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.]

Adopted by the Board of Health on April 15, 2020. Effective June 14, 2020.

CHAPTER ONE – STATE EMERGENCY MEDICAL AND TRAUMA CARE SYSTEM STANDARDS

Index to Sections

100. Definitions

1. Adult – Any patient age 15 and older is considered an adult in the trauma system.

2. Advisory – The trauma facility is experiencing a specific resource limitation.

3. Bypass – EMS transport of a trauma patient past a routinely used or closer receiving facility for the purpose of accessing a higher level of trauma or specialty care.

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

5. Designated – A status that the Department assigns to a health care facility based on the level of trauma services the facility is capable of and committed to providing to injured persons. Designation levels include Levels I through V, as defined in 25-3.5-703(4)(a)-(e), C.R.S., Regional Pediatric Trauma Centers as defined in 25-3.5-703(4)(f), and nondesignated facilities.

6. Disaster Medical Care – Medical care provided during the occurrence or imminent threat of widespread or severe damage, injury, illness, or loss of life resulting from an epidemic or a natural, man-made, technological, or other cause.

7. Divert Status – The facility cannot currently accept EMS traffic. EMS shall transport trauma patients to an alternative designation in accordance with the prehospital trauma triage algorithm.

8. Facility – For purposes of these rules, any designated health care facility, Regional Pediatric Trauma Center (RPTC), or nondesignated health care facility.

9. Interfacility Transfer – The movement of a trauma patient from one licensed health care facility participating in the trauma system to another licensed health care facility participating in the trauma system.

10. Nondesignated – A facility that has not met the criteria of Levels I-V or RPTC, but that receives and is accountable for injured persons, including having a transfer agreement to transfer persons to Level to V or RPTC facilities as set forth in Section 25-3.5-703(4)(a.5)-(f), C.R.S. and these rules. “Nondesignated” is considered a designation level pursuant to Section 25-3.5-703(4)(a), C.R.S.

11. Pediatric – Any patient from birth through age 14 is considered a pediatric patient in the trauma system.

12. Prehospital Transport – Transport by air or ground ambulance service of a trauma patient to the most appropriate receiving facility consistent with the Regional Emergency Medical and Trauma Services Advisory Council (RETAC) destination protocols and guidelines and the best interest of the patient.

13. Regional Emergency Medical and Trauma Services 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.

14. Trauma Transport Protocols – Written standards adopted by the State Board of Health that address the use of appropriate resources to move trauma victims from one level of care to another on a continuum of care.

15. Trauma Care System – An organized approach to providing quality and coordinated care to trauma victims throughout the state on a twenty-four-hour per day basis by transporting a trauma victim to the appropriate designated facility.

101. Prehospital Care

1. Prehospital Algorithms

   A. Adult patients: Scene transport for adults with trauma or suspected trauma shall be in accordance with national best practice guidelines, the algorithm found in Exhibit A of these rules, and applicable RETAC protocols.

   B. Pediatric patients: Scene transport for pediatric patients with trauma or suspected trauma shall be in accordance with national best practice guidelines, the algorithm found in Exhibit B of these rules, and applicable RETAC protocols.

2. Facility Divert Status

A. Facilities may go on to 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) Internal/external disaster

(7) Lack of equipment/staff necessary to safely and adequately care for the trauma patient.

B. When a trauma center is on divert status, destination of the trauma patient shall be in accordance with the prehospital trauma triage algorithms (Exhibits A and B).

C. Trauma facilities must keep a record of times and reasons for going on divert status for at least 3 years. This information must be made available for RETAC and/or department audit upon request.

D. Trauma facilities must notify impacted EMS agencies and impacted local facilities of divert status in a manner consistent with RETAC protocols.

3. Bypass for Trauma Patients

A. At times, the best interests of the patient and 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 of specialty care.

B. Whether bypass is necessary must initially be determined by the criteria in the algorithms. However, deviations from the algorithms may occur due to the patient's emergency conditions, excessive transport time to the nearest trauma center, specific medical direction, or if it is determined that air transport is the most appropriate option for the patient.

4. Advisory for Trauma Patients

The trauma facility may issue an advisory when it is experiencing specific resource limitations but is able to accept trauma patients who do not require the limited resource. Ambulance agencies are advised to consider transport to other trauma facilities as time and conditions allow for patients impacted by the specific advisory.

102. Transport Protocols

1. When an air or ground ambulance service transports a trauma patient to a receiving facility, its determination of what constitutes the most appropriate receiving facility must conform with:

A. The applicable RETAC plan assessment of regional considerations as required by Chapter Four, 6 CCR 1015-4, Section 405.3.B.(1); and

B. The RETAC trauma destination protocol as required by 6 CCR 1015-4, Chapter Four, Section 406 and Chapter One, Exhibits A and B.

2. Each designated and nondesignated facility shall meet the transfer requirements, including transfer agreements as required by statute and in rule, appropriate to its designation level, as set forth in 6 CCR 1015-4, Chapter Three.

3. Every licensed health care facility that participated in the trauma system shall develop and implement protocols that, at a minimum, address the following components of the trauma system as set forth in 6 CCR 1015-4, Chapter Three:

A. When a patient arrives at a facility, the facility will provide the patient with the appropriate available care based on the patient's injury, which may include stabilization before transferring to a higher level of care or specialty care;

B. If the patient requires a higher level of care or specialty care that is not available, the facility shall transfer the patient as soon as medically feasible to the appropriate facility, which may be in or out of state; and

C. When determining what receiving facility is the most appropriate trauma facility for the injured person, the sending facility shall consider, at a minimum:

(1) Accessibility to the receiving facility by ground or air transport,

(2) Transport time to the receiving facility by ground or air transport,

(3) Treatment options and transport modes that best meet the needs of the patient during ground or air transport, and

(4) Whether the best interests of the patient require the attending physician at the sending facility to exercise his or her discretion to bypass a closer facility.

103. Hospital/Facility Care

Hospital/facility care includes all care provided to the trauma patient in licensed healthcare facilities that are governed by the rules and regulations of 6 CCR 1015-4, Chapter Three and 6 CCR 1015-4, Chapter Four, Section 406.

104. Rehabilitative Care

Each facility shall meet the rehabilitative care requirements appropriate to its designation level, as set forth in 6 CCR 1015-4, Chapter Three.

105. Injury Prevention

Each facility shall meet the injury prevention program requirements appropriate to its designation level, as required by 6 CCR 1015-4, Chapter Three and 6 CCR 1015-4, Chapter Four.

106. Education and Research

Each facility shall meet the requirements pertaining to public information, education, and research (as applicable) appropriate to its designation level, as required by 6 CCR 1015-4, Chapter Three.

107. State Trauma Registry and Epidemiology

Each facility shall meet the State registry requirements appropriate to its designation level, as required by 6 CCR 1015-4, Chapter Two.

108. Disaster Medical Care

1. Each facility must provide trauma patients with appropriate access to disaster medical care to the extent necessary and subject to each facility's capabilities and resources. Facilities shall collaborate with and coordinate their planning and provision of disaster medical care with local, regional, and state emergency medical and trauma organizations, and any other entities involved in disaster response.

2. For purposes of these rules, "Disaster Medical Care" is defined in Section 100.6 of these rules.

109. Trauma Communications

1. Each facility shall meet the trauma communications requirements appropriate to its designation level, as required by 6 CCR 1015-4, Chapter Three.

2. Each RETAC biennial plan shall ensure access to emergency medical and trauma services through the 911 telephone system or its local equivalent, and include adequate provisions for services, as required by 6 CCR 1015-4, Chapter Four.

