

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Disease Control and Environmental Epidemiology Division

DETECTION, MONITORING, AND INVESTIGATION OF ENVIRONMENTAL AND CHRONIC DISEASE

6 CCR 1009-7

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

Adopted by the Board of Health on November 15, 2017. Effective January 14, 2018.

REGULATION 1 REPORTABLE ENVIRONMENTAL AND CHRONIC DISEASES

The Department has the power and duty to promote, protect, and maintain the public's health by preventing, delaying, or detecting the onset of environmental and chronic diseases dangerous to public health and to investigate and determine the epidemiology of those diseases that contribute to preventable or premature sickness, death and disability.

I. DEFINITIONS

For the purpose of this regulation:

- A. "Chronic disease" means impairment or deviation from the normal functioning of the human body which: (a) is permanent; (b) leaves residual disability; (c) is caused by nonreversible pathological alterations; (d) requires special patient education and instruction for rehabilitation; or (e) may require a long period of supervision, observation, and care.
- B. "Environmental disease" means an impairment or deviation from the normal functioning of the human body which: (a) may be either temporary or permanent; (b) may leave residual disability; (c) may result in birth defects, damage to tissues and organs, and chronic illness; and (d) is caused by exposure to hazardous chemical or radiological materials present in the environment.
- C. "Investigatory material" includes but is not limited to medical, coroner and laboratory records or reports; clinical specimens or clinical material; testing and test results; samples or samplings; environmental media (including water, air, soil or sediment); confidential commercial, geological, or geophysical data.
- D. "Reportable environmental and chronic diseases" means a chronic disease, environmental disease, syndrome or condition that is:
 - 1. A disease, syndrome, or condition identified in Appendix A, Reportable Environmental and Chronic Diseases Table, or
 - 2. A disease, syndrome, or condition that is known or suspected to be related to an exposure to a toxic substance, prescription drug, over-the-counter medication or remedy, controlled substance, environmental media, or contaminated product that results in hospitalization, treatment in an emergency department, or death, and is:
 - a. Suspected of being a cluster, outbreak or epidemic,
 - b. A risk to the public due to ongoing exposure,

- c. At an increased incidence beyond expectations,
- d. Due to exposure to food, environmental media (including water, air, soil or sediment), or other material, such as marijuana products, that is contaminated by a toxic substance, hazardous substance, pollutant or contaminant,
- e. A case of a newly recognized or emerging disease or syndrome,
- f. Related to a healthcare setting or contaminated medical devices or products, such as diverted drugs, or
- g. May be caused by or related to a suspected intentional or unintentional release of chemical or radiological agents.

The Department may temporarily require reporting, or a change in manner or frequency of reporting for reportable environmental and chronic diseases or other diseases, syndromes, conditions, illnesses or exposures that are potentially dangerous to the public health and need to be monitored to prevent, treat, or control, environmental disease or chronic disease.

II. REPORTING

When the reportable environmental and chronic disease is listed in Appendix A, reporters will report in the manner and time frame delineated in Appendix A. Any other disease that meets one or more criteria in definition D.2 of Regulation 1 must be reported within 24 hours.

- A. Each report will include the minimum necessary information to achieve the public health purpose of these regulations. For all conditions listed in Appendix A, or any other disease that meets one or more criteria in definition D.2 of Regulation 1, except for adverse drug reactions, each report shall include the patient's:
 - 1. Full name
 - 2. Date of birth
 - 3. Gender
 - 4. Race
 - 5. Ethnicity
 - 6. Phone number
 - 7. Address (including city and county)
 - 8. Name and address of responsible physician or other health care provider, and
 - 9. Any other information that is needed to locate the patient for follow up.
- B. For adverse drug reactions identified in Appendix A, the report shall include the patient's:
 - 1. Age
 - 2. Gender
 - 3. Race
 - 4. Ethnicity, and
 - 5. County

If the Department identifies an imminent need to treat, control, investigate, or prevent adverse drug reactions that are dangerous to public health, patient-identifying information identified in II. A of Regulation 1, must be reported to the Department in a timely manner.

- C. With regard to birth defects, developmental disabilities, chromosomal abnormalities, and neural tube defects reported pursuant to Regulation 1, the Department shall collect no additional information about pregnancy outcome other than what is required for the vital record form.
- D. All laboratory information reported shall include specimen accession number or comparable identifier. Reports will be submitted in the manner prescribed by the Department.

REGULATION 2 INDIVIDUALS AND ENTITIES RESPONSIBLE FOR REPORTING

When the reportable environmental and chronic disease is listed in Appendix A, reporters include health care providers, laboratories; coroners; and hospitals.

When the reportable environmental and chronic disease is any other disease that meets one or more criteria in definition D.2 of Regulation 1, reporters include laboratories, coroners, hospitals, and community clinics with emergency rooms.

REGULATION 3 PROCEDURES FOR THE INVESTIGATION OF ENVIRONMENTAL AND CHRONIC DISEASES

The Department and county, district, and municipal public health agencies shall employ reasonable investigative techniques as part of systematic surveillance for reportable environmental and chronic diseases. Reporting in one community may lead the Department or county, district or municipal public health agencies to investigate whether or not public health is endangered either in the same community or in other communities physically removed but environmentally similar to that of the reported case.

Investigations shall be limited to information that is pertinent, relevant and necessary to the investigation, as determined by the agency conducting the investigation. Such investigative techniques include but are not limited to:

1. Review by authorized personnel of investigatory material to identify and characterize the index case and other cases in a region, community, or workplace; such review of investigatory material may occur without patient consent and shall be conducted at reasonable times and with such notice as is reasonable under the circumstances. Where feasible, facilities are encouraged to provide remote electronic access to authorized department and/or county, district or municipal public health agency staff for this purpose;
2. Performing follow-up interview(s) to collect pertinent and relevant information about the cause or risk factors for the reportable environmental or chronic disease;
3. Medical examination and testing of persons with the explicit consent of such persons;
4. Obtaining from public or private businesses or institutions the lists of persons with a similar or common potential exposure to a reported case; such exposure may be current or have occurred in the past;
5. Interviewing or administering questionnaire surveys confidentially to any resident of a community or any agent, owner, operator, employer, or employee of a public or private business or institution, that is either epidemiologically associated with a reported case or has had a similar exposure to a reported case;
6. Collecting and analyzing samples or measurements of items that may be related to the cause of the outbreak or reportable disease, such as food, environmental media (including water, air, soil or sediment), other substances or material, such as marijuana products, a prescription drug, an over-the-counter medication or remedy, a controlled substance, or physical agents;

7. Taking photographs or video related to the purpose of the investigation; if the photographs/video are taken in a business, the employer shall have the opportunity to review the photographs/video taken or obtained for the purpose of identifying those which contain or might reveal a trade secret;
8. Entering a public or private entity, such as a business or school, for the purpose of conducting investigations of those processes, conditions, structures, machines, apparatus, devices, equipment, records, and materials within the place of employment which are relevant, pertinent, and necessary to the investigation; such investigations shall be conducted during regular working hours or at other reasonable times and with such notice as is reasonable under the circumstances;
9. Review of workers' compensation claims;
10. Review of toxic tort or product liability claims filed with state or federal courts within the state; and
11. Review of previously conducted environmental or product sampling data that may be related to the cause of the outbreak or reportable disease.

The Department and county, district, and municipal public health agencies shall have access to investigatory material. This may include requiring access to trade secrets such as product formulations, manufacturing processes or devices. Investigatory material is to be used by the department and county, district, and municipal public health agencies to the extent necessary for disease control efforts and the development of prevention programs.

REGULATION 4 INFORMATION SHARING

When the Department learns of a reportable environmental or chronic disease, it shall notify the affected county, district or municipal public health agency in a timely manner, usually within the timeframe for reporting in appendix a. When a county, district or municipal public health agency learns of a reportable environmental or chronic disease, it shall notify the Department in a timely manner, usually within the timeframe for reporting in Appendix A. If it is a disease that meets one or more criteria in definition D.2 of Regulation 1, the Department and affected county, district or municipal public health agency shall notify each other usually within 24 hours.

Information is shared only between authorized personnel and only the minimum necessary to treat, control, investigate, or prevent environmental disease or chronic disease that is dangerous to public health.

Sharing of trade secrets, and confidential commercial, geological, or geophysical data shall be performed in a manner that preserves the confidentiality of the information.

REGULATION 5 CONFIDENTIALITY

All investigatory material acquired or created and held by the Department or a county, district or municipal health agency in compliance with these regulations shall be held as confidential pursuant to C.R.S. 25-1-122(4). In addition, trade secrets and confidential commercial, geological, or geophysical data submitted to or held by the department or county, district or municipal public health agencies in compliance with these regulations shall be confidential to the extent permitted by law. This information is to be used by the public health agencies as source material for necessary disease control efforts and the development of prevention programs.

