COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

From: Jeanne-Marie Bakehouse, Chief, EMTS Branch

Through: Randy Kuykendall, Director, Health Facilities and Emergency Medical Services Division, DRK

Date: February 19, 2020

Subject: Request for a Rulemaking Hearing concerning 6 CCR 1015-4, Chapters One-Four, Statewide Emergency Medical and Trauma Care System

---

In 2017 the Health Facilities and Emergency Medical Services Division, in conjunction with affected stakeholders, began a comprehensive review of all four chapters of the trauma system regulations. The goal of the trauma system rules has always been to get the right trauma patient to the right trauma center in the right amount of time. This is not changing. However the rules have been significantly revised and streamlined with a goal of providing clarity for end users.

Three separate task forces comprised of subject matter experts were convened by the State Emergency Medical and Trauma Services Advisory Council (SEMTAC) and the Division to provide input and guidance on the revision of the trauma rules. Overall, the chapters were modified to reflect the realities of trauma system development over the past 20 years, reorganized to provide a more logical flow of information, and streamlined to reduce redundancy. Some of the chapters, specifically Chapter Two, State Emergency and Medical Trauma Care System Standards, and Chapter Four, Regional Emergency Medical and Trauma Advisory Councils, were reviewed in their entirety for necessary substantive changes. Chapter Three, Designation of Trauma Facilities, received a more targeted substantive review and focused on areas where the existing regulations did not reflect the current practice of trauma medicine and how trauma services are currently delivered. Chapter One, which includes the requirements for the trauma registry, was significantly revised in 2016. Thus the current review focused on non-substantive editorial updates.

The four sets of rules were presented to SEMTAC for review in January 2020. The Division will submit the final sets of rules to SEMTAC for a recommendation of approval in April 2020.

The Division requests that the Board of Health set a rulemaking hearing for April 15, 2020.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1015-4, Chapters One-Four, Statewide Emergency Medical and Trauma Care System

Basis and Purpose.

The proposed rules provide significant change to several chapters which have, prior to this, had only minor edits over the past 15 years. The new language more clearly espouses implementation of best practice-based standards and care focused on the unique needs of the patient.

Changes to Chapters One through Four
Completed non-substantive editorial changes including standardization of punctuation and verbiage between the various chapters.

- Updated references.
- Updated definitions and added definitions as necessary. The added definitions provide significantly more clarity to concepts previously mentioned but not defined.
- Removed extraneous definitions.
- Removed duplicative language.
- Added references where appropriate.

Changes to Chapter One – The Trauma Registry

- No substantive changes to this chapter. However, it is being moved, renumbered, and renamed "Chapter Two – The Trauma Registry." This change will provide a more logical flow to the entire 6 CCR 1015-4 rule set.

Changes to Chapter Two – State Emergency Medical and Trauma Care System Standards

- This chapter will be moved and renamed, "Chapter One - State Emergency Medical and Trauma Care System Standards." Moving this chapter places the standards that establish the construct of the trauma system first.
- The content of the new Chapter One is significantly reduced from the previous version, deleting antiquated language and concepts.
- New content better aligns with the components of a trauma system as outlined in Section 25-3.5-701, et seq., C.R.S. and is organized to provide an index of components, directing users to the chapter and section where specific rules can be found.
- New content better reflects the current realities of the Emergency Medical and Trauma Systems as they have evolved over the past 20 years by updating concepts such as air medical transport, scene times, divert, and bypass.
- References are inserted where similar content is discussed in other chapters to eliminate redundant language throughout 6 CCR 1015-4.
- The Prehospital Trauma Triage Algorithms, as contained in Exhibits A and B, are altered to create more consistent language and formatting. In addition, several clarifying statements are added or amended. Further, the potential issues associated with an aging population and trauma services are more significantly acknowledged in the proposed language.

Changes to Chapter Three – Designation of Trauma Facilities

- Combines the Level I and II rules into one unified rule set. The few differences between a Level I and Level II trauma center are highlighted. Redundant language is eliminated.
- Edits to create better uniformity in language across designation levels.
- Combines Level IV and V trauma center regulations, highlighting the few differences between a Level IV and Level V trauma center and eliminating redundant language.
- Clarifies requirements for nondesignated trauma facilities to provide necessary treatment to patients and to ensure the timely movement of trauma patients to designated centers. It also requires facilities to renew nondesignation agreements at least every three years.
- Consolidates rules regarding consultation and transfer into one chapter. Current rules are spread over 6 CCR 1015-4, Chapters Two and Three. Current rules also require many consultations between trauma centers for consideration of transfer. Proposed rules should significantly reduce the number of consultations required while encouraging consultation for unique circumstances or when lower level facilities simply need additional expertise.
- Completes revisions and additions to two sections regarding quality improvement and scope of care at Level III-V trauma centers.
- Removes duplicative language.
- Incorporates additional rules with regard to the management of pediatric nonaccidental trauma.
- Recognizes the value of board certification and Advanced Trauma Life Support (ATLS) certification for continued competency over traditional continuing medical education requirements.
- Adds continuing education requirements for physicians admitting patients at Level IV trauma centers that do not have continuous availability of a surgeon on the trauma call panel.
- Increases board eligibility to seven from five years consistent with current practice.
- Adds requirement for all general surgeons taking trauma call to maintain current ATLS.
- Adds the requirement for a tourniquet for all Level III-V facilities.
- Deletes antiquated requirement for diagnostic peritoneal lavage kit at Level III.
- Completes non-substantive editorial changes including standardization of punctuation and verbiage between the various levels of trauma centers.
- No changes to fees are proposed in this revision.

Changes to Chapter Four – Regional Emergency Medical and Trauma Advisory Councils

- Edits to conform rules to statutory language, to language in other chapters, and to changes in the RETAC program over the years.
- Adds language regarding the statutorily required annual financial report.
- Simplifies and clarifies biennial plan requirements.
- Integrates communication requirements from current Chapter Two into the biennial plan communications system.
- Adds requirement that RETACs develop prehospital destination protocols that are consistent with the Prehospital Trauma Triage Algorithms, as contained in New Chapter One, Exhibits A and B.
- Makes conforming changes to eliminate reference to repealed RETAC requirements contained in Regulation 4, 6 CCR 1009-5, Preparations For Bioterrorist Event, Pandemic Influenza, Or An Outbreak By A Novel And Highly Fatal Infectious Agent Or Biological Toxin.

Specific Statutory Authority.

Statutes that require or authorize rulemaking:
Section 25-3.5-101, et seq., C.R.S.
Section 25-3.5-605(2.5), C.R.S. regarding RETAC biennial plans
Section 25-3.5-704(2), C.R.S., authority for rules establishing a statewide emergency medical and trauma care system including, but not limited to, required services, transport protocols, RETAC duties, facility designation and participation, a statewide trauma registry, injury prevention, and trauma care for pediatric patients.

Other Relevant Statutes:

State Board of Health general authority to promulgate rules section 25-1-108(1)(c)(I), C.R.S.. Colorado Administrative Procedures Act, section 24-4-103, C.R.S., governing the rulemaking process

---

Is this rulemaking due to a change in state statute?

_____ Yes, the bill number is _____. Rules are ___ authorized ___ required.

____X__ No

Does this rulemaking include proposed rule language that incorporate materials by reference?

___X___ Yes ___ URL

_____ No

Does this rulemaking include proposed rule language to create or modify fines or fees?

_____ Yes

___X___ No

Does the proposed rule language create (or increase) a state mandate on local government?

_X__ No.

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed;
- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or;
- The proposed rule reduces or eliminates a state mandate on local government.

___ Yes.

REGULATORY ANALYSIS
For amendments to
6 CCR 1015-4, Chapters One-Four, Statewide Emergency Medical and Trauma Care System

1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.

Group of Persons/Entities Affected by the Proposed Rule	Size of the Group	Relationship to the Proposed Rule Select category: C/CLG/S/B
Regional Pediatric Trauma Center and Staff	1	C*/S
Level I Trauma Centers and Staff	5	C*/S
Level II Trauma Centers and Staff	12	C*/S
Level III Trauma Centers and Staff	27	C*/S
Level IV Trauma Centers and Staff	36	C*/S
Level V Trauma Centers and Staff	4	C*/S
Nondesignated Facilities and Staff	+/- 55	C*/S
EMS Providers and Agencies	19,000+ providers ~200 ground ambulance agencies, 34 air ambulance agencies	C/CLG/S
Regional Emergency Medical and Trauma Advisory Councils (RETAC)	11	C/CLG/S
Trauma Patients in Colorado	EMS (2018): 90,000 transports of injured patients (~80,000 were 911 responses, ~10,000 interfacility transports) In 2018, there were 34,098 inpatient records with a primary diagnosis of trauma at Level I-III facilities, plus several thousand patients admitted at Level IV/V trauma centers.	B

* Note: Impact on CLG is limited to any trauma center that is part of a special tax district or operates as a unit of a local government. However, trauma designation is voluntary in Colorado, and the requirements apply uniformly to all trauma centers providing certain services, not specifically to those operating as a part of a local government. Requirements for CLGs are the same as any other similar trauma center.

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, please use this relationship categorization key:

C = individuals/entities that implement or apply the rule.
CLG = local governments that must implement the rule in order to remain in compliance with the law.
S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.
B = the individuals that are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by or be at-risk because of the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

Please note that throughout the information below CLG (Local government) is included in Consumers. Nothing in this this rule applies uniquely to local government and nothing is required of local government that is not required of any other entity seeking trauma designation or nondesignation status.

In addition, some RETACs function within local governments while others are incorporated in other ways. All rules apply regardless of how the RETAC is incorporated.

Changes to Chapters One – Four
Economic Outcomes:
None

Non-economic Outcomes:
These changes should provide non-economic benefit particularly for customers, local governments that operate a trauma center, RETACs, stakeholders, and the general public in that they reduce redundancy and provide better clarity for users.

Changes to Chapter One – The Trauma Registry (Becoming Chapter Two)
Economic Outcomes: None
Non-economic Outcomes: None

Changes to Chapter Two – State Emergency Medical and Trauma Care System Standards (This is moving to become Chapter One)
The rules have been significantly revised and streamlined with a goal of providing clarity for end users.

Economic Outcomes:

C and CLG: Trauma patients may be routed past one trauma center in the prehospital setting to get the patient to the most appropriate trauma center (the center with the resources necessary for optimal patient care.) Please note this is NOT a new impact.

S: As above.

B: The economic impact of the Chapter Two rule is not new. Some facilities may be bypassed in the prehospital setting. The positive economic impact for patients is that they will be routed to the facility with the most appropriate resources, not necessarily the closest facility, avoiding a potentially costly interfacility transfer.

Non-Economic Outcomes:

C and CLG: New and revised definitions should create improved clarity for the regulated community. Language regarding mandatory transfer and consultation was moved from Chapter Two to Chapter Three, creating one place where trauma facilities need to look for all rules pertaining to designation. Inclusion of references to national best practice guidelines also provides for the provision of up-to-date care while improving the flexibility of the rules based on the constant changes in current medical practice.

S: The addition of a definition for "advisory" should benefit EMS by providing clarity about which patients should bypass a facility that is having a temporary issue limiting current availability of a specific resource. Again, the goal is to avoid unnecessary transfers.

B: Patients arriving via EMS should arrive at a facility that has the resources to meet their immediate needs during the first EMS transport, benefitting the patient by timeliness and appropriateness of care. This also benefits EMS by reducing interfacility transports.

Changes to Chapter Three – Designation of Trauma Facilities

The rule revision will potentially impact all trauma facilities, including nondesignated facilities, as well as all residents and visitors to Colorado who may need the resources of a trauma center. The benefit to affected classes will be more standardization in the trauma care offered across the state.

Economic Outcomes:

C and CLG: Proposed rules allow certain patients that were previously covered by mandatory transfer rules to be retained in Level III and IV facilities, after a consultation with a higher level of care, when the facility has appropriate resources to safely keep the patient. Further, the proposed revision limits patient costs associated with unnecessary transport. In addition, the revised rules contain fewer situations requiring consultation resulting in the need for fewer phone calls that do not result in actual patient transfer.

New rules require some additional consultations for pediatric patients being admitted for nonaccidental trauma. The consultations will create a new requirement for trauma centers admitting such patients, but this is balanced by not requiring transfer of all such patients. The fiscal impact of such required consults should be negligible as many consults happen already and are generally not billed.

The mandatory transfer criteria are not new, although the concept has evolved in this iteration of the rules. The task force concluded that requiring certain transfers ensures that potential pitfalls in care are not overlooked by lower level facilities or facilities with resource limitations when diagnosing and treating patients with complicated injuries. This revenue stream cannot be analyzed by Department

personnel since costs are not collected in trauma registry data; however, it would appear that the number of patients affected by the proposed changes is small, and the revenue will still be captured elsewhere in the trauma system.

There are new requirements for Level III-V facilities stating explicit mandatory transfer for certain pediatric patients. These rules generally codify current practice. Few of these children were kept at lower level trauma centers. The task force proposed these changes for mandatory transfers in order to ensure this vulnerable population receives the care it needs.

Discontinuing the requirement for most physicians to have a certain amount of continuing medical education should have a significant positive economic impact on trauma centers. Large facilities, some with hundreds of physicians to track, should see a reduction in FTE necessary to track such extensive requirements. Even the smallest facilities should see a reduction in the time spent tracking this requirement.

S: N/A

B: The department cannot quantify economic impact, as we do not have those data. However, the proposed rules should be at least cost-neutral to the trauma patient as they do not increase costs for trauma centers. Furthermore, if the rules have the intended impact of reducing interfacility transfers by getting patients to the right place the first time or by allowing the patient to remain closer to home, the rules should actually reduce costs for consumers.

Non-economic Outcomes**:**

C and CLG: Patients will benefit from the new regulations in that numerous rules have been rewritten to stress what resources are necessary to ensure the safe care of the patient. In addition the proposed rules encourage rapid and appropriate transfer of patients, after stabilization, if the facility does not have the resources to meet all patient needs.

All designated trauma centers and nondesignated facilities will benefit from having more clearly stated expectations for the transfer and care of patients. The proposed rules also work to ensure that potential pitfalls in care are not overlooked by lower level facilities when it comes to the diagnosis and treatment of complex trauma patients.

In addition, rule changes reflect the changing nature of trauma care and encourage use of current best practice models when available, encourage consultation and consideration of transfer when there is uncertainty, and require specialty consultation for at-risk pediatric patients.

Requirements for every level trauma center to have an explicit scope of practice should benefit facilities and patients alike by providing clearer parameters for which patients are able to be admitted. Again, the goal is to reduce unnecessary transfer.

S: EMS providers in the trauma system benefit by the implementation of revised prehospital trauma triage algorithms, providing better clarity on the destination for trauma patients.

B: The revised Chapter Three rules will mostly benefit individuals who live in medically underserved areas; one such change is the decrease in mandatory consultations for "consideration of transfer." These consultations have been problematic in that they are often seen as only a requirement to fulfill and not as a valuable source of information. The proposed revisions provide clarity that the focus is on the needs of patient. The revised rules also protect patients by requiring transfer when all concomitant services are not available. For example, current Rule 305.2.A requires Level III and IV trauma facilities to conduct a mandatory consultation after performing emergent surgery if they do not have the resources to care for the patient; transfer is discretionary. The proposed rule mandates transfer to a trauma center with the resources to meet the patient's needs.

The rules also assure that patients are kept at the closest hospital where all necessary services are available and are treated according to best practice standards.

Additional requirements for pediatric patients with nonaccidental trauma should help ensure the safe and comprehensive treatment of this vulnerable population without multiple additional transfers. Stakeholders were extensively involved in the development of these criteria and achieved agreement that the proposed rules are in the best interest of an extremely vulnerable trauma population.

Changes to Chapter Four – Regional Emergency Medical and Trauma Advisory Councils

Economic Outcomes:

In general, the revised Chapter Four reorganizes and updates the language of the existing RETAC rules and does not impose significant new requirements on the RETACs or local government.

C and CLG: The Department's Office of Emergency Preparedness and Response (OEPR) Regulation 4 (6 CCR 1009-5) required RETACs to perform a series of different emergency preparedness functions such as maintaining contact notification lists, conducting notification tests, and advising pre-hospital EMS agencies within the region on emergency plan development. The OEPR concluded that Regulation 4 was redundant due to the number of other entities within the state that are performing these same functions. In May 2019, the Board repealed Regulation 4 as unnecessary and unenforceable. Consequently, the proposed changes to Chapter Four delete the requirement that RETACs comply with the repealed bioterrorism rule.

The Prehospital Trauma Triage Algorithms in the current Chapter Two and the new Chapter One, 6 CCR 1015-4, require EMS providers to follow "Destination Instructions Per RETAC Protocol." Proposed Section 403.4 ensures uniform RETAC compliance by codifying the requirement that RETACs must develop prehospital destination protocols that conform to the algorithms. Minimal costs to implement this requirement are expected since RETACs have already been developing regional destination protocol guidelines. However, this change will help ensure that all trauma patients within the state get to "the right place" without unnecessary transfers or travel.

Proposed Section 405 requires the RETAC to submit an annual financial report to the State Emergency Medical and Trauma Services Advisory Council (SEMTAC) detailing how the

RETAC has spent moneys received. The annual financial report has been a statutory requirement since 2002 and is now being added to the rules. There should not be any new economic burdens on Cs and CLGs.

S: No economic outcome.

B: No economic outcome.

Non-economic Outcomes:

C and CLG: The requirement that the RETACs must develop prehospital destination protocols that conform to the new Chapter One Prehospital Trauma Triage Algorithms will result in a regional prehospital destination plan that ensures consistent, timely, and safe prehospital transport to the appropriate trauma facility.

S: Under proposed Section 403.4 RETACs will be required to develop prehospital destination protocols that conform to the Prehospital Trauma Triage Algorithms in the new Chapter One, 6 CCR 1015-4. EMS providers in the trauma system will benefit by receiving clear guidance concerning prehospital emergency transport. Additionally, the required guidelines will reduce the need for interfacility transports.

B: The regional destination protocol guidelines will also benefit patients by ensuring that all trauma patients within the RETAC are transported to "the right place at the right time."

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

A. Anticipated CDPHE personal services, operating costs, or other expenditures:

These rule changes should be cost neutral to CDPHE. For instance, compliance with rule changes with regard to trauma destination will be reviewed during trauma designation site reviews, staff visits, and reports on plans of correction, as they are currently handled.

Anticipated CDPHE Revenues:

N/A

B. Anticipated personal services, operating costs, or other expenditures by another state agency: None.

C. Anticipated Revenues for another state agency:

N/A

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

Along with the costs and benefits discussed above, the proposed revisions:

__XX Comply with a statutory mandate to promulgate rules.
___ Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
__XX_ Maintain alignment with other states or national standards.
__XX_ Implement a Regulatory Efficiency Review (rule review) result
__XX_ Improve public and environmental health practice.
__XX_ Implement stakeholder feedback.

Advance the following CDPHE Strategic Plan priorities (select all that apply):

1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO2e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO2e per year by June 30, 2020 and to 113.144 million metric tons of CO2e by June 30, 2023. ___ Contributes to the blueprint for pollution reduction ___ Reduces carbon dioxide from transportation ___ Reduces methane emissions from oil and gas industry ___ Reduces carbon dioxide emissions from electricity sector
2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023. ___ Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the oil and gas industry. ___ Supports local agencies and COGCC in oil and gas regulations. ___ Reduces VOC and NOx emissions from non-oil and gas contributors
3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023. ___ Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes. ___ Increases physical activity by promoting local and state policies to improve active transportation and access to recreation. ___ Increases the reach of the National Diabetes Prevention Program and Diabetes Self-Management Education and Support by collaborating with the Department of Health Care Policy and Financing.
4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by June 30, 2023. ___ Ensures access to breastfeeding-friendly environments.
5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023. ___ Reverses the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by

June 30, 2020 and increase to 95% by June 30, 2023.

___ Performs targeted programming to increase immunization rates.

___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).

6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023.

___ Creates a roadmap to address suicide in Colorado.

___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate.

___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries.

___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.

7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020.

___ Conducts a gap assessment.

___ Updates existing plans to address identified gaps.

___ Develops and conducts various exercises to close gaps.

8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023.

___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident.

___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment.

___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.

9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023.

___ Implements the CDPHE Digital Transformation Plan.

___ Optimizes processes prior to digitizing them.

___ Improves data dissemination and interoperability methods and timeliness.

10. Reduce CDPHE's Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023.

___ Reduces emissions from employee commuting

___ Reduces emissions from CDPHE operations

11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023. ___ Used a budget equity assessment

_X_ Advance CDPHE Division-level strategic priorities.

The Division's goal is to provide the regulated community a set of standards that are simple, clear, and not redundant. This rule revision significantly clarifies the requirements while reducing redundancy. It provides additional freedom to facilities that have additional resources while protecting the minimum standards upon which all facilities are measured.

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include:
N/A

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

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. The specific revisions proposed in this rulemaking were developed in conjunction with stakeholders. The benefits, risks, and costs of these proposed revisions were compared to the costs and benefits of other options. The proposed revisions provide the most benefit for the least amount of cost, are the minimum necessary, or are the most feasible manner to achieve compliance with statute.

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

The Chapter Two task force encountered two policy issues at the beginning of the stakeholder process that resulted in rulemaking suggestions the Department could not support as the requested actions exceeded the scope of the Department's rulemaking authority.

A. Existing 6 CCR 1015-4, Chapter Two, 202B sets forth prehospital ambulance response times. Consequently, the Chapter Two task force understandably perceived the subject matter of this existing rule and its underlying policy to lie within its rulemaking authority. However, the Department's internal review of this rule led it to conclude that it does not possess the statutory authority to impose rulemaking governing prehospital transport response times. While this process is an important component of the trauma system, the General Assembly has placed regulation of ground ambulance response times within the purview of counties. See Section 25-3.5-308(3), C.R.S.

Therefore, the Department advised the task force that the Department lacks the statutory authority to regulate prehospital ambulance response times. Some task force members countered that regulated response times that conform with best

practice standards would improve the state trauma system for which it was crafting rules. Ultimately, the task force recognized that its jurisdiction does not extend to ground ambulance prehospital response times and agreed to eliminate the rule.

B. Reacting to constraints such as the one discussed above, the Chapter Two task force proposed that it author and forward to SEMTAC a "vision statement" addressing statewide trauma care system best practices for global trauma issues, including those over which the Department lacks regulatory authority. The Department commended the stakeholders for their desire to improve the state trauma system but advised that we lack statutory authority to recommend regulation of entities and subject matters that lie outside our rulemaking boundaries.

C. Additional documentation regarding alternative rules that were considered can be found in the Stakeholder Engagement Section of this packet. See pp. SE 3-9.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

Chapters One – Four

The Department and task forces did not utilize numerical data. Rather, they relied heavily on the expertise and experience of task force members, as well as upon information and opinions provided by professional organizations, when developing the proposed rules. The national organization and federal regulation resources include:

The recommendations and standards published by the American College of Surgeons; Committee on Trauma (https://www.facs.org/quality-programs/trauma/tqp/center-programs/vrc);
Recommendations and practice guidelines published by the American College of Emergency Physicians (https://www.acep.org/, click on practice);
The American Academy of Pediatrics (https://www.aap.org/en-us/Pages/Default.aspx); and
42 C.F.R. § 482.15 (2019).

In order to ensure that the Department received the broadest amount of expertise and experience, staff reached out to potentially affected facilities to ensure that those facilities had the opportunity to attend meetings or provide written feedback.

STAKEHOLDER ENGAGEMENT
for Amendments to
6 CCR 1015-4, Chapters One-Four, Statewide Emergency Medical and Trauma Care System

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:
The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

Organization	Representative Name and Title (if known)
EMTS on the Go (newsletter mailing list)	This weekly newsletter is emailed to a list of 1800+ constituents from the EMS and trauma systems and provides details for all public meetings hosted by the EMTS Branch. The newsletter notified recipients of all meetings for each chapter over the course of the stakeholder process.
Chapter Two Revision Task Force	Kim Muramoto, Centura Health, chair. For list of members and interested parties see attachments.
Chapter Three Revision Task Force	Same as Chapter Two Task Force
Chapter Four Revision Task Force	John Hall, Summit County Ambulance, chair. For list of members and interested parties see attachments.
Expanded Scope Task Force	Charles Mains, Centura Health, chair
Trauma Coordinators and Trauma Program Managers	This list of 200 employees and managers represents the leadership of trauma programs at each of the 85 designated trauma centers and other interested parties.
RETAC Forum (RETAC Coordinators and RETAC Board Members)	This includes RETAC coordinators, other staff, and RETAC board members representing each of the 11 EMS and trauma regions. Over 60 individuals were updated about the trauma rulemaking processes on a quarterly basis.
State Emergency Medical and Trauma Services Advisory Council	32-member, governor appointed advisory council which MUST recommend any draft rule changes prior to presenting the proposed rules to the Board of Health. Periodic updates concerning the proposed rules were given throughout the rule revision process. The Department provided SEMTAC with the final proposed rules for all four chapters in January 2020.

	The Department will ask SEMTAC for a vote of support in April 2020.
Statewide Trauma Advisory Committee	11-member committee representing a variety of EMTS disciplines and comprised of a minimum of six SEMTAC members. Periodic updates concerning the proposed rules were given throughout the rule revision process.
Colorado Hospital Association	Gail Finley, Amber Burkhart
Pediatric Emergency Care Committee	Christine Darr, MD; Kathleen Adelgais, MD
Regional Medical Directors (representing most of the 11 RETACs)	Jeff Beckman, MD; Matt Angelidis, MD; Bill Clark; Michelle Flemmings, MD; Avery MacKenzie, MD; Addy Marantino; Joshua Poles, DO; Pat Thompson, MD; Sarah Weatherred; Kevin Weber, MD

Changes to Chapter One – The Trauma Registry

This chapter is not being changed, with the exception of the title, which will now be "Chapter Two – The Trauma Registry." With no substantive changes, this chapter did not require early stakeholder engagement. However, the State Emergency Medical and Trauma Services Advisory Council (SEMTAC), the Regional Emergency Medical and Trauma Advisory Councils, and the Statewide Trauma Advisory Committee have all been informed of the changes.

Chapter Two – State Emergency Medical and Trauma Care System Standards

The Chapter Two Task Force met monthly from November 2017 – November 2018. The meetings were public, and participation was available via telephone and web conference. Members represented SEMTAC, regional medical directors, the Colorado Hospital Association, RETACs, Emergency Medical Services Association of Colorado (EMSAC-the professional association for EMS providers), EMS Chiefs or Managers, Level I, II, III, and Level IV-V trauma centers, rural areas, EMS systems or emergency management, pediatric care representatives, and interested parties.

Chapter Three – Designation of Trauma Facilities

The Chapter Three Task Force met monthly from February 2019 – December 2019. The meetings were public, and participation was available via telephone and web conference. Membership was continuous from the Chapter Two Task Force and again represented SEMTAC, regional medical directors, the Colorado Hospital Association, RETACs, EMSAC, EMS Chiefs or Managers, Level I, II, and III, and Level IV-V trauma centers, rural areas, EMS systems or emergency management, pediatric care representatives, and interested parties.

Chapter Four – Regional Emergency Medical and Trauma Advisory Councils

The Chapter Four Task Force met monthly from December 2017 – October 2018 and inSeptember 2019 for some additional conforming language. The meetings were public, and participation was available via telephone and web conference. Membership represented each of the 11 RETACs, the Colorado Office of Emergency Preparedness and Response, a county commissioner from SEMTAC, and interested parties.

Each of the above committees met with a planned agenda and draft regulatory language to consider. Information about each meeting was sent to the public through the weekly "EMTS on the Go." A sample advert is listed here:

> **"Trauma Chapter Three Task Force** -- July 10, 8 to 9:45 a.m.; Adams State University, McDaniel Hall, Alamosa, Teleconferencing will be available at 1-669-900-6833, meeting ID: 589-098-195. The meeting will also be broadcast over Zoom. All meeting materials will be available here. If you have questions please email Martin Duffy."

Agendas, draft minutes, and all other documents were posted on a google drive with public access. Task Force members and interested parties were encouraged to engage other stakeholders in the discussions and to provide verbal or written comment for consideration at the next meeting.

Stakeholders were involved in every phase of this rule development process, including the initiation of three task forces that recommended the rule changes. Membership of the task forces encompassed care-givers (both physicians and nurses) from level I though V trauma centers, RETACs, and other interested parties. (See Attached Membership Rosters) All task force meetings were public. During the three years of task force meetings, there were many points of disagreement, but what the Board of Health is currently considering is a consensus document approved by task forces.

Additionally, the draft rule change was advertised as a discussion point at the October 2019 and January 2020 Statewide Trauma Advisory Committee and State Emergency Medical and Trauma Services Advisory Council meetings. The State Emergency Medical and Trauma Services Advisory Council will vote in April 2020 to recommend that the proposed rule change be brought to the Board of Health by the Department.

Stakeholder Group Notification

The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

_XX_ N/A. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

____ Yes.

Summary of Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received:

There were several points of disagreement along the way in this rule revision process. The Department presented all feedback to the task forces for additional discussion. When task force members or the public disagreed at task force meetings, the group explored options where consensus could be reached. In the few instances where consensus could not be reached, the task force membership voted, and majority-approved language was adopted. Each Task Force unanimously approved the modifications to the chapters it reviewed. The draft that the Board is considering is a compilation of those task forces' work.

Changes to Chapter One – The Trauma Registry – no changes, no disagreement.

Changes to Chapter Two – State Emergency Medical and Trauma Care System Standards

A. Communication Rules Moved from Chapter Two to Chapter Four:

Section 202.A of the existing Chapter Two rules addresses the minimum coordinated communications and dispatch system standards with which regions must comply. The Chapter Two task force concluded that these regional standards are more aptly considered by RETACs. Therefore, it requested the Chapter Four task force to consider whether regional communications standards should more appropriately be included in Chapter Four. The Chapter Four task force agreed that regional communications standards properly fall within RETAC jurisdiction and elected to incorporate the substance of Chapter Two's Section 202.A into Chapter Four as newly promulgated Section 406.B.7. Pursuant to that new rule, each RETAC must address and describe a myriad of communication system issues and methods employed within the region.

The Chapter Two task force addressed trauma communications in Chapter One, Section 109. The rule requires trauma facilities to meet all communications requirements appropriate to their designation levels.

B. Divert and Bypass Standards Moved from Chapter Two to Renumbered Chapter One, and conforming "Divert" definition revised in Chapter Three:

The current Chapter Two rules include a section that addresses the seven circumstances in which trauma facilities may go on "divert" status, as well as operating guidelines that govern facility diversion. (Section 202.E). Current Section 202.F provides that the prehospital trauma algorithms and other unique situations may require prehospital emergency transport providers to "bypass" the nearest trauma facility in favor of another. The Chapter Two task force determined that these standards should be updated to the extent necessary to reflect current best practices.

Discussion concerning the divert rule centered upon two notions: first, that facilities should be discouraged from going on divert status unless necessary; second, whether RETACs should be required to develop protocols informing and coordinating divert communications. The task force came to consensus upon a streamlined definition of "divert status" to reflect "[t]he facility cannot currently accept EMS traffic. EMS shall transport trauma patients to an alternate destination in accordance with the prehospital trauma triage algorithm." See proposed Chapter One, Section 100.7. The task force also elected to relocate the substance of current Section 202.E into proposed Chapter One, Section 101.2.A-D. And rather than imposing an extra-jurisdictional divert requirement upon RETACs, the task force promulgated new Section 101.2.D which requires trauma facilities to notify all impacted EMS agencies and local facilities of the divert status. The definition of "divert" was modified in Chapter Three to comport with the new Chapter One definition, and Chapter Three designation rules were modified to conform with and reflect that designated trauma facilities must provide complying divert notifications.

The task force engaged in robust debate concerning the new bypass definition and attendant rules. Bypass is now defined in Chapter One, Section 100.3 as "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." Disagreement primarily occurred over the new bypass rules (Section 101.3.A-B), based upon stated concerns that EMS providers may possibly allow personal bias, opinion, or value judgments about trauma facilities and/or facility staff to influence their invocation of "bypass" protocols. To address these concerns, the task force solicited stakeholder and public opinion concerning whether RETACs should be required to develop bypass protocols, or whether medical directors should be required to provide input before bypass protocols are invoked. The Department disagreed with these suggested policies on the grounds that they might result in additional complications. For example, the Department pointed out that mandatory medical director input might very well result in the appearance of bias should the medical director instruct EMS providers to bypass to other trauma facilities within the medical director's system. The Department advocated that EMS providers in the trauma system should be directed to follow the RETAC protocols and to solicit medical director guidance in circumstances where those protocols fail to address the bypass situation. The Department and Chapter Two task force reached consensus on the issue by agreeing to new language (Chapter One, Section 101.3.A-B) which provides that bypass protocols are driven by the best interests of the patient and the RETAC protocols contained in the algorithms.

The task force also amended Chapter Three Level I and II designation rules to incorporate conforming bypass provisions.

C. New Advisory Definition and Rule:

No dissension was encountered over the Chapter Two task force's decision to include a new definition and rule concerning a trauma facility's advisory status for trauma patients. The task force distinguished a divert situation, where all traffic must be routed away from the trauma facility, from circumstances where the trauma facility might experience a shortage of a specific resource only. Therefore, the task force promulgated this definition for "advisory"—"The trauma facility is experiencing a specific resource limitation." The accompanying Chapter One rule, Section 101.4 provides that, unlike divert status, "[t]he 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." Under these circumstances, "[a]mbulance agencies are advised to consider transport to other trauma facilities as time and conditions allow for patients impacted by the specific advisory."

D. Adult and Pediatric Prehospital Algorithms:

The Chapter Two task force addressed the use of prehospital algorithms by requiring EMS providers to transport adult and pediatric trauma patients in accordance with national best practice guidelines and the algorithms included in Chapter One as Exhibits A and B. The Chapter Two task force also updated the prehospital algorithms, most notably to include two new conditions on the adult algorithm (*e.g.*, low impact mechanism for older adults with suspicion of injury; and suspicion of nonaccidental trauma).

The task force discussed whether to develop a separate geriatric trauma algorithm. After consideration of the medical evidence, the task force was not able to come to consensus concerning the necessity of a separate algorithm, so it did not develop one.

Changes to Chapter Three – Designation of Trauma Facilities

A. Patient-Centric Rules:

Numerous references were changed in Chapter Three to create additional emphasis on the needs of the patient as opposed to the requirements of the facility. The phrase "…with the necessary resources to meet the patient's needs…" was added eight times to emphasize that the needs of the patient are paramount to other concerns such as convenience of the facility or staff, proximity, or organizational affiliation. There was no disagreement among the regulated community on this point, since the best interest of the patient is a stated value across the industry and is consistent with the legislative intent of the trauma system.

B. Continuing Medical Education (CME):

One issue that received substantial and sometimes disparate public feedback was the issue of continuing medical education and the value of required ATLS for physicians, particularly those who are also required to maintain board certification. Most of the task force and interested parties agreed that there is not an industry standard for how much continuing education is required to create a "safer" environment, and that education, on its own, does not necessarily change or improve practice.

The stakeholder community engaged in a robust discussion on this topic. Most stakeholders were in agreement that continuing education requirements for trauma were redundant with the physicians' requirements for continued board certification. In addition, the amount of time and energy required for tracking physician CME, particularly at larger institutions, is not commensurate with identifiable benefits. Finally, the national standards put forth by the American College of Surgeons have removed requirements for CME. As a result, most requirements for physician CME and some certification requirements were removed from these proposed rules. Stakeholders agreed with these recommendations.

One recommendation engendered significant debate. Chapter Three, 307.2.F.(5) reads, "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." The discussion took place over several meetings between which the trauma program staff reached out to potentially affected facilities. After this outreach, outreach by the Colorado Hospital Association, and some clarification of the proposed language, the task force voted unanimously to endorse this new requirement. It was noted that these physicians are already required to have CME for their board renewal requirements, and this simply requires that some of those CME be devoted to topics of use in the care of trauma patients.

C. Neurosurgery and Orthopedic Surgery in Level I and II Facilities:

The task force discussed the idea that Level I and II trauma centers have very similar clinical platforms and that with a few exceptions (research, training, and some sub-specialties), the requirements for the levels should align, particularly in terms of response requirements.

The proposed language for both neurosurgery and orthopedic surgery indicate that the basic requirements for these specialties should be congruent between Level I and Level II facilities. The task force and stakeholders also agreed that the requirements should be congruent between the two specialties. The goal is to assure that whether trauma patients arrive at a Level I or Level II facility, they will have prompt access to a neurosurgeon or an orthopedic surgeon in the event of an emergency condition that requires those service lines.

D. Mandatory Transfers, Consults, and Scope of Care:

Current Chapter Two, which is being reorganized and renamed as Chapter One, contains mandatory transfer and mandatory consult criteria for pediatric and adult patients across all levels of trauma centers. Since compliance with these mandatory criteria has been assessed as part of the trauma designation process, it makes sense to reorganize these criteria into Chapter Three, the trauma designation rule set.

All trauma centers will now be required to write a detailed scope of care that describes what inpatient services are and are not available to pediatric and adult patients. In keeping with the patient-centric focus of the rules, facilities of all levels are directed to transfer patients requiring a specialty or service not available to a trauma center with the resources necessary to meet that specific need. While the Level I and II clinical platforms are very similar, there are resources that are limited even at this level of care, for example, burn care, pediatric specialties, microvascular surgery. Facilities are to determine if a trauma patient might benefit if transported to a lower level of care that offers more focused resources for the specific patient.

During this rule drafting process, stakeholders raised the issue of the significant burden that mandatory consults add to the trauma system. Consults must be documented on both ends of the conversation and are sometimes seen as not providing value to patient care. The task force viewed these concerns seriously and has proposed a rule set that contains fewer requirements for mandatory consult. Those that do exist focus on cases where the patient has unique injuries that require expertise not widely available (e.g., nonaccidental trauma or minor head trauma at Level III and IV facilities). The proposed rules should result in fewer consultations performed just to “check a box.”

Mandatory Transfer and Scope of Care, Level I and II: Even for Level I and II facilities, the scope of care policy will help inform decisions regarding mandatory transfers. The scope of care gives more freedom in determining which patients are appropriate for admission. For example, will pediatric head injuries be admitted or transferred? However, the policy will also be used to assess whether the facility is following its own scope of care or admitting patients that would be better served elsewhere.

Mandatory Transfers Level III –V Trauma Centers: Existing language was considered and some criteria were directly moved to Chapter Three, including mandatory transfer of aortic tears and liver injuries requiring packing. Other criteria were discussed and debated with decisions being made on the basis of what services are mandatory at every Level III or Level IV center. Decisions regarding the proposed transfer requirements focused on whether an injury was likely to be manageable at a Level III or IV facility not offering an expanded scope of care.

While all of these issues (scope of care, mandatory transfers, mandatory consults) generated discussion and significant rewording of some items, in the end, the lists of mandatory consults and transfers were adopted by the task force with agreement that the draft rules were in the best interest of patients.

E. Disaster Management:

Disaster management and emergency preparedness requirements were updated for Level I and II facilities. The current rule references outdated standards, whereas the proposed rules reference current federal standards issued by the Centers for Medicare and Medicaid Services that all hospitals must meet as a condition of program participation. Thus, the new rules will ensure that Level I and II trauma centers are prepared for emergencies while not creating any additional burden above federal requirements. No stakeholders disagreed with this change.

F. Nondesignated Facility Rules:

The Chapter Two task force decided to move all interfacility transfer and consultation provisions pertaining to nondesignated facilities into Chapter Three. Thus the current Chapter Two provisions that address nondesignated facility transfer and consultation (Sections 202.C.4, 202.D.6, 202.D.7, and 202.D.9), are now codified in Chapter Three, Section 301.3.A-B.

After extensive review of the existing rules, the Chapter Three task force agreed that trauma patient safety concerns require rule modifications to ensure the safe and timely delivery of Colorado trauma patients to the most appropriate trauma facility. Three rule revisions demonstrate the task force's patient-centric intent.

First, in Section 301.3.A.3, the task force developed a more refined triage, treatment, and interfacility transport rule based on different levels of patient need. In particular, the task force imposed a more prescriptive one-hour transfer timeline for trauma patients requiring emergent surgery, but kept the two-hour transfer timeline for other sets of trauma patients. These revised proposed rules ensure the safe and timely transfer of trauma patients to appropriate facilities with the resources necessary to meet the patient's needs. The proposed rule also clarifies triage and mandatory transfer responsibilities attendant to nondesignated facilities when dealing with different classes of trauma patients.

Second, the current rule requires transfer from a nondesignated facility "to the closest appropriate trauma facility as defined by RETAC protocols." The task force considered stakeholder input from rural and urban settings and weighed the value to trauma patients of retaining the geographic "closest appropriate" language. Ultimately the task force promulgated new Section 301.3.A.3, which substitutes language requiring "transfer to a trauma center with the resources necessary to meet the patient's [emergent] needs." The consensus of the task force was that the new rule requiring safe and timely transfer to a trauma facility with resources most appropriate for the patient advances the safety interests of the trauma patient in any setting.

Third, proposed Section 303.3.B requires nondesignated facilities to communicate and consult with its RETAC at least once every three years. The purpose of the rule is to ensure that nondesignated facilities are aware of the key resource facilities, communication systems, and various trauma resources within their regions that they

can access and utilize when treating and transporting trauma patients. Again, the task force advanced this new rule to bolster the safety and best interests of trauma patients who are treated, triaged, and transported by nondesignated facilities.

G. New Pediatric Nonaccidental Trauma Rules

Currently, Chapter Three Section 306.3.D.11 requires Level IV facilities to transfer trauma patients of all ages who have suspected or actual nonaccidental trauma injuries and require additional social or clinical resources. Task force consultation with pediatric trauma specialists led to the policy conclusion that pediatric nonaccidental trauma patients merit additional protections that are found in designated trauma facilities. To that end, it proposed two new rules to ensure pediatric nonaccidental trauma patient safety.

Section 303.9.C will require Level I and II facilities to transfer pediatric nonaccidental trauma patients requiring care beyond the facility's resources to a regional pediatric trauma center or facility with the necessary resources. Further, the task force unanimously agreed that these facilities shall consult with a child maltreatment specialist affiliated with a trauma center for diagnostic and care purposes.

Renumbered Section 305.3.C.5.k continues to require Level III and IV facilities to transfer nonaccidental trauma patients of all ages who require additional resources. However, in new Section 305.3.B.4, the task force unanimously agreed to impose the additional mandatory child maltreatment specialist consultation requirement upon Level III and IV facilities that admit pediatric patients with nonaccidental traumatic injury.

Changes to Chapter Four – Regional Emergency Medical and Trauma Advisory Councils

A. Role of RETAC

The Chapter Four task force initially addressed the role of RETACs in the state trauma system and concluded that RETACs are resources, not regulators. Accordingly, the proposed rule more clearly aligns the biennial plans with statutory requirements.

The Task Force also discussed whether the RETAC rules should incorporate the guiding principles of "EMS Agenda 2050: A PEOPLE-CENTERED VISION FOR THE FUTURE OF EMERGENCY MEDICAL SERVICES"[1] and the "people centered" focus of the Agenda. Again, the Task Force decided to focus on the relevant statutory provisions when revising the current rule.

[1] Guiding Principles: Inherently Safe & Effective; Integrated & Seamless; Reliable & Prepared; Socially Equitable; Sustainable & Efficient; and Adaptable & Innovative. EMS Agenda 2050 Technical Expert Panel. (2019, January). EMS Agenda 2050: A People-Centered Vision for the Future of Emergency Medical Services (Report No. DOT HS 812 664). Washington, DC: National Highway Traffic Safety Administration.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

These rules are designed to benefit all people who receive emergency medical and trauma services in Colorado. They also enhance focus on patient safety in the trauma system.

Overall, after considering the benefits, risks and costs, the proposed rule:

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.	X	Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.		Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce.
	Improves access to food and healthy food options.		Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
X	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.	X	Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.
	Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.		Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.
	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.	X	Ensures a competent public and environmental health workforce or health care workforce.
	Other:_____ _____		Other:_____ _____

ATTACHMENT 1: Chapters Two and Three Task Forces Membership Roster

Role	Name	Affiliation	RETAC
SEMTAC and Task Force Chair	Kim Muramoto	RN, Centura Health	Mile-High
Regional medical directors	Stein Bronsky	MD, Penrose, Medical director P2P	P2P
Colorado Hospital Association	Gail Finley	CHA	
	Amber Burkhart	CHA	
RETACs	Addy Marantino	RETAC Coordinator, NWRETAC	NW
	Kim Schallenberger	P2P RETAC	P2P
EMSAC or Chiefs, Managers, etc.	Mitch Wagy	EMSAC	NE
	Tim Nowak	EMSAC	P2P
Level I trauma centers	Mitch Cohen	MD, Surgeon, Denver Health	Mile-High
	Melissa Sorensen	RN, Swedish Medical Center	Mile-High
Level II trauma centers	Vic Janoski	RN, Parkview	Southern
	Marilyn Sykes-Johnson	RN, Injury Prev, North Colo Medical Ctr	NE
Level III trauma centers	Keyan Riley	MD, TMD, Memorial North	P2P
	David Steinbruner	Memorial/Memo North	P2P
Level IV-V trauma centers	Jodi Kramer	RN, TPM, St. Joseph	Mile-High
	Patti Thompson	RN, San Luis Valley Reg. Medical Center	SLV
Rural Representative	Elizabeth Reis	Pagosa Mountain Hospital	SW
	Diana Koelliker,	Telluride Medical Center	Western
EMS systems or emergency mgmt	Kathy Mayer	Flight For Life	Foothills
Pediatric care rep	Kathleen Adelgais	MD, Children's, PECC	Mile-High
	Christine Darr	MD, Emergency physician, P/SL, PECC	Mile-High
Interested Parties	Linda Underbrink	Foothills RETAC	Foothills
	Jenna Steege	Longmont United	Foothills
	Wendy Erickson	St. Francis	P2P
	Cassie Greene	Colorado Plains	NE
	Pamela Howes	RN, MedEvac	NE
	Pam Bourg	RN, TPM, Centura Health	Foothills
	Krista Turner	MD, Surgeon, The Medical Ctr of Aurora	Mile-High
	Kathy Beauchamp	MD, neurosurgeon, Denver Health	Mile-High
	Robbie Dumond	RN, TPM, University of CO (Anschutz)	Mile-High
	Pam Bourg	RN, TPM, Centura Health	Foothills
	Heather Finch	RN, TPM, Memorial, with Marissa Mclean	P2P
	Marissa McLean	Backup to Heather Finch	
	Thomas Schroeppel	MD, TMD, Memorial	P2P
	Heather Sieracki	RN, Penrose (backup to Dr Hamilton)	P2P
	David Hamilton	MD, TMD, Penrose	P2P
	Abigail Blackmore	RN, TPM, St Anthony	Foothills
	George Theofanous	Comm Center Director, MedEvac	NE
	Carolle Anne Banville	Denver Health	Mile-High
	Barry Platnick	Denver Health	Mile-High
	Lara Rappaport	Denver Health	Mile-High
	Nate Hinze	Backup to Adelgais	
	Cecile D'Huyvetter	RN, MSN, South State Director, Centura	P2P
	Rick Lewis	EMS Chief, South Metro	Mile-High

	Bill Hall	MD, St. Mary's Grand Junction	NW

ATTACHMENT 2: Chapter Four Task Force Membership Roster

Role	Name	Affiliation	Position
SEMTAC Commissioner	Sean Wood		
SEMTAC Commissioner	David Weaver		Backup
SEMTAC and Task Force Chair	John Hall		Chair
RETACs	Jamie Woodworth	Central Mountains RETAC	Primary
	Anne Montera	Central Mountains RETAC	Secondary
	Tom Candlin	Foothills RETAC	Primary
	Linda Underbrink	Foothills RETAC	Secondary
	Charlie Mains	Mile-High RETAC	Primary
	Shirley Terry	Mile-High RETAC	Secondary
	Dave Bressler	Northeast Colorado RETAC	Primary
	Jeff Schanhals	Northeast Colorado RETAC	Secondary
	Mel Stewart	Northwest RETAC	Primary
	Addy Marantino	Northwest RETAC	Secondary
	Wendy Erickson	Plains to Peaks RETAC	Primary
	Kim Schallenberger/Tim Dienst	Plains to Peaks RETAC	Secondary
	Rodney King	San Luis Valley RETAC	Primary
	Jon Montano	San Luis Valley RETAC	Secondary
	Aaron Eveatt	Southeastern Colorado RETAC	Primary
	Josh Eveatt	Southeastern Colorado RETAC	Secondary
	Tom Anderson	Southern RETAC	Primary
	Brandon Chambers	Southern RETAC	Secondary
	Patrick Cain	Southwest RETAC	Primary
	Terri Foechterle	Southwest RETAC	Secondary
	Glenn Boyd	Western RETAC	Primary
	Kim Mitchell	Western RETAC	Secondary
	Danny Barela	Western RETAC	Secondary
Interested Parties	Gail Finley	Colorado Hospital Association	
	Amber Burkhardt	Colorado Hospital Association	
	Julie Bridges		
	Bill Clark		
	Kirby Clock		
	Richard Cornelius		
	Caroline Dullien		
	Ben Dunn		
	Chris Duran		
	Heather Finch		
	John Foechterle		
	Tim Grey		
	Josh Hadley		
	Stephanie Haley-Andrews		
	Tim Hurtado		
	Marissa McLean		

	Kathy Marden		
	Lori McDonald		
	Chris Montera		
	Toni Moses		
	Tim Nowak		
	Jordan Ourada		
	Bobby Putnam		
	John Recicar		
	Paul Reckard		
	Ron Seedorf		
	Mary Jo Seiter		
	Heather Sieracki		
	Elizabeth Spradlin		
	Andrew Srotnak		
	Pam Vanderberg		
	Reg Vickers		

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STATEWIDE EMERGENCY MEDICAL AND TRAUMA CARE SYSTEM

6 CCR 1015-4

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

CHAPTER ~~TWO~~ONE - STATE EMERGENCY MEDICAL AND TRAUMA CARE SYSTEM STANDARDS

INDEX TO SECTIONS

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

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

~~A. Communication~~

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

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

~~2. Adequate dispatch services.~~

~~3. Paging and alerting system for notification of emergency medical/trauma personnel who routinely respond to emergency medical/trauma incidents.~~

~~4. Two-way communications between and among ambulances.~~

~~5. Two-way communications between ambulances and non-designated facilities and designated trauma facilities.~~

~~6. Two-way communications between ambulances and trauma facilities outside the Regional Emergency Medical and Trauma Advisory Council (RETAC) area.~~

7. A plan for utilization of an alternative communications system to serve as a back-up to the primary system.

8. A disaster communications plan.

9. A system for notification and alerting trauma teams, fixed and rotary wing emergency services, and trauma centers.

10. A system that is compatible with systems in adjacent regions.

B. Prehospital

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

1. Minimum acceptable level of service:

a. Basic life support (BLS) service - Must have at least 1 person who is at first responder or higher level of training

b. Advanced life support (ALS) service - Must have at least 1 person who is at EMT-I or EMT-P level of training

2. Emergency response times for ground transport agencies:

	Time Limit
a. High density areas (metropolitan)	
(1) Provider service area encompasses 100,000 people or more	11 minutes, 90% of the time
b. Mid-density areas (urban or mixed)	
(1) Provider service area encompasses12,000 to 100,000 people	20 minutes, 90% of the time
c. Low density areas (rural, frontier)	
(1) Provider service area encompasses <12,000 people	45 minutes, 90% of the time

3. Optimal scene time limits 15 minutes, 90% of the time

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

4. Agencies shall conduct quality improvement monitoring for all response and scene times that exceed these parameters and make a plan of correction where necessary

5. Triage and transport of trauma patients must be in accordance with the prehospital transport destination algorithms (exhibits A and B to these regulations)

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

1. Levels II and III trauma centers caring for the critically injured adult trauma patients listed below must comply with the actions required:

a. Bilateral pulmonary contusions requiring nontraditional ventilation

b. Patient with multisystem trauma with pre-existing coagulopathy (hemophilia)

c. Pelvic fractures with unrelenting hemorrhage

d. Aortic tears

e. Liver injuries requiring emergency surgery and requirement for liver packing or vena cava injury

Actions Required:

(1) Mandatory, timely (but within 6 hours after recognition of condition) consultation is required with a Level I trauma surgeon (who is a member of the attending staff) for consideration of transfer of the patient. The attending trauma surgeon of the referring facility should initiate the consultation.

(2) Consultation with the attending trauma surgeon is required in the determination of the necessity of transfer and the circumstances of transfer including, but not limited to, additional diagnostic/therapeutic issues, availability of resources, weather conditions.

2. Level III trauma centers caring for the high risk adult trauma patients with the following traumatic injuries must comply with the actions required:

a. Significant head injuries (intracranial bleeding or Glasgow Coma Scale (GCS) ≤ 10) or spinal cord injury with neurologic deficit where neurosurgical consultation and evaluation are not promptly available

b. Significant multisystem trauma as defined by:

(1) Head injury (intracranial bleeding or GCS ≤ 10) or spinal cord injury with neurologic deficit complicated by either significant chest and/or abdominal injuries as defined by:

(a) Chest Injury (as part of multisystem injuries):

i) Multiple rib fractures > 4 unilaterally or > 2 bilaterally

ii) Hemothorax

(b) Abdominal Injury (as part of multisystem trauma):

i) Significant intra or retroperitoneal bleeding

ii) Hollow organ or solid visceral injury

c. Bilateral femur fracture or posterior pelvic fracture complicated by significant chest and/or abdominal injuries as defined above

d. Trauma patient on mechanical ventilation for > 4 days

e. Life threatening complications, such as acute renal failure (creatinine > 2.5 mg/dl) or coagulopathy (twice the normal value for individual facility)

Actions Required:

(1) Mandatory timely (but within 12 hours after recognition of condition) consultation is required with a Level I or key resource facility trauma surgeon (who is a member of the attending staff) for consideration of transfer of the patient. The primary attending physician at the Level III facility should initiate the consultation.

(2) Consultation with the trauma surgeon is required in the determination of the necessity of transfer and the circumstances of transfer including, but not limited to, additional diagnostic/therapeutic issues, availability of resources, weather conditions.

(3) Consultation and/or transfer decisions in patients with traumatic injuries less severe than those listed above shall be determined by the RETAC based on resources, facilities, and personnel available in the region and shall be made in accordance with RETAC protocols.

3. Level IV trauma centers caring for patients with the following traumatic injuries must comply with the actions required:

a. Critical injuries listed in 6 CCR 1015-4, Chapter Two, Section 202, C.1

b. Significant head injuries (intracranial bleeding or GCS ≤ 10) or spinal cord injury with neurologic deficit

c. Significant multisystem trauma as defined by:

(1) Head injury (intracranial bleeding or GCS ≤ 10) or spinal cord injury with neurologic deficit complicated by either significant chest and/or abdominal injuries as defined by:

(a) Chest Injuries (as part of multisystem trauma):

i) Multiple rib fractures > 4 unilaterally or > 2 bilaterally

ii) Hemothorax

(b) Abdominal Injuries (as part of multisystem trauma):

i) Significant intra or retroperitoneal bleeding

ii) Hollow organ or solid visceral injury

d. Bilateral femur fracture or posterior pelvic fracture complicated by either significant chest or abdominal injuries as defined above

e. Trauma patient on mechanical ventilation

f. Life threatening complications, such as acute renal failure (creatinine > 2.5 mg/dl) or coagulopathy (twice the normal value for individual facility)

Actions required:

(1) Mandatory timely (but within 6 hours after recognition of condition) transfer is required for patients with the above defined injuries.

(2) The primary attending physician at the level IV trauma center shall consult with the attending trauma surgeon at the key resource facility prior to transfer to determine the most appropriate destination for such patients and to discuss the circumstances of transfer such as additional diagnostic/therapeutic issues, availability of resources, weather conditions, etc.

(3) Consultation and/or transfer decisions in patients with traumatic injuries less severe than those listed above shall be determined by the RETAC based on resources, facilities, and personnel available in the region and shall be in accordance with RETAC protocols.

4. Nondesignated Facilities

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

5. Noncomplicated Trauma Injuries

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

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

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

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

D. Interfacility Transfer and Consultation [1,2] - Pediatric - Age 0-14

1. For the purpose of 6 CCR 1015-4, Chapter Two, Section 202.D. “critical injuries” are defined as any of the following:

a. Bilateral pulmonary contusions requiring non-traditional ventilation

b. Multisystem trauma with preexisting or life threatening coagulopathy

c. Pelvic fractures with unrelenting hemorrhage

d. Aortic tears

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

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

2. For the purpose of 6 CCR 1015-4, Chapter Two, Section 202.D,”high risk injuries” are defined as any of the following:

a. Penetrating injuries to head, neck, torso, or proximal extremities

b. Injuries resulting in the need for mechanical ventilation of > 16 hours

c. Persistent in-hospital evidence of physiologic compromise including: tachycardia relative to age plus signs of poor perfusion (capillary refill test > 2 seconds, cool extremities, decreased pulses, altered mental status, or respiratory distress), hypotension

d. Hemodynamically stable children with documented visceral injury admitted for "observational" management and requiring blood transfusion or fluids > 40cc/kg

e. Injury Severity Score ≥ 9 including, but not limited to:

(1) Multisystem blunt injuries (> 2 systems)

(2) Pelvic or long bone fractures in conjunction with multisystem injuries

(3) Altered mental status (GCS <10) with significant trauma

3. For the purpose of 6 CCR 1015-4, Chapter Two, Section 202.D. "high risk mechanisms" are defined as any of the following high energy transfer mechanisms:

a. Falls > 20 feet

b. Auto crashes with significant vehicle body damage

c. Significant motorcycle crashes

d. All terrain vehicle crashes

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

Actions required:

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

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

Actions required:

a. Children 0 - 5 years of age with critical injuries shall be transferred with prior consultation [1,2] to a RPTC. If such a center is not available, then transfer [1,2] shall be to a LI/PC. If such a center is not available, then transfer shall be to a LII/PC. If no center with pediatric commitment is available, transfer [1,2] shall be to the highest level trauma center available.

b. Children 6 - 14 years of age with critical injuries. Mandatory timely (but within 6 hours after recognition of condition) consultation [1,2] is required with an attending trauma surgeon at a RPTC or a LI/PC for consideration of transfer of the patient.

c. Children 0 - 14 years of age with high risk injuries. Mandatory timely (but within 6 hours of recognition of condition) consultation [1,2] is required with an attending trauma surgeon at a RPTC or LI/PC for consideration of transfer of the patient.

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

Actions required:

a. Children 0 - 5 years of age with critical injuries shall be transferred [1,2] to a RPTC. If such a center is not available, then transfer [1,2] shall be to a LI/PC. If such a center is not available, then transfer shall be to a LII/PC. If no center with pediatric commitment is available, transfer [1,2] shall be to the highest level trauma center available.

b. Children 6 - 14 years of age with critical injuries shall be transferred [1,2] to a RPTC or a LI/PC. If such a center is not available, then to a LII/PC. If no center with pediatric commitment is available, transfer [1,2] to the highest level trauma center available.

c. Children 0 - 5 years of age with high risk injuries shall be transferred [1,2] to either a RPTC or a LI/PC. If such a center is not available, then to a LII/PC. If no center with pediatric commitment is available transfer [1,2] to the highest level trauma center available.

d. Children 6 - 14 years of age with high risk injuries shall be transferred with prior consultation [1,2] to either a RPTC, LI/PC or LII/PC. If no center with pediatric commitment is available then transfer to the highest level trauma center available.

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

Actions required:

a. Mandatory timely (but within 6 hours) consultation [1,2] is required with an attending trauma surgeon from a RPTC , LI/PC or LII/PC for consideration of transfer.

8. Consultation and/or transfer decisions in pediatric patients with traumatic injuries less severe than those listed above shall be determined by the RETAC based on resources, facilities, and personnel available in the region and shall be in accordance with the RETAC protocols.

9. Nondesignated Facilities

Nondesignated facilities that receive and are accountable for pediatric trauma patients (age 0-14 years) with any traumatic conditions other than non-complicated, non-life threatening, single system injuries must transfer those patients to the appropriate, designated trauma center. Transfer agreements are required.

10. RETACs must monitor transport of pediatric trauma patients within their regions and report systematic exceptions to the protocols or regulations to the department.

11. Where superscript [1] and/or [2] appear, the following shall apply:

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

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

E. Divert

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

1. Lack of critical equipment

2. Operating room saturation

3. Emergency department saturation

4. Intensive care unit saturation

5. Facility structural compromise

6. Disaster

7. Lack of critical staff

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

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

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

F. Bypass

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

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

203. Exemptions or Variances

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

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

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 NON-DESIGNATED 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 ALTERNATE DESTINATION IN ACCORDANCE WITH THE PREHOSPITAL TRAUMA TRIAGE ALGORITHM.

8. FACILITY – FOR PURPOSES OF THESE RULES, ANY DESIGNATED HEALTH CARE FACILITY, REGIONAL PEDIATRIC TRAUMA CENTER, OR NON-DESIGNATED HEALTH CARE FACILITY.

9. INTERFACILITY TRANSFER - THE MOVEMENT OF A TRAUMA PATIENT FROM ONE LICENSED HEALTHCARE FACILITY PARTICIPATING IN THE TRAUMA SYSTEM TO ANOTHER LICENSED HEALTHCARE FACILITY PARTICIPATING IN THE TRAUMA SYSTEM.

10. NON-DESIGNATED – A FACILITY THAT HAS NOT MET THE CRITERIA OF LEVELS I-V OR REGIONAL PEDIATRIC TRAUMA CENTERS (RPTC) , BUT THAT RECEIVES AND IS ACCOUNTABLE FOR INJURED PERSONS, INCLUDING HAVING A TRANSFER AGREEMENT TO TRANSFER PERSONS TO LEVEL I TO V OR RPTC FACILITIES AS SET FORTH IN SECTION 25-3.5-703(4)(a.5)-(f), C.R.S. AND THESE RULES. “NON-DESIGNATED” 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 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 - MEANS 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, AND APPLICABLE RETAC PROTOCOLS.

2. FACILITY DIVERT STATUS

A. FACILITIES MAY GO ON DIVERT STATUS FOR THE FOLLOWING REASONS:

(1) LACK OF CRITICAL EQUIPMENT

(2) OPERATING ROOM SATURATION

(3) EMERGENCY DEPARTMENT SATURATION

(4) INTENSIVE CARE UNIT SATURATION

(5) FACILITY STRUCTURAL COMPROMISE

(6) 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.

Commented [BM1]: Moved and edited from current rules Chapter Two, 202.E (very similar to existing language)

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 OR FOR 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.

Commented [BM2]: Moved and edited from current rules Chapter Two, 202.F (somewhat similar to existing language)

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 406.2.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 NON-DESIGNATED 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 HEALTHCARE FACILITY THAT PARTICIPATES IN THE TRAUMA SYSTEM SHALL DEVELOP AND IMPLEMENT PROTOCOLS THAT, AT 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 THE STATE; AND

C. WHEN DETERMINING WHAT RECEIVING FACILITY IS THE MOST APPROPRIATE TRAUMA FACILITY FOR THE INJURED PERSON, THE SENDING FACILITY SHALL CONSIDER, AT MINIMUM:

(1) ACCESSIBLITY 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

~~Any one of the following (~~**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 ~~(humerus and/or femur)~~
4. Unstable pelvic fracture
5. Paralysis or NEUROLOGIC DEFICIT ~~other evidence of spinal cord injury~~
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

~~Any one of the following:~~

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 ~~(auto going > or = 20 mph)~~
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

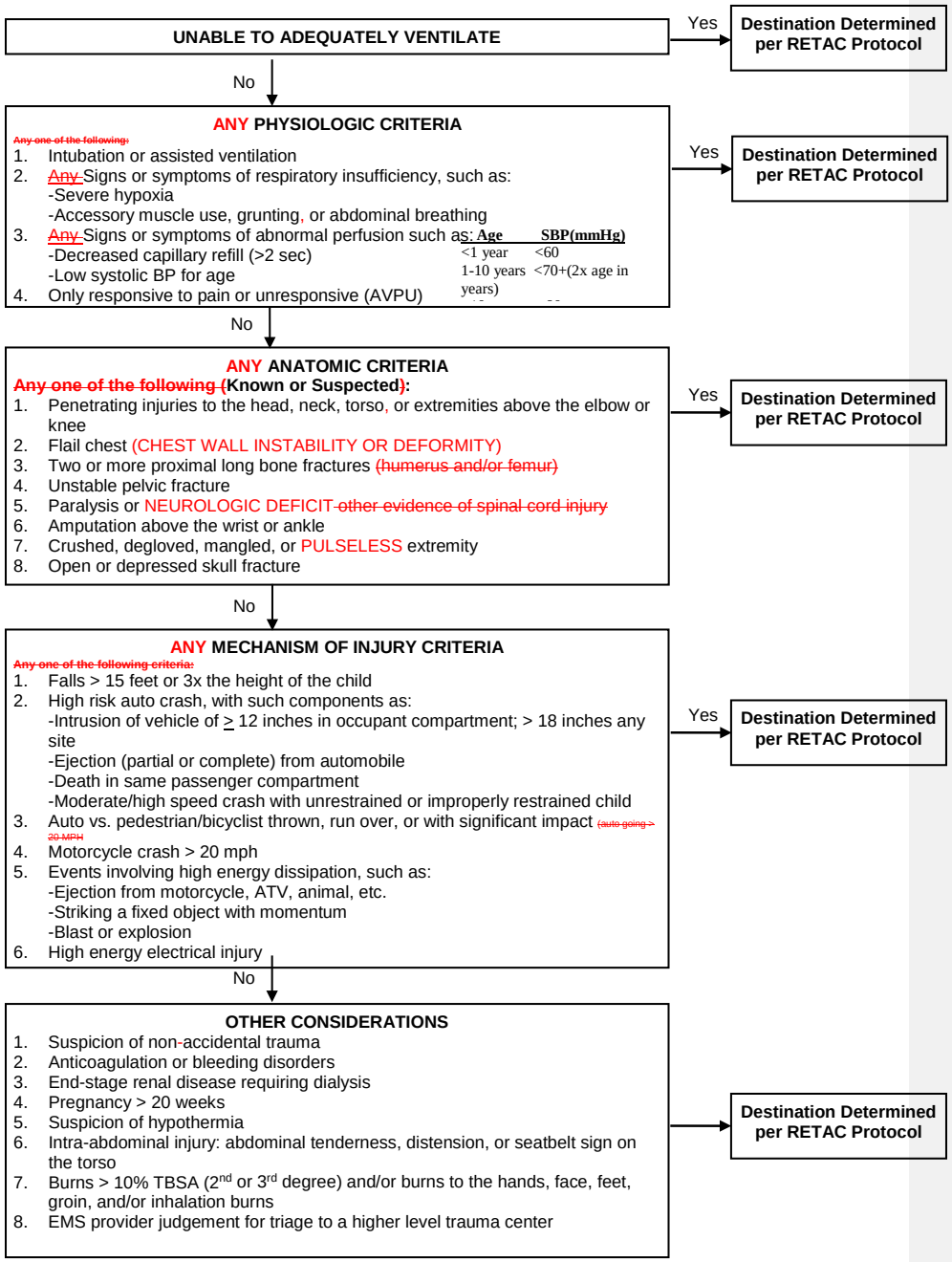
OTHER CONSIDERATIONS

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 MECHANISM 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)



DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STATEWIDE EMERGENCY MEDICAL AND TRAUMA CARE SYSTEM

6 CCR 1015-4

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

CHAPTER ~~1~~TWO - THE TRAUMA REGISTRY

~~1~~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 Clinics and Emergency Centers (CCEC) - Facilities as licensed by the D~~d~~epartment under 6 CCR 1011-1, Chapter IX.

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

5. Facility - A health facility licensed by the Department that receives ambulances such as a hospital, hospital unit, Critical Access Hospital (CAH) or Community Clinics and Emergency Centers (CCEC) caring for trauma patients.

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

13. Thermal injury - Any trauma resulting from the application of heat or cold, such as thermal burns, 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.

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

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

(3)~~iii.~~ 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)~~iv.~~ Emergency department information: clinical data upon arrival; procedures; providers; response times; disposition from the emergency department;

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

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

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

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

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

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

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

(3)~~iii.~~ 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)~~iv.~~ 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 non-designated 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.

~~1~~202. Provision of technical assistance and training

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

~~1~~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.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STATEWIDE EMERGENCY MEDICAL AND TRAUMA CARE SYSTEM

6 CCR 1015-4

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

CHAPTER 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 ~~d~~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

~~trauma surgeon (who is a member of the attending staff)~~ at a receiving TRAUMA CENTER~~facility~~ WITH THE RESOURCES NECESSARY TO MEET THE PATIENT'S NEEDS. Trauma consultation shall include written documentation completed by STAFF AT BOTH FACILITIES ~~the trauma surgeon at the Levels II and III facilities, or the attending physicians at the Level IV facility~~. Disagreements as to patient disposition will be documented at both facilities FOR DEPARTMENT REVIEW.

Commented [SG3]: Discussed and recommended by task force.

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

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

~~A. Bilateral pulmonary contusions requiring nontraditional ventilation,~~

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

~~C. Pelvic fractures with unrelenting hemorrhage,~~

~~D. Aortic tears,~~

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

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

~~A. Bilateral pulmonary contusions requiring nontraditional ventilation,~~

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

~~C. Pelvic fractures with unrelenting hemorrhage,~~

~~D. Aortic tears,~~

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

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

Commented [SG4]: Concepts removed from chapter 2 and 3

4~~6~~. Department - The Colorado Department of Public Health and Environment, unless the context requires otherwise.

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

Commented [SG5]: Suggest changing to new chapter one definition to be consistent. See language inserted below.

5. DIVERT – THE FACILITY CANNOT CURRENTLY ACCEPT EMS TRAFFIC. EMS SHALL TRANSPORT TRAUMA PATIENTS TO AN ALTERNATE DESTINATION IN ACCORDANCE WITH THE PREHOSPITAL TRAUMA TRIAGE 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 PRE-HOSPITAL TRAUMA TRIAGE ALGORITHM; OR 3) A TRAUMATIC INJURY THAT REQUIRES EMERGENT SURGERY.

Commented [SG6]: Recommended by task force

7~~8~~. 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.

89. 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.

Commented [SG7]: New definition. Term is used in this chapter but was not previously defined.

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

11. Met with R~~r~~eservations - 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 pre-hospital care to discharge or death. The multi-disciplinary group of health professionals shall meet on a regular basis, but not less than every two months, 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.

Commented [SG8]: Added from quality improvement rules, Section 304

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 ~~required~~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.

Commented [SG9]: Recommended by task force

154. 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.

165. Plan of C~~c~~orrection - Identifies how the facility plans to correct deficiencies or standards identified as met with reservations cited in the ~~d~~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 ~~d~~Department to address a temporary issue identified by the ~~d~~Department or the facility.

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

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

Commented [SG10]: Additional language added from quality improvement section 304

19~~8~~. 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.

Commented [SG11]: Recommended by task force

21~~19~~. 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~~0~~. State Emergency Medical and Trauma Services Advisory Council (SEMTAC) - ~~The council created in the Department p~~ 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.

Commented [OK12]: THIS NEW LANGUAGE COMES FROM 25-3.5-104(4)(a) AND CONFORMS WITH NEW CHAP. 4 RETAC'S DEFINITION OF SEMTAC.

23~~1~~. 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.

Commented [SG13]: Recommended by task force Feb 19

25~~2~~. Trauma Nurse Coordinator - The terms "trauma nurse coordinator," "trauma coordinator" and "trauma program manager" are used interchangeably in these regulations (6 CCR 1015). The trauma nurse coordinator (TNC) works to promote optimal care for the trauma patient through participation in clinical programs, administrative functions, and professional and public education. The TNC shall be actively involved in the state trauma system. The essential responsibilities of the TNC include maintenance of the trauma registry, continuous quality improvement in trauma care, ~~and~~ educational activities, AND~~to include~~ injury prevention.

26~~3~~. 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 ~~d~~Department. The burden shall be upon the applicant to prove that the program is equivalent to the TNCC.

27~~4~~. Trauma Service - The Trauma Service is an organized, identifiable program which includes: a Trauma Medical Director, a Trauma Nurse Coordinator, a Multi-disciplinary Trauma Committee, A Quality Improvement Program, Injury Prevention and Data Collection/Trauma Registry.

28~~5~~. 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 ~~hospital~~ FACILITY who takes responsibility for overseeing the program.

29~~26~~. Trauma Team - A facility-defined team of clinicians and ancillary staff, including those required by these rules.

30~~27~~. Trauma Team Activation - A facility-defined method (protocol) for notification of the trauma team of the impending arrival of a trauma patient based on the prehospital trauma triage algorithms as set forth in 6 CCR 1015-4, Chapter ~~Two~~ONE.

~~28. Verifiable, External Continuing Medical Education (CME) - A facility-defined, trauma-related continuing medical education program outside the facility, or a program given within the facility by visiting professors or invited speakers, or teaching an ATLS course.~~

Commented [SG14]: No longer necessary with the removal of CME requirements

31~~29~~. Waiver - A waiver is an exception to the trauma rules approved by the ~~d~~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:

(~~4~~1) Nondesignated facility - a hospital, CCEC, or other licensed facility that receives and is accountable for injured persons, but chooses not to seek trauma center designation.

(~~1~~2) New facility - a hospital, community clinic and emergency center (CCEC), or other licensed facility that is seeking trauma center designation for the first time or seeking to change to a different level of designation.

(~~2~~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.

(~~3~~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 ~~d~~Department may move to revoke, suspend, or otherwise limit a facility's designation consistent with the enforcement and disciplinary process contained in Section 302 of this chapter.

3. ~~New Facility~~ 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 COMORBID 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.

Commented [SG15]: This section is relocated from section 301.6 below. It has been stricken below with renumbering taking place in all sections in between. All changes recommended by task force.

Commented [SG16]: This is directly from current rule Chapter 2, 202.C.4 and 5 with addition for clarity.

Commented [SG17]: Proposed by staff, recommended by task force.

Commented [SG18]: This is directly from current rule Chapter 2, 202.C.4.

(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 6 CCR 1015-4, CHAPTER FOUR, 402.10.

(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.

Commented [SG19]: New language recommended by task force

~~3~~4. New Facility

A. Application Procedure

(1) A new facility shall submit a written notice to the ~~d~~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 ~~d~~Department's form and submit it along with the designation fee before the site visit according to the deadline specified by the ~~d~~Department.

(3) After an initial assessment of the application by the ~~d~~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 ~~d~~Department may delay or cancel the review process. The ~~d~~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 D~~d~~epartment. 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 ~~d~~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 ~~d~~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 ~~d~~Department will select the new facility review team according to the following specifications:

a. Level I-II facilities:

i. A minimum of one trauma surgeon and one trauma nurse who live and work outside the State of Colorado,

ii. One state observer,

iii. Departmental discretion to designate additional reviewers up to a full team as set forth in 301.~~5~~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.~~5~~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.~~5~~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 ~~d~~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 ~~d~~Department, in writing, no later than seven (7) calendar days after the ~~d~~Department's announcement of the proposed team members. Such notice shall contain all details of any alleged bias along with supporting documentation. The ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~Department to schedule a full review within 12-14 months.

(3) Prior to the full review, the facility shall follow the application procedures described in 301.~~5~~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.~~5~~6.B through D.

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

~~4~~5. Replacement Facility

A. Application Procedure

(1) A trauma designation review is required when the ~~d~~Department issues a new hospital or CCEC license based upon a change of location.

(2) A replacement facility shall submit a written notice to the ~~d~~Department at least 180 days in advance of the anticipated date of opening.

(3) The facility shall provide the ~~d~~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 ~~d~~Department before the site visit according to the specified deadline.

(4) After an initial assessment of the application and updated information by the ~~d~~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 ~~d~~Department may delay or cancel the review process. The ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~Department will select the site review team for the replacement facility according to the following specifications:

a. Level I-II facilities:

i. A minimum of one trauma surgeon and one trauma nurse who live and work outside the State of Colorado,

ii. One state observer,

iii. Departmental discretion to designate additional reviewers up to a full team as set forth in 301.~~5~~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.~~5~~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 ~~d~~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 ~~d~~Department, in writing, no later than seven (7) calendar days after the ~~d~~Department's announcement of the proposed team members. Such notice shall contain all details of any alleged bias along with supporting documentation. The ~~d~~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 ~~d~~Department.

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

D. Designation Decision Procedure

The designation decision procedure shall follow the one described for existing facility renewal at Section 301.~~5~~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.

~~5~~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 ~~d~~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 ~~d~~Department's form and submit it to the ~~d~~Department before the site visit according to the deadline specified by the ~~d~~Department.

(3) After an initial assessment of the application by the ~~d~~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 ~~d~~Department may delay or cancel the review process. The ~~d~~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 ~~d~~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

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

Commented [SG20]: Billing method has changed. No longer applicable

(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 ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~Department, in writing, no later than seven (7) calendar days after the ~~d~~Department's announcement of the proposed team members. Such notice shall contain all details of any alleged bias along with supporting documentation. The ~~d~~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 ~~d~~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 ~~d~~Department on the facility designation.

(2) If the ~~d~~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 ~~d~~Department shall notify the applicant in writing of its decision within thirty (30) calendar days of receiving the recommendation.

(4) The ~~d~~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 ~~d~~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.

~~6. Non-designated Facility~~

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

~~(1) The facility chooses not to seek such designation.~~

~~(2) The facility acknowledges and agrees that it may only treat patients who have single system injuries that are not threatening to life or limb and whose care is not complicated by co-morbid conditions.~~

~~(3) The facility has established transfer agreements as required by Section 25-3.5-703(4)(a), C.R.S.~~

~~(4) Within two hours of recognition that a patient has experienced a significant injury or mechanism as defined in 6 CCR 1015-4, Chapter Two, Section 202.C, 202.D or the prehospital algorithms, the facility shall resuscitate, stabilize and/or initiate transfer of the patient, after consultation with a trauma surgeon or emergency physician at the closest designated trauma center, as required by 6 CCR 1015-4, Chapter Two, Section 202.C.4 and Section 202.D.9. Transfer shall be to the closest appropriate trauma facility as defined by RETAC protocols and as determined in consultation with the trauma surgeon or emergency physician.~~

Commented [SG21]: Replaced by new section 3 above.

7. Waivers

A. The ~~d~~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 ~~d~~Department's form. The ~~d~~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 ~~A2~~
4300 Cherry Creek Drive South
Denver, CO 80246

E. At the same time the notice is posted in the facility, the facility shall also distribute a copy of the notice to prehospital emergency medical service providers active in the community served by the facility.

F. The completed waiver application shall be submitted to the ~~d~~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 ~~d~~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 ~~d~~Department. The ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~Department prior to any change of ownership of the facility as defined in 6 CCR 1011-1, Chapter ~~I~~2—GENERAL LICENSURE STANDARDS, Part 2.~~7~~6.

J. Facilities wishing to maintain a waiver beyond its expiration shall submit a new waiver application to the ~~d~~Department no less than ninety (90) days prior to the expiration of the waiver.

K. The ~~d~~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 ~~d~~Department determines that a change in federal or state law prohibits continuation of the waiver.

L. If the ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~Department in the form and manner required by the ~~d~~Department,

(2) Submitted within thirty (30) calendar days after the date of the ~~d~~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 ~~d~~Department has the discretion to approve, modify, or reject plans of correction.

(1) If the plan of correction is accepted, the ~~d~~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 ~~d~~Department shall notify the facility in writing, and the facility shall re-submit changes to the ~~d~~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 ~~d~~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 ~~d~~Department may impose disciplinary sanctions as set forth below.

3. Re-Review Fee Structure

A. In the event the ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~Department's regulations.

B. If the facility does not meet the level of designation criteria for which it has applied, the ~~d~~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 ~~d~~Department denies an application for designation or waiver, the ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~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 ~~d~~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 ~~l~~Lesser ~~l~~Level

A. The ~~d~~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 ~~d~~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, ~~and~~ Transfer Requirements, AND EMERGENT SURGERY

A. THE FACIILTY SHALL PROVIDE ON-GOING CONSULTATION, EDUCATION, AND TECHNICAL SUPPORT TO REFERRING FACILITIES, INDIVIDUALS, OR RETACS.

Commented [SG22]: This is directly from the definition of key resource facility.

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

C~~B~~. ~~A decision to transfer a patient shall be based solely on the clinical needs of the patient and not on the requirements of the patient's specific provider network or the patient's ability to pay.~~ 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.

Commented [SG23]: Revised language recommended by task force and used across levels for consistency.

D~~C~~. If the facility does not have a burn service, a reimplantation service, a pediatric trauma service, or an acute rehabilitation service, the facility shall have written transfer guidelines for patients in these categories.

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.

Commented [SG24]: This is added to provide consistent language for level I-V as recommended by task force

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) LEVEL I AND II TRAUMA CENTERS THAT ONLY ADMIT CHILDREN HAVING A SINGLE EXTREMITY ORTHOPEDIC FRACTURE OR MINOR HEAD TRAUMA, AS DETERMINED BY BEST PRACTICE GUIDELINES, SHALL TRANSFER ANY OTHER PEDIATRIC PATIENTS, AFTER EMERGENT SURGERY, IF 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.

Commented [DM25]: New language recommended by task force

3. Performance Improvement Process

A. General Provisions

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

(2) The facility shall be able to demonstrate that the trauma patient population can be identified for separate review regardless of the institutional performance improvement processes.

(3) Performance improvement shall be supported by a reliable method of data collection that consistently obtains valid and objective information necessary to identify opportunities for improvement. The process of analysis shall include multidisciplinary review and shall occur at regular intervals to meet the needs of the program. The results of analysis shall define corrective strategies and shall be documented.

(4) The facility shall demonstrate that the trauma registry is used to support the performance improvement program.

(5) The performance improvement program shall have defined audit filters based upon a regular review of registry and/or clinical data.

(6) There shall be appropriate, objectively defined standards to determine the quality of care.

(7) If more than 10 percent of injured patients with an Injury Severity Score greater than or equal to nine (excluding isolated hip fractures) are admitted to non-surgical services, the trauma facility shall demonstrate the appropriateness of that practice through the performance improvement program.

(8) Identified problem trends shall undergo peer review by the Peer Review/Performance Improvement Committee.

~~(9) A representative from the emergency department shall participate in prehospital peer review/performance improvement.~~

Commented [SG26]: Duplicate of 303.1.D

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

~~(11) If a facility conducts an internal trauma educational process in lieu of external trauma CME, that process shall be, at least in part, based on information from the peer review/performance improvement process and the principles of practice-based learning.~~

Commented [SG27]: Unnecessary per CME changes

(1012) The facility shall demonstrate that its graded activation criteria are regularly evaluated by the performance improvement program.

~~(13) The Level I or II adult facility that admits only children with single extremity orthopedic fracture or minor head trauma with a negative computed tomography~~

~~exam shall demonstrate the oversight of pediatric care through a pediatric-specific peer review/performance improvement process.~~

Commented [SG28]: (Duplicate 303.9.B.(3))

~~(14) The Level I or II adult facility that admits children having other than single extremity orthopedic fracture or minor head trauma with a negative computed tomography exam shall have a pediatric-specific peer review/performance improvement process, which shall include pediatric-specific process filters and outcome measures.~~

Commented [SG29]: (Duplicate 303.9.C(5))

(11~~15~~) Physician availability to the trauma patient in the ICU shall be monitored by the peer review/performance improvement program.

B. Multidisciplinary Trauma Committee

(1) The facility shall have a multidisciplinary committee to address trauma program operational issues.

(2) A multidisciplinary trauma committee shall continuously evaluate the trauma program's processes and outcomes.

(3) The committee shall include, at a minimum, the trauma medical director or designee and all core surgeons as well as liaisons from orthopedic surgery, neurosurgery, emergency medicine, radiology, and anesthesia. Each of these liaisons shall attend at least 50 percent of the meetings.

(4) The exact format of the committee may be hospital specific, but shall be multidisciplinary and consist of hospital and medical staff members who work to identify and correct trauma program system issues.

(5) The committee minutes shall reflect the review of operational issues and, when appropriate, the analysis and proposed corrective actions. The process shall identify problems and shall demonstrate problem resolution.

(6) The committee shall monitor compliance with all required time frames for availability of trauma personnel~~,~~ including, but not limited to, response times for general surgery, orthopedics, neurosurgery, anesthesiology, radiology, and radiology, MRI, or CT techs.

(7) The availability of anesthesia services and the absence of delays in airway control or operations shall be monitored.

(8) Radiologists shall be involved in protocol development and trend analysis that relate to diagnostic imaging.

(9) The multidisciplinary committee shall review and address issues related to the availability of necessary personnel and equipment to monitor and resuscitate patients in the PACU.

C. Peer Review/Performance Improvement Committee

(1) The facility shall have a Peer Review/Performance Improvement Committee chaired by the trauma medical director or physician designee.

(2) The committee shall include, at a minimum, the core group of general surgeons and a physician liaison from orthopedic surgery, neurosurgery, emergency medicine, radiology, and anesthesia. Each liaison shall attend at least 50 percent of the meetings.

(3) Each liaison shall be available to the trauma medical director for committee issues that arise in his or her department.

(4) The Peer Review/Performance Improvement Committee shall document evidence of committee attendance and participation.

(5) The committee shall review the overall quality of care for the trauma service, selected deaths, complications, and sentinel events with the objective of identifying issues and appropriate responses.

(6) Trauma patient care may be evaluated initially by individual specialties within their usual ~~d~~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.

Commented [SG30]: Change approved by TF and added in other places with similar language for consistency.

(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) A multidisciplinary trauma committee shall continuously evaluate the trauma program's processes and outcomes.~~

Commented [SG31]: (Duplicate 303.3.B.(2))

(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.

Commented [SG32]: Recommended by task force and consistent with other level facility rules

(2) The trauma program members or a representative of the program shall participate in state and regional trauma system planning, development, and operation.

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

C. Trauma Medical Director

(1) The trauma medical director shall be a board -certified (not board -eligible) surgeon, as those boards are defined under the "Clinical Requirements for General Surgery" as described in Section 303.5.C or shall be a Fellow of the American College of Surgeons with special interest in trauma care, shall take trauma call, and shall ~~have successfully completed an~~ REMAIN CURRENT IN ATLS ~~course~~.

(2) The trauma medical director shall demonstrate membership and active participation in state and either regional or national trauma organizations.

(3) The trauma medical director shall have the authority to correct deficiencies in trauma care and exclude from taking trauma call all trauma team members who do not meet required criteria. Through the performance improvement program and hospital policy, the trauma medical director shall have the responsibility and authority to determine each general surgeon's ability to participate on the trauma panel based on an annual review.

(4) ~~The trauma medical director shall accrue an average of 16 hours verifiable, external, trauma-related CME annually or 48 hours in the three years prior to the designation site review, including no less than one national meeting per three years.~~

Commented [DM33]: Task force recommends deletion

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~~3~~) 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.

Commented [SG34]: Moved, previously in ICU where redundant.

(4~~1~~) 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. ~~, and~~

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

Commented [DM35]: Task force recommended for deletion

5. Clinical Requirements for General Surgery

A. Role/Availability

(1) The on-call attending trauma surgeon shall be in the emergency department on patient arrival, as set forth below, for the highest level of activation, with adequate notification from the field. The maximum response time is 15 minutes, tracked from patient arrival, 80 percent of the time. The Multidisciplinary Trauma Committee shall monitor compliance of the attending surgeon's arrival times.

(2) A resident in postgraduate year four or five may begin resuscitation while awaiting arrival of the attending surgeon based on facility-defined criteria.

B. Equipment/Resources

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

C. Qualifications/Board Certification

(1) Except as provided below in subparagraph 2, all general surgeons on the trauma panel shall be fully credentialed in critical care and board certified in surgery by the American Board of Surgery (ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working toward certification, and less than five years out of residency.

(2) A foreign-trained, non-ABS boarded surgeon shall have the foreign equivalent of ABS certification in general surgery, clinical expertise in trauma care, an unrestricted Colorado license, and unrestricted credentials in surgery and critical care at the facility.

~~(3) The performance of all surgeons on the trauma panel shall be reviewed annually by the trauma medical director.~~

Commented [SG36]: Moved to D.(5) below

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.

Commented [SG37]: This is moved verbatim from 303.5. C.(3)

E. Education/Continuing Education: ~~(1)~~ ~~All general surgeons on the trauma panel shall~~ REMAIN CURRENT IN ~~have successfully completed the American College of Surgeons~~ ATLS. ~~course at least once.~~

~~(2) All general surgeons who take trauma call shall accrue an average of 16 hours annually of verifiable, external, trauma-related CME or demonstrate participation in an internal educational process conducted by the trauma program based on the peer review/performance improvement program and the principles of practice-based learning.~~

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

F. Participation in Statewide Trauma System

Each Level I AND II trauma facility shall provide a qualified surgeon as a state reviewer a minimum of one day per year, if requested by the ~~d~~Department.

6. Requirements for Emergency Medicine and the Emergency Department

A. Role/Availability

(1) The facility shall have a designated emergency department physician director supported by additional physicians to ensure immediate care for injured patients.

(2) A physician shall be present in the emergency department at all times.

(3) In facilities with emergency medicine residents, an in-house attending emergency physician shall provide supervision of the residents 24 hours per day.

(4) The facility shall designate an emergency physician to serve as the emergency medicine liaison to the trauma service.

B. Equipment/Resources

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

C. Qualifications/Board Certification

~~(1) Except as provided below in subparagraph 2, all emergency physicians on the trauma panel shall be board certified in emergency medicine by the American Board of Medical Specialties (ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working on certification, and less than five years out of residency.~~

~~(2) A foreign-trained, non-ABS boarded emergency physician shall have the foreign equivalent of ABS certification in emergency medicine, clinical expertise in trauma care, an unrestricted Colorado license, and unrestricted credentials at the facility.~~

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

(1) ALL EMERGENCY PHYSICIANS ON THE TRAUMA PANEL SHALL HAVE SUCCESSFULLY COMPLETED ATLS AT LEAST ONCE.

Commented [SG38]: Revised per new CME/board certification discussion. Recommended by TF

Commented [SG39]: Delete per new CME requirements.

Commented [SG40]: Delete per newCME/eligibility requirements

Commented [SG41]: Moved to D.3 below

Commented [SG42]: Moved from 303.6.E.(1)

(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.

Commented [DM43]: New language recommended by task force

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.

Commented [SG44]: Moved from 303.6.C.(3)

~~E. Education/Continuing Education~~

~~(1) All emergency physicians on the trauma panel shall have successfully completed the American College of Surgeons ATLS course at least once.(2)The trauma service emergency medicine liaison shall accrue an average of 16 hours annually of verifiable, external, trauma-related CME or 48 hours in the three years before the designation site review.~~

~~(3) All other emergency physicians on the trauma panel shall be reviewed annually by the emergency medicine liaison or designated representative to assure compliance with the facility's CME policy.~~

Commented [SG45]: Deleted per new CME/boarding requirements approved by TF

E~~F~~. Nursing Services

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

(2) The nurse/patient ratio shall be appropriate for the acuity of the trauma patients in the emergency department.

7. Clinical Requirements for Neurosurgery

A. Role/Availability

(1) The facility shall designate a neurosurgeon to serve as the neuroSURGICAL~~logical~~ liaison to the trauma service.

~~(2) The facility shall provide a neurotrauma on-call schedule, dedicated only to that facility, available 24 hours per day and either a posted second call or a contingency plan that includes transfer agreements with another designated Level I facility.~~ (moved below)

~~(3) Neurotrauma care shall be promptly available as defined by the facility. For less severe head injuries or injuries of the spine, neurotrauma care shall be available~~

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

Commented [SG46]: Deleted with revised requirements below,

(2) THE FACILITY SHALL DEFINE CRITERIA FOR NEUROSURGICAL ATTENDING RESPONSE.

(3) NEUROSURGICAL CARE MUST BE CONTINUOUSLY AVAILABLE FOR ALL TRAUMATIC BRAIN IINJURY AND SPINAL CORD INJURY PATIENTS AND MUST BE PRESENT WITHIN 30 MINUTES, BASED ON THE FACILITY'S NEUROSURGICAL RESPONSE CRITERIA.

Commented [DM47]: New language recommended by task force

(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.

Commented [SG48]: Moved from A.~~(3)~~ with edits

(5~~2~~) LEVEL I AVAILABILITY:

The facility shall provide a ~~neurotrauma~~ NEUROSURGICAL on-call schedule, dedicated only to that facility, available 24 hours per day, and either a posted ~~second call~~ BACKUP CALL SCHEDULE or a contingency plan that includes BYPASS AND transfer GUIDELINES ~~agreements~~ 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. ~~facility~~

Commented [SG49]: New language recommended by TF

(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.

Commented [DM50]: New language recommended by task force

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.

Commented [DM51]: New language recommended by TF

(2) ALL BOARD CERTIFICATIONS SHALL BE ISSUED BY A CERTIFYING ENTITY THAT IS NATIONALLY RECOGNIZED IN THE UNITED STATES.

Commented [SG52]: New language recommended by TF

~~(1) Except as provided below in subparagraph 2, all neurosurgeons who take trauma call shall be board certified in neurosurgery by the American Board of Surgery (ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working on certification, and less than five years out of residency.~~

~~(2) A foreign-trained, non-ABS-boarded neurosurgeon shall have the foreign equivalent of ABS certification in neurosurgery, clinical expertise in trauma care, an unrestricted Colorado license, and unrestricted credentials in neurosurgery at the facility.~~

Commented [SG53]: Deleted per new CME/boarding requirements approved by TF

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

Commented [SG54]: Moved below to D.(3)

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.

Commented [SG55]: Moved from 303.7.C.3.

~~E. Education/Continuing Education~~

~~(1) The trauma service neurosurgery liaison shall accrue an average of 16 hours annually of verifiable, external, trauma-related CME or 48 hours in the three years before the designation site review.~~

~~(2) All other neurosurgeons on the trauma panel shall be reviewed annually by the liaison or designated representative to assure compliance with the facility's CME policy.~~

Commented [SG56]: Deleted per revised CME changes

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.

Commented [SG57]: New language recommended by TF

(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.

Commented [SG58]: Moved from 303.8.A(2) below

(~~5~~2) LEVEL I 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 ~~second~~ BACKUP call

SCHEDULE or a contingency plan that includes BYPASS AND transfer ~~agreements~~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.. ~~Compliance with the facility-defined availability criteria shall be monitored by the Multidisciplinary Trauma Committee.(Moved above.)~~

(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.

~~(4) Plastic surgery, hand surgery, and treatment of spinal injuries shall be available to the orthopedic patient.~~

(7~~5~~) A fully credentialed spine surgeon shall be promptly available, as defined by the facility, 24 hours per day.

(8~~2~~) 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.

~~(1) Except as provided below in subparagraph (2), all orthopedic surgeons who take trauma call shall be board certified in orthopedic surgery by the American Board of Surgery (ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working on certification, and less than five years out of residency.~~

Commented [OK59]: CONFORMING CHANGES WITH NEURO

Commented [SG60]: Moved from 304.8.D.(2).)

Commented [OK61]: CONFORMING CHANGES WITH NEURO

Commented [SG62]: Redundant, dealt with under surgical specialties.

Commented [DM63]: New language recommended by TF

~~(2) A foreign-trained, non-ABS orthopedic surgeon shall have the foreign equivalent of ABS certification in orthopedic surgery, clinical expertise in trauma care, an unrestricted Colorado license, and unrestricted credentials in orthopedic surgery at the facility.~~

Commented [SG64]: Deleted per revised CME/Boarding requirements.

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

Commented [SG65]: Moved verbatim below

D. Clinical Commitment/Involvement

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

~~(2) A published orthopedic surgery back-up call schedule shall be available with the back-up surgeon promptly available.~~

(2~~3~~) 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.

Commented [SG66]: Moved verbaim from above

~~E. Education/Continuing Education~~

~~(1) The trauma service orthopedic surgical liaison shall accrue an average of 16 hours annually of verifiable, external, trauma-related CME or 48 hours in the three years before the designation site review.~~

Commented [SG67]: Deleted per new CME/boarding requirements approved by TF

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.

Commented [SG68]: Recommended by task force

D~~C~~. 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 ~~with a negative computed tomography~~ shall meet the following additional criteria:

(1) All physicians providing care to pediatric trauma patients shall be credentialed for pediatric trauma care by the hospital's credentialing body.

(2) The facility shall provide appropriate pediatric medical equipment in the emergency department.

(3) The facility shall provide a pediatric intensive care area 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.

(~~4~~5) The facility shall provide appropriate pediatric resuscitation equipment in all pediatric care areas.

(~~5~~6) The facility shall have a pediatric-specific peer review/performance improvement process, which shall include pediatric-specific process filters and outcome measures.

(~~6~~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 ~~in-house~~ 24 hours per day for emergency operations and airway problems in the injured patient. Compliance with the facility-defined availability criteria shall be monitored by the Multidisciplinary Trauma Committee.

Commented [SG69]: Moved to below

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.

Commented [SG70]: (Moved from 303.10.A.(1)b.)

(2) Qualifications

~~a. All anesthesiologists who take trauma call shall be board certified or board eligible, working toward certification, and less than five years out of residency.~~

a. LEVEL 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.

Commented [DM71]: New language recommended by TF

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

~~(3) Education/Continuing Education~~

~~a. The trauma service anesthesiologist liaison shall accrue an average of 16 hours annually of verifiable, external, trauma-related CME or 48 hours in the three years prior to the designation site review.~~

~~b. All other members of the anesthesiology team on the trauma panel shall be reviewed annually by the anesthesia liaison or designated representative to assure compliance with facility CME policy.~~

Commented [SG72]: Deleted per new CME/boarding requirements approved by TF

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.

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

Commented [SG73]: (Duplicate 303.3.B.(9))

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

c~~b~~. 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.

Commented [SG74]: Moved from 304.10.D.(1)b.)

(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.

Commented [SG75]: Moved from 304.10.E.(1)a.)

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.

Commented [SG76]: Moved from below

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

(2) Responsibility for Trauma Patients: a. The trauma surgeon shall retain oversight of the patient while in the ICU.

Commented [SG77]: Moved above to e.

b. The trauma service shall maintain oversight of the patient throughout the course of hospitalization.

Commented [SG78]: Moved to 303.4.E.(4)

(~~3~~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.

(~~4~~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~~c~~. Arterial pressure monitoring, pulmonary artery catheterization, patient rewarming, intracranial pressure monitoring, and other equipment to provide critical care consistent with current practice shall also be available.

c. VENTILATORY SUPPORT SHALL BE AVAILABLE FOR TRAUMA PATIENTS 24 HOURS PER DAY.

d~~b~~. ~~LEVEL I ONLY: Non-conventional ventilatory 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) T~~t~~horacic, 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. ~~and their respective support teams.~~

(2) A respiratory therapist shall be promptly available to care for trauma patients.

(3) Acute hemodialysis shall be promptly available for the trauma patient.

(4) Services shall be available 24 hours per day for the standard analyses of blood, urine, and other body fluids, coagulation studies, blood gases, and microbiology, including microsampling when appropriate.

(5) The blood bank shall be capable of blood typing and cross-matching and shall have an adequate supply of red blood cells, fresh frozen plasma, platelets, cryoprecipitate, and appropriate coagulation factors to meet the needs of injured patients.

11. Rehabilitation Requirements

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

Commented [SG79]: Moved from 304.10.E.(4)b.)

Commented [SG80]: The concept of non-conventional ventilatory support is not mentioned elsewhere in the rules. TF recommends deleting since not defined.

(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~~s~~, at a minimum:

(1) LEVEL I

a. Providing or participating in one ATLS course annually,

~~(2)~~ 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

~~(3)~~ 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.

Commented [SG81]: Moved from 304.13.B.)

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 ~~Joint Commission~~ U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES.

(1) These rules incorporate by reference the ~~*2011 Comprehensive Accreditation Manual for Hospitals: The Official Handbook*, effective December 2010~~ 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 ~~d~~Department maintains copies of the complete text of the incorporated materials for public inspection during regular business hours, and shall provide certified copies of any non-copyrighted material to the public at cost

upon request. Information regarding how the incorporated materials may be obtained or examined is available from the Division by contacting:

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

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

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

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

~~E.~~ (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 Facility Designation Criteria – Level II Facilities~~

Commented [SG82]: This entire section has been integrated with the Level I rules.

~~1. Prehospital Trauma Care Integration~~

~~A. The facility shall participate in the development and improvement of prehospital care protocols and patient safety programs.~~

~~B. The trauma medical director shall be involved in the development of the trauma facility's divert protocol as it affects the trauma service.~~

~~C. A trauma surgeon shall be involved in any decision regarding divert as it affects the care of the trauma patient.~~

~~D. A liaison from the emergency department shall participate in prehospital peer review/performance improvement.~~

~~2. Interfacility Consultation and Transfer Requirements~~

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

B. A decision to transfer a patient shall be based solely on the clinical needs of the patient and not on the requirements of the patient's specific provider network or the patient's ability to pay.

C. If the facility does not have a burn service, a reimplantation service, a pediatric trauma service or an acute rehabilitation service, the facility shall have written transfer guidelines for patients in these categories.

3. Performance Improvement Process

A. General Provisions

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

(2) The facility shall be able to demonstrate that the trauma patient population can be identified for separate review regardless of the institutional performance improvement processes.

(3) Performance improvement shall be supported by a reliable method of data collection that consistently obtains valid and objective information necessary to identify opportunities for improvement. The process of analysis shall include multidisciplinary review and shall occur at regular intervals to meet the needs of the program. The results of analysis shall define corrective strategies and shall be documented.

(4) The facility shall demonstrate that the trauma registry is used to support the performance improvement program.

(5) The performance improvement program shall have defined audit filters based upon a regular review of registry and/or clinical data.

(6) There shall be appropriate objectively defined standards to determine the quality of care.

(7) If more than 10 percent of injured patients with an Injury Severity Score greater than or equal to nine (excluding isolated hip fractures) are admitted to non-surgical services, the trauma facility shall demonstrate the appropriateness of that practice through the performance improvement program.

(8) Identified problem trends shall undergo peer review by the Peer Review/Performance Improvement Committee.

(9) A representative from the emergency department shall participate in prehospital peer review/performance improvement.

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

(11) If a facility conducts an internal trauma educational process in lieu of external trauma CME, that process shall be, at least in part, based on information from the peer review/performance improvement process and the principles of practice-based learning.

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

(13) The Level II adult facility that admits only children with single extremity orthopedic fracture or minor head trauma with a negative computed tomography exam shall demonstrate the oversight of pediatric care through a pediatric-specific peer review/performance improvement process.

(14) The Level II adult facility that admits children having other than single extremity orthopedic fracture or minor head trauma with a negative computed tomography exam shall have a pediatric-specific peer review/performance improvement process, which shall include pediatric-specific process filters and outcome measures.

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

B. Multidisciplinary Trauma Committee

(1) The facility shall have a multidisciplinary committee to address trauma program operational issues.

(2) A multidisciplinary trauma committee shall continuously evaluate the trauma program's processes and outcomes.

(3) The committee shall include, at a minimum, the trauma medical director or designee and all core surgeons as well as liaisons from orthopedic surgery, neurosurgery, emergency medicine, radiology and anesthesia. Each of these liaisons shall attend at least 50 percent of the meetings.

(4) The exact format of the committee may be hospital specific, but shall be multidisciplinary and consist of hospital and medical staff members who work to identify and correct trauma program system issues.

(5) The committee minutes shall reflect the review of operational issues and, when appropriate, the analysis and proposed corrective actions. The process shall identify problems and shall demonstrate problem resolution.

(6) The committee shall monitor compliance with all required time frames for availability of trauma personnel, including, but not limited to, response times for general surgery, orthopedics, neurosurgery, anesthesiology, radiology, and radiology, MRI or CT techs.

(7) The availability of anesthesia services and the absence of delays in airway control or operations shall be monitored.

(8) Radiologists shall be involved in protocol development and trend analysis that relate to diagnostic imaging.

(9) The multidisciplinary committee shall review and address issues related to the availability of necessary personnel and equipment to monitor and resuscitate patients in the PACU.

C. Peer Review/Performance Improvement Committee

(1) The facility shall have a Peer Review/Performance Improvement Committee chaired by the trauma medical director or physician designee.

(2) The committee shall include, at a minimum, the core group of general surgeons and a physician liaison from orthopedic surgery, neurosurgery, emergency medicine, radiology and anesthesia. Each liaison shall attend at least 50 percent of the meetings.

(3) Each liaison shall be available to the trauma medical director for committee issues that arise in his or her department.

(4) The Peer Review/Performance Improvement Committee shall document evidence of committee attendance and participation.

(5) The committee shall review the overall quality of care for the trauma service, selected deaths, complications and sentinel events with the objective of identifying issues and appropriate responses.

(6) Trauma patient care may be evaluated initially by individual specialties within their usual departmental review structures; however, identified problem trends shall undergo review within the Peer Review/Performance Improvement Committee.

(7) The facility shall also, in this committee or in another appropriate forum, provide for morbidity and mortality review of trauma cases. All trauma deaths shall be systematically reviewed and categorized as preventable, non-preventable or potentially preventable.

(8) When a consistent problem or inappropriate variation is identified, corrective actions shall be taken and documented.

(9) The trauma medical director shall ensure dissemination of committee information to all non-core general surgeons with documentation.

(10) The Peer Review/Performance Improvement Committee shall review and monitor the organ donation rate.

(11) The committee shall demonstrate that the program complies with required surgical response times at least 80% of the time.

(12) The peer review/performance improvement program shall monitor changes in interpretation of diagnostic information.

4. Facility Organization and the Trauma Program

A. Facility Governing Body and Medical Staff Commitment

(1) The facility shall demonstrate the commitment of the facility's governing body and medical staff through a written document. The document shall be reaffirmed every three years and be current at the time of the site review.

(2) The administrative structure of the hospital/trauma facility shall include, at a minimum, an administrator, a trauma medical director and a trauma program manager.

B. Trauma Program

(1) A multidisciplinary trauma committee shall continuously evaluate the trauma program's processes and outcomes.

(2) The trauma program members or a representative of the program shall participate in state and regional trauma system planning, development and operation.

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

C. Trauma Medical Director

(1) The trauma medical director shall be a board-certified surgeon (not board-eligible), as those boards are defined under the "Clinical Requirements for General Surgery" as described in Section 304.5.C or shall be a Fellow of the American College of Surgeons with special interest in trauma care, shall take trauma call and shall have successfully completed an ATLS course.

(2) The trauma medical director shall demonstrate membership and active participation in state and either regional or national trauma organizations.

(3) The trauma medical director shall have the authority to correct deficiencies in trauma care and exclude from taking trauma call all trauma team members who do not meet required criteria. Through the performance improvement program and hospital policy, the trauma medical director shall have the responsibility and authority to determine each general surgeon's ability to participate on the trauma panel based on an annual review.

(4) The trauma medical director shall accrue an average of 16 hours verifiable, external trauma-related CME annually or 48 hours in the three years prior to the designation site review, including no less than one national meeting per three years.

D. Trauma Resuscitation Team

(1) The facility shall define criteria for trauma resuscitation team activation.

(2) The criteria for a graded activation shall be clearly defined and continuously evaluated by the performance improvement program.

E. Trauma Service

(1) A trauma service admission is a patient who is admitted to or evaluated by an identifiable surgical service staffed by credentialed trauma providers.

(2) The facility shall demonstrate or provide documentation that the trauma service has sufficient infrastructure and support to ensure the adequate provision of care.

F. Trauma Program Manager

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

(1) Administrative ability,

(2) Evidence of educational preparation,

(3) Documented clinical experience, and

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

5. Clinical Requirements for General Surgery

A. Role/Availability

(1) The on-call attending trauma surgeon shall be in the emergency department on patient arrival, as set forth below, for the highest level of activation, with

~~adequate notification from the field. The maximum response time is 15 minutes, tracked from patient arrival, 80 percent of the time. The Multidisciplinary Trauma Committee shall monitor compliance of the attending surgeon's arrival times.~~

~~(2) A resident in postgraduate year four or five may begin resuscitation while awaiting arrival of the attending surgeon based on facility-defined criteria.~~

~~B. Equipment/Resources~~

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

~~C. Qualifications/Board Certification~~

~~(1) Except as provided below in subparagraph 2, all general surgeons on the trauma panel shall be fully credentialed in critical care and board certified in surgery by the American Board of Surgery (ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working toward certification and less than five years out of residency.~~

~~(2) A foreign-trained, non-ABS boarded surgeon shall have the foreign equivalent of ABS certification in general surgery, clinical expertise in trauma care, an unrestricted Colorado license and unrestricted credentials in surgery and critical care at the facility.~~

~~(3) The performance of all surgeons on the trauma panel shall be reviewed annually by the trauma medical director.~~

~~D. Clinical Commitment/Involvement~~

~~(1) All general surgeons on the trauma panel shall have general surgical privileges.~~

~~(2) The general surgeon on-call shall be dedicated to one trauma facility when taking trauma call.~~

~~(3) A published general surgery back-up call schedule shall be available. The back-up surgeon shall be present within 30 minutes of being requested to respond.~~

~~(4) An attending surgeon shall be present at all trauma operations. The surgeon's presence shall be documented.~~

~~E. Education/Continuing Education~~

~~(1) All general surgeons on the trauma panel shall have successfully completed the American College of Surgeons ATLS course at least once.~~

~~(2) All general surgeons who take trauma call shall accrue an average of 16 hours annually of verifiable, external trauma-related CME or demonstrate participation in an internal educational process conducted by the trauma program based on the peer review/performance improvement program and the principles of practice-based learning.~~

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

~~F. Participation in Statewide Trauma System~~

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

~~6. Requirements for Emergency Medicine and the Emergency Department~~

~~A. Role/Availability~~

~~(1) The facility shall have a designated emergency department physician director supported by additional physicians to ensure immediate care for injured patients.~~

~~(2) A physician shall be present in the emergency department at all times.~~

~~(3) In facilities with emergency medicine residents, an in-house attending emergency physician shall provide supervision of the residents 24 hours per day.~~

~~(4) The facility shall designate an emergency physician to serve as the emergency medicine liaison to the trauma service.~~

~~B. Equipment/Resources~~

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

~~C. Qualifications/Board Certification~~

~~(1) Except as provided below in subparagraph 2, all emergency physicians hired or contracted on or after the effective date of these rules to participate on the trauma panel shall be board certified in emergency medicine by the American Board of Medical Specialties (ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working on certification and less than five years out of residency.~~

~~(2) A foreign-trained, non-ABS boarded emergency physician shall have the foreign equivalent of ABS certification in emergency medicine, clinical expertise in trauma care, an unrestricted Colorado license, and unrestricted credentials at the facility.~~

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

~~D. Clinical Commitment/Involvement~~

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

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

~~E. Education/Continuing Education~~

~~(1) All emergency physicians on the trauma panel shall have successfully completed the American College of Surgeons ATLS course at least once.~~

~~(2) Physicians certified by boards other than emergency medicine who treat trauma patients in the emergency department shall remain current in ATLS.~~

(3) The trauma service emergency medicine liaison shall accrue an average of 16 hours annually of verifiable, external trauma-related CME or 48 hours in the three years before the designation site review.

(4) All other emergency physicians on the trauma panel shall be reviewed annually by the emergency medicine liaison or designated representative to assure compliance with the facility's CME policy.

F. Nursing Services

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

(2) The nurse/patient ratio shall be appropriate for the acuity of the trauma patients in the emergency department.

7. Clinical Requirements for Neurosurgery

A. Role/Availability

(1) The facility shall designate a neurosurgeon to serve as the neurological liaison to the trauma service.

(2) The facility shall define criteria for neurosurgical (attending and resident) activation.

(3) If neurosurgeons take call at more than one facility (either trauma or non-trauma) at a time, written primary and back-up call schedules are required, unless the combined volume of trauma-related emergency neurosurgical operative procedures in those facilities is less than an average of 25 per year over the last three calendar years for which data are available.

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

B. Equipment/Resources

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

C. Qualifications

(1) Except as provided below in subparagraph 2, all neurosurgeons who take trauma call shall be board certified in neurosurgery by the American Board of Surgery (ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working on certification and less than five years out of residency.

(2) A foreign-trained, non-ABS boarded neurosurgeon shall have the foreign equivalent of ABS certification in neurosurgery, clinical expertise in trauma care, an unrestricted Colorado license and unrestricted credentials in neurosurgery at the facility.

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

D. Clinical Commitment/Involvement

(1) Neurosurgeons shall be credentialed by the hospital with general neurosurgical privileges.

(2) Qualified neurosurgeons shall be regularly involved in the care of the head and spinal cord injured patients.

E. Education/Continuing Education

(1) The trauma service neurosurgery liaison shall accrue an average of 16 hours annually of verifiable, external trauma-related CME or 48 hours in the three years before the designation site review.

(2) All other neurosurgeons on the trauma panel shall be reviewed annually by the liaison or designated representative to assure compliance with the facility's CME policy.

8. Clinical Requirements for Orthopedic Surgery

A. Role/Availability/Specialists

(1) The facility shall designate an orthopedic surgeon to serve as the orthopedic liaison to the trauma program.

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

(3) Plastic surgery, hand surgery and treatment of spinal injuries shall be available to the orthopedic patient.

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

B. Equipment/Resources

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

C. Qualifications

(1) Except as provided below in subparagraph 2, all orthopedic surgeons who take trauma call shall be board certified in orthopedic surgery by the American Board of Surgery (ABS), the Bureau of Osteopathic Specialists and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; or shall be board eligible, working on certification and less than five years out of residency.

(2) A foreign-trained, non-ABS orthopedic surgeon shall have the foreign equivalent of ABS certification in orthopedic surgery, clinical expertise in trauma care, an unrestricted Colorado license and unrestricted credentials in orthopedic surgery at the facility.

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

~~D. Clinical Commitment/Involvement~~

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

~~(2) If orthopedic surgeons take call at more than one facility (either trauma or non-trauma) at a time, written primary and back-up call schedules are required.~~

~~(3) Orthopedic surgeons on the call panel shall be regularly involved in the care of the trauma patient.~~

~~E. Education/Continuing Education~~

~~(1) The trauma service orthopedic surgical liaison shall accrue an average of 16 hours annually of verifiable, external trauma-related CME or 48 hours in the three years before the designation site review.~~

~~(2) All other members of the orthopedic team on the trauma panel shall be reviewed annually by the liaison or designated representative to assure compliance with facility CME policy.~~

~~9. Pediatric Trauma Care~~

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

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

~~(1) Provide evidence of safe pediatric trauma care to include age-specific medical devices and equipment as appropriate for the resuscitation and stabilization of the pediatric patient.~~

~~(2) Assure that the physician and nursing staff providing care to the pediatric patient demonstrates competency in the care of the injured child appropriate to the type of injured child.~~

~~(3) Demonstrate oversight of the pediatric care provided through a pediatric-specific peer review/performance improvement process.~~

~~C. A Level II adult trauma facility that admits children having other than single extremity orthopedic fracture or minor head trauma with a negative computed tomography shall meet the following additional criteria:~~

~~(1) All physicians providing care to pediatric trauma patients shall be credentialed for pediatric trauma care by the hospital's credentialing body.~~

~~(2) The facility shall provide appropriate pediatric medical equipment in the emergency department.~~

~~(3) The facility shall provide a pediatric intensive care area or a transfer protocol and transfer agreements for pediatric patients requiring intensive care.~~

~~(4) The facility shall provide appropriate pediatric resuscitation equipment in all pediatric care areas.~~

~~(5) The facility shall have a pediatric-specific peer review/performance improvement process, which shall include pediatric-specific process filters and outcome measures.~~

(6) The facility shall assure that the nursing staff providing care to the pediatric patient has specialized training in the care of the injured child.

10. Collaborative Clinical Services

A. Anesthesiology

(1) Role/Availability

a. The facility shall designate an anesthesiologist to serve as the anesthesia liaison to the trauma program.

b. Anesthesiology services shall be promptly available as defined by the facility 24 hours per day for emergency operations and airway problems in the injured patient. Compliance with the facility-defined availability criteria shall be monitored by the Multidisciplinary Trauma Committee.

c. When anesthesiology residents or certified registered nurse anesthetists are used to fulfill availability requirements, the staff anesthesiologist on call shall be notified and be present in the operating department. The process shall be monitored through the performance improvement process.

(2) Qualifications

a. All anesthesiologists who take trauma call shall be board certified or board eligible, working toward certification and less than five years out of residency.

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

(3) Education/Continuing Education

a. The trauma service anesthesiologist liaison shall accrue an average of 16 hours annually of verifiable, external trauma-related CME or 48 hours in the three years prior to the designation site review.

b. All other members of the anesthesiology team on the trauma panel shall be reviewed annually by the anesthesia liaison or designated representative to assure compliance with facility CME policy.

B. Operating Room

(1) General Requirements

a. A dedicated operating room team shall always be available.

b. If the primary operating room team is occupied, there shall be a mechanism in place to staff a second operating room.

c. There shall be a facility-defined access policy for urgent trauma cases of all specialties.

(2) Equipment Requirements

a. The facility shall have rapid infusers, thermal control equipment for patients and fluids, intraoperative radiological capabilities, equipment for

fracture fixation, equipment for endoscopic evaluation (bronchoscopy and gastrointestinal endoscopy) and other equipment to provide operative care consistent with current practice.

b. The facility shall have the necessary equipment to perform a craniotomy.

C. Postanesthesia Care Unit (PACU)

(1) Qualified nurses shall be available 24 hours per day to provide care for the trauma patient, if needed, in the recovery phase.

(2) If the availability of PACU nurses is met with an on-call team from outside the hospital, the availability of the PACU nurses and absence of delays shall be monitored by the peer review/performance improvement program.

(3) The PACU shall provide all of the necessary resources including instruments, equipment and personnel to monitor and resuscitate patients consistent with the facility-defined process of care.

(4) Recovery of the trauma patient in a critical care (intensive care) unit is also acceptable.

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

D. Radiology

(1) Role/Availability

a. Qualified radiologists shall be promptly available as defined by the facility for the interpretation of imaging studies and shall respond in person when requested.

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

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

(2) Clinical Commitment/Involvement

a. Diagnostic information shall be communicated in written form in a timely manner as defined by the facility.

b. Critical information that is deemed to immediately affect patient care shall be promptly communicated to the trauma team.

c. The final report shall accurately reflect the chronology and content of communications with the trauma team, including changes between the preliminary and final interpretation.

(3) Radiology Support Services

a. The facility shall have policies designed to ensure that trauma patients who may require resuscitation and monitoring are accompanied by appropriately trained providers during transport to and while in the radiology department.

b. Conventional radiography and computed tomography (CT) shall be promptly available as defined by the facility 24 hours per day and available in less than 30 minutes when requested by a trauma surgeon.

c. An in-house radiographer and in-house CT technologist shall be promptly available as defined by the facility 24 hours per day and available in less than 30 minutes when requested by a trauma surgeon.

d. Conventional catheter angiography and sonography shall be promptly available as defined by the facility 24 hours per day and available in less than 30 minutes when requested by a trauma surgeon.

e. Magnetic resonance imaging capability shall be promptly available as defined by the facility 24 hours per day and available in less than 30 minutes when requested by a trauma surgeon.

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

E. Critical Care

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

a. This service shall be directed or co-directed by a qualified surgeon with expertise in the care of injured patients.

b. This service may be staffed by critical care trained physicians from different specialties.

c. Physician coverage of critically ill trauma patients shall be promptly available as defined by the facility 24 hours per day. These physicians shall be capable of rapid response to deal with urgent problems as they arise. Availability shall be monitored by the peer review/performance improvement program.

d. All trauma surgeons shall be fully credentialed by the facility to provide all intensivist services in the ICU. There shall be full hospital privileges for critical care.

(2) Responsibility for Trauma Patients

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

b. The trauma service shall maintain oversight of the patient throughout the course of hospitalization.

(3) Nursing Services

a. A qualified nurse shall be available 24 hours per day to provide care for patients during the ICU phase of care.

b. The nurse/patient ratio shall be appropriate for the acuity of the trauma patients in the ICU.

c. The facility shall assure that the nursing staff providing care to the pediatric patient has specialized training in the care of the injured child.

(4) Equipment

a. The ICU shall have the necessary resources including instruments and equipment to monitor and resuscitate patients consistent with the facility-defined process of care.

b. Ventilatory support shall be available for trauma patients 24 hours per day.

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

F. Other Surgical Specialties

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

G. Medical Consultants

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

(2) A respiratory therapist shall be promptly available to care for trauma patients.

(3) Acute hemodialysis shall be promptly available for the trauma patient.

(4) Services shall be available 24 hours per day for the standard analyses of blood, urine, and other body fluids, coagulation studies, blood gases, and microbiology, including microsampling when appropriate.

(5) The blood bank shall be capable of blood typing and cross-matching and shall have an adequate supply of red blood cells, fresh frozen plasma, platelets, cryoprecipitate and appropriate coagulation factors to meet the needs of injured patients.

11. Rehabilitation Requirements

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

(1) Within the hospital's physical facilities; or

(2) At a freestanding rehabilitation hospital. In this circumstance, the trauma facility shall have appropriate transfer agreements.

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

(1) Physical, occupational and speech therapy, and

(2) Social services.

12. Trauma Registry

A. Trauma registry data shall be collected and analyzed by every trauma facility. It shall contain detailed, reliable and readily accessible information that is necessary to operate a trauma facility.

B. Trauma data shall be submitted to the National Trauma Data Bank on an annual basis.

C. The facility shall demonstrate that the trauma registry is used to support the performance improvement program.

D. Trauma data shall be submitted to the Colorado Trauma Registry within 60 days of the end of the month during which the patient was discharged.

E. The trauma program shall have in place appropriate measures to assure that trauma data remain confidential.

F. The facility shall monitor data validity.

13. Outreach and Education

A. Public Outreach and Education

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

B. Professional Outreach and Education

The trauma facility shall engage in professional outreach and education activities that include, at minimum, internal and external trauma-related educational opportunities for physicians, nurses and allied health professionals.

14. Prevention

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

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

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

(1) Selecting a target injury population,

(2) Gathering and analyzing data,

(3) Developing evidenced based intervention strategies based on local data and best practices,

(4) Formulating a plan,

(5) Implementing the program, and

(6) Evaluating and revising the program as necessary.

D. The facility shall demonstrate collaboration with or participation in national, regional or state injury prevention programs.

E. The facility shall have a mechanism to identify patients who may have an alcohol addiction. The facility shall also have the capability to provide an intervention for patients identified as potentially having an alcohol addiction.

~~F. The facility shall collaborate and mentor lower level trauma centers regarding injury prevention.~~

~~15. Organ Procurement Activities~~

~~A. The facility shall have an established relationship with a recognized organ procurement organization (OPO).~~

~~B. The facility shall have a written policy for triggering notification of the regional OPO.~~

~~C. The facility shall have written protocols defining clinical criteria and confirmatory tests for the diagnosis of brain death.~~

~~16. Disaster Planning and Management~~

~~A. The facility shall meet the Emergency Management-related requirements of the Joint Commission. These rules incorporate by reference the *2011 Comprehensive Accreditation Manual for Hospitals: The Official Handbook*, effective December 2010.~~

~~B. Such incorporation does not include later amendments to or editions of the referenced material. The Health Facilities and Emergency Medical Services Division of the department maintains copies of the complete text of the incorporated materials for public inspection during regular business hours, and shall provide certified copies of any non-copyrighted material to the public at cost upon request. Information regarding how the incorporated materials may be obtained or examined is available from the Division by contacting:~~

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

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

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

~~17. RETAC Integration~~

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

30~~4~~5. 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 pre-hospital to rehabilitative care. The plan shall ensure the continuity of care for all admitted patients. ~~If the facility does not have the resources available to manage medical co-morbidities, then the patient shall be transferred.~~

Commented [SG83]: Deleted section is duplicate 306.3.A.(4).

A. In Level III facilities, this plan may be parallel to, and interactive with, the hospital-wide quality improvement program as defined in ~~C.R.S. §~~ 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 ~~specific~~FACILITY-defined, trauma-related indicators AND components ~~is overseen by the TMD.~~ Trauma-related issues must be documented separately, and the TMD has ~~purview~~ AUTHORITY over any trauma issues.

Commented [SG84]: Duplicate language

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

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.

~~B. The committee will establish attendance requirements.~~

~~C~~ 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.

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

~~E.~~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 pre-hospital trauma care review.

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

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

(6) Establishing and enforcing policies and procedures.

(7) Reviewing 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 pre-hospital to discharge or death.

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

Commented [SG85]: CONFLICTS with requirement below.

Commented [SG86]: Moved from section 305.5.

Commented [SG87]: Moved from section 305.5. and slightly revised

Commented [SG88]: Moved from section 305.5.

Commented [SG89]: Conflicts with above mandatory attendance requirements

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 ~~C.R.S. §~~SECTION 12-36.5-104, 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.

Commented [SG90]: Inserted to allow for multiple methods. Language consistent across all levels.

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.

30~~5~~6. ~~Expanded~~ Scope of Care for Designated Trauma Centers Level III – ~~I~~V

Commented [SG91]: Please note that while this section 305 looks completely new, it is only rearranged for a more logical flow of ideas. New language is marked as such.

1. GENERAL REQUIREMENTS

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

Commented [SG92]: Moved to 305.1.B.

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

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

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

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

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

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

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

Commented [SG93]: Moved with edits to 305.3.A.(1)

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

Commented [SG94]: Moved to section 305.4.A, C-E.

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

Commented [SG95]: Moved to 305.4.B

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.

Commented [SG96]: Moved from **305. 1. A.** with edits

2. Emergent Surgery at Level III and IV Trauma Centers

A. All Level III and IV trauma centers may ~~attempt~~ PERFORM emergent surgery if appropriate resources are available. ~~Once the patient is stabilized to the extent of the facility's capabilities, i~~If AFTER THE EMERGENT SURGERY IS PERFORMED, the facility does not have the POST-OPERATIVE ~~clinical platform~~ RESOURCES to care for the patient and for potential complications, the facility shall ~~consult with a higher level trauma center or T~~transfer TO A TRAUMA CENTER WITH THE NECESSARY RESOURCES TO MEET THE PATIENT'S NEEDS.~~at the discretion of the surgeon.~~

B~~C~~. If the surgeon on call AT A LEVEL III OR IV 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 ~~transfer to or~~consult with OR TRANSFER TO a higher level trauma center.

Commented [SG97]: Switched B and C for more logical flow of ideas

C~~B~~. 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, ~~to determine if the time to transfer would exceed the time to surgeon and operating room availability. If the surgeon's arrival and operating room capability time exceeds the transfer time,~~ the patient shall be transferred ~~to a higher level trauma center~~.

3. Mandatory Transfers~~r~~ and CONSULTATION,~~Consideration for Transfer~~ LEVEL III-V TRAUMA CENTERS

~~A. Nothing in these rules shall preclude any facility with the appropriate resources from providing emergent surgery as described above.~~

Commented [SG98]: Moved to 305.3.A.(2)

~~B. All Level III and IV trauma centers shall transfer patients with any injuries requiring resources beyond those available under the facility's scope of care and patients with the~~

Commented [SG99]: Moved to 305.3.A.(3)

following injuries, in addition to patients with injuries described in 6 CCR 1015-4, Chapter Two:

(1) Hemodynamically unstable pelvic fracture.

(2) Pelvic fracture requiring operative fixation.

(3) Fracture or dislocation with vascular injury requiring operative vascular repair.

Commented [SG100]: Moved to 3035.3.C.(1)

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

Commented [SG101]: Moved and revised. See 305.3.B.(1)

D. All Level IV trauma centers shall transfer trauma patients under the following conditions, in addition to patients with injuries described in 6 CCR 1015-4, Chapter Two:

(1) Bilateral femur fractures.

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

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

b. Chest injury - multiple rib fractures (> 4 unilaterally or > 2 bilaterally) or hemothorax.

c. Abdomen - hollow organ or solid visceral injury, intra or retroperitoneal bleeding.

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

(4) Flail chest; 3 or more ribs, any age.

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

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

(7) Mechanical ventilation anticipated to be greater than twenty-four (24) hours if the facility does not have the clinical platform to provide ongoing ventilator management.

(8) Solid visceral or hollow organ injury if the facility does not have the clinical platform to care for the patient.

(9) Vascular injury requiring operative vascular repair.

(10) Crushed, de-gloved or mangled extremity.

(11) Suspected or actual evidence of non-accidental trauma requiring social or clinical care beyond the facility's resources.

Commented [SG102]: Moved almost verbatim to 305.3.C.(5)

E. Level III trauma centers with no neurosurgical/orthopedic spine coverage and all level IV and V trauma centers receiving trauma patients of any age under the following conditions, in addition to patients with injuries described in 6 CCR 1015-4, Chapter Two:

~~(1) Shall transfer the following:~~

~~a. Glasgow Coma 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.~~

Commented [SG103]: Moved to 305.3.C.(3)

~~(2) Shall consider transferring the following:~~

~~a. Any patient with intracranial hemorrhage or evidence of cerebral edema due to trauma. Consult a neurosurgeon at a higher level of care for consideration of transfer. If the patient is admitted at the level III or IV, after consultation, the trauma surgeon shall admit and manage the patient through the course of high acuity care.~~

Commented [SG104]: Moved to 305.3.B.(2)

~~b. Any patient with a spinal column fracture other than a lumbar or thoracic transverse process fracture. Consult a spinal specialist at a higher level of care for consideration of transfer.~~

Commented [SG105]: Moved to 305.3.B.(3)

~~F. All level III trauma centers with part-time neurosurgical/orthopedic spine coverage shall:~~

~~(1) Have a published call schedule.~~

~~(2) Communicate with pre-hospital regarding availability of neurosurgical coverage.~~

~~(3) Meet the standards in 6 CCR 1015-4, Chapter Three 306.3.E. when there is no neurosurgical/orthopedic spine coverage.~~

Commented [SG106]: Moved to 305.4.J.(1)(a-c)

~~G. 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.~~

Commented [SG107]: Moved to 305.3.C.(4)

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

~~(1) Severe chronic obstructive pulmonary disease with home O2 requirement > 4L.~~

~~(2) Pulmonary hypertension.~~

~~(3) Critical aortic stenosis.~~

~~(4) Coronary artery disease and/or recent myocardial infarction within 6 months.~~

~~(5) Renal disease requiring dialysis.~~

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

~~(7) Unmanageable coagulopathy.~~

~~(8) Body mass index > 40.~~

~~(9) Pregnancy > 20 weeks.~~

Commented [SG108]: Moved to 305.3.C.(2)

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

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

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

Commented [SG109]: Moved to 305.4.J.

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.

Commented [SG110]: Weather, disaster, moved from section **306.**1.C.

(2) NOTHING IN THESE RULES SHALL PRECLUDE ANY FACILITY WITH THE APPROPRIATE RESOURCES FROM PROVIDING EMERGENT SURGERY AS PROVIDED IN SECTION 305.2.

Commented [SG111]: Moved from **306.**.3.A. with slight rewording in the reference language only

(3) PATIENTS OF ANY AGE WITH A TRAUMATIC INJURY REQUIRING RESOURCES BEYOND THOSE AVAILABLE IN THE FACILITY'S SCOPE OF CARE SHALL BE TRANSFERRED.

Commented [SG112]: Moved from **306.**3.B. with slight rewording

(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 TRAUMA PATIENTS. THE RECEIVING TRAUMA CENTER MUST MEET THE REQUIREMENTS SET FORTH IN 6 CCR 1015-4, CHAPTER THREE, SECTION 303.9.D.

Commented [DM113]: New language recommended by the TF

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.

Commented [SG114]: Moved and edited from **306.**3.C. and 4.F(2).

(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, AFTER CONSULTATION, A GENERAL SURGEON ON THE TRAUMA PANEL SHALL ADMIT AND MANAGE THE PATIENT THROUGH THE COURSE OF HIGH ACUITY CARE.

Commented [SG115]: Moved from current section **306.3.**E(2) a. with some edits.

(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.

Commented [SG116]: Moved from current section**306.3.E.(2) b.** with edits.

(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 CONSIDERATION PURPOSES.

C. MANDATORY TRANSFERS FOR PATIENTS OF ALL AGES

(1) LEVEL III - V TRAUMA CENTERS SHALL TRANSFER 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 O_2 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.

Commented [SG117]: Recommended by task force, language edited to be consistent with Level I/II

Commented [SG118]: Moved verbatim from **306.**3.B, 1-3

Commented [DM119]: New language recommended by TF

Commented [SG120]: Moved almost verbatim from section **306.** 3.H.

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.

Commented [SG121]: Moved verbatim from **306.** 3.E(1)(a-g).

(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.

Commented [SG122]: Moved verbatim from **306.** 3.G.

(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 OF 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.

Commented [SG123]: Moved almost verbatim from **306.** 3.D.

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

Commented [DM124]: New pediatric language recommended by the TF

4. ~~Expanded Scope Required Resources~~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.

Commented [SG125]: Moved verbatim with addition of general surgery from 306.1.A.

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.

Commented [SG126]: Moved verbatim from 306.1.E

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.

FA. An Eemergency Ddepartment with:

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

(2) A massive transfusion protocol. If the facility initiates the MTP, consultation with a higher level trauma facility will be required to expedite transfer or discuss further stabilization.

GB 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.

HC Inpatient services with:(1) Mmedical consultation with a physician appropriately credentialed by the facility to treat medical co-morbidities.

ID 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 Ccomplications recognition and care.

c. Recognition and care of hemodynamic instability.

J. WITH RESPECT TO LEVEL 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 PRE-HOSPITAL 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.

Commented [SG127]: Moved verbatim from 306. 1 B-D

Commented [SG128]: This section and following are re-lettered because they are current language just moved within the same section

Commented [SG129]: Moved to 305.3.B.1

Commented [SG130]: Moved verbatim from **306.** 3.F.

(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.

~~J.5. Performance Improvement and Patient Safety~~

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

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

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

Commented [SG131]: Moved almost verbatim from section **306**.3.I. above.

Commented [SG132]: Moved from 306.3.J, with addtions. Recommended by TF

Commented [SG133]: Deleted, duplicative

Commented [SG134]: Moved to section 304.3. (quality improvement for level III-V)

306~~7~~. 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. ~~Administration and Organization Criteria.~~ A Level III Trauma Center shall have~~:A. A~~ a trauma program with:

A. ~~(1)~~ An administrative organizational structure that identifies the institutional support and commitment. The program's location within that structure must be placed so that it may interact with at least equal authority with other departments providing patient care within the facility.

B. ~~(2)~~ Medical staff commitment to support the program demonstrated by a written commitment to provide the specialty care needed to support optimal care of the injured patient and specific delineation of surgical privileges.

C. ~~(3)~~ Policies that identify and establish the scope of ~~trauma~~ care for both adult and pediatric patients~~,~~ including, but not limited to:

(1)~~a.~~ Initial resuscitation and stabilization;

(2)~~b.~~ Admission and inter~~-~~facility consultation and transfer criteria;

(3)~~c.~~ Surgical capabilities;

(4)~~d.~~ Critical care capabilities;

(5)~~e.~~ Rehabilitation capabilities, if available;

(6)~~f.~~ Neurosurgical capabilities, if available;

(7)~~g.~~ Spinal ~~C~~cord surgical capabilities, if available;

(8)~~h.~~ Other ~~specialist~~ capabilities, if available;~~ and~~

(9)~~i.~~ 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.~~(4)~~ A Trauma Medical Director who is a board certified general surgeon, or is board qualified working toward board certification. A facility may have another physician as a co-trauma medical director. The Trauma Medical Director:

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

a.~~i.~~ Trauma multidisciplinary program,

b.~~ii.~~ Trauma quality improvement program,

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

d.~~iv.~~ Policy and procedure development and enforcement, and

e.~~v.~~ Peer review.

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

(3)~~c.~~ Functions as trauma medical director at only one facility.

(4)~~d.~~ Participates in the on-call schedule.

(5)~~e.~~ Participates in regional trauma system development.

E.~~(5)~~ A facility-defined trauma team, with an identifiable team leader.

F.~~(6)~~ A facility-defined trauma team activation protocol that includes who is notified and the response requirements. The protocol shall base activation of the team on the anatomical, physiological, mechanism of injury criteria, and ~~co-morbid factors~~OTHER CONSIDERATIONS as outlined in the pre-hospital trauma triage algorithms as set forth in 6 CCR 1015-4, Chapter ONE~~Two~~.

Commented [SG135]: Conforming change with chapter one algorithm

G.~~(7)~~ A facility-defined trauma service with the personnel and resources identified as needed to provide care for the injured patient.

H.~~(8)~~ A registered nurse identified as the Trauma Nurse Coordinator with educational preparation and clinical experience in care of the injured patient as defined by the facility. This position is responsible for the organization of services and systems necessary for a multidisciplinary approach to care of the injured patient.

I.~~(9)~~ A m~~M~~ulti-disciplinary trauma committee with specialty representation. This ~~committee is involved in the development of a plan of care for the injured patient and i~~s 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.~~(10)~~ A quality improvement program as defined in Section 304~~8~~ of this chapter.

K. POLICIES, PROCEDURES, AND PRACTICE 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~~(11)~~ Divert protocols, to include:

(1)~~a.~~ Coordination with the RETAC,

(2)~~b.~~ Notification of pre-hospital providers AND OTHER IMPACTED FACILITIES, CONSISTENT WITH RETAC PROTOCOLS, IF ANY.

(3)~~c.~~ Reason for divert, AND

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

M.~~(12)~~ A trauma registry as required in Chapter TWO~~1~~ of these rules, and trauma data entry support~~,~~.

N.~~(13)~~ Participation in the RETAC and statewide quality improvement programs as required in rule.

~~B. Hospital departments/divisions/sections~~

~~(1) Surgery~~

~~(2) Emergency Medicine~~

~~(3) Anesthesia~~

Commented [SG136]: Duplicative

2. A Level III trauma center shall meet all of the following clinical capabilities criteria:

A. Emergency Medicine in house 24 hours a day.

B. ~~The following service~~ GENERAL SURGERY available in person 24 hours a day within 20 minutes of trauma team activation~~:~~,

(1) ~~General surgery:~~ ~~C~~coverage shall be provided by.:

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

(2) W~~w~~ho may only take call at one facility at any one time, AND

(3)~~b.~~ The surgeon will meet those patients meeting facility-defined Trauma Team Activation criteria upon arrival, by ambulance, in the emergency department. For those patients meeting Trauma Team Activation criteria where adequate prior notification is not possible, the surgical response shall be 20 minutes from notification.

C. The following services on - call and available within 30 minutes of request by the trauma team leader:

(1) ANESTHESIA COVERAGE SHALL BE BY AN ANESTHESIOLOGIST OR A CERTIFIED REGISTERED NURSE ANESTHETIST (CRNA).

Commented [SG137]: Language from below streamlined.

~~a. A board certified anesthesiologist, or board qualified anesthesiologist working toward certification,; or~~

~~b. A Certified Registered Nurse Anesthetist (CRNA).~~

Commented [SG138]: Conforming changes regarding board certification

(2) Orthopedic surgery. ~~Coverage shall be by: a. A board certified or board qualified orthopedic surgeon working toward certification.~~

D. The following non-surgical specialists on call, credentialed, and available in person or by tele-radiology for patient service upon request of the trauma team leader:

(1) A radiologist, and

(2) Internal medicine.

3. A Level III trauma center shall have all of the following facilities, resources, and capabilities:

A. An ~~E~~emergency ~~D~~department with:

(1) Personnel, to include:

a. A designated physician director who is board certified in emergency medicine, family practice, internal medicine, or surgery, and whose primary practice is in emergency medicine.

~~b. Physician(s) designated as member(s) of the trauma team:~~

~~i. Physically present in the Emergency Department 24 hours/day.~~

~~ii. And who are board certified in emergency medicine, family practice, internal medicine, or surgery. and~~

~~ii. Who are Advanced Trauma Life Support verified unless board certified in emergency medicine.~~

~~iii. Whose primary practice is in emergency medicine.~~

~~iv. All physicians hired or contracted for services after 2005 must be board certified in emergency medicine or board qualified working toward certification.1~~

~~c~~b. Registered ~~N~~nurses in-house 24 hours a day who:

i. Provide continuous monitoring of the trauma patient until release from the ~~E~~emergency ~~D~~department, and

ii. At least one ~~R~~registered ~~N~~nurse in the ~~E~~emergency ~~D~~department 24 hours/day who maintains current ~~verification~~ 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 CO_2 determination;

d. Suction devices;

e. Electrocardiograph ~~oscilloscope~~ AND defibrillator;

Commented [DM139]: Conforming amendments regarding board eligibility

Commented [SG140]: Conforming changes regarding board certification

Commented [SG141]: Removed because conflicts with 2.A above

Commented [SG142]: Removed per new CME/ATLS/boarding requirements

Commented [SG143]: Antequated language

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.

~~v. Peritoneal lavage~~

Commented [SG144]: Task force approved deletion; antequated language

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.

Commented [SG145]: Added per best practice. Also added elsewhere for consistency.

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 SECTION 305.3 AND 305.4.

~~(1) Acute Spinal Cord Management with:~~

~~a. Neurosurgeons or orthopedic surgeons with special qualifications in acute spinal cord management, on-call and available within a facility-defined time of request of the trauma team leader, or~~

~~b. Written transfer guidelines for patients with spinal cord injuries.~~

~~(2) Acute Brain Injury Management with a:~~

~~a. Neurosurgeon on-call and available within 30 minutes of the request of the trauma team leader, or~~

~~b. Written transfer guidelines for patients with acute brain injuries.~~

Commented [SG146]: New and more detailed language now included section 305

I. Organized burn care for those patients identified in Section 308~~9~~ of this chapter, and transfer and consultation guidelines with a burn center as defined in Section 308~~9~~ 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 Eemergency Ddepartment and Iintensive Ccare Uunit with facility-defined competency testing and orientation programs.

M. CONTINUING MEDICAL EDUCATION REQUIREMENTS~~CME requirements for surgeons, orthopedic surgeons, emergency physicians, anesthesiologists/CRNA's and neurosurgeons if providing trauma care, to include:~~

~~(1) 10 hours of trauma-related, facility-defined CME annually or 30 hours over the three-year period preceding any site review,~~

(1~~2~~) LEVEL III PHYSICIANS PROVIDING INITIAL RESUSCITATION IN THE EMERGENCY DEPARTMENT ~~All emergency physicians on the trauma panel~~ shall have successfully completed ATLS at least once.

(2) LEVEL III PHYSICIANS PROVIDING INITIAL RESUSCITATION IN THE EMERGENCY DEPARTMENT SHALL BE BOARD CERTIFIED IN EMERGENCY MEDICINE OR HAVE CURRENT ATLS.

(3) LEVEL III GENERAL SURGEONS ON THE TRAUMA CALL PANEL SHALL BE CURRENT IN ATLS.

(4) 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.

(5) ALL BOARD CERTIFICATIONS SHALL BE ISSUED BY A CERTIFYING ENTITY THAT IS NATIONALLY RECOGNIZED IN THE UNITED STATES.

~~Current Advanced Trauma Life Support verification for all physicians providing emergency department coverage who are not board certified in emergency medicine,~~

~~(3) Documentation of successful completion of an Advanced Trauma Life Support course for surgeons and all emergency physicians who are board certified in emergency medicine.~~

30~~7~~8. Trauma Facility Designation Criteria - Level IV AND V

~~Standards for facilities designated as Level IV Trauma Centers~~

~~The facility~~ LEVEL IV TRAUMA CENTERS must be licensed as ~~one of the following~~: a general hospital, a ~~c~~Community ~~c~~Clinic and ~~e~~Emergency ~~c~~Center (CCEC), AS DEFINED IN 6 CCR 1011-1 CHAPTER 9, PART 2.101.(3) and (4), ~~and be open 24 hours a day, 365 days a year~~ or a Ccritical Aaccess Hhospital ~~(~~CAH~~)~~ and be open 24 hours a day, 365 days a year with physician coverage for trauma patients arriving by ambulance ~~as described in the clinical capabilities criteria~~.

Commented [SG147]: Conforming with new requirements throughout

Commented [SG148]: New language recommended by task force

Level V Trauma Centers ~~- The facility~~ must be licensed as: a general hospital, a Ccommunity Cclinic and Eemergency Cceenter (CCEC), or a Ccritical Aaccess Hhospital ~~(CAH)~~ AND HAVE A POLICY ABOUT HOURS OF OPERATION AS DESCRIBED BELOW.

1. ~~Administration and Organization Criteria.~~ 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~~/g~~ and system development activities.

C. A trauma program with policies that identify and establish the scope of ~~trauma~~ care for both adult and pediatric patients~~,~~ including, but not limited to:

(1) Initial resuscitation and stabilization;

(2) Rehabilitation capabilities if available; ~~and~~

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

(4) HOSPITALS ONLY (NOT APPLICABLE TO CCECS) Admission criteria;

(5) LEVEL IV ONLY:

a. Surgical capabilities, if available;

b. Critical care capabilities, if available;

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.

Commented [SG149]: Moved from Level V rules

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 ~~co-morbid factors~~ as outlined in the prehospital trauma triage algorithms as set forth in 6 CCR 1015-4, Chapter ONE ~~Two~~.

Commented [SG150]: Conforming language change from chapter one algorithm

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. An identified multidisciplinary committee involved in the development of a plan of care for the injured patient and is responsible for trauma program performance. Membership will be established by the facility and the committee will establish attendance.~~

Commented [SG151]: REDUNDANT WITH SECTION 304 regarding performance improvement for level III-V trauma centers

~~I~~H. A quality improvement program as defined in Section 30~~48~~ 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 pre-hospital 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. ~~(if applicable)~~

L. Interfacility transfer policies and protocols.

M. Participation in the state trauma registry as required in Chapter ~~1~~TWO.

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

O. If licensed as a Community Clinic with Emergency Care (CCEC):

(1) A central log on each trauma patient/individual presenting with an emergency condition who comes seeking assistance and whether he or she refused treatment, was refused treatment, or whether the individual was transferred, admitted and treated, died, stabilized and transferred, or discharged.

(2) A policy requiring the provision of a medical screening of all individuals with trauma-related emergencies that come to the clinic and request an examination or treatment. The policy shall not delay the provision of a medical screening in order to inquire about an 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 meet all of the following clinical capabilities criteria:~~

Commented [SG152]: Redundant since paragraph below is moved

~~A. The physician must be present in the emergency department at the time of arrival of the trauma patient meeting facility-defined Trauma Team Activation criteria, arriving by~~

Commented [SG153]: MOVED BELOW

~~ambulance. For those patients where adequate prior notification is not possible, the emergency physician shall be available within 20 minutes of notification.~~

~~2~~3. A Level IV OR V trauma center shall have all of the following facilities, resources, and capabilities:

A. An ~~E~~emergency ~~D~~department with:

(1) A. ~~The~~ 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.

Commented [SG154]: Moved from above.

~~(1) Physicians who are credentialed by the facility to provide emergency medical care and maintain current Advanced Trauma Life Support (ATLS) verification.~~

Commented [SG155]: CHANGED SEE F.1. below

(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 ~~verification~~ 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.

Commented [SG156]: Moved from Level V rules

(3) Equipment for the resuscitation of patients of all ages ~~shall~~ include~~d~~ING, 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 CO_2 determination;

d. Suction devices;

e. Electrocardiograph ~~oscilloscope~~ AND defibrillator;

Commented [SG157]: Antequated language

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 a 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.

a. LEVEL IV: ~~available~~ 24 hours a day.

b. LEVEL V: DURING HOURS OF OPERATION.

D. Clinical laboratory services available, INCLUDING: ~~24 hours a day.~~ A~~a~~ spun hematocrit, dip urinalysis, and the ability to collect blood samples to be sent with transferred patients must be available.

a. LEVEL IV: 24 HOURS A DAY.

b. LEVEL V: DURING HOURS OF OPERATION.

E. Participates in local/regional/statewide ~~I~~injury ~~P~~prevention/~~P~~public ~~E~~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.

Commented [SG158]: Moved from level V rules

Commented [SG159]: Inserted per best practice

Commented [SG160]: Moved from Level V

Commented [SG161]: Moved from level V

(4) ALL BOARD CERTIFICATIONS SHALL BE ISSUED BY A CERTIFYING ENTITY THAT IS NATIONALLY RECOGNIZED IN THE UNITED STATES.

Commented [SG162]: New language recommended by task force

~~10 hours of trauma-related, facility-defined CME annually or 30 hours over the 3 year period preceding any site review.~~

(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.

Commented [DM163]: New language; Task force recommended

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

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

Commented [SG164]: Level V combined with level IV and now redundant

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

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

~~A. Commitment by administration and medical staff to support the trauma program as demonstrated by written commitment from the facility's Board of Directors, owner/operators, or administrator to provide the required services.~~

~~B. A written commitment to regional planning and system development activities.~~

~~C. A trauma program with policies that identify and establish the scope of trauma care for both adult and pediatric patients, including but not limited to:~~

~~(1) Initial resuscitation and stabilization;~~

~~(2) Admission criteria;~~

~~(3) Hours of operation. If the facility is not open 24 hours a day, the services as defined in the scope of trauma service policy shall include after-hours plan for availability of services; and~~

~~(4) Critical care capabilities if available;~~

~~(5) Rehabilitation capabilities if available; and~~

~~(6) Written procedure for transfer of patients by fixed and rotary aircraft.~~

~~D. A physician designated by the facility as the Trauma Medical Director who takes responsibility for the trauma program. Responsibilities include:~~

~~(1) Participation in trauma educational activities for healthcare providers or the public;~~

~~(2) Leadership for the trauma program and oversight of the trauma quality improvement process; and~~

~~(3) Administrative authority for the trauma program, including recommendations for trauma privileges, policy and procedure enforcement, and peer review.~~

E. A facility defined trauma team activation protocol that includes who is notified and the response expectations. The protocol shall base activation of personnel on anatomical, physical, mechanism of injury criteria and co-morbid factors as outlined in the prehospital trauma triage algorithms as set forth in 6 CCR 1015-4, Chapter Two.

F. A defined method of activating trauma response personnel consistent with the scope of trauma care provided by the facility.

G. A staff person identified as the Trauma Coordinator with clinical experience in care of the injured person, who is responsible for coordination of the trauma program functions.

H. An identified multidisciplinary committee involved in the development of a plan of care for the injured patient and is responsible for trauma program performance. Membership will be established by the facility and the committee will establish attendance.

I. A quality improvement program as defined in Section 308 of this chapter.

J. Divert protocols, to include:

(1) Coordination with the Regional Emergency Medical and Trauma Advisory Councils (RETACs)

(2) Notification of prehospital providers

(3) Reason for divert

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

K. Interfacility transfer criteria/guidelines as a transferring facility (if applicable).

L. Interfacility transfer policies and protocols.

M. Participation in the state trauma registry as required in Chapter 1.

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

O. If licensed as a Community Clinics with Emergency Care (CCEC):

(1) A central log on each trauma patient/individual presenting with an emergency condition who comes seeking assistance and whether he or she refused treatment, was refused treatment, or whether the individual was transferred, admitted and treated, died, stabilized and transferred, or discharged.

(2) A policy requiring the provision of a medical screening of all individuals with trauma related emergencies that come to the clinic and request an examination or treatment. The policy shall not delay the provision of a medical screening in order to inquire about an individuals' method of payment or insurance status.

(3) Provide further medical examination and such treatment as may be required to stabilize the traumatic injury within the staff and facility's capabilities available at the clinic, or to transfer the individual. The transferring clinic must provide the medical treatment, within its' capacity, which minimizes the risk to the individual, send all pertinent medical records available at the time of transfer, effect the transfer through qualified persons and transportation equipment, and obtain the consent of the receiving trauma center.

2. A Level V trauma center shall meet all of the following clinical capabilities criteria:

A. The physician must be present in the emergency department at the time of arrival of the trauma patient meeting facility defined Trauma Team Activation criteria, arriving by ambulance. For those patients where adequate prior notification is not possible, the emergency physician shall be available with 20 minutes of notification.

3. A Level V trauma center shall have all of the following facilities, resources, and capabilities:

A. Emergency Department with:

(1) Physicians who are credentialed by the facility to provide emergency medical care and maintain current Advanced Trauma Life Support (ATLS) verification.

(2) Registered nurses who provide continuous monitoring of the trauma patient until release from the emergency department. At least one RN in house during hours of operation that maintains current Trauma Nurse Core Course verification or equivalent.

(3) Equipment for resuscitation of patients of all ages, including but not limited to:

a. Airway control and ventilation equipment including laryngoscopes and endotracheal tubes of all sizes, bag mask resuscitators, and oxygen;

b. Pulse oximetry;

c. End-tidal CO_2 determination;

d. Suction devices;

e. Electrocardiograph-oscilloscope-defibrillator;

f. Standard intravenous fluids and administration devices; including large bore intravenous catheters;

g. Sterile surgical sets for:

i. Airway control/cricothyrotomy

ii. Vascular access to include central line insertion and I/O access

iii. Thorocostomy- needle and tube

h. Gastric decompression;

i. Drugs necessary for emergency care;

j. X-ray availability

k. Two way communication with emergency transport vehicles

l. Spinal immobilization equipment

m. Thermal control equipment for patients/fluids

n. Medication chart, tape or other system to assure ready access to information on proper dose-per-kilogram for resuscitation drugs and equipment sizes for pediatric patients

~~B. If an operating room and/or intensive care unit are utilized for the trauma patient, there must be policies that identify and define the scope of care that include the supervision, staffing and equipment requirements that the facility will utilize.~~

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

~~D. Clinical laboratory services available during hours of operation. A spun hematocrit, dip urinalysis and the ability to collect blood samples to be sent with transferred patients must be available.~~

~~E. Participates in local/regional/statewide Injury Prevention/Public Education.~~

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

~~(1) Current ATLS, and~~

~~(2) 10 hours of trauma related facility defined CME annually or 30 hours over the 3 year period preceding any site review.~~

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

30810. 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.

30911. 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 ~~p~~Pediatric ~~p~~Prehospital ~~t~~Trauma ~~t~~Triage ~~a~~Algorithms as set forth in 6 CCR 1015-4, Chapter ~~Two~~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, ~~verification~~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. ~~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~~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~~r~~.

(2) The following services on call and available for patient consultation or management:

a. ~~c~~Cardiology;

b. ~~i~~Infectious disease;

c. ~~h~~Hand surgery~~r~~;

d. ~~m~~Microvascular surgery;

e. ~~p~~Plastic surgery;

f. ~~p~~Pulmonary medicine;

g. ~~n~~Nephrology; and

h. ~~h~~Hematology.

3. Facilities/resources/capabilities criteria:

A. An emergency department with:

(1) Personnel, to include:

a. ~~a~~A designated physician director who is board certified in pediatric emergency medicine;

b. ~~p~~Physician(s) designated as a member of the Trauma Team, physically present in the ~~E~~emergency ~~D~~department 24 hours a day, who:

i. ~~a~~Are board certified in pediatric emergency medicine; or

ii. ~~a~~Are in a pediatric emergency medicine fellowship at PGY5 level~~:~~; OR

iii. ~~or h~~Have completed pediatric emergency medicine training within the past five years.

c. ~~r~~Registered nursing personnel who provide continuous monitoring of the trauma patient until release from the ~~E~~emergency ~~D~~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-~~oscilloscope~~ AND defibrillator with internal paddles - adult and pediatric;

Commented [SG165]: Antequated language. Removal conforms with other levels.

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. peritoneal lavage;~~

Commented [SG166]: Antequated language. Removal conforms with other levels.

v~~i~~. central line insertion; and

vi~~i~~. 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. ~~c~~Cardiopulmonary bypass capability;

b. ~~o~~Operating microscope and microinstruments;

c. ~~t~~Thermal control equipment for:

i. ~~p~~Patients; and

ii. ~~b~~Blood and fluids.

d. ~~x~~X-ray capability, including C-arm image intensifier;

e. ~~e~~Endoscopes;

f. ~~c~~Craniotomy instruments;

g. ~~e~~Equipment for fixation of long bone and pelvic fracture; and

h. ~~e~~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. ~~p~~Patients; and

b. ~~b~~Blood and fluids~~,~~;

(4) Compartmental pressure monitoring equipment.

D. Intensive care unit for injured patients with:

(1) Personnel, to include:

a. ~~a~~A surgical director, who:

i. ~~i~~Is responsible for setting policies and administration related to pediatric trauma ICU patients; and

ii. ~~h~~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~~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. ~~r~~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. ~~i~~In-house radiology technician available within 10 minutes of notification; and

b. ~~i~~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. ~~a~~Angiography;

c. ~~s~~Sonography;

d. ~~c~~Computed tomography (CT); and

e. ~~i~~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 3089 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. ~~p~~Protocols/procedures for the early assessment of the rehabilitation needs of the injured child;

b. ~~p~~Physical therapy;

c. ~~o~~Occupational therapy;

d. ~~s~~Speech therapy; and

e. ~~s~~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~~A designated prevention coordinator;

b. ~~o~~Outreach activities and program development;

c. ~~i~~Information resources for the public; and

d. ~~c~~Collaboration with existing national, regional, and state programs.

(2) Injury control research, which may include:

a. ~~c~~Collaboration with other facilities in prevention research;

b. ~~m~~Monitoring progress/effect of prevention programs; and

c. ~~s~~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. ~~p~~Proposals reviewed by an Internal Review Board (IRB);

b. ~~p~~Presentations at local/regional/national meetings;

c. ~~p~~Publications in peer-reviewed journals; and

d. ~~p~~Peer-reviewed extramural funding for research activities.

O. Continuing medical education (CME), with

(1) In-house CME for:

a. ~~s~~Staff physicians;

b. ~~n~~Nurses;

c. ~~a~~Allied health personnel; and

d. ~~c~~Community physicians.

(2) Physician CME requirements for emergency medicine, trauma surgery, orthopedics, and neurosurgery -16 ~~hours~~ CME HOURS annually or 48 CME hours over THE 3 YEAR PERIOD PRECEEDING ANY SITE REVIEW ~~3 years~~, with half outside own facility.

(3) Nursing CME requirements for emergency department and ICU - 8 hours annually or 24 hours over 3 years.

P. Organ/tissue procurement protocols/procedures.

Q. Trauma divert protocols, to include:

(1) A method to report trauma diverts to the Regional Emergency Medical and Trauma Advisory Council (RETAC) for monitoring;

(2) A method for notification of prehospital providers when on divert;

(3) Facility-defined criteria for going on divert, not to exceed those identified in 6 CCR 1015-4, CHAPTER ONE~~the definition section of this chapter~~; and

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

R. Trauma transfer agreements as a transferring and receiving facility, renewed every 3 years.

S. Interfacility consultation protocols/procedures for attending surgeon availability for responding to mandatory consultations and arranging transfers from Level I, II, III, IV, V, and nondesignated trauma centers.

T. A trauma registry as required in 6 CCR 1015-4, Chapter ~~1~~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 ~~Two~~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

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

CHAPTER FOUR - REGIONAL EMERGENCY MEDICAL AND TRAUMA SERVICES ADVISORY COUNCILS

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

400~~1~~. Definitions. As used in this article, unless the context otherwise requires:

1. "Biennial Plan" - AN ~~regional~~ 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 ~~the Council~~ SEMTAC and the Department, and submitted to ~~the Council~~ SEMTAC ~~for approval~~ FOR A DETERMINATION OF ADEQUACY every other year on July 1~~, beginning July 1, 2003~~.

2. "City and County" - A city that shares the same boundaries as the county IN WHICH it resides ~~in~~.

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

~~4. "Council" – The State Emergency Medical and Trauma Services Advisory Council created in section 25-3.5-104~~.

~~5.~~4. "Department" – The Colorado Department of Public Health and Environment.

~~6.~~5. "EMTS System" - ~~Emergency Medical and Trauma Services 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 ~~the Council~~ 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 ~~C.R.S. 25-3.5~~ 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.

~~9.~~10. ~~"RETAC" -~~ Regional Emergency Medical and Trauma SERVICES Advisory Council (RETAC) – the representative body appointed by the governing bodies of counties or ~~cites~~ CITIES and counties for the purpose of providing recommendations concerning regional area emergency medical and trauma service plans for such counties or cities and counties.

~~10.~~11. ~~"SEMTAC" -~~ ~~The~~ 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.

402~~2~~1. Organizational Requirements

~~A.~~1. ~~On or before July 1, 2002,~~ ~~The~~ 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.

~~B.~~2. ~~County government from counties comprising each RETAC shall determine how members are selected.~~ RETACS MUST BE COMPRISED OF COUNTIES THAT ARE CONTIGUOUS.

~~C.~~3. ~~Membership shall reflect, as equally as possible, representation between hospital and prehospital providers, and from each participating county, and city and county.~~ THE GOVERNING BODY FROM THE COUNTIES AND/OR CITIES AND COUNTIES COMPRISING EACH RETAC SHALL DETERMINE HOW MEMBERS ARE APPOINTED.

~~D.~~4. ~~There shall be at least one member from each participating county and city and county in the RETAC~~. THE PARTICIPATING COUNTIES SHALL DEFINE THE NUMBER OF MEMBERS ON THE RETAC.

~~E.~~5. ~~The participating counties shall define the number of members on the RETAC.~~ MEMBERSHIP SHALL REFLECT, AS EQUALLY AS POSSIBLE, REPRESENTATION BETWEEN HOSPITAL AND PREHOSPITAL PROVIDERS, AND FROM EACH PARTICIPATING COUNTY AND/OR CITY AND COUNTY.

~~F.~~6. ~~Each RETAC shall meet a minimum if four times per year~~. THERE SHALL BE AT LEAST ONE MEMBER FROM EACH PARTICIPATING COUNTY AND/OR CITY AND COUNTY IN THE RETAC.

~~G.~~7. ~~After the appointment of members to the RETAC, the RETAC shall establish By-laws, which includes responsibilities and other pertinent matters concerning the structure and operations of the organization. A chairperson shall be elected and that person or his/her designee shall serve as the liaison for the region's communications with the Department~~. EACH RETAC SHALL MEET A MINIMUM OF FOUR TIMES PER YEAR.

~~H.~~8. ~~RETACs must be comprised of counties that are contiguous~~. AFTER THE APPOINTMENT OF MEMBERS TO THE RETAC, THE RETAC SHALL ESTABLISH AND MAINTAIN BY-LAWS, 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.

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

~~J.~~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~~, medical, and age specific~~ care issues that arise in the region~~,~~ and in coordinating patient destination and inter-facility transfer policies to assure that patients are transferred to the appropriate facility for treatment in or outside of the region.

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

403~~2~~. MINIMUM Operational Requirements

~~A.~~1. EACH RETAC~~s~~ must establish A continuing quality improvement plan FOR ITS REGION with goals AND system-monitoring protocols. ~~and periodically assess the quality of their emergency medical and trauma system. The regional continuous quality improvement system plan shall be utilized in evaluating the effectiveness of the regional EMTS systems as defined elsewhere in the rules pertaining to Statewide Emergency Medical and Trauma Care System.~~

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 THE EFFECTIVENESS OF ITS REGIONAL EMTS SYSTEM IN RELATION TO 6 CCR 1015-4, CHAPTER ONE, THE STATEWIDE EMERGENCY MEDICAL AND TRAUMA CARE SYSTEM.

~~B.~~3. RETACs shall coordinate with the Department and ~~local health departments~~ THE COUNTY OR DISTRICT PUBLIC HEALTH AGENCY in developing and implementing regional injury prevention, public information, and educational programs promoting the development of the ~~EMTS~~ REGIONAL EMERGENCY MEDICAL AND TRAUMA system. These programs should include, but not be limited to, ~~a~~ pediatric injury prevention and public awareness component~~S~~.

~~C.~~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.

~~D.~~5. ~~Regional Patient Destination Protocols~~

~~(Reserved)~~

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.

~~E. RETACS must comply with Board of Health Regulation 4 of the rules and regulations pertaining to preparation for a bioterrorism event, pandemic influenza, or an outbreak by of novel and highly and infectious agent or biological toxin.~~

404~~3~~. Waivers

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

405~~4~~. Annual Financial Report

~~(Reserved)~~

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.

406. RETAC EMTS System Biennial Plan Requirements

~~On July 1, 2003 and every odd numbered year thereafter on July 1, each Regional Emergency Medical and Trauma Advisory Council, with the approval from the governing bodies for the RETAC, must prepare~~

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

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

~~1. Transfer agreements and protocols used by facilities to move patients to higher levels of care.~~

~~2. Facility defined triage and transport plans to be developed by all facilities within the RETAC.~~

~~3. Geographical barriers to the transportation of patients.~~

~~4. Population density challenges to providing care.~~

~~5. Out of hospital resources within the region for the treatment and transportation of sick and injured persons.~~

~~6. Accessibility to Department designated facilities within and outside the region~~

~~B. The plan shall describe the commitment of each of the member counties or city and counties. Commitment includes but may not be limited to:~~

~~1. Cooperation among county and local organizations in the development and implementation of the statewide EMTS system.~~

~~2. Participation and representation within the RETAC.~~

~~3. Dedicated financial and in-kind resources for regional systems development.~~

~~4. Cooperation among county and local organizations in the development and implementation of a coordinated statewide communications system.~~

~~C. The plan shall include the description of processes used to ensure facilities, agencies, counties, and city and counties adherence to the RETAC EMTS plan. Processes shall include but not be limited to:~~

~~1. A compliance reporting process as defined by SEMTAC and the Department.~~

~~2. A continuing quality improvement system as defined by SEMTAC and the Department.~~

~~D. The plan shall include a description of public information, education, and prevention programs used within the region to reduce illness and injury.~~

~~E. The plan shall describe any functions of the RETAC accomplished through contracted services.~~

F. The plan shall identify any needs of the REGIONAL EMTS system through the use of a needs assessment instrument. The needs assessment instrument used by the RETAC must be approved by the RETAC member counties and city and counties. Needs assessment instruments must be approved by or supplied by the Department.

G. The plan shall include a description of the following communication issues:

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

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

3. Communication methods used between ambulances and other responders and between ambulances and designated and undesignated facilities.

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

5. Communication methods used among service agencies to coordinate prehospital and day-to-day requests for service.

6. Communication methods used within and between the RETAC to coordinate service during multicasualty events (interoperability).

H. The plan components shall include:

1. Integration of Health Services - Activities to improve patient care through collaborative efforts among health related agencies, facilities and organizations within the region. The desired outcome of this component is to improve the system by encouraging groups involved in EMTS to work with other entities (e.g. health related, state, local and private agencies and institutions) to share expertise, to evaluate and make recommendations, and mutually address and solve problems within the region.

2. EMTS Research - Determines the effectiveness and efficiency of the EMTS system through scientific investigation. A continuous and comprehensive effort to validate current EMTS system practices in an effort to improve patient care, determine the appropriate allocation of resources and prevent injury and illness and ultimately death and disability.

3. Legislation and Regulation - Issues related to legislation, regulation and policy that affects all components of the EMTS system. This component defines the level of authority and responsibility for system planning, implementation and evaluation.

4. System Finance - Defines the financial resources necessary to develop and maintain a quality EMTS system.

5. Human Resource - The acquisition of knowledge and skills, recruitment and retention of providers are priorities for a quality EMTS system.

6. Education Systems - Includes the education and training of all providers within the EMTS system and includes efforts to coordinate and evaluate programs to ensure they meet the needs of the EMTS system.

7. Public Access - Includes all means by which users can access the system (9-1-1). This component also includes the provision of pre-arrival instructions provided by emergency medical dispatchers.

~~8. Evaluation - A process of assessing the attributes (system integration and components) of the EMTS system to ensure that continual improvement can be designed and implemented.~~

~~9. Communications System - The efficient transfer of information by voice and data occurring between dispatch centers, EMTS providers, physicians, facilities, public safety agencies and patients seeking care through emergency medical dispatch. Includes EMTS system communications interoperability within and outside the region for multicasualty incidents.~~

~~10. Medical Direction - Supervision and direction of patient care within the EMTS system by qualified and authorized physicians, including the medical communities involvement in maintaining quality of care through accepted standards of medical practice and through innovation.~~

~~11. Clinical Care - Clinical methods, technologies and delivery systems utilized in providing EMTS in and out of the hospital. Includes emerging community health services, rescue services and mass casualty management.~~

~~12. Mass Casualty - Defines the responsibility and authority for planning, coordination and infrastructure for all medical care during incidents where the normal capacity to respond is exceeded.~~

~~13. Public Education - Includes the public's involvement in learning experiences to promote and encourage good health and reduce morbidity and mortality.~~

~~14. Prevention - Solutions designed through data collection and analysis, education and intervention strategies to reduce morbidity and mortality related to intentional and unintentional injury and illness~~

~~15. Information Systems - The collection of data and analysis as a tool to monitor and evaluate the EMTS system. Information systems are key to providing a means of improving the effectiveness and integration of healthcare delivery.~~

~~406.1 RETACs must submit their Biennial Plan to SEMTAC on or before July 1, 2003 and every odd numbered year by July 1. If the plan is found to be inadequate, it will be returned to the RETAC with recommendations for revisions. The revised plan shall be submitted to the Council by September 14th. If the revised plan is not approved, the Department will design a plan for the RETAC. Plan submissions must occur by the dates stated or the opportunity for further submissions is forfeited.~~

406~~6~~5. RETAC EMERGENCY MEDICAL AND TRAUMA SYSTEM BIENNIAL PLAN REQUIREMENTS

1. ~~A.~~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. THIS 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.

~~B.~~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.

~~2.~~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 PROVISION OF PRE-ARRIVAL INSTRUCTIONS PROVIDED BY EMERGENCY MEDICAL DISPATCHERS.

(8) EVALUATION - A PROCESS OF ASSESSING THE ATTRIBUTES (SYSTEM INTEGRATION AND COMPONENTS) OF THE EMTS SYSTEM TO ENSURE THAT CONTINUAL IMPROVEMENT CAN BE DESIGNED AND IMPLEMENTED.

(9) COMMUNICATIONS SYSTEM - THE EFFICIENT TRANSFER OF INFORMATION BY VOICE AND DATA OCCURRING BETWEEN DISPATCH CENTERS, EMTS PROVIDERS, PHYSICIANS, FACILITIES, PUBLIC SAFETY AGENCIES, AND PATIENTS SEEKING CARE THROUGH EMERGENCY

MEDICAL DISPATCH. INCLUDES EMTS SYSTEM COMMUNICATIONS INTEROPERABILITY WITHIN AND OUTSIDE THE REGION FOR MULTICASUALTY INCIDENTS.

(10) MEDICAL DIRECTION - SUPERVISION AND DIRECTION OF PATIENT CARE WITHIN THE EMTS SYSTEM BY QUALIFIED AND AUTHORIZED PHYSICIANS, INCLUDING THE MEDICAL COMMUNITIES INVOLVEMENT IN MAINTAINING QUALITY OF CARE THROUGH ACCEPTED STANDARDS OF MEDICAL PRACTICE AND THROUGH INNOVATION.

(11) CLINICAL CARE - CLINICAL METHODS, TECHNOLOGIES, AND DELIVERY SYSTEMS UTILIZED IN PROVIDING 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:

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:

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 FUNCTIONS 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 MEDICAL AND 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 AND 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.