110. Regional Emergency Medical and Trauma Advisory Councils

1. The rules governing RETACS in the trauma system are set forth in 6 CCR 1015-4, Chapter Four.

2. Each facility shall meet the RETAC requirements as set forth in 6 CCR 1015-4, Chapters Three and Four.

111. Trauma Care for Pediatrics

1. Each facility shall meet the requirements pertaining to the care of pediatric patients that is appropriate to its designation level, as required by 6 CCR 1015-4, Chapter Three.

2. Scene transport, diversion, bypass, and RETAC destination protocols pertaining to pediatric patients shall be in accordance with this chapter and as outlined in Exhibit B.

EXHIBIT A

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

UNABLE TO ADEQUATELY VENTILATE

Yes → **Destination Determined per RETAC Protocol**

No

ANY PHYSIOLOGIC CRITERIA

1. Intubation or assisted ventilation
2. Respiratory rate < 10 or > 29
3. Systolic BP < 90 or < 110 for age 65 plus
4. GCS motor score ≤ 5

Yes → **Destination Determined per RETAC Protocol**

No

ANY ANATOMIC CRITERIA

Known or Suspected:

1. Penetrating injuries to the head, neck, torso, or extremities above the elbow or knee
2. Flail chest (chest wall instability or deformity)
3. Two or more proximal long bone fractures
4. Unstable pelvic fracture
5. Paralysis or neurologic deficit
6. Amputation above the wrist or ankle
7. Crushed, degloved, mangled, or pulseless extremity
8. Open or depressed skull fracture

Yes → **Destination Determined per RETAC Protocol**

No

ANY MECHANISM OF INJURY CRITERIA

1. Falls > 20 feet
2. High risk auto crash, with such components as:
   -Intrusion of vehicle of ≥ 12 inches in occupant compartment; > 18 inches any site
   -Ejection (partial or complete) from automobile
   -Death in same passenger compartment
3. Auto vs. pedestrian/bicyclist thrown, run over, or with significant impact
4. Motorcycle crash > 20 mph
5. Events involving high energy dissipation, such as:
   -Ejection from motorcycle, ATV, animal, etc.
   -Striking a fixed object with momentum
   -Blast or explosion
6. High energy electrical injury

Yes → **Destination Determined per RETAC Protocol**

No

OTHER CONSIDERATIONS

1. Older adult: Risk of death increases after age 55 years
2. Anticoagulation or bleeding disorders
3. End-stage renal disease requiring dialysis
4. Pregnancy > 20 weeks
5. Suspicion of hypothermia
6. Suspicion of abdominal injury or seatbelt sign
7. Burns > 10% TBSA (2nd or 3rd degree) and/or burns to the hands, face, feet, groin, and/or inhalation burns
8. EMS provider judgement for triage to a higher level trauma center
9. Low impact mechanisms for older adults with suspicion of injury
10. Suspicion of nonaccidental trauma

→ **Destination Determined per RETAC Protocol**

EXHIBIT B

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

UNABLE TO ADEQUATELY VENTILATE

Yes → **Destination Determined per RETAC Protocol**

No ↓

ANY PHYSIOLOGIC CRITERIA

1. Intubation or assisted ventilation
2. Signs or symptoms of respiratory insufficiency, such as:
   -Severe hypoxia
   -Accessory muscle use, grunting, or abdominal breathing
3. Signs or symptoms of abnormal perfusion such as:
   -Decreased capillary refill (>2 sec)
   -Low systolic BP for age
4. Only responsive to pain or unresponsive (AVPU)

Age	SBP(mmHg)
<1 year	<60
1-10 years	<70+(2x age in yrs)
>10 years	<90

Yes → **Destination Determined per RETAC Protocol**

No ↓

ANY ANATOMIC CRITERIA

Known or Suspected:

1. Penetrating injuries to the head, neck, torso, or extremities above the elbow or knee
2. Flail chest (chest wall instability or deformity)
3. Two or more proximal long bone fractures
4. Unstable pelvic fracture
5. Paralysis or neurologic deficit
6. Amputation above the wrist or ankle
7. Crushed, degloved, mangled, or pulseless extremity
8. Open or depressed skull fracture

Yes → **Destination Determined per RETAC Protocol**

No ↓

ANY MECHANISM OF INJURY CRITERIA

1. Falls > 15 feet or 3x the height of the child
2. High risk auto crash, with such components as:
   -Intrusion of vehicle of ≥ 12 inches in occupant compartment; > 18 inches any site
   -Ejection (partial or complete) from automobile
   -Death in same passenger compartment
   -Moderate/high speed crash with unrestrained or improperly restrained child
3. Auto vs. pedestrian/bicyclist thrown, run over, or with significant impact
4. Motorcycle crash > 20 mph
5. Events involving high energy dissipation, such as:
   -Ejection from motorcycle, ATV, animal, etc.
   -Striking a fixed object with momentum
   -Blast or explosion
6. High energy electrical injury

Yes → **Destination Determined per RETAC Protocol**

No ↓

OTHER CONSIDERATIONS

1. Suspicion of non-accidental trauma
2. Anticoagulation or bleeding disorders
3. End-stage renal disease requiring dialysis
4. Pregnancy > 20 weeks
5. Suspicion of hypothermia
6. Intra-abdominal injury: abdominal tenderness, distension, or seatbelt sign on the torso
7. Burns > 10% TBSA (2nd or 3rd degree) and/or burns to the hands, face, feet, groin, and/or inhalation burns
8. EMS provider judgement for triage to a higher level trauma center

→ **Destination Determined per RETAC Protocol**

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Adopted by the Board of Health on April 21, 2021.

CHAPTER TWO – THE TRAUMA REGISTRY

200. Definitions

1. Admission – Inpatient or observation status for a principal diagnosis of trauma.

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

3. Community Clinic Providing Emergency Services – Facilities as licensed by the Department under 6 CCR 1011-1, Chapter 9.

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

5. Facility – A health facility licensed by the Department that receives ambulances such as a hospital, hospital unit, Critical Access Hospital (CAH), Freestanding Emergency Department (FSED), or Community Clinic Providing Emergency Services.

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

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

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

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

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

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

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

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

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

201. Reporting of Trauma Data by Facilities

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

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

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

        (2) 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;

        (3) Prehospital information: transport mode from the injury scene; name of agency providing transport to the facility; physiologic and anatomic conditions; times of notification, arrival at scene, departure from scene and arrival at destination;

        (4) Emergency department information: clinical data upon arrival; procedures; providers; response times; disposition from the emergency department;

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

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

        (7) Readmission information: patient's name, date of birth, gender, 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 admission at the readmitting facility;

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

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

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

(1) Inpatient information: name, age, gender, zip code of residence, medical record number, admission date, discharge date, injury type, and cause;

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

(3) Readmission information: patient's name, age, gender and zip code of residence; medical record number, name of facility and the date of admission at the original facility; medical record number, name of facility, date of readmission, and the reason for admission at the readmitting facility;

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

B. Level IV, V, and nondesignated facilities shall fulfill the reporting requirement by participating in a reporting system approved by the Department with submission dates determined by the data system operator.

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

202. Provision of Technical Assistance and Training

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.

203. Confidentiality

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

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

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

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CHAPTER THREE – DESIGNATION OF TRAUMA FACILITIES

Purpose and Authority for Rules

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

Index to Sections

300. Definitions

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 or V facility, of a referring facility and an appropriate attending physician from the trauma service at a receiving trauma center with the resources necessary to meet the patient's needs. Trauma consultation shall include written documentation completed by staff at both facilities. Disagreements as to patient disposition will be documented at both facilities for Department review.

