COLORADO
Department of Public Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

To: Members of the State Board of Health

From: Jeanne-Marie Bakehouse, Branch Chief, Emergency Medical and Trauma Services

Through: Michelle Reese, Interim Division Director, Health Facilities and Emergency Medical Services, MR

Date: October 18, 2018

Subject: **Rulemaking Hearing**
Proposed Amendments to 6 CCR 1015-4 Statewide Emergency Medical and Trauma Care System, Chapter Three – Designation of Trauma Facilities

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

In March 2017, the Board of Health adopted rules for an expanded scope of care platform for orthopedic surgery at Level III and Level IV designated trauma centers. The current rule revision builds on that work and represents the platform needed for emergent surgery at Level III and Level IV trauma centers. The proposed regulations will add criteria to assure that Level III and Level IV facilities meet best practice standards for all patients admitted and quickly identify and transfer patients that exceed the facility's scope.

The Department is proposing revisions to 6 CCR 1015-4, Chapter Three, Section 306, Expanded Scope of Care for Designated Trauma Centers Level III and IV. These rule revisions add a definition for 'Emergent Surgery,' expand transfer criteria to include transferring any patient(s) whose injuries surpass the facility's scope of care, add criteria for when patients require emergent surgery and add additional medical conditions which Level IVs are required to transfer to a higher Level facility. These revisions will ensure that patients at Level III and IV facilities get the care necessary, and if the facility is not able to provide that care, the revisions ensure that patients are transferred to a facility equipped to handle their medical conditions.

Based on feedback received since the request for hearing in August 2018, the Department has moved the provisions related to emergent surgery from the originally proposed sections of 306.2.B through D in Mandatory Transfers and Consideration for Transfer to a new heading of Emergent Surgery at Level III and IV Trauma Centers, which has been created as new 306.2. The Mandatory Transfers and Consideration for Transfers section is now numbered as 306.3.

This change is to clarify that the ability to perform emergent surgery is a separate consideration from the requirements of mandatory transfer and consultation.

Previous versions of this regulation have not included criteria for facilities offering more services than the minimum required. The proposed regulations will add criteria to assure that Level III and IV facilities meet best practice standards for all patients admitted and quickly identify and transfer patients that exceed the facility's scope. These changes are necessary to ensure similar levels of care for certain types of patients who may be safely kept at Level III or IV trauma centers.

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

Basis and Purpose.

The proposed rule amendments will add a definition for emergent surgery which will allow Level III and IV trauma designated facilities to perform life-saving surgery when the facility has the clinical capacity to do so. This will allow patients to receive the care they need at a broader range of facilities when the life-saving surgery for the trauma patient is necessary. The proposed rule amendments also require Level IV trauma designated facilities to make a quantitative determination whether the time taken to transfer an endangered patient is in excess of the time required to get a surgeon and operating room availability. Also, additional conditions were added to the rule for mandatory transfer by Level IVs because the conditions require surgical expertise to manage the patients but do not necessarily require surgery to treat.

Specific Statutory Authority.
Statutes that require or authorize rulemaking:

§ 25-3.5-702(3) (2017), C.R.S

§ 25-3.5-704(2)(d) (2017), C.R.S

Statutes that inform or direct the rule content:
§ 25-3.5-702(3) (2017), C.R.S – "(3) The general assembly, therefore, declares that it is necessary to enact legislation directing the board of health to adopt rules that govern the implementation and oversight of the trauma care system. The general assembly further declares that to ensure the availability and coordination of resources necessary to provide essential care, it is necessary to enact legislation that directs the department of public health and environment to collaborate with existing agencies and organizations, including governing bodies for counties and cities and counties, in implementing and monitoring a statewide trauma care system."

§ 25-3.5-704(2)(d) (2017), C.R.S – " The board shall adopt rules for the statewide emergency medical and trauma care system, including but not limited to the following: . . . (d) Designation of facilities."

Is this rulemaking due to a change in state statute?

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

__X__ No

Does this rulemaking incorporate materials by reference?

