COLORADO
Department of Public Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

To: Members of the State Board of Health

From: Mike Van Dyke Ph.D., CIH, Environmental Epidemiology, Occupational Health, and Toxicology Branch Chief, Disease Control and Environmental Epidemiology Division (DCEED)

Through: Tony Cappello, Ph.D., DCEED Director ***TC***

Date: November 15, 2017

Subject: **Public Rulemaking Hearing**
Proposed amendments to 6 CCR 1009-7, Detection, Monitoring, and Investigation of Environmental and Chronic Disease

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The Colorado Department of Public Health and Environment (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 and to investigate and determine the epidemiology of those conditions, per Sections 25-1.5-105, 25-1.5-102, 25-1-122, 25-1.5-101(1)(k) and (l), C.R.S.

The proposed changes fall into three categories: 1) improve the clarity of the rule, 2) ensure consistency with the most recent national guidance, the authorizing statute, and similar state regulations that affect end users of the rule, and 3) enable a more efficient response to emerging issues. The proposed rule has been reorganized to parallel 6 CCR 1009-1, Epidemic and Communicable Disease Control. The Department seeks alignment of the rules to bring clarity, consistency and completeness to end users as both rules have the same stakeholders.

The Department has reached out to a wide variety of stakeholders to solicit input regarding the proposed amendments to 6 CCR 1009-7 and has modified the proposed changes based on stakeholder feedback. In general, stakeholders are supportive of the proposed amendments. The Department, Board and Colorado Hospital Association are committed to patient confidentiality. The Department and the Colorado Hospital Association have reviewed the procedures to protect confidentiality and will structure data sharing so that only the minimum information necessary is shared. The proposed rule revisions add "minimum necessary" language to affirm this commitment.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to 6 CCR 1009-7
Detection, Monitoring, and Investigation of Environmental and Chronic Disease

**Basis and Purpose.**

The Colorado Department of Public Health and Environment (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, and to investigate and determine the epidemiology of those conditions, Sections 25-1.5-105, 25-1.5-102, 25-1-122, 25-1.5-101(1)(k) and (l), C.R.S.

The overall purpose of this rule is two-fold: 1) to ensure that non-infectious diseases and conditions, that could be related to an exposure to contaminated environmental media or consumer products, are reported to the Department for further analysis or investigation to ensure there is not an ongoing threat to public health from the causative exposure; and 2) to ensure appropriate follow-up, linkage to care, and aggregate surveillance of non-infectious conditions that may require special medical care or may be related to environmental media or consumer products.

There are several motivating circumstances that led to the proposed rule changes:

1) In 2013, there was an outbreak associated with the consumption of synthetic marijuana products in which more than 200 individuals were treated in emergency departments as a result of a new synthetic cannabinoid. This was the first outbreak declared by the Department due to a non-infectious agent. This outbreak declaration allowed the Department to establish temporary reporting from hospitals to ascertain the clinical and spatial characteristics of the outbreak. While the Department has broad statutory authority with respect to environmental and chronic diseases, several hospitals commented that the Department's regulatory authority to require temporary reporting for a non-infectious agent was unclear. Furthermore, initial reporting was delayed as it was not clear in rule that the Department already required reporting of clusters of health conditions resulting from exposure to a toxic product.
2) Under Section 25-1.5-110, C.R.S., the Department is responsible for monitoring health effects associated with marijuana use. This responsibility has resulted in ongoing annual analyses of hospital and emergency department discharge data to report trends of health outcomes potentially related to marijuana use. However, there is not clear language in rule to ensure timely reporting by health care providers of acute health events that might be related to exposure to contaminated marijuana products.
3) There have been many examples of exposures to toxic substances (harmful algal blooms, carbon monoxide, uranium in water, etc.) that result in a healthcare encounter and may be an ongoing public health risk, but are not reported to the Department by the health care provider. Sometimes these events are reported to the Department by the individual experiencing health issues or through other channels, but, otherwise, they may go unreported. This lack of reporting is likely due to the lack of clarity in the current rule as well as lack of knowledge about the rule. The Department plans to conduct outreach to physicians and other health care providers that we already interact with for the Department's more widely known communicable disease rules.
4) The opioid overdose epidemic stands alone as one of the most important current public health issues. The Department currently lacks clear rules to allow for ongoing retrospective surveillance to identify geographic and demographic risk factors important for the prevention of drug overdoses. Furthermore, the lack of clear rules does not currently allow for linking of databases on prescriptions and health outcomes, which is important in identifying local trends and evaluating prevention strategies.
5) There is a need to update specific conditions such as the reportable elevated blood lead level and birth defect conditions to reflect the most recent national guidance.
6) Based upon feedback during the request for rulemaking presentation, the Department determined that language in Regulation 4 indicating that "These requirements shall not apply if the Department

and county, district or municipal public health agency mutually agree not to share information on reported cases" was unnecessary as the current practice is to only share what is necessary.