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

5. Divert – The facility cannot currently accept EMS traffic. EMS shall transport trauma patients to an alternate destination in accordance with the prehospital trauma algorithm.

6. Emergent Intervention – Provision of medical services that can be undertaken to address: 1) uncontrolled bleeding; 2) Physiologic criteria as outlined in Chapter One, Exhibit A or B of the prehospital trauma triage algorithm; or 3) a traumatic injury that requires emergency surgery.

7. Emergent Surgery – A surgical procedure for which it has been determined that no alternative therapy is available and for which the delay could result in death or permanent impairment of health.

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

9. Focused Review – A type of interim trauma designation review focusing on the areas of concern from a previous review or plan of correction. Both the application and the review process may be shortened to focus on previous deficits.

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

11. Met with Reservations – Evidence of some degree of compliance with regulatory standards, but where further action is required for full compliance.

12. 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 prehospital 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, or every quarter for Level IV and V facilities. 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.

13. 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 requirements will be established by the committee. Membership will be established by the facility.

14. Multisystem Trauma – Two or more body regions or systems that are injured with physiologic criteria or the potential for physiologic compromise, as defined in Chapter One Exhibits A and B of the prehospital trauma triage algorithm.

15. 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 nondesignated facilities. Timely and appropriate communication, consultation, and feedback are imperative to patient outcome.

16. 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.

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

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

19. 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.

20. Resources or Necessary Resources – As used in this 6 CCR 1015-4, Chapter Three are the instruments, equipment, medications, training, and qualified personnel required to provide appropriate care for the patient.

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

22. State Emergency Medical and Trauma Services Advisory Council (SEMTAC) – Pursuant to Section 25-3.5-104(4), C.R.S., the State Emergency Medical and Trauma Services Advisory Council is a board appointed by the governor that advises and makes recommendations to the Department on all matters relating to emergency medical and trauma services.

23. 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.

24. Transfer Agreement – A written agreement with one or more hospitals or healthcare institutions for the transfer of patients from one to another.

25. 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, educational activities, and injury prevention.

26. 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.

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

28. Trauma Medical Director (TMD) – 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 and V, the Trauma Medical Director may be a physician so designated by the facility who takes responsibility for overseeing the program.

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

30. 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 One.

31. 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. Nondesignation and Designation Processes

1. General Provisions

   A. Any Colorado facility receiving trauma patients by ambulance or other means shall follow the process for designation or nondesignation 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 or nondesignation agreement 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 statuses are:

(1) Nondesignated facility – A hospital, freestanding emergency department (FSED), community clinic providing emergency services, or other licensed facility that receives and is accountable for injured persons but chooses not to seek trauma center designation.

(2) New facility – A hospital, FSED, community clinic providing emergency services, or other licensed facility that is seeking trauma center designation for the first time or seeking to change to a different level of designation.

(3) 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.

(4) Existing facility renewal – A currently designated trauma center seeking renewal at the same designation level.

B. The specific administrative and clinical criteria for each of the Level I-V and RPTC designations are set forth in Section 303 through Section 307 and Section 309 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. Nondesignated Facilities

A. A facility requesting nondesignation status shall file a nondesignation 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 admit patients with single system injuries that are not threatening to life or limb and whose care is not complicated by co-morbid conditions.

(3) The facility acknowledges and agrees that it shall triage and treat patients according to the following:

Patient Condition	Time Frame	Required Action
Traumatic injury requiring emergent intervention	One hour	Initiate resuscitation and transfer to a trauma center with the resources necessary to meet the patient's emergent needs. Transfer must be initiated but need not be completed within one hour. Transfer shall not be encumbered by restrictions to keep patients within a particular healthcare organization.
Any non-emergent traumatic injury meeting mandatory transfer or consult criteria as described in 6 CCR 1015-4, Chapter Three, Section 305.	Two hours	Initiate resuscitation and transfer to a trauma center with the resources necessary to meet the patient's needs. Transfer must be initiated but need not be completed within two hours.
Any non-emergent trauma patient that has experienced a significant injury or mechanism as defined in 6 CCR 1015-4, Chapter One, prehospital algorithms, or requiring care beyond the resources of the facility.	Two hours	Initiate resuscitation and transfer to a trauma center with the resources necessary to meet the patient's needs. Transfer must be initiated but need not be completed within two hours. Decisions regarding transfer shall include consideration of co-morbid conditions, potential complications, etc.

(4) The facility has identified key resource facilities for adult, pediatric, and specialty care patients.

(5) The facility has established transfer agreements as required by Section 25-3.5-703(4)(a), C.R.S.

(6) Nondesignation agreements shall be renewed on a triennial basis.

B. Upon initiation or renewal of a nondesignation agreement, each nondesignated facility shall contact its RETAC. The communication will be documented and a copy of the documentation shall accompany the signed nondesignation agreement described in Section 301.6.A. The documentation shall demonstrate that the following was discussed:

(1) Key resource facilities identified by the RETAC per CCR 1015-4, Chapter Four, 401.10.

(2) Trauma system resources available for all types of trauma patients, including specialty services such as burns, reimplantation, and pediatric care. Such resources may be located within or outside the RETAC.

(3) Communication systems available within the RETAC, system capabilities, and how to integrate with those systems.

(4) Resources available for prehospital and interfacility transport.

4. 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

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

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

Level I/RPTC:	$17,500
Level II:	$17,500
Level III:	$11,300
Level IV/V:	$8,500

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 and Section 309 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 and Section 309 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 301.6.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 301.6.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 301.6.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 and RPTC 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 301.6.A.(2) through (4).

(4) The subsequent site review and designation decision procedures shall follow those described for renewal of existing facilities at 301.6.B. through D.

(5) Designation following the full review will mark the beginning of a full three-year designation cycle.

5. Replacement Facility

A. Application Procedure

(1) A trauma designation review is required when the Department issues a new hospital, FSED, or community clinic providing emergency services 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/RPTC:	$6,500
Level II:	$6,500
Level III:	$1,800
Level IV/V:	$1,800

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 301.6.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 301.6.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 301.6.D of this chapter.

E. Designation Period

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

6. 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) Facilities seeking state designation only:

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

Level I/RPTC:	$12,300
Level II:	$12,300
Level III:	$7,000
Level IV/V: Emergency Department Visits > 15,000 per year	$5,000
Level IV/V: Emergency Department Visits between 5,000 - 15,000 per year	$4,000
Level IV/V: Emergency Department Visits < 5,000 per year	$3,000

(2) Facilities seeking state designation and simultaneous ACS verification must pay each of the following fees separately:

a. Facilities seeking verification by the ACS shall pay any fees associated with the verification by the ACS directly to the ACS and the state fees identified below.

b. Facilities requesting simultaneous verification by the ACS at the time of the Colorado state trauma designation survey shall pay the following annual fee to the Department for the state designation process only:

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

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

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

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 or RPTC 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

(1) 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.

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 Branch
ATTN: Branch Chief
CDPHE, HFEMSD
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 2 – General Licensure Standards, Part 2.6.

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 findings, 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 or RPTC 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 and 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, Transfer Requirements, and Emergent Surgery

A. The facility shall provide on-going consultation, education, and technical support to referring facilities, individuals, or RETACS.

B. Provisions for direct physician-to-physician contact shall be included in the process of transferring a patient between facilities.

C. The decision to transfer a patient shall be based on the clinical needs of the patient. Physicians shall be allowed to transfer when in the best interest of the patient and shall not be encumbered by restrictions to keep patients within a particular healthcare organization or based on the patient's ability to pay.

