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: Randi Rycroft, Director Colorado Central Cancer Registry, Office of e-Health and Data *RKR*

Through: Chris Wells, PhD, Director of the eHealth and Data Office *CW*

Date: February 1, 2016

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to 6 CCR 1009-3, Colorado Central Cancer Registry, with a request for the rulemaking hearing to occur in April of 2016

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. Pursuant to Executive Order D 2012-002 (EO2), 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 and provide needed updates.

The Department requests that the Board of Health set this matter for rulemaking in April of 2016.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1009-3, 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. Replacing the term 'physician' with 'physician or other health care practitioner' throughout the Rule.
2. Updating the references to the Colorado Revised Statutes [line 9].
3. Specifying that case reports should be in electronic format, in accordance with current practice [line 27].
4. Adding the phrase 'demographic information' to the list of required elements of a case report [line28]. This is in accordance with current practice and clarifies that additional demographic information beyond name and address of the patient are required for meaningful reporting of cancer incidence and mortality.
5. Changing the timeliness standard from '…six months from diagnosis date…' to '…six months from the date of first contact…'[line 31-21]. Since cancer treatments often do not begin until more than six months after diagnosis, a treating facility could be out of compliance before a patient ever presents to the facility for treatment if this part of the rule is not changed.
6. Adding a requirement for hospitals with fewer than 50 licensed beds to provide an electronic medical record index for the purposes of case finding [lines 37-39]. Hospitals do provide this information now, but it is often not in an electronic format, which allows for efficiencies in finding cases through data linkages.
7. Adding a requirement to allow CDPHE staff to gain remote access to electronic medical records when feasible [line 41]. This change is in alignment with current medical record keeping practices and will save the Department in travel costs to gather the data.
8. General updates, clarifications and corrections.

Specific Statutory Authority.
These rules are promulgated pursuant to the following statutes:
Section 25-1-122(4), Colorado Revised Statutes
Section 25-1.5-101(q)(I), Colorado Revised Statutes

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

_____ Yes, the bill number is _____; 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 1009-3, Colorado Central Cancer Registry

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.**

   Clarifications to the rule will benefit those required to report cancer by making requirements more clear. Reporters include hospitals, outpatient treatment centers, pathology laboratories, and physicians or other health care practitioners.

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.**

   We do not foresee any significant economic impact to affected classes of persons. The expansion of the phrase 'physician' throughout the rule, to 'physician or other health care practitioner' is not expected to have a significant impact on health care practitioners. Very few health care practitioners are expected to actively report cancer; changing the terminology simply acknowledges the variety of health care practitioners who may be involved in the diagnosis and/or treatment of cancer.

   Hospitals with fewer than 50 licensed beds that are able to provide remote access to health records may incur costs, but our experience has been that most of these hospitals already have the capacity and infrastructure in place to set up remote access.

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.**

   We do not anticipate any significant additional costs to the Department due to the proposed changes to this rule. The proposed changes bring the rule into alignment with current practices. The Department may incur costs if Office of Information Technology support is required to facilitate setting up remote access to hospital electronic records systems; however, long-term cost savings will offset the expenditure.

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

   The benefits of changing the rule are to provide clarity to those affected by the rule and to update the cancer reporting timeliness requirement. We do not anticipate any costs associated with these changes. We anticipate cost savings to the Department by reducing travel costs to gather data from hospitals with fewer than 50 licensed beds if they provide remote access. Inaction could lead to 1) decreased data quality (e.g., not providing demographic information such as age, race/ethnicity, and gender) since the only demographic information in the present rule is name and address of the patient; 2) Hospitals being out of compliance with cancer reporting before the patient ever presents for treatment.

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

None, the proposed changes are clarifying or improve practice.

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

None, in order to update the rule, a rulemaking is required.

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. There is also internal coordination with the Prevention Services Division.

STAKEHOLDER COMMENTS
for Amendments to
6 CCR 1009-3, Colorado Central Cancer Registry

The following individuals and/or entities were included in the development of these proposed rules:

Office of e-Health and Data
Board of Health Administration

The following individuals and/or entities were notified that this rule-making was proposed for consideration by the Board of Health:

Colorado Hospital Association
Colorado tumor registrar community
Colorado Medical Society
Prevention Services Division

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.

None to date. As our community has an opportunity to review the proposed changes, the Department will review and update the rulemaking packet.

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

The changes are clarifying and align with current practice and thus, the proposal has no health equity and environmental justice impacts. However, the Department studies cancer incidence in relation to poverty, gender, race/ethnicity and county. This demographic information is essential to effectively prevent, screen, diagnose, treat and improve survivorship. More information is available on the Department's website at: https://www.colorado.gov/pacific/cdphe/cancerregistry and https://www.colorado.gov/pacific/cdphe/cancer .

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

~~Disease Control and Environmental Epidemiology Division~~Office of e-Health and Data

THE COLORADO CENTRAL CANCER REGISTRY

6 CCR 1009-3

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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.~~who do not refer cancer patients to any other facility for diagnosis and/or treatment.~~

II. Cancer Registry Established.

The ~~Executive Director of the~~ Colorado Department of Public Health and Environment shall establish a "registry" pursuant to Section 25-~~1~~1.5-~~107(1)(z)~~101(q)(I), Colorado Revised Statutes ~~1989~~. The function of the registry shall be to collect, compile, 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~~who do not refer cancer patients to any other facility for diagnosis and/or treatment~~; 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.

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.

Information concerning all Colorado patients diagnosed ~~and/or treated~~ as having cancer ~~by every Colorado hospital, diagnostic and/or treatment clinic, pathology laboratory and diagnosing physician who does not refer cancer patient to any other facility for diagnosis and/or treatment~~ shall be reportable to the Colorado Department of Public Health and Environment. These reports shall be made in a standard electronic format, designated by the Colorado Department of Public Health and Environment, shall 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 shall be submitted no later than six months from ~~diagnosis date~~the date of first contact of a patient at a reporting entity for the diagnosis or treatment of the reportable cancer.

Active case reporting of all cases of cancer shall be required of the following Colorado health care entities: hospitals licensed for 50 beds or more; free-standing diagnostic and/or treatment clinics; pathology laboratories; and diagnosing and/or treating physicians or other health care practitioners (except as noted below).

In lieu of active case reporting, Colorado hospitals licensed for fewer than 50 beds shall 1) provide electronic medical record indices (or equivalent) of patients with cancer diagnosis codes to authorized Department of Public Health and Environment personnel for the purpose of case finding; and 2) shall allow access to any medical record or report pertaining to the diagnosis and/or treatment of cancer patients. Hospitals shall allow secure remote access to electronic records whenever feasible. ~~every hospital licensed for less than 50 beds, diagnostic and/or treatment clinic and pathology laboratory shall allow access to any medical record or report pertaining to the diagnosis and/or treatment of cancer patients by authorized Department of Public Health and Environment personnel. Those hospitals with 50 beds or more must report all cases of cancer diagnosed in Colorado residents in 1988 or later with the standard data listed above required by the Colorado Department of Public Health and Environment.~~

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 a formal agreement with a Colorado hospital to report all cancer cases on his/her behalf.

IV. Confidentiality 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 ~~1989~~.