In response to these circumstances outlined above and stakeholder feedback, the proposed rule clarifies types of conditions that should be reported, who should report and what information is needed in order to initiate investigations to protect public health. Overall, the proposed changes improve readability, clarify and align the rule language with statute and current practice, incorporate the most recent national guidance and update the rule to enable the public health community to respond to opioid overdose, atypical reactions to marijuana, and other public health concerns related to legal and illegal drug use.

In the context of this rule, there are two separate categories of criteria that specify "reportable" conditions.

1) Regulation 1.I.D.1 requires reporting of any disease, syndrome or condition identified in Appendix A, Reportable Environmental and Chronic Diseases Table. Appendix A is a prescriptive list that identifies specific conditions and timeframes for reporting. This list includes such conditions as elevated blood lead levels, birth defects and developmental disorders. The primary public health uses of data obtained through Appendix A reporting are ensuring appropriate clinical follow-up, linkage to specialty care, identification of potential clusters of disease, and ongoing surveillance to measure public health burdens. Many of the diseases and conditions in this appendix have been updated to reflect current guidelines and terminology.
2) Regulation 1.I.D.2 requires reporting of general health conditions that may have been caused by exposure to contaminated environmental media or consumer products. This second set of criteria limits reporting requirements to those conditions where there has been treatment in an emergency department, hospitalization, or death AND the clinical suspicion of an exposure-related cause with the potential to cause health effects in other individuals. The primary public health use of data obtained from the second category of criteria is to initiate an exposure investigation to determine whether there is an ongoing risk to the public.

The proposed rule changes include:

A. Definitions and Terminology
The proposed rule adds definitions from the authorizing statute 25-1.5-105, C.R.S., and other definitions to help reporters, county, district or municipal public health agencies and the Department understand when the rule needs to be applied. The two relevant statutory definitions are:

- "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.

- "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.

Technology advances and current surveillance practices were also incorporated into the proposed rule. For example, the reference to photographs has been expanded to photographs or video. "Environmental sampling data" is also acknowledged.

B. Align with 6 CCR 1009-1, Epidemic and Communicable Disease Control (6 CCR 1009-1)
To the extent feasible, the format of the rule and the rule language parallels the language in 6 CCR 1009-1. This benefits end-users as many apply both rules.

C. Consolidated Table of Reportable Conditions
The specific diseases and conditions that were in List A (Environmental and Chronic Diseases Reportable by Physicians or Other Health Care Providers), List B (Environmental and Chronic

Diseases Reportable by Hospitals and Other Health Care Facilities), and List C (Environmental and Chronic Diseases Reportable by Laboratories) have been moved to the proposed new Appendix A. The table identifies the reportable condition, the timeframe for reporting, the reporting mechanism, and the reporting entities.

D. Acknowledge Modified or Additional Reporting
Colorado statute authorizes the Department to modify or initiate time-limited reporting to address an emergency health need. Acknowledging this practice within the rule helps the public and public health community understand the full continuum of disease control authorized under the statute, and provides the public health community an anchor in current practice when responding to a new environmental or chronic disease or outbreak.

E. Acknowledge Passive Reporting Through Administrative Datasets For Some Conditions
The Department currently receives data for some conditions through administrative datasets rather than directly from laboratories, healthcare providers and other reporters. By acknowledging surveillance of head injuries, spinal cord injuries, birth defects, developmental disabilities, and medical risk factors for developmental delay, in addition to the new reporting requirement for adverse drug reactions, within the rule helps the public, reporters and the public health community understand how data is collected for these conditions. These changes more clearly reflect current practice and clarify expectations of physicians and other healthcare providers.

F. Update Two Reportable Conditions
   i. Lead level, elevated - The Department proposes to change the reporting time for elevated blood lead results greater than 5 µg/dl in those under 18 years old from 30 days to 7 days. The Department also proposes to require reporting for blood lead results greater than 5 µg/dl in those over 18 years old. These changes were made to ensure consistency with the current Centers for Disease Control and Prevention's reference levels for elevated blood lead.

   ii. Birth defects, developmental disabilities, and medical risk factors for developmental delay in Colorado residents diagnosed prenatally, at birth, or through the third birthday - The Department proposes updating terminology in Appendix A to bring it into alignment with terminology used in the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). ICD-10-CM is a morbidity classification for diagnosis and reason for visits in all U.S. health care settings and is based on the ICD-10 statistical classification of disease published by the World Health Organization. ICD-10-CM replaced ICD-9-CM and is now the standard used to classify diseases and causes of illness recorded on health records, claims, and other vital information. Transitioning to ICD-10-CM terminology will improve accuracy and clarity in reporting.

