Public Safety, and Military Affairs, and county health departments and nursing services, to plan for, respond to, and protect the safety of the citizens of Colorado in the event of a bioterrorism incident.

The Department also is the lead agency for the Governor's Expert Emergency Epidemic Response Committee (the Committee). The Committee was created in March 2000 by the General Assembly to advise and provide the Governor with expert public health advice in the event of an emergency epidemic. Additionally, effective June 30, 2001, the State Board of Health adopted new rules to prepare for bioterrorism statewide. These rules include requiring the Department, local public health agencies, hospitals, and managed care organizations to adopt plans for responding to emergency epidemics. Each entity's plan is to address specific areas such as organization of personnel, protection of personnel, creation of an emergency command center, and disease control.

Although we did not audit the Emergency Preparedness and Bioterrorism Response Section, within the Division, certain functions of the Communicable Disease Epidemiology Program overlap with those of the Bioterrorism Response Section. One of the Bioterrorism Section's CDC-required focus areas—Focus Area B—is epidemiology and surveillance. One of the objectives of this focus area is to integrate surveillance and epidemiology response to bioterrorism events within the existing state health department infrastructure. The Department's existing infrastructure for surveillance and epidemiology includes CEDRS, which is discussed in detail in Chapter 1. Staff told us that improving CEDRS to be more rapid, accurate, and comprehensive would benefit not only the Communicable Disease Epidemiology Program but also the Bioterrorism Section.

#### **Audit Scope and Methodology**

Our performance audit focused primarily on the Communicable Disease Epidemiology Program within the Division and its activities related to communicable disease reporting (surveillance) and investigation and follow-up. As part of the audit, we evaluated the contents of CEDRS. This review included a download of the CEDRS database for Calendar Years 1999 through 2002. We reviewed the cases in the database for timeliness, completeness, and accuracy. We also conducted site visits to five local health departments, which serve a total of 13 counties in the State and two public health nursing services located in Eagle and Garfield counties. During these site visits, we interviewed public health staff and reviewed files and other documents. Audit work also involved contacting numerous private and public health entities including the Centers for Disease Control and Prevention, laboratories, and other health care providers.

## **Communicable Disease Reporting**

#### Chapter 1

#### **Background**

According to the World Health Organization (WHO):

Communicable disease surveillance is the process of systematic collection, consolidation, and analysis of data including dissemination to those who need to know and provide information on relevant action. Appropriate surveillance systems provide the essential information to monitor, evaluate, and model the impact of prevention and control activities for endemic communicable and zoonotic diseases, detect and track epidemics of emerging diseases and other public health threats, and locate geographically the spread of diseases....

In addition, according to WHO, "Strengthening communicable disease surveillance systems is essential for the rapid detection and effective control of epidemics and monitoring of endemic communicable disease programs." However, when "data are untimely, incomplete, unrepresentative, and of poor quality, confidence in the entire system is undermined." According to a recent General Accounting Office (GAO) report, surveillance systems are "the public health officials' most important tool for detecting and monitoring both existing and emerging infectious diseases."

In this chapter we discuss issues related to communicable disease reporting. As described in the following sections, Board of Health regulations require that certain communicable diseases be reported. However, regulations do not specify the method of reporting. Therefore, reports may be made via telephone, mail, fax, and the Colorado Electronic Disease Reporting System (CEDRS). We identify the strengths and weaknesses we found and also make recommendations for improving the Department of Public Health and Environment's management of this essential component in communicable disease control and prevention.

# **Colorado Electronic Disease Reporting System**

According to Section 25-1-122 (1), C.R.S., the State Board of Health (the Board) has the authority to require reporting of epidemic and communicable diseases, environmental and chronic diseases, venereal diseases, tuberculosis, rabies, and animal bites "by any person having knowledge of such to the State and local health departments, within their respective jurisdictions." Board regulations require communicable disease reports be made in designated time frames—24 hours or 7 days—depending upon the particular disease, as indicated in the sample of diseases shown below. (A complete list of reportable diseases is located in Appendix A.)

#### 24-Hour Reportable Diseases

Animal bites by dogs, cats, bats, skunks, or other wild carnivores Meningitis

Anthrax Measles (rubeola)

Botulism Plague

Cholera Rabies in man

Diphtheria Rubella
Active Tuberculosis disease Typhoid fever

#### 7-Day Reportable Diseases

Brucellosis Mumps

Encephalitis Pertussis syndrome

Giardiasis Q fever Hepatitis B Tetanus

Legionellosis West Nile virus

In 1999 the Division implemented the Colorado Electronic Disease Reporting System. CEDRS is the repository for communicable disease surveillance data in Colorado, with the exception of tuberculosis, sexually transmitted diseases, and HIV infections. In Calendar Year 2002 approximately 16,000 communicable disease case reports were entered into CEDRS. In addition to being a Web-based system for reporting disease cases, CEDRS is used to view individual case reports, create aggregate reports and map displays, and export data for more complex analyses. CEDRS users include hospital infection control practitioners, public health nurses, and disease control staff in state and local health departments. The Division also

utilizes the CEDRS Web page to disseminate various communicable disease topics of interest to users across the State in a weekly electronic newsletter called "Hot Topics." The goals of CEDRS are:

- C Improved timeliness of disease reporting.
- C Improved information flow between hospitals, and state and local health departments.
- C Single, shared database for state and local health departments.
- C Improved response to public health events and evaluation of control measures.

In addition, CEDRS is one component of the State's mandatory reportable disease surveillance system. According to the Division's work plan for its Centers for Disease Control and Prevention (CDC) bioterrorism grant, the State's mandatory reportable disease surveillance system will be used to detect illnesses and conditions possibly resulting from bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies.

#### **Utilization of CEDRS**

The Department has not optimized the use of CEDRS for reporting and surveillance purposes. We found that a significant number of public health entities and others do not access CEDRS on a routine basis, either to report data directly or to use as a tool for disease surveillance. Consequently, we believe the system is not as effective or efficient as it could be. We found the following with regard to the use of the system by health care providers:

- **Hospital Laboratories** Forty-one of the seventy hospital laboratories identified by the Division as those with which they have regular contact entered reports directly into CEDRS in Calendar Year 2002. Of the remaining 29 hospital laboratories, 19 had data to report but did not enter it into CEDRS. Another 10 had no disease cases to report.
- Private Commercial Laboratories Commercial labs do not have access to CEDRS and the Division has no plans to offer them direct access. As a result, Division staff enter all private laboratory-reported cases into CEDRS. In Calendar Year 2002, 42 percent of the disease reports entered by Division staff originated with two large private laboratories. According to Department management, efforts are under way to electronically transfer information

from these two laboratories' databases into CEDRS. Although this may be more efficient than the current practice, it still will not be as efficient, for the Division, as direct access.

- Local Health Departments All local health departments utilize CEDRS in some form.
- **Public Health Nursing Services** Eight of the thirty-eight public health nursing services in the State did not access CEDRS for any purpose in Calendar Year 2002.
- **Division staff** At least one of the Division's five regional epidemiologists does not access CEDRS on a regular basis. Division staff state that this is likely due to a slow Internet connection. We note that the Division has a responsibility to ensure all regional epidemiologists have reliable access to CEDRS and use it as part of their "daily" surveillance activities.

Additionally, we found entities do not always fully understand or utilize CEDRS' capabilities. As a result, the usefulness of CEDRS as a means of facilitating information flow and improving response to public health events is diminished.

Although the "reporting" of communicable diseases, as outlined in Board of Health regulations, is required, the use of CEDRS as the reporting mechanism is not. Rather, disease reports can be made to the Division via telephone, fax, or hardcopy correspondence. In fact, one-half (50 percent) of disease reports in Calendar Year 2002 were entered into CEDRS by Division staff because reporting entities used these alternate methods. According to Division documents, "Communicable disease reports transmitted by telephone, mail, and fax may cause delays in public health system notification, transcription errors, and duplication of effort from data re-entry." We understand there are instances, such as in the case of some 24-hour reportables, when calling in a report to the Division is the more rapid means of notification. However, this should not preclude reporting entities from entering reports into CEDRS in a timely fashion. Such direct data entry would be more efficient and would also better serve the purposes for which the system was intended. In addition, we believe the Division's practice of entering data for reporting entities is not an efficient use of state resources. If Division staff were not required to perform such a significant volume of data entry, they would have more time for other important functions such as CEDRS quality control and training.

