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, Emergency Medical and Trauma Services Branch

Through: D. Randy Kuykendall, Division Director, Health Facilities & Emergency Medical Services, D.R.K

Date: January 18, 2017

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to 6 CCR 1015-4 Statewide Emergency Medical and Trauma Care System, Chapter Three – Designation of Trauma Facilities with a request for a rulemaking hearing to be set for March of 2017

Trauma designation determines which injuries a hospital can treat. The goal is to ensure that patients receive the appropriate level of care for their injuries. However, changes in medical practice and population growth in Colorado have resulted in hospitals providing a higher level of care without obtaining a higher level designation. The Department, the Statewide Trauma Advisory Committee and interested stakeholders developed a task force to review the current rules regarding the scope of services offered by designated trauma centers. The proposed rule changes are to ensure that patient safety and adequate care are provided by standardizing expectations about what will be available in facilities choosing to expand their scope of care beyond the minimum requirements for the designation level. The changes do not affect the current standards for Level III and IV trauma designation but lay out additional requirements about what is expected of a trauma center providing an expanded scope of care.

During the scope of care rule revision, it became necessary to implement some additional standards for the quality improvement process at Level III and IV trauma centers with expanded scope of care. Staff and the task force worked together to revise the current rules in Section 308 to include performance improvement processes which apply to expanded scope facilities. In addition, the group reorganized the entire section into a more logical format.

While these issues were being explored, the American College of Surgeons (ACS) announced that it would be increasing fees and moving to an annual payment structure. Currently, any designated trauma center in Colorado wishing to be verified by the ACS is paying the Department to set up the review. Given the fee increases and change to annual payment, the Division is also changing its fee structure to an annual payment structure. The Division will no longer facilitate payment to the ACS; after the implementation of the rule change, any hospital wishing to be ACS verified will pay the ACS directly.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1015-4 Statewide Emergency Medical and Trauma Care System, Chapter Three – Designation of Trauma Facilities

Basis and Purpose.

The proposed rule amendments will provide clarity regarding the minimum requirements for a facility that wishes to offer an expanded scope of care. They also create a standard by which the Department can ensure consistency of trauma care across the state. The requirements related to trauma quality improvement for Level III to V facilities were prioritized, moved and modified to account for expanded scope of care.

The fee changes are brought about by changes made by the American College of Surgeons (ACS), including fee increases and moving to an annual payment schedule. The fee structure being proposed in the amendments will match the ACS's move to an annual payment. In addition, the department will no longer collect fees related to ACS verification; the department will only collect those fees associated with state designation.

Specific Statutory Authority.
These rules are promulgated pursuant to the following statutes:

§ 25-3.5-704, C.R.S

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

If "Yes," the rule needs to provide the URL of where the material is available on the internet (CDPHE website recommended) or the Division needs to provide one print or electronic copy of the incorporated material to the State Publications Library. § 24-4-103(12.5)(c), C.R.S.

Does this rule create or modify fines or fees?

___X___ Yes
_____ No

REGULATORY ANALYSIS
for Amendments to
6 CCR 1015-4 Statewide Emergency Medical and Trauma Care System, Chapter Three – Designation of Trauma Facilities

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 changes will affect all designated trauma facilities in varying ways. Moving to an annual payment plan from a triennial plan will allow for facilities to more accurately budget payments. The changes to fees and the fee structure enable the Department to cover anticipated costs for the next three year cycle and allow the Department to facilitate state designation without involvement in the American College of Surgeons verification fee payments.

Currently there are 82 designated trauma facilities within the state: 3 Level I facilities, all of which are ACS verified; 13 Level II facilities, all of which are ACS verified; 21 Level III facilities, one of which is verified; 44 Level IV/V facilities, none of which are ACS verified; and one Regional Pediatric Trauma Center (RPTC), which is ACS verified. The fee change will have the following effects on the individual facilities:

Level	Current Fee New Facility Designation	New Fee	Percentage Change
I	$20,000	$17,500	-12.50%
II	$19,800	$17,500	-11.62%
III	$14,330	$11,300	-21.14%
IV/V	$6,800	$8,500	25.00%
RPTC	$20,000	$17,500	-12.50%

Level	Current Fee Replacement Facility	New Fee	Percentage Change
I	$8,700	$6,500	-25.29%
II	$8,100	$6,500	-19.75%
III	$3,080	$1,800	-41.56%
IV/V	$2,800	$1,800	-35.71%
RPTC	$8,700	$6,500	-25.29%

Level	Current Fee Existing Facility Designation	New Fee	Percentage Change
I ACS (3 Facilities)	$34,200	$24,300	-28.95%
I Non ACS (0 Facilities)	$34,200	$36,900	7.89%
II ACS (13 Facilities)	$34,200	$24,300	-28.95%
II Non ACS (0 Facilities)	$34,200	$36,900	7.89%

III ACS (1 Facility)	$16,600	$15,000	-9.64%
III Non ACS (20 Facilities)	$16,600	$21,000	26.51%
IV Non ACS (>15,000) (7 Facilities)	$11,100	$15,000	35.14%
IV/V Non ACS (5,000-14,999) (17 Facilities)	$8,000	$12,000	50.00%
IV/V Non ACS (<5000) (20 Facilities)	$6,800	$9,000	32.35%
RPTC ACS (1 Facilities)	$34,200	$24,300	-28.95%
RPTC Non ACS (0 Facilities)	$34,200	$36,900	7.89%

Other major amendments to the rule include the introduction of the necessary platform a facility needs to offer for an expanded scope of care beyond its designated level. This addition to the rules will only affect Level III and IVs. The expanded scope of services will be optional for facilities and creates no additional burden on facilities unless they choose to offer expanded services.

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.

Currently, there are a number of Level III and IV trauma centers offering an expanded scope of care. The absence of rules regarding this issue has made it difficult to standardize and regulate these services throughout the state. With the introduction of the proposed new Section 306, patients can be assured that similar care meets similar standards across the state. Facilities will also be prepared with the information they need to make a business decision to offer expanded scope services.

The revision of current Section 308 will standardize quality improvement processes throughout the entire system for level III-V facilities.

The fee restructure to an annual payment will ensure that facilities have accurate fees accounted for in their annual budget, instead of having to factor it in every 3 years. The increase in fees for the state designation process reflects the direct and indirect costs related to the state designation process. Finally, removing the Department from passing through ACS verification fees will simplify payments for both the department and the facility.

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

There is no anticipated direct cost increase to the agency for the enforcement of the proposed rule changes. The agency will modify current processes to accommodate the new rules. While some fees are being increased, others are being reduced. The benefit of moving to an annual fee structure, is that the triennial payment methodology created significant variances in the revenue. This variance will be eliminated by having all designated facilities submitting annual payments. This, coupled with the Department no longer collecting fees on behalf of the American College of Surgeons, makes the fee

changes neutral for TABOR purposes. The Department anticipates an average annual cost of $421,546 per year to perform the work required under the statute and this regulation. The Department anticipates that the revenue will be between $445,700 and $459,355. The additional revenue is anticipated to be slightly higher than expenses. This revenue, retained in fund balance, will allow the Department to anticipate future expenses such as travel increases and increased cost for trauma reviewers. The Department will continue to monitor revenue and expenses to ensure the fund does not exceed the 16.5% statutory limitation on fund balances.

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

The financial cost of the rule change is relatively minimal to high level facilities. This will be the first fee increase in the 18 years of the program for the smallest trauma centers and could result in facilities deciding not to continue with designation. However, facilities appear to be universally in favor of changing to an annual fee rather than a triennial fee as this is much easier to budget for.

The cost of meeting the new scope of care regulations should also be relatively minimal to most level III and IV facilities. Most of the items required are already in place in facilities and merely require additional policies to provide best practice guidelines for care.

Inaction will leave the state's trauma program without the means to hold facilities to the medical standards expected for the same patients when treated at a higher level of care. Without a fee increase, the state's trauma program would not be able to support itself based on the current fee revenue.

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

The proposed amendments related to expanded scope of care are only affecting facilities that choose to offer expanded services. By placing them in rule, the department can ensure standardization in the care patients receive. The changes to the quality improvement standards are largely organizational or directly related to the expanded scope issue and thus only affect facilities choosing to offer additional services. The fee change is unavoidable as program costs have increased.

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

The introduction of rules related to expanded scope of care is to provide structure for those facilities that choose to offer such services. The goal of the proposed language is to maintain consistent standards for care of patients across the trauma system. This is being put into rule instead of policy or guidance to ensure that all facilities are operating at the same level in providing patient care. The alternative would be to continue as things are without the ability to enforce uniform standards across the designation levels.

Alternate fee structures were proposed to the public with more of the system costs being assumed by smaller facilities, but this proposal was rejected by stakeholders as onerous for those facilities that are least able to afford participation.

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.

A budget analysis of previous years' revenues and expenditures along with projections for the next three years were used to determine potential fee alternatives. In addition, historical data on trauma designation site reviews and previous deficiency lists were used to discuss possibilities for development of the scope of care rules and additions to the quality improvement rules.

STAKEHOLDER COMMENTS
for Amendments to
6 CCR 1015-4 Statewide Emergency Medical and Trauma Care System, Chapter Three – Designation of Trauma Facilities

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:

Since January 7, 2016, an "expanded scope of care" sub-committee has been meeting roughly on a monthly basis. The sub-committee was formed from the Statewide Trauma Advisory Committee (STAC) and is made up of representatives from Level I, II, III, and IV trauma facilities. All meetings have been open to the public and published in advance through the EMTS on the GO weekly newsletter. Minutes are published on our public website for viewing and comment. Updates on its progress have been provided to the STAC committee and SEMTAC as a whole on Jan 13-14, 2016, April 13-14, 2016, July 13-14, 2016, and Oct 12-13, 2016.

The members of the sub-committee are:

Charles Mains –SEMTAC member, STAC chair
Wade Smith – Level I orthopedist
George Chaus – Level II orthopedist
Joel Schaefer – Level II Trauma Medical Director
Carole Ann Banville – Level II Trauma Program Manager
Jodie Taylor – Level III Trauma Medical Director
Nancy Frizell – Level III Trauma Program Manager
Doug Huene – Level IV orthopedist
Bruce Gross – Level IV Trauma Medical Director
Paula Golden – Level IV Trauma Program Manager
Patti Thompson – Rural Administrator

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).

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

____ Yes.

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

The proposed rule changes are to ensure that patient safety and adequate care are provided by standardizing expectations about what will be available in facilities choosing to expand their scope of care beyond the minimum requirements for the designation level. Stakeholder comment was accepted by the task force and collated by the department with feedback and edits based on that comment provided at each of the monthly meetings.

Staff and the task force worked together to revise the current quality improvement rules in Section 308 to include performance improvement processes which apply to expanded scope facilities. In addition, the group reorganized the entire section into a more logical format.

There has been little to no comment on the re-organization of the trauma quality improvement rules. Any relevant feedback on the scope of care rules above, resulted in concomitant changes in the related quality rules.

Stakeholders were provided with several scenarios to arrive at a balanced program budget and helped the department select a fee structure that provided the most benefit to the most under-resourced facilities.

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 proposed rule will ensure that the expanded scope of care model will provide consistent and equitable care for patients whether in a rural or urban environment.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
Health Facilities and Emergency Medical Services Division

STATEWIDE EMERGENCY MEDICAL AND TRAUMA CARE SYSTEM

6 CCR 1015-4

Adopted by the Board of Health on _____, 2016. Effective _____, 2016.

*****

CHAPTER THREE - DESIGNATION OF TRAUMA FACILITIES

Purpose and Authority for Rules

These rules address the designation process for trauma facilities, the enforcement and disciplinary procedures applicable to trauma facilities, and the designation criteria for Level I through V trauma facilities. The authority for the promulgation of these rules is set forth in Section 25-3.5-701 *et seq.,* C.R.S.

Index to Sections

300 - Definitions

301 - Designation Process

302 - Enforcement and Disciplinary Process

303 - Trauma Facility Designation Criteria - Level I

304 - Trauma Facility Designation Criteria - Level II

305 – Trauma Quality Improvement Programs for Designated Trauma Centers Levels III-V

306 – Expanded Scope of Care for Designated Trauma Centers, Level III-IV

307 - Trauma Facility Designation Criteria - Level III

308 - Trauma Facility Designation Criteria - Level IV

309 - Trauma Facility Designation Criteria - Level V

~~308 - Trauma Quality Improvement Programs for Designated Trauma Centers Levels III - V~~

310 - Burn Unit Referral Criteria

311 - Trauma Facility Designation Criteria - Regional Pediatric Trauma Centers

300. Definitions

1. Advanced Trauma Life Support (ATLS) or equivalent - The training provided in accordance with the American College of Surgeons curriculum for Advanced Trauma Life Support. An equivalent program is one which has been approved by the department. The burden shall be upon the applicant to prove that the program is equivalent to ATLS.

2. Consultation - Telephone or telemedicine, as specified in this chapter, to determine the necessity of transfer and the circumstances of transfer, including but not limited to additional diagnostic/therapeutic issues, availability of resources and weather conditions. Consultation

occurs between the attending trauma surgeon (or physician in a Level IV facility) of a referring facility and an attending trauma surgeon (who is a member of the attending staff) at a receiving facility. Trauma consultation shall include written documentation completed by the trauma surgeon at the Levels II and III facilities, or the attending physicians at the Level IV facility. Disagreements as to patient disposition will be documented at both facilities.

3. Core group - the core group of surgeons is comprised of those surgeons identified by the trauma medical director who provide coverage for at least 60 percent of the trauma call schedule.

4. Critical Injuries (Adult) - Critical injuries for adult patients are defined as any of the following:

A. Bilateral pulmonary contusions requiring nontraditional ventilation,

B. Multi-system trauma with pre-existing coagulopathy (hemophilia),

C. Pelvic fractures with unrelenting hemorrhage,

D. Aortic tears,

E. Liver injuries with vena cava injury or requiring emergency surgery with liver packing.

5. Critical Injuries (Pediatric) - Critical injuries for pediatric patients (age 0-14 years) are defined as any of the following:

A. Bilateral pulmonary contusions requiring nontraditional ventilation,

B. Multi-system trauma with pre-existing or life threatening coagulopathy (hemophilia),

C. Pelvic fractures with unrelenting hemorrhage,

D. Aortic tears,

E. Liver injuries with vena cava injury or requiring emergency surgery with liver packing,

F. Coma for longer than 6 hours or with focal neurologic deficit.

6. Department - The Colorado Department of Public Health and Environment, unless the context requires otherwise.

7. Divert - Redirection of the trauma patient to a different receiving facility. Redirection shall be in accordance with the prehospital trauma triage algorithms, as set forth in 6 CCR 1015-4, Chapter Two. Reasons for going on divert are limited to lack of critical equipment or staff; operating room, emergency department, or intensive care unit saturation; disaster or facility structural compromise.

8. Expanded Scope of Care – An expanded scope of care is any specialty or service line that provides treatment at a trauma center beyond the minimum requirements of the trauma center's designation level, either on a part-time or full-time basis.

9. Key Resource Facilities - Level I and II designated trauma centers which have an expanded responsibility in providing on-going consultation, education and technical support to referring facilities, individuals, or RETACS.

10. Met with reservations - Evidence of some degree of compliance with regulatory standards, but where further action is required for full compliance.

11. Morbidity and Mortality Review - A case presentation of all complications, deaths and cases of interest for educational purposes to improve overall care to the trauma patient. Case presentations shall include all aspects and contributing factors of trauma care from pre-hospital care to discharge or death. The multi-disciplinary group of health professionals shall meet on a regular basis, but not less than every two months. The documentation of the review shall include date, reason for review, problem identification, corrective action, resolution and education. Documented minutes shall be maintained on site and readily available.

12. Multidisciplinary Trauma Committee - This committee is responsible for the development, implementation and monitoring of the trauma program at each designated trauma center. Functions include but are not limited to: establishing policies and procedures; reviewing process issues, e.g., communications; promoting educational offerings; reviewing systems issues, e.g., response times and notification times; and reviewing and analyzing trauma registry data for program evaluation and utilization. Attendance required will be established by the committee. Membership will be established by the facility.

13. Outreach - The act of providing resources to other facilities in order to improve response to the injured patient. These resources shall include, but not be limited to, clinical consultation and public and professional education. Trauma centers shall be centers of excellence and shall share this expertise with other trauma centers and non-designated facilities. Timely and appropriate communication, consultation and feedback are imperative to patient outcome.

14. Plan of correction - Identifies how the facility plans to correct deficiencies or standards identified as met with reservations cited in the department's written notice to the facility, within an identified timeline. A plan of correction may also be required to meet a waiver request or fulfill a request from the department to address a temporary issue identified by the department or the facility.

15. Promptly Available - Unless otherwise specified, promptly available shall be a facility-defined timeframe based on current standards of clinically appropriate care.

16. Quality/Performance Improvement Program - A defined plan for the process to monitor and improve the performance of a trauma program is essential. This plan shall address the entire spectrum of services necessary to ensure optimal care to the trauma patient, from pre-hospital to rehabilitative care. This plan may be parallel to, and interactive with, the hospital-wide quality improvement program but shall not be replaced by the facility process.

17. Regional Emergency Medical and Trauma Advisory Council (RETAC) - The representative body appointed by the governing bodies of counties or cities and counties for the purpose of providing recommendations concerning regional area emergency medical and trauma service plans for such counties or cities and counties.

18. Scope of Care – A scope of care is a description of the facility's capabilities to manage the trauma patient. This description must include administrative support and specialty availability that ensures continuity of care for all admitted patients.

19. State Emergency Medical and Trauma Services Advisory Council (SEMTAC) - The council created in the department pursuant to Section 25-3.5-104, C.R.S.

20. Special Audit for Trauma Deaths - All trauma deaths shall be audited. A comprehensive review audit shall be initiated by the Trauma Medical Director in Levels I, II, III facilities and by the appropriate personnel designated by the Level IV and V facilities. The trauma nurse coordinator

shall participate in these audits. A written critique shall be used to document the process to include the assessment, corrective action and resolution.

21. Trauma Nurse Coordinator - The terms "trauma nurse coordinator," "trauma coordinator" and "trauma program manager" are used interchangeably in these regulations (6 CCR 1015). The trauma nurse coordinator (TNC) works to promote optimal care for the trauma patient through participation in clinical programs, administrative functions, and professional and public education. The TNC shall be actively involved in the state trauma system. The essential responsibilities of the TNC include maintenance of the trauma registry, continuous quality improvement in trauma care, and educational activities to include injury prevention.

22. Trauma Nurse Core Course (TNCC) or equivalent - the training provided in accordance with the Emergency Nurses Association curriculum. An equivalent program is one that has been approved by the department. The burden shall be upon the applicant to prove that the program is equivalent to the TNCC.

23. Trauma Service - The Trauma Service is an organized, identifiable program which includes: a Trauma Medical Director, a Trauma Nurse Coordinator, a Multi-disciplinary Trauma Committee, Quality Improvement Program, Injury Prevention and Data Collection/Trauma Registry.

24. Trauma Medical Director - The Trauma Medical Director is a board certified general surgeon who is responsible for: service leadership, overseeing all aspects of trauma care, and administrative authority for the hospital trauma program including: trauma multidisciplinary committee, trauma quality improvement program, physician appointment to and removal from trauma service, policy and procedure enforcement, peer review, trauma research program, and key resource facility functions, if applicable; participates in the on-call schedule; practices at the facility for which he/she is medical director on a full time basis; and participates in all facility trauma-related committees. In Level I facilities, the Trauma Medical Director shall participate in an organized trauma research program with regular meetings with documented evidence of productivity. In Level IV, the Trauma Medical Director may be a physician so designated by the hospital who takes responsibility for overseeing the program.

25. Trauma Team - A facility-defined team of clinicians and ancillary staff, including those required by these rules.

26. Trauma Team Activation - A facility-defined method (protocol) for notification of the trauma team of the impending arrival of a trauma patient based on the prehospital trauma triage algorithms as set forth in 6 CCR 1015-4, Chapter Two.

27. Verifiable, External Continuing Medical Education (CME) - A facility-defined, trauma-related continuing medical education program outside the facility, or a program given within the facility by visiting professors or invited speakers, or teaching an ATLS course.

28. Waiver - A waiver is an exception to the trauma rules approved by the department. The request for a waiver shall demonstrate that the alternative meets the intent of the rule. Waivers are generally granted for a limited term and shall be granted for a period no longer than the designation cycle. Waivers cannot be granted for any statutory requirement under state or federal law, requirements under state licensing, federal certification or local safety, fire, electrical, building, zoning or similar codes.

301. Designation Process

*****

3. New Facility

*****

B. Fee Structure

Facilities seeking simultaneous verification or consultation by the American College of Surgeons (ACS) shall pay any money associated with the verification directly to the ACS and the state designation fees identified below will be paid to the Department. If the ACS is unable to supply all required team members for the designation review, the facility shall pay the Department an additional $3,000 per reviewer obtained by the state.

The facility shall submit the non-refundable state designation fee with its application. The new facility designation fee is:

Level I/RPTC:	~~$20,000~~ $17,500
Level II:	~~$19,800~~ $17,500
Level III:	~~$14,330~~ $11,300
Level IV/V:	~~$ 6,800~~ $8,500

*****

4. Replacement Facility

*****

B. Fee Structure

The facility shall submit the non-refundable designation fee with its application. The replacement facility designation fee is:

Level I/RPTC:	~~$8,700~~ $6,500
Level II:	~~$8,100~~ $6,500
Level III:	~~$3,080~~ $1,800
Level IV/V:	~~$2,800~~ $1,800

*****

5. Renewal of Existing Facility

*****

B. Fee Structure

(1) Facilities seeking state designation only:

a. The facility shall submit the required annual designation fee in the manner specified by the department. The renewal of existing facility designation fee is:

Level I/RPTC:	~~$34,200~~ $12,300
Level II:	~~$34,200~~ $12,300
Level III:	~~$16,600~~ $7,000
Level IV/V: Emergency Department Visits > 15,000 per year	~~$11,100~~ $5,000
Level IV/V: Emergency Department Visits between 5,000 - 15,000 per year	~~$8,000~~ $4,000
~~Level IV/V: Emergency Department Visits between 5,000 - 9,999 per year~~	~~$7,200~~
Level IV/V: Emergency Department Visits < 5,000 per year	~~$6,800~~ $3,000

b. Fees submitted with the renewal application may be forfeited if the application is incomplete and the facility does not respond in a timely manner.

(2) Facilities seeking state designation and simultaneous ACS verification:

a. Facilities seeking verification by the American College of Surgeons (ACS) shall pay any money associated with the verification directly to the ACS and the state fees identified below.

b. Facilities requesting simultaneous verification by the ~~American College of Surgeons (~~ACS~~)~~ at the time of the Colorado state trauma designation survey shall pay ~~one hundred percent of any increase in the ACS verification fees over the calendar year 2010 fees~~ the following annual fee for the state designation process only:

LEVEL I/RPTC:	$8,100
LEVEL II:	$8,100
LEVEL III:	$5,000
LEVEL IV/V:	N/A

c. If the ACS is unable to supply all required team members for the designation review, the facility shall pay the Department an additional $3,000 per reviewer obtained by the state.

(3) The new fees shall be in effect on July 1, 2017, and the first annual payment shall be due on July 1 of the state fiscal year in which the current state designation expires. ~~subsequent to the effective date of these rules~~.

*****

7. Waivers

*****

D. The notice shall describe where to send comments within that 30-day period. Comments should be directed to:

EMTS Branch ~~Section~~
ATTN: ~~Section~~ Branch Chief
CDPHE, HFEMSD-A2
4300 Cherry Creek Drive South
Denver, CO 80246

*****

305. TRAUMA QUALITY IMPROVEMENT PROGRAMS FOR DESIGNATED TRAUMA CENTERS LEVEL III-V

1. All designated Level III-V trauma centers shall have an organized, trauma quality improvement program that demonstrates a plan, process and accountability for continuous quality improvement in the delivery of trauma care.

A. Each facility shall define its Scope of Care (SOC) based on the resources that are available to the facility.

B. Each facility shall have a formal transfer policy when specialty resources are not available.

C. Administration must support the trauma program and the trauma medical director in providing staff education commensurate with the level of care and based on patient population served.

2. The trauma quality plan shall address the entire spectrum of services necessary to ensure optimal care to the trauma patient, from pre-hospital to rehabilitative care. The plan shall ensure the continuity of care for all admitted patients. If the facility does not have the resources available to manage medical co-morbidities, then the patient shall be transferred.

A. In Level III facilities, this plan may be parallel to, and interactive with, the hospital-wide quality improvement program as defined in § 25-3-109, C.R.S. but may not be replaced by the facility process.

B. In Level IV- V facilities, this plan may be part of the hospital-wide quality improvement program, but must have specific defined trauma-related indicators, components and is overseen by the Trauma Medical Director (TMD). Trauma related issues must be documented separately, and the TMD has purview over any trauma issues.

C. This plan shall include identification of:

(1) The trauma center's organizational structure responsible for the administration of the plan, to include a description of who has the authority to change policies, procedures or protocols related to trauma care.

(2) The responsibility of the trauma medical director, in coordination with the trauma nurse coordinator, for:

a. The identification of and responsibility for the oversight of the plan.

b. The facility-defined standards of medical care for the trauma patient.

c. The data sources to support an effective monitoring system, to include but not be limited to retrospective and concurrent medical record review, including;

i. Primary level of review at least weekly.

ii. Secondary level of review TMD in collaboration with TNC at least twice a month.

iii. Tertiary level of review at least every other month at Level IIIs and at least quarterly at Level IV and Vs.

d. Identification of systems issues to be addressed in multidisciplinary committee.

e. Identification of peer issues to be addressed in trauma peer review.

f. Review of all inpatients, transfers in or out and trauma deaths.

g. Provide appropriate physician, mid level, ancillary and nursing staff education commensurate with the scope of care.

h. Provide a mechanism for external review of specialty specific trauma cases that are not just limited to deaths.

3. The trauma quality program shall include a multidisciplinary committee responsible for trauma program performance.

A. Membership will be established by the facility and shall include representation from specialties that care for trauma patients.

B. The committee will establish attendance requirements.

C. The committee must meet on a regular basis, but not less than every two months for Level III facilities and quarterly for Level IV-V facilities, to assure timely review and corrective action.

D. The committee must review all services essential to the care and management of the trauma patient.

E. Performance management functions include but are not limited to:

(1) A process for issue identification, case summarization, discussion, action plan, resolution or outcome for loop closure.

(2) Initiation of corrective action as needed.

(3) A process for pre-hospital trauma care review.

(4) A process for the identification and review of facility-defined audit filters, patient sentinel events, complications and trends.

(5) Facility specific nursing audits for nursing documentation.

(6) Establishing and enforcing policies and procedures.

(7) Reviewing systems issues, e.g., communications, notification times, and response times.

(8) Promoting educational offerings.

(9) Reviewing and analyzing trauma registry data for program evaluation and utilization.

(10) Provision for case presentations of interest for educational purposes to improve overall care to the trauma patient to including all aspects and contributing factors of trauma care from pre-hospital to discharge or death.

4. The trauma quality program shall include a method and process for conducting multidisciplinary trauma peer review comparable to the peer review defined in § 12-36.5-104 *et.seq*, C.R.S..

A. The facility shall define standards of care for the trauma patient.

B. The performance improvement process shall monitor compliance with, or adherence to, facility-defined standards.

C. Documentation of findings and recommendations must be maintained with an identified reporting process for loop closure.

D. Review any event that deviates from an anticipated outcome.

E. Compliance with all facility trauma care policies, protocols and practice guidelines.

F. Conducting a review of all trauma deaths with:

(1) A report summary of the trauma peer review findings to the trauma multidisciplinary committee.

(2) All trauma centers shall have a policy that includes the process and criteria for utilization of a resource outside the facility for specialty specific peer review. Qualifications of outside peer reviewer must be identified by the facility as defined in §12-36.5-104, C.R.S.

(3) The deaths shall be identified as unanticipated mortality with opportunity for improvement (preventable), anticipated mortality without opportunity for improvement (potentially preventable), or mortality without opportunity for improvement (non-preventable).

5. The trauma quality program shall demonstrate accountability by:

A. The development and implementation of on-going reporting and trending of facility-specific audit filters.

B. Documenting and maintaining minutes available for trauma multidisciplinary committee, trauma peer review committee or any other committees used in this process. Written documentation of the process to include date, issue identification, case summarization, assessment, any corrective action, recommendations, policy revision, education and resolution.

C. Maintaining a system (such as a log) for tracking patient disposition and deaths.

D. Evidence of provider response times when the trauma team is activated.

E. Evidence of provider response times when consultations are required.

F. Evidence that nursing care issues are reviewed as part of the trauma program.

306. EXPANDED SCOPE OF CARE FOR DESIGNATED TRAUMA CENTERS, LEVEL III – IV

1. All designated Level III-IV trauma centers shall define their Scope of Care (SOC) based on the resources that are available at the facility. Physicians shall be allowed to transfer patients when in the best interest of the patient and shall not be encumbered by organizational restrictions to keep patients within a system. Facilities that provide an expanded scope of care shall have:

A. A written policy for the management of each expanded scope service line being offered, for example, orthopedic surgery, plastic surgery or neurosurgery.

B. A written policy and plan for patient management when each service is not available, to include:

(1) A defined service that manages inpatient care for continuity.

(2) A written plan to ensure continuity of care for all admitted patients when the service is not available.

(3) Regular communication with transport providers and referring hospitals on availability of the expanded scope service(s).

(4) Hospital defined continuity of care plan that includes time of availability and proof of communication between services.

C. Formal transfer guidelines for times when a facility does not have specialty coverage and for unusual conditions such as weather, disaster, etc.

D. Management guidelines based on the defined scope of care and nationally recognized best practice standards.

E. For Level IV facilities, if there is an emergency physician serving as the trauma medical director, there shall be a physician with surgical expertise to assist with performance improvement.

2. Mandatory Transfers and Consideration for Transfer

A. All Level III-IV Trauma Centers shall transfer patients with the following injuries, in addition to patients described in 6 CCR 1015-4, Chapter Two:

(1) Hemodynamically unstable pelvic fracture.

(2) Pelvic fracture requiring operative fixation.

(3) Fracture or dislocation with vascular disruption that cannot be revascularized by reduction

B. All Level III and IV trauma centers shall consult the trauma surgeon at a Level I or II key resource facility regarding any multiply injured patient requiring massive transfusion protocol. The consult for consideration of transfer shall occur within 2 hours of the initiation of the massive transfusion protocol.

C. All Level IV Trauma Centers shall transfer trauma patients under the following conditions, in addition to patients described in 6 CCR 1015-4, Chapter Two:

(1) Bilateral femur fractures.

(2) Femoral shaft fracture with any of the following:

a. Head injury with any evidence of blood on the brain, depressed skull fracture or skull fracture with sinus involvement.

b. Chest injury – Multiple rib fractures > 4 unilaterally or > 2 bilaterally, or hemothorax.

c. Abdomen – Hollow organ or solid visceral injury, intra or retroperitoneal bleeding.

D. All Level III-IV trauma centers shall transfer orthopedic patients if the facility does not have the resources and clinical expertise to manage medical co-morbidities such as:

(1) Severe COPD – with home O2 requirement > 4L.

(2) Pulmonary hypertension.

(3) Critical aortic stenosis.

(4) CAD and/or recent MI within 6 months.

(5) Renal disease requiring dialysis.

(6) End stage liver disease – with a MELD score >19.

(7) Unmanageable coagulopathy.

(8) BMI > 40.

(9) Pregnancy > 20 weeks.

E. All Level IV trauma centers with part-time specialty coverage:

(1) Level IV facilities with part time orthopedic coverage shall not operate on femoral fractures unless there is general surgery availability.

(2) Cases shall be reviewed for projected length of stay. If the length of stay is greater than the service coverage and general surgery availability, then the patient shall be transferred.

3. Expanded Scope Required Resources

A. An Emergency Department with:

(1) A defined call response time for each specialty consultation.

(2) A Massive Transfusion Protocol. If the facility initiates the MTP then immediate consultation with a higher level of care will be required to expedite transfer or discuss further stabilization.

B. An Operating Room with:

(1) Defined operating room availability, within 30 minutes if the facility is providing emergent surgery as part of an expanded scope of care.

(2) Anesthesia service and appropriate operating room staff shall match fully functional operating room availability.

(3) Facilities shall match specialty provider availability with operating room availability.

(4) Intra-operative equipment and radiology capability commensurate with the scope of care provided.

C. Inpatient services with:

(1) Medical consultation with a physician appropriately credentialed by the facility to treat medical co-morbidities.

D. Education, including:

(1) Administrative support for the trauma program and the trauma medical director in providing appropriate staff education commensurate with the scope of care and based on patient population served.

(2) It is the physician specialists' responsibility to provide education to the team looking after their patients, including:

a. Post operative care.

b. Complication recognition and care.

c. Recognition and care of hemodynamic instability.

4. Performance Improvement and Patient Safety

A. Attendance at multidisciplinary committee shall include representation from all specialties and service lines involved in the care of trauma patients to include 50% attendance by emergency medicine, orthopedics, general surgery, anesthesia and medicine.

B. Level III - IV facilities shall have a mechanism for outside review of specialty specific trauma cases.

C. Facility defined specialty care filters based on the written scope of care and nationally recognized best practice guidelines.

~~305~~307. Trauma Facility Designation Criteria - Level III

*****

~~306~~308. Trauma Facility Designation Criteria - Level IV

*****

~~307~~309. Trauma Facility Designation Criteria - Level V

*****

~~**308. Trauma Quality Improvement Programs for Designated Trauma Centers Levels III-V**~~
(COMMENT: SUBSTANCE REVISED AND MOVED TO 305. This comment is informational to assist the reader and will not be part of the published rule if adopted by the Board of Health.)

~~1. All designated Level III-V trauma centers shall have an organized, trauma quality improvement program that demonstrates a plan, process and accountability for continuous quality improvement in the delivery of trauma care. The program shall include, but not be limited to:~~

~~A. A plan that shall address the entire spectrum of services necessary to ensure optimal care to the trauma patient, from prehospital to rehabilitative care. This plan may be parallel to, and interactive with, the hospital-wide quality improvement program as defined in C.R.S. § 25-3-109 but may not be replaced by the facility process. In Level IV-V clinics or facilities, this plan may be part of the hospital-wide quality improvement program, but must have specific defined trauma-related indicators and components. This plan shall include identification of:~~

~~(1) The trauma center's organizational structure responsible for the administration of the plan, to include a description of who has the authority to change policies, procedures or protocols related to trauma care;~~

~~(2) The responsibility of the trauma medical director, or in Level IV-V centers the physician responsible for coordination of the service in coordination with the trauma nurse coordinator for:~~

~~a. The identification of and responsibility for the oversight of the plan;~~

~~b. Initiation of corrective action as needed;~~

~~c. Conducting a special audit of all trauma deaths with:~~

i. Written documentation of the process to include the assessment, any corrective action and resolution; and

ii. The deaths shall be identified as preventable, potentially preventable, or non-preventable, and

iii. Reporting a summary of the audit findings to the trauma multidisciplinary committee;

d. The facility-defined standards of medical care for the trauma patient;

e. A process for corrective action, to include problem identification, action plan, resolution or outcome for loop closure;

f. The method for documentation and maintenance of minutes on site and readily available of special death audits, trauma multidisciplinary committee, or any other committees used in this process;

g. The process for prehospital trauma care review;

h. The data sources to support an effective monitoring system, to include but not be limited to retrospective and concurrent medical record review;

I. A process for the identification and review of facility-defined patient sentinel events, complications and trends;

j. The development and evidence of on-going reporting and trending of facility specific audit filters to facilitate the quality improvement program to identify at a minimum, but not limited to:

i. Program structure (systems issues) with: all trauma transfers in or out, except those with isolated extremity fractures;

ii. Program process (medical issues) with: provider response times when the trauma team is activated; and

iii. Program outcomes with compliance with: initial resuscitation and stabilization as defined in facility policy;

k. Facility specific nursing audits with:

i. Evidence that nursing performance improvement issues are reviewed as part of the trauma program;

ii. Clinical filters for nursing documentation; and

iii. Ongoing monitoring and/or trending.

l. Methods and process for conducting multidisciplinary peer review to include;

i. A process of peer review as defined in C.R.S. § 12-36.5-104 et.seq. This process shall monitor compliance with, or adherence to, facility-defined standards of medical care for the trauma patient. All trauma centers shall have a policy that

~~includes the process and criteria for utilization of a resource outside the facility for peer review. Documentation of findings and recommendations must be maintained with an identified reporting process for loop closure. Qualifications of outside peer reviewer must be identified by the facility as defined in C.R.S. § 12-36.5-104;~~

~~m. Provision for case presentations of interest for educational purposes to improve overall care to the trauma patient to include:~~

~~i. All aspects and contributing factors of trauma care from prehospital to discharge or death; and~~

~~ii. A review of any event that deviates from an anticipated outcome; and~~

~~iii. Documentation of the review shall include date, reason for review, problem identification, recommendations, resolution and education.~~

~~B. The trauma multidisciplinary committee is responsible for trauma program performance at each trauma center. Membership will be established by the facility and the committee will establish attendance requirements. This includes, but is not limited to:~~

~~(1) The review of all services essential to the care and management of the trauma patient;~~

~~(2) Meeting on a regular basis, but not less than every two months for Level III facilities, and quarterly for Level IV-V clinics or facilities, to assure timely review and corrective action.~~

~~(3) Performance management functions include but are not limited to:~~

~~a. Establishing and enforcing policies and procedures;~~

~~b. Reviewing process issues, e.g., communications; reviewing systems issues, e.g., response times and notification times; and promoting educational offerings; and~~

~~c. Reviewing and analyzing trauma registry data for program evaluation and utilization, with defined intervals for data collection and analysis;~~

~~i. Level III facilities shall maintain a trauma registry as required by regulation in Chapter 1;~~

~~ii. In Level IV-V clinics or facilities shall fulfill the reporting requirement for the submission of data as required by regulation in Chapter 1;~~

~~iii. In Level IV-V clinics or facilities with non-participation in the Colorado Hospital Association discharge data set, the trauma registry as defined in Chapter 1 of these rules may, at a minimum, be in the form of a hard-copy abstract approved by the department;~~

~~iv. Maintaining a system (such as a log) for tracking patient disposition, and deaths.~~

~~309~~310. Burn Unit Referral Criteria

*****

~~310~~311. Facility Designation Criteria - Regional Pediatric Trauma Center

*****

583