_____ Yes ___ URL or ___ Sent to State Publications Library

__X__ No

Does this rulemaking create or modify fines or fees?

_____ Yes

__X__ No

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

__X__ No. This rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed. Though the rule does not contain a state mandate, the rule may apply to a local government if the local government has opted to perform an activity, or local government may be engaged as a stakeholder because the rule is important to other local government activities.

___ No. This rulemaking reduces or eliminates a state mandate on local government.

___ Yes. This rule includes a new state mandate or increases the level of service required to comply with an existing state mandate, and local government will not be reimbursed for the costs associated with the new mandate or increase in service.

The state mandate is categorized as:

___ Necessitated by federal law, state law, or a court order
___ Caused by the State's participation in an optional federal program
___ Imposed by the sole discretion of a Department
___ Other: _____

Has an elected official or other representatives of local governments disagreed with this categorization of the mandate? ___Yes ___No

If yes, please explain why there is disagreement in the categorization.

Please elaborate as to why a rule that contains a state mandate on local government is necessary.

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

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

A. Identify each group of individuals/entities that rely on the rule to maintain their own businesses, agencies or operation, and the size of the group:

Designated trauma centers of all levels (currently 81) will be interested in the outcome of the rule; the proposed changes will specifically affect Level III and IV trauma centers providing expanded scope services (<20 of the 81). The Level III and IV facilities will be tasked with following the rule requirements only if they choose to provide services above and beyond the minimum services as already set in regulation. Local governments may be affected if they provide funding for any Level III or IV trauma facility that chooses to offer services under the expanded scope services. Requirements will be enforced through the current regular state review processes and designation procedures.

Local Government Impact:
No direct impact. Any Level III or IV trauma center that is part of a special tax district and that chooses to provide expanded scope services will be affected.

B. Identify each group of individuals/entities interested in the outcomes the rule and those identified in #1.A achieve, and if applicable, the size of the group:

All designated trauma centers, currently 81, as well as non-designated centers (50+) that may consider designation as a Level III or IV in the future and that intend to offer expanded scope services are or may be affected.

The Colorado Hospital Association, through its representation of over 100 hospitals that operate in the state, also has an interest in the promulgation of these rules. The Colorado Hospital Association has been involved and engaged during the development and recommendation of this rule set.

The State Emergency Medical and Trauma Services Advisory Council and its committees have been engaged in the process of developing these draft regulations and have sought public input at each step during the development process.

The rule revision will potentially impact all residents and visitors to Colorado who may need the resources of a Level III or IV facility. The benefit to this group will be more standardization in the trauma care offered for certain conditions that are suitable for treatment at Level III or IV facilities with expanded scope services. The rule will ultimately impact the general public because it will allow certain individuals to be safely cared for who may have previously experienced a mandatory transfer. It is considered good to keep patients as close to home and to family as possible while still receiving optimal care. This will mostly benefit individuals who live in an underserved geographic area.

C. Identify each group of individuals/Entities that benefit from, may be harmed by or at-risk because of the rule, and if applicable, the size of the group:

The Department does not foresee any potential harm in the proposed rules. Level III and IV facilities can choose to continue to offer the current level of services at no detriment to their state designation. Only if a facility chooses to offer the expanded scope services would a facility face a possible significant financial impact.

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.

A. For those that rely on the rule to maintain their own businesses, agencies or operations:

Adding a definition for 'Emergent Surgery' as well as criteria for performing such will have the impact of giving facilities the flexibility to provide patients with much needed care without having the requirement to provide such services all day and every day. It will avoid the transfer of some unstable patients until surgical stabilization can be accomplished during times when the resources are available. This will ultimately be beneficial for patients in general because they will get the care that they require in a timely manner and often closer to their support systems. Lower level facilities would no longer be required to transfer patients when such life-saving surgery is within their clinical capabilities. It also protects patients by requiring transfer of patients for whom all concomitant services are not available.

