COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

From: John Arend, Program Manager, Colorado Central Cancer Registry

Through: Chris Wells, Division Director, Center for Health and Environmental Data
Approved by *CW*

Date: May 17, 2023

Subject: **Rulemaking Hearing**
Proposed amendments to 6 CCR 1009-3 THE COLORADO CENTRAL CANCER REGISTRY

The Colorado Central Cancer Registry rules establish a statewide cancer registry, describe mandatory cancer case reporting, including the entities that are required to report cancer, and address confidentiality of reports and Registry data. As part of regular operations, the Department reviewed this rule to ensure that it was efficient, effective and essential. We propose several changes based on the review, most of which are intended to clarify language. The proposed changes would bring the rule into alignment with current practices.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1009-3 THE COLORADO CENTRAL CANCER REGISTRY

Basis and Purpose.
The Colorado Central Cancer Registry rules establish a statewide cancer registry, describe mandatory cancer case reporting, including the entities that are required to report cancer, and address confidentiality of reports and Registry data. The proposed changes include:

1. General updates to language and formatting.
2. Adding the phrase 'and any other required data as determined by the Department' to the list of required elements of a case report [line 42]. This is in alignment with current practices and ensures that all data elements required at the national level, along with new and emerging data elements, are able to be appropriately collected.
3. Adding the phrase 'and independent from a larger hospital system' to the active reporting exemption for hospitals with fewer than 50 licensed beds [line 47-48]. Hospitals with fewer than 50 beds have been exempted from actively reporting cancer cases as they typically do not have the staff, training, and/or resources required to abstract cancer cases. Larger hospital systems who acquire these smaller facilities do not face these same constraints.
4. Removed the phrase 'when determined to be feasible by a hospital' [line 53-54].
5. Addition of statutory text from Section 25-1-122(4) for clarity on data release [line 64-73].
6. Adding permissions to release personal data with national partners for the explicit purpose of medical or scientific research [line 74-78]. These permissions align with current practices and federal standards; ensure continued federal funding for the Colorado Central Cancer Registry; and permit Colorado data to be used in advancing cancer prevention, control, treatment, and research at the national level.
7. Adding permissions to enter into agreements with other states in order to acquire cancer cases of Colorado residents diagnosed and/or treated elsewhere, and share data with other states relating to their residents [line 79-80]. Cancer patients may be diagnosed or treated in other states for a myriad of reasons and it is important that each state have access to data related to the residents of their state in order to accurately access the cancer burden. This aligns with current practice and federal standards. Currently, 48 state and/or territorial population-based cancer registries have signed the National Inter-Registry Data Exchange Agreement.

Specific Statutory Authority.
Statutes that require or authorize rulemaking:
Section 25-1.5-101(q)(I)
Section 25-1-122(4)

Is this rulemaking due to a change in state statute?

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

___X___ No

Does this rulemaking include proposed rule language that incorporate materials by reference?

_____ Yes ___ URL

__X____ No

Does this rulemaking include proposed rule language to create or modify fines or fees?

_____ Yes

__X____ No

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

_X__ No.

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed;
- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or;
- The proposed rule reduces or eliminates a state mandate on local government.

REGULATORY ANALYSIS
for Amendments to
6 CCR 1009-3, Colorado Central Cancer Registry

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

Group of persons/entities Affected by the Proposed Rule	Size of the Group	Relationship to the Proposed Rule Select category: C/CLG/S/B
Cancer Reporting Entities (hospitals, outpatient treatment centers, pathology laboratories, and physicians or other health care practitioners).	85+ hospitals, 40+ pathology laboratories, 50+ treatment clinics, 35+ physician offices, 54 state/territorial cancer registries	C
Cancer researchers/Data Requestors	120+ individuals annually	C
National partners (Centers for Disease Control and Prevention, National Cancer Institute, North American Association of Central Cancer Registries)		S
Cancer patients, cancer survivors, general population		B

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.

Clarifications to the rule will benefit those required to report cancer by making requirements more clear. Proposed rule changes should also clarify what data are and are not available for research and other purposes.
We do not foresee any significant economic impact to affected classes of persons.