Department management told us they encourage and support the use of CEDRS by health care entities. However, we believe more proactive efforts should be undertaken to increase the system's use, with an ultimate goal of making direct reporting into CEDRS a responsibility of all reporting entities. To this end, the Department should:

C Expand access - This could be accomplished by systematically reviewing and determining the reasons public health entities currently do not use the system. According to Division staff, some hospital laboratories, for example, have so few cases to report each year, that it is not cost-effective for them to use the system. Division staff are also concerned that entities will not stay proficient on a technical Web-based application that they may use only a few times per year. Because CEDRS is a Web-based system, which does not require significant investment in resources, other than Internet access, this should not be cost-prohibitive for most entities. Additionally, as we have discussed, CEDRS is not only used for disease reporting purposes but can be used for surveillance functions such as reviewing individual or aggregate case reports and creating map displays.

Also, the Department should continue to implement methods of electronically linking private laboratories' systems with CEDRS or begin granting CEDRS access to private labs. According to a May 2003 report by the General Accounting Office, "Public health and private laboratories are another vital part of the surveillance network because only laboratory results can definitively identify pathogens." Staff at one of three private laboratories we contacted expressed interest in making reports directly to CEDRS as well as accessing CEDRS data. Based on the average number of reports entered in 2002, it would be unlikely that any private laboratory would have to enter more than seven reports per day. We do not believe this to be an excessive burden on private laboratory resources.

C Make more useful and user-friendly - The Division should consult with reporting entities on a regular basis and assess the usefulness and usability of CEDRS. In 2001 the Department conducted a survey of CEDRS users regarding the usefulness of the system. Twenty-five percent of the survey respondents indicated they did not have a complete understanding of the system's use. Additionally, staff at some local health departments we visited told us they maintain their own data systems, in part, because CEDRS data are not easy to manipulate. For example, staff stated that it would be helpful if CEDRS had better sorting capabilities. We also found useful information is regularly missing from cases in CEDRS. For example, in 2002 the majority of reports in CEDRS did not indicate the location at which the person was exposed to the disease (i.e., in a public facility) or whether the provider was aware that the health department may be contacting their patient. According to Division staff, these fields are useful in some cases but were not intended to be completed in all cases. The "case note" section of the

database could be a useful mechanism for recording these and other types of case information. The Division should reevaluate the importance of CEDRS fields, communicate their findings to local health agencies, and encourage or eliminate their use.

C **Provide training** - During our site visits, we found that county staff do not know how to fully use CEDRS. In addition, some infection control practitioners at local hospital labs told us they are not aware of some of CEDRS' capabilities. The Division provided initial training to some CEDRS users when the system was created in 1999. However, only limited training has been provided since that time, even though several upgrades and changes have been made to the system.

According to the Department's CDC bioterrorism grant, one of the purposes of the program is to develop a system to "Rapidly detect a terrorist event through a highly functioning, mandatory, reportable disease surveillance system as evidenced by ongoing timely and complete reporting by providers and laboratories in a jurisdiction, especially of illnesses and conditions possibly resulting from bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies." CEDRS is an integral component of the disease surveillance "system." To ensure that this and other Departmental mandates for disease control and prevention are accomplished, the Department should take the steps outlined above to optimize the use of CEDRS.

#### **Recommendation No. 1:**

The Department of Public Health and Environment should optimize the use and usefulness of the Colorado Electronic Disease Reporting System (CEDRS) as an integral component of the communicable disease reporting and surveillance system by:

- a. Determining and addressing the reasons authorized users do not fully utilize the system.
- b. Expanding access to other users, including commercial clinical laboratories.
- c. Assessing the usefulness and accessibility of the system with users on a regular basis.
- d. Providing ongoing training to users.

# Department of Public Health and Environment Response:

- a. Agree. Implementation: Implemented and ongoing. The Department will continue to conduct interviews to identify and address remediable reasons for agencies not using CEDRS to report or retrieve cases of communicable diseases. The Department has been assessing reasons for hospitals not using CEDRS over the past two years. The main reasons have been that data entry for busy hospital staff is more time consuming than faxing reports to the department. For smaller, rural hospitals, they have very few if any cases to report. Of the 29 hospitals that did not enter any data directly into CEDRS during 2002, 10 had no cases to report and nine had fewer than seven cases each to report for the entire calendar year. This is too few cases to make it practical for hospitals in this category to have to report directly to CEDRS. Reporting via fax or telephone is timely and much more practical in these instances.
- b. Agree. Implementation: Implemented and ongoing. The Department has been developing expanded "access" to CEDRS over the past two years. A year ago, the Department successfully implemented electronic transfer of data from the state laboratory to CEDRS. Access to CEDRS is being further expanded to include the two main commercial laboratories through the direct transfer of data from their computer systems to the CEDRS database. Direct data transfer is more efficient and cost effective than having laboratories key the data into their own systems and then into CEDRS. A pilot version of electronic reporting from commercial laboratories will be implemented by August 2004.
- c. Agree. Implementation: Implemented and ongoing. The Department conducted a survey of CEDRS users regarding the usefulness and accessibility of the system in the fall of 2001. A follow-up survey is currently underway. The Department will continue to assess the usefulness and accessibility of CEDRS by convening a CEDRS users group by February 2004, that meets twice yearly.
- d. Agree. Implementation: Implemented and ongoing. The Department provided initial training to CEDRS users. More recently, the Department provided formal training sessions during Spring 2002 to Western Slope CEDRS users and to Denver metropolitan area users. The Department currently provides individual user support as requested over the phone and onsite. The Department will continue to provide CEDRS training and support through production and dissemination of a user's guide by

November 2003 to the "new" version of CEDRS, and through ongoing individual training provided to users at their work site by regional epidemiologists and bioterrorism epidemiologists.

It is important to note that while the audit states that CEDRS can be an important tool in the Department's bioterrorism preparedness efforts, the effectiveness of our bioterrorism program is not dependent on the use of CEDRS. What is critical are the surveillance and communications systems linking the state, local agencies, hospitals and providers to allow for the most timely dissemination of information. Data entry into CEDRS might be useful but certainly not vital in such emergency situations. In fact, it is essential that other forms of notification and communication be prioritized well ahead of data entry into CEDRS. It could be disastrous to use precious time accessing CEDRS when what is required for response efforts is quick and efficient person-to-person communication.

#### Auditor's Addendum:

As advised by the World Health Organization, "strengthening communicable disease surveillance systems is essential for the rapid detection and effective control of epidemics and monitoring of endemic communicable disease programs." It is important for the State to have a reliable system to compile and analyze data and provide information statewide. At the present time, we are concerned that a significant number of hospital laboratories do not regularly use CEDRS; none of the private laboratories in the state have access to CEDRS; more than 20 percent of the Public Health Nursing Services in the state do not access CEDRS; many users are unaware of CEDRS's capabilities; and Department staff enter 50 percent of disease reports into CEDRS because reporting entities do not or can not enter reports directly.

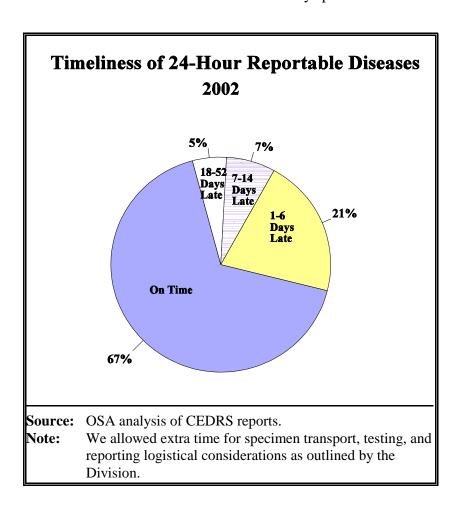
#### **Timeliness of Disease Reports**

As previously stated, Board of Health Regulations require communicable disease reports be made in designated time frames—24 hours or 7 days—depending upon the particular disease. According to Division documents, "Public health surveillance systems that can provide rapid, accurate, and accessible data are crucial for identifying, preventing, and evaluating changes in public health problems." In addition, "Improved timeliness of reporting can lead to more accurate disease monitoring, faster detection of outbreaks, and improved chances for timely public health intervention." Also, according to the CDC, rapid identification and prompt

reporting of cases is important because measures can be taken to prevent transmission to other persons.