Having additional conditions which require transfer from a Level IV to a higher level facility will help protect patients by ensuring they are ultimately being treated at the facility which can provide the appropriate level of care. It also ensures that potential pitfalls in care are not overlooked by lower level facilities when it comes to the diagnosis and treatment of complex trauma patients.

Favorable economic outcomes:
Being able to keep patients locally will provide financial benefits to local economies. In addition, patients will not be burdened by the expense of an unnecessary transfer.

Favorable non-economic outcomes:
Adding a definition for 'Emergent Surgery' as well as criteria for performing such will have the impact of giving facilities the flexibility to provide patients with much needed care when the facility has the resources available. This allows for facilities to make rational decisions based on the need of the patient and the resources currently available.

Requiring certain transfers ensures that potential pitfalls in care are not overlooked by lower level facilities when it comes to the diagnosis and treatment of patients.

Unfavorable non-economic outcomes:

None identified.

Anticipated financial impact:

Anticipated Costs:	Anticipated Benefits:
Description of costs that must be incurred. • There are no costs that must be incurred by these proposed rules. The department is only adding requirements if a facility chooses to offer the expanded scope of services.	Description of financial benefit. • Savings in transportation costs • Financial benefit to small communities by keeping patients locally
Cost or cost range. $_____ or __X__ No data available.	Savings or range of savings. $_____ or __X__ No data available.
Dollar amounts that have not been captured and why: • None	Dollar amounts that have not been captured and why: • None

B. For those that are affected by or interested in the outcomes the rule and those identified in #1.A achieve.

Adding a definition for 'Emergent Surgery' as well as criteria for performing such will have the impact of giving facilities the flexibility to provide patients with much needed care without having an administrative burden of an automatic transfer or consultation. This will ultimately be beneficial for patients in general because they will get the care that they require without being forced to leave their local area and support systems when such life-saving surgery is within the facility's clinical capabilities. Being in a local community where there is social support is real benefit to the patient and the family.

It also protects patients by requiring transfer of patients for whom all concomitant services are not available. Having additional conditions which require transfer from a Level IV to a higher level facility will help protect patients by ensuring they are being transferred to a facility which can provide an appropriate level of care. It also ensures that potential pitfalls in care are not overlooked by lower level facilities when it comes to the diagnosis and treatment of complex trauma patients.

Favorable non-economic outcomes:

1

The ability for Level III and IV facilities to keep patients local contributes to the social support available for the patient. The patient will enjoy a much stronger social support system which will help in the recovery process. The local community is also benefitted by no longer burdening family/friends with 50+ minute travel times to see a sick/injured friend or loved one.

Unfavorable non-economic outcomes:

Required transfers may still take place to ensure that patients are at facilities that have the necessary resources for treatment. This may not be convenient for the patient's family and social support network.

Any anticipated financial costs monitored by these individuals/entities?

No quantifiable financial impact of the rule change to these individuals.

Any anticipated financial benefits monitored by these individuals/entities?

No direct financial impact of the rule change to regulated entities.

C. For those that benefit from, are harmed by or are at risk because of the rule, the services provided by individuals identified in #1.A, and if applicable, the stakeholders or partners identified in #1.B.

Describe the favorable or unfavorable outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

The Department believes that this proposed regulation balances the interests of the patient with the interests of the regulated community.

Financial costs to these individuals/entities:
Cost neutral. There will be costs associated with trauma care regardless of where it is provided.

Financial benefits to or cost avoidance for these individuals/entities:
Cost neutral. There will be costs associated with trauma care regardless of where it is provided.

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:

There should be no additional costs to CDPHE as the cost of trauma review and designation are already built into the system.

Type of Expenditure	Year 1	Year 2
	$ none	$ none
	$ none	$ none
Total	None	None

Anticipated CDPHE Revenues:
None additional to current regulation

This rulemaking modifies fees:

Entity Type	# of Entities	Current Fee	Proposed Fee	% increase or decrease
N/A				

Entity Type	# of Entities	Current Fee	Proposed Fee	% increase or decrease
N/A				

Type of Revenue	Year 1	Year 2
Cash Fund	$	$
	$	$
Total		

B. Anticipated personal services, operating costs or other expenditures by another state agency:
No additional costs.

Anticipated Revenues for another state agency:
No additional revenues.