G. Add "Adverse Drug Reaction" as a Reportable Condition
CDPHE Strategic Plan Goal 5 is, "Prepare for and Respond to All Emerging Issues." A priority for the Department is to ensure the foundational elements and infrastructure to detect, prepare for and respond to emerging issues is in place. One effort to advance this goal is to align reporting requirements with current public health concerns. In the February 15, 2017, presentation to the Board of Health, the Department discussed and received the Board's support to propose rule revisions that would better enable the Department and its partners to respond to opioids, marijuana and other legal or illegal drugs. The proposed rule adds "adverse drug reaction" as a reportable condition:

- Adverse drug reaction - The Department proposes to add "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". The Department proposes this condition be reported passively through existing administrative datasets, such as data the Department currently receives from the Colorado Hospital Association. The purpose of collecting this data is to improve or initiate data collection on opioid overdose, atypical reactions to marijuana, and other public health concerns related to legal and illegal drug use, such as synthetic opioids.

While adverse drug reaction data is kept confidential under law, the Department acknowledges this data is sensitive patient information. To the greatest extent possible, patient-identifying information will not be gathered. If patient-identifying information is necessary, the Department shall keep such information strictly confidential, and will share only the minimum information necessary to allow state and local public health to investigate a risk to public health.

The Department is fully committed to ensuring data the Department maintains is secure, confidential and accurate. The Department is considered a "public health authority" under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA allows for the existing practice of sharing personal health information (PHI) with public health authorities that are authorized by law to collect or receive such information to aid them in their mission of protecting the health of the public. However, the Department still follows the "minimum necessary" standard that says PHI should not be used or disclosed when it is not necessary. When the Department receives datasets from organizations, such as the Colorado Hospital Association, those data are provided through a secure site to the Department's Center for Health and Environmental Data (CHED), which serves as a steward of these data. CHED, in turn, shares only the appropriate data with Department programs per data use agreements, statutory authority, and Board of Health rule. There are a number of processes, safeguards and requirements currently in place. Some examples are:

- Systems are ONLY accessible with valid user ID's and passwords managed by both OIT and Department employees.
- System access is based on permissions only given to Department employees who need to work with that particular dataset.
- Systems maintained by the Department are all housed behind a network firewall that prevent against access by external users.
- Any data the Department makes available to the public must adhere to applicable data licensing/user agreements and HIPAA principles to protect privacy and maintain confidentiality.
- Data integrity is maintained through ongoing manual and automated deduplication efforts and system-generated unique identifiers for each record.
- Full system backups are performed at least once a day with incremental transaction log backups performed hourly.

Improved reporting and monitoring of adverse drug reactions and overdoses is critical for the Department and public health partners, including health care and behavioral health providers, emergency responders, and other entities to take steps to prevent misuse and abuse of legal and illegal substances, enable providers and first responders to better respond to overdoses and individuals experiencing an adverse drug reaction, and improve services and outcomes for individuals receiving treatment. Along with improving the systems and supports, faster identification of spikes in adverse drug reactions, improves real-time response rates and improves our capacity to develop and tailor interventions to reduce harm and improve individual health outcomes. Prescription drug abuse, opioids, and adverse drug reactions are not unique to Colorado; however, the concern for Coloradans is considerable. Timely and consistent reporting as well as procedures to ensure data quality, provide public health one more mechanism to address this growing public health concern.

The Department anticipates that in making adverse drug reactions reportable, it will be able to evaluate the positive and unintended negative impacts of changes in policy and health care on the evolving opioid overdose epidemic at the population level. This proposed addition would allow the Department access to de-identified investigatory material on an ongoing basis without patient consent, to collect information that is more complete, assess the quality of existing data that we use to describe the epidemic, and evaluate strategies to address the epidemic. As stated above, patient-identifying information will only be requested and shared when necessary, to allow state and county, district, and municipal public health to investigate a risk to public health. Furthermore, in an imminent public health need situation, it would allow the Department to link existing data sets from the

Prescription Drug Monitoring Program with outcome data and toxicology results to improve public health's ability to target resources in the areas of greatest need.

**Specific Statutory Authority.**
These rules are promulgated pursuant to the following statutes: Sections 25-1.5-105, 25-1.5-102, 25-1-122, 25-1.5-101(1)(k) and (l), C.R.S.

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SUPPLEMENTAL QUESTIONS

**Is this rulemaking due to a change in state statute?**

_____ Yes; rules are ___ authorized ___ required.
___x__ No

**Is this rulemaking due to a federal statutory or regulatory change?**

_____ Yes
___x___ No

**Does this rule incorporate materials by reference?**

_____ Yes
___x___ No

**Does this rule create or modify fines or fees?**

_____ Yes
___x___ No

**REGULATORY ANALYSIS**
for Amendments to
6 CCR 1009-7
Detection, Monitoring, and Investigation of Environmental and Chronic Disease

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

Classes of persons affected by the proposed rule changes include 1) clinical laboratory personnel; 2) personnel at hospitals responsible for reporting; 3) health care providers; 4) county, district, and municipal public health personnel; 5) county coroners; and 6) personnel at community clinics with emergency rooms.

All of the classes identified above will benefit from increased efficiency of environmental and chronic disease investigation, which could result in quicker identification and resolution of the outbreak, more accurate risk communication and prevention.