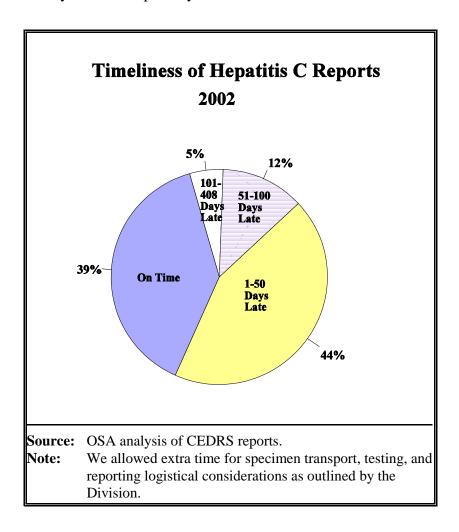
We reviewed the timeliness of communicable diseases reported in CEDRS. We found a significant number of communicable diseases are not being reported within the required 24-hour and 7-day time frames. (A detailed explanation of the methodology used in our analysis can be found in Appendix B.) Specifically, we found the following for Calendar Year 2002:

C 24-Hour Reportables - About one-third of the 24-hour reportables we reviewed (56 of 168 disease cases) were entered into CEDRS beyond the 24-hour time requirement. In fact, as the following exhibit shows, some 24-hour reportables such as hepatitis A and haemophilus influenzae were entered into CEDRS as much as 18 to 52 days past the 24-hour limit.



C **Hepatitis C** - As the following exhibit shows, about 61 percent of hepatitis C cases were entered into CEDRS beyond the required reporting time frame of

7 days. According to Department management, the approximately 6,000 hepatitis C reports in CEDRS should not be included in our timeliness review, because the hepatitis C program is an entirely separate program. Therefore, we removed all hepatitis C cases from our overall CEDRS review and analyzed them separately.



C 7-day reportables - About 18 percent of 7-day reportable disease cases (excluding hepatitis C) were reported or entered into CEDRS beyond the 7-day reporting requirement. Although not as threatening to the public health as 24-hour reportable diseases, 7-day reportables should also be reported in a timely fashion, as required by Board of Health regulations.

As previously mentioned, reporting entities may enter disease cases directly into CEDRS, or they may phone, fax, or mail reports that are then entered into CEDRS by Division staff. It is the Division's standard practice to enter all disease reports received via phone, fax, or mail into CEDRS the same day in which they are

received. However, we found this to not always be the case. We selected a sample of 28 cases reported to the Division in Calendar Year 2003 and found 11 of the 28 (39 percent) cases were not entered by Division staff the same day as the report was received. According to Division staff, standard practice is followed, to the extent possible. However, some cases may not be entered on the same day because reporting entities do not include all required information in their reports. As a result, Division staff spend time gathering needed information before entering the case into CEDRS. As we discuss in the following sections, the Department should ensure reporting entities are following statutes and regulations by submitting complete reports. If the Department received complete reports from reporting entities, staff would not have to spend valuable time gathering report information before entry into CEDRS.

#### **Reliance on CEDRS**

One of the reasons timely reporting is so important is that local health agencies rely on CEDRS to notify them of disease occurrences. Staff at several local health agencies in our sample stated they review CEDRS on a daily basis for notification of new disease cases in their area(s). Additionally, CEDRS is one of the methods used by the Department and local health departments for identifying outbreaks or assisting during outbreak investigations. For example, CEDRS was used during an outbreak of salmonellosis in Steamboat Springs. According to a Division report, staff reviewed CEDRS daily for reports of new cases of salmonellosis. Local health agency staff also rely on CEDRS to notify them of cases that may require follow-up investigations. During our file reviews at local health agencies, we determined follow-up investigations typically are not conducted until the case is reported in CEDRS.

The Department needs to take immediate steps to ensure timely reporting. These steps should, at a minimum, include:

- C **Evaluating the timeliness of disease reports -** The Division is responsible for ensuring prompt reporting of diseases; however, staff do not conduct formal and systematic tests of disease reports to ensure entities are reporting within the required time frames. We believe the Division should periodically conduct timeliness tests of reporting.
- C **Designing reporting protocols for improving timeliness** The Division should work with local health agencies and reporting entities to identify the barriers responsible for untimely reporting and take steps to address and/or eliminate these barriers.

#### **Recommendation No. 2:**

The Department of Public Health and Environment should ensure timely reporting and entry of information into CEDRS by:

- a. Following standard internal practices for one-day data entry.
- b. Developing a review process to identify untimely disease reports.
- c. Working with local health agencies and reporting entities to create an action plan to address untimely disease reports.

# Department of Public Health and Environment Response:

- a. Agree. Implementation: Implemented. The Department already follows internal unwritten policies for one-day entry of reported cases into CEDRS to the extent possible. Under this policy, cases are entered into CEDRS as soon as patient contact information (e.g., address, county, phone number) is available. Since laboratories do not typically have this information to report, Department staff in many cases must contact providers' offices by phone to obtain patient contact information. Often there are delays in providers' offices returning phone calls. Entry of cases into CEDRS without patient address and/or phone number is not useful to local health departments since their access to CEDRS records is determined by patient address (specifically county), and initiation of follow-up typically requires a patient phone number.
- b. Agree: Implementation: Implemented and ongoing. The Department currently identifies untimely disease reports and provides feedback to laboratories via phone calls for two out of the three main 24-hour reportable diseases. The Department will continue to identify untimely disease reports by implementing by September 2003 a review process to identify all untimely 24-hour disease reports as they occur and provide immediate phone feedback to laboratories. The Department will also implement by February 2004 a review process to identify untimely 7-day disease reports based on analyzing CEDRS data on a twice yearly basis and providing written feedback to reporting entities.

Regarding 24-hour reportable diseases, the Department's first priority is not data entry of information into CEDRS, but rather quick response to

address potential disease outbreaks. When the Department receives a positive result from a laboratory, the Department's first course of action is to telephone the local health department covering the area of the reported case. This immediate, effective and efficient person-to-person notification is followed by the local health department investigating the disease, contacting other persons who could have been exposed to the disease, and making arrangements for the delivery of medicine to treat the affected parties. Identification and prophylactic treatment to prevent disease must happen first as the most immediate priority.

Within the audit report, there is much discussion regarding hepatitis C as a 7-day reportable disease. It is important to note that hepatitis C is primarily a chronic disease and not a communicable disease. While every effort is made to report hepatitis C cases within the 7-day time frame, there is no public health risk if hepatitis C case data is entered after the 7-day period. Surveillance of hepatitis C is similar to surveillance of cancer. As a chronic disease, it is not an immediate health risk. It is further important to note that when hepatitis C was identified as a reportable disease, there were two existing categories of regulations under the Board of Health (7-day and 24-hour reportables). Rather than create an additional category of regulation, hepatitis C was placed under the 7-day reportable regulations.

c. Agree: Implementation: February 2004. The Department will hold discussions with a working group of local health agencies and reporting entities and develop an action plan to address untimely disease reporting in conjunction with No. 2b above.

While timely entry of data is clearly a priority for the Department and while this recommendation is taken seriously by DCEED, it is important to reiterate that the first priority of local health departments is to respond to potential disease transmission and outbreaks as quickly as possible.

#### **CEDRS** Completeness and Accuracy

#### **Completeness**

State statutes and Board regulations require certain information be reported for all communicable diseases. Section 25-1-122 (1), C.R.S., requires communicable disease reports to "contain the name, address, age, sex, diagnosis, and such other

relevant information as the board determines is necessary to protect the public health...." In addition, Board of Health Regulation 6-CCR-1009-1, requires that disease reports include the patient's date of birth, race, ethnicity, address (including city and county), and physician name and address.

Contrary to statute and regulation, we found reportable disease data contained in CEDRS are not always complete. While most information is reported, and all disease cases we reviewed contained the patient's first and last name, other required information is often not reported. The following table details our findings regarding cases reported in CEDRS for Calendar Year 2002. Of the approximately 8,000 disease reports in CEDRS (excluding hepatitis C, STD, and HIV cases) for Calendar Year 2002, we found:

Completeness of CEDRS Disease Reports (Excluding Hepatitis C, STD, and HIV) Calendar Year 2002			
Element Required by Board Regulation	Percent Missing		
Patient's Ethnicity	68		
Patient's Race	62		
Physician Name	3		
Patient's Birth Date	3		
Source: Office of the State Auditor's analysis of the CEDRS database.			

As stated previously, according to Department management, the approximately 6,000 hepatitis C reports in CEDRS should not be included in our review because the hepatitis C Program is an entirely separate program. Therefore we analyzed hepatitis C cases separately. As with the other disease reports we reviewed, we found similar missing information for hepatitis C cases as shown in the following table:

Completeness of Hepatitis C Disease Reports in CEDRS Calendar Year 2002			
Element Required by Board Regulation	Percent Missing		
Patient's Ethnicity	81		
Patient's Race	79		
Patient's County	46		
Physician Name	21		
Patient's Birth Date	3		
Source: Office of the State Auditor's analysis of the CEDRS database.			

