

CABINET FOR HEALTH AND FAMILY SERVICES

Department for Public Health

Office of the Commissioner

(Amendment)

902 KAR 28:030. Kentucky's trauma system level IV criteria.

RELATES TO: KRS 211.490, 211.492, 211.494, 211.496

STATUTORY AUTHORITY: KRS 211.494(8)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.494(8) authorizes the Department for Public Health to promulgate administrative regulations in accordance with KRS Chapter 13A to implement a statewide trauma care system. This administrative regulation establishes the criteria for a Level IV trauma center in the Kentucky Trauma Care System.

Section 1. Level IV Trauma Centers.

(1) A hospital that seeks designation as a Level IV trauma center shall meet the criteria established in this subsection.

(a) Trauma program.

1. A trauma program shall be created with agreement from the hospital's board of directors, administration, and medical staff.

2. The board of directors, administration, medical, nursing, and ancillary staff shall commit to provide trauma care at the level for which the facility is seeking trauma center verification.

3. A board resolution advising of that commitment shall be submitted with the KYTAC-Application-1, ~~[KYTAC1-application]~~ incorporated by reference in 902 KAR 28:020, Section 5 ~~[6]~~.

4. The trauma program shall adopt and meet the "Pediatric Readiness in the Emergency Department" policy guidance for care of children, as endorsed by the American Academy of Pediatrics (AAP), the American College of Emergency Physicians (ACEP), the American College of Surgeons, and the Emergency Nurses Association (ENA), and published at [https://www.annemergmed.com/article/S0196-0644\(18\)31167-3/pdf](https://www.annemergmed.com/article/S0196-0644(18)31167-3/pdf).

(b) Trauma services medical director.

1. The trauma services medical director shall be a physician on staff at the facility.

2. The job description shall include roles and responsibilities for trauma care, including trauma team formation, supervision and leadership, and continuing education.

3. The medical director shall act as the medical staff liaison to administration and ~~[,]~~ nursing staff, and as the primary contact for that facility with other trauma centers in the region.

4. The medical director shall maintain certification as an Advanced Trauma Life Support (ATLS) provider if not Board Certified/Board Eligible by the American Board of Emergency Medicine (ABEM) or the American Osteopathic Board of Emergency Medicine (AOBEM). The trauma services medical director may participate in a Rural Trauma Team Development Course (RTTDC) ~~[participation shall be required for the trauma services medical director]~~.

(c) Trauma coordinator ~~[services manager]~~.

1. The facility shall have a trauma coordinator ~~[services manager]~~ who may be referred to as the trauma services manager or trauma program manager ~~[coordinator]~~.

2. The trauma coordinator ~~[manager]~~ shall work with the medical director to coordinate and implement the facility's trauma care response.

3. The job description of this position shall include time dedicated to the trauma program, separate from other duties the trauma coordinator~~[program manager]~~ may have at the facility.

(d) Emergency department coverage.

1. The facility shall have twenty-four (24) hour physician coverage of the emergency department and a designated physician medical director for the emergency department.

2. A mid-level provider, such as a nurse practitioner or physician~~[physician's]~~ assistant, may serve as the trauma team leader. A designated emergency department physician shall be present for immediate consultation during trauma team activations.

(e) Emergency department physicians. Physicians assigned to the emergency department of a Level IV Trauma Center shall:

1. Be licensed in the Commonwealth of Kentucky; and

2.

a. Maintain current Advanced Trauma Life Support[®] (ATLS) provider certification; or

b. Be certified by ABEM or AOBEM.

(f) Surgical staff.

1. Orthopedic surgery, plastic surgery, and radiology medical staff availability shall be documented by published call schedules.

2. If surgical services are provided, anesthesia coverage shall be provided.

3. Surgical staff shall document completion of fifteen (15) hours of annual trauma-related continuing medical education for surgeons completed every three (3) years as part of the CME required by the Kentucky Board of Medical Licensure.

4. Surgical specialties participating in the trauma team shall have at least one (1) representative of its specialty attend more than half of the hospital's multi-disciplinary trauma review committee meetings.