Proposed changes may result in very modest cost savings/cost avoidance to the Department as staff would no longer have to pursue remote access to those newly acquired facilities, learn the varied systems, and abstract cancer cases. Of the 36 independent hospitals in Colorado with fewer than 50 licensed beds, 4 have been acquired

by larger health systems within the last 5 years.

Economic outcomes
Summarize the financial costs and benefits, include a description of costs that must be incurred, costs that may be incurred, any Department measures taken to reduce or eliminate these costs, any financial benefits.

C: Large health systems that acquire hospitals with fewer than 50 licensed beds may incur additional costs in abstracting and reporting cases seen at that hospital, however, in our experience, these smaller facilities account for a very small percentage of overall case reports (<1%) within the system and are typically already required to be abstracted internally by the health system.

Please describe any anticipated financial costs or benefits to these individuals/entities.

S: No anticipated financial costs or benefits.

B: No anticipated financial costs or benefits.

Non-economic outcomes
Summarize the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and, if known, the likelihood of the outcomes for each affected class of persons by the relationship category.

C: Clarifications to the rule will benefit those required to report cancer by making requirements more clear.
Clarifications will also benefit those looking to access cancer data for research and medical purposes as there is less ambiguity on what data can and cannot be released.

S: Federal entities, namely the Centers for Disease Control and Prevention (CDC) and/or the National Cancer Institute, provide funding and oversight for the majority of population-based cancer registries in the United States. These revisions better align with federal requirements and ensure that Colorado data may be included in research studies and analyses of cancer burden at the national level.

B: Ultimately these revisions ensure that cancer data are being appropriately collected, monitored, analyzed, and made available to, and included in, research studies, while continuing to maintain appropriate safeguards for patient confidentiality, in order to provide more effective cancer control for the citizens of Colorado.

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

A. Anticipated CDPHE personal services, operating costs or other expenditures:
No operational changes are being proposed as part of this rulemaking, therefore no

new or additional costs are expected.

Anticipated CDPHE Revenues:
NA

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

Anticipated Revenues for another state agency: NA

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

Along with the costs and benefits discussed above, the proposed revisions:

_X__ Comply with a statutory mandate to promulgate rules.
_X__ Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
_X__ Maintain alignment with other states or national standards.
_X__ Implement a Regulatory Efficiency Review (rule review) result
_X__ Improve public and environmental health practice.
___ Implement stakeholder feedback.

Advance the following CDPHE Strategic Plan priorities (select all that apply):

1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO2e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO2e per year by June 30, 2020 and to 113.144 million metric tons of CO2e by June 30, 2023. ___ Contributes to the blueprint for pollution reduction ___ Reduces carbon dioxide from transportation ___ Reduces methane emissions from oil and gas industry ___ Reduces carbon dioxide emissions from electricity sector
2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023. ___ Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the oil and gas industry. ___ Supports local agencies and COGCC in oil and gas regulations. ___ Reduces VOC and NOx emissions from non-oil and gas contributors
3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023. ___ Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes. ___ Increases physical activity by promoting local and state policies to improve active transportation and access to recreation.

___ Increases the reach of the National Diabetes Prevention Program and Diabetes Self-Management Education and Support by collaborating with the Department of Health Care Policy and Financing.
4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by June 30, 2023. ___ Ensures access to breastfeeding-friendly environments.
5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023. ___ Reverses the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023. ___ Performs targeted programming to increase immunization rates. ___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).
6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023. ___ Creates a roadmap to address suicide in Colorado. ___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate. ___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries. ___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.
7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020. ___ Conducts a gap assessment. ___ Updates existing plans to address identified gaps. ___ Develops and conducts various exercises to close gaps.
8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023. ___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident. ___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment. ___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.