One of the purposes of CEDRS is to improve the response to public health incidents and the evaluation of control measures. We believe the lack of complete information may impede surveillance and follow-up investigation efforts. County designation allows authorized persons to view the case in CEDRS and designates the local health agency responsible for conducting the investigation. Additionally, Division staff stated that, in regard to hepatitis C, the number of cases assigned to each county can be useful to counties when applying for grant funds. Without the patient's address it may be difficult to complete follow-up investigations. If a case is missing the date-of-birth, it may frustrate efforts to identify and eliminate duplicate entries in CEDRS. Finally, demographic information such as sex, age, race, and ethnicity is useful in identifying higher-risk populations.

#### **Accuracy**

According to a CDC manual for the surveillance of vaccine-preventable diseases, "Detailed and accurate information (e.g., date of onset, laboratory results, duration of symptoms) may indicate the source of infection and possible contacts allowing interventions to prevent the spread of disease." Our test work found the following inaccuracies:

C **Inconsistent data** - 1,535 (34 percent) hepatitis C cases and 110 cases (1 percent) excluding hepatitis C had positive test results but were not listed as confirmed cases. Two percent of cases excluding hepatitis C and 1 percent of hepatitis C cases with positive test results had no test date listed.

- C Erroneous dates We also found that the Division cannot necessarily rely on the accuracy of other dates collected in CEDRS. For example, we identified 192 hepatitis C cases (3 percent) and 145 other disease cases (2 percent) in which the patient was tested for a disease before he/she became sick or was diagnosed with an illness. CEDRS asks for an onset/diagnosis date for each disease reported. Staff from several reporting entities told us these dates often refer to two different points in time. Also, CEDRS collects a test date. This term is often confusing because a "test date" could refer to several different dates, including specimen collection date, laboratory receipt date, or test completion date. As a result, timeliness analysis is limited and the reliability of date information in CEDRS is reduced. According to the CDC, to determine the source and prevent the spread of disease, it is important to obtain a discrete onset date. Additionally, it is important that the onset date be accurate because one of several ways the Division reports disease statistics is by onset month.
- C **Discrepancies between CEDRS and case file data** We found a few examples in which local health agencies' case files contained information that did not match information listed in CEDRS. For example, one county had a different test date listed in the case file than was listed in CEDRS. Another report in CEDRS listed a patient as alive, while the local health department case file indicated the patient was deceased.

#### **Quality Control Review**

Incomplete and/or inaccurate cases indicate the need for improved system controls. Currently the Division does not have an adequate CEDRS quality control review process to ensure case information is complete and accurate. We found the following problems:

- C There was no indication of staff review in about 3,200 cases of the approximately 8,300 cases we reviewed. The vast majority of these cases were entered directly by Division staff. According to staff, they review these data for completeness and accuracy as they enter them. However, there is no subsequent internal review for data entry errors. We believe staff should review a sample of cases for quality assurance purposes.
- C Staff do not ensure all required information is provided.
- C Staff sometimes "correct" errors or add missing information without verifying corrections with the reporting entity. Staff fill in the onset/diagnosis date,

type of lab test, and sex ID without confirming these changes with the reporting entity.

C Division staff do not review CEDRS cases to ensure consistency of dates and other information. We found 47 (0.6 percent) cases in which the date of entry into CEDRS preceded the date the case was reported. Logically, the case report date should precede or be the same as the date of entry into the system. Adequate system controls would detect and minimize these kinds of errors.

#### **Recommendation: No. 3:**

The Department of Public Health and Environment should increase efforts to ensure the completeness and accuracy of the information in CEDRS by systematically reviewing data entered directly by reporting entities or indirectly by Division staff.

# Department of Public Health and Environment Response:

Agree: Implementation: Implemented and ongoing: The Department already mails copies of the reporting rules and regulations along with convenient "wall charts" which list the reportable diseases and which information should accompany disease reports, on a yearly basis to reporting entities. The Department already reviews each record entered into CEDRS for completeness and accuracy.

Other than race and ethnicity for general communicable diseases (except hepatitis C), the reporting of required information is 97-99 percent complete. In addition, as the auditor's completeness on hepatitis C analysis showed, the percentage of completeness has improved since the year 2000 for some hepatitis C data elements, such as county. In Fiscal Year 2003, the hepatitis C program began more intensive follow-up efforts to contact persons reporting the disease to request missing data items. The hepatitis C program also implemented routine visits to laboratories to educate them on the reporting requirements and the importance of complete reporting. These efforts are ongoing and their results will be systematically reviewed quarterly.

Regarding the reporting of race and ethnicity, it is important to note that these factors have no bearing on immediate disease control. Rather, disease intervention is based on epidemiological factors. In addition, there are healthcare systems that have never included race and ethnicity in their record-keeping systems. Given that reporting of race and ethnicity is not

complete and that this information is not necessary for the routine control of communicable diseases, the Department will request by November 2003 that the Board of Health remove the requirement for reporting race and ethnicity with general communicable disease reports (except for hepatitis).

However, this will not preclude the Department from actively collecting race and ethnicity as needed, as for example in the case of special surveillance and prevention assessment purposes. Race and ethnicity may be helpful to identify populations disproportionately affected by a certain disease and enabling the Department to target the affected group with a particular intervention (e.g., vaccination).

The Department will continue to stress the importance of complete submission of required information by sending reminder notices and "wall charts" twice yearly to reporting entities. The "new" version of CEDRS which will be implemented by November 2003, will have some revised data fields to provide more accurate data. In addition, the Department will work to ensure more accurate data in CEDRS by implementing by February 2004 a quarterly quality assurance review process based on programmable queries of key data fields (e.g., confirmed status, test results, dates).

It is important to note that of the approximately 8,300 general communicable disease cases entered into CEDRS (except for hepatitis C), the auditors identified 47 cases or just 0.6% of cases where there was an inconsistency between the date a case was reported and the date that the case was entered into the data system.

#### **Regulations**

Throughout our review of reporting activities and follow-up investigations (see Chapter 2), we identified a number of areas in which current practice does not necessarily support or reinforce existing Board of Health communicable disease regulations. This has resulted in discrepancies, confusion, and a general lack of clarity. Specifically, we found:

C Timing of Reportables - The Board of Health has identified seven agents as being Immediately Reportable suspected bioterrorism agents. These include but are not limited to anthrax, botulism, plague, smallpox, tularemia, viral hemorrhagic fever, and brucellosis. We found that a number of these are categorized in regulation, both as Immediate Reportables and 24-hour reportables, or as Immediate Reportables and 7-day reportables. Specifically,

anthrax, botulism, and plague are categorized as "Immediately Reportable Suspected Bioterrorist Agents" and as 24-hour Reportable Diseases Upon Physician Diagnosis." Brucellosis and tularemia are both classified as Immediate Reportables and 7-Day Reportables. According to Department management, health care personnel must use their clinical judgment to determine whether a bioterrorism situation exists and, therefore, which reporting requirement applies.

- C **Required Information** As noted, CEDRS reports do not always contain all of the information required in regulation. Division staff are aware of data omissions. In fact, staff told us that not all required information, such as race and ethnicity, is routinely necessary to adequately perform their disease control function. This discrepancy is evident in Division guidelines that are disseminated to laboratories and local health agencies. Division guidelines do not state that specific information is required to be reported, only that it should be reported.
- C **Reportable Diseases** Board of Health regulations require animal bites by dogs, cats, bats, skunks, or other wild carnivores be reported within 24 hours. According to Division management, domestic animal bite incidents (e.g., dogs, cats) are typically addressed or investigated by local animal control agencies. By contrast, according to the Division, investigations of wild animal bites (e.g., bats, skunks, raccoons) are the responsibility of public health and public health agencies. While this may be the practice, Board regulations do not make this distinction. In addition, because animal control personnel do not have access to CEDRS, they are not privy to any domestic animal bite information reported in the system.

The Department needs to conduct a systematic review of existing communicable disease regulations and ensure they are clear and consistent with regard to the timing of communicable disease reports, the inclusion or exclusion of certain diseases or incidents, the data to be reported, and the identification of responsible entities. If revisions are needed, Department staff should make proposals for change to the Board. The Department also needs to make clear, through its actions and practices, that Board regulations, unless otherwise specified, are not "guidelines," but "requirements." One way in which this could be done is for the Department to ensure that its printed materials or other information disseminated to public health agencies are consistent with statutes and regulations. Also, appropriate actions to inform entities about reporting responsibilities and the possible penalties for failure to comply should be taken as described in the next section of the report.

#### **Recommendation No. 4:**

The Department of Public Health and Environment should ensure that its practices are consistent with Board of Health regulations for communicable diseases by:

- a. Reviewing existing rules and regulations and proposing appropriate regulatory changes related to the specific diseases and incidents requiring reporting, the required timing of reports, the information to be reported, and the identification of responsible entities.
- b. Ensuring printed materials and other information are consistent with Board of Health rules and regulations.

# Department of Public Health and Environment Response:

a. Agree. Implementation: Implemented and ongoing: The Department routinely reviews existing rules and regulations and proposes appropriate changes to the Board of Health. Prior to these audit findings, the Department was already scheduled to appear before the Board this fall with proposed changes to the rules and regulations. The Department will propose some additional changes by November 2003, to ensure that public health practices in the area of disease control and Board of Health rules and regulations are consistent.

The issue of reporting mammal bits requires some clarification. First, responding to animal bites is the responsibility of local health departments, which work cooperatively with area animal control agencies to conduct investigations. Second, animal control agencies have the responsibility for handling animal bites in which criminal charges may be filed, or a citation may be issued. Third, CEDRS is not and never has been the primary method for tracking or reporting bites. The unique characteristics of animal bites make reporting and tracking through CEDRS inefficient and cumbersome with no advantage from a public health standpoint. Reporting of mammal bite cases on the local level varies from written reports to telephone calls, depending on the circumstances and most appropriate course of action.

b. Agree. Implementation: January 2004. The Department will ensure its printed materials for reporting entities are consistent with Board of Health rules and regulations, beginning with the version of materials that will

reflect changes to be adopted by the Board which will take effect January 2004.

#### **Enforcement of Reporting Requirements**

According to Section 25-1-114, C.R.S., "It is unlawful for any person, association or corporation, and the officers thereof: (a) to willfully violate, disobey, or disregard the provisions of the public health laws or the terms of any lawful notice, order, standard, rule, or regulation issued pursuant thereto; or (b) to fail to make or file reports required by law or rule of the board relating to the existence of disease or other facts and statistics relating to the public health...." Statutory penalties for violations are also provided. Specifically, violators shall be punished by a fine of not more than one thousand dollars, or by imprisonment in the county jail for not more than one year. Other states, such as California, Wisconsin, and West Virginia, also have penalties for noncompliance with disease reporting requirements. These states' penalties are detailed in statutes and regulations and include fines and imprisonment.

According to statute, the Department's Division of Administration has the power and duty to enforce Colorado's public health laws and the standards, orders, rules, and regulations established, issued, or adopted by the Board. Department management and staff were unaware of this statutory charge and the existence of penalties. In addition, management indicated that they would prefer not to refer cases for prosecution. Consequently, there have been no penalties assessed to reporting entities for noncompliance with statutory or Board communicable disease reporting requirements. We agree, voluntary compliance is preferable to enforcement. However, adequate steps have not been taken to ensure voluntary compliance, as evidenced by the findings of our review. Statutory penalties clearly indicate that the General Assembly intended for individuals and entities to comply with public health laws and regulations. The Department should take steps to ensure compliance with communicable disease reporting requirements by monitoring data entry and reviewing for the timeliness of reports, as recommended previously. Also, the Department should communicate the mandatory nature of specific reporting requirements and inform entities and individuals of the potential penalties for failure to comply. If these actions are insufficient to ensure voluntary compliance and/or repeated or flagrant violations are identified, appropriate steps toward enforcement should be taken.

#### **Recommendation No. 5:**

The Department of Public Health and Environment should ensure compliance with statutory and regulatory communicable disease reporting requirements by informing public health and other health care agencies and individuals about the mandatory nature of the requirements and the possible penalties for noncompliance and by undertaking enforcement actions, when appropriate.

# Department of Public Health and Environment Response:

Partially Agree. Implemented and ongoing. As a result of this audit, the Department has reinforced with DCEED staff its authority to enforce the public health laws and regulations. The Department has never had to take enforcement actions for a public health reporting requirement due to the cooperative and good faith working relationship the Department has had and continues to have with its "public health partners" and because the current method of reporting of communicable diseases is a system that works. The Department will continue to make our reporting entities aware of their reporting requirements through the ongoing mailing of materials identified in our response to Recommendation 3. While we agree that continued education regarding the requirements for reporting is useful for promoting compliance, we disagree with the recommendation that would emphasize the penalties that could be imposed. Our considerable success in disease control in Colorado, and throughout the nation, relies on our collaborative working relationships with our community partners. The perception of the threat of penalties could damage this relationship, and could negatively impact reporting and disease control efforts. In the event of willful and/or ongoing noncompliance with reporting requirements, the Department would pursue enforcement actions.

# Communicable Disease Control Oversight

#### Chapter 2

#### **Follow-Up Investigations**

Follow-up is one of the most critical phases of communicable disease control. Follow-up investigations for many communicable diseases are critical for:

- C Determining the source of infection.
- C Determining the risk of spreading the infection to others.
- C Educating the patient about how he or she acquired the infection and the ways in which to prevent further spread.

Adequate follow-up reduces the chances for the unnecessary spread and/or outbreak of diseases. According to the Centers for Disease Control and Prevention (CDC), identification of all case contacts and follow-up of susceptible persons may reveal previously undiagnosed and unreported cases. Follow-up investigations also identify persons in need of treatment, thereby assisting in the prevention of disease spread. Rules and regulations promulgated by the Board of Health state that follow-up investigations may be conducted to confirm the diagnosis, treatment, and causes of reportable conditions and shall be considered official duties of the health department or health agency.

Despite the importance of follow-up investigations, we found they are not conducted in all cases. As part of our audit, we requested information from seven local health agencies on communicable disease cases reported in Calendar Year 2002. Our purpose in requesting this information was to determine the nature and extent of follow-up on 24-hour and 7-day reportable diseases. We found a number of problems that raise concerns about the adequacy, consistency, and completeness of follow-up for controlling and preventing communicable diseases statewide. Specifically:

C **Documentation of Investigations is Inadequate** - In some cases, communicable disease follow-up documentation does not exist, is located at local health agencies, is located at the Division, or does not contain all relevant information. For example, two local health agencies were unable to provide documentation of follow-up conducted for any of the 19 cases we requested. The Division was able to provide documentation for some of these. Local health departments were unable to provide documentation for four of the six West Nile virus cases we requested. Again, Division staff provided documentation. However, follow-up on West Nile cases will now be the responsibility of local health departments. Therefore, these agencies need to be aware of the types of information to be recorded in these cases.

Standard procedures are not always recorded during follow-ups. previously stated, one of the purposes of some follow-up investigations is to ensure that individuals are educated about their disease and the ways in which to prevent transmission, such as proper hand washing. We found disease cases in which there was no documentation that education was provided. In one hepatitis A case, there was no evidence that proper hygiene education was provided or that the individual had been advised to stay home from work. Hepatitis A can be a foodborne disease, is reportable within 24 hours, and is considered dangerous to the public's health. In this particular case, the patient worked with and served food to an at-risk population. According to the case notes, the patient admitted that he had poor hygiene. Maintaining documentation for follow-up investigations is important. According to information provided by the Department, during an investigation a local agency should record everything because factors which seem irrelevant at the time may become relevant in the future (i.e., if there were an outbreak).

- C **Investigations Are Not Conducted** One local health agency in our sample does not conduct follow-up investigations for cases of acute hepatitis B. Follow-up investigations should be conducted in these cases to determine the source and prevent the spread of the disease.
- C **Investigations Are Conducted Inconsistently** We identified numerous examples in which the same communicable disease was followed up by one public health entity but not by another. For example, in Calendar Year 2002, staff at one local health agency we visited investigated cases of one 7-day reportable (kawasaki syndrome-a relatively rare but serious illness occurring in children) while other agencies in our sample did not.

It is important to note that we originally intended to review data on 88 cases. However, the final number of cases included in our analysis was 53. The reduction in our sample size was due to inconsistent directives from the Division on the

specific diseases for which follow-up is indicated. Therefore, the findings from 35 cases included in our original sample were removed from this analysis because Division staff indicated they were not applicable for follow-up. The issue of inconsistent direction is central to problems we identified with follow-up investigations.

#### **Need for Guidelines**

Overall, there are no comprehensive standards or guidelines for the local public health agencies to apply in conducting communicable disease follow-up investigations. As a result, inconsistencies, confusion, and conflicting practices surround this important component of the State's communicable disease control system. The following section discusses three main areas where the Department should focus its efforts for improving communicable disease follow-up.