D. 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.

E. All Level I and II trauma centers may perform emergent surgery if appropriate resources are available. If after the emergent surgery is performed, the facility does not have the post-operative resources to care for the patient and for potential complications, the facility shall transfer to a trauma center with the necessary resources to meet the patient's needs.

F. Mandatory Transfers

(1) Patients of any age with a traumatic injury requiring resources beyond those available in the facility's scope of care, see 6 CCR 1015-4, Chapter Three, 303.4.B(1), shall be transferred.

(2) Levels I and II trauma centers that only admit children have a single extremity orthopedic fracture or minor head trauma, as determined by best practice guidelines, shall transfer any other pediatric patients, after emergency surgery, as necessary.

(a) Transfer shall be to a Regional Pediatric Trauma Center or to a Level I or II trauma center that admits pediatric trauma patients.

(b) The receiving trauma center must meet the requirements set forth in 6 CCR 1015-4, Chapter Three, Section 303.9.D and have a pediatric intensive care area staffed by a board certified or board eligible pediatric intensivist available for consultation or have a transfer protocol and transfer agreements for pediatric patients requiring intensive care.

(c) The receiving trauma center must have a neurosurgeon on call with qualifications necessary to manage pediatric neurotrauma.

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) The facility shall review any diversion or double transfer (from another facility and then transferred for additional acute trauma care) of trauma patients.

(10) The facility shall demonstrate that its graded activation criteria are regularly evaluated by the performance improvement program.

(11) 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 or equivalent taxonomy.

(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 percent 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) Scope of care: All designated Level I and II trauma centers shall define their scope of care based on the resources that are available at the facility for adult and pediatric patients.

(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 remain current in ATLS.

(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.

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.

(3) The trauma service shall maintain oversight of the admitted patient until trauma care is no longer necessary.

(4) Level I only: 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.

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, and

(3) Documented clinical experience.

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.

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.

(5) The performance of all surgeons on the trauma panel shall be reviewed annually by the Trauma Medical Director.

E. Education/Continuing Education: All general surgeons on the trauma panel shall remain current in ATLS.

F. Participation in Statewide Trauma System

Each Level I and 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) All emergency physicians on the trauma panel shall have successfully completed ATLS at least once.

(2) Physicians providing initial resuscitation in the emergency department shall be:

(a) Board certified in emergency medicine, or

(b) Have current ATLS.

(3) Board certification shall be issued by a certifying entity that is nationally recognized in the United States.

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.

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

E. 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 neurosurgical liaison to the trauma service.

(2) The facility shall define criteria for neurosurgical attending response.

(3) Neurosurgical care must be continuously available for all traumatic brain injury and spinal cord injury patients and must be present within 30 minutes, based on the facility's neurosurgical response criteria.

(4) Compliance with the 30 minute response time to neurosurgical presence shall be monitored by the trauma program and presented to the multidisciplinary trauma committee.

(5) Level I availability:

The facility shall provide a neurosurgical on-call schedule, dedicated only to that facility, available 24 hours per day, and either a posted backup call schedule or a contingency plan that includes bypass and transfer guidelines with another designated Level I, or in the event that no other Level I is available, then to a Level II facility with the necessary resources to meet the patient's needs.

(6) Level II availability:

a. The facility shall provide a neurosurgical on-call schedule, dedicated only to that facility, available 24 hours per day, and either a posted backup call schedule or a contingency plan that includes bypass and transfer guidelines with a designated Level I or II facility with the necessary resources to meet the patient's needs; or

b. If neurosurgeons take call at more than one facility (either trauma or non-trauma) at a time, written primary and backup call schedules are required and a contingency plan that includes bypass and transfer guidelines with a designated Level I or II facility.

B. Equipment/Resources

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

C. Qualifications

(1) Neurosurgeons must be:

a. Board certified in neurosurgery, or

b. Board eligible and less than seven years from residency, or

c. Have current ATLS, if no longer boarded or board eligible.

(2) All board certifications shall be issued by a certifying entity that is nationally recognized in the United States.

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.

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

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 define criteria for the orthopedic surgeon attending response.

(3) Orthopedic care must be continuously available for patients and must be present within 30 minutes based on the facility's orthopedic response criteria.

(4) Compliance with the 30 minute response time to orthopedic presence shall be monitored by the trauma program and presented to the multidisciplinary trauma committee.

(5) Level I availability:

The facility shall provide an orthopedic on-call schedule, dedicated only to that facility, available 24 hours per day and either a posted backup call schedule or a contingency plan that includes bypass and transfer guidelines with another designated Level I, or in the event that no other Level I is available, then to a Level II facility with the necessary resources to meet the patient's needs.

(6) Level II availability:

a. The facility shall provide an orthopedic on-call schedule, dedicated only to that facility, available 24 hours per day and either a posted backup call schedule or a contingency plan that includes bypass and transfer guidelines with a designated Level I or II facility with the necessary resources to meet the patient's needs; or

b. If orthopedic surgeons take call at more than one facility (either trauma or non-trauma) at a time, written primary and backup call schedules are required and a contingency plan that includes bypass and transfer guidelines with a designated Level I or II facility.

(7) A fully credentialed spine surgeon shall be promptly available, as defined by the facility, 24 hours per day.

(8) Level I only: 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.

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) Orthopedic surgeons must be:

a. Board certified, or

b. Board eligible and less than seven years from residency, or

c. Have current ATLS, if no longer boarded or board eligible.

(2) All board certifications shall be issued by a certifying entity that is nationally recognized in the United States.

D. Clinical Commitment/Involvement

(1) Orthopedic surgeons shall be credentialed by the hospital with general orthopedic privileges.

(2) Orthopedic surgeons on the call panel shall be regularly involved in the care of the trauma patient.

(3) The performance of all orthopedic surgeons on the trauma panel shall be reviewed annually by the liaison or designated representative.

9. Pediatric Trauma Care

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

B. Level I and II adult trauma facilities can and will receive pediatric trauma patients. All adult Level I and 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. Nonaccidental Trauma

(1) Pediatric patients with suspected or evidence of nonaccidental trauma requiring social or clinical care beyond the facility's resources shall be transferred to a Regional Pediatric Trauma Center or to a Level I or II trauma center with the necessary resources that admits pediatric trauma patients. The receiving trauma center must meet the requirements set forth in 6 CCR 1015-4, Chapter Three, Section 303.9.D.

(2) All Level I-II facilities admitting pediatric patients with nonaccidental traumatic injury shall consult with a specialist in child maltreatment affiliated with a trauma center for diagnostic and care consideration purposes.

D. A Level I or II adult trauma facility that admits children having other than single extremity orthopedic fracture or minor head trauma as determined by best practice guidelines 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 staffed by a board certified or board eligible pediatric intensivist available for consultation or have a transfer protocol and transfer agreements for pediatric patients requiring intensive care.

(4) A neurosurgeon on call with qualifications necessary to manage pediatric neurotrauma.

(5) The facility shall provide appropriate pediatric resuscitation equipment in all pediatric care areas.

(6) The facility shall have a pediatric-specific peer review/performance improvement process, which shall include pediatric-specific process filters and outcome measures.

(7) 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.

d. Level I only: Anesthesiology coverage shall be in house.

(2) Qualifications

a. Levels I-II anesthesiologists and nurse anesthetists must be:

i. Board certified, or

ii. Board eligible and less than seven years from residency, or

iii. Have current ATLS, if no longer boarded or board eligible.

b. All board certifications shall be issued by a certifying entity that is nationally recognized in the United States.

c. The performance of all anesthesiologists on the trauma panel shall be reviewed annually by the anesthesiology liaison or designated representative.