(g) Prior to being assigned to the facility's trauma team, nurses responsible for trauma care at the facility shall have completed one of the following professional education courses specific to trauma care:

1. Trauma Nursing Core Course (TNCC); or

2. Advanced Trauma Care for Nurses (ATCN).

(h) Transfer Protocols.

1. The facility shall have a written transfer protocol describing the method to transfer the trauma patient requiring a higher level of care.

2. The transfer protocol shall address:

a. Available ground or air transport services;

b. Alternative transport services;

c. Receiving trauma centers and trauma surgeon contact information;

d. What supplies, records, and resources shall be available for use to affect the transfer; and

e. Specific anatomic and physiologic criteria that will immediately initiate transfer to definitive care.

3. The transfer protocol shall be developed with involvement of each local ground EMS provider and regional air medical provider to assure seamless patient care during transfer and be consistent with the protocol examples found in the Kentucky Trauma Hospital Reference~~[Resource]~~ Manual.

(i) Transfer agreements. A Level IV Trauma Center shall have:

1. A written agreement with a verified Level I, II, or III trauma center or a hospital whose capabilities exceed that of a Level IV facility regarding the transfer and care

of adult and pediatric trauma patients;

2. A written agreement with back-up transfer agreements specifically for burn patients if the primary regional receiving facility does not have the required capacity; and

3. Transfer plans that shall be defined and consistent with the examples found in the Kentucky Trauma Hospital ~~Reference~~~~Resource~~ Manual.

(j) Radiology.

1. The facility shall have a radiologic technologist available on-site twenty-four (24) hours a day to provide basic plain films used in the evaluation of trauma patients.

2. A twenty (20) minute response time for trauma team activation shall be required. Response times shall be documented and monitored by the trauma coordinator and the facility's process improvement program.

3. The facility shall have computed tomography and sonography capabilities.

(k) Clinical laboratory.

1. The facility shall have a lab technician available on duty or on-call twenty-four (24) hours a day to perform basic studies used in the initial evaluation of trauma patients, including Complete Blood Count, typing, coagulation profile, and Arterial Blood Gas.

2. A twenty (20) minute response time from trauma team activation shall be required for a lab technician. Response times shall be documented and monitored by the trauma coordinator and the facility's process improvement program.

3. The lab or facility blood bank shall have at least two (2) units of O-negative blood available for trauma patients, to be infused at the facility or while ~~en route~~~~en route~~ to definitive care.

4. Access to blood and blood products during an emergency situation if the lab is not staffed shall be documented.

5. The facility shall have the capability to conduct micro-sampling.

(l) Respiratory therapy.

1. The facility shall have a respiratory care practitioner on duty or on-call twenty-four (24) hours a day to respond to the emergency department if the trauma team is activated.

2. A twenty (20) minute response time from trauma team activation shall be required if a respiratory care practitioner is not on-site. Response times shall be documented and monitored by the trauma coordinator and the facility's process improvement program.

3. Other trained health care personnel may fulfill the respiratory care practitioner's role until the designated respiratory care practitioner arrives.

(2) Trauma Team Activation Protocol. A facility designated as a Level IV Trauma Center shall have a written trauma team activation protocol in place that:

(a) Documents the members of the trauma team and their response requirements if activated;

(b) Establishes the criteria based on severity, anatomy, or physiology of the injury for trauma team activation and provides the names of each person authorized to activate the trauma team; and

(c) Is consistent with the examples of trauma team activation protocols found in the Kentucky Trauma Hospital ~~Reference~~~~Resource~~ Manual.

(3) Performance improvement.

(a) A facility designated as a Level IV Trauma Center shall develop a performance improvement program that includes:

1. An in-house trauma registry or a secure on-line trauma registry system; and

2. A written policy outlining the quality and performance improvement (PI) portion of the trauma program, which shall include:

- a. The names of each person responsible for performing PI reviews;
 - b. The names of the multidisciplinary trauma review committee;
 - c. The composition by name and position of the morbidity and mortality review committee;
 - d. The minimum number of cases to be reviewed annually including:
 - (i) Patients requiring transfer;
 - (ii) Record of each trauma death;
 - (iii) Noncompliance of trauma team members to response time requirements;
 - (iv) Bypasses;
 - (v) Transfers; and
 - (vi) Trauma care provided by physicians not meeting minimal education requirements;
 - e. Frequency of performance improvement meetings;
 - f. Minimum requirements for member attendance by position; and
 - g. ~~[Evidence of a quality assurance program as required by 902 KAR 20:016, Section 3(8)(b)6; and]~~
 - ~~[h.]~~ Feedback obtained from patients transferred to a Level I, II, or III trauma center.
- (b) Each performance improvement program shall be consistent with the examples in the Kentucky Trauma Hospital Reference~~[Resource]~~ Manual.
- (4) Level IV Trauma Center emergency department.
- (a) Basic and essential equipment and supplies for the care and treatment of both adult and pediatric patients shall be present in a Level IV Trauma Center emergency room.
 - (b) A Level IV Trauma Center emergency room shall contain items described as the minimum equipment and supply lists found in the Kentucky Trauma Hospital Reference~~[Resource]~~ Manual.
- (5) Level IV Trauma Center designated treatment rooms~~[operating room]~~.
- (a) Any operating room available and used for the surgical care of victims of trauma shall have the following:
 1. Operating room staff available within thirty (30) minutes of notification;
 2. Anesthesia staff available within thirty (30) minutes of notification; and
 3. Age-specific equipment including thermal control equipment for patients, fluids, and blood products.
 - (b) ~~[C-arm capability shall be required if orthopedic procedures are to be performed.]~~
 - ~~[(c)]~~ Post-anesthetic recovery shall contain equipment for monitoring and resuscitation, pulse oximetry, and thermal control.
 - ~~[(d)]~~ Required resuscitation equipment shall include:
 1. Airway and ventilation;
 2. Pulse oximetry;
 3. Suction;
 4. Electro Cardiogram;
 5. Defibrillator;
 6. IV administration sets;
 7. Large bore vascular catheters;
 8. Cricothyroidotomy;
 9. Thoracostomy;
 10. Emergency drugs;
 11. Broselow or Handtevy pediatric resuscitation system equipment and supplies~~[tape]~~;
 12. Fluid and body warmer,
 13. Qualitative CO2 detector; and
 14. EMS communication equipment.

(6) Trauma diversion.

(a) The Level IV trauma center shall have a policy in place that outlines the circumstances that shall trigger a trauma diversion and the procedures to be followed, including procedures if one (1) or more hospital resources are functioning at maximum capacity or are otherwise unavailable.

(b) This process shall be coordinated with the EMS providers in the service area and potential receiving facilities.

(c) ~~EMS providers shall coordinate diversion plans under the provisions of 202 KAR 7:501, Section 5(3).~~

~~(d)~~ Examples of trauma diversion protocols shall be found in the Kentucky Trauma Hospital Reference~~Resource~~ Manual.

(7) Other Level IV requirements. A facility designated as a Level IV trauma center may:

(a) Host or participate in a joint RTTDC program. Participation by physicians, members of administration, nursing, ancillary support staff, and local prehospital care providers shall be strongly encouraged;

(b) Conduct or participate in local or regional outreach education, specifically ATLS, APLS, ENPC, TNCC, and ITLS/PHTLS courses, and conduct or participate in local or regional presentations of trauma-related CME for physicians, nurses, prehospital staff, and other personnel; and

(c) Participate in injury prevention programs organized by the facility or in cooperation with the Kentucky Injury Prevention Research Center (KIPRC), law enforcement, fire, EMS and other safety organizations. Documentation of injury prevention program activities shall be available for review during the trauma center verification or reverification process.

Section 2. Level IV Site Visits.

(1) A hospital may request a site visit from a peer review team for a consultation visit, a verification visit, or a reverification visit.

(a) A consultation visit shall be conducted to assess the facility's system of trauma care delivery or to prepare for a verification visit.

1. A consultation visit shall follow the same format as a verification visit.

2. Site visit reviewers shall provide recommendations to aid a facility in attaining verification readiness.

(b) A verification visit shall be conducted to confirm the facility is performing as a trauma center according to the criteria listed in Section 1 of this administrative regulation.