- C **Guidelines** One local health agency within our sample has adopted its own follow-up guidelines. In addition, El Paso County Department of Health and Environment staff suggested that the Department could develop something similar to the comprehensive manual used by the County of Los Angeles Department of Health Services. The Department needs to provide guidelines for conducting follow-up investigations on all 24-hour and 7-day reportable diseases and incidents. At a minimum, these guidelines should delineate the following:
  - < The diseases and conditions that do or do not require follow-up.
  - < The specific follow-up protocols, including the steps to be taken and time frames in which steps should be completed.
  - < The entities or individual(s) responsible for conducting follow-up investigations.
  - < The extent and format of follow-up documentation. This could include encouraging the use of CEDRS for recording case notes.

Although, the Division has developed follow-up guidelines for such diseases as hepatitis A and West Nile virus, this is not sufficient. Staff at several local health agencies we visited during our site visits expressed the need for additional guidelines. We found that other states including Missouri, New Jersey, Ohio, and West Virginia have created disease control manuals that provide guidelines for conducting follow-up investigations. Colorado's Public Health Department should do the same and, in addition, should make

its guidelines available online for easy access by all local health agencies and other interested individuals and entities.

Communication - Division personnel have a responsibility to share information with local health agencies and other public health personnel in the State regarding the types of diseases requiring follow-up investigations. According to Division staff, not all 24-hour and 7-day reportable diseases require follow-up. Specifically, staff told us that there are at least nine diseases, conditions, or incidents that do not necessitate routine follow-up. These are group A and B streptococci, influenza, streptococcus pneumoniae, animal bites, toxic shock syndrome, kawasaki syndrome, aseptic meningitis, legionnaires disease, and cases of chronic hepatitis B.

Not all public health officials are in agreement with the Division's position in this area. For example, according to CDC information, cases of chronic hepatitis B are potentially infectious to others. Additionally, documents on the Department's Web site state that household contacts of chronically infected hepatitis B persons are a risk group. Therefore, education could be useful in helping to prevent the spread of chronic hepatitis B. Chronic hepatitis B carriers should be advised not to share personal care items such as razors or toothbrushes. Further, other states follow up on cases of chronic hepatitis B. The County of Los Angeles Department of Health Service's manual states precautions, such as prevention of transmission via sexual routes, should be stressed to chronic hepatitis B carriers and contacts of the carrier should be evaluated.

In addition, some local health agencies conduct follow-up on diseases and incidents that Division staff have indicated do not routinely necessitate follow-up. Denver Public Health follows up on cases of kawasaki syndrome. Northeast Colorado Health Department conducts follow-up on animal bite cases. El Paso County Department of Health and Environment conducts follow-up on chronic hepatitis B cases. We believe the Division should communicate its expectations regarding follow-up on these cases to local health agencies. Denver and Northeast Health Departments may determine that their resources could be used more effectively elsewhere if they were made aware that follow-up was not needed for certain diseases or in animal bite cases.

C **Training** - According to the CDC, training and documentation should be available to health agency personnel participating in surveillance activities, including topics such as reporting requirements, epidemiologic methods, case findings, and investigations. The Division did develop a training course in 1999. However, we believe the Division has not provided adequate guidance,

including training, to local health agencies regarding follow-up investigations. Staff at many local health agencies stressed their concern regarding expectations for conducting follow-up investigations. They are not always clear about who is responsible for conducting investigations, what information is to be collected and documented during investigations, and the time frames for completing investigations. For example, as discussed in the following section, two state regional epidemiologists are even unclear about who is responsible for conducting follow-up investigations. Because the Department often relies on local health agencies to be the first line of response in the event of a communicable disease outbreak or epidemic, it is critical that the roles and responsibilities of the various health entities be clearly identified.

Finally, we believe the Department should monitor the follow-up activities of local health agencies to ensure investigations are occurring. The Department could encourage local health agencies to utilize CEDRS case notes to document follow-up conducted. The use of CEDRS case notes would increase communication between the State and local health agencies and would also allow Division staff to ensure follow-up is conducted.

#### **Recommendation No. 6:**

The Department of Public Health and Environment should ensure that statutory responsibilities for investigating communicable diseases are fulfilled by providing statewide guidance and oversight as follows:

- a. Identifying and communicating to local health agencies those reportable diseases and conditions that do or do not require follow-up.
- b. Providing training to local health agencies.
- c. Developing and providing comprehensive guidelines to local health agencies for conducting and documenting follow-up investigations.
- d. Monitoring the follow-up conducted by local health agencies to ensure investigations are adequate and complete.

### Department of Public Health and Environment Response:

a. Agree. Implementation: November 2003. The Department provides ongoing technical guidance and support to local health agencies regarding the investigation and follow-up of reportable diseases. To further clarify, the Department will communicate, in the form of a memo to local health agencies, which diseases require public health follow-up. In some instances, follow-up investigations are conducted by the Department and not by the local health departments. This has been particularly true for "new" diseases such as SARS and West Nile Virus, which require a statewide epidemiological strategy and statewide dissemination of public health information, and for rare diseases such as plague, for which the state has specialized expertise. In these cases, primary documentation would be maintained at the state level rather than by local health agencies.

Regarding communicable disease follow-up, the Department agrees that the current practices on the local level need to be more formalized and documented to a greater degree. However, the absence of a more consistent system should not be interpreted to represent a lack of follow-up investigations by local agencies.

The audit report also raises an apparent difference of opinion between the diseases identified for follow-up by the Department and those identified by other health agencies. It is important to clarify that local health departments are responsive to the needs of their communities, and tailor their programs to address local priorities. For example, El Paso County has made hepatitis B a public health priority for its community. While at the state level hepatitis B is not as critical a priority as other communicable diseases, the Department encourages and supports El Paso County in its efforts to address this disease within its region.

In fact, all evidence available regarding disease outbreak outcomes over the past decade supports that disease control follow-up in Colorado, performed at the local public health level with support from the state, is outstanding and a model for the nation.

b. Agree. Implementation: Implemented and ongoing: The Department has provided formal training to local agencies regarding the investigation and control of communicable diseases. The Department will continue to

provide training to local health agencies, in addition to the technical guidance provided in "c", below, tailored to agencies' specific needs.

c. Agree. Implementation: Implemented and ongoing: The Department has developed a number of disease-specific guidelines and manuals for conducting follow-up investigations, which are posted on the Department's web site. The Department supplied to the auditors a list of six sets of comprehensive, disease-specific guidelines for many of the diseases requiring follow-up, and one additional guidance manual for foodborne diseases as examples of the Department's work in this area. Additional guidelines are in draft form and will be disseminated to local health agencies.

To provide ongoing and more comprehensive guidance to local health agencies in this area, the Department will develop and disseminate, by May 2004, a manual on communicable disease control for local health agencies. Included will be the nature and documentation required on follow-up investigations for each reportable disease.

d. Agree. Implementation: Implemented and ongoing: The Department already monitors follow-up conducted by local health agencies by coordinating and collaborating on the investigations of many individual disease reports and on disease outbreaks. To expand this monitoring process, the Department will conduct a yearly survey of local health agencies regarding their follow-up policies, processes, and content. Deficiencies will be identified and addressed in the form of formal written communication and discussion. The baseline assessment will be implemented by November 2003.

#### **Regional Epidemiologists**

The Department employs five regional epidemiologists who are physically assigned to various geographic regions and specific local health agencies throughout the State. We reviewed the roles and responsibilities of the regional epidemiologists and found they are unclear. Consequently, it is difficult to determine whether they have been effective in achieving the purposes for which they are employed or if they are an efficient use of resources. This problem is further complicated by the recent addition of 13 bioterrorism epidemiologists to Colorado's statewide bioterrorism response program.

We spoke with all of the Department's regional epidemiologists and found they have an inconsistent view of their roles within the State's communicable disease control system. For example, three of the regional epidemiologists stated that their primary responsibility is to ensure communicable disease follow-up investigations are completed either directly, or indirectly, by local health agency personnel. The other two regional epidemiologists stated that they are unclear who is responsible for conducting follow-up investigations. This lack of clarity is shared by local public health agency personnel. Staff from local public health agencies we visited told us that they are unsure of the functions their respective state regional epidemiologists serve. Local health agency staff did indicate, however, that the regional epidemiologists are always responsive to requests for assistance.

