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: Grace Sandeno, Trauma Section Manager
Jeanne-Marie Bakehouse, EMTS Branch Chief
Health Facilities and Emergency Medical Services Division

Through: D. Randy Kuykendall, Director D.R.K
Michelle Reese, Deputy Director
Health Facilities and Emergency Medical Services Division

Date: October 21, 2015

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to **6 CCR 1015-4, Chapter One, The Prehospital and Trauma Registries** with a request for the rulemaking hearing to occur in December of 2015.

The department is proposing an amendment to 6 CCR 1015-4, Chapter One, The Prehospital and Trauma Registries. The department is recommending a complete revision of the Chapter One rules and the removal of references to the prehospital registry which are now covered in 6 CCR 1015-3, Chapter Three, Rules Pertaining to Emergency Medical Services Data and Information Collection and Record Keeping.

Chapter One does not reflect the current practice of the trauma system in the state of Colorado, as it has not been revised for many years. Additional definitions are being added to provide clarity. Finally the chapter is being re-organized to provide a format consistent with recently revised chapters within 6 CCR 1015-4. The title will also be changed to reflect that the prehospital dataset is not covered by the regulation.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1015-4, Chapter One, The Prehospital and Trauma Registries

Basis and Purpose.

The proposed amendments modify rules that were last revised in 2005. The current rules no longer adequately reflect trauma terminology used in data collection. In addition current rules are ambiguous regarding data elements and collection methodology. The proposed amendment will significantly modify the current chapter in the following ways:

- Remove all references to the prehospital registry as they are redundant. These data are currently regulated under 6 CCR 1015-3, Chapter Three.
- Modify and add definitions to clarify the requirements of the trauma registry.
- Reformat the chapter to clearly define which data elements are required from each level trauma center.
- Replace obsolete language.
- Reformat the entire chapter to be consistent with other rules.

The rules governing technical assistance training and confidentiality were not altered.

Specific Statutory Authority.

These rules are promulgated pursuant to the following statutes:

C.R.S § 25-3.5-704(2)(f)

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 1015-4, Chapter One, The Prehospital and Trauma Registries

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.

The proposed rule change affects the trauma data registry maintained by the department. This rule change will clarify expectations for the submittal of data and re-format the chapter to be consistent with later chapters within 6 CCR 1015-4. No new requirements are being put in place. Facilities designated as Level I-V and non-designation facilities will be affected by this rule change.

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 information the department requires to be submitted is not changing. The impact on trauma hospitals will be minimal. As the department is clarifying the requirements for smaller, low volume facilities, a resource impact on the time and effort of trauma staff may take place in the short term as they become better aware of the expectations of the department. However, the department has been working already to minimize this impact by creating an excel spreadsheet that is limited to 26 elements to be submitted directly to the department.

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 will be no cost to the department to implement this rule change.

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

As it currently exists, the language in Chapter One does not reflect how trauma data are being collected by trauma facilities or the department. The updates in this rule change will help the department better collect and analyze the data coming in to the trauma registry and make comparisons of care across like facilities. Such comparisons will lead to the identification of best practices which could be implemented across the state. Additionally, the current rule is not in step with changes made within the state regarding trauma care and is inconsistent with other chapters within 6 CCR 1015-4.

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

As the requirements for what is to be reported have not changed, there will be no need for trauma facilities to expand their existing data collection. The department has worked with facilities to minimize costs by developing an excel spreadsheet that lower level facilities can submit instead of using expensive software.

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

Department staff met with stakeholders in the drafting of the rule language. Multiple drafts of rule language were reviewed to reach the proposed modifications.

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 long term consequences of this rule change will be the ability to compare like trauma facilities and regions within Colorado in order to help determine best practices. The clarifications within the rule will result in the data submitted to the department being more complete, which will allow the state to increase and localize its training to those facilities in need. In the short term, there will be a learning curve in the education of level IV and V facilities on the spreadsheet, and department staff will be heavily involved in that training.

STAKEHOLDER COMMENTS
for Amendments to
6 CCR 1015-4, Chapter One, The Prehospital and Trauma Registries

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

Proposed amendments were developed with the assistance of an ad hoc work group composed of trauma nurse coordinators, trauma registrars representing different level trauma facilities and the department's Trauma Section staff.

The proposed amendments were first presented to the Statewide Trauma Advisory Committee (STAC) on July 29, 2015. Membership of the STAC is attached. This public meeting was focused on the detailed review of this document and was well attended by physicians, trauma nurse coordinators, trauma program managers and trauma registrars.