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. Level I only: 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.

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. The facility shall designate a radiologist to serve as the radiology liaison to the trauma program.

c. Interventional Radiology Requirements:

i. Level I: 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.

ii. Level II: Personnel qualified in interventional procedures shall be promptly available as defined by the facility 24 hours per day when requested by a trauma surgeon.

(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. ICU service leadership:

i. Level I: 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.

ii. Level II: 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.

e. The trauma surgeon shall retain oversight of the patient while in the ICU.

f. Level I only: A facility-defined team shall provide daily multidisciplinary rounds to patients in the ICU.

(2) 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.

(3) 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. 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.

c. Ventilator support shall be available for trauma patients 24 hours per day.

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:

(1) Thoracic, peripheral vascular, obstetric, gynecological, otolaryngologic, urologic, ophthalmologic, facial trauma, and plastic.

(2) In addition, Level I only: cardiac, microvascular, and hand.

G. Medical Consultants

(1) The facility shall have the following medical specialists and their respective support teams on staff: cardiology, infectious disease, internal medicine, pulmonary medicine, and nephrology.

(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 include, at a minimum:

(1) Level I:

a. Providing or participating in one ATLS course annually,

b. 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

c. Providing a mechanism to offer trauma-related education to nurses involved in trauma care.

(2) Level II: 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. Level I only: 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 U.S. Department of Health and Human Services.

(1) These rules incorporate by reference the 42 CFR § 482.15, “Condition of Participation: Emergency Preparedness Federal Regulations" (eff. November 29, 2019).

(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 Branch Chief
Health Facilities and EMS Division
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
Denver, CO 80246-1530

These materials are available and may be accessed at:

https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=cd395e8123ef3c266ed31b354bb524f2&ty=HTML&h=L&mc=true&n=pt42.5.482&r=PART#se42.5.482_11

B. Level I only:

(1) A surgeon from the trauma panel shall participate on the hospital's disaster committee.

(2) The facility shall have a disaster preparedness plan in its policy and procedure manual or equivalent.

(3) Hospital drills that test the facility's preparedness plan shall be conducted no less than every six months.

(4) 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 Quality Improvement Programs for Designated Trauma Centers Level III-V

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

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

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

C. Administration must support the trauma program and the Trauma Medical Director (TMD) in providing staff education commensurate with the level of care and based on patient population served.

2. The trauma quality improvement plan shall address the entire spectrum of services necessary to ensure optimal care to the trauma patient, from prehospital to rehabilitative care. The plan shall ensure the continuity of care for all admitted patients.

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

B. In Level IV-V facilities, this plan may be part of the hospital-wide quality improvement program but must have facility-defined, trauma-related indicators and components. Trauma-related issues must be documented separately, and the TMD has authority over any trauma issues.

C. This plan shall include identification of:

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

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

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

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

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

i. Primary level of review at least weekly.

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

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

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

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

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

g. Provide appropriate physician, mid-level, ancillary, and nursing staff education commensurate with the scope of care as described in 304.1.A.

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

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

A. At a minimum, attendance at multidisciplinary committee shall include representation from specialties and service lines involved in the care of trauma patients.

B. At a minimum, attendance requirements shall be 50 percent attendance by emergency medicine, orthopedics, general surgery, neurosurgery, anesthesia, and medicine in facilities where those specialties are involved in the care of trauma patients.

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

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

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

F. Performance management functions include, but are not limited to:

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

(2) Initiation of corrective action as needed.

(3) A process for prehospital trauma care review.

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

(5) Facility-specific nursing audits for nursing documentation.

(6) Establishing and enforcing policies and procedures.

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

(8) Promoting educational offerings.

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

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

4. The trauma quality program shall include a method and process for conducting multidisciplinary trauma peer review comparable to the peer review defined in Section 12-30-201 et seq., C.R.S.

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

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

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

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

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

F. Conducting a review of all trauma deaths with:

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

(2) All trauma centers shall have a policy that includes the process and criteria for utilization of a resource outside the facility for specialty specific peer review. Qualifications of outside peer reviewer must be identified by the facility as defined in Section 12-30-201 et seq., C.R.S.

(3) The deaths shall be identified as unanticipated mortality with opportunity for improvement (preventable), anticipated mortality with opportunity for

improvement (potentially preventable), or mortality without opportunity for improvement (non-preventable), or equivalent taxonomy.

5. The trauma quality program shall demonstrate accountability by:

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

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

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

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

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

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

305. Scope of Care for Designated Trauma Centers Level III–V

1. General Requirements

   A. All designated Level III-V trauma centers shall define their Scope of Care (SOC) based on the resources that are available at the facility.

   B. A decision to transfer a patient shall be based on the clinical needs of the patient. Physicians shall be allowed to transfer when in the best interest of the patient and shall not be encumbered by restrictions to keep patients within a particular healthcare organization or based on the patient's ability to pay.

2. Emergent Surgery at Level III and IV Trauma Centers

   A. All Level III and IV trauma centers may perform emergent surgery if appropriate resources are available. If after the emergent surgery is performed, the facility does not have the post-operative resources to care for the patient and for potential complications, the facility shall transfer to a trauma center with the necessary resources to meet the patient's needs.

   B. If the surgeon on call at a Level III or IV trauma center is encumbered in the operating room, the attending emergency department physician shall consult the surgeon to determine the plan of care, including the potential to consult with or transfer to a higher level trauma center.

   C. For patients at Level IV trauma centers that require emergent surgery, the emergency physician shall consult the trauma surgeon on call. If the time to surgeon and operating room availability exceeds the transfer time to a trauma center with the necessary resources, the patient shall be transferred.

3. Mandatory Transfer and Consultation, Level III-V Trauma Centers

   A. General Requirements for Transfer

(1) Every trauma center shall establish a policy and procedure for addressing when a patient or patient's representative refuses transfer and for when weather, disaster, or other extreme conditions prohibit the safe transfer of the patient.

(2) Nothing in these rules shall preclude any facility with the appropriate resources from providing emergency surgery as provided in Section 305.2.

(3) Patients of any age with a traumatic injury requiring resources beyond those available in the facility's scope of care shall be transferred.

(4) Pediatric patients requiring transfer but not requiring emergent intervention shall be transferred to a Regional Pediatric Trauma Center or to a Level I or II trauma center that admits pediatric patients. The receiving trauma center must meet requirements set forth in 6 CCR 1015-4, Chapter Three, Section 303.9.D.

B. Mandatory Consultation

(1) All Level III and IV trauma centers treating patients with a traumatic injury requiring a massive transfusion shall consult a trauma surgeon at a Level I or II key resource facility for diagnostic and care consideration purposes, including consideration of transfer.

(2) Level III trauma centers with no neurosurgical/orthopedic spine coverage and all Level IV trauma centers treating any patient with intracranial hemorrhage or evidence of cerebral edema due to trauma shall consult a neurosurgeon at a higher level of care for consideration of transfer. If the patient is admitted at the Level III or IV trauma center, after consultation, a general surgeon on the trauma panel shall admit and manage the patient through the course of high acuity care.

(3) All Level III and IV trauma centers shall consult a spinal specialist at a higher level of care to determine the need for transfer for any spinal column fracture other than a lumbar or thoracic transverse process fracture.

(4) All Level III-V facilities admitting pediatric patients with nonaccidental traumatic injury shall consult with a specialist in child maltreatment affiliated with a trauma center for diagnostic and care purposes.