Reasonable efforts shall be made by the Department or investigating county, district or municipal health department to consult with the attending physician or medical facility caring for the patient prior to any further patient follow-up by the department or a county, district or municipal health agency.

Appendix A. Reportable Environmental and Chronic Diseases

Disease/Event	Type	Time	Reporter
<i>Adverse drug reaction or overdose caused by taking a prescription drug, over-the-counter medication or remedy, controlled substance (legally or illegally obtained) that results in treatment in an emergency department, hospitalization, or death</i>		120 days ¹	P*
<i>Autism Spectrum Disorders (ASD) (Age less than or equal to ten years) (Including Autistic Disorder, Asperger's Syndrome, and Pervasive Developmental Disorder-Not Otherwise Specified)</i>		30 days	P**
<i>Chromosomal abnormalities and neural tube defects diagnosed by prenatal testing or by genetic testing in Colorado residents through the third birthday</i>		90 days	P
<i>Fetal Alcohol Syndrome (Age ≤ 10 years)</i>		30 days	P
<i>Head injuries requiring admission to hospitals or resulting in death</i>		120 days ¹	L & P*
<i>Lead Level, elevated</i>			
	<i>Blood lead level ≥ 5 µg/dL AND age ≤ 18 years</i>	7 days	L & P***
	<i>Blood lead level ≥ 5 µg/dL if age >18 years</i>	30 days	L & P***
	<i>Blood lead level <5 µg/dL AND age ≤ 18 years</i>	30 days	L & P***
<i>Mercury Level, elevated</i>			
	<i>Blood mercury >0.5 µg/dL</i>	30 days	L
	<i>Urine mercury >20 µg/L</i>	30 days	L
<i>Muscular Dystrophies</i>		120 days ¹	P

Disease/Event	Type	Time	Reporter
Spinal Cord Injuries		120 days ¹	L & P*
<i>Birth defects, developmental disabilities, and medical risk factors for developmental delay in Colorado residents diagnosed prenatally, at birth, or through the third birthday; with the exception of muscular dystrophies, which shall be reported without age limit²</i>			
	Major congenital malformations, deformations and chromosomal abnormalities	120 days ¹	L & P*
	Congenital (perinatal) infections, including: Congenital syphilis Congenital rubella Cytomegalovirus Toxoplasmosis/herpes viral/herpes simplex Neonatal viral hepatitis	120 days ¹	L & P*
	Sensory impairments, including: Hearing loss Blindness and low vision	120 days ¹	L & P*
	Other disabilities, including: Specific delays in development Change to Intellectual Disability Infantile cerebral palsy Autism spectrum disorders (ASD)	120 days ¹	L & P*
	Newborn genetic/endocrine/metabolic and newborn immunodeficiencies diseases	120 days ¹	L & P*
	Infections, including: Encephalitis Meningitis	120 days ¹	L & P*
	Injuries, including: Traumatic brain injuries Spinal cord injuries	120 days ¹	L & P*
	Other disabilities and medical conditions related to development, including: Convulsions/seizures Specific delays in development Intellectual disabilities Infantile cerebral palsy Autism spectrum disorders (ASD) Drug withdrawal syndrome in	120 days ¹	L & P*

Disease/Event	Type	Time	Reporter
	the newborn Failure to thrive Infantile spasms Muscular dystrophies Noxious influences affecting fetus (includes Fetal Alcohol Syndrome) Werdnig Hoffman disease Amniotic bands Perinatal Intracranial hemorrhage Slow fetal growth and fetal malnutrition		

1 Reporting time is 120 days unless it is to be reported sooner under a different statutory or regulatory authority.

2 Listed conditions relate directly to the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)

Reporter: The party responsible for reporting is indicated by one of the following:

- L = Laboratory (whether or not associated with a hospital; by out-of-state laboratories that maintain an office or collection facility in Colorado; and by in-state laboratories which send specimens to an out-of-state laboratory referral laboratory).
- P = Health care providers, coroners, laboratories, hospitals.
- * Reporting requirement is fulfilled through Department access to administrative data sets including but not limited to hospitalization and emergency discharge data and vital records data, unless notified by the Department that additional data are necessary or otherwise required by statute or regulation.
- ** Condition reportable only among residents of seven-county Denver Metropolitan Area (Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas and Jefferson Counties).
- *** Laboratory as specified above or by the physician, healthcare provider, or clinic when blood lead specimens are analyzed in an office or outpatient setting (i.e., using LeadCare® II instrument).

Editor's Notes

History

Regulation 1, List C eff. 03/30/2012.

Entire rule eff. 01/14/2018.