The revised document was set to the entire trauma community for comment on August 14, 2015. It was sent to the following email groups:

Regional Emergency Medical and Trauma Advisory Councils (RETAC) Coordinators
RETAC Chairs
State Emergency Medical and Trauma Advisory Council members
Trauma Program Managers
Trauma Program Other
Trauma Registrars
Trauma Nurse Coordinators

Any changes based on comments received will be discussed at the Oct. 7, 2015, STAC meeting for the greater trauma community to participate in. The proposed rules will be presented to SEMTAC on Oct. 8, 2015 for recommendation of approval by SEMTAC to the department.

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

Emails were sent to the following:
RETAC Coordinators
RETAC Chairs
SEMTAC members
Trauma Program Managers
Trauma Program Other
Trauma Registrars
Trauma Nurse Coordinators

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.

As the requirements of what is to be submitted to the department are not changing, there were few issues encountered. The trauma community is supportive of these changes, as they provide clarity as to requirements and consistency to other chapters within 6 CCR 1015-4.

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?

There is no impact on health equity or environmental justice as this is a data registry change.

STAC Committee Membership
Updated September 2015

SEMTAC Appointed (6)	Department Appointed (5)	Affiliation	Term expiration
Kathy Beauchamp - appt			Sept-17
Patti Thompson - appt			Sept-16
	Lori McDonald RN (trauma program manager)	Univ. of Colorado Health - North	Sept-17
Barry Platnick – appt		Castle Rock Fire	Sept-16
	Kyle Dahm RN (air transportation community)	Airlife Denver	Sept-15
	Tamara Connell RN (injury prevention)	Castle Rock Adventist Hospital	Sept-16
	Robert Handley RN (advocate/stakeholder)	Limon Ambulance Service	Sept-15
Deborah Moynihan - reappt		Mt. San Rafael Hospital	Sept-18
Carl Smith - reappt		Member of the public	Sept-18
Jeff Beckman MD		Exempla Lutheran	Sept-16
	Charlie Mains MD (at large)	St. Anthony Hospital	Sept-17

There shall be 11 members, 6 of whom are members of SEMTAC and appointed by the SEMTAC Chair.
Five members are appointed by the Department. The 5 Department-appointed members shall be:

a. A Registered Nurse with experience as a trauma nurse coordinator or trauma program manager
b. A representative from the Public Health/Injury Prevention community
c. A representative from the Colorado EMS Air Transportation community
d. A consumer/advocate/stakeholder interested in the development of the Colorado trauma system
e. An at-large representative

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

Statewide Emergency Medical and Trauma Care System

6 CCR 1015-4

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CHAPTER 1 - THE TRAUMA REGISTRY

100. Definitions

1. Admission - inpatient or observation status for a principal diagnosis of trauma.

2. Blunt injury - Any injury other than penetrating or thermal.

3. Community clinics and community clinics with emergency centers (CCEC) – Facilities as licensed by the department under 6 CCR 1011-1, Chapter IX.

4. Department - The Colorado Department of Public Health and Environment.

5. Facility - A health facility licensed by the Department that receives ambulances.

6. Injury type - Can be blunt, penetrating or thermal and is based on the mechanism of injury.

7. Interfacility Transfer - The movement of a trauma patient from one facility as defined by these rules to another facility. Transfers may occur between the emergency department of one facility and a second facility, or from inpatient status at one facility to a second facility.

8. Penetrating injury - Any wound or injury resulting in puncture or penetration of the skin and either entrance into a cavity, or for the extremities, into deeper structures such as tendons, nerves, vascular structures, or deep muscle beds.

9. Re-admission - A patient who is readmitted (for greater than 12 hours) to the same or to a different facility within 30 days of discharge from inpatient status, for missed diagnoses or complications from the first admission. Readmission does not include subsequent hospitalizations that are part of routine care for a particular injury (such as removal of orthopedic hardware, skin grafts, colostomy takedowns, etc.)

10. Severity - An indication of the likelihood that the injury or all injuries combined will result in a significant decrease in functionality or loss of life.

11. State Emergency Medical and Trauma Services Advisory Committee (SEMTAC) - A council created in the Department pursuant to Section 25-3.5-104, C.R.S., which advises the Department on all matters relating to emergency medical and trauma services.

12. Statewide trauma registry - The statewide trauma registry means a statewide data base of information concerning injured persons and licensed facilities receiving injured persons, which information is used to: evaluate and improve the quality of patient management, facilitate trauma education, conduct research, and promote injury prevention programs.

13. Thermal injury - Any trauma resulting from the application of heat or cold, such as thermal burns, frostbite, scald, chemical burns, electrical burns, lightning or radiation.