C. Mandatory Transfers for Patients of All Ages

(1) Level III-V trauma centers shall transfer patients with the following traumatic injuries:

a. Hemodynamically unstable pelvic fracture.

b. Pelvic fracture requiring operative fixation.

c. Fracture or dislocation with vascular injury requiring operative vascular repair.

d. Aortic tears.

e. Abdominal or pelvic injury requiring emergent surgery and packing with non-definitive closure.

f. Burns in accordance with 6 CCR 1015-4, Chapter Three, Section 308.

(2) All Level III-V trauma centers shall transfer patients if the facility does not have the resources and clinical expertise to manage their medical co-morbidities, including, but not limited to:

a. Severe chronic obstructive pulmonary disease with home O2 requirement > 4L.

b. Pulmonary hypertension.

c. Critical aortic stenosis.

d. Coronary artery disease and/or recent myocardial infarction within 6 months.

e. Renal disease requiring dialysis.

f. End stage liver disease.

g. Unmanageable coagulopathy.

h. Body mass index > 40.

i. Pregnancy > 20 weeks.

(3) Level III trauma centers with no neurosurgical/orthopedic spine coverage and all Level IV and V trauma centers receiving trauma patients shall transfer under the following conditions:

a. Glasgow Motor Score ≤ 4 due to trauma with a normal CT scan.

b. Any intracranial hemorrhage on anti-coagulation or anti-platelet therapy.

c. Lateralizing or focal neurologic deficit.

d. Any open, depressed, or basilar skull fracture.

e. Any unstable spinal column fracture.

f. Spinal column fracture with any motor or sensory deficit.

g. No spinal column fracture but nerve root injury with focal motor deficit or bilateral sensory deficit.

(4) All Level III trauma centers with full or part-time neurosurgical/orthopedic spine coverage shall transfer any patient with a Glasgow Coma Score < 9 due to trauma or any spinal cord injury except those with a transient or unilateral sensory deficit.

(5) In addition, Level IV-V trauma centers shall transfer trauma patients of any age with the following traumatic injuries:

a. Bilateral femur fractures.

b. Femoral shaft fracture with any of the following:

i. Head injury with any evidence or intracranial hemorrhage, depressed skull fracture, or skull fracture with sinus involvement.

ii. Chest injury – Multiple rib fractures (> 4 unilaterally or > 2 bilaterally) or hemothorax.

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

c. Flail chest.

d. Age greater than 65 years with multiple rib fractures (> 4 unilaterally or > 2 bilaterally).

e. Persistent pneumothorax that is unresponsive after adequately placed chest tube having a massive or prolonged air leak.

f. Hemothorax treated with an initial chest tube that does not achieve complete evacuation within twenty four (24) hours.

g. Mechanical ventilation anticipated to be greater than twenty four (24) hours, if the facility does not have the necessary resources to provide ongoing ventilator management.

h. Solid visceral or hollow organ injury, if the facility does not have the necessary resources to care for the patient.

i. Vascular injury requiring operative vascular repair.

j. Crushed, de-gloved, or mangled extremity.

k. Suspected or evidence of nonaccidental trauma requiring social or clinical care beyond the facility's resources.

D. Mandatory transfers for pediatric patients: In addition to the injuries listed above, all Level III-V trauma centers shall transfer patients ages 0-14 with:

(1) Intracranial hemorrhage, evidence of cerebral edema due to trauma, Glasgow Motor Score ≤ 4 with a normal CT scan, or lateralizing or focal neurologic deficit.

(2) Intracranial, intrathoracic, or intra-abdominal penetrating injuries or penetrating injuries with orthopedic or neurovascular compromise.

(3) Injuries resulting in the need for mechanical ventilation.

(4) Injuries resulting in the need for a transfusion of packed red blood cells.

(5) Hemothorax.

(6) Pulmonary contusions resulting in associated hypoxia.

(7) Multiple rib fractures or flail chest.

(8) Abdominal hollow organ or solid visceral injury, intra- or retroperitoneal bleeding.

(9) Vascular injury requiring operative vascular repair.

4. Level III and IV trauma centers providing an expanded scope of care shall have:

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

B. For Level IV facilities, if there is an emergency physician serving as the Trauma Medical Director, there shall be a physician with surgical expertise to assist with performance improvement.

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

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

(2) A written plan to ensure continuity of care for all admitted patients.

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

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

D. Formal transfer guidelines for times when a facility does not have specialty coverage.

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

F. An emergency department with:

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

(2) A massive transfusion protocol.

G. An Operating Room with:

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

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

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

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

H. Inpatient services with medical consultation with a physician appropriately credentialed by the facility to treat medical co-morbidities.

I. Education, including:

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

(2) The facility shall ensure that the physician specialists direct and/or provide education to the team looking after their patients, including:

a. Post-operative care.

b. Recognition and care of potential complications.

c. Recognition and care of hemodynamic instability.

J. With respect to Levels III-IV trauma centers that provide an expanded scope of care with part-time specialty coverage:

(1) All Level III trauma centers with part-time neurosurgical/orthopedic spine coverage shall:

a. Have a published call schedule.

b. Communicate with prehospital regarding availability of neurosurgical/orthopedic spine coverage.

c. Meet the standards in 6 CCR 1015-4, Chapter Three, 305.3.C.(3) when there is no neurosurgical/orthopedic spine coverage.

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

(3) Cases shall be reviewed for projected length of stay and monitored through the performance improvement process. If the length of stay for any patient requiring an expanded scope service is greater than the specialty coverage and general surgery availability, then the patient shall be transferred.

306. Trauma Facility Designation Criteria – Level III

Standards for facilities designated as Level III trauma centers – The facility must be licensed as a general or critical access hospital.

1. A Level III trauma center shall have a trauma program with:

A. 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.

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. Policies that identify and establish the scope of care for both adult and pediatric patients including, but not limited to:

(1) Initial resuscitation and stabilization;

(2) Admission and interfacility consultation and transfer criteria;

(3) Surgical capabilities;

(4) Critical care capabilities;

(5) Rehabilitation capabilities, if available;

(6) Neurosurgical capabilities, if available;

(7) Spinal cord surgical capabilities, if available;

(8) Other capabilities, if available;

(9) Written procedure for receipt and transfer of patients by fixed and rotary wing aircraft; and

(10) Any expanded scope of care capabilities not already described.

D. 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:

(1) Is responsible for service leadership, overseeing all aspects of trauma care, with administrative authority for the hospital trauma program including:

a. Trauma multidisciplinary program,

b. Trauma quality improvement program,

c. Provision of recommendations for physician appointment to and removal from the trauma service,

d. Policy and procedure development and enforcement, and

e. Peer review.

(2) Participates on a local or statewide basis in trauma educational activities for healthcare providers or the public.

(3) Functions as Trauma Medical Director at only one facility.

(4) Participates in the on-call schedule.

(5) Participates in regional trauma system development.

E. A facility-defined trauma team, with an identifiable team leader.

F. 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 other considerations as outlined in the prehospital trauma triage algorithms as set forth in 6 CCR 1015-4, Chapter One.

G. A facility-defined trauma service with the personnel and resources identified as needed to provide care for the injured patient.

H. 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.

I. A multidisciplinary trauma committee with specialty representation. This committee is responsible for trauma program performance. Membership will be established by the facility and attendance requirements established by the committee. Minimum acceptable standards are set forth in Section 304.

J. A quality improvement program as defined in Section 304 of this chapter.

K. Policies, procedures, and practices consistent with the scope of care and expanded scope of care, as applicable, for designated Level III trauma centers as found in Section 305 of this chapter.