The majority of the modifications are clarifying, resulting in no or minimal costs. Adverse drug reaction data is currently captured through existing passive reporting. Similarly, temporary reporting is already current practice, and these rule revisions represent codification of this practice. There may be minimal costs for community clinics with emergency rooms, hospitals and coroners that need to report in the rare instance where Regulation 1.I.D.2 applies. The Department's most recent experience with this sort of reporting was the synthetic marijuana outbreak in 2013. During this event, through existing electronic data feeds, hospital emergency departments reported approximately 250 individual cases. Mandatory reporting for this outbreak lasted approximately four weeks and no single hospital reported more than 100 cases.

There are minimal costs to laboratories and healthcare providers associated with modifying the elevated lead levels and birth defects reporting; however, the changes align with national practice and the current standards of care. The benefit is streamlined reporting that improves public health and patient care.

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

The impact of the updated rule is improved public health response and improved health care. All of the persons and entities identified above will benefit from the proposed changes to the rule. The benefit of these changes include: clearer, updated rules that are more easily applied; more complete reporting of diseases and conditions of public health significance; enable a more efficient response to emerging issues; and, better data collection for adverse reactions or overdoses to drugs. Health care providers' ability to prevent and treat adverse drug reactions is increased by adding adverse drug reactions to the list of reportable conditions; this may increase efficiency and reduce health care or health care consumer costs. Each of these proposed changes will provide better or timelier data to the Department and county, district, and municipal public health agencies. These agencies, in turn, will be able to use this data to detect, prevent, and treat environmental and chronic disease in communities and through partners across Colorado, benefitting the general public.

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

There is no cost to the Department for the vast majority of the proposed changes. Any costs associated with adding adverse drug reactions to the reportable conditions will be minimal and can be absorbed. The Department is already involved in efforts to address adverse drug reaction or overdose caused by taking a medication or controlled substance. The increased effort for some work units is offset by efficiencies for other work units. There is no anticipated effect on state revenues.

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

The benefit of these changes include clearer, updated rules that are more easily interpreted and therefore, followed; and more complete reporting of diseases of public health importance. Additionally, the proposed changes will provide greater consistency in the reporting of emerging environmental and chronic disease. Finally, the proposed changes include updated language that is meant to mirror current national standards and terminology.

In Colorado, nine in ten poisoning-related fatalities are related to drugs. Colorado's opioid death rates tend to fall in about the middle of all states, ranking number 31 with a rate of 15.4 deaths per 100,000 in 2015. However, according to the National Survey on Drug Use and Health, Colorado has the second highest prescription drug misuse rate in the country. The best solution to address the opioid crisis is a multifaceted one, made up of multiple strategies addressing different points of the substance use spectrum. It is important to address the upstream drivers of opioid misuse, such as over-prescribing prescription drugs and drug diversion, while simultaneously working to prevent overdose deaths and getting those addicted to opioids into treatment. The Department does not currently have the necessary tools to conduct surveillance to identify trends and risk factors related to drug poisonings. More specifically, the opioid epidemic is rapidly changing in terms of the demographics and the specific drugs involved. The Department has spent several years assessing the burden of this epidemic using passively collected data from the Colorado Hospital Association. However, these analyses have been limited in usefulness as current authority does not allow collection of sufficient identifiers to link to other datasets or assess geospatial trends finer than the county level. In order to evaluate the rapidly changing local and state policies, additional authority is needed to collect identifiers and link datasets to identify associations between prescribing practices and adverse events. Several states have similar regulatory authority to collect identifiable data for adverse events and other poisonings.

The proposed rule changes provide additional tools for public health to identify trends and risk factors related to drug poisonings without significantly adding to the reporting burden for healthcare providers. Adding adverse drug reactions as a passively collected condition through current datasets allows for the necessary retrospective surveillance to identify trends and risk factors. Clarifying the reporting requirements under D.2 to include conditions resulting from exposure to drugs or controlled substances that are newly recognized, at increased incidence beyond expectations, or a risk to the public due to ongoing exposure provides the necessary authority for public health investigation of potential outbreak events such as was observed with synthetic marijuana in 2013. This balanced approach minimizes burden on reporters, while authorizing the Department to collect the information it needs to identify trends and risk factors associated with drug poisonings.

Inaction would result in a continued lack of clarity in the rules, lack of alignment with national standards and 6 CCR 1009-1, and lack of information about newly emerging conditions of public health importance.

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

Costs associated with the rule are minimal and align with current efforts of the affected entities. The proposed changes improve public health and health care response, increase transparency and alignment of activities between the Department and its partners. There is no less costly or less intrusive method to achieve the purpose of the rule.

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

The only alternative considered was to leave the rule as adopted. This was rejected because recent updates to ICD-10CM, an increasing need for clarity and consistency among end users of this rule, and emerging conditions of public health concern necessitated changes in this rule.

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

The most recent guidance from CDC in 2012 changed the reference level for elevated blood lead in children from ≥ 10 micrograms per deciliter (µg/dL) to ≥ 5 µg/dL. This was based on the 97.5th percentile of the National Health and Nutrition Examination Survey's (NHANES) blood lead distribution in children. (Centers for Disease Control and Prevention. (n.d.). Standard Surveillance Definitions and Classifications. https://www.cdc.gov/nceh/lead/data/definitions.htm)

The most recent guidance from NIOSH in 2015 changed the reference level for elevated blood lead in adults from ≥10 micrograms per deciliter (µg/dL) to ≥ 5 µg/dL. This case definition is used by the ABLES program, the Council of State and Territorial Epidemiologists (CSTE), and CDC's National Notifiable Diseases Surveillance System (NNDSS). (Centers for Disease Control and Prevention. (n.d.). Adult Blood Lead Epidemiology and Surveillance (ABLES). https://www.cdc.gov/niosh/topics/ables/description.html)

Extensive analyses on the potential adverse health effects associated with marijuana from passively collected hospitalization and emergency discharge data have been conducted by the Department (Colorado Retail Marijuana Public Health Advisory Committee. 2017. Monitoring Health Concerns Related to Marijuana in Colorado: 2016, Colorado Department of Public Health and Environment, Denver, CO, (https://www.colorado.gov/pacific/cdphe/retail-marijuana-public-health-advisory-committee)

Data from Colorado's 2013 synthetic marijuana outbreak (Ghosh, T., Herlihy, R., Van Dyke, M., Kuhn, S., Burrer, S., Halliday, M, Spelke, B., Bayleyegn, T., Wolkin, A., Lewis, L., Fechter-Leggett, E., Olayinka, O. Notes from the Field: Severe Illness Associated with Reported Use of Synthetic Marijuana – Colorado, August-September 2013. MMWR. 2013 62(49):1016-1017)

Safe States. Consensus Recommendations for National and State Poisoning Surveillance: Report from the Injury Surveillance Work-group (ISW7) [Internet]. Atlanta: Safe States; 2012. (http://c.ymcdn.com/sites/www.safestates.org/resource/resmgr/imported/ISW7 Full Report_3.pdf)

"Examining Opioid and Heroin-related Deaths in Colorado" (HealthWatch 100): https://drive.google.com/file/d/0B2nM-3jK5N8pblQ3M1hDRGlIV0U/view

The Department explored whether data from VA Clinics could be included in the dataset and concluded this is not feasible at this time. While this data will not be included in our analysis, the Department believes veterans and VA Clinics will benefit from the improved surveillance and reporting. The Department will continue to work with the VA Clinic population health personnel and other partners working to address veterans' behavioral health and mental health needs. The efforts occurring under this rule will assist with the other strategies discussed in #4 above

STAKEHOLDER COMMENTS
for Amendments to
6 CCR 1009-7
Detection, Monitoring, and Investigation of Environmental and Chronic Disease

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

Early Stakeholder Engagement

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

County, District or Municipal Public Health Agency Directors and Environmental Health Directors, Laboratory Directors, Infection Preventionists, School Nurses, Colorado schools and child care facilities, Colorado Academy of Family Physicians, Colorado Chapter of the American Academy of Pediatrics, the American Congress of Obstetricians and Gynecologists, Colorado Section, Colorado Hospital Association, Colorado Consortium for Prescription Drug Abuse Prevention, Colorado Lead Coalition, Colorado County Coroners, Colorado Health Care Association, Colorado Medical Directors Association, Colorado Medical Society, Colorado Home Care Association, Colorado Association of Home and Services for the Aging, Emergency Medical Services Association of Colorado, County Sheriff's of Colorado, Colorado State Fire Chiefs Association, Colorado Association of Chiefs of Police, Colorado Assisted Living Association, Colorado Department of Public Safety, LeadingAge Colorado, Colorado Behavioral Healthcare Council, Colorado Department of Human Services (CDHS) Office of Behavioral Health, Mental health and substance use treatment providers in Colorado, Individuals and families with lived experience; Behavioral health Advocacy organizations, and the Rocky Mountain Academy of Occupational and Environmental Medicine.

The Colorado Department of Human Services (CDHS), Office of Behavioral Health included an announcement of the proposed rule to make drug overdose reportable and a request for feedback in the CDHS monthly e-newsletter distributed on October 26, 2017. The e-newsletter was sent to roughly 3400 behavioral health stakeholders representing: mental health and substance use treatment providers in Colorado, including behavioral health crisis services, detox services, and providers working in community mental health centers; individuals and families with lived experience; advocacy organizations; and other local partners.

Stakeholder Group Notification

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

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

_X___ Yes.

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

The Department's outreach to stakeholders has been ongoing with open communication among all stakeholder groups. An email detailing the proposed changes was sent to an initial set of 410 stakeholders, with a reminder email sent one week later. The Department conducted outreach to specific stakeholders (Agency representatives for Colorado schools and child care facilities, Colorado Academy of Family

Physicians, Colorado Chapter of the American Academy of Pediatrics, Colorado Hospital Association, Colorado Department of Public Safety and the Colorado Consortium for Prescription Drug Abuse Prevention) asking for assistance in broader distribution of our proposed changes to this rule.