14. Traumatic Injury - A blunt, penetrating, or thermal injury or wound to a living person caused by the application of an external force or by violence. Injuries that are not considered to be trauma include such conditions as: injuries due to repetitive motion, pathological fractures as determined by a physician, and scheduled elective surgeries.

101. Reporting of trauma data by facilities

1. Facilities designated as Level I, II, III or Regional Pediatric Trauma Centers, as defined in Section 25-3.5-703(4), C.R.S., shall submit data as defined by the Department based on recommendations by SEMTAC or a committee thereof. These data elements include but are not limited to:

    A. The data for discharges, inpatients, transfers, readmits and deaths in a particular month shall be submitted as an electronic data file to the Department within 60 days of the end of that month. These data elements include but are not limited to:

        i. Patient information: name; date of birth; gender; race/ethnicity; address; pre-existing medical diagnoses; medical record number;

        ii. Injury information: date, time and location of injury; cause of injury; injury circumstances; whether or not protective devices were used by the patient; evidence of alcohol or other intoxication;

        iii. Pre-hospital information: transport mode from the injury scene; name of agency providing transport to the facility; physiologic and anatomic conditions; times of notification, arrival at scene, departure from scene, and arrival at destination;

        iv. Emergency department information: clinical data upon arrival; procedures; providers; response times; disposition from the emergency department;

        v. Interfacility transfer information: transfer mode from the referring facility; name of the referring facility; arrival and discharge times from the referring facility; whether the patient was seen in the emergency department only or was admitted as an inpatient at the referring hospital;

        vi. Inpatient care information: name and address of the facility; admission date and time; admission service; surgical procedures performed; date and time of all surgical procedures; co morbid factors; total days in the Intensive Care Unit (ICU); date and time of discharge; discharge disposition; payer source; discharge diagnoses, including International Classification of Disease (ICD) codes, Abbreviated Injury Scale (AIS), body region, diagnosis description, and Injury Severity Score (ISS);

        vii. Readmissions information: patient's name, date of birth, gender, and address; medical record number, name of facility, and the date of admission at the original facility; and medical record number, name of facility, date of readmission and the reason for readmission at the readmitting facility;

        viii. Death information: patient's name, date of birth, gender, and address; patient's injury type, diagnostic codes, severity, and cause; the time and date of arrival at the facility; the date of the death; autopsy status if performed (i.e. complete, pending, not done).

2. Level IV, V and non-designated facilities, as defined in Section 25-3.5-703(4), C.R.S., shall submit data as defined by the Department based on recommendations by SEMTAC or a committee thereof.

    A. Data shall be submitted to the Department for all discharges, transfers and deaths on a quarterly basis within 60 days of the end of that quarter. These data elements include but are not limited to:

i. Inpatient information: name, age, gender, place of residence zip code, medical record number, admission date, discharge date, injury type, and cause;

ii. Interfacility transfer information: whether from the emergency department or after inpatient admission; the patient's name, age, gender, and place of residence zip code;

iii. Readmissions information: patient's name, age, gender, and place of residence zip code; medical record number, name of facility, and the date of admission at the original facility; and medical record number, name of facility, date of readmission and the reason for readmission at the readmitting facility;

iv. Death information: patient's name, age, gender, and place of residence zip code; patient's injury type, and cause; the time and date of arrival at the facility; the date of the death.

B. Level IV, V, and non-designated facilities may fulfill the reporting requirement by participating in the reporting system designated by the department with submission dates determined by the data system operator.

3. All facilities shall submit to the Department such additional information regarding the care, medical evaluation, and clinical course of specified individual patients with trauma as requested by the Department for the purpose of evaluating the quality of trauma management and care. Such information shall be defined by the Department based on recommendations by SEMTAC or a committee thereof.

102. Provision of technical assistance and training

1. The Department may contract with any public or private entity to perform its duties concerning the statewide trauma registry, including but not limited to, duties of providing technical assistance and training to facilities within the state or otherwise facilitating reporting to the registry.

103. Confidentiality

1. Any data maintained in the trauma registry that identifies patients or physicians or is part of the patient's medical record shall be strictly confidential pursuant to Section 25-3.5-704(2)(f)(III), C.R.S., whether such data is recorded on paper or stored electronically. The data shall not be admissible in any civil or criminal proceeding.

2. The data in the trauma registry may not be released in any form to any agency, institution, or individual if the data identifies patients or physicians.

~~1.~~3. The Department may establish procedures to allow access by outside agencies, institutions or individuals to information in the registry that does not identify patients or physicians. These procedures are outlined in the Colorado Trauma Registry Data Release Policy and other applicable Department data release policies.