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

Check mark all that apply:
___ Inaction is not an option because the statute requires rules be promulgated.

___ The proposed revisions are necessary to comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.

___ The proposed revisions appropriately maintain alignment with other states or national standards.

_X_ The proposed revisions implement a Regulatory Efficiency Review (rule review) result, or improve public and environmental health practice.

_X_ The proposed revisions implement stakeholder feedback.

___ The proposed revisions advance the following CDPHE Strategic Plan priorities:

Goal 1, Implement public health and environmental priorities
Goal 2, Increase Efficiency, Effectiveness and Elegance
Goal 3, Improve Employee Engagement
Goal 4, Promote health equity and environmental justice
Goal 5, Prepare and respond to emerging issues, and
Comply with statutory mandates and funding obligations

Strategies to support these goals:
___ Substance Abuse (Goal 1)
___ Mental Health (Goal 1, 2, 3 and 4)
___ Obesity (Goal 1)
___ Immunization (Goal 1)

___ Air Quality (Goal 1)
___ Water Quality (Goal 1)
___ Data collection and dissemination (Goal 1, 2, 3, 4 and 5)
___ Implements quality improvement or a quality improvement project (Goal 1, 2, 3 and 5)
___ Employee Engagement (career growth, recognition, worksite wellness) (Goal 1, 2 and 3)
___ Incorporate health equity and environmental justice into decision-making (Goal 1, 3 and 4)
___ Establish infrastructure to detect, prepare and respond to emerging issues (Goal 1, 2, 3, 4, and 5)

_X_ Other favorable and unfavorable consequences of inaction:

- An unfavorable consequence of inaction is that trauma patients will be transferred prior to stabilization when such services are available at the lower level trauma center they first present at.

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

The proposed amendments related to expanded scope of services only affect facilities that choose to offer expanded services. By placing them in rule, the department can ensure standardization in the care patients receive.

As the proposed changes have few cost implications, there were no less costly methods that were explored.

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

Alternatives considered were requiring transferring patients, as opposed to allowing emergent surgery to be performed by Level III and IV's and stable patients to be kept with a consult. This would have resulted in the unnecessary transfer of some patients who do not need the increased resources of a higher level facility based on their injury but may have been identified as high risk. This alternative would also have the impact of removing scarce prehospital resources from communities for an extended period of time which may leave additional patients within the geographical area without the proper care/resources.

Another alternative was to leave the rule as it is. However, this would mean that no standards would be in place for facilities seeking to retain certain patients. As no requirement currently exists for facilities to set standards, there is limited means for the Department to promote best practice standards of patient care related to emergent surgery.

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.

Gaps in the current rules were identified over the past six years with regard to patient care for certain patients in Level III and IV trauma centers.

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

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

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

Organization	**Representative**
State Emergency Medical and Trauma Services Advisory Council (SEMTAC)	Statewide EMS and trauma community
Regional Emergency Medical and Trauma Advisory Councils (RETAC)	Represent regional EMS and trauma communities
Colorado Trauma Network	Trauma registrars and program managers from across state
Expanded Scope of Care Task Force	Surgical faculty and trauma program management from Level I-IV trauma centers statewide, including rural and urban
Trauma program staff and physicians at designated trauma facilities	Statewide hospital/clinic staff
Colorado Hospital Association	Member facilities in Colorado
General trauma and EMS community	Weekly communication advertising all open meetings to interested parties

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).

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

X Yes.

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

There were multiple issues identified through stakeholder feedback. One concern came from Level I and II facilities that would have the patient transferred immediately as opposed to being retained at a lower level facility. However, this concern was remedied by the relatively narrow set of circumstances in which Level III and IV's are allowed to retain trauma patients. This policy is ultimately seen as better for the trauma patients as it combines the flexibility needed to make case by case determinations of whether a patient should be transferred with best practice standards already adopted by most hospitals.

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

The proposed regulation will allow rural and lower level facilities to maintain the same best practice standards as found in higher level facilities.

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.	X	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.		Ensures a competent public and environmental health workforce or health care workforce.

	Other:_____ _____		Other:_____ _____

COLORADO
Department of Public
Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

State Emergency Medical and Trauma Services Advisory Council

July 11, 2018

Mr. Rick Brown, President
State Board of Health
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South, EDO-A5
Denver, CO 80246-1530

Dear Mr. Brown:

At the July 11, 2018, meeting of the State Emergency Medical and Trauma Services Advisory Council (SEMTAC) of the Colorado Department of Public Health and Environment proposed revisions to 6 C.C.R 1015-4, Chapter Three, Section 306, Expanded Scope of Care for Designated Trauma Centers Level III-IV, were reviewed and discussed. These rule revisions add a definition for "Emergent Surgery," expand transfer criteria to include transferring any patient(s) whose injuries surpass the facilities' scope of care, add criteria for when patients require emergent surgery and add additional medical conditions which Level IVs are required to transfer to a higher level facility.

These revisions will ensure that patients at Level III-IV facilities get the care necessary, and if the facility is not able to provide that care, the revisions ensure that the patient is transferred to a facility equipped to handle their medical condition. A motion was made and passed to approve the proposed revisions.

Sincerely yours,

Dr. Charles W. Mains
Vice Chairman

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STATEWIDE EMERGENCY MEDICAL AND TRAUMA CARE SYSTEM

6 CCR 1015-4

Adopted by the Board of Health on _____, 2018. Effective _____, 2018.

CHAPTER THREE - DESIGNATION OF TRAUMA FACILITIES

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300. Definitions

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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.

~~8.~~ 9. 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.~~10. Key Resource Facilities - Level I and II designated trauma centers which have an expanded responsibility in providing on-going consultation, education and technical support to referring facilities, individuals, or RETACS.

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

~~11.~~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. The documentation of the review shall include date, reason for review, problem identification, corrective action, resolution and education. Documented minutes shall be maintained on site and readily available.

~~12.~~ 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 will be established by the committee. Membership will be established by the facility.

~~13.~~14. Outreach - The act of providing resources to other facilities in order to improve response to the injured patient. These resources shall include, but not be limited to, clinical consultation and public and professional education. Trauma centers shall be centers of excellence and shall share this expertise with other trauma centers and non-designated facilities. Timely and appropriate communication, consultation and feedback are imperative to patient outcome.

~~14.~~15. Plan of correction - Identifies how the facility plans to correct deficiencies or standards identified as met with reservations cited in the department's written notice to the facility, within an identified timeline. A plan of correction may also be required to meet a waiver request or fulfill a request from the department to address a temporary issue identified by the department or the facility.

~~15.~~16. Promptly Available - Unless otherwise specified, promptly available shall be a facility-defined timeframe based on current standards of clinically appropriate care.

~~16.~~17. Quality/Performance Improvement Program - A defined plan for the process to monitor and improve the performance of a trauma program is essential. This plan shall address the entire spectrum of services necessary to ensure optimal care to the trauma patient, from pre-hospital to rehabilitative care. This plan may be parallel to, and interactive with, the hospital-wide quality improvement program but shall not be replaced by the facility process.

~~17.~~18. Regional Emergency Medical and Trauma Advisory Council (RETAC) - The representative body appointed by the governing bodies of counties or cities and counties for the purpose of providing recommendations concerning regional area emergency medical and trauma service plans for such counties or cities and counties.

~~18.~~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.

~~19.~~20. State Emergency Medical and Trauma Services Advisory Council (SEMTAC) - The council created in the department pursuant to Section 25-3.5-104, C.R.S.

~~20.~~21. Special Audit for Trauma Deaths - All trauma deaths shall be audited. A comprehensive review audit shall be initiated by the Trauma Medical Director in Levels I, II, III facilities and by the appropriate personnel designated by the Level IV and V facilities. The trauma nurse coordinator shall participate in these audits. A written critique shall be used to document the process to include the assessment, corrective action and resolution.