9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023. ___ Implements the CDPHE Digital Transformation Plan. ___ Optimizes processes prior to digitizing them. ___ Improves data dissemination and interoperability methods and timeliness.
10. Reduce CDPHE's Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023. ___ Reduces emissions from employee commuting ___ Reduces emissions from CDPHE operations
11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023. ___ Used a budget equity assessment

___ Advance CDPHE Division-level strategic priorities.

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include:

Current language in this rule has led to extensive back-and-forth between the program, individuals requesting data, and the CDPHE Privacy Officer. Inaction would lead to additional time spent answering/asking questions and a general lack of clarity for all involved parties.

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

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. The specific revisions proposed in this rulemaking were developed in conjunctions with stakeholders. The benefits, risks and costs of these proposed revisions were compared to the costs and benefits of other options. The proposed revisions provide the most benefit for the least amount of cost, are the minimum necessary or are the most feasible manner to achieve compliance with statute.

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

A number of stakeholders requested to include the word "research" in Section IV, line 69-74. We firmly believe that research is an inherent part of "treatment, control, investigation, and prevention of cancer" but would prefer for it to be recognized explicitly within the rules and regulations. As lines 64-73 are statutory language, it was

determined that this section should not be modified.

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.

Because the proposed changes are largely clarifying and align with current practice, there is no specific data that was relied upon. The Department partners with entities such as the North American Association of Central Cancer Registries; the Surveillance, Epidemiology and End Results (SEER) at the National Cancer Institute; the CDC National Program of Cancer Registries and National Comprehensive Cancer Control Program, and; the American College of Surgeons and National Cancer Database for data, statistics and best practices.

STAKEHOLDER ENGAGEMENT
for Amendments to
6 CCR 1009-3 THE COLORADO CENTRAL CANCER REGISTRY

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:

Organization	Representative Name and Title (if known)
University of Colorado Comprehensive Cancer Center	Cathy Bradley, Ph.D., Deputy Director
Colorado School of Public Health	Marcelo Perraillon, Ph.D., Associate Professor
Colorado Cancer Registrars Association	Amy Kendall, CTR, President Shirley Delmont, CTR, Vice-President
Colorado Cancer Coalition	Christie Cahill, Executive Director
Centura Health	Shawn Bonner, CTR, Accreditation Specialist
Denver Health	Amy Kendall, CTR, Registry Manager
Health One	Amanda Lemons, CTR
Intermountain Health	Catherine Bieker, CTR
Kaiser Permanente Colorado	Kristin Lu, CTR
UC Health	Amy Walde, CTR

Stakeholders were provided an advanced draft of the rule revisions, encouraged to share within their respective organizations, and invited to provide feedback.

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.

No major factual or policy issues were encountered.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

Because the proposed changes are largely clarifying and align with current practices, this rulemaking will have negligible effects on the experience or outcomes for previously disenfranchised, un-served or underserved, or marginalized populations or the network of partners (state agencies, local governments, community-based organizations, etc.) that serve disenfranchised, un-served or underserved populations.

Overall, after considering the benefits, risks and costs, the proposed rule:

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.		Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.		Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce.
	Improves access to food and healthy food options.		Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
X	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.	X	Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.
	Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.		Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.
X	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.	X	Ensures a competent public and environmental health workforce or health care workforce.
	Other:_____ _____		Other:_____ _____

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

~~**Office of e-Health and Data**~~ **Center for Health and Environmental Data**

THE COLORADO CENTRAL CANCER REGISTRY

6 CCR 1009-3

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

Adopted by the Board of Health on ~~April 20, 2016~~

I. General Purpose.

The purpose of this regulation is to establish a statewide cancer registry in the Colorado Department of Public Health and Environment and to provide for the reporting of information relating to Colorado cancer cases to the Department by hospitals, diagnostic and/or treatment clinics, pathology laboratories and diagnosing physicians or other health care practitioners.

II. Cancer Registry Established.

The Colorado Department of Public Health and Environment shall establish ~~a "registry"~~ and maintain a statewide cancer registry pursuant to Section 25-1.5-101(q)(I), Colorado Revised Statutes. The function of the registry shall be to collect~~,~~ and compile reports of cancer and related data; to make data~~, and tabulate general statistical information with regard to cancer cases from hospitals, diagnostic and/or treatment clinics, pathology laboratories and diagnosing and/or treating physicians or other health care practitioners; to record statistical and numerical data relating thereto and tabulate such information in such form and manner as to make the same~~ available upon proper request for release to the medical profession, persons or institutions engaged in treating cancer patients, research studies and other lawful purposes; and to analyze and disseminate appropriate information regarding incidence, diagnosis, treatment, and end results and any other data designed to provide more effective cancer control for the citizens of Colorado.

~~The registry shall provide a free flow of information relative to the incidence, characteristics, geographical location and control of cancer essential to the protection of the public health from which the Department may disclose general, non-individual identifying information, numerical and statistical data developed therefrom or related thereto, and upon proof of proper written authorization therefore by the patient or the patient's representative, the entire registry record of such patient.~~

III. Reporting Required.

The following Colorado health care entities shall report all cases of cancer to the Colorado Department of Public Health and Environment:

a) Hospitals (except as noted below)
b) Free-standing diagnostic and/or treatment clinics
c) Pathology laboratories
d) Diagnosing and/or treating physicians or other health care practitioners (except as noted below)

Health care entities shall report information concerning all Colorado patients diagnosed as having cancer in the form and format as determined ~~a standard electronic format, designated~~ by the Colorado Department of Public Health and Environment. Reports shall be in standard electronic format and include the name and address of the patient, demographic information, medical history, environmental factors, date and method of diagnosis, primary site, stage of disease, tissue diagnosis, laboratory data, methods

of treatment, ~~and~~ physician names, and any other required data as determined by the Department. ~~CDPHE shall publish a list of required data elements once per year.~~ Reporting entities shall submit case reports no later than six months from the date in which the reporting entity first has contact with a patient who has a definitive diagnosis of cancer (clinical or pathologic).

In lieu of actively reporting cancer cases, Colorado hospitals licensed for fewer than 50 beds and independent from a larger hospital system shall provide authorized Colorado Department of Public Health and Environment personnel 1) electronic medical record indices (or equivalent) of patients with cancer diagnosis codes for the purpose of case finding. Hospitals shall provide the medical record indices in a structured file format to be determined by each hospital in conjunction with CDPHE staff; and 2) access to any medical record or report pertaining to the diagnosis and/or treatment of cancer patients. Colorado hospitals shall allow secure remote access to electronic records ~~when determined to be feasible by a hospital.~~

Physicians and other health care practitioners are exempted from actively reporting a new incident cancer case when the cancer patient has been admitted to a Colorado hospital or other Colorado diagnostic or treatment facility for further diagnosis or treatment, or the physician or other health care practitioner has an agreement with a Colorado hospital to report all cancer cases on his/her behalf.

IV. Confidentiality and Release of Reports and Registry Data.

All reports of cancer cases received by the Colorado Department of Public Health and Environment, in connection with the registry, from hospitals and the other designated sources shall be and remain strictly privileged and confidential as “medical records AND reports” within the purview and intent of Section 25-1-122(4), Colorado Revised Statutes.

Such reports and records shall not be released, shared with any agency or institution, or made public upon subpoena, search warrant, discovery proceedings, or otherwise, except under any of the following circumstances:

a) Release may be made of medical and epidemiological information in a manner such that no individual person can be identified.
b) Release may be made of medical and epidemiological information to the extent necessary for the treatment, control, investigation, and prevention of cancer; except that every effort shall be made to limit disclosure of personal identifying information to the minimal amount necessary.
c) Release may be made to the person who is the subject of a medical record or report with written authorization from such person.

The Department may exchange personal data with the National Cancer Institute, the Centers for Disease Control and Prevention, the North American Association of Central Cancer Registries, and any other governmental agency or contractual designee for the purpose of medical or scientific research, provided such entity, governmental agency, or contractual designee shall not further disclose information that is confidential under this section.

The Department is further authorized to acquire cancer data concerning Colorado residents from other states, and, in return, to provide those states with data relating to their residents.

Editor’s Notes

History

Entire rule eff. 06/14/2016.