To date, eleven stakeholders reached back to the Department to ask questions or provide feedback; where appropriate the Department has responded to these stakeholders with individual calls or emails to clarify intent. The Department and the Colorado Hospital Association met to review data sharing procedures and rule language to ensure data is protected and patient confidentiality is maintained to the maximum extent feasible. New language was added to the proposed rule revision that affirms this shared understanding. The proposed amendments have not generated any controversy.

**Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?**

The proposed rule modifications promote health equity as they are meant to clarify and streamline the rules so they are more easily understood and applied to all eligible citizens. Furthermore, the improved data quality on adverse drug reactions provided by this proposal will allow for more detailed analyses to identify important social determinants of health to better target prevention resources.

November 6, 2017

Rick Brown
Board President, Colorado Board of Health
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
Denver, CO 80246

Dear Mr. Brown:

On behalf of our more than 100 hospital and health system members statewide, the Colorado Hospital Association (CHA) would like to express our support of the proposed amendments to 6 CCR 1009-7, *Detection, Monitoring, and Investigation of Environmental and Chronic Disease*.

Combatting Colorado's opioid overdose crisis is a priority for both the Colorado Department of Public Health and Environment (the Department) and CHA, and we are supportive of the Department's efforts to better understand the epidemic's characteristics and drivers. Adding "adverse drug reaction" as a reportable condition, however, raised significant patient confidentiality concerns for CHA. Given the sensitivity of this type of patient-identified information, the Association wanted to ensure – before final approval of the rule – that safeguards were in place to protect patient privacy to the greatest extent possible.

CHA worked closely with the Department to find a solution that satisfies the Department's needs while protecting our hospitals and the confidentiality of the individuals struggling with substance use disorders across Colorado. The new "minimum necessary" language included in the rule sufficiently alleviates the Association's concerns around patient confidentiality, and we are supportive of the overall rule.

CHA greatly appreciates the Department's partnership on this issue, and we look forward to working with Department staff on implementing the proposed amendments.

Sincerely,

Katherine Mulready
Chief Strategy Officer & Vice President of Legislative Policy

**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**

**Adopted by the Board of Health on _____, 2017. Effective _____, 2018.**

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## 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. CASES 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, 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 1. Reportable Diseases~~

~~For the purpose of these regulations, the diseases named in the lists below and any epidemic of environmental or chronic disease are declared to be dangerous to the public health and shall be reportable in accordance with the provisions of these regulations.~~

~~Reportable outbreaks or epidemics of environmental or chronic diseases include those which may be a risk to the public and which may affect large numbers or specific groups of persons or be outbreaks caused by a chemical or radioactive terrorist agent or incident or be a newly recognized entity. Such outbreaks may include, but are not limited to, those related to environmental contamination by any hazardous chemical, radiological material, or biologic substance.~~

~~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 chemical or radioactive terrorist 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 chemical or radioactive terrorist agent or incident. Chemical terrorist agents include, but are not limited to, Sarin (GB), VX (V agent), and HD (distilled mustard).~~

~~**List A. Environmental and Chronic Diseases Reportable by Physicians or Other Health Care Providers**~~

| ~~Diagnosis (Confirmed or Suspected)~~ | ~~Reportable Within:~~ |
|---|---|
| ~~Fetal Alcohol Syndrome (Age less than or equal to ten years)~~ | ~~30 days~~ |
| ~~Muscular Dystrophies~~ | ~~120 days~~ |

~~**List B. Environmental and Chronic Diseases Reportable by Hospitals and Other Health Care Facilities**~~

| ~~Diagnosis (Confirmed or Suspected)~~ | ~~Reportable Within:~~ |
|---|---|
| ~~Spinal cord injuries~~ | ~~120 days~~ |
| ~~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 limit~~ | ~~120 days~~ |
| ~~Head injuries requiring admission to hospitals or~~ | ~~120 days~~ |

~~resulting in death~~
~~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)~~ ~~30 days **~~

~~* Appendix A is an inclusive list of conditions that must be reported.~~

~~** Seven-county Metro Denver Area (Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas, Jefferson).~~

~~**List C. Environmental and Chronic Diseases Reportable by Laboratories**~~

~~All of the findings below are to be reported within 30 days.~~

~~Blood lead level ≥ 10 µg/dL if age >18 years.~~

~~Report all blood lead levels if age ≤ 18 years and report levels ≥ 10 µg/dL within one week of analysis.~~

~~Blood mercury >0.5 µg/dL~~

~~Urine mercury >20 µg/L~~

~~Chromosomal abnormalities and neural tube defects diagnosed by prenatal testing or by genetic testing in Colorado residents through the third birthday (reportable within 90 days)~~

~~Physicians, health care providers, and clinics performing blood lead level testing in an office or outpatient setting are required to report results the same as the requirement above for laboratories.~~

**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 2. Manner of Reporting and Information To Be Submitted**~~

~~The diseases in the lists in Regulation 1 shall be reported to the Department of Health within the specified time frame after the diagnosis is made by the physician, health care provider, or confirmed in a laboratory.~~

