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: Mandy Bakulski, Maternal Wellness & Early Childhood Unit Supervisor, Prevention Service Division

Through: Elizabeth Whitley, Prevention Services Division Director - *EW*

Date: January 29, 2015

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to 6 CCR 1009-8, Reporting of Selected Causes of Morbidity and Mortality in Colorado with a request for the rulemaking hearing to occur on February 17, 2016

Multiple work units at CDPHE have reviewed 6 CCR 1009-8, which concerns the reporting of selected causes of morbidity and mortality. For many work units the rule is obsolete. However, staff members in the Maternal Wellness and Early Childhood Unit continue to rely on the rule for the purposes of conducting maternal mortality reviews. The proposed changes update the rule to eliminate the obsolete components and tailor the rule to the current practices for maternal mortality. The department is requesting the Board of Health approve the suggested amendments to the rule. No public comments were received during the open comment period, and there are no anticipated areas of concern with the proposed changes.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1009-8, Reporting of Selected Causes of Morbidity and Mortality in Colorado

Basis and Purpose.

The statutory intent of 6 CCR 1009-8 is to clarify how the department will implement 25-1.5-101(1)(c)(I), C.R.S. More specifically, 6 CCR 1009-8 defines how the department will fulfill its duties to collect, compile and tabulate reports of morbidity and mortality, including maternal mortality. With regards to maternal mortality, 6 CCR 1009-8 indicates that the department will tabulate fatalities "that occur in association with pregnancy or for up to one year postpartum". The rule further describes how the department will investigate maternal deaths, including what may be collected and reviewed. The purpose of Colorado's maternal mortality work is to determine the causes of maternal morbidity and mortality in Colorado and identify public health and clinical interventions to improve systems of care.

In addition to allowing the department to compile and tabulate morbidity and mortality related to pregnancy, the current rule also allows for compilation and tabulation of firearm related injuries (fatal or non-fatal) and morbidity related to sexual assaults. These components of the statute are now obsolete as the information is collected through other means.

The purpose of the proposed changes is to update the rule to eliminate the obsolete components and tailor the rule to the current practices for maternal mortality to improve clarity on who uses the rule and how it is used.

Specific Statutory Authority.

These rules are promulgated pursuant to the following statutes:

Section 25-1.5-101(1)(c)(I), C.R.S., which states the Department has the power and duty "to collect, compile, and tabulate reports of...deaths and morbidity and to require any person having information with regard to the same to make such reports and submit such information as the board [of Health] shall by rule or regulation provide."

Section 25-1.5-101(1)(c)(II), C.R.S. states that the Board is authorized to require reporting of morbidity and mortality in accordance is Section 25-1-122, C.R.S. (With respect to investigations of epidemic and communicable diseases, morbidity and mortality, cancer in connection with the statewide cancer registry, environmental and chronic diseases, sexually transmitted infections, tuberculosis, and rabies and mammal bites, the board has the authority to require reporting, without patient consent, of occurrences of those diseases and conditions by any person having knowledge of such to the state department of public health and environment and county, district, and municipal public health agencies, within their respective jurisdictions. Any required reports shall contain the name, address, age, sex, and diagnosis and such other relevant information as the board determines is necessary to protect the public health. The board shall set the manner, time period, and form in which such reports are to be made.)

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 1009-8, Reporting of Selected Causes of Morbidity and Mortality in Colorado

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.

Due to the nature and variability of these deaths, the department interacts with a diverse group of hospitals and clinics to collect medical records – some on a regular basis and others only sporadically. There is some minimal cost associated with the effort of compiling these records by the hospital and clinic staff. Typically a total of 25-40 records are requested in a year. Medical records sent to the department are sent in paper form, averaging 150 pages per record, with an average of 2-3 separate medical records requested per death. In addition, there is a cost to the department related to internal staff time associated with the compilation and review of records.

The purpose of Colorado's maternal mortality work is to determine the causes of maternal morbidity and mortality in Colorado and identify public health and clinical interventions to improve systems of care. Therefore the citizens of Colorado receive the benefit of the proposed rule through improved public health and health care practices in the state.