The lack of clarity with regard to the responsibilities of the Department's regional epidemiologists raises questions we believe the Department should resolve to ensure the cost-effective use of resources in controlling and preventing communicable diseases and epidemics. Some of the issues we identified are:

- Gaps in services The job descriptions for the five regional epidemiologists list many functions that are to be performed on a daily and weekly basis. The job descriptions include identifying and resolving surveillance and reporting problems, and also educating, and providing information to, local health agencies, physicians, nurses, laboratories, hospitals, and schools about disease control and new technical data. We found that a number of tasks are not conducted on a regular or daily basis by all five regional epidemiologists. As previously mentioned, not all regional epidemiologists ensure follow-up investigations are conducted, and local health agency staff in our sample indicated a need for additional CEDRS training.
- Potential duplication of job duties In Fiscal Year 2003, Colorado received \$3.3 million in CDC bioterrorism funding for the Surveillance and Epidemiology topic area listed in the Department's work plan. Of this total, the Department allocated approximately \$917,000 to 13 local health departments to hire bioterrorism epidemiologists. There appears to be overlap between the job duties of the State's regional epidemiologists and the job duties of these 13 bioterrorism epidemiologists. Both are charged with monitoring surveillance and reporting activities, educating local health agencies, and disseminating information. We understand that some overlap in job duties may be necessary to ensure Colorado has trained health professionals. However, as the Department is finalizing the duties and responsibilities of the bioterrorism epidemiologists, it should coordinate functions to ensure there is no unnecessary duplication of services.

C Geographical distribution - The geographical territories of the Department's five epidemiologists cover all of the counties in the State except for those counties in the Metro Denver area. However, it does not appear that all of the remaining counties receive uniform coverage by the regional epidemiologists. For example, one local health department reports that they have limited contact with their regional epidemiologist. With the addition of 13 local epidemiologists, it is even more important that the Department evaluate the statewide need for and coverage of the epidemiologists it employs.

We believe the Department should evaluate the need for the five regional epidemiologists. If it is determined that a need exists, the Department should clearly define the epidemiologists' roles and functions and ensure there are no gaps in services provided to local health agencies, there is no duplication of effort occurring between the five regional epidemiologists and the 13 bioterrorism epidemiologists, and the geographical distribution of the epidemiologists' jurisdictions is appropriate. The five epidemiologists could be used to provide CEDRS and follow-up investigation training, assist in the development of follow-up investigation guidelines, and work with local health agencies and laboratories to ensure timely reporting of communicable disease cases.

#### **Recommendation No. 7:**

The Department of Public Health and Environment, in conjunction with local health agencies, should ensure the effectiveness and usefulness of its five regional epidemiologists by identifying and clearly defining programmatic functions and geographical jurisdictions.

### Department of Public Health and Environment Response:

Agree. Implementation: Implemented and ongoing: The Department has defined programmatic functions of its regional epidemiologists. By necessity, this has changed somewhat over time as funding sources and expressed needs of local health agencies have changed. The Department has clearly defined their geographical jurisdictions. To further ensure the regional epidemiologists' effectiveness and usefulness, the Department will convene a working group including local health agencies, by February 2004, to continue to assess the functions, responsibilities, and geographic jurisdictions of its regional epidemiologists.

The audit report's finding of potential duplication of job duties among the bioterrorism epidemiologists and the regional epidemiologists requires some clarification. The epidemiologists who are funded by the bioterrorism grant have very specific, prescribed duties that must adhere to the guidelines issued by the CDC for bioterrorism preparedness. The primary function of the state's regional epidemiologists is to assist local agencies and public health nurses on a day-to-day basis in addressing communicable disease issues. By design, there is some cross-training among these two groups of epidemiologists in order to ensure that Colorado has trained health professionals in place and ready to respond in an emergency situation.

#### **Records Retention**

Section 24-80-102.7, C.R.S., requires agencies with public records to consult with State Archives and the Attorney General and develop retention and disposition policies. The Department has developed medical record retention policies for certain diseases such as HIV, STDs, tuberculosis, and vaccine-preventable diseases. However, the Department has not provided these policies to local health agencies. Additionally, the Department has not adopted any communicable disease record retention policies for other diseases, such as hepatitis A.

In the absence of clear direction, local public health agencies have developed their own record retention policies and practices. We found, however, that these policies are not consistent with the schedules for specific communicable diseases approved by the Colorado State Archivist. For example, surveillance case reports for vaccine-preventable diseases such as pertussis, measles, rubella, mumps, and bacterial meningitis are required to be kept for five years. We found local health agencies maintain these types of communicable disease records from one year to indefinitely. Additionally, local health agencies store records in various locations, including file cabinets, storerooms, and electronic databases. Maintaining the security of the confidential communicable disease records is critical. Although staff at the local health agencies we visited were mindful of the need for security and confidentiality, it is unclear whether all storage locations are sufficiently secure.

Other states, such as Texas, have adopted record retention policies for public health records, including directives for communicable disease surveillance forms. Establishing standard policies for the retention of communicable disease records is important because there are risks associated with keeping communicable disease records for too long or for an insufficient amount of time. If records are kept for too long, there is a greater risk for a breach of confidentiality requirements. Also, according to the Colorado State Archivist, storage space for paper as well as

electronic information is costly, resulting in unnecessary expenses for records that are maintained longer than needed. Keeping records for an insufficient amount of time may result in the loss of data needed for statistical purposes or for other matters such as legal actions. In addition to establishing a length of time for record retention, defining appropriate methods of storage and of record destruction are important components of a comprehensive record retention policy.

During our site visits, staff from several local health agencies told us they would appreciate guidance from the Department regarding appropriate standards for communicable disease record retention, storage, and destruction. We believe the Department would render a valuable service by providing this direction to local public health agencies through the adoption and dissemination of policies.

#### **Recommendation No. 8:**

The Department of Public Health and Environment should adopt and disseminate comprehensive communicable disease record retention policies to local public health agencies and ensure these policies are approved in accordance with Section 24-80-102.7, C.R.S.

### **Department of Public Health and Environment Response:**

Agree. Implementation: November 2003. The Department has already drafted and will adopt and disseminate approved communicable disease record retention policies to local public health agencies.

#### **Performance Measures**

According to guidelines created by the Office of State Planning and Budgeting (OSPB), performance measures should be in direct support of, or compatible with, a department's statement of strategic intent or the program's mission statements. Although the CDPHE has developed performance objectives for many of its program areas, we found the Division lacks some comprehensive performance measures to adequately reflect its mission. Some of the Division's objectives include:

- Investigate an control communicable disease cases and outbreaks.
- Detect, report, and analyze diseases of public health significance.

• Disseminate information and/or provide training regarding prevention, diagnosis, or treatment of contagious diseases.

The Division's mission states that it works to track, control, and prevent the spread of communicable diseases throughout the State. Although the Division has performance objectives that relate to case investigations or follow-up, which are integral steps in controlling and preventing the spread of disease, the link between the Division's performance measures and its performance objectives in this area is weak. For example, the six measures related to the Division's objective of investigating and controlling communicable disease outbreaks do not apply to investigations or outbreaks. Rather, they are designed to measure the number of cases, such as the number of hepatitis A cases reported for investigation, the number of vaccine reportable diseases reported for investigation, and the number of zoonotic diseases reported for investigation. They do not adequately reflect the ways in which the Division intends to accomplish its objective of investigating and controlling communicable disease outbreaks.

Without comprehensive performance measures, the Department cannot adequately measure performance related to its mission. Updating performance measures would provide the Division, the Department, the Joint Budget Committee, and others who monitor and evaluate the Department's activities with the benchmarks to measure accomplishments and assess the effectiveness and efficiency of operations.

#### **Recommendation No. 9:**

The Department of Public Health and Environment should review the performance measures reported to the Joint Budget Committee in its annual budget request and adopt measures of efficiency and effectiveness related to its mission of controlling and preventing the spread of communicable diseases through investigations and/or follow-up.

### Department of Public Health and Environment Response:

Agree. Implementation: July 2004. The Department does review its performance measures submitted to the Joint Budget Committee and has revised them on several occasions in recent years. Based on this audit, the Department will review its performance measures for the next annual budget request cycle and will revise them by July 2004, to more clearly relate the measures of efficiency and effectiveness to its mission of communicable disease control.

#### **Disease Statistics**

The Division is inaccurately counting some disease statistics. Department regulations specify that all 24-hour and certain 7-day reportable diseases be counted only when confirmatory laboratory data become available. The Centers for Disease Control and Prevention (CDC) publishes guidelines for all communicable diseases to assist health agencies in designating disease status. According to the CDC, diseases may be classified as suspect, probable, or confirmed. CEDRS contains a field for reporting entities or Division staff to assign one of these designations for each case entered. The Division states that this regulation, in practice, does not reflect its programmatic needs and further reports that this field is inconsistently completed or updated. As recommended previously, the Division should ensure that its practices are consistent with Board of Health regulations for communicable diseases by reviewing existing rules and regulations and proposing appropriate regulatory changes.