~~The information to be submitted shall consist of the diagnosis; the patient's name, age, sex, race/ethnicity, and address; the name and address of responsible physician; the employer (for reportable work-related conditions); and such other information as is needed by the Department to locate the patient for follow-up. 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. When hospitals and laboratories transmit disease reports electronically using systems and protocols developed by the department that ensure protection of confidentiality, such reporting is acceptable and is considered good faith reporting.~~

~~Laboratory findings in List C of regulation 1 shall be reported by all laboratories which maintain an office or collection facility in Colorado or which arrange for collection of specimens in Colorado. Results must be reported by the laboratory which performs the test, but an in-state laboratory which sends specimens to an out of state referral laboratory is also responsible for reporting the results.~~

~~In addition to physicians, health facilities, and laboratories, any person having knowledge of a reportable disease, outbreak, or epidemic, such as coroners, persons in charge of schools (including school nursing staff), or persons or employees having knowledge of exposure of large numbers or specific groups of persons to a known or suspected public health hazard shall report such disease, outbreak, or epidemic.~~

~~The Department shall develop systems and forms for reporting for physicians, other health care providers, hospitals, and laboratories. For birth defects and developmental disabilities, hospitalized head injuries, and spinal cord injuries, hospital reporting shall be through a central computerized data system operated by or for the department.~~

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

**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.

~~The State or local health department shall employ reasonable investigative techniques as part of systematic surveillance for environmental and chronic diseases. Reports of diseases related to exposure to a hazardous substance or agent in one environmental setting may lead the state or local health department to investigate whether or not the public health is endangered either in the same setting or in other settings physically removed but environmentally similar to that of the reported case. Investigations shall be considered official duties of the health department or health agency and shall be pertinent, relevant and only as intrusive as necessary. Such investigative techniques include but are not limited to:~~

~~(a) review by authorized personnel of pertinent, relevant medical records necessary to identify and characterize the index case and other cases in a region, community, or workplace; such review of records may occur without patient consent and shall be conducted at reasonable times and with such notice as is reasonable under the circumstances;~~

~~(b) review of Workers' Compensation claims;~~

~~(c) review of toxic tort or product liability claims filed with state or federal courts within the state;~~

~~(d) medical examination and testing of persons with the explicit consent of such persons;~~

~~(e) obtaining from public or private businesses or institutions lists of persons with a similar or common potential exposure to the hazardous substance or agent as a reported case; such exposure may be current or have occurred in the past;~~

~~(f) performing follow-up interview(s) with a reported case or persons knowledgeable about the case to collect pertinent and relevant information about the cause and/or risk factors associated with the reportable environmental or chronic disease;~~

~~(g) 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 hazardous environmental exposure as a reported case;~~

~~(h) collecting environmental samples of substances or measurements of physical agents;~~

~~(i) taking photographs related to the purpose of the investigation; if the photographs are taken in a business, the employer shall have the opportunity to review the photographs taken or obtained for the purpose of identifying those which contain or might reveal a trade secret;~~

~~(j) entering a place of employment 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.~~

**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.

~~Whenever a local health department or health agency learns of a case of a reportable disease in Regulation 1 or an environmental exposure potentially threatening the public health, it shall notify the State Department of Health in a timely manner, usually within the timeframe for reporting in Regulation 1.~~

~~The State Department of Health shall, in turn, notify the appropriate local health department or agency in a timely manner, usually within the timeframe for reporting in Regulation 1, whenever it learns of a case of a disease reportable in Regulation 1 or it learns of an environmental exposure potentially threatening the public health.~~

~~These requirements shall not apply if the State and local health agencies mutually agree not to share information on reported cases.~~

~~Sharing of medical information on persons with reportable diseases or illnesses as defined in Regulation 1 between authorized personnel of State and local health departments shall be restricted to information~~

~~necessary for the treatment, control, investigation, and prevention of environmental and chronic diseases dangerous to the 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. Reporting of Diseases Among Animals**~~

~~Every veterinarian, livestock owner, veterinary diagnostic laboratory director, or other person having the care of, or knowledge of, the existence of animals having or suspected of having any disease that constitute a Reportable Environmental or Chronic Condition shall promptly report to the Department or the appropriate local public health agency.~~

**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.

~~All personal medical records and reports held by the state or local health department in compliance with these regulations shall be confidential information subject 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 Colorado Department of Health in compliance with these regulations shall be confidential. This information is to be used by the Department as source material for necessary disease control efforts and the development of prevention programs. Reasonable efforts shall be made by the Department to consult with the attending physician or medical facility caring for the patient prior to any further follow-up by State or local health departments or health agencies.~~

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Appendix A. Reportable Environmental and Chronic Diseases

| Disease/Event | Type | Time | Reporter |
|---|---|---|---|
| *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* | | 120 days[1] | P* |
| *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)* | | 30 days | P** |
| *Chromosomal abnormalities and neural tube defects diagnosed by prenatal testing or by genetic testing in Colorado residents through the third birthday* | | 90 days | P |
| *Fetal Alcohol Syndrome (Age ≤ 10 years)* | | 30 days | P |
| *Head injuries requiring admission to hospitals or resulting in death* | | 120 days[1] | L & P* |
| *Lead Level*, elevated | | | |
| | *Blood lead level ≥ 5 µg/dL AND age ≤ 18 years* | 7 days | L & P*** |
| | *Blood lead level ≥ 5 µg/dL if age >18 years* | 30 days | L & P*** |
| | *Blood lead level <5 µg/dL AND age ≤ 18 years* | 30 days | L & P*** |
| *Mercury Level*, elevated | | | |
| | *Blood mercury >0.5 µg/dL* | 30 days | L |
| | *Urine mercury >20 µg/L* | 30 days | L |
| *Muscular Dystrophies* | | 120 days[1] | P |

| | | | |
|---|---|---|---|
| *Spinal Cord Injuries* | | 120 days[1] | L & P* |
| *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 limit*[2] | | | |
| | **Major congenital malformations, deformations and chromosomal abnormalities** | 120 days[1] | L & P* |
| | **Congenital (perinatal) infections, including:**<br>Congenital syphilis<br>Congenital rubella<br>Cytomegalovirus<br>Toxoplasmosis/herpes viral/herpes simplex<br>Neonatal viral hepatitis | 120 days[1] | L & P* |
| | **Sensory impairments, including:**<br>Hearing loss<br>Blindness and low vision | 120 days[1] | L & P* |
| | **Other disabilities, including:**<br>Specific delays in development<br>Change to Intellectual Disability<br>Infantile cerebral palsy<br>Autism spectrum disorders (ASD) | 120 days[1] | L & P* |
| | **Newborn genetic/endocrine/metabolic and newborn immunodeficiencies diseases** | 120 days[1] | L & P* |
| | **Infections, including:**<br>Encephalitis<br>Meningitis | 120 days[1] | L & P* |
| | **Injuries, including:**<br>Traumatic brain injuries<br>Spinal cord injuries | 120 days[1] | L & P* |
| | **Other disabilities and medical conditions related to development, including:**<br>Convulsions/seizures<br>Specific delays in development<br>Intellectual disabilities<br>Infantile cerebral palsy<br>Autism spectrum disorders (ASD)<br>Drug withdrawal syndrome in | 120 days[1] | L & P* |

| | |
|---|---|
| | the newborn<br>Failure to thrive<br>Infantile spasms<br>Muscular dystrophies<br>Noxious influences affecting fetus (includes Fetal Alcohol Syndrome)<br>Werdnig Hoffman disease<br>Amniotic bands<br>Perinatal Intracranial hemorrhage<br>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 ~~d~~Department access to administrative data sets including but not limited to hospitalization and emergency discharge data and vital records data, unless notified by the ~~d~~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).

~~**Reportable Birth Defects and Developmental Disabilities**~~

~~**[Listed conditions relate directly to ICD-9-CM codes (International Classification of Diseases)]**~~

~~Major congenital anomalies and chromosomal abnormalities~~

~~Congenital (perinatal) infections~~

~~Congenital syphilis~~

~~Congenital rubella~~

~~Cytomegalovirus~~

~~Toxoplasmosis/herpes simplex~~

~~Neonatal hepatitis~~

~~Sensory impairments~~

~~Hearing loss~~

~~Blindness and low vision~~

~~Other disabilities~~

~~Specific delays in development~~

~~Mental retardation~~

~~Infantile cerebral palsy~~

~~Autism spectrum disorders (ASD)~~

~~Genetic and endocrine/metabolic diseases~~

~~Hypothyroidism~~

~~Disorders of amino acid transport and metabolism~~

~~Disorders of carbohydrate transport and metabolism~~

~~Lipodoses~~

~~Disorders of copper metabolism~~

~~Cystic fibrosis~~

~~Other disorders of purine and pyrimidine metabolism~~

~~Mucopolysaccharidosis~~

~~Sickle cell anemia~~

~~Biotinidase deficiency~~

~~Congenital adrenal hyperplasia~~

~~Infections~~

~~Encephalitis~~

~~Meningitis~~

~~Injuries~~

~~Traumatic brain injuries~~

~~Spinal cord injuries~~

~~Other diagnoses~~

~~Amniotic bands~~

~~Cerebral cysts~~

~~Cerebral lipidoses~~

~~Child maltreatment syndrome~~

~~Chorioretinitis~~

~~Convulsions/seizures~~

~~Drug withdrawal syndrome in the newborn~~

~~Failure to thrive~~

~~Familial degenerative CNS disease~~

~~Infantile spasms~~

~~Muscular dystrophies~~

~~Noxious influences affecting fetus (includes Fetal Alcohol Syndrome)~~

~~Renal tubular acidosis~~

~~Retinal degeneration~~

~~Werdnig Hoffman disease~~

~~Intracranial hemorrhage~~

~~Birth trauma~~

~~Slow fetal growth and fetal malnutrition~~