1. Site visit reviewers shall provide a report of findings to the KyTAC.

2. The KyTAC, upon receipt and review of the report, shall recommend to the Commissioner of Public Health that:

a. A Certificate of Designation~~Verification~~ be issued, and that the Commissioner designate the facility as a Level IV Trauma Center; or

b. The facility be notified of deficiencies in writing and a focus review visit scheduled within eight (8)~~six (6)~~ months of the date of the original verification visit to review~~identify~~ those deficiencies and verify that they have been isolated and corrected~~can be isolated and correctable~~.

(c) A reverification visit shall be requested by a facility previously issued a certificate of designation~~verification~~ if the facility does not want its certificate of ~~verification and~~ designation to expire.

1. The facility shall schedule a reverification visit at least four (4)~~six (6)~~ months prior to the expiration date of its current certificate of ~~verification and~~ designation as a Level IV Trauma Center.

2. A facility whose current certificate of ~~designation~~~~[verification]~~ has lapsed due to the facility's failure to initiate reverification shall submit a new KYTAC-Application-1~~[KYTAC1]~~ as required by 902 KAR 28:020 and this administrative regulation.

3. A reverification visit shall follow the same procedures established in subsection (2) of this section.

(2) Site visit teams.

(a) A site visit team shall be composed of a minimum number of persons as follows:

1. Consultation visit: Two (2) members;
2. Verification visit: ~~Two (2)~~~~[Three (3)]~~ members;
3. Reverification visit: ~~Two (2)~~~~[Three (3)]~~ members; or
4. Focus review visit: Two (2) members, one (1) of whom shall have been on the original verification team.

(b) ~~At least one (1)~~ ~~[Each]~~ site visit team member shall be a physician or registered nurse trauma center program manager~~[member of either the:]~~

~~[1:] [American College of Surgeons; or]~~

~~[2:] [American Board of Emergency Medicine.]~~

~~[(e)] [The Commissioner of Public Health shall solicit from the KyTAC two (2) names for each team member position for the requested visit.]~~

~~[(d)] [The Commissioner of Public Health shall select the team members from the list provided and notify KyTAC of the team members selected.]~~

~~[(e)] [Only one (1) of each team's members may be a KyTAC member].~~

Section 3. Incorporation by Reference.

(1) The following material is incorporated by reference:

~~(a)~~ "Kentucky Trauma Hospital Reference~~[Resource]~~ Manual", May 2024; and

~~(b)~~ "Pediatric Readiness in the Emergency Department", Annals of Emergency Medicine, December 2018 ~~[April, 2012, is incorporated by reference].~~

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Department for Public Health, Commissioner's Office, 275 East Main Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

~~(3)~~ "Kentucky Trauma Hospital Reference Manual" is available online at <https://www.kyha.com/kentucky-trauma-system/>.

~~(4)~~ "Pediatric Readiness in the Emergency Department", Annals of Emergency Medicine, is available online at [https://www.annemergmed.com/article/S0196-0644\(18\)31167-3/pdf](https://www.annemergmed.com/article/S0196-0644(18)31167-3/pdf).

STEVEN J. STACK, MD, MBA, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: August 26, 2024

FILED WITH LRC: September 9, 2024 at 11:20 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on November 25, 2024, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by November 18, 2024, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do

not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until November 30, 2024. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-7476; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Julie Brooks or Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes the criteria for a Level IV trauma center in the Kentucky Trauma Care System.

(b) The necessity of this administrative regulation:

Trauma is a severe health problem in the state, a major cause of death and long-term disability and an essential public health service. It is essential for persons in need of trauma care to receive that care within sixty (60) minutes immediately following the injury. This administrative regulation is necessary to establish the criteria for Level IV trauma centers to ensure timely access to an elevated level of emergency care.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

KRS 211.494 establishes a comprehensive statewide trauma care program in the Department for Public Health to reduce or prevent death and disability from trauma, provide optimal care for trauma victims, and recognize levels of care for the appropriate delivery of a full range of medical services to all trauma patients in the Commonwealth.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This administrative regulation will help to ensure a statewide, coordinated trauma care system by providing a method for hospitals to receive designation as a Level IV trauma center.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

The amendment to this administrative regulation adds the requirement that the Level IV trauma centers adopt the Pediatric Readiness in the Emergency Department policy guidelines, revises the job descriptions for the trauma center medical director and the trauma center coordinator or managers, extends the timeline for a hospital to correct identified deