

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STATEWIDE EMERGENCY MEDICAL AND TRAUMA CARE SYSTEM

6 CCR 1015-4

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

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

CHAPTER TWO - STATE EMERGENCY MEDICAL AND TRAUMA CARE SYSTEM STANDARDS

201. In order to ensure effective system development, all regions must comply with the following minimum standards.

202. Minimum Standards for Regional Emergency Medical and Trauma Care Resources

A. Communication

The region must provide communication and dispatch systems that insure coordinated coverage, specifically:

1. Utilization of the universal 9-1-1 or a local equivalent that is well publicized and accessible for citizens and visitors to the region.
2. Adequate dispatch services.

3. Paging and alerting system for notification of emergency medical/trauma personnel who routinely respond to emergency medical/trauma incidents.
4. Two-way communications between and among ambulances.
5. Two-way communications between ambulances and non-designated facilities and designated trauma facilities.
6. Two-way communications between ambulances and trauma facilities outside the Regional Emergency Medical and Trauma Advisory Council (RETAC) area.
7. A plan for utilization of an alternative communications system to serve as a back-up to the primary system.
8. A disaster communications plan.
9. A system for notification and alerting trauma teams, fixed and rotary wing emergency services, and trauma centers.
10. A system that is compatible with systems in adjacent regions.

B. Prehospital

First response units and ambulance services must meet the following criteria:

1. Minimum acceptable level of service:
 - a. Basic life support (BLS) service - Must have at least 1 person who is at first responder or higher level of training
 - b. Advanced life support (ALS) service - Must have at least 1 person who is at EMT-I or EMT-P level of training
2. Emergency response times for ground transport agencies:

		<u>Time Limit</u>
a.	High density areas (metropolitan)	
	(1) Provider service area encompasses 100,000 people or more	11 minutes, 90% of the time
b.	Mid-density areas (urban or mixed)	
	(1) Provider service area encompasses 12,000 to 100,000 people	20 minutes, 90% of the time
c.	Low density areas (rural, frontier)	
	(1) Provider service area encompasses <12,000 people	45 minutes, 90% of the time
3.	Optimal scene time limits	15 minutes, 90% of the time

Scene time = time of arrival of transport agency at the scene to departure of the scene

4. Agencies shall conduct quality improvement monitoring for all response and scene times that exceed these parameters and make a plan of correction where necessary
5. Triage and transport of trauma patients must be in accordance with the prehospital transport destination algorithms (exhibits A and B to these regulations)

C. Interfacility Transfer and Consultation - Adult - Age 15 and older

1. Levels II and III trauma centers caring for the critically injured adult trauma patients listed below must comply with the actions required:
 - a. Bilateral pulmonary contusions requiring nontraditional ventilation
 - b. Patient with multisystem trauma with pre-existing coagulopathy (hemophilia)
 - c. Pelvic fractures with unrelenting hemorrhage
 - d. Aortic tears
 - e. Liver injuries requiring emergency surgery and requirement for liver packing or vena cava injury

Actions Required:

- (1) Mandatory, timely (but within 6 hours after recognition of condition) consultation is required with a Level I trauma surgeon (who is a member of the attending staff) for consideration of transfer of the patient. The attending trauma surgeon of the referring facility should initiate the consultation.
 - (2) Consultation with the attending trauma surgeon is required in the determination of the necessity of transfer and the circumstances of transfer including, but not limited to, additional diagnostic/therapeutic issues, availability of resources, weather conditions.
2. Level III trauma centers caring for the high risk adult trauma patients with the following traumatic injuries must comply with the actions required:
 - a. Significant head injuries (intracranial bleeding or Glasgow Coma Scale (GCS) \leq 10) or spinal cord injury with neurologic deficit where neurosurgical consultation and evaluation are not promptly available
 - b. Significant multisystem trauma as defined by:
 - (1) Head injury (intracranial bleeding or GCS \leq 10) or spinal cord injury with neurologic deficit complicated by either significant chest and/or abdominal injuries as defined by:
 - (a) Chest Injury (as part of multisystem injuries):
 - i) Multiple rib fractures > 4 unilaterally or > 2 bilaterally
 - ii) Hemothorax

- (b) Abdominal Injury (as part of multisystem trauma):
 - i) Significant intra or retroperitoneal bleeding
 - ii) Hollow organ or solid visceral injury
- c. Bilateral femur fracture or posterior pelvic fracture complicated by significant chest and/or abdominal injuries as defined above
- d. Trauma patient on mechanical ventilation for > 4 days
- e. Life threatening complications, such as acute renal failure (creatinine > 2.5 mg/dl) or coagulopathy (twice the normal value for individual facility)

Actions Required:

- (1) Mandatory timely (but within 12 hours after recognition of condition) consultation is required with a Level I or key resource facility trauma surgeon (who is a member of the attending staff) for consideration of transfer of the patient. The primary attending physician at the Level III facility should initiate the consultation.
 - (2) Consultation with the trauma surgeon is required in the determination of the necessity of transfer and the circumstances of transfer including, but not limited to, additional diagnostic/therapeutic issues, availability of resources, weather conditions.
 - (3) Consultation and/or transfer decisions in patients with traumatic injuries less severe than those listed above shall be determined by the RETAC based on resources, facilities, and personnel available in the region and shall be made in accordance with RETAC protocols.
- 3. Level IV trauma centers caring for patients with the following traumatic injuries must comply with the actions required:
 - a. Critical injuries listed in 6 CCR 1015-4, Chapter Two, Section 202, C.1
 - b. Significant head injuries (intracranial bleeding or GCS \leq 10) or spinal cord injury with neurologic deficit
 - c. Significant multisystem trauma as defined by:
 - (1) Head injury (intracranial bleeding or GCS \leq 10) or spinal cord injury with neurologic deficit complicated by either significant chest and/or abdominal injuries as defined by:
 - (a) Chest Injuries (as part of multisystem trauma):
 - i) Multiple rib fractures > 4 unilaterally or > 2 bilaterally
 - ii) Hemothorax
 - (b) Abdominal Injuries (as part of multisystem trauma):
 - i) Significant intra or retroperitoneal bleeding

- ii) Hollow organ or solid visceral injury
- d. Bilateral femur fracture or posterior pelvic fracture complicated by either significant chest or abdominal injuries as defined above
- e. Trauma patient on mechanical ventilation
- f. Life threatening complications, such as acute renal failure (creatinine > 2.5 mg/dl) or coagulopathy (twice the normal value for individual facility)

Actions required:

- (1) Mandatory timely (but within 6 hours after recognition of condition) transfer is required for patients with the above defined injuries.
- (2) The primary attending physician at the level IV trauma center shall consult with the attending trauma surgeon at the key resource facility prior to transfer to determine the most appropriate destination for such patients and to discuss the circumstances of transfer such as additional diagnostic/therapeutic issues, availability of resources, weather conditions, etc.
- (3) Consultation and/or transfer decisions in patients with traumatic injuries less severe than those listed above shall be determined by the RETAC based on resources, facilities, and personnel available in the region and shall be in accordance with RETAC protocols.

4. Nondesignated Facilities

Within two hours of recognition that a patient has experienced a significant injury or mechanism as defined in 6 CCR 1015-4, Chapter Two, Sections 202C, 202D or the prehospital algorithms (exhibits A and B), the facility shall resuscitate, stabilize and/or initiate transfer of the patient, after consultation with a trauma surgeon or emergency physician at the closest designated trauma center. Transfer shall be to the closest appropriate trauma facility as defined by RETAC protocols and as determined in consultation with the trauma surgeon or emergency physician. Nondesignated facilities must transfer all trauma patients except those defined in 6 CCR 1015-4, Chapter Two, Section 202.C.5.

5. Noncomplicated Trauma Injuries

Interfacility transfer of single system injuries that are not threatening to life or limb and whose care is not complicated by co-morbid conditions shall be made in accordance with RETAC protocols. RETACs must monitor transport within their regions and report systematic exceptions to the protocols or regulations to the department.

6. RETACs must monitor treatment and transfer of patients with the above conditions.

Documentation and quality improvement monitoring must be completed on such patients. Systematic exceptions of the standards must be reported to the department. For example, if significantly injured patients with multisystem trauma injuries are consistently transported to undesignated or level IV facilities, such transport deviation from the standards would constitute a systematic exception that must be reported.

7. RETACs are responsible for ensuring that interfacility transfer agreements exist in all facilities transferring patients within and outside the area.

D. Interfacility Transfer and Consultation ^{1,2} - Pediatric - Age 0-14

1. For the purpose of 6 CCR 1015-4, Chapter Two, Section 202.D. "critical injuries" are defined as any of the following:
 - a. Bilateral pulmonary contusions requiring non-traditional ventilation
 - b. Multisystem trauma with preexisting or life threatening coagulopathy
 - 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
2. For the purpose of 6 CCR 1015-4, Chapter Two, Section 202.D, "high risk injuries" are defined as any of the following:
 - a. Penetrating injuries to head, neck, torso, or proximal extremities
 - b. Injuries resulting in the need for mechanical ventilation of > 16 hours
 - c. Persistent in-hospital evidence of physiologic compromise including: tachycardia relative to age plus signs of poor perfusion (capillary refill test > 2 seconds, cool extremities, decreased pulses, altered mental status, or respiratory distress), hypotension
 - d. Hemodynamically stable children with documented visceral injury admitted for "observational" management and requiring blood transfusion or fluids > 40cc/kg
 - e. Injury Severity Score ≥ 9 including, but not limited to:
 - (1) Multisystem blunt injuries (> 2 systems)
 - (2) Pelvic or long bone fractures in conjunction with multisystem injuries
 - (3) Altered mental status (GCS <10) with significant trauma
3. For the purpose of 6 CCR 1015-4, Chapter Two, Section 202.D. "high risk mechanisms" are defined as any of the following high energy transfer mechanisms:
 - a. Falls > 20 feet
 - b. Auto crashes with significant vehicle body damage
 - c. Significant motorcycle crashes
 - d. All terrain vehicle crashes

4. Level II trauma centers with pediatric commitment designation (LII/PC) that care for pediatric patients (age 0-14 years) with critical injuries must comply with the actions required:

Actions required:

- a. Mandatory timely (but within 6 hours after recognition of condition) consultation ^{1,2} is required with an attending trauma surgeon from a Regional Pediatric Trauma Center (RPTC) or a Level I trauma center with Pediatric Commitment (LI/PC).

5. Level I and II trauma centers without pediatric commitment and Level III centers caring for pediatric trauma patients (age 0-14 years) with critical injuries or high risk injuries must comply with the actions required:

Actions required:

- a. Children 0 - 5 years of age with critical injuries shall be transferred with prior consultation ^{1,2} to a RPTC. If such a center is not available, then transfer ^{1,2} shall be to a LI/PC. If such a center is not available, then transfer shall be to a LII/PC. If no center with pediatric commitment is available, transfer ^{1,2} shall be to the highest level trauma center available.
- b. Children 6 - 14 years of age with critical injuries. Mandatory timely (but within 6 hours after recognition of condition) consultation ^{1,2} is required with an attending trauma surgeon at a RPTC or a LI/PC for consideration of transfer of the patient.
- c. Children 0 - 14 years of age with high risk injuries. Mandatory timely (but within 6 hours of recognition of condition) consultation ^{1,2} is required with an attending trauma surgeon at a RPTC or LI/PC for consideration of transfer of the patient.

6. Level IV trauma centers and nondesignated facilities caring for pediatric patients (age 0-14 years) with critical injuries or high risk injuries must comply with the actions required:

Actions required:

- a. Children 0 - 5 years of age with critical injuries shall be transferred ^{1,2} to a RPTC. If such a center is not available, then transfer ^{1,2} shall be to a LI/PC. If such a center is not available, then transfer shall be to a LII/PC. If no center with pediatric commitment is available, transfer ^{1,2} shall be to the highest level trauma center available.
- b. Children 6 - 14 years of age with critical injuries shall be transferred ^{1,2} to a RPTC or a LI/PC. If such a center is not available, then to a LII/PC. If no center with pediatric commitment is available, transfer ^{1,2} to the highest level trauma center available.
- c. Children 0 - 5 years of age with high risk injuries shall be transferred ^{1,2} to either a RPTC or a LI/PC. If such a center is not available, then to a LII/PC. If no center with pediatric commitment is available transfer ^{1,2} to the highest level trauma center available.
- d. Children 6 - 14 years of age with high risk injuries shall be transferred with prior consultation ^{1,2} to either a RPTC, LI/PC or LII/PC. If no center with pediatric commitment is available then transfer to the highest level trauma center available.

7. Level IV trauma centers and nondesignated facilities caring for pediatric patients (age 0-14 years) who are injured by high risk mechanisms shall comply with the actions required:

Actions required:

- a. Mandatory timely (but within 6 hours) consultation ^{1,2} is required with an attending trauma surgeon from a RPTC , LI/PC or LII/PC for consideration of transfer.
8. Consultation and/or transfer decisions in pediatric patients with traumatic injuries less severe than those listed above shall be determined by the RETAC based on resources, facilities, and personnel available in the region and shall be in accordance with the RETAC protocols.
9. Nondesignated Facilities

Nondesignated facilities that receive and are accountable for pediatric trauma patients (age 0-14 years) with any traumatic conditions other than non-complicated, non-life threatening, single system injuries must transfer those patients to the appropriate, designated trauma center. Transfer agreements are required.
10. RETACs must monitor transport of pediatric trauma patients within their regions and report systematic exceptions to the protocols or regulations to the department.
11. Where superscript ¹ and/or ² appear, the following shall apply:

¹ Consultation is required in the determination of the necessity of transfer and the circumstances of transfer including, but not limited to, additional diagnostic/therapeutic issues, availability of resources, weather conditions.

² Consultation must be initiated by the attending trauma surgeon of the referring Level I, II, or III trauma center or attending physician of the Level IV or nondesignated facility.

E. Divert

If coordinated within the RETAC and pursuant to protocol, facilities may go on divert status for the following reasons:

1. Lack of critical equipment
2. Operating room saturation
3. Emergency department saturation
4. Intensive care unit saturation
5. Facility structural compromise
6. Disaster
7. Lack of critical staff

Redirection of trauma patient transport shall be in accordance with the prehospital trauma triage algorithms (exhibits A and B) and these regulations when a trauma center is on divert status.

Trauma facilities must keep a record of times and reasons for going on divert status. This information must be made available for RETAC and/or department audit.

RETACs must audit facility diversion of trauma patients in their areas. Upon consideration of the reason for divert status, the authorizing personnel and other pertinent facts, RETACs may institute corrective action if the diversion was not reasonable or necessary.

F. Bypass

At times the prehospital trauma triage algorithms (exhibits A and B) may require that prehospital providers bypass the nearest facility to transport the patient to a higher level trauma center. The necessity for such bypass must be initially determined by the physiologic criteria in the algorithms. However, certain situations may require different transport such as excessive expected transport time to the nearest trauma center, or lengthy extrication time requiring air evacuation, or other emergency conditions (traumatic cardiac arrest or transfer to a subspecialty center).

RETACs must develop protocols for patient destination within their areas that address bypass for situations not addressed in the algorithms. Bypass situations must be monitored, and the RETAC must require justification for deviation.

203. Exemptions or Variances

The State Emergency Medical and Trauma Services Advisory Council (SEMTAC) may grant exemptions from one or more standards of these regulations if the applicant submits information that demonstrates that such exemption is justified.

SEMTAC must find, based upon the information submitted and other pertinent factors, that particular standards are inappropriate because of special circumstances, which would render such compliance unreasonable, burdensome or impractical. Exemptions or variances may be limited in time, or may be conditioned, as SEMTAC considers necessary to protect the public welfare.

EXHIBIT A – Prehospital Trauma Triage Algorithm – Adult Patients (Ages 15 and older)

EXHIBIT A

Prehospital Trauma Triage Algorithm Adult Patients (Ages 15 and older)

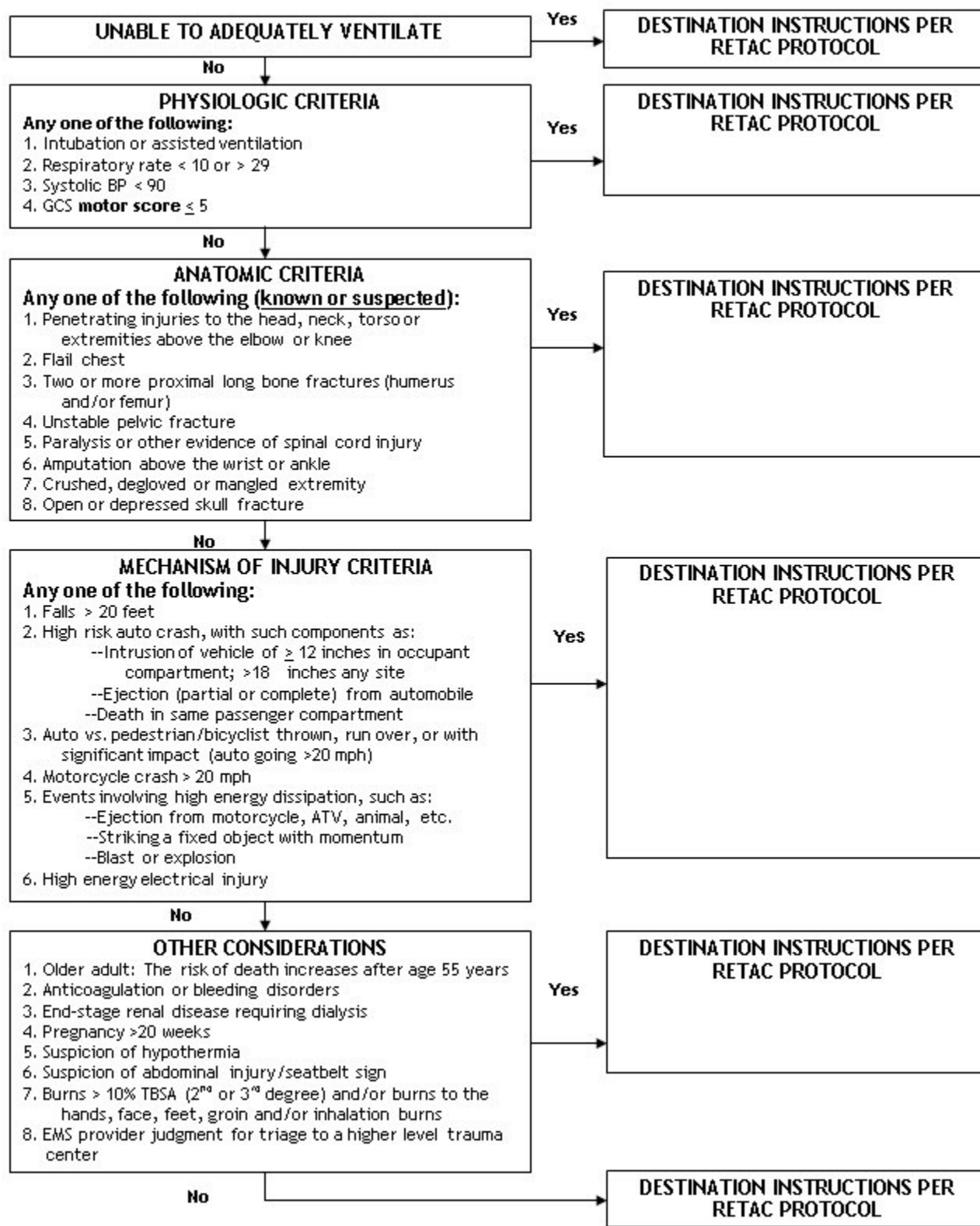
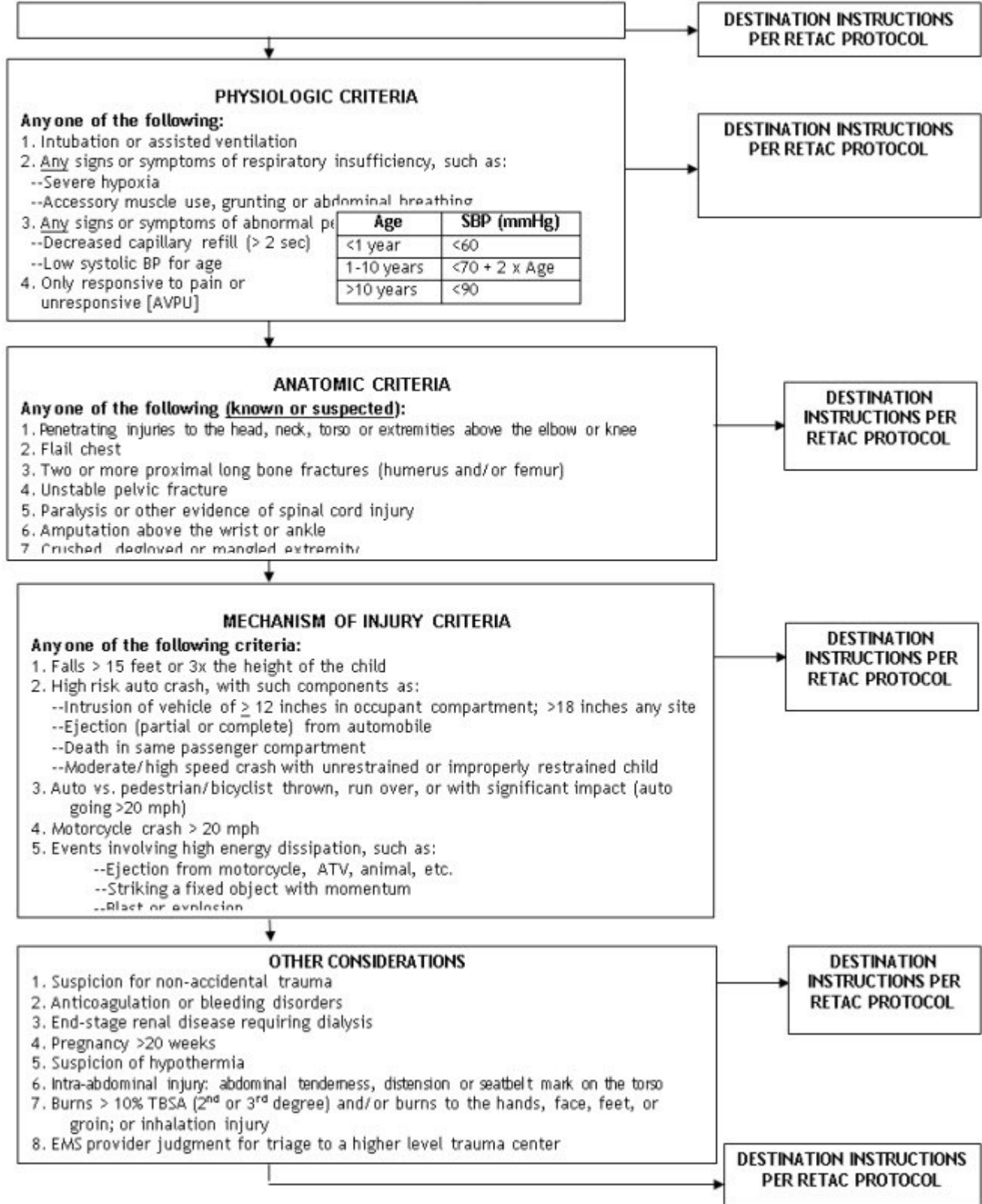


EXHIBIT B – Prehospital Trauma Triage Algorithm – Pediatric Patients (Less than 15 years old)

EXHIBIT B

Prehospital Trauma Triage Algorithm Pediatric Patients (Less than 15 years old)



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.

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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. 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.
9. Met with reservations - Evidence of some degree of compliance with regulatory standards, but where further action is required for full compliance.
10. 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.
11. 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.

12. 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.
13. 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.
14. Promptly Available - Unless otherwise specified, promptly available shall be a facility-defined timeframe based on current standards of clinically appropriate care.
15. 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.
16. 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.
17. 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.
18. 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.
19. 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.
20. 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.
21. 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.
22. 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.

23. Trauma Team - A facility-defined team of clinicians and ancillary staff, including those required by these rules.
24. 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.
25. 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.
26. 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

1. General Provisions
 - A. Any Colorado facility receiving trauma patients by ambulance or other means shall follow the process for designation or non-designation based upon its operational status as set forth in 301.2.A.
 - B. Healthcare facilities shall have state licensure before obtaining designation as a trauma center.
 - C. A separate designation is required for each distinct physical location where a facility provides trauma care services.
2. Process to be Applied
 - A. The current operational status of the facility will determine the designation process to be applied. The four types of operational status are:
 - (1) New facility - a hospital, community clinic and emergency center (CCEC), or other licensed facility that is seeking trauma center designation for the first time or seeking to change to a different level of designation.
 - (2) Replacement facility - an existing trauma center requesting designation at the current level for a new physical location and not retaining trauma center status at the old location.
 - (3) Existing facility renewal - a currently designated trauma center seeking renewal at the same designation level.

- (4) Non-designated facility - a hospital, CCEC or other licensed facility that receives and is accountable for injured persons, but chooses not to seek trauma center designation.
 - B. The specific administrative and clinical criteria for each of the Level I-V designations are set forth in Section 303 through Section 307 of this chapter.
 - C. Applications for designation are public documents. The facility is responsible for identifying any proprietary information. Proprietary documents are defined here as those that are protected by copyright, or are used, produced or marketed under exclusive legal right of the facility.
 - D. At any time, the department may move to revoke, suspend or otherwise limit a facility's designation consistent with the enforcement and disciplinary process contained in Section 302 of this chapter.
3. New Facility
- A. Application Procedure
 - (1) A new facility shall submit a written notice to the department at least 180 days in advance of either the anticipated date of opening or commencement of operation at a higher designation level. Facilities moving to a lower level of designation shall provide notice no later than 90 days in advance. The notice shall state the level of designation the facility is requesting.
 - (2) The facility shall complete a trauma designation application for new facilities on the department's form and submit it along with the designation fee before the site visit according to the deadline specified by the department.
 - (3) After an initial assessment of the application by the department, the facility shall have ten (10) calendar days to respond to written notice of any application deficiency.
 - (4) If a facility does not correct application deficiencies in a timely manner, the department may delay or cancel the review process. The department may also consider the facility's failure to respond in a timely manner as grounds for denial of designation.

B. Fee Structure

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

Level I:	\$20,000
Level II:	\$19,800
Level III:	\$14,330
Level IV:	\$ 6,800
Level V:	\$ 6,800

C. Site Review Procedure

- (1) Any facility requesting a new Level I through V designation shall undergo an on-site review. The department will set a review date no more than ninety (90) days before the new facility opens or commencement of operation at the new designation level.
- (2) All equipment and policies for the requested designation level as currently required by Section 303 through Section 307 of this chapter shall be in place for inspection or evidence of their placement shall be provided to the department before the facility's opening or commencement of operation at the new designation level.
- (3) All personnel for the requested designation level as currently required by Section 303 through Section 307 of this chapter shall be identified and available for interview.
- (4) The department will select the new facility review team according to the following specifications:
 - a. Level I-II facilities:
 - i. A minimum of one trauma surgeon and one trauma nurse who live and work outside the State of Colorado,
 - ii. One state observer,
 - iii. Departmental discretion to designate additional reviewers up to a full team as set forth in 301.5.C(1)a of this section.
 - b. Level III facilities:
 - i. A minimum of one trauma surgeon and one trauma nurse who live and work outside the facility's RETAC area,
 - ii. One state observer,
 - iii. Departmental discretion to designate additional reviewers up to a full team as set forth in 301.5.C(1)b of this section.
 - c. Level IV-V facilities:
 - i. A minimum of one emergency physician or trauma surgeon and one trauma nurse who live and work outside the facility's RETAC area,
 - ii. One state observer,
 - iii. Departmental discretion to designate additional reviewers up to a full team as set forth in 301.5.C(1)c of this section.
- (5) All review team members shall also meet the following criteria:
 - a. Physician reviewers shall be certified by the American Board of Medical Specialties or the American Board of Osteopathic Medicine,

- b. Physician reviewers shall be board certified in the specialty they are representing,
 - c. Be currently active in trauma care at the level being reviewed or above,
 - d. Have no conflict of interest with the facility under review, and
 - e. Live and work outside the facility's RETAC area.
- (6) The department will provide the applicant with the names of the on-site reviewers once they have been selected.
- (7) If the applicant believes that a potential reviewer has a financial, professional or personal bias that may adversely affect the review, the facility shall notify the department, in writing, no later than seven (7) calendar days after the department's announcement of the proposed team members. Such notice shall contain all details of any alleged bias along with supporting documentation. The department shall consider such notice and make a decision concerning replacement of the reviewer in question.
- (8) The review may consist of, but is not limited to, consideration of the following:
 - a. Review of application,
 - b. Equipment check throughout the facility,
 - c. Review of all policies and procedures,
 - d. Review of quality improvement plans and other quality improvement documentation as may be appropriate,
 - e. Physical inspection of facility,
 - f. Interviews with staff,
 - g. Transfer protocols,
 - h. Call schedules,
 - i. Credentials of staff,
 - j. Review of the facility's planned interaction with prehospital transport, and
 - k. Other documents deemed appropriate by the department.
- (9) The review team shall provide a verbal report of its findings to the applicant before leaving the facility.

D. Designation Decision Procedure

- (1) The department shall present a summary of the Level I-II results to SEMTAC or a summary of the Level III-V results to the Designation Review Committee (DRC) for a recommendation on the new facility designation.

- (2) The department shall consider all evidence and notify the applicant in writing of its decision within thirty (30) calendar days of receiving the recommendation.
- (3) The department's final determination regarding each application shall be based upon consideration of all pertinent factors including, but not limited to, the application, the evaluation and recommendations of the on-site review team, the recommendation from SEMTAC or DRC, the best interests of trauma patients, and any unique attributes or circumstances that make the facility capable of meeting particular or special community needs.
- (4) If the department denies new facility designation, the provisions of Section 302.4 of this chapter shall apply.

E. Period of Designation

- (1) A new facility designation is a one-time designation valid for 18 months.
- (2) Once a new facility designation is issued, the facility will coordinate with the department to schedule a full review within 12-14 months.
- (3) Prior to the full review, the facility shall follow the application procedures described in 301.5.A(2) through (4).
- (4) The subsequent site review and designation decision procedures shall follow those described for renewal of existing facilities at 301.5.B through D.
- (5) Designation following the full review will mark the beginning of a full three-year designation cycle.

4. Replacement Facility

A. Application Procedure

- (1) A trauma designation review is required when the department issues a new hospital or CCEC license based upon a change of location.
- (2) A replacement facility shall submit a written notice to the department at least 180 days in advance of the anticipated date of opening.
- (3) The facility shall provide the department with a copy of its last renewal application along with updated statistical data and information on any policy changes. The facility shall submit the application, designation fee and additional information to the department before the site visit according to the specified deadline.
- (4) After an initial assessment of the application and updated information by the department, the facility shall have ten (10) calendar days to respond to written notice of any application deficiency.
- (5) If a facility does not correct application deficiencies in a timely manner, the department may delay or cancel the review process. The department may also consider the facility's failure to respond in a timely manner as grounds for denial of designation.

- (6) The facility will coordinate with the department to schedule a date for the replacement review to occur no sooner than the move to the replacement physical plant and no later than thirty (30) calendar days after the move.
- (7) The facility's existing trauma designation continues until a replacement review occurs and the department makes a decision on the replacement facility application.

B. Fee Structure

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

Level I:	\$8,700
Level II:	\$8,100
Level III:	\$3,080
Level IV:	\$2,800
Level V:	\$2,800

C. Site Review Procedure

- (1) Any facility requesting replacement designation at the same level for a new physical plant shall undergo an on-site review at the new location.
- (2) All equipment and policies required by the facility's current designation level shall be in place for inspection at the replacement facility.
- (3) The department will select the site review team for the replacement facility according to the following specifications:
 - a. Level I-II facilities:
 - i. A minimum of one trauma surgeon and one trauma nurse who live and work outside the State of Colorado,
 - ii. One state observer,
 - iii. Departmental discretion to designate additional reviewers up to a full team as set forth in 301.5.C(1)a.
 - b. Level III-V facilities:
 - i. A minimum of one trauma nurse who lives and works outside the facility's RETAC area,
 - ii. One state observer,
 - iii. Departmental discretion to designate additional reviewers up to a full team as set forth in 301.5.C(1)b and c.

- (4) All review team members shall also meet the following criteria:
 - a. Physician reviewers shall be certified by the American Board of Medical Specialties or the American Board of Osteopathic Medicine,
 - b. Physician reviewers shall be board certified in the specialty they are representing,
 - c. Be currently active in trauma care at the level being reviewed or above,
 - d. Have no conflict of interest with the facility under review, and
 - e. Live and work outside the facility's RETAC area.
- (5) The department will provide the applicant with the names of the on-site reviewers once they have been selected.
- (6) If the applicant believes that a potential reviewer has a financial, professional or personal bias that may adversely affect the review, the facility shall notify the department, in writing, no later than seven (7) calendar days after the department's announcement of the proposed team members. Such notice shall contain all details of any alleged bias along with supporting documentation. The department shall consider such notice and make a decision concerning replacement of the reviewer in question.
- (7) The on-site review may consist of, but is not limited to, consideration of the following:
 - a. Equipment check throughout the facility,
 - b. Physical inspection of facility,
 - c. Review of all policies and procedures,
 - d. Interviews with staff,
 - e. Review of effects of the facility move on prehospital transport protocols, and
 - f. Other documents deemed appropriate by the department.
- (8) The team shall provide a verbal report of its findings to the applicant before leaving the facility.

D. Designation Decision Procedure

The designation decision procedure shall follow the one described for existing facility renewal at Section 301.5.D of this chapter.

E. Designation Period

Designation following the replacement review will continue until the end of the facility's existing designation cycle.

5. Renewal of Existing Facility

A. Application Procedure

- (1) Existing facilities shall submit a letter of intent to maintain their current trauma level designation to the department no later than 120 days before the current designation expiration date.
- (2) The facility shall complete a trauma designation application for renewal of existing facilities on the department's form and submit it to the department before the site visit according to the deadline specified by the department.
- (3) After an initial assessment of the application by the department, the facility shall have ten (10) calendar days to respond to written notice of any application deficiency.
- (4) If a facility does not correct application deficiencies in a timely manner, the department may delay or cancel the review process. The department may also consider the facility's failure to respond in a timely manner as grounds for denial of designation.

B. Fee Structure

- (1) The facility shall submit the required designation fee in the manner specified by the department. The renewal of existing facility designation fee is:

Level I:	\$34,200
Level II:	\$34,200
Level III:	\$16,600
Level IV/V: Emergency Department Visits > 25,000 per year	\$11,100
Level IV/V: Emergency Department Visits between 10,000 - 25,000 per year	\$8,000
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

- (2) Fees submitted with the renewal application may be forfeited if the facility does not respond in a timely manner to application deficiencies.
- (3) 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.
- (4) These fees shall apply to all on-site trauma reviews conducted subsequent to the effective date of these rules.

C. Site Review Procedure

- (1) The department will select the site review members for renewal of an existing facility designation according to the following specifications:
 - a. Level I-II facilities - An out-of-state multidisciplinary team consisting of two trauma surgeons, one trauma nurse coordinator or RN involved in trauma program management, one emergency physician, and one state observer.
 - b. Level III facilities - A team consisting of one trauma surgeon, one emergency physician, one trauma nurse coordinator or registered nurse involved in trauma program management and one state observer.

- c. Level IV-V facilities - A team consisting of one emergency physician or trauma surgeon, one trauma nurse coordinator or registered nurse involved in trauma program management and one state observer.
- (2) All review team members shall also meet the following criteria:
 - a. Physician reviewers shall be certified by the American Board of Medical Specialties or the American Board of Osteopathic Medicine,
 - b. Physician reviewers shall be board certified in the specialty they are representing,
 - c. Be currently active in trauma care at the level being reviewed or above,
 - d. Have no conflict of interest with the facility under review, and
 - e. Live and work outside the facility's RETAC area.
- (3) The department will provide the applicant with the names of the on-site reviewers once they have been selected.
- (4) If the applicant believes that a potential reviewer has a financial, professional or personal bias that may adversely affect the review, the facility shall notify the department, in writing, no later than seven (7) calendar days after the department's announcement of the proposed team members. Such notice shall contain all details of any alleged bias along with supporting documentation. The department shall consider such notice and make a decision concerning replacement of the reviewer in question.
- (5) The on-site review team shall evaluate the capability of the facility to meet the responsibilities, required equipment and performance criteria appropriate to its designation level as identified in these rules through the following:
 - a. Review of application,
 - b. Physical inspection of the facility,
 - c. Review of trauma patient medical records,
 - d. Review of patient discharge summaries,
 - e. Review of patient care logs,
 - f. Review of quality improvement/management/assurance records and meeting minutes,
 - g. Review of rosters, schedules and meeting minutes,
 - h. Interviews with appropriate facility personnel and other medical providers,
 - i. Review of research, prevention, and educational programs as applicable, and
 - j. Review of other documents as deemed appropriate by the team.

- (6) The review team shall provide a verbal report of its findings to the applicant before leaving the facility.

D. Designation Decision Procedure

- (1) The department shall present a summary of the Level I-II results to SEMTAC or a summary of the Level III-V results to the Designation Review Committee (DRC) for a recommendation to the department on the facility designation.
- (2) If the department determines that a plan of correction is appropriate, the facility shall follow the process set forth in Section 302.2 of this chapter.
- (3) The department shall notify the applicant in writing of its decision within thirty (30) calendar days of receiving the recommendation.
- (4) The department's final determination regarding each application shall be based upon consideration of all pertinent factors, including but not limited to the application, the evaluation and recommendations of the on-site review team, the recommendation from SEMTAC or DRC, compliance history, the best interests of trauma patients, and any unique attributes or circumstances that make the facility capable of meeting particular or special community needs.
- (5) If the department denies renewal of existing facility designation, the provisions of Section 302.4 of this chapter shall apply.

E. Period of Designation

Renewal of existing facility designation will be valid for three years from the prior expiration date, unless voluntarily relinquished by the facility, revoked, suspended or otherwise sanctioned pursuant to these rules.

6. Non-designated Facility

- A. A facility requesting non-designation status shall file a non-designation agreement that, at a minimum, states the following:

- (1) The facility chooses not to seek such designation.
- (2) The facility acknowledges and agrees that it may only treat patients who have single system injuries that are not threatening to life or limb and whose care is not complicated by co-morbid conditions.
- (3) The facility has established transfer agreements as required by Section 25-3.5-703(4)(a), C.R.S.
- (4) Within two hours of recognition that a patient has experienced a significant injury or mechanism as defined in 6 CCR 1015-4, Chapter Two, Section 202.C, 202.D or the prehospital algorithms, the facility shall resuscitate, stabilize and/or initiate transfer of the patient, after consultation with a trauma surgeon or emergency physician at the closest designated trauma center, as required by 6 CCR 1015-4, Chapter Two, Section 202.C.4 and Section 202.D.9. Transfer shall be to the closest appropriate trauma facility as defined by RETAC protocols and as determined in consultation with the trauma surgeon or emergency physician.

7. Waivers

- A. The department may grant a waiver from one or more criteria that are established in this chapter for Level I-V trauma centers.
- B. Facilities seeking a waiver shall submit a completed waiver application on the department's form. The department may require the applicant to provide additional information, and the application will not be considered complete until the required information is provided.
- C. The facility seeking the waiver shall also post notice of the waiver application and a meaningful description of the substance of the request at all public entrances to the facility and in at least one area commonly used by the patients. The notice shall be posted no later than the application's submission date and shall remain posted for at least thirty (30) calendar days.
- D. The notice shall describe where to send comments within that 30-day period. Comments should be directed to:

EMTS Section

ATTN: Section Chief

CDPHE, HFEMSD-A2

4300 Cherry Creek Drive South

Denver, CO 80246

- E. At the same time the notice is posted in the facility, the facility shall also distribute a copy of the notice to prehospital emergency medical service providers active in the community served by the facility.
- F. The completed waiver application shall be submitted to the department at least thirty (30) calendar days before a SEMTAC meeting in order to be placed on the next agenda. Applications completed less than thirty (30) calendar days in advance will be placed on the subsequent agenda.
- G. The department shall distribute a copy of the public notice of the SEMTAC meeting regarding the waiver to all other designated trauma centers.
- H. SEMTAC shall review the request and make recommendations to the department. The department shall make a decision and send notice of that decision to the facility administrator within thirty (30) calendar days of the recommendation.
 - (1) If the waiver is granted, the department may:
 - a. Specify the terms and conditions of the waiver.
 - b. Specify the duration of the waiver. Under no circumstances shall a waiver be granted for a period longer than the designation cycle for that facility.
 - (2) The department may require the submission of progress reports from any facility granted a waiver.

- (3) If the waived rule is amended or repealed, obviating the need for the waiver, the waiver shall expire on the effective date of the rule change.
 - I. A facility shall notify the department prior to any change of ownership of the facility as defined in 6 CCR 1011-1, Chapter II, Part 2.7.
 - J. Facilities wishing to maintain a waiver beyond its expiration shall submit a new waiver application to the department no less than ninety (90) days prior to the expiration of the waiver.
 - K. The department may revoke or suspend a waiver if it determines:
 - (1) That its continuation jeopardizes the health, safety, and/or welfare of the patients,
 - (2) The applicant has provided false or misleading information in the waiver application,
 - (3) The applicant has failed to comply with conditions of the waiver, or
 - (4) The department determines that a change in federal or state law prohibits continuation of the waiver.
 - L. If the department denies, revokes or suspends a waiver, the pertinent provisions of Sections 302.4, 302.5 or 302.6 of this chapter shall apply.
8. Designation Review Committee
- A. The Designation Review Committee (DRC) shall make recommendations to the department about the designation of Level III-V facilities and shall report such recommendations to SEMTAC.
 - B. The DRC shall be comprised of nine members. A minimum of five members shall be current SEMTAC members. The members shall represent the following constituencies and disciplines:
 - (1) One healthcare facility administrator,
 - (2) One board-certified general surgeon;
 - (3) One board-certified general surgeon with experience as a site reviewer or a trauma medical director at a Level III-V facility,
 - (4) One physician board-certified in emergency medicine,
 - (5) One physician board-certified in emergency medicine with experience as a site reviewer or a trauma medical director at a Level III-V facility,
 - (6) One trauma program manager or trauma nurse coordinator,
 - (7) One trauma program manager or trauma nurse coordinator with experience as a site reviewer or a Level III-V trauma nurse coordinator,
 - (8) One member representing the prehospital/EMS community/or public, and
 - (9) One member representing a RETAC.

- C. SEMTAC shall make recommendations to the department on the membership of the DRC along with the criteria to be used by the DRC.
- D. The DRC meetings shall be public.
- E. The DRC shall have access to a facility's application with any proprietary material extracted, a summary of the site review finding, and any plan of correction submitted by the facility.

302. Enforcement and Disciplinary Process

1. Unscheduled or Interim, Focused or Re-Reviews

- A. At any time the department may require and conduct an unscheduled or interim, focused or re-review of a currently designated facility based upon, but not limited to, the following criteria:
 - (1) Recent review results,
 - (2) A complaint, or
 - (3) Monitoring of the EMTS system.

2. Plans of Correction

- A. Prior to making a designation decision, or after an unscheduled or interim, focused or re-review, the department shall require a plan of correction from any facility with review deficiencies and/or met with reservations.
- B. A plan of correction shall include, but not be limited to, the following:
 - (1) Identification of the problem(s) with the current activity and what the facility will do to correct each deficiency,
 - (2) A description of how the facility will accomplish the corrective action,
 - (3) A description of how the facility will monitor the corrective action to ensure the deficient practice is remedied and will not recur,
 - (4) A timeline with the expected implementation and completion date. Completion date is the date that the facility deems it can achieve compliance.
- C. Completed plans of correction shall be:
 - (1) Submitted to the department in the form and manner required by the department,
 - (2) Submitted within thirty (30) calendar days after the date of the department's written notice of deficiencies and/or criteria identified as met with reservations when areas of non-compliance with rules pertaining to the designation of trauma centers have been identified, and
 - (3) Signed by the facility administrator and facility trauma director.
- D. The department has the discretion to approve, modify or reject plans of correction.

- (1) If the plan of correction is accepted, the department shall notify the facility by issuing a written notice of acceptance within thirty (30) calendar days of receipt of the plan.
- (2) If the plan of correction is unacceptable, the department shall notify the facility in writing, and the facility shall re-submit changes to the department within fifteen (15) calendar days of the date of the written notice.
- (3) If the facility fails to comply with the requirements or deadlines for submission of a plan or fails to submit requested changes to the plan, the department may reject the plan of correction and impose disciplinary sanctions as set forth below.
- (4) If the facility fails to timely implement the actions agreed to in the plan of correction, the department may impose disciplinary sanctions as set forth below.

3. Re-Review Fee Structure

- A. In the event the department designates a facility with a required interim, focused or re-review per Section 302.1.A.(1) above, the facility shall submit the required fee in the manner specified by the department. The methodology used to determine the re-review fee for an existing facility is:

Levels I and II:	100% of costs of review team excluding state observer time
Levels III through V:	75% of costs of review team excluding state observer time

- B. These fees shall apply to all on-site trauma re-reviews conducted subsequent to the effective date of these rules.

4. Denials

- A. The department may deny an application for Level I-V designation to a new, replacement or existing facility for reasons including, but not limited to, the following:
- (1) The facility does not meet the criteria for designation as set forth in these regulations,
 - (2) The facility's application or accompanying documents contain a false statement of material fact,
 - (3) The facility refuses any part of an on-site review,
 - (4) The facility's failure to comply with or to successfully complete a plan of correction, or
 - (5) The facility is substantially out of compliance with any of the department's regulations.
- B. If the facility does not meet the level of designation criteria for which it has applied, the department may recommend designation at a lesser level. Such action, unless agreed to by the applicant, shall represent a denial of the application.
- C. If the department denies an application for designation or waiver, the department shall provide the facility with a notice explaining the basis for the denial. The notice shall also inform the facility of its right to appeal the denial and the procedure for appealing the denial.

- D. Appeals of departmental denials shall be conducted in accordance with the State Administrative Procedure Act, Section 24-4-101, *et seq.* , C.R.S.

5. Revocation or Temporary Suspension

- A. The department may revoke the designation of a facility if any owner, officer, director, manager, or other employee:
 - (1) Fails or refuses to comply with the provisions of these regulations,
 - (2) Makes a false statement of material fact about facility capabilities or other pertinent circumstances in any record or in a matter under investigation for any purposes connected with this chapter,
 - (3) Prevents, interferes with, or attempts to impede in any way, the work of a representative of the department in implementing or enforcing these regulations or the statute,
 - (4) Falsely advertises or in any way misrepresents the facility's ability to care for trauma patients based on its designation status,
 - (5) Is substantially out of compliance with these regulations and has not rectified such noncompliance,
 - (6) Fails to provide reports required by the registry or the state in a timely and complete fashion, or
 - (7) Fails to comply with or complete a plan of correction in the time or manner specified.
- B. If the department revokes or temporarily suspends a designation or waiver, it shall provide the facility with a notice explaining the basis for the action. The notice shall also inform the facility of its right to appeal and the procedure for appealing the action.
- C. Appeals of departmental revocations or suspensions shall be conducted in accordance with the State Administrative Procedure Act, Section 24-4-101, *et seq.* , C.R.S.

6. Summary Suspension

- A. The department may summarily suspend a designation or waiver if it finds, after investigation, that a facility has engaged in a deliberate and willful violation of these regulations or that the public health, safety, or welfare requires immediate action.
- B. If the department summarily suspends a designation or waiver, it shall provide the facility with a notice explaining the basis for the summary suspension. The notice shall also inform the facility of its right to appeal and that it is entitled to a prompt hearing on the matter.
- C. Appeals of summary suspensions shall be conducted in accordance with the State Administrative Procedure Act, Section 24-4-101, *et. seq.* , C.R.S.

7. Redesignation at a lesser level

- A. The department may determine that a facility be redesignated at a lesser level due to the facility's inability to meet the designation criteria at its current level, notwithstanding any waiver previously granted.
- B. If the department seeks to redesignate the facility, it shall provide the facility with a notice explaining the basis for its action. The notice shall also inform the facility of its right to appeal and the procedure for appealing the action.
- C. Appeals of involuntary redesignation shall be conducted in accordance with the State Administrative Procedure Act, Section 24-4-101, *et. seq.* , C.R.S.

8. Monetary Penalties

Any facility, provider or employee of a facility that falsely misrepresents a facility's designation level or violates any rule adopted by the board shall be subject to a civil penalty of \$500 per violation. The fee shall be assessed in accordance with Section 25-3.5-707(2), C.R.S.

303. Trauma Facility Designation Criteria - Level I Facilities

1. Prehospital Trauma Care Integration

- A. The facility shall participate in the development and improvement of prehospital care protocols and patient safety programs.
- B. The trauma medical director shall be involved in the development of the trauma facility's divert protocol as it affects the trauma service.
- C. A trauma surgeon shall be involved in any decision regarding divert as it affects the care of the trauma patient.
- D. A liaison from the emergency department shall participate in prehospital peer review/performance improvement.

2. Interfacility Consultation and Transfer Requirements

- A. Provisions for direct physician-to-physician contact shall be included in the process of transferring a patient between facilities.
- B. A decision to transfer a patient shall be based solely on the clinical needs of the patient and not on the requirements of the patient's specific provider network or the patient's ability to pay.
- C. If the facility does not have a burn service, a reimplantation service, a pediatric trauma service or an acute rehabilitation service, the facility shall have written transfer guidelines for patients in these categories.

3. Performance Improvement Process

A. General Provisions

- (1) The facility shall demonstrate a clearly defined trauma performance improvement program that shall be coordinated with the hospital-wide program.

- (2) The facility shall be able to demonstrate that the trauma patient population can be identified for separate review regardless of the institutional performance improvement processes.
- (3) Performance improvement shall be supported by a reliable method of data collection that consistently obtains valid and objective information necessary to identify opportunities for improvement. The process of analysis shall include multidisciplinary review and shall occur at regular intervals to meet the needs of the program. The results of analysis shall define corrective strategies and shall be documented.
- (4) The facility shall demonstrate that the trauma registry is used to support the performance improvement program.
- (5) The performance improvement program shall have defined audit filters based upon a regular review of registry and/or clinical data.
- (6) There shall be appropriate objectively defined standards to determine the quality of care.
- (7) If more than 10 percent of injured patients with an Injury Severity Score greater than or equal to nine (excluding isolated hip fractures) are admitted to non-surgical services, the trauma facility shall demonstrate the appropriateness of that practice through the performance improvement program.
- (8) Identified problem trends shall undergo peer review by the Peer Review/Performance Improvement Committee.
- (9) A representative from the emergency department shall participate in prehospital peer review/performance improvement.
- (10) The facility shall review any diversion or double transfer (from another facility and then transferred for additional acute trauma care) of trauma patients.
- (11) If a facility conducts an internal trauma educational process in lieu of external trauma CME, that process shall be, at least in part, based on information from the peer review/performance improvement process and the principles of practice-based learning.
- (12) The facility shall demonstrate that its graded activation criteria are regularly evaluated by the performance improvement program.
- (13) The Level I adult facility that admits only children with single extremity orthopedic fracture or minor head trauma with a negative computed tomography exam shall demonstrate the oversight of pediatric care through a pediatric-specific peer review/performance improvement process.
- (14) The Level I adult facility that admits children having other than single extremity orthopedic fracture or minor head trauma with a negative computed tomography exam shall have a pediatric-specific peer review/performance improvement process, which shall include pediatric-specific process filters and outcome measures.
- (15) Physician availability to the trauma patient in the ICU shall be monitored by the peer review/performance improvement program.

B. Multidisciplinary Trauma Committee

- (1) The facility shall have a multidisciplinary committee to address trauma program operational issues.
- (2) A multidisciplinary trauma committee shall continuously evaluate the trauma program's processes and outcomes.
- (3) The committee shall include, at a minimum, the trauma medical director or designee and all core surgeons as well as liaisons from orthopedic surgery, neurosurgery, emergency medicine, radiology and anesthesia. Each of these liaisons shall attend at least 50 percent of the meetings.
- (4) The exact format of the committee may be hospital specific, but shall be multidisciplinary and consist of hospital and medical staff members who work to identify and correct trauma program system issues.
- (5) The committee minutes shall reflect the review of operational issues and, when appropriate, the analysis and proposed corrective actions. The process shall identify problems and shall demonstrate problem resolution.
- (6) The committee shall monitor compliance with all required time frames for availability of trauma personnel, including, but not limited to response times for general surgery, orthopedics, neurosurgery, anesthesiology, radiology, and radiology, MRI or CT techs.
- (7) The availability of anesthesia services and the absence of delays in airway control or operations shall be monitored.
- (8) Radiologists shall be involved in protocol development and trend analysis that relate to diagnostic imaging.
- (9) The multidisciplinary committee shall review and address issues related to the availability of necessary personnel and equipment to monitor and resuscitate patients in the PACU.

C. Peer Review/Performance Improvement Committee

- (1) The facility shall have a Peer Review/Performance Improvement Committee chaired by the trauma medical director or physician designee.
- (2) The committee shall include, at a minimum, the core group of general surgeons and a physician liaison from orthopedic surgery, neurosurgery, emergency medicine, radiology and anesthesia. Each liaison shall attend at least 50 percent of the meetings.
- (3) Each liaison shall be available to the trauma medical director for committee issues that arise in his or her department.
- (4) The Peer Review/Performance Improvement Committee shall document evidence of committee attendance and participation.
- (5) The committee shall review the overall quality of care for the trauma service, selected deaths, complications and sentinel events with the objective of identifying issues and appropriate responses.

- (6) Trauma patient care may be evaluated initially by individual specialties within their usual departmental review structures; however, identified problem trends shall undergo review within the Peer Review/Performance Improvement Committee.
- (7) The facility shall also, in this committee or in another appropriate forum, provide for morbidity and mortality review of trauma cases. All trauma deaths shall be systematically reviewed and categorized as preventable, non-preventable or potentially preventable.
- (8) When a consistent problem or inappropriate variation is identified, corrective actions shall be taken and documented.
- (9) The trauma medical director shall ensure dissemination of committee information to all non-core general surgeons with documentation.
- (10) The Peer Review/Performance Improvement Committee shall review and monitor the organ donation rate.
- (11) The committee shall demonstrate that the program complies with required surgical response times at least 80% of the time.
- (12) The peer review/performance improvement program shall monitor changes in interpretation of diagnostic information.

4. Facility Organization and the Trauma Program

A. Facility Governing Body and Medical Staff Commitment

- (1) The facility shall demonstrate the commitment of the facility's governing body and medical staff through a written document. The document shall be reaffirmed every three years and be current at the time of the site review.
- (2) The administrative structure of the hospital/trauma facility shall include, at a minimum, an administrator, a trauma medical director and a trauma program manager.

B. Trauma Program

- (1) A multidisciplinary trauma committee shall continuously evaluate the trauma program's processes and outcomes.
- (2) The trauma program members or a representative of the program shall participate in state and regional trauma system planning, development and operation.
- (3) The trauma program shall have authority to address issues that involve multiple disciplines. The trauma medical director shall have the authority and administrative support to lead the program.

C. Trauma Medical Director

- (1) The trauma medical director shall be a board-certified (not board-eligible) surgeon, as those boards are defined under the "Clinical Requirements for General Surgery" as described in Section 303.5.C or shall be a Fellow of the

American College of Surgeons with special interest in trauma care, shall take trauma call and shall have successfully completed an ATLS course.

- (2) The trauma medical director shall demonstrate membership and active participation in state and either regional or national trauma organizations.
- (3) The trauma medical director shall have the authority to correct deficiencies in trauma care and exclude from taking trauma call all trauma team members who do not meet required criteria. Through the performance improvement program and hospital policy, the trauma medical director shall have the responsibility and authority to determine each general surgeon's ability to participate on the trauma panel based on an annual review.
- (4) The trauma medical director shall accrue an average of 16 hours verifiable, external trauma-related CME annually or 48 hours in the three years prior to the designation site review, including no less than one national meeting per three years.

D. Trauma Resuscitation Team

- (1) The facility shall define criteria for trauma resuscitation team activation.
- (2) The criteria for a graded activation shall be clearly defined and continuously evaluated by the performance improvement program.

E. Trauma Service

- (1) A trauma service admission is a patient who is admitted to or evaluated by an identifiable surgical service staffed by credentialed trauma providers.
- (2) An adult trauma facility shall demonstrate an annual volume of at least 320 trauma patients with an Injury Severity Score (ISS) of 16 or greater.
- (3) The facility shall demonstrate or provide documentation that the trauma service has sufficient infrastructure and support to ensure the adequate provision of care

F. Trauma Program Manager

The trauma program manager shall, at a minimum, be a registered nurse and demonstrate the following qualifications:

- (1) Administrative ability,
- (2) Evidence of educational preparation,
- (3) Documented clinical experience, and
- (4) Accrue an average of 16 hours of verifiable, external trauma-related continuing education per year or 48 hours in the three years prior to the designation site review including no less than one national trauma meeting per three years.

5. Clinical Requirements for General Surgery

A. Role/Availability

- (1) The on-call attending trauma surgeon shall be in the emergency department on patient arrival, as set forth below, for the highest level of activation, with adequate notification from the field. The maximum response time is 15 minutes, tracked from patient arrival, 80 percent of the time. The Multidisciplinary Trauma Committee shall monitor compliance of the attending surgeon's arrival times.
- (2) A resident in postgraduate year four or five may begin resuscitation while awaiting arrival of the attending surgeon based on facility-defined criteria.

B. Equipment/Resources

The facility shall provide all of the necessary resources, including instruments, equipment and personnel, for current surgical trauma care.

C. Qualifications/Board Certification

- (1) Except as provided below in subparagraph 2, all general surgeons on the trauma panel shall be fully credentialed in critical care and board certified in surgery by the American Board of Surgery (ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working toward certification and less than five years out of residency.
- (2) A foreign-trained, non-ABS boarded surgeon shall have the foreign equivalent of ABS certification in general surgery, clinical expertise in trauma care, an unrestricted Colorado license, and unrestricted credentials in surgery and critical care at the facility.
- (3) The performance of all surgeons on the trauma panel shall be reviewed annually by the trauma medical director.

D. Clinical Commitment/Involvement

- (1) All general surgeons on the trauma panel shall have general surgical privileges.
- (2) The general surgeon on-call shall be dedicated to one trauma facility when taking trauma call.
- (3) A published general surgery back-up call schedule shall be available. The back-up surgeon shall be present within 30 minutes of being requested to respond.
- (4) An attending surgeon shall be present at all trauma operations. The surgeon's presence shall be documented.

E. Education/Continuing Education

- (1) All general surgeons on the trauma panel shall have successfully completed the American College of Surgeons ATLS course at least once.
- (2) All general surgeons who take trauma call shall accrue an average of 16 hours annually of verifiable, external trauma-related CME or demonstrate participation in an internal educational process conducted by the trauma program based on the peer review/performance improvement program and the principles of practice-based learning.

- (3) All general surgeons on the trauma panel shall be reviewed annually by the trauma medical director or designated representative to assure compliance with the facility's CME policy.

F. Participation in Statewide Trauma System

Each Level I trauma facility shall provide a qualified surgeon as a state reviewer a minimum of one day per year if requested by the department.

6. Requirements for Emergency Medicine and the Emergency Department

A. Role/Availability

- (1) The facility shall have a designated emergency department physician director supported by additional physicians to ensure immediate care for injured patients.
- (2) A physician shall be present in the emergency department at all times.
- (3) In facilities with emergency medicine residents, an in-house attending emergency physician shall provide supervision of the residents 24 hours per day.
- (4) The facility shall designate an emergency physician to serve as the emergency medicine liaison to the trauma service.

B. Equipment/Resources

The trauma facility shall provide all of the necessary resources, including instruments, equipment and personnel, for current emergency trauma care.

C. Qualifications/Board Certification

- (1) Except as provided below in subparagraph 2, all emergency physicians on the trauma panel shall be board certified in emergency medicine by the American Board of Medical Specialties (ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working on certification and less than five years out of residency.
- (2) A foreign-trained, non-ABS boarded emergency physician shall have the foreign equivalent of ABS certification in emergency medicine, clinical expertise in trauma care, an unrestricted Colorado license and unrestricted credentials at the facility.
- (3) The performance of all emergency physicians on the trauma panel shall be reviewed annually by the emergency medicine liaison or designated representative.

D. Clinical Commitment/Involvement

- (1) The roles and responsibilities of the emergency physician shall be defined, agreed on and approved by the trauma medical director.

- (2) Emergency physicians on the call panel shall be regularly involved in the care of the injured patient.

E. Education/Continuing Education

- (1) All emergency physicians on the trauma panel shall have successfully completed the American College of Surgeons ATLS course at least once.
- (2) The trauma service emergency medicine liaison shall accrue an average of 16 hours annually of verifiable, external trauma-related CME or 48 hours in the three years before the designation site review.
- (3) All other emergency physicians on the trauma panel shall be reviewed annually by the emergency medicine liaison or designated representative to assure compliance with the facility's CME policy.

F. Nursing Services

- (1) A qualified nurse shall be available 24 hours per day to provide care for patients during the emergency department phase of care. Nursing personnel with special capability in trauma care shall provide continual monitoring of the trauma patient from hospital arrival to disposition in Intensive Care Unit (ICU), Operating Room (OR), or Patient Care Unit (PCU).
- (2) The nurse/patient ratio shall be appropriate for the acuity of the trauma patients in the emergency department.

7. Clinical Requirements for Neurosurgery

A. Role/Availability

- (1) The facility shall designate a neurosurgeon to serve as the neurological liaison to the trauma service.
- (2) The facility shall provide a neurotrauma on-call schedule, dedicated only to that facility, available 24 hours per day and either a posted second call or a contingency plan that includes transfer agreements with another designated Level I facility.
- (3) Neurotrauma care shall be promptly available as defined by the facility. For less severe head injuries or injuries of the spine, neurotrauma care shall be available when necessary. When requested, an attending neurosurgeon shall be promptly available as defined by the facility to the trauma service. Compliance with the facility-defined availability criteria shall be monitored by the Multidisciplinary Trauma Committee.

B. Equipment/Resources

The facility shall provide all of the necessary resources, including instruments, equipment and personnel, for current neurotrauma care.

C. Qualifications

- (1) Except as provided below in subparagraph 2, all neurosurgeons who take trauma call shall be board certified in neurosurgery by the American Board of Surgery

(ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working on certification and less than five years out of residency.

- (2) A foreign-trained, non-ABS boarded neurosurgeon shall have the foreign equivalent of ABS certification in neurosurgery, clinical expertise in trauma care, an unrestricted Colorado license and unrestricted credentials in neurosurgery at the facility.
- (3) The performance of all neurosurgeons on the trauma panel shall be reviewed annually by the liaison or designated representative.

D. Clinical Commitment/Involvement

- (1) Neurosurgeons shall be credentialed by the hospital with general neurosurgical privileges.
- (2) Qualified neurosurgeons shall be regularly involved in the care of the head and spinal cord injured patients.

E. Education/Continuing Education

- (1) The trauma service neurosurgery liaison shall accrue an average of 16 hours annually of verifiable, external trauma-related CME or 48 hours in the three years before the designation site review.
- (2) All other neurosurgeons on the trauma panel shall be reviewed annually by the liaison or designated representative to assure compliance with the facility's CME policy.

8. Clinical Requirements for Orthopedic Surgery

A. Role/Availability/Specialists

- (1) The facility shall designate an orthopedic surgeon to serve as the orthopedic liaison to the trauma program.
- (2) At least one orthopedic traumatologist with a minimum of six to twelve months of fellowship training (or equivalent) shall be a part of the trauma team.
- (3) The facility shall provide an orthopedic on-call schedule, dedicated only to that facility, available 24 hours per day and either a posted second call or a contingency plan that includes transfer agreements with another designated Level I facility. Compliance with the facility-defined availability criteria shall be monitored by the Multidisciplinary Trauma Committee.
- (4) Plastic surgery, hand surgery and treatment of spinal injuries shall be available to the orthopedic patient.
- (5) A fully credentialed spine surgeon shall be promptly available, as defined by the facility, 24 hours per day.

B. Equipment/Resources

The facility shall provide all of the necessary resources including instruments, equipment and personnel, for current musculoskeletal trauma care.

C. Qualifications

- (1) Except as provided below in subparagraph 2, all orthopedic surgeons who take trauma call shall be board certified in orthopedic surgery by the American Board of Surgery (ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working on certification and less than five years out of residency.
- (2) A foreign-trained, non-ABS orthopedic surgeon shall have the foreign equivalent of ABS certification in orthopedic surgery, clinical expertise in trauma care, an unrestricted Colorado license and unrestricted credentials in orthopedic surgery at the facility.
- (3) The performance of all orthopedic surgeons on the trauma panel shall be reviewed annually by the liaison or designated representative.

D. Clinical Commitment/Involvement

- (1) Orthopedic surgeons shall be credentialed by the hospital with general orthopedic privileges.
- (2) A published orthopedic surgery back-up call schedule shall be available with the back-up surgeon promptly available.
- (3) Orthopedic surgeons on the call panel shall be regularly involved in the care of the trauma patient.

E. Education/Continuing Education

- (1) The trauma service orthopedic surgical liaison shall accrue an average of 16 hours annually of verifiable external trauma-related CME or 48 hours in the three years before the designation site review.
- (2) All other members of the orthopedic team on the trauma panel shall be reviewed annually by the liaison or designated representative to assure compliance with facility CME policy.

9. Pediatric Trauma Care

A. Pediatric trauma care shall refer to care delivered to children under age 15.

B. Level I adult trauma facilities can and will receive pediatric trauma patients. All adult Level I facilities shall:

- (1) Provide evidence of safe pediatric trauma care to include age-specific medical devices and equipment as appropriate for the resuscitation and stabilization of the pediatric patient.
- (2) Assure that the physician and nursing staff providing care to the pediatric patient demonstrates competency in the care of the injured child appropriate to the type of injured child.

- (3) Demonstrate oversight of the pediatric care provided through a pediatric-specific peer review/performance improvement process.
- C. A Level I adult trauma facility that admits children having other than single extremity orthopedic fracture or minor head trauma with a negative computed tomography shall meet the following additional criteria:
 - (1) All physicians providing care to pediatric trauma patients shall be credentialed for pediatric trauma care by the hospital's credentialing body.
 - (2) The facility shall provide appropriate pediatric medical equipment in the emergency department.
 - (3) The facility shall provide a pediatric intensive care area or a transfer protocol and transfer agreements for pediatric patients requiring intensive care.
 - (4) The facility shall provide appropriate pediatric resuscitation equipment in all pediatric care areas.
 - (5) The facility shall have a pediatric-specific peer review/performance improvement process, which shall include pediatric-specific process filters and outcome measures.
 - (6) The facility shall assure that the nursing staff providing care to the pediatric patient has specialized training in the care of the injured child.
- 10. Collaborative Clinical Services
 - A. Anesthesiology
 - (1) Role/Availability
 - a. The facility shall designate an anesthesiologist to serve as the anesthesia liaison to the trauma program.
 - b. Anesthesiology services shall be promptly available as defined by the facility in-house 24 hours per day for emergency operations and airway problems in the injured patient. Compliance with the facility-defined availability criteria shall be monitored by the Multidisciplinary Trauma Committee.
 - c. When anesthesiology residents or certified registered nurse anesthetists are used to fulfill availability requirements, the staff anesthesiologist on call shall be notified and be present in the operating department. The process shall be monitored through the performance improvement process.
 - (2) Qualifications
 - a. All anesthesiologists who take trauma call shall be board certified or board eligible, working toward certification and less than five years out of residency.

- b. The performance of all anesthesiologists on the trauma panel shall be reviewed annually by the anesthesiology liaison or designated representative.
 - (3) Education/Continuing Education
 - a. The trauma service anesthesiologist liaison shall accrue an average of 16 hours annually of verifiable, external trauma-related CME or 48 hours in the three years prior to the designation site review.
 - b. All other members of the anesthesiology team on the trauma panel shall be reviewed annually by the anesthesia liaison or designated representative to assure compliance with facility CME policy.
- B. Operating Room
 - (1) General Requirements
 - a. A dedicated operating room team shall always be available.
 - b. If the primary operating room team is occupied, there shall be a mechanism in place to staff a second operating room.
 - c. There shall be a facility-defined access policy for urgent trauma cases of all specialties.
 - (2) Equipment Requirements
 - a. The facility shall have rapid infusers, thermal control equipment for patients and fluids, intraoperative radiological capabilities, equipment for fracture fixation, equipment for endoscopic evaluation (bronchoscopy and gastrointestinal endoscopy) and other equipment to provide operative care consistent with current practice.
 - b. The facility shall have the necessary equipment to perform a craniotomy.
 - c. The facility shall have cardiopulmonary bypass equipment and an operating microscope available 24 hours per day.
- C. Postanesthesia Care Unit (PACU)
 - (1) Qualified nurses shall be available 24 hours per day to provide care for the trauma patient, if needed, in the recovery phase.
 - (2) If the availability of PACU nurses is met with an on-call team from outside the hospital, the availability of the PACU nurses and absence of delays shall be monitored by the peer review/performance improvement program.
 - (3) The PACU shall provide all of the necessary resources including instruments, equipment and personnel to monitor and resuscitate patients consistent with the facility-defined process of care.
 - (4) Recovery of the trauma patient in a critical care (intensive care) unit is also acceptable.

- (5) The peer review/performance improvement program shall review and address issues related to the availability of necessary personnel and equipment to monitor and resuscitate patients in the PACU.

D. Radiology

(1) Role/Availability

- a. Qualified radiologists shall be promptly available as defined by the facility for the interpretation of imaging studies and shall respond in person when requested.
- b. Personnel qualified in advanced neuro, endovascular and interventional procedures shall be promptly available as defined by the facility 24 hours per day and available in less than 30 minutes when requested by a trauma surgeon.
- c. The facility shall designate a radiologist to serve as the radiology liaison to the trauma program.

(2) Clinical Commitment/Involvement

- a. Diagnostic information shall be communicated in written form in a timely manner as defined by the facility.
- b. Critical information that is deemed to immediately affect patient care shall be promptly communicated to the trauma team.
- c. The final report shall accurately reflect the chronology and content of communications with the trauma team, including changes between the preliminary and final interpretation.

(3) Radiology Support Services

- a. The facility shall have policies designed to ensure that trauma patients who may require resuscitation and monitoring are accompanied by appropriately trained providers during transport to and while in the radiology department.
- b. Conventional radiography and computed tomography (CT) shall be promptly available as defined by the facility 24 hours per day and available in less than 30 minutes when requested by a trauma surgeon.
- c. An in-house radiographer and in-house CT technologist shall be promptly available as defined by the facility 24 hours per day and available in less than 30 minutes when requested by a trauma surgeon.
- d. Conventional catheter angiography and sonography shall be promptly available as defined by the facility 24 hours per day and available in less than 30 minutes when requested by a trauma surgeon.
- e. Magnetic resonance imaging capability shall be promptly available as defined by the facility 24 hours per day and available in less than 30 minutes when requested by a trauma surgeon.

- f. The peer review/performance improvement program shall review and address any variance from facility-defined response times.

E. Critical Care

(1) Organization of the Intensive Care Unit (ICU)

- a. This service shall be led by a qualified surgeon who is board certified in critical care by the American Board of Surgery. The surgical director shall have obtained critical care training during residency or fellowship and shall have expertise in the perioperative and post injury care of injured patients.
- b. This service may be staffed by critical care trained physicians from different specialties.
- c. Physician coverage of critically ill trauma patients shall be promptly available as defined by the facility 24 hours per day. These physicians shall be capable of rapid response to deal with urgent problems as they arise. Availability shall be monitored by the peer review/performance improvement program.
- d. All trauma surgeons shall be fully credentialed by the facility to provide all intensivist services in the ICU. There shall be full hospital privileges for critical care.
- e. A facility-defined team shall provide daily multidisciplinary rounds to patients in the ICU.

(2) Responsibility for Trauma Patients

- a. The trauma surgeon shall retain oversight of the patient while in the ICU.
- b. The trauma service shall maintain oversight of the patient throughout the course of hospitalization.

(3) Nursing Services

- a. A qualified nurse shall be available 24 hours per day to provide care for patients during the ICU phase of care.
- b. The nurse/patient ratio shall be appropriate for the acuity of the trauma patients in the ICU.
- c. The facility shall assure that the nursing staff providing care to the pediatric patient has specialized training in the care of the injured child.

(4) Equipment

- a. The ICU shall have the necessary resources including instruments and equipment to monitor and resuscitate patients consistent with the facility-defined process of care.
- b. Non-conventional ventilatory support shall be available for trauma patients 24 hours per day.

- c. Arterial pressure monitoring, pulmonary artery catheterization, patient rewarming, intracranial pressure monitoring and other equipment to provide critical care consistent with current practice shall also be available.

F. Other Surgical Specialties

The facility shall have a full spectrum of surgical specialists on staff including but not limited to the following surgical specialties: cardiac, thoracic, microvascular, peripheral vascular, obstetric, gynecological, otolaryngologic, urologic, ophthalmologic, facial trauma, hand and plastic.

G. Medical Consultants

- (1) The facility shall have the following medical specialists on staff: cardiology, infectious disease, internal medicine, pulmonary medicine and nephrology and their respective support teams.
- (2) A respiratory therapist shall be promptly available to care for trauma patients.
- (3) Acute hemodialysis shall be promptly available for the trauma patient.
- (4) Services shall be available 24 hours per day for the standard analyses of blood, urine and other body fluids, coagulation studies, blood gases and microbiology, including microsampling when appropriate.
- (5) The blood bank shall be capable of blood typing and cross-matching and shall have an adequate supply of red blood cells, fresh frozen plasma, platelets, cryoprecipitate and appropriate coagulation factors to meet the needs of injured patients.

11. Rehabilitation Requirements

A. Rehabilitation services shall be available to the trauma patient:

- (1) Within the hospital's physical facilities; or
- (2) At a freestanding rehabilitation hospital. In this circumstance, the trauma facility shall have appropriate transfer agreements.

B. The following services shall be available during the trauma patient's ICU and other acute phases of care:

- (1) Physical, occupational and speech therapy, and
- (2) Social services.

12. Trauma Registry

- A. Trauma registry data shall be collected and analyzed by every trauma facility. It shall contain detailed, reliable and readily accessible information that is necessary to operate a trauma facility.
- B. Trauma data shall be submitted to the National Trauma Data Bank on an annual basis.

- C. The facility shall demonstrate that the trauma registry is used to support the performance improvement program.
- D. Trauma data shall be submitted to the Colorado Trauma Registry within 60 days of the end of the month during which the patient was discharged.
- E. The trauma program shall have in place appropriate measures to assure that trauma data remain confidential.
- F. The facility shall monitor data validity.

13. Outreach and Education

A. Public Outreach and Education

The facility shall engage in public education that includes prevention activities, referral and access to trauma facility resources.

B. Professional Outreach and Education

The facility shall engage in professional outreach and education that includes, at a minimum:

- (1) Providing or participating in one ATLS course annually,
- (2) Providing a continuous rotation in trauma surgery for senior residents that is part of a program accredited by the Accreditation Council for Graduate Medical Education in either general surgery, orthopedic surgery, neurosurgery, or family medicine; or support of a critical care fellowship or an acute care surgery fellowship consistent with the educational requirements of the American Association for the Surgery of Trauma, and
- (3) Providing a mechanism to offer trauma-related education to nurses involved in trauma care.

14. Prevention

A. The facility shall participate in injury prevention. The facility shall provide documentation of the presence of prevention activities that center on priorities based on local data.

B. The facility shall demonstrate evidence of a job description and salary support for an injury prevention coordinator who is a separate person from but collaborates with the trauma program manager.

C. The trauma service shall develop an injury prevention program that, at a minimum, incorporates the following:

- (1) Selecting a target injury population,
- (2) Gathering and analyzing data,
- (3) Developing evidenced based intervention strategies based on local data and best practices,
- (4) Formulating a plan,

- (5) Implementing the program, and
 - (6) Evaluating and revising the program as necessary.
 - D. The facility shall demonstrate collaboration with or participation in national, regional or state injury prevention programs.
 - E. The facility shall have a mechanism to identify patients who may have an alcohol addiction. The facility shall also have the capability to provide an intervention for patients identified as potentially having an alcohol addiction.
 - F. The facility shall collaborate and mentor lower level trauma centers regarding injury prevention.
15. Research and Scholarship
- A. The facility shall meet one of the following options:
 - (1) Twenty peer-reviewed articles published in journals included in *Index Medicus* in a three-year period. These articles shall result from work related to the trauma facility.
 - a. Of the 20 articles, there shall be at least one authored or coauthored by members of the general surgery trauma team, and
 - b. There shall be at least one each from three of the following seven disciplines: neurosurgery, emergency medicine, orthopedics, radiology, anesthesia, nursing, or rehabilitation; or
 - (2) Ten peer-reviewed articles published in journals included in *Index Medicus* in a three-year period. These articles shall result from work related to the trauma facility.
 - a. Of the 10 articles, there shall be at least one authored or coauthored by members of the general surgery team, and
 - b. There shall be at least one each from three of the following seven disciplines: neurosurgery, emergency medicine, orthopedics, radiology, anesthesia, nursing, or rehabilitation; and
 - c. Four of the following scholarly activities shall be demonstrated:
 - i. Leadership in major trauma organizations.
 - ii. Peer-reviewed funding for trauma research.
 - iii. Evidence of dissemination of knowledge to include review articles, book chapters, technical documents, Web-based publications, editorial comments, training manuals and trauma-related course materials.
 - iv. Display of scholarly application of knowledge as evidenced by case reports or reports of clinical series in journals included in MEDLINE.

- v. Participation as a visiting professor or invited lecturer at national or regional trauma conferences.
 - vi. Support of resident participation in facility-focused scholarly activity, including laboratory experiences, clinical trials, or resident trauma paper competitions at the state, regional or national level.
 - vii. Mentorship of residents and fellows, as evidenced by the development of a trauma fellowship program or successful matriculation of graduating residents into trauma fellowship programs.
 - B. The facility shall demonstrate support for the trauma research program by providing such items as basic laboratory space, sophisticated research equipment, advanced information systems, biostatistical support, salary support for basic and social scientists or seed grants for less experienced faculty.
16. Organ Procurement Activities
- A. The facility shall have an established relationship with a recognized organ procurement organization (OPO).
 - B. The facility shall have a written policy for triggering notification of the regional OPO.
 - C. The facility shall have written protocols defining clinical criteria and confirmatory tests for the diagnosis of brain death.
17. Disaster Planning and Management
- A. The facility shall meet the Emergency-Management-related requirements of the Joint Commission.
 - (1) These rules incorporate by reference the *2011 Comprehensive Accreditation Manual for Hospitals: The Official Handbook* , effective December 2010.
 - (2) Such incorporation does not include later amendments to or editions of the referenced material. The Health Facilities and Emergency Medical Services Division of the department maintains copies of the complete text of the incorporated materials for public inspection during regular business hours, and shall provide certified copies of any non-copyrighted material to the public at cost upon request. Information regarding how the incorporated materials may be obtained or examined is available from the Division by contacting:

EMTS Section Chief

Health Facilities and EMS Division

Colorado Department of Public Health and Environment

4300 Cherry Creek Drive South

Denver, CO 80246-1530

These materials have been submitted to the state publications depository and distribution center and are available for interlibrary loan. The incorporated material may be examined at any state publications depository library.

These materials are available for purchase from Joint Commission Resources at: WWW.JCRINC.COM.

- B. A surgeon from the trauma panel shall participate on the hospital's disaster committee.
- C. The facility shall have a disaster preparedness plan in its policy and procedure manual or equivalent.
- D. Hospital drills that test the facility's preparedness plan shall be conducted no less than every six months.
- E. The facility disaster preparedness plan shall be integrated into local, regional and state disaster preparedness plans.

18. RETAC Integration

The facility shall demonstrate integration and cooperation with its Regional Emergency Medical and Trauma Advisory Council (RETAC). Evidence of such integration may include but is not limited to: attendance at periodic RETAC meetings, participation in RETAC injury prevention activities, participation in RETAC data and or quality improvement projects, etc.

304. Trauma Facility Designation Criteria - Level II Facilities

1. Prehospital Trauma Care Integration

- A. The facility shall participate in the development and improvement of prehospital care protocols and patient safety programs.
- B. The trauma medical director shall be involved in the development of the trauma facility's divert protocol as it affects the trauma service.
- C. A trauma surgeon shall be involved in any decision regarding divert as it affects the care of the trauma patient.
- D. A liaison from the emergency department shall participate in prehospital peer review/performance improvement.

2. Interfacility Consultation and Transfer Requirements

- A. Provisions for direct physician-to-physician contact shall be included in the process of transferring a patient between facilities.
- B. A decision to transfer a patient shall be based solely on the clinical needs of the patient and not on the requirements of the patient's specific provider network or the patient's ability to pay.
- C. If the facility does not have a burn service, a reimplantation service, a pediatric trauma service or an acute rehabilitation service, the facility shall have written transfer guidelines for patients in these categories.

3. Performance Improvement Process

A. General Provisions

- (1) The facility shall demonstrate a clearly defined trauma performance improvement program that shall be coordinated with the hospital-wide program.
- (2) The facility shall be able to demonstrate that the trauma patient population can be identified for separate review regardless of the institutional performance improvement processes.
- (3) Performance improvement shall be supported by a reliable method of data collection that consistently obtains valid and objective information necessary to identify opportunities for improvement. The process of analysis shall include multidisciplinary review and shall occur at regular intervals to meet the needs of the program. The results of analysis shall define corrective strategies and shall be documented.
- (4) The facility shall demonstrate that the trauma registry is used to support the performance improvement program.
- (5) The performance improvement program shall have defined audit filters based upon a regular review of registry and/or clinical data.
- (6) There shall be appropriate objectively defined standards to determine the quality of care.
- (7) If more than 10 percent of injured patients with an Injury Severity Score greater than or equal to nine (excluding isolated hip fractures) are admitted to non-surgical services, the trauma facility shall demonstrate the appropriateness of that practice through the performance improvement program.
- (8) Identified problem trends shall undergo peer review by the Peer Review/Performance Improvement Committee.
- (9) A representative from the emergency department shall participate in prehospital peer review/performance improvement.
- (10) The facility shall review any diversion or double transfer (from another facility and then transferred for additional acute trauma care) of trauma patients.
- (11) If a facility conducts an internal trauma educational process in lieu of external trauma CME, that process shall be, at least in part, based on information from the peer review/performance improvement process and the principles of practice-based learning.
- (12) The facility shall demonstrate that its graded activation criteria are regularly evaluated by the performance improvement program.
- (13) The Level II adult facility that admits only children with single extremity orthopedic fracture or minor head trauma with a negative computed tomography exam shall demonstrate the oversight of pediatric care through a pediatric-specific peer review/performance improvement process.
- (14) The Level II adult facility that admits children having other than single extremity orthopedic fracture or minor head trauma with a negative computed tomography exam shall have a pediatric-specific peer review/performance improvement

process, which shall include pediatric-specific process filters and outcome measures.

- (15) Physician availability to the trauma patient in the ICU shall be monitored by the peer review/performance improvement program.

B. Multidisciplinary Trauma Committee

- (1) The facility shall have a multidisciplinary committee to address trauma program operational issues.
- (2) A multidisciplinary trauma committee shall continuously evaluate the trauma program's processes and outcomes.
- (3) The committee shall include, at a minimum, the trauma medical director or designee and all core surgeons as well as liaisons from orthopedic surgery, neurosurgery, emergency medicine, radiology and anesthesia. Each of these liaisons shall attend at least 50 percent of the meetings.
- (4) The exact format of the committee may be hospital specific, but shall be multidisciplinary and consist of hospital and medical staff members who work to identify and correct trauma program system issues.
- (5) The committee minutes shall reflect the review of operational issues and, when appropriate, the analysis and proposed corrective actions. The process shall identify problems and shall demonstrate problem resolution.
- (6) The committee shall monitor compliance with all required time frames for availability of trauma personnel, including, but not limited to response times for general surgery, orthopedics, neurosurgery, anesthesiology, radiology, and radiology, MRI or CT techs.
- (7) The availability of anesthesia services and the absence of delays in airway control or operations shall be monitored.
- (8) Radiologists shall be involved in protocol development and trend analysis that relate to diagnostic imaging.
- (9) The multidisciplinary committee shall review and address issues related to the availability of necessary personnel and equipment to monitor and resuscitate patients in the PACU.

C. Peer Review/Performance Improvement Committee

- (1) The facility shall have a Peer Review/Performance Improvement Committee chaired by the trauma medical director or physician designee.
- (2) The committee shall include, at a minimum, the core group of general surgeons and a physician liaison from orthopedic surgery, neurosurgery, emergency medicine, radiology and anesthesia. Each liaison shall attend at least 50 percent of the meetings.
- (3) Each liaison shall be available to the trauma medical director for committee issues that arise in his or her department.

- (4) The Peer Review/Performance Improvement Committee shall document evidence of committee attendance and participation.
- (5) The committee shall review the overall quality of care for the trauma service, selected deaths, complications and sentinel events with the objective of identifying issues and appropriate responses.
- (6) Trauma patient care may be evaluated initially by individual specialties within their usual departmental review structures; however, identified problem trends shall undergo review within the Peer Review/Performance Improvement Committee.
- (7) The facility shall also, in this committee or in another appropriate forum, provide for morbidity and mortality review of trauma cases. All trauma deaths shall be systematically reviewed and categorized as preventable, non-preventable or potentially preventable.
- (8) When a consistent problem or inappropriate variation is identified, corrective actions shall be taken and documented.
- (9) The trauma medical director shall ensure dissemination of committee information to all non-core general surgeons with documentation.
- (10) The Peer Review/Performance Improvement Committee shall review and monitor the organ donation rate.
- (11) The committee shall demonstrate that the program complies with required surgical response times at least 80% of the time.
- (12) The peer review/performance improvement program shall monitor changes in interpretation of diagnostic information.

4. Facility Organization and the Trauma Program

A. Facility Governing Body and Medical Staff Commitment

- (1) The facility shall demonstrate the commitment of the facility's governing body and medical staff through a written document. The document shall be reaffirmed every three years and be current at the time of the site review.
- (2) The administrative structure of the hospital/trauma facility shall include, at a minimum, an administrator, a trauma medical director and a trauma program manager.

B. Trauma Program

- (1) A multidisciplinary trauma committee shall continuously evaluate the trauma program's processes and outcomes.
- (2) The trauma program members or a representative of the program shall participate in state and regional trauma system planning, development and operation.

- (3) The trauma program shall have authority to address issues that involve multiple disciplines. The trauma medical director shall have the authority and administrative support to lead the program.

C. Trauma Medical Director

- (1) The trauma medical director shall be a board-certified surgeon (not board-eligible), as those boards are defined under the "Clinical Requirements for General Surgery" as described in Section 304.5.C or shall be a Fellow of the American College of Surgeons with special interest in trauma care, shall take trauma call and shall have successfully completed an ATLS course.
- (2) The trauma medical director shall demonstrate membership and active participation in state and either regional or national trauma organizations.
- (3) The trauma medical director shall have the authority to correct deficiencies in trauma care and exclude from taking trauma call all trauma team members who do not meet required criteria. Through the performance improvement program and hospital policy, the trauma medical director shall have the responsibility and authority to determine each general surgeon's ability to participate on the trauma panel based on an annual review.
- (4) The trauma medical director shall accrue an average of 16 hours verifiable, external trauma-related CME annually or 48 hours in the three years prior to the designation site review, including no less than one national meeting per three years.

D. Trauma Resuscitation Team

- (1) The facility shall define criteria for trauma resuscitation team activation.
- (2) The criteria for a graded activation shall be clearly defined and continuously evaluated by the performance improvement program.

E. Trauma Service

- (1) A trauma service admission is a patient who is admitted to or evaluated by an identifiable surgical service staffed by credentialed trauma providers.
- (2) The facility shall demonstrate or provide documentation that the trauma service has sufficient infrastructure and support to ensure the adequate provision of care.

F. Trauma Program Manager

The trauma program manager shall, at a minimum, be a registered nurse and demonstrate the following qualifications:

- (1) Administrative ability,
- (2) Evidence of educational preparation,
- (3) Documented clinical experience, and

- (4) Accrue an average of 16 hours of verifiable, external trauma-related continuing education per year or 48 hours in the three years prior to the designation site review including no less than one national trauma meeting per three years.

5. Clinical Requirements for General Surgery

A. Role/Availability

- (1) The on-call attending trauma surgeon shall be in the emergency department on patient arrival, as set forth below, for the highest level of activation, with adequate notification from the field. The maximum response time is 15 minutes, tracked from patient arrival, 80 percent of the time. The Multidisciplinary Trauma Committee shall monitor compliance of the attending surgeon's arrival times.
- (2) A resident in postgraduate year four or five may begin resuscitation while awaiting arrival of the attending surgeon based on facility-defined criteria.

B. Equipment/Resources

The facility shall provide all of the necessary resources, including instruments, equipment and personnel, for current surgical trauma care.

C. Qualifications/Board Certification

- (1) Except as provided below in subparagraph 2, all general surgeons on the trauma panel shall be fully credentialed in critical care and board certified in surgery by the American Board of Surgery (ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working toward certification and less than five years out of residency.
- (2) A foreign-trained, non-ABS boarded surgeon shall have the foreign equivalent of ABS certification in general surgery, clinical expertise in trauma care, an unrestricted Colorado license and unrestricted credentials in surgery and critical care at the facility.
- (3) The performance of all surgeons on the trauma panel shall be reviewed annually by the trauma medical director.

D. Clinical Commitment/Involvement

- (1) All general surgeons on the trauma panel shall have general surgical privileges.
- (2) The general surgeon on-call shall be dedicated to one trauma facility when taking trauma call.
- (3) A published general surgery back-up call schedule shall be available. The back-up surgeon shall be present within 30 minutes of being requested to respond.
- (4) An attending surgeon shall be present at all trauma operations. The surgeon's presence shall be documented.

E. Education/Continuing Education

- (1) All general surgeons on the trauma panel shall have successfully completed the American College of Surgeons ATLS course at least once.
- (2) All general surgeons who take trauma call shall accrue an average of 16 hours annually of verifiable, external trauma-related CME or demonstrate participation in an internal educational process conducted by the trauma program based on the peer review/performance improvement program and the principles of practice-based learning.
- (3) All general surgeons on the trauma panel shall be reviewed annually by the trauma medical director or designated representative to assure compliance with the facility's CME policy.

F. Participation in Statewide Trauma System

Each Level II trauma facility shall provide a qualified surgeon as a state reviewer a minimum of one day per year if requested by the department.

6. Requirements for Emergency Medicine and the Emergency Department

A. Role/Availability

- (1) The facility shall have a designated emergency department physician director supported by additional physicians to ensure immediate care for injured patients.
- (2) A physician shall be present in the emergency department at all times.
- (3) In facilities with emergency medicine residents, an in-house attending emergency physician shall provide supervision of the residents 24 hours per day.
- (4) The facility shall designate an emergency physician to serve as the emergency medicine liaison to the trauma service.

B. Equipment/Resources

The trauma facility shall provide all of the necessary resources, including instruments, equipment and personnel, for current emergency trauma care.

C. Qualifications/Board Certification

- (1) Except as provided below in subparagraph 2, all emergency physicians hired or contracted on or after the effective date of these rules to participate on the trauma panel shall be board certified in emergency medicine by the American Board of Medical Specialties (ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working on certification and less than five years out of residency.
- (2) A foreign-trained, non-ABS boarded emergency physician shall have the foreign equivalent of ABS certification in emergency medicine, clinical expertise in trauma care, an unrestricted Colorado license, and unrestricted credentials at the facility.

- (3) The performance of all emergency physicians on the trauma panel shall be reviewed annually by the emergency medicine liaison or designated representative.

D. Clinical Commitment/Involvement

- (1) The roles and responsibilities of the emergency physician shall be defined, agreed on and approved by the trauma medical director.
- (2) Emergency physicians on the call panel shall be regularly involved in the care of the injured patient.

E. Education/Continuing Education

- (1) All emergency physicians on the trauma panel shall have successfully completed the American College of Surgeons ATLS course at least once.
- (2) Physicians certified by boards other than emergency medicine who treat trauma patients in the emergency department shall remain current in ATLS.
- (3) The trauma service emergency medicine liaison shall accrue an average of 16 hours annually of verifiable, external trauma-related CME or 48 hours in the three years before the designation site review.
- (4) All other emergency physicians on the trauma panel shall be reviewed annually by the emergency medicine liaison or designated representative to assure compliance with the facility's CME policy.

F. Nursing Services

- (1) A qualified nurse shall be available 24 hours per day to provide care for patients during the emergency department phase of care. Nursing personnel with special capability in trauma care shall provide continual monitoring of the trauma patient from hospital arrival to disposition in Intensive Care Unit (ICU), Operating Room (OR), or Patient Care Unit (PCU).
- (2) The nurse/patient ratio shall be appropriate for the acuity of the trauma patients in the emergency department.

7. Clinical Requirements for Neurosurgery

A. Role/Availability

- (1) The facility shall designate a neurosurgeon to serve as the neurological liaison to the trauma service.
- (2) The facility shall define criteria for neurosurgical (attending and resident) activation.
- (3) If neurosurgeons take call at more than one facility (either trauma or non-trauma) at a time, written primary and back-up call schedules are required, unless the combined volume of trauma-related emergency neurosurgical operative procedures in those facilities is less than an average of 25 per year over the last three calendar years for which data are available.

- (4) When requested, an attending neurosurgeon shall be promptly available as defined by the facility to the trauma service. Compliance with the facility-defined availability criteria shall be monitored by the Multidisciplinary Trauma Committee.

B. Equipment/Resources

The facility shall provide all of the necessary resources, including instruments, equipment and personnel, for current neurotrauma care.

C. Qualifications

- (1) Except as provided below in subparagraph 2, all neurosurgeons who take trauma call shall be board certified in neurosurgery by the American Board of Surgery (ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working on certification and less than five years out of residency.
- (2) A foreign-trained, non-ABS boarded neurosurgeon shall have the foreign equivalent of ABS certification in neurosurgery, clinical expertise in trauma care, an unrestricted Colorado license and unrestricted credentials in neurosurgery at the facility.
- (3) The performance of all neurosurgeons on the trauma panel shall be reviewed annually by the liaison or designated representative.

D. Clinical Commitment/Involvement

- (1) Neurosurgeons shall be credentialed by the hospital with general neurosurgical privileges.
- (2) Qualified neurosurgeons shall be regularly involved in the care of the head and spinal cord injured patients.

E. Education/Continuing Education

- (1) The trauma service neurosurgery liaison shall accrue an average of 16 hours annually of verifiable, external trauma-related CME or 48 hours in the three years before the designation site review.
- (2) All other neurosurgeons on the trauma panel shall be reviewed annually by the liaison or designated representative to assure compliance with the facility's CME policy.

8. Clinical Requirements for Orthopedic Surgery

A. Role/Availability/Specialists

- (1) The facility shall designate an orthopedic surgeon to serve as the orthopedic liaison to the trauma program.
- (2) The facility shall provide an orthopedic on-call schedule dedicated only to that facility, available 24 hours per day and either a posted second call or a contingency plan that includes transfer agreements with another designated Level I or II facility. Compliance with the facility-defined availability criteria shall be monitored by the Multidisciplinary Trauma Committee.

- (3) Plastic surgery, hand surgery and treatment of spinal injuries shall be available to the orthopedic patient.
- (4) A fully credentialed spine surgeon shall be promptly available, as defined by the facility, 24 hours per day.

B. Equipment/Resources

The facility shall provide all of the necessary resources including instruments, equipment and personnel, for current musculoskeletal trauma care.

C. Qualifications

- (1) Except as provided below in subparagraph 2, all orthopedic surgeons who take trauma call shall be board certified in orthopedic surgery by the American Board of Surgery (ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working on certification and less than five years out of residency.
- (2) A foreign-trained, non-ABS orthopedic surgeon shall have the foreign equivalent of ABS certification in orthopedic surgery, clinical expertise in trauma care, an unrestricted Colorado license and unrestricted credentials in orthopedic surgery at the facility.
- (3) The performance of all orthopedic surgeons on the trauma panel shall be reviewed annually by the liaison or designated representative.

D. Clinical Commitment/Involvement

- (1) Orthopedic surgeons shall be credentialed by the hospital with general orthopedic privileges.
- (2) If orthopedic surgeons take call at more than one facility (either trauma or non-trauma) at a time, written primary and back-up call schedules are required.
- (3) Orthopedic surgeons on the call panel shall be regularly involved in the care of the trauma patient.

E. Education/Continuing Education

- (1) The trauma service orthopedic surgical liaison shall accrue an average of 16 hours annually of verifiable, external trauma-related CME or 48 hours in the three years before the designation site review.
- (2) All other members of the orthopedic team on the trauma panel shall be reviewed annually by the liaison or designated representative to assure compliance with facility CME policy.

9. Pediatric Trauma Care

- A. Pediatric trauma care shall refer to care delivered to children under age 15.
- B. Level II adult trauma facilities can and will receive pediatric trauma patients. All adult Level II facilities shall:

- (1) Provide evidence of safe pediatric trauma care to include age-specific medical devices and equipment as appropriate for the resuscitation and stabilization of the pediatric patient.
 - (2) Assure that the physician and nursing staff providing care to the pediatric patient demonstrates competency in the care of the injured child appropriate to the type of injured child.
 - (3) Demonstrate oversight of the pediatric care provided through a pediatric-specific peer review/performance improvement process.
- C. A Level II adult trauma facility that admits children having other than single extremity orthopedic fracture or minor head trauma with a negative computed tomography shall meet the following additional criteria:
- (1) All physicians providing care to pediatric trauma patients shall be credentialed for pediatric trauma care by the hospital's credentialing body.
 - (2) The facility shall provide appropriate pediatric medical equipment in the emergency department.
 - (3) The facility shall provide a pediatric intensive care area or a transfer protocol and transfer agreements for pediatric patients requiring intensive care.
 - (4) The facility shall provide appropriate pediatric resuscitation equipment in all pediatric care areas.
 - (5) The facility shall have a pediatric-specific peer review/performance improvement process, which shall include pediatric-specific process filters and outcome measures.
 - (6) The facility shall assure that the nursing staff providing care to the pediatric patient has specialized training in the care of the injured child.

10. Collaborative Clinical Services

A. Anesthesiology

- (1) Role/Availability
 - a. The facility shall designate an anesthesiologist to serve as the anesthesia liaison to the trauma program.
 - b. Anesthesiology services shall be promptly available as defined by the facility 24 hours per day for emergency operations and airway problems in the injured patient. Compliance with the facility-defined availability criteria shall be monitored by the Multidisciplinary Trauma Committee.
 - c. When anesthesiology residents or certified registered nurse anesthetists are used to fulfill availability requirements, the staff anesthesiologist on call shall be notified and be present in the operating department. The process shall be monitored through the performance improvement process.
- (2) Qualifications

- a. All anesthesiologists who take trauma call shall be board certified or board eligible, working toward certification and less than five years out of residency.
 - b. The performance of all anesthesiologists on the trauma panel shall be reviewed annually by the anesthesiology liaison or designated representative.
- (3) Education/Continuing Education
 - a. The trauma service anesthesiologist liaison shall accrue an average of 16 hours annually of verifiable, external trauma-related CME or 48 hours in the three years prior to the designation site review.
 - b. All other members of the anesthesiology team on the trauma panel shall be reviewed annually by the anesthesia liaison or designated representative to assure compliance with facility CME policy.
- B. Operating Room
 - (1) General Requirements
 - a. A dedicated operating room team shall always be available.
 - b. If the primary operating room team is occupied, there shall be a mechanism in place to staff a second operating room.
 - c. There shall be a facility-defined access policy for urgent trauma cases of all specialties.
 - (2) Equipment Requirements
 - a. The facility shall have rapid infusers, thermal control equipment for patients and fluids, intraoperative radiological capabilities, equipment for fracture fixation, equipment for endoscopic evaluation (bronchoscopy and gastrointestinal endoscopy) and other equipment to provide operative care consistent with current practice.
 - b. The facility shall have the necessary equipment to perform a craniotomy.
- C. Postanesthesia Care Unit (PACU)
 - (1) Qualified nurses shall be available 24 hours per day to provide care for the trauma patient, if needed, in the recovery phase.
 - (2) If the availability of PACU nurses is met with an on-call team from outside the hospital, the availability of the PACU nurses and absence of delays shall be monitored by the peer review/performance improvement program.
 - (3) The PACU shall provide all of the necessary resources including instruments, equipment and personnel to monitor and resuscitate patients consistent with the facility-defined process of care.
 - (4) Recovery of the trauma patient in a critical care (intensive care) unit is also acceptable.

- (5) The peer review/performance improvement program shall review and address issues related to the availability of necessary personnel and equipment to monitor and resuscitate patients in the PACU.

D. Radiology

(1) Role/Availability

- a. Qualified radiologists shall be promptly available as defined by the facility for the interpretation of imaging studies and shall respond in person when requested.
- b. Personnel qualified in interventional procedures shall be promptly available as defined by the facility 24 hours per day when requested by a trauma surgeon.
- c. The facility shall designate a radiologist to serve as the radiology liaison to the trauma program.

(2) Clinical Commitment/Involvement

- a. Diagnostic information shall be communicated in written form in a timely manner as defined by the facility.
- b. Critical information that is deemed to immediately affect patient care shall be promptly communicated to the trauma team.
- c. The final report shall accurately reflect the chronology and content of communications with the trauma team, including changes between the preliminary and final interpretation.

(3) Radiology Support Services

- a. The facility shall have policies designed to ensure that trauma patients who may require resuscitation and monitoring are accompanied by appropriately trained providers during transport to and while in the radiology department.
- b. Conventional radiography and computed tomography (CT) shall be promptly available as defined by the facility 24 hours per day and available in less than 30 minutes when requested by a trauma surgeon.
- c. An in-house radiographer and in-house CT technologist shall be promptly available as defined by the facility 24 hours per day and available in less than 30 minutes when requested by a trauma surgeon.
- d. Conventional catheter angiography and sonography shall be promptly available as defined by the facility 24 hours per day and available in less than 30 minutes when requested by a trauma surgeon.
- e. Magnetic resonance imaging capability shall be promptly available as defined by the facility 24 hours per day and available in less than 30 minutes when requested by a trauma surgeon.

- f. The peer review/performance improvement program shall review and address any variance from facility-defined response times.

E. Critical Care

(1) Organization of the Intensive Care Unit (ICU)

- a. This service shall be directed or co-directed by a qualified surgeon with expertise in the care of injured patients.
- b. This service may be staffed by critical care trained physicians from different specialties.
- c. Physician coverage of critically ill trauma patients shall be promptly available as defined by the facility 24 hours per day. These physicians shall be capable of rapid response to deal with urgent problems as they arise. Availability shall be monitored by the peer review/performance improvement program.
- d. All trauma surgeons shall be fully credentialed by the facility to provide all intensivist services in the ICU. There shall be full hospital privileges for critical care.

(2) Responsibility for Trauma Patients

- a. The trauma surgeon shall retain oversight of the patient while in the ICU.
- b. The trauma service shall maintain oversight of the patient throughout the course of hospitalization.

(3) Nursing Services

- a. A qualified nurse shall be available 24 hours per day to provide care for patients during the ICU phase of care.
- b. The nurse/patient ratio shall be appropriate for the acuity of the trauma patients in the ICU.
- c. The facility shall assure that the nursing staff providing care to the pediatric patient has specialized training in the care of the injured child.

(4) Equipment

- a. The ICU shall have the necessary resources including instruments and equipment to monitor and resuscitate patients consistent with the facility-defined process of care.
- b. Ventilatory support shall be available for trauma patients 24 hours per day.
- c. Arterial pressure monitoring, pulmonary artery catheterization, patient rewarming, intracranial pressure monitoring and other equipment to provide critical care consistent with current practice shall also be available.

F. Other Surgical Specialties

The facility shall have a full spectrum of surgical specialists on staff including but not limited to the following surgical specialties: thoracic, peripheral vascular, obstetric, gynecological, otolaryngologic, urologic, ophthalmologic, facial trauma, spine and plastic.

G. Medical Consultants

- (1) The facility shall have the following medical specialists on staff: cardiology, infectious disease, internal medicine, pulmonary medicine and nephrology and their respective support teams.
- (2) A respiratory therapist shall be promptly available to care for trauma patients.
- (3) Acute hemodialysis shall be promptly available for the trauma patient.
- (4) Services shall be available 24 hours per day for the standard analyses of blood, urine, and other body fluids, coagulation studies, blood gases, and microbiology, including microsampling when appropriate.
- (5) The blood bank shall be capable of blood typing and cross-matching and shall have an adequate supply of red blood cells, fresh frozen plasma, platelets, cryoprecipitate and appropriate coagulation factors to meet the needs of injured patients.

11. Rehabilitation Requirements

A. Rehabilitation services shall be available to the trauma patient:

- (1) Within the hospital's physical facilities; or
- (2) At a freestanding rehabilitation hospital. In this circumstance, the trauma facility shall have appropriate transfer agreements.

B. The following services shall be available during the trauma patient's ICU and other acute phases of care:

- (1) Physical, occupational and speech therapy, and
- (2) Social services.

12. Trauma Registry

- A. Trauma registry data shall be collected and analyzed by every trauma facility. It shall contain detailed, reliable and readily accessible information that is necessary to operate a trauma facility.
- B. Trauma data shall be submitted to the National Trauma Data Bank on an annual basis.
- C. The facility shall demonstrate that the trauma registry is used to support the performance improvement program.
- D. Trauma data shall be submitted to the Colorado Trauma Registry within 60 days of the end of the month during which the patient was discharged.

- E. The trauma program shall have in place appropriate measures to assure that trauma data remain confidential.
 - F. The facility shall monitor data validity.
13. Outreach and Education
- A. Public Outreach and Education

The facility shall engage in public education that includes prevention activities, referral and access to trauma facility resources.
 - B. Professional Outreach and Education

The trauma facility shall engage in professional outreach and education activities that include, at minimum, internal and external trauma-related educational opportunities for physicians, nurses and allied health professionals.
14. Prevention
- A. The facility shall participate in injury prevention. The facility shall provide documentation of the presence of prevention activities that center on priorities based on local data.
 - B. The facility shall demonstrate evidence of a job description and salary support for an injury prevention coordinator who is a separate person from but collaborates with the trauma program manager.
 - C. The trauma service shall develop an injury prevention program that, at a minimum, incorporates the following:
 - (1) Selecting a target injury population,
 - (2) Gathering and analyzing data,
 - (3) Developing evidenced based intervention strategies based on local data and best practices,
 - (4) Formulating a plan,
 - (5) Implementing the program, and
 - (6) Evaluating and revising the program as necessary.
 - D. The facility shall demonstrate collaboration with or participation in national, regional or state injury prevention programs.
 - E. The facility shall have a mechanism to identify patients who may have an alcohol addiction. The facility shall also have the capability to provide an intervention for patients identified as potentially having an alcohol addiction.
 - F. The facility shall collaborate and mentor lower level trauma centers regarding injury prevention.
15. Organ Procurement Activities

- A. The facility shall have an established relationship with a recognized organ procurement organization (OPO).
- B. The facility shall have a written policy for triggering notification of the regional OPO.
- C. The facility shall have written protocols defining clinical criteria and confirmatory tests for the diagnosis of brain death.

16. Disaster Planning and Management

- A. The facility shall meet the Emergency-Management-related requirements of the Joint Commission. These rules incorporate by reference the *2011 Comprehensive Accreditation Manual for Hospitals: The Official Handbook* , effective December 2010.
- B. Such incorporation does not include later amendments to or editions of the referenced material. The Health Facilities and Emergency Medical Services Division of the department maintains copies of the complete text of the incorporated materials for public inspection during regular business hours, and shall provide certified copies of any non-copyrighted material to the public at cost upon request. Information regarding how the incorporated materials may be obtained or examined is available from the Division by contacting:

EMTS Section Chief

Health Facilities and EMS Division

Colorado Department of Public Health and Environment

4300 Cherry Creek Drive South

Denver, CO 80246-1530

These materials have been submitted to the state publications depository and distribution center and are available for interlibrary loan. The incorporated material may be examined at any state publications depository library.

These materials are available for purchase from Joint Commission Resources at WWW.JCRINC.COM .

17. RETAC Integration

The facility shall demonstrate integration and cooperation with its Regional Emergency Medical and Trauma Advisory Council (RETAC). Evidence of such integration may include but is not limited to: attendance at periodic RETAC meetings, participation in RETAC injury prevention activities, participation in RETAC data and or quality improvement projects, etc.

305. Trauma Facility Designation Criteria - Level III

Standards for facilities designated as Level III Trauma Centers - The facility must be licensed as a general hospital.

1. Administration and Organization Criteria. A Level III Trauma Center shall have:

- A. A trauma program with:

- (1) An administrative organizational structure that identifies the institutional support and commitment. The program's location within that structure must be placed so that it may interact with at least equal authority with other departments providing patient care within the facility.
- (2) Medical staff commitment to support the program demonstrated by a written commitment to provide the specialty care needed to support optimal care of the injured patient and specific delineation of surgical privileges.
- (3) Policies that identify and establish the scope of trauma care for both adult and pediatric patients, including but not limited to:
 - a. Initial resuscitation and stabilization;
 - b. Admission and inter-facility consultation and transfer criteria;
 - c. Surgical capabilities;
 - d. Critical care capabilities;
 - e. Rehabilitation capabilities if available;
 - f. Neurosurgical capabilities if available;
 - g. Spinal Cord surgical capabilities if available;
 - h. Other specialist capabilities if available; and
 - i. Written procedure for receipt and transfer of patients by fixed and rotary wing aircraft.
- (4) A Trauma Medical Director who is a board certified general surgeon, or is board qualified working toward board certification. A facility may have another physician as a co-trauma medical director. The Trauma Medical Director:
 - a. Is responsible for service leadership, overseeing all aspects of trauma care, with administrative authority for the hospital trauma program including:
 - i. Trauma multidisciplinary program,
 - ii. Trauma quality improvement program,
 - iii. Provision of recommendations for physician appointment to and removal from the trauma service,
 - iv. Policy and procedure development and enforcement, and
 - v. Peer review.
 - b. Participates on a local or statewide basis in trauma educational activities for healthcare providers or the public.
 - c. Functions as trauma medical director at only one facility.

- d. Participates in the on-call schedule.
 - e. Participates in regional trauma system development.
- (5) A facility defined trauma team, with an identifiable team leader.
- (6) A facility defined trauma team activation protocol that includes who is notified and the response requirements. The protocol shall base activation of the team on the anatomical, physiological, mechanism of injury criteria and co-morbid factors as outlined in the pre-hospital trauma triage algorithms as set forth in 6 CCR 1015-4, Chapter Two.
- (7) A facility defined trauma service with the personnel and resources identified as needed to provide care for the injured patient.
- (8) A registered nurse identified as the Trauma Nurse Coordinator with educational preparation and clinical experience in care of the injured patient as defined by the facility. This position is responsible for the organization of services and systems necessary for a multidisciplinary approach to care of the injured patient.
- (9) Multi-disciplinary trauma committee with specialty representation. This committee is involved in the development of a plan of care for the injured patient and is responsible for trauma program performance. Membership will be established by the facility and attendance requirements established by the committee.
- (10) A quality improvement program as defined in Section 308 of this chapter.
- (11) Divert protocols, to include:
- a. Coordination with the RETAC
 - b. Notification of pre-hospital providers
 - c. Reason for divert
 - d. A method for monitoring times and reasons for going on divert.
- (12) A trauma registry as required in Chapter 1 of these rules, and trauma data entry support,
- (13) Participation in the RETAC and statewide quality improvement programs as required in rule.

B. Hospital departments/divisions/sections

- (1) Surgery
- (2) Emergency Medicine
- (3) Anesthesia

2. A Level III trauma center shall meet all of the following clinical capabilities criteria:
 - A. Emergency Medicine in house 24 hours a day.
 - B. The following service available in person 24 hours a day within 20 minutes of trauma team activation:
 - (1) General surgery. Coverage shall be provided by.
 - a. The attending board certified surgeon or board qualified surgeon working toward certification, who may only take call at one facility at any one time, and
 - b. The surgeon will meet those patients meeting facility defined Trauma Team Activation criteria upon arrival, by ambulance, in the emergency department. For those patients meeting Trauma Team Activation criteria where adequate prior notification is not possible, the surgical response shall be 20 minutes from notification.
 - C. The following services on - call and available within 30 minutes of request by the trauma team leader:
 - (1) Anesthesia. Coverage shall be by:
 - a. A board certified anesthesiologist, or board-qualified anesthesiologist working toward certification, or
 - b. A Certified Registered Nurse Anesthetist (CRNA).
 - (2) Orthopedic surgery. Coverage shall be by:
 - a. A board certified or board qualified orthopedic surgeon working toward certification.
 - D. The following non-surgical specialists on call, credentialed and available in person or by tele-radiology for patient service upon request of the trauma team leader:
 - (1) A radiologist, and
 - (2) Internal medicine.
3. A Level III trauma center shall have all of the following facilities, resources, and capabilities:
 - A. An Emergency Department with:
 - (1) Personnel, to include:
 - a. A designated physician director who is board certified in emergency medicine, family practice, internal medicine, or surgery, and whose primary practice is in emergency medicine.
 - b. Physician(s) designated as member(s) of the trauma team:

- i. Physically present in the Emergency Department 24 hours/day. And who are board certified in emergency medicine, family practice, internal medicine or surgery and
 - ii. Who are Advanced Trauma Life Support verified unless board certified in emergency medicine and
 - iii. Whose primary practice is in emergency medicine.
 - iv. All physicians hired or contracted for services after 2005 must be board certified in emergency medicine or board qualified working toward certification.
 - c. Registered Nurses in-house 24 hours a day who:
 - i. Provide continuous monitoring of the trauma patient until release from the Emergency Department, and
 - ii. At least one Registered Nurse in the Emergency Department 24 hours/day who maintains current verification in Trauma Nurse Core Course or equivalent.
- (2) Equipment for the resuscitation of patients of all ages shall include but not be limited to:
 - a. Airway control and ventilation equipment including laryngoscopes and endotracheal tubes of all sizes, bag mask resuscitators, and oxygen
 - b. Pulse oximetry
 - c. End - tidal CO₂ determination
 - d. Suction devices
 - e. Electrocardiograph-oscilloscope-defibrillator
 - f. Internal paddles - adult and pediatric
 - g. Apparatus to establish central venous pressure monitoring
 - h. Standard intravenous fluids and administration devices, including large bore intravenous catheters
 - i. Sterile surgical sets for:
 - i. Airway control/cricothyrotomy
 - ii. Thorocostomy - needle and tube
 - iii. Thoracotomy
 - iv. Vascular access to include central line insertion and interosseous access
 - v. Peritoneal lavage

- j. Gastric decompression
 - k. Drugs necessary for emergency care
 - l. X-ray availability, 24 hours a day
 - m. Two-way communication with emergency transport vehicles
 - n. Spinal immobilization equipment/cervical traction devices
 - o. Arterial catheters
 - p. Thermal control equipment for:
 - i. Patients
 - ii. Blood and fluids
 - q. Rapid infuser system
 - r. Medication chart, tape or other system to assure ready access to information on proper dose-per-kilogram for resuscitation drugs and equipment sizes for pediatric patients
- B. An operating room available 24/hours a day with:
- (1) Facility defined operating room team on-call and available within 30 minutes of request by trauma team leader,
 - (2) Equipment for all ages shall include, but not be limited to:
 - a. Thermal control equipment for:
 - i. Patients
 - ii. Blood and fluids
 - b. X-ray capability, including c-arm image intensifier
 - c. Endoscope, broncoscope
 - d. Equipment for fixation of long bone and pelvic fractures
 - e. Rapid infuser system
 - f. Equipment for the continuous monitoring of temperature, hemodynamics and gas exchange
- C. Postanesthesia Care Unit (surgical intensive care unit is acceptable) with:
- (1) Registered nurses available within 30 minutes of request, 24 hours a day
 - (2) Equipment for the continuous monitoring of temperature, hemodynamics, and gas exchange

- (3) Thermal control equipment for:
 - a. Patients
 - b. Blood and fluids
- D. Intensive Care Unit for injured patients with:
 - (1) Personnel, to include:
 - a. A director, or co-director who is a surgeon with facility privileges to admit patients to the critical care area, and is responsible for setting policies and oversight of the care related to trauma ICU patients;
 - b. A physician, approved by the trauma director who is available within 30 minutes of notification to respond to the needs of the trauma ICU patient; and
 - c. Registered nurses.
 - (2) Equipment for the continuous monitoring of temperature, hemodynamics and gas exchange.
- E. Radiological Services, available 24 hours a day, with:
 - (1) A radiology technician available within 30 minutes of notification of Trauma Team Activation;
 - (2) A Computed Tomography technician available within 30 minutes of request;
 - (3) Computed tomography (CT); and
 - (4) Ultrasound.
- F. Clinical Laboratory Services, to include:
 - (1) Standard analysis of blood, urine and other body fluids;
 - (2) Blood typing and cross matching;
 - (3) Coagulation studies;
 - (4) Blood and blood components available from in-house, or through community services, to meet patient needs and blood storage capability;
 - (5) Blood gases and pH determination;
 - (6) Microbiology;
 - (7) Serum alcohol and toxicology determination; and
 - (8) A clinical laboratory technician in-house.
- G. Respiratory therapy services, in-house.

- H. Neuro-trauma Management
 - (1) Acute Spinal Cord Management with:
 - a. Neurosurgeons or orthopedic surgeons with special qualifications in acute spinal cord management, on-call and available within a facility defined time of request of the trauma team leader, or
 - b. Written transfer guidelines for patients with spinal cord injuries.
 - (2) Acute Brain Injury Management with a:
 - a. Neurosurgeon on-call and available within 30 minutes of the request of the trauma team leader, or
 - b. Written transfer guidelines for patients with acute brain injuries.
- I. Organized burn care for those patients identified in Section 309 of this chapter, and transfer and consultation guidelines with a burn center as defined in Section 309 of this chapter.
- J. Rehabilitation services with:
 - (1) A physician who is credentialed by the facility to provide leadership for physical medicine and rehabilitation, and
 - (2) Policies and procedures for the early assessment of the rehabilitation needs of the injured patient, and
 - (3) Physical therapy, and
 - (4) Occupational therapy, and
 - (5) Speech therapy, and
 - (6) Social Services; or
 - (7) Transfer guidelines for access to rehabilitation services.
- K. Injury Prevention/Public Education, with:
 - (1) Outreach activities and program development;
 - (2) Information resources for the public; and
 - (3) Facility developed or collaboration with existing national, regional and state programs.
- L. In-house trauma related continuing education, for:
 - (1) Non-physician trauma team members, and
 - (2) Nurses in the Emergency Department and Intensive Care Unit with facility defined competency testing and orientation programs.

- M. CME requirements for surgeons, orthopedic surgeons, emergency physicians, anesthesiologists/CRNA's and neurosurgeons if providing trauma care, to include:
- (1) 10 hours of trauma related, facility defined CME annually or 30 hours over the three-year period preceding any site review,
 - (2) Current Advanced Trauma Life Support verification for all physicians providing emergency department coverage who are not board certified in emergency medicine,
 - (3) Documentation of successful completion of an Advanced Trauma Life Support course for surgeons and all emergency physicians who are board certified in emergency medicine.

306. Trauma Facility Designation Criteria - Level IV

Standards for facilities designated as Level IV Trauma Centers-

The facility must be licensed as one of the following: a general hospital; a community clinic and emergency center (CCEC), and be open 24 hours a day, 365 days a year; or a critical access hospital (CAH) and be open 24 hours a day, 365 days a year with physician coverage for trauma patients arriving by ambulance as described in the clinical capabilities criteria.

1. Administration and Organization Criteria. A Level IV Trauma Center shall have:
 - A. Commitment by administration and medical staff to support the trauma program demonstrated by written commitment from the facility's board of directors, owner/operator, or administrator to provide the required services.
 - B. A written commitment to regional planning and system development activities.
 - C. A trauma program with policies that identify and establish the scope of trauma care for both adult and pediatric patients, including but not limited to:
 - (1) Initial resuscitation and stabilization;
 - (2) Admission criteria;
 - (3) Surgical capabilities if available;
 - (4) Critical care capabilities if available;
 - (5) Rehabilitation capabilities if available; and
 - (6) Written procedure for transfer of patients by fixed and rotary wing aircraft.
 - D. A physician designated by the facility as the Trauma Medical Director who takes responsibility for the trauma program. Responsibilities include:
 - (1) Participation in trauma educational activities for healthcare providers or the public;
 - (2) Leadership for the trauma program and oversight of the trauma quality improvement process; and

- (3) Administrative authority for the trauma program, including, recommendations for trauma privileges, policy and procedure enforcement, and peer review.
- E. A facility defined trauma team activation protocol that includes who is notified and the response expectations. The protocol shall base activation of personnel on anatomical, physiological, mechanism of injury criteria and co-morbid factors as outlined in the prehospital trauma triage algorithms as set forth in 6 CCR 1015-4, Chapter Two.
- F. A defined method of activating trauma response personnel consistent with the scope of trauma care provided by the facility.
- G. A staff person identified as the Trauma Coordinator with clinical experience in care of the injured patient, who is responsible for coordination of the trauma program functions.
- H. An identified multidisciplinary committee involved in the development of a plan of care for the injured patient and is responsible for trauma program performance. Membership will be established by the facility and the committee will establish attendance.
- I. A quality improvement program as defined in Section 308 of this chapter.
- J. Divert protocols, to include:
 - (1) Coordination with the Regional Emergency Medical and Trauma Advisory Council
 - (2) Notification of pre-hospital providers
 - (3) Reason for divert
 - (4) A method for monitoring times and reasons for going divert.
- K. Interfacility transfer criteria/guidelines as a transferring facility (if applicable).
- L. Interfacility transfer policies and protocols.
- M. Participation in the state trauma registry as required in Chapter 1.
- N. Participation in the RETAC and statewide quality improvement programs as required in rule.
- O. If licensed as a Community Clinic with Emergency Care (CCEC):
 - (1) A central log on each trauma patient/individual presenting with an emergency condition who comes seeking assistance and whether he or she refused treatment, was refused treatment, or whether the individual was transferred, admitted and treated, died, stabilized and transferred, or discharged.
 - (2) A policy requiring the provision of a medical screening of all individuals with trauma related emergencies that come to the clinic and request an examination or treatment. The policy shall not delay the provision of a medical screening in order to inquire about an individuals' method of payment or insurance status.
 - (3) Provide further medical examination and such treatment as may be required to stabilize the traumatic injury within the staff and facility's capabilities available at the clinic, or to transfer the individual. The transferring clinic must provide the

medical treatment, within its capacity, which minimizes the risk to the individual, send all pertinent medical records available at the time of transfer, effect the transfer through qualified persons and transportation equipment, and obtain the consent of the receiving trauma center.

2. A Level IV trauma center shall meet all of the following clinical capabilities criteria:
 - A. The physician must be present in the emergency department at the time of arrival of the trauma patient meeting facility defined Trauma Team Activation criteria, arriving by ambulance. For those patients where adequate prior notification is not possible, the emergency physician shall be available within 20 minutes of notification.
3. A Level IV trauma center shall have all of the following facilities, resources, and capabilities:
 - A. An Emergency Department with:
 - (1) Physicians who are credentialed by the facility to provide emergency medical care and maintain current Advanced Trauma Life Support (ATLS) verification.
 - (2) Registered nurses who provide continuous monitoring of the trauma patient until release from the ED. At least one registered nurse in house 24 hours a day who maintains current Trauma Nurse Core Course verification or equivalent
 - (3) Equipment for the resuscitation of patients of all ages shall include but not limited to:
 - a. Airway control and ventilation equipment including laryngoscopes and endotracheal tubes of all sizes, bag mask resuscitators, and oxygen
 - b. Pulse oximetry
 - c. End-tidal CO₂ determination
 - d. Suction devices
 - e. Electrocardiograph-oscilloscope-defibrillator
 - f. Standard intravenous fluids and administration devices, including large bore intravenous catheters
 - g. Sterile surgical sets for:
 - i. Airway control/cricothyrotomy
 - ii. Vascular access to include central line insertion and interosseous access
 - iii. Thorocostomy - needle and tube
 - h. Gastric decompression
 - i. Drugs necessary for emergency care
 - j. X-ray availability, 24 hours a day

- k. Two-way communication with emergency transport vehicles
 - l. Spinal immobilization equipment
 - m. Thermal control equipment for patients and fluids
 - n. Medication chart, tape or other system to assure ready access to information on proper dose-per-kilogram for resuscitation drugs and equipment sizes for pediatric patients
- B. If an operating room and/or intensive care unit are utilized for the trauma patient, there must be policies that identify and define the scope of care that include the supervision, staffing and equipment requirements that the facility will utilize.
- C. Radiological capabilities available 24 hours a day with a radiology technician or person with limited certification in x-ray available within 30 minutes of notification of trauma team activation.
- D. Clinical laboratory services available 24 hours a day. A spun hematocrit, dip urinalysis and the ability to collect blood samples to be sent with transferred patients must be available.
- E. Participates in local/regional/statewide Injury Prevention/Public Education.
- F. Continuing education for all physicians providing trauma care, with:
 - (1) Current ATLS, and
 - (2) 10 hours of trauma related facility defined CME annually or 30 hours over the 3 year period preceding any site review.
- G. Facility defined, trauma related continuing medical education requirements for nurses.

307. Trauma Facility Designation Criteria - Level V

Standards for facilities designated as Level V Trauma Centers - The facility must be licensed as a general hospital, a community clinic and emergency center (CCEC) or a critical access hospital (CAH).

1. Administration and Organization Criteria. A Level V Trauma Center shall have:
 - A. Commitment by administration and medical staff to support the trauma program as demonstrated by written commitment from the facility's Board of Directors, owner/operators, or administrator to provide the required services.
 - B. A written commitment to regional planning and system development activities.
 - C. A trauma program with policies that identify and establish the scope of trauma care for both adult and pediatric patients, including but not limited to:
 - (1) Initial resuscitation and stabilization;
 - (2) Admission criteria;

- (3) Hours of operation. If the facility is not open 24 hours a day, the services as defined in the scope of trauma service policy shall include after-hours plan for availability of services; and
 - (4) Critical care capabilities if available;
 - (5) Rehabilitation capabilities if available; and
 - (6) Written procedure for transfer of patients by fixed and rotary aircraft.
- D. A physician designated by the facility as the Trauma Medical Director who takes responsibility for the trauma program. Responsibilities include:
 - (1) Participation in trauma educational activities for healthcare providers or the public;
 - (2) Leadership for the trauma program and oversight of the trauma quality improvement process; and
 - (3) Administrative authority for the trauma program, including recommendations for trauma privileges, policy and procedure enforcement, and peer review.
- E. A facility defined trauma team activation protocol that includes who is notified and the response expectations. The protocol shall base activation of personnel on anatomical, physical, mechanism of injury criteria and co-morbid factors as outlined in the prehospital trauma triage algorithms as set forth in 6 CCR 1015-4, Chapter Two.
- F. A defined method of activating trauma response personnel consistent with the scope of trauma care provided by the facility.
- G. A staff person identified as the Trauma Coordinator with clinical experience in care of the injured person, who is responsible for coordination of the trauma program functions.
- H. An identified multidisciplinary committee involved in the development of a plan of care for the injured patient and is responsible for trauma program performance. Membership will be established by the facility and the committee will establish attendance.
- I. A quality improvement program as defined in Section 308 of this chapter.
- J. Divert protocols, to include:
 - (1) Coordination with the Regional Emergency Medical and Trauma Advisory Councils (RETACs)
 - (2) Notification of prehospital providers
 - (3) Reason for divert
 - (4) A method for monitoring times and reasons for going on divert.
- K. Interfacility transfer criteria/guidelines as a transferring facility (if applicable).
- L. Interfacility transfer policies and protocols.
- M. Participation in the state trauma registry as required in Chapter 1.

- N. Participation in the RETAC and statewide quality improvement programs as required in rule.
 - O. If licensed as a Community Clinics with Emergency Care (CCEC):
 - (1) A central log on each trauma patient/individual presenting with an emergency condition who comes seeking assistance and whether he or she refused treatment, was refused treatment, or whether the individual was transferred, admitted and treated, died, stabilized and transferred, or discharged.
 - (2) A policy requiring the provision of a medical screening of all individuals with trauma related emergencies that come to the clinic and request an examination or treatment. The policy shall not delay the provision of a medical screening in order to inquire about an individuals' method of payment or insurance status.
 - (3) Provide further medical examination and such treatment as may be required to stabilize the traumatic injury within the staff and facility's capabilities available at the clinic, or to transfer the individual. The transferring clinic must provide the medical treatment, within its' capacity, which minimizes the risk to the individual, send all pertinent medical records available at the time of transfer, effect the transfer through qualified persons and transportation equipment, and obtain the consent of the receiving trauma center.
2. A Level V trauma center shall meet all of the following clinical capabilities criteria:
- A. The physician must be present in the emergency department at the time of arrival of the trauma patient meeting facility defined Trauma Team Activation criteria, arriving by ambulance. For those patients where adequate prior notification is not possible, the emergency physician shall be available with 20 minutes of notification.
3. A Level V trauma center shall have all of the following facilities, resources, and capabilities:
- A. Emergency Department with:
 - (1) Physicians who are credentialed by the facility to provide emergency medical care and maintain current Advanced Trauma Life Support (ATLS) verification.
 - (2) Registered nurses who provide continuous monitoring of the trauma patient until release from the emergency department. At least one RN in house during hours of operation that maintains current Trauma Nurse Core Course verification or equivalent.
 - (3) Equipment for resuscitation of patients of all ages, including but not limited to:
 - a. Airway control and ventilation equipment including laryngoscopes and endotracheal tubes of all sizes, bag mask resuscitators, and oxygen;
 - b. Pulse oximetry;
 - c. End-tidal CO₂ determination;
 - d. Suction devices;
 - e. Electrocardiograph-oscilloscope-defibrillator;

- f. Standard intravenous fluids and administration devices; including large bore intravenous catheters;
 - g. Sterile surgical sets for:
 - i. Airway control/cricothyrotomy
 - ii. Vascular access to include central line insertion and I/O access
 - iii. Thoracostomy- needle and tube
 - h. Gastric decompression;
 - i. Drugs necessary for emergency care;
 - j. X-ray availability
 - k. Two way communication with emergency transport vehicles
 - l. Spinal immobilization equipment
 - m. Thermal control equipment for patients/fluids
 - n. Medication chart, tape or other system to assure ready access to information on proper dose-per-kilogram for resuscitation drugs and equipment sizes for pediatric patients
- B. If an operating room and/or intensive care unit are utilized for the trauma patient, there must be policies that identify and define the scope of care that include the supervision, staffing and equipment requirements that the facility will utilize.
- C. Radiological capabilities available during hours of operation with a radiology technician or person with limited certification in x-ray available within 30 minutes of notification of trauma team activation.
- D. Clinical laboratory services available during hours of operation. A spun hematocrit, dip urinalysis and the ability to collect blood samples to be sent with transferred patients must be available.
- E. Participates in local/regional/statewide Injury Prevention/Public Education.
- F. Continuing education for physicians providing trauma care, with:
- (1) Current ATLS, and
 - (2) 10 hours of trauma related facility defined CME annually or 30 hours over the 3 year period preceding any site review.
- G. Facility defined, trauma related continuing medical education requirements for nurses.

308. Trauma Quality Improvement Programs for Designated Trauma Centers Levels 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. 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. Burn Unit Referral Criteria

A burn unit may treat adults or children or both. The attending surgeon at a burn unit shall be consulted for any of the following burn injuries:

1. Partial thickness burn greater than 10% total body surface area (TBSA).
2. Burns that involve the face, hands, feet, genitalia, perineum, or major joints.
3. Third-degree burns in any age group.
4. Electrical burns, including lightning injury.
5. Chemical burns.
6. Inhalation injury.
7. Burn injury in patients with pre-existing medical disorders that could complicate management, prolong recovery, or affect mortality.
8. Any patients with burns and concomitant trauma (such as fractures) in which the burn injury poses the greatest risk of morbidity or mortality. In such cases, if the trauma poses the greater immediate risk, the patient may be initially stabilized in a trauma center before being transferred to a burn unit. Physician judgment will be necessary in such situations and should be in concert with the regional medical control plan and triage protocols.
9. Burned children in hospitals without qualified personnel or equipment for the care of children.
10. Burn injury in patients who will require special social, emotional, or long-term rehabilitative intervention.

310. Facility Designation Criteria - Regional Pediatric Trauma Centers

1. Administration and organization criteria. A Regional Pediatric Trauma Center as defined in Section 25-3.5-703(4)(f) C.R.S. shall have a trauma program with:
 - A. An administrative organizational structure which identifies the institutional support and commitment. The program's location within that structure must be placed so that it may interact with at least equal authority with other departments providing patient care within the facility.
 - B. Medical staff commitment to support the program demonstrated by a written commitment to provide the specialty care needed to support optimal care of the injured patient and specific delineation of surgical privileges.
 - C. A Trauma Medical Director who is a board certified pediatric surgeon, credentialed by the facility for pediatric trauma care.
 - D. A facility defined Trauma Team, with an identifiable team leader.
 - E. A facility defined Trauma Team activation protocol. The protocol shall base activation of the team on the anatomical, physiological, mechanism of injury, and co-morbid factors as outlined in the pediatric prehospital trauma triage algorithms as set forth in 6 CCR 1015-4, Chapter Two.
 - F. A facility defined trauma service comprised of the personnel and resources identified as needed to provide care for the injured patient. All multi-system trauma patients shall be admitted to this service. The Trauma Medical Director shall direct the service and the cadre of residents or other allied health personnel assigned to that service at any given time.
 - G. A full time registered nurse identified as the Trauma Program Manager, with educational preparation, verification, and clinical experience in care of the injured as defined by the facility. This position is responsible for the organization of services and systems necessary for a multidisciplinary approach to care of the injured patient
 - H. A multi-disciplinary Trauma Committee with specialty representation. This committee is involved in the development of a plan of care for the injured patient and is responsible for trauma program performance.
 - I. A multidisciplinary Peer Review Committee as defined by the facility. This committee is responsible for monitoring compliance to the facility defined clinical and system standards of care for trauma patients.
 - J. Hospital departments/divisions/sections
 - (1) General Pediatric Surgery;
 - (2) Neurological Surgery;
 - (3) Orthopedic Surgery;
 - (4) Emergency Medicine; and
 - (5) Anesthesia.

K. Support services/ancillary services, with policies and procedures for access to:

- (1) Chemical dependency services;
- (2) Child and adult protection services;
- (3) Clergy or pastoral care;
- (4) Nutritionist services;
- (5) Occupational therapy services;
- (6) Pediatric therapeutic recreation;
- (7) Pharmacy, with a in-house pharmacist;
- (8) Physical therapy services;
- (9) Psychological services;
- (10) Rehabilitation services;
- (11) Social services; and
- (12) Speech therapy services.

2. Clinical capabilities criteria

A. The following services in house and available 24 hours a day with:

- (1) Pediatric surgery within five minutes of Trauma Team activation. Coverage shall be provided by:
 - a. an attending board certified pediatric surgeon credentialed by the facility for pediatric trauma care who may only take call at one facility at any one time or have a published backup call schedule; or
 - b. a post graduate year four (PGY4) or above surgical resident may initiate evaluation and treatment upon the patient's arrival until the arrival of the attending surgeon. In this case, the attending surgeon shall be available within 20 minutes of request by the resident,
- (2) Pediatric neurosurgery. Coverage shall be provided by:
 - a. the attending board certified neurosurgeon, who may only take call at one facility at any one time or have a published backup call schedule; or
 - b. a surgeon who has been judged competent by the chief of neurosurgery to initiate measures to stabilize the patient and initiate diagnostic procedures. In this case, the attending neurosurgeon shall be available within 30 minutes of notification or request by the Trauma Team leader,
- (3) Pediatric anesthesiology. Coverage shall be provided by:

- a. a board certified anesthesiologist in the O.R. at time of arrival of the patient; and
 - b. a chief resident or fellow within 5 minutes of request by the Trauma Team leader,
 - (4) Pediatric emergency medicine. Coverage shall be provided by:
 - a. a physician board certified in pediatric emergency medicine; or
 - b. a physician in a pediatric emergency medicine fellowship at PGY5 level or higher; or
 - c. a physician having completed pediatric emergency medicine training within the past five years.
 - B. The following surgical services on-call and present within 30 minutes of request by the Trauma Team leader:
 - (1) Cardio/thoracic surgery;
 - (2) Ophthalmic surgery;
 - (3) Oral/maxillofacial/ENT surgery;
 - (4) Orthopedic surgery with a board certified orthopedic surgeon, who may only take call at one facility at any one time or have a published backup call schedule; and
 - (5) Urologic surgery.
 - C. The following non-surgical and surgical specialties including:
 - (1) A pediatric radiologist on call and available for patient service within 30 minutes of request by the Trauma Team leader,
 - (2) The following services on call and available for patient consultation or management:
 - a. cardiology;
 - b. infectious disease;
 - c. hand surgery,
 - d. microvascular surgery;
 - e. plastic surgery;
 - f. pulmonary medicine;
 - g. nephrology; and
 - h. hematology.
3. Facilities/resources/capabilities criteria

- A. An emergency department with:
- (1) Personnel, to include:
 - a. a designated physician director who is board certified in pediatric emergency medicine;
 - b. physician(s) designated as a member of the Trauma Team, physically present in the Emergency Department 24 hours a day, who:
 - i. are board certified in pediatric emergency medicine; or
 - ii. are in a pediatric emergency medicine fellowship at PGY5 level;
 - iii. or have completed pediatric emergency medicine training within the past five years.
 - c. registered nursing personnel who provide continuous monitoring of the trauma patient until release from the Emergency Department, who have successfully completed a Trauma Nurse Core Course (TNCC) or equivalent course, and a Pediatric Advanced Life Support (PALS) course,
 - (2) Equipment for the resuscitation of patients of all ages shall include but not be limited to:
 - a. airway control and ventilation equipment including laryngoscopes and endotracheal tubes of all sizes, bag mask resuscitators, and oxygen;
 - b. pulse oximetry;
 - c. end-tidal CO₂ determination;
 - d. suction devices;
 - e. electrocardiograph-oscilloscope-defibrillator with internal paddles - adult and pediatric;
 - f. apparatus to establish central venous pressure monitoring;
 - g. standard intravenous fluids and administration devices, including large bore intravenous catheters;
 - h. sterile surgical sets for:
 - i. airway control/cricothyrotomy;
 - ii. thoracostomy needle and tube;
 - iii. thoracotomy;
 - iv. vascular/intraosseous access;
 - v. peritoneal lavage;

- vi. central line insertion; and
- vii. ICP monitoring equipment.
- i. gastric decompression;
- j. drugs necessary for emergency care;
- k. X-ray availability, 24 hours a day;
- l. two-way communication with emergency transport vehicles;
- m. spinal immobilization equipment;
- n. arterial catheters;
- o. thermal control equipment for:
 - i. patients; and
 - ii. blood and fluids.
- p. rapid infuser system; and
- q. length-based emergency tape (LBET).
- (3) Protocols/procedures for management of the injured child in the emergency department.

B. An operating room available within 30 minutes of request 24 hours a day with:

- (1) Facility-defined operating room team in-house and available within 10 minutes of request of Trauma Team leader,
- (2) Equipment for all ages shall include, but not be limited to:
 - a. cardiopulmonary bypass capability;
 - b. operating microscope and microinstruments;
 - c. thermal control equipment for:
 - i. patients; and
 - ii. blood and fluids.
 - d. x-ray capability, including C-arm image intensifier;
 - e. endoscopes;
 - f. craniotomy instruments;
 - g. equipment for fixation of long bone and pelvic fracture; and
 - h. equipment for spinal immobilization and instrumentation.

- C. Postanesthesia Care Unit (surgical intensive care unit is acceptable) with:
 - (1) Registered nurses available within 30 minutes of request 24 hours a day;
 - (2) Equipment for the continuous monitoring of temperature, hemodynamics, gas exchange and intracranial pressure;
 - (3) Thermal control equipment for:
 - a. patients; and
 - b. blood and fluids,
 - (4) Compartmental pressure monitoring equipment.
- D. Intensive care unit for injured patients with:
 - (1) Personnel, to include:
 - a. a surgical director, who:
 - i. is responsible for setting policies and administration related to pediatric trauma ICU patients; and
 - ii. has obtained critical care training during residency or fellowship and has expertise in the perioperative and post injury care of the injured child.
 - b. a physician, credentialed in pediatric critical care, or a pediatric intensivist, approved by the Trauma Medical Director, who is in the hospital and available within 30 minutes of notification.
 - c. registered nurses with facility-defined trauma education program.
 - (2) Equipment for monitoring and resuscitation, to include: intracranial pressure monitoring, compartment pressure monitoring, and continuous monitoring of temperature, hemodynamics, and gas exchange.
- E. Acute hemodialysis available in house.
- F. Radiological services, available 24 hours a day to the trauma patient, with:
 - (1) The following technicians:
 - a. in-house radiology technician available within 10 minutes of notification; and
 - b. in-house CT technician available within 10 minutes of notification.
 - (2) The following services:
 - a. MRI, on site without vehicular transfer of the patient;
 - b. angiography;

- c. sonography;
 - d. computed tomography (CT); and
 - e. interventional radiology.
- (3) Physician and technical support staff for the services identified above shall be in-house or available within 30 minutes.
- G. Clinical laboratory services, to include:
 - (1) Standard analysis of blood, urine, and other body fluids;
 - (2) Blood typing and cross matching;
 - (3) Coagulation studies;
 - (4) Blood and blood components available from in-house, or through community services, to meet patient needs and blood storage capability;
 - (5) Blood gases and pH determination;
 - (6) Microbiology;
 - (7) Serum alcohol and toxicology determination; and
 - (8) Clinical laboratory technician available in house.
- H. Respiratory therapy services, in house.
- I. Acute spinal cord management, with surgeons capable of addressing acute spinal cord injury, and with protocols/procedures to address early assessment of the spinal cord injured patient for management or transfer.
- J. Organized burn care for those patients identified in Section 309 of this chapter with:
 - (1) Specialty designation as a burn center; or
 - (2) Transfer agreements with a facility with a specialty designation as a burn center.
- K. Rehabilitation services, with:
 - (1) Leadership of the service by a physician who is a physiatrist or who specializes in orthopedic or neurologic rehabilitation, and
 - a. protocols/procedures for the early assessment of the rehabilitation needs of the injured child;
 - b. physical therapy;
 - c. occupational therapy;
 - d. speech therapy; and
 - e. social services.

- L. Outreach program, with telephone and on-site consultations with physicians of the community and outlying areas regarding pediatric trauma care.
- M. Injury prevention/public education, with:
 - (1) Injury prevention with:
 - a. a designated prevention coordinator;
 - b. outreach activities and program development;
 - c. information resources for the public; and
 - d. collaboration with existing national, regional, and state programs.
 - (2) Injury control research, which may include:
 - a. collaboration with other facilities in prevention research;
 - b. monitoring progress/effect of prevention programs; and
 - c. special surveillance project/data collection projects.
- N. Trauma research program, with:
 - (1) A designated director;
 - (2) Regular meetings of the research group;
 - (3) Evidence of productivity, to include:
 - a. proposals reviewed by an Internal Review Board (IRB);
 - b. presentations at local/regional/national meetings;
 - c. publications in peer-reviewed journals; and
 - d. peer-reviewed extramural funding for research activities.
- O. Continuing medical education (CME), with
 - (1) In-house CME for:
 - a. staff physicians;
 - b. nurses;
 - c. allied health personnel; and
 - d. community physicians.
 - (2) Physician CME requirements for emergency medicine, trauma surgery, orthopedics, and neurosurgery -16 hours CME annually or 48 hours over 3 years, with half outside own facility.

- (3) Nursing CME requirements for emergency department and ICU - 8 hours annually or 24 hours over 3 years.
- P. Organ/tissue procurement protocols/procedures.
- Q. Trauma divert protocols, to include:
 - (1) A method to report trauma diverts to the Regional Emergency Medical and Trauma Advisory Council (RETAC) for monitoring;
 - (2) A method for notification of prehospital providers when on divert;
 - (3) Facility defined criteria for going on divert, not to exceed those identified in the definition section of this chapter; and
 - (4) A method for monitoring times and reasons for going on divert.
- R. Trauma transfer agreements as a transferring and receiving facility, renewed every 3 years.
- S. Interfacility consultation protocols/procedures for attending surgeon availability for responding to mandatory consultations and arranging transfers from Level I, II, III, IV, and non-designated trauma centers.
- T. A trauma registry as required in 6 CCR 1015-4, Chapter 1 and trauma data entry support.
- U. A performance improvement process in accordance with Section 303.3.A of this chapter.
- V. Participation in RETAC quality improvement programs established in accordance with 6 CCR 1015-4, Chapter Two.

CHAPTER FOUR - REGIONAL EMERGENCY MEDICAL AND TRAUMA ADVISORY COUNCILS

400. In order to ensure effective system development and regional emergency medical and trauma planning, all regions must comply with the following minimum standards and planning regulations.

401. Definitions. As used in this article, unless the context otherwise requires:

- 1. "Biennial Plan" - A regional emergency medical and trauma services system plan that shall be in a format specified by the Council and the Department, and submitted to the Council for approval every other year on July 1, beginning July 1, 2003.
- 2. "City and County" - A city that shares the same boundaries as the county it resides in.
- 3. "Continuing Quality Improvement" - The ongoing issue of improving the quality of the regional emergency medical and trauma services system.
- 4. "Council" - The State Emergency Medical and Trauma Services Advisory Council created in section 25-3.5-104
- 5. "Department" - The Colorado Department of Public Health and Environment
- 6. "EMTS System" - Emergency Medical and Trauma Services System.

7. "Financial Report" - A regional financial accounting in a format specified by the Council and the Department that details the expenditure of money received.
8. "Key Resource Facility" – A Level I or II certified trauma facility that provides consultation and technical assistance to a RETAC, regarding education, quality, training, communication, and other trauma issues described in CRS 25-3.5 Part 7 that relate to the development of the Statewide Trauma Care System.
9. "RETAC" - Regional Emergency Medical and Trauma Advisory Council – 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.
10. "SEMTAC" - The State Emergency Medical and Trauma Services Advisory Council

402. Organizational Requirements

- A. On or before July 1, 2002, the governing body of each county or city and county throughout the state shall establish a RETAC, with the governing body of four or more counties, or with the governing body of a city and county, to form a multicounty RETAC.
- B. County government from the counties comprising each RETAC shall determine how members are selected.
- C. Membership shall reflect, as equally as possible, representation between hospital and prehospital providers, and from each participating county, and city and county.
- D. There shall be at least one member from each participating county and city and county in the RETAC.
- E. The participating counties shall define the number of members on the RETAC.
- F. Each RETAC shall meet a minimum of four times per year.
- G. After the appointment of members to the RETAC, the RETAC shall establish By-laws, which includes responsibilities and other pertinent matters concerning the structure and operations of the organization. A chairperson shall be elected and that person or his/her designee shall serve as the liaison for the region's communications with the Department.
- H. RETACs must be comprised of counties that are contiguous.
- I. At least seventy-five percent of the council membership must reside in, or provide health care services within the region.
- J. Each RETAC must identify one or more key resource facilities for the region. The key resource facility shall provide consultation and technical assistance to the RETAC in resolving trauma, medical, and age specific care issues that arise in the region, and in coordinating patient destination and inter-facility transfer policies to assure that patients are transferred to the appropriate facility for treatment in or outside of the region.
- K. Each region shall utilize designated staff to manage the day-to-day business of the RETAC, and provide administrative support and technical assistance to the council as it carries its statutory obligations.

403. Operational Requirements

- A. RETACs must establish continuing quality improvement plans with goals, system-monitoring protocols, and periodically assess the quality of their emergency medical and trauma system. The regional continuous quality improvement system plan shall be utilized in evaluating the effectiveness of the regional EMTS systems as defined elsewhere in the rules pertaining to the Statewide Emergency Medical and Trauma Care System.
- B. RETACs shall coordinate with the Department and local health departments in developing and implementing regional injury prevention, public information, and educational programs promoting the development of the EMTS system. These programs should include, but not be limited to, a pediatric injury prevention and public awareness component.
- C. RETACs must provide technical assistance and serve as a resource, and to the extent possible, integrate the provision of emergency medical and trauma services with other local, state, and federal agency disaster plans.
- D. Regional Patient Destination Protocols
(Reserved)
- E. RETACs must comply with Board of Health regulation 4 of the rules and regulations pertaining to preparations for a bioterrorism event, pandemic influenza, or an outbreak by a novel and highly infectious agent or biological toxin.

404. Waivers

- A. The Department may grant waivers from one or more standards of these rules, to the extent not contrary to statute, based on a waiver review process reviewed and approved by SEMTAC and adopted by the Department.

405. Annual Financial Report

(Reserved)

406. RETAC EMTS System Biennial Plan Requirements

Beginning July 1, 2003 and every odd numbered year thereafter on July 1, each Regional Emergency Medical and Trauma Advisory Council, with the approval from the governing bodies for the RETAC, must prepare a regional emergency medical and trauma services system plan to create and maintain coordinated, integrated emergency medical and trauma system services throughout the region. The Department shall provide technical assistance to any RETAC for preparation, implementation, and modification of the plan. This plan shall be submitted to SEMTAC for evaluation and recommendations for approval to the Department. The plan will be in a format specified by the Department with advice from SEMTAC. If the RETAC fails to submit a plan, does not include a county or city and county within their region in the plan, or the plan is not approved through the evaluation process established by the council, the Department shall design a plan for the RETAC. This plan, referred to hereafter as the Biennial Plan, shall be comprised of fifteen components. The components are listed below. Each component, at a minimum, shall address the current level of activity within that component. The RETAC should develop their plan based on data collected from sources such as, but not limited to, county plans, EMS Council plans, agency profiles, financial reports and strategic planning documents. Every RETAC plan shall provide the following:

- A. The plan shall identify the needs of the region to provide minimum services to sick and injured patients at the most appropriate facility. Needs shall be based on but not limited to the following factors:

1. Transfer agreements and protocols used by facilities to move patients to higher levels of care.
 2. Facility defined triage and transport plans to be developed by all facilities within the RETAC.
 3. Geographical barriers to the transportation of patients.
 4. Population density challenges to providing care.
 5. Out of hospital resources within the region for the treatment and transportation of sick and injured persons.
 6. Accessibility to Department designated facilities within and outside the region
- B. The plan shall describe the commitment of each of the member counties or city and counties. Commitment includes but may not be limited to:
1. Cooperation among county and local organizations in the development and implementation of the statewide EMTS system.
 2. Participation and representation within the RETAC.
 3. Dedicated financial and in-kind resources for regional systems development.
 4. Cooperation among county and local organizations in the development and implementation of a coordinated statewide communications system.
- C. The plan shall include the description of processes used to ensure facilities, agencies, counties, and city and counties adherence to the RETAC EMTS plan. Processes shall include but not be limited to:
1. A compliance reporting process as defined by SEMTAC and the Department.
 2. A continuing quality improvement system as defined by SEMTAC and the Department.
- D. The plan shall include a description of public information, education, and prevention programs used within the region to reduce illness and injury.
- E. The plan shall describe any functions of the RETAC accomplished through contracted services.
- F. The plan shall identify any needs of the RETAC EMTS system through the use of a needs assessment instrument. The needs assessment instrument used by the RETAC must be approved by the RETAC member counties and city and counties. Needs assessment instruments must be approved by or supplied by the Department.
- G. The plan shall include a description of the following communication issues:
1. Communication method in place to ensure citizen access to emergency medical and trauma services through the 911 telephone system or its local equivalent.
 2. Primary communication method for dispatch of personnel who respond to provide prehospital care.

3. Communication methods used between ambulances and other responders and between ambulances and designated and undesignated facilities.
4. Communication methods used among trauma facilities and between facilities and other medical care facilities.
5. Communication methods used among service agencies to coordinate prehospital and day-to-day requests for service.
6. Communication methods used within and between the RETAC to coordinate service during multicasualty events (interoperability).

H. The plan components shall include:

1. Integration of Health Services - Activities to improve patient care through collaborative efforts among health related agencies, facilities and organizations within the region. The desired outcome of this component is to improve the system by encouraging groups involved in EMTS to work with other entities (e.g. health related, state, local and private agencies and institutions) to share expertise, to evaluate and make recommendations, and mutually address and solve problems within the region.
2. EMTS Research - Determines the effectiveness and efficiency of the EMTS system through scientific investigation. A continuous and comprehensive effort to validate current EMTS system practices in an effort to improve patient care, determine the appropriate allocation of resources and prevent injury and illness and ultimately death and disability.
3. Legislation and Regulation - Issues related to legislation, regulation and policy that affects all components of the EMTS system. This component defines the level of authority and responsibility for system planning, implementation and evaluation.
4. System Finance - Defines the financial resources necessary to develop and maintain a quality EMTS system.
5. Human Resource - The acquisition of knowledge and skills, recruitment and retention of providers are priorities for a quality EMTS system.
6. Education Systems - Includes the education and training of all providers within the EMTS system and includes efforts to coordinate and evaluate programs to ensure they meet the needs of the EMTS system.
7. Public Access - Includes all means by which users can access the system (9-1-1). This component also includes the provision of pre-arrival instructions provided by emergency medical dispatchers.
8. Evaluation - A process of assessing the attributes (system integration and components) of the EMTS system to ensure that continual improvement can be designed and implemented.
9. Communications System - The efficient transfer of information by voice and data occurring between dispatch centers, EMTS providers, physicians, facilities, public safety agencies and patients seeking care through emergency medical dispatch. Includes EMTS system communications interoperability within and outside the region for multicasualty incidents.

10. Medical Direction - Supervision and direction of patient care within the EMTS system by qualified and authorized physicians, including the medical communities involvement in maintaining quality of care through accepted standards of medical practice and through innovation.
11. Clinical Care - Clinical methods, technologies and delivery systems utilized in providing EMTS in and out of the hospital. Includes emerging community health services, rescue services and mass casualty management.
12. Mass Casualty - Defines the responsibility and authority for planning, coordination and infrastructure for all medical care during incidents where the normal capacity to respond is exceeded.
13. Public Education - Includes the public's involvement in learning experiences to promote and encourage good health and reduce morbidity and mortality.
14. Prevention - Solutions designed through data collection and analysis, education and intervention strategies to reduce morbidity and mortality related to intentional and unintentional injury and illness
15. Information Systems - The collection of data and analysis as a tool to monitor and evaluate the EMTS system. Information systems are key to providing a means of improving the effectiveness and integration of healthcare delivery.

406.1

RETACs must submit their Biennial Plan to SEMTAC on or before July 1, 2003 and every odd numbered year by July 1. If the plan is found to be inadequate, it will be returned to the RETAC with recommendations for revisions. The revised plan shall be submitted to the Council by September 14th. If the revised plan is not approved, the Department will design a plan for the RETAC. Plan submissions must occur by the dates stated or the opportunity for further submissions is forfeited.

Editor's Notes

History

Chapters Two and Three eff. 08/30/2007.

Chapter Three eff. 11/30/2008.

Chapter Two eff. 03/02/2011.

Chapter Three eff. 06/30/2011.

Section 303.4.E(1) – (3) eff. 06/14/2014.