We compared the disease statistics for Calendar Year 2001 posted on the Division's Web site with cases reported in the 2001 CEDRS database to determine if the Division is counting only confirmed cases. We found the Division does not always limit its counts to confirmed cases only. Rather, unconfirmed cases are included in some of the counts. For example, of the 7-day reportable diseases specified in regulation to be counted only upon confirmation, we found that 9 of the 14 were counted even when they were not listed in CEDRS as confirmed. The degree of this inaccurate counting varies substantially for each disease. In total, the Department reported 2,206 cases for these 14 diseases when 2,096 cases were listed in CEDRS as confirmed cases. The cases most frequently counted when not confirmed were aseptic meningitis and pertussis.

The reliability of disease surveillance and summary statistics is diminished if they are not based on accurate, consistent, and complete information. The Department should ensure its communicable disease statistics are accurately compiled and reported, particularly when the steps to do so are easily implemented:

C Familiarize staff with and apply regulations - Division staff were unaware of the Board regulations requiring only confirmed cases be counted. In addition, when informed of the regulation, staff indicated that they do not necessarily agree, because there are legitimate reasons for counting probable cases for some diseases, such as pertussis. While this may be so, existing regulations differ. The Department needs to make staff aware of the regulations and ensure compliance with them, or take steps to change them.

C Apply the data entry review process - Division staff told us that they review all cases entered into CEDRS to ensure reporting entities have assigned a case status (i.e., confirmed, probable, etc.). We found, however, that Division staff do not consistently apply the review process. In fact, 28 percent of the total hepatitis C cases and 1 percent of the cases, excluding hepatitis C, reported in 2002 had a blank or unknown case status. Furthermore, we found that staff not only mistakenly counted cases with a case status other than "confirmed" but also counted cases with no case status reported. The Department needs to ensure that Division staff apply CEDRS review processes and that they do not inaccurately count disease cases.

#### **Recommendation No. 10:**

The Department should improve the accuracy and reliability of disease statistics by ensuring staff comply with Board of Health regulations and follow CEDRS data entry review procedures.

### Department of Public Health and Environment Response:

Agree. Implementation: February 2004. The Department maintains accurate and reliable disease statistics. We count all cases, whether confirmed or probable, if they are important to the implementation of timely and effective disease control measures and the protection of public health. In these instances, the accepted public health benefit of counting these cases necessitates a change in the current Board of Health rules and regulations, which only address the counting of confirmed cases. The Department will request, by November 2003, that the Board of Health revise the communicable disease rules and regulations by deleting the stipulation that cases be counted (only) when confirmatory laboratory data become available. To clarify and ensure more consistent programmatic practices, the Department will develop a written policy, by February 2004, which addresses the criteria for officially "counting" cases and the review process for cases entered into CEDRS.

#### Appendix A

### Rules and Regulations Pertaining to Epidemic and Communicable Disease Control

#### 6 CCR-1009-1 Regulation 1. Reportable Diseases

For the purpose of these regulations, the diseases named in the following lists are declared to be dangerous to the public health and shall be reportable in accordance with the provisions of these regulations.

The Colorado Board of Health also requires the reporting of any unusual illness, or outbreak, or epidemic of illnesses which may be of public concern whether or not known to be, or suspected of being, communicable. Such illnesses include, but are not limited to, Lassa fever, typhus, or yellow fever, which have the potential to be brought into Colorado, are readily transmitted, and are likely to be fatal. Such outbreaks or epidemics of illnesses include those which may be a risk to the public and which may affect large numbers of persons or be outbreaks of a bioterrorist agent or of a newly recognized entity; such outbreaks or epidemics shall include but are not limited to those related to contaminated medical devices or products or suspected to be related to environmental contamination by any infectious agent or toxic product of such an agent.

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

24-Hour Reportable Diseases Upon Physician's Diagnosis - Confirmed or Suspected		
Animal bites by dogs, cats, bats, skunks, or other wild carnivores	Meningitis caused by Neisseria meningitidis or Haemophilus influenzae	
Anthrax	Poliomyelitis	
Botulism	Plague	
Cholera	Rabies in Man	
Diphtheria	Rubella	
Group outbreaks- including food poisoning	Syphilis	
Hepatitis A	Active Tuberculosis	
Measles (rubeola)	Typhoid fever	

7-Day Reportable Diseases Upon Physician's Diagnosis		
Brucellosis	Pertussis syndrome	
Encephalitis	Q fever	
Giardiasis	Relapsing fever	
Hepatitis B	Rubella, congenital	
Legionellosis	Tetanus	
Malaria	Transmissible spongioform encephalopathy	
Meningitis, aseptic	Trichinosis	
Mumps	Tularemia	

7-Day Reportable Diseases Upon Laboratory Confirmation		
Amebiasis	Hemolytic uremic syndrome, if 18 years or less	
Bites by animals not on 24-hour list	Kawasaki syndrome	
Campylobacteriosis	Leprosy	
Chancroid	Listeriosis	
Cryptosporidiosis	Lyme disease	
Cyclospora	Lymphogranuloma venereum	
Escherichia coli 0157:H7 and shiga toxin-producing Escherichia coli	Psittacosis	
Gonorrhea	Rocky Mountain Spotted fever	
Hantavirus	Salmonellosis	
Hepatitis C, acute	Shigellosis	
Hepatitis, other viral	Toxic shock syndrome	

#### 7-Day Reportable Diseases **Upon Confirmatory Lab Tests Laboratories Only** Bacillus anthracis Mumps Bordetella pertussis Mycobacterium tuberculosis Borrelia burgdorferi Neisseria gonorrhoeae Brucella species Plasmodium species Poliomyelitis Campylobacter jejuni Chlamydia trachomatis Q fever Clostridium botulinum Rabies Corynebacterium diphtheriae Relapsing fever (Borrelia species) Cryptosporidium Rocky Mountain Spotted fever Cyclospora Rubella (acute infection) Dengue fever St. Louis Encephalitis Escherichia coli 0157:H7 and shiga toxin-Salmonella species, including typhi producing Escherichia coli Entamoeba histolytica Shigella species Francisella tularensis Treponema pallidum Giardia lamblia Vancomycin resistant Staphylococcus aureus Vibrio cholerae Haemophilus ducreyi Vibrios, non-cholera\* Hantavirus Influenza Western equine encephalitis Legionellosis West Nile virus Listeria monocytogenes Yersinia pestis Yersinia, non-pestis\* Measles (acute infection)

**Note:** \*Condition reportable only in the Denver Metropolitan Area - Adams, Arapahoe, Denver, Douglas, and Jefferson counties.

In addition, a laboratory shall report when any of the following results are found:

Group A streptococci - positive culture from a normally sterile site\*
Group B streptococci - positive culture from a normally sterile site\*
Haemophilus influenzae - positive culture from a normally sterile site
Hepatitis A - positive IgM anti-HAV
Hepatitis B - positive HBsAg or IgM anti-HBc
Hepatitis C - positive antibody titer or more specific tests
Neisseria meningitidis - positive culture from a normally sterile site
Streptococcus pneumoniae - positive culture from a normally sterile site.

\*Condition reportable only in the Denver Metropolitan Area (Adams, Arapahoe, Denver, Douglas, and Jefferson Counties).

#### Appendix B

#### **Timeliness Methodology**

We reviewed all communicable disease reports made in CEDRS in Calendar Year 2002 to assess their timeliness. CEDRS does not contain the specific dates needed to calculate the exact timeliness (i.e., discrete clinical diagnosis and test completion dates). However, we used the dates available in CEDRS (i.e., "test date," which Division staff stated is most often the specimen collection date) and, based on information provided by the Division, allowed three days, the estimated amount of time to accommodate logistical considerations related to specimen transport, testing, and reporting. In addition, we allowed one day for data entry for those cases entered by Division staff.

Of the approximately 16,000 communicable disease reports made in Calendar Year 2002, we did not review about 1,000 cases for timeliness, because the test date or the report date was either missing or unreliable. We also did not review reports of animal bites, because CEDRS does not designate between the different types of bites to be reported in 24 hours and 7 days. Of the remaining 15,000 disease reports evaluated for timeliness, 1 percent were 24-hour reportables, 39 percent were hepatitis C cases reportable in 7 days, and 60 percent were 7-day reportable conditions (not including hepatitis C).

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