~~21.~~22. Trauma Nurse Coordinator - The terms "trauma nurse coordinator," "trauma coordinator" and "trauma program manager" are used interchangeably in these regulations (6 CCR 1015). The trauma nurse coordinator (TNC) works to promote optimal care for the trauma patient through participation in clinical programs, administrative functions, and professional and public education. The TNC shall be actively involved in the state trauma system. The essential responsibilities of the TNC include maintenance of the trauma registry, continuous quality improvement in trauma care, and educational activities to include injury prevention.

~~22.~~23. Trauma Nurse Core Course (TNCC) or equivalent - the training provided in accordance with the Emergency Nurses Association curriculum. An equivalent program is one that has been approved by the department. The burden shall be upon the applicant to prove that the program is equivalent to the TNCC.

~~23.~~24. Trauma Service - The Trauma Service is an organized, identifiable program which includes: a Trauma Medical Director, a Trauma Nurse Coordinator, a Multi-disciplinary Trauma Committee, Quality Improvement Program, Injury Prevention and Data Collection/Trauma Registry.

~~24.~~25. Trauma Medical Director - The Trauma Medical Director is a board certified general surgeon who is responsible for: service leadership, overseeing all aspects of trauma care, and administrative authority for the hospital trauma program including: trauma multidisciplinary committee, trauma quality improvement program, physician appointment to and removal from trauma service, policy and procedure enforcement, peer review, trauma research program, and key resource facility functions, if applicable; participates in the on-call schedule; practices at the facility for which he/she is medical director on a full time basis; and participates in all facility trauma-related committees. In Level I facilities, the Trauma Medical Director shall participate in an organized

trauma research program with regular meetings with documented evidence of productivity. In Level IV, the Trauma Medical Director may be a physician so designated by the hospital who takes responsibility for overseeing the program.

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

~~26.~~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.

~~27.~~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.

~~28.~~29. Waiver - A waiver is an exception to the trauma rules approved by the department. The request for a waiver shall demonstrate that the alternative meets the intent of the rule. Waivers are generally granted for a limited term and shall be granted for a period no longer than the designation cycle. Waivers cannot be granted for any statutory requirement under state or federal law, requirements under state licensing, federal certification or local safety, fire, electrical, building, zoning or similar codes.

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

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

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

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

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

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

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

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

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

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

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

2. EMERGENT SURGERY AT LEVEL III AND IV TRAUMA CENTERS

A. ALL LEVEL III AND IV TRAUMA CENTERS MAY ATTEMPT EMERGENT SURGERY IF APPROPRIATE RESOURCES ARE AVAILABLE. ONCE THE PATIENT IS STABILIZED TO THE EXTENT OF THE FACILITY'S CAPABILITIES, IF THE FACILITY DOES NOT HAVE THE CLINICAL PLATFORM TO CARE FOR THE PATIENT AND FOR POTENTIAL COMPLICATIONS, THE FACILITY SHALL CONSULT WITH A HIGHER LEVEL TRAUMA CENTER OR TRANSFER AT THE DISCRETION OF THE SURGEON.

B. FOR PATIENTS AT LEVEL IV TRAUMA CENTERS THAT REQUIRE EMERGENT SURGERY, THE EMERGENCY PHYSICIAN SHALL CONSULT THE TRAUMA SURGEON ON CALL 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.

C. IF THE SURGEON ON CALL 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 A HIGHER LEVEL TRAUMA CENTER.

~~2.~~3. Mandatory Transfers and Consideration for Transfer

A. All Level III AND IV ~~Trauma Centers~~ TRAUMA CENTERS shall transfer patients with ANY INJURIES REQUIRING RESOURCES BEYOND THOSE AVAILABLE UNDER THE FACILITY'S SCOPE OF CARE AND PATIENTS WITH the 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.

B. All Level III and IV trauma centers shall consult a trauma surgeon at a ~~level~~ 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.

C. All Level IV ~~Trauma Centers~~ 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.

D. 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.

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

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

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

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