L. Divert protocols, to include:

(1) Coordination with the RETAC,

(2) Notification of prehospital providers and other impacted facilities, consistent with RETAC protocols, if any.

(3) Reason for divert, and

(4) A method for monitoring times and reasons for going on divert.

M. A trauma registry as required in Chapter Two of these rules, and trauma data entry support.

N. Participation in the RETAC and statewide quality improvement programs as required in rule.

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. General surgery available in person 24 hours a day within 20 minutes of trauma team activation coverage shall be provided by:

(1) The attending board certified surgeon or board qualified surgeon working toward certification,

(2) Who may only take call at one facility at any one time, and

(3) Who 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 an anesthesiologist or a certified registered nurse anesthetist (CRNA).

(2) Orthopedic surgery.

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. 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 certification 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 and 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, and

iv. Vascular access to include central line insertion and interosseous access;

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, and

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; and

s. Tourniquet.

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, and

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; and

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; and

(3) Thermal control equipment for:

a. Patients, and

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 as required in Sections 305.3 and 305.4.

I. Organized burn care for those patients identified in Section 308 of this chapter, and transfer and consultation guidelines with a burn center as defined in Section 308 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/or 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. Continuing Medical Education Requirements

(1) Level III physicians providing initial resuscitation in the emergency department shall have successfully completed ATLS at least once, and

a. Shall be board certified in emergency medicine, or

b. Have current ATLS.

(2) Level III general surgeons on the trauma call panel shall be current in ATLS.

(3) Level III orthopedic surgeons, neurosurgeons, anesthesiologists, and nurse anesthetists must be:

a. Board certified, or

b. Board eligible and less than seven years from residency, or

c. Have current ATLS, if no longer boarded or board eligible.

(4) All board certifications shall be issued by a certifying entity that is nationally recognized in the United States.

307. Trauma Facility Designation Criteria – Level IV and V

Level IV trauma centers must be licensed as: a general hospital, FSED, a community clinic providing emergency services, or a Critical Access Hospital per 42 CFR 485.601, et seq., and be open 24 hours a day, 365 days a year with physician coverage for trauma patients arriving by ambulance.

Level V trauma centers must be licensed as: a general hospital, FSED, a community clinic providing emergency services, or a Critical Access Hospital, per 42 CFR 485.601, et seq., and have a policy about hours of operation as described below:

1. A Level IV or V 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 care for both adult and pediatric patients including, but not limited to:

(1) Initial resuscitation and stabilization;

(2) Rehabilitation capabilities if available;

(3) Written procedure for transfer of patients by fixed and rotary wing aircraft;

(4) Hospitals only (not applicable to Community Clinics Providing Emergency Services or FSEDs) admission criteria;

(5) Level IV only:

a. Surgical capabilities, if available;

b. Critical care capabilities, if available; and

c. Any expanded scope of care capabilities as required in Section 305.

(6) Level V only: Hours of operation. The services as defined in the scope of trauma service policy shall include an after-hours plan for availability of services.

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 other considerations as outlined in the prehospital trauma triage algorithms as set forth in 6 CCR 1015-4, Chapter One.

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 Nurse Coordinator with clinical experience in care of the injured patient, who is responsible for coordination of the trauma program functions.

H. A quality improvement program as defined in Section 304 of this chapter.

I. Policies, procedures, and practice consistent with the scope of care and expanded scope of care, as applicable, for designated trauma centers Level IV-V as found in Section 305 of this chapter.

J. Divert protocols, to include:

(1) Coordination with the Regional Emergency Medical and Trauma Advisory Council (RETAC);

(2) Notification of prehospital providers and other impacted facilities, consistent with RETAC protocols, if any;

(3) Reason for divert; and

(4) A method for monitoring times and reasons for going divert.

K. Interfacility transfer criteria/guidelines as a transferring facility.

L. Interfacility transfer policies and protocols.

M. Participation in the state trauma registry as required in Chapter Two.

N. Participation in the RETAC and statewide quality improvement programs as required in rule.

O. If licensed as a Community Clinic Providing Emergency Services or FSED:

(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 individual's 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 or V trauma center shall have all of the following facilities, resources, and capabilities:

A. An emergency department with:

(1) A physician who 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.

(2) Registered nurses who provide continuous monitoring of the trauma patient until release from the ED.

a. Level IV: At least one registered nurse in house 24 hours a day who maintains current Trauma Nurse Core Course certification or equivalent;

b. Level V: At least one registered nurse in-house during hours of operation that maintains current Trauma Nurse Core Course certification or equivalent.

(3) Equipment for the 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 and 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:

i. Level IV: 24 hours per day.

ii. Level V: during hours of operation.

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; and

o. Tourniquet.

B. Level IV only: 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 or expanded scope of care, if applicable, that include the supervision, staffing and equipment requirements that the facility will utilize.

C. Radiological capabilities available with a radiology technician or person with limited certification in x-ray available within 30 minutes of notification of trauma team activation.

(1) Level IV: 24 hours per day.

(2) Level V: during hours of operation.

D. Clinical laboratory services available, including a spun hematocrit, dip urinalysis, and the ability to collect blood samples to be sent with transferred patients must be available.

(1) Level IV: 24 hours per day.

(2) Level V: during hours of operation.

E. Participates in local/regional/statewide injury prevention/public education.

F. Continuing education for all physicians providing trauma care, with:

(1) Level IV and V physicians providing initial resuscitation in the emergency department shall be board certified in emergency medicine or have current ATLS.

(2) Level IV general surgeons on the trauma call panel shall be current in ATLS.

(3) Level IV orthopedic surgeons, anesthesiologists, and nurse anesthetists on the trauma call panel must be:

a. Board certified, or

b. Board eligible and less than seven years from residency, or

c. Have current ATLS, if no longer boarded or board eligible.

(4) All board certifications shall be issued by a certifying entity that is nationally recognized in the United States.

(5) Physicians admitting trauma patients at Level IV facilities without the continuous availability of a surgeon on the trauma call panel, as demonstrated by a published call schedule, shall have 10 trauma-specific CME hours annually or 30 CME hours over the three year period preceding any site review.

G. Facility-defined, trauma-related continuing medical education requirements for nurses.

308. 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.

309. 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 One.

   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, certification, 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 an 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; or

iii. 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 CO 2 determination;

d. Suction devices;

e. Electrocardiograph and 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. Thorocostomy – needle and tube;

iii. Thoracotomy;

iv. Vascular/intraosseous access;

v. Central line insertion; and

vi. 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 308 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 CME hours annually or 48 CME hours over the three year period preceding any site review, 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 6 CCR 1015-4, Chapter One; 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, V, and nondesignated trauma centers.

T. A trauma registry as required in 6 CCR 1015-4, Chapter Two 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 Four.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STATEWIDE EMERGENCY MEDICAL AND TRAUMA CARE SYSTEM

6 CCR 1015-4

Adopted by the Board of Health on April 15, 2020

CHAPTER FOUR – REGIONAL EMERGENCY MEDICAL AND TRAUMA SERVICES ADVISORY COUNCILS

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

1. Biennial Plan – An emergency medical and trauma services system plan developed by the RETAC that details and updates the RETAC's original EMTS Plan, including any revisions pursuant to Section 25-3.5-704(2)(c), C.R.S., by describing methods for providing the appropriate services and care to persons who are ill or injured. The biennial plan shall be in a format specified by SEMTAC and the Department, and submitted to SEMTAC for a determination of adequacy every other year on July 1.

2. City and County – A city that shares the same boundaries as the county in which it resides.

3. Continuing Quality Improvement – The ongoing issue of improving the quality of the regional emergency medical and trauma services system.