The proposed changes do not increase the time or cost for hospital, clinic or department staff. The updates to the rule will provide clarity for hospital and clinic staff that are reporting and will assist the rule when training staff that are new to morbidity and mortality reporting.

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 department requests all pieces of information relevant to a maternal death, including coroner reports, autopsies, labor and delivery records, hospital incident records, prenatal records, postpartum records, motor vehicle records and police reports. The proposed changes do not increase the reporting burden. Large hospital systems or coroners, who have a medical records department, may interact with the department more frequently. Some of the prenatal records requested by the department come from small, private prenatal clinics. These clinics may only sporadically interact with the department and it can be challenging to track down and provide the prenatal records.

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.

Pregnancy-related death is not a reportable condition in Colorado as such it is the responsibility of department staff to identify and obtain the needed information. Maternal mortality work includes staff from Vital Statistics and the Prevention Services Division and requires approximately 1.2 FTE across all associated programs for implementation.

Maternal mortality staffs are charged with the following:

- identifying deaths for review,
- collecting records,
- reviewing and abstracting records,
- presenting case summaries to the Maternal Mortality Review Committee,
- inputting associated information into the state's database,
- analyzing data to explore relevant trends,
- translating data into action to improve the care of pregnant and postpartum women, and
- providing general program management and administration.

The proposed changes align with the current allocation of resources. There is no increased cost or 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.

There is no cost associated with the proposed rule. The benefit is to provide clarity to those that rely upon these rules. There is no benefit to inaction. As written the rule is vague and contains obsolete language, thus it is difficult to determine who is in fact relying upon it.

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

Currently there are no less costly or intrusive methods for achieving the purpose of the proposed rule. The department does not have compatible technology for the identification or receipt of electronic health records. Thus, the most efficient manner to collect maternal death records is by individually requesting records from hospitals and clinics.

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

No alternative rules or alternatives to rulemaking were considered. Rulemaking is needed to update the rule and provide necessary clarification that will assist the Department and the maternal wellness community.

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.

Information from the Center for Disease Control was relied upon when reviewing and developing the proposed changes. The proposed changes clarify the language to ensure department staff and stakeholders know how the rule is being used and who is using it. Because the proposed changes are clarifying, additional data was not relied upon.

STAKEHOLDER COMMENTS
for Amendments to
6 CCR 1009-8, Reporting of Selected Causes of Morbidity and Mortality in Colorado

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

Public Health divisions and the Environmental Health and Sustainability Division were asked whether staff relied upon the rule. The Violence & Injury Prevention, Mental Health Promotion Branch in the Prevention Services Division provided edits on the components of the rule that could be deleted. The Maternal Wellness & Early Childhood Unit in the Prevention Services Division provided edits to improve the alignment of the statute with the current practices for maternal mortality.

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

The proposed rule was shared with all members of the Maternal Mortality Review Committee (includes physicians, coroners, mental health professionals, public health staff, vital statistics employees among others). It was also shared as a highlighted item in the Maternal Wellness & Early Childhood Update, which is a monthly communication distributed to a broad spectrum of nearly 350 maternal and early childhood stakeholders throughout Colorado. The proposed rule was also posted on the department's website page for maternal mortality.

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 stakeholder feedback was received in response to the public comment period.

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?

This proposal impacts Coloradoans equitably as all maternal deaths occurring in Colorado are reviewed regardless of the conditions or nature of death. Through the review of maternal deaths there is an opportunity to identify trends associated with inequalities and highlight those findings through reports on the data, as well as through recommendations for public health and clinical interventions that could improve systems of care.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

~~**Disease Control and Environmental Epidemiology Division**~~

RULES AND REGULATIONS PERTAINING TO THE REPORTING OF ~~SELECTED~~ CAUSES OF MATERNAL MORBIDITY AND MORTALITY IN COLORADO

6 CCR 1009-8

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Authority for Establishing Rules and Regulations

The following regulations are promulgated pursuant to ~~CRS~~ Section 25-1.5-101~~7~~(1)(c~~f~~)(1), C.R.S., which states the Department has the power and duty "to collect, compile, and tabulate reports of...deaths and morbidity and to require any person having information with regard to the same to make such reports and submit such information as the board [of Health] shall by rule or regulation provide."