~~**CHAPTER 1 - THE PREHOSPITAL AND TRAUMA REGISTRIES**~~

~~**SECTION 1: THE COLORADO TRAUMA REGISTRY**~~

~~**1.1 Definitions**~~

~~**Acute trauma injury:** An injury or wound to a living person caused by the application of an external force or by violence. Trauma includes any serious life-threatening or limb-threatening situations. Acute trauma involves the initial presentation for care at the facility. Injuries that are not considered to be acute include such conditions as: injuries due to repetitive motion or stress, and scheduled elective surgeries.~~

~~**Admission:** inpatient or observation status for greater than 12 hours.~~

~~**Community clinics and community clinics with emergency centers:** As defined in the Department's rules concerning community clinics at 6 CCR 1011-1, Chapter IX.~~

~~**Department:** The Colorado Department of Public Health and Environment~~

~~**Facility:** A health facility licensed by the Department that, under an organized medical staff, offers and provides services 24 hours a day, 7 days a week to people in Colorado.~~

~~**Injury type:** Can be blunt, penetrating or thermal and is based on the first mechanism of injury.~~

~~**Penetrating injury:** Any wound or injury resulting in puncture or penetration of the skin and either entrance into a cavity, or for the extremities, into deeper structures such as tendons, nerves, vascular structures, or deep muscle beds. Penetrating trauma requires more than one layer of suturing for closure.~~

~~**Thermal injury:** Any trauma resulting from the application of heat or cold, such as thermal burns, frostbite, scald, chemical burns, electrical burns, lightning and radiation.~~

~~**Blunt injury:** Any injury other than penetrating or thermal.~~

~~**Interfacility Transfer:** The movement of a trauma patient from one facility to another. Transfers may occur between the emergency department of one facility and a second facility, or from inpatient status at one facility to a second facility.~~

~~**Prehospital Provider:** Reserved~~

~~**Re-admission:** A patient who is readmitted (for greater than 12 hours) to the same or to a different facility within 30 days of discharge from inpatient status, for missed diagnoses or complications from the first admission. Readmission does not include subsequent hospitalizations that are part of routine care for a particular injury (such as removal of orthopedic hardware, skin grafts, colostomy takedowns, etc.)~~

~~**Severity:** An indication of the likelihood that the injury or all injuries combined will result in a significant decrease in functionality or loss of life. Examples of scoring systems for injury severity include the Injury Severity Score (ISS), the New Injury Severity Score (NISS), the Revised Trauma Score (RTS), TRISS, ASCOT (A Severity Characterization of Trauma), etc.~~

~~**Statewide trauma registry:** The statewide trauma registry means a statewide data base of information concerning injured persons and licensed facilities receiving injured persons, which information is used to evaluate and improve the quality of patient management and care and the quality of trauma education, research, and injury prevention programs. The database integrates medical and trauma systems information related to patient diagnosis and provision of care. Such information includes epidemiologic and demographic information.~~

~~**1.2 Reporting of trauma data by facilities**~~

~~1. Each licensed facility (including specialty facilities), clinic, or prehospital provider that provides any service or care to or for persons with trauma injury in this state shall submit to the Department the following information about any such person who is admitted to a hospital as an inpatient or transferred from one facility to another or who dies from trauma injury.~~

~~a. For patients with an acute trauma injury admitted to a hospital or specialty facility as an~~ inpatient ~~: such information shall include the patient's name, date of birth, sex, and address; and the patient's medical record number, admission date, discharge date, injury type, diagnostic codes, severity and cause;~~

~~b. For patients readmitted to a facility as a hospital inpatient for care of the trauma injury: such information shall include the patient's name, date of birth, sex, and address; medical record number, name of facility, and the date of admission at the original facility; and~~

~~medical record number, name of facility, date of readmission and the reason for readmission at the readmitting facility;~~

~~c. For patients with an acute trauma injury transferred between facilities whether from the emergency department or after inpatient admission: such information shall include the patient's name, date of birth, sex, and address; the patient's diagnoses, injury type, severity, and cause; and the name of the facilities and providers involved in the transfer. Both the transferring and receiving facility or provider are required to report this information. For patients who are transferred to an out-of-state facility or provider, the transferring facility or provider in Colorado shall be required to report the required information to the Colorado Trauma Registry;~~

~~d. For individuals who die from an acute trauma injury while in the emergency department, clinic or after admission to a hospital or specialty facility as an inpatient (any length of stay): such information shall include the patient's name, date of birth, sex, and address; and the patient's injury type, diagnostic codes, severity, and cause; the time and date of arrival at the facility and the date of death.~~

~~The information outlined above shall be submitted to the Department for all discharges or deaths in a particular month within 60 days of the end of that month. The information submitted shall be provided in the format specified by the Department.~~

~~2. Facilities designated as Level I, II, III or Regional Pediatric Trauma Centers shall submit supplementary information in addition to the information outlined in Regulation 1 above. The required supplementary information shall be defined by the Department based on recommendations by SEMTAC or a committee thereof. This supplementary information includes:~~

~~a. Patient information: name; date of birth; medical record number; sex; race/ethnicity; patient address; pre-existing medical diagnoses;~~

~~b. Injury information: date, time and location of injury; cause of injury; injury circumstances; whether or not protective devices were used by the patient; evidence of alcohol or other intoxication;~~

~~c. Pre-hospital information: transport mode from the injury scene; name of the transport agency (ies); triage risk assessment, including physiologic and anatomic conditions; times of notification, arrival at scene, departure from scene, and arrival at destination; clinical data upon arrival at the emergency department; and disposition from the emergency department;~~

~~d. Interfacility transfer information: transfer mode from the referring facility; name of the referring facility; arrival and discharge times from the referring facility; patient status in the referring facility (seen in the ED only or admitted as an inpatient);~~

~~e. Inpatient care information: name and address of the facility; initials of the individual collecting the information; admission date and time; admission service; surgical procedures performed; date and time of all surgical procedures; co morbid factors; total days in the ICU; date and time of discharge; discharge disposition; payer source; discharge diagnoses, including ICD codes, AIS scores, body region, diagnosis description, and ISS score; functional ability at discharge; and for deaths, autopsy status if performed (i.e. complete, pending, not done).~~

~~Information from Level I, II, III or Regional Pediatric Trauma Centers shall be submitted in electronic data files. As stated above, the data for discharges and deaths in a particular month shall be submitted to the state health department within 60 days of the end of that month.~~

~~3. Level IV, V and undesignated clinics or facilities, shall fulfill the reporting requirement by submission of data through a central computerized data system operated by or for the Department, or for clinics or facilities with low volume (less than 20 acute trauma patients per month), arrangements can be made for submission of paper records to the Department. This arrangement requires pre-~~

approval by the Trauma and Injury Epidemiology Program staff at the Department. For those reporting electronically, additional paper reports may be required for reporting additional information on patients transferred out-of-state or to other Level IV, V or undesignated facilities. Whether submission is by electronic file or paper record, the required information shall be submitted to the Department for all discharges and deaths in a particular month within 60 days of the end of that month.

4. All facilities shall submit to the Department such additional information regarding the care, medical evaluation, and clinical course of specified individual patients with acute trauma injury as is requested by the Department for the purpose of evaluating the quality of trauma management and care. Such information shall be defined by the Department based on recommendations by SEMTAC or a committee thereof.

1.3 Provision of technical assistance and training

1. The Department may contract with any public or private entity to perform its duties concerning the statewide trauma registry, including but not limited to, duties of providing technical assistance and training to facilities within the state or otherwise facilitating reporting to the registry.

1.4 Confidentiality

1. Any data maintained in the trauma registry that identifies patients or physicians or is part of the patient's medical record shall be strictly confidential pursuant to § 25-3.5-704(2)(f)(III), C.R.S., whether such data is recorded on paper or stored electronically. The data shall not be admissible Department in any civil or criminal proceeding.

2. The data in the trauma registry may not be released in any form to any agency, institution, or individual if the data identifies patients or physicians.

3. The may establish procedures to allow access by outside agencies, institutions or individuals to information in the registry that does not identify patients or physicians. These procedures are outlined in the Colorado Trauma Registry Data Release Policy and other applicable Department data release policies.

SECTION 2: THE COLORADO PREHOSPITAL REGISTRY

2.1 Definitions

Service Agency : A fixed-based or mobile prehospital provider of emergency medical services that employs emergency medical technicians to render medical care to patients.

Service Agency that transports patients or injured persons - means licensed transport agencies (including ground and air ambulance), as well as ski patrol, search and rescue, and critical care transport. First responders are not included in this definition if they only provide care at the scene and do not transport patients.

Transports patients or injured persons - means moving a patient from the scene, or from any point along the route to the final destination, as part of the agency's regular business (i.e., not when the transport of a patient is a rare or unusual occurrence due to the immediate needs of the situation). "Ambocabs" are not included in the definition of agencies that transport patients.

2.2 Reporting of prehospital data by service agencies

Reserved

2.3 Confidentiality

Reserved