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

5. EMTS System – Pursuant to Section 25-3.5-101, C.R.S., et seq., the emergency medical and trauma services system consists of the totality of the various subsystems that, in Colorado, are designed to prevent premature mortality and to reduce the morbidity that arises from trauma and medical emergencies.

6. EMTS Plan – The original emergency medical and trauma services plan that a RETAC developed, upon formation, for its region.

7. Financial Report – A regional financial accounting in a format specified by SEMTAC and the Department that details the expenditure of money received.

8. Key Resource Facility – As defined in Section 25-3.5-703(6.5), C.R.S., means 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 Title 25, Article 3.5, Part 7 of the Colorado Revised Statutes that relate to the development of the Statewide Trauma Care System.

9. Region – A distinct part of the statewide emergency medical and trauma care system that is the area to be served by the RETAC.

10. Regional Emergency Medical and Trauma Services 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.

11. State Emergency Medical and Trauma Services Advisory Council (SEMTAC) – Pursuant to Section 25-3.5-104(4), C.R.S., a board appointed by the governor that advises and makes recommendations to the Department on all matters relating to emergency medical and trauma services.

401. Organizational Requirements

1. 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 other counties, or with the governing body of a city and county, to form a multicounty RETAC.

2. RETACS must be comprised of counties that are contiguous.

3. The governing body from the counties and/or cities and counties comprising each RETAC shall determine how members are appointed.

4. The participating counties shall define the number of members on the RETAC.

5. Membership shall reflect, as equally as possible, representation between hospital and prehospital providers, and from each participating county and/or city and county.

6. There shall be at least one member from each participating county and/or city and county in the RETAC.

7. Each RETAC shall meet a minimum of four times per year.

8. After the appointment of members to the RETAC, the RETAC shall establish and maintain bylaws, which include responsibilities and other pertinent matters concerning the structure and operations of the organization. A chairperson shall be elected, and that person or their designee shall serve as the liaison for the region's communications with the Department.

9. At least seventy-five percent of the RETAC membership must reside in or provide health care services within the region.

10. 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 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.

11. Each RETAC shall utilize designated staff to manage the day-to-day business of the RETAC and provide administrative support and technical assistance to SEMTAC as it carries out its statutory obligations.

402. Minimum Operational Requirements

1. Each RETAC must establish a continuing quality improvement plan for its region with goals and system-monitoring protocols.

2. When formulating its biennial plan, each RETAC shall periodically assess the quality of its regional emergency medical and trauma system. As part of this assessment, each RETAC shall utilize its regional continuous quality improvement system plan to evaluate its effectiveness of its regional EMTS system in relation to 6 CCR 1015-4, Chapter One, the statewide emergency medical and trauma care system.

3. RETACs shall coordinate with the Department and the county or district public health agency in developing and implementing regional injury prevention, public information, and educational programs promoting the development of the regional emergency medical and trauma system. These programs should include, but not be limited to, pediatric injury prevention and public awareness components.

4. 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.

5. Regional Patient Destination Protocols

   RETACS shall develop prehospital destination protocols for adult and pediatric patients with trauma or suspected trauma in accordance with the algorithms contained in Exhibits A and B in 6 CCR 1015-4, Chapter One.

403. Waivers

   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.

404. Annual Financial Report

   On or before October 1 of each year, the RETAC shall submit an annual financial report to SEMTAC that details the expenditure of moneys received in a format specified by SEMTAC and the Department.

   If SEMTAC finds the annual financial report is inadequate, the RETAC shall resubmit the report to SEMTAC by December 1 of the same year.

405. RETAC Emergency Medical and Trauma System Biennial Plan Requirements

1. On July 1 of every odd numbered year, each RETAC, 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. The plan shall be submitted to SEMTAC for evaluation. Once SEMTAC has determined the plan is adequate, it will make a recommendation to the Department for approval. The plan shall be submitted in the form and manner required by the Department, based on the advice from SEMTAC. If the RETAC fails to submit a plan, does not include a county and/or city and county within their region in the plan, or the plan is not approved through the evaluation process established by SEMTAC, the Department shall design a plan for the RETAC.

2. In developing the biennial plan, the RETAC shall review data collected from sources such as, but not limited to, county plans, SEMTAC plans, organizational profiles, financial reports, and strategic planning documents.

3. The biennial plan shall be comprised of two sections: system components and statutory requirements.

   A. One section of every biennial plan shall include the system components listed below. Each plan component, at a minimum, shall address the current level of activity within that component:

      (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); share expertise; 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 affect 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 911 system. This component also includes the provisions 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 through innovation.

(11) Clinical care – Clinical methods, technologies, and delivery systems utilized in providing emergency medical and trauma services in and out of the hospital that 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.

B. The other section of every biennial plan shall address the following issues, as required by statute.

(1) Those regional factors that impact the provision of minimum services and care to sick and injured patients at the most appropriate facility. Such factors include, but are not limited to, the following:

a. Interfacility transfer agreements and protocols used by facilities to move patients to higher levels of care.

b. Facility-defined triage and transport plans to be developed by all facilities within the RETAC.

c. Geographical barriers to the transportation of patients.

d. Population density challenges to providing care.

e. Out-of-hospital resources within the region for the treatment and transportation of sick and injured persons.

f. Accessibility to designated trauma facilities within and outside the region.

(2) The level of commitment of each of the member counties and/or city and counties. Commitment includes, but may not be limited to, the following:

a. Cooperation among county and local organizations in the development and implementation of the statewide emergency medical and trauma care system.

b. Participation and representation within the RETAC(s).

c. Dedicated financial and in-kind resources for regional systems development.

d. Cooperation among county and local organizations in the development and implementation of a coordinated statewide communications system.

(3) Methods for ensuring facility, agency, and county, and/or city and county adherence to the RETAC emergency medical and trauma services system plan. Methods shall include, but not be limited to, the following:

a. A compliance reporting process as defined by SEMTAC and the Department.

b. A continuing quality improvement system as defined by SEMTAC and the Department.

(4) Description of public information, education, and prevention programs used within the region to reduce illness and injury.

(5) Any function of the RETAC accomplished through contracted services.

(6) Identification of regional emergency medical and trauma system needs through the use of a needs assessment instrument developed by the Department; except that the use of such instrument shall be subject to approval by the counties and/or city and counties included in a RETAC. Approval by the counties and/or city and counties shall not be unreasonably withheld.

(7) A description of the following communications system issues:

a. Communication method in place to ensure citizen access to emergency and medical trauma services through the 911 telephone system or its local equivalent.

b. Primary communication method for dispatch of personnel who respond to provide prehospital care.

c. Communication methods used between ambulances and other responders and between ambulances and designated and nondesignated facilities.

d. Communication methods used among trauma facilities and between facilities and other medical care facilities.

e. Communication methods used among service agencies to coordinate prehospital and day-to-day requests for service during multicasualty (disaster) activities.

f. Communication methods used among counties and RETACS to coordinate prehospital and day-to-day requests for service and during multicasualty (disaster) activities.

(8) Each biennial plan shall identify the key resource facilities for the region.

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.
Rules 303.4.E.(1)-(3) eff. 06/14/2014.
Chapter 1 eff. 02/14/2016.
Chapter Three eff. 05/15/2017.
Rules 300, 306 eff. 12/15/2018.
Rule 306.3 eff. 06/14/2019
Entire rule eff. 06/14/2020.
Rules 200.2-200.5, 301.2.A.(1)-(2), 301.5.A.(1), 307, 307.1.C.(1)-(4), 307.O, 307.1.O.(1) eff. 07/01/2021.