Regulation 1. Reportable Causes of Morbidity and Mortality

For the purpose of tabulating accurate reports of significant causes of morbidity and mortality in Colorado, diseases and conditions directly or indirectly related to a pregnancy and fatalities that occur in association with pregnancy or for up to one year postpartum ~~the diseases and conditions named in the list below~~ shall be reportable by physicians, other health care providers, hospitals, health care facilities and coroners in accordance with the provisions of these regulations.

~~REPORTABLE CAUSES OF MORBIDITY AND MORTALITY~~

~~Diagnosis (Confirmed or Suspected) Reportable Within:~~

~~Firearm-related injuries (fatal or non-fatal) 120 days~~

~~Sexual assault-related morbidity 60 days~~

The Department shall identify and tabulate maternal death cases, as defined as a death within one year of pregnancy with a direct or indirect causation related to the pregnancy or postpartum period. ~~also tabulate fatalities in persons less than 17 years of age, and fatalities that occur in association with pregnancy or for up to one year postpartum.~~ These occurrences will be reviewed to compile potential risk factors. ~~To accomplish this work, the Department may have access without patient consent to medical records of those cases for which an autopsy was not performed or was insufficient to fully determine risk factors for the death. To tabulate sexual assault-related morbidity and risk factors for such morbidity, the Department may, without patient consent, have access to and obtain information from pertinent patient medical, coroner, and laboratory records in the custody of physicians, hospitals, clinics, laboratories, and coroners, which are relevant and necessary. Information on cases of sexual assault morbidity that is voluntarily submitted by agencies providing services to victims of sexual assault or by law enforcement agencies shall be included as part of the public health investigation record of a case of sexual assault morbidity.~~

Regulation 2. Manner of Reporting, Information To Be Submitted, and Investigations To Confirm the Diagnosis and Causes of Morbidity and Mortality

The diseases and conditions listed in Regulation 1 shall be reported to the Department of Health within the specified time frame after the diagnosis is made by the physician, other health care provider, hospital, health care facility or coroner~~, or hospital~~.

The information that shall be submitted for reportable causes of morbidity and mortality shall consist of the diagnosis; the patient's name, age, sex, race/ethnicity, and address; the name and address of responsible physician; pregnancy status; ~~the employer (for reportable work-related conditions as pertinent);~~ and such other information as is needed by the Department to accurately compile and tabulate the causes of morbidity and mortality. ~~The Board of Health determines that name and address of reported victims of sexual Code of Colorado Regulations 2 assault is not relevant or necessary to protect the public health and shall not be included in such case reports.~~

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

Investigations may be conducted to confirm the diagnosis and causes of reportable conditions in Regulation 1 and shall be considered official duties of the state health department ~~or health agency~~. Such investigations may include:

(a) review of pertinent, relevant medical records by authorized personnel, if necessary to confirm the diagnosis; 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) performing follow-up interview(s) with persons knowledgeable about the case to collect pertinent and relevant information about the cause(s) of the ~~the~~ reportable condition.

The Department shall develop systems and forms for reporting by physicians, other health care ~~and mental health~~ providers, hospitals, health care facilities or coroners~~, and hospitals, and laboratories~~. ~~For firearm-related injuries, hospital reporting shall be through a central computerized data system.~~

Reports required by these Regulations do not substitute for or relieve the requirement to comply with Colorado Vital Statistics Regulations (5 CCR 1006-1).

~~**Regulation 3. Information sharing**~~

~~Whenever a local health department or health agency learns of a case of a reportable disease in Regulation 1, 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.~~

~~These requirements shall not apply if the State and local health department or agency 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 causes of morbidity and mortality 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 3~~4~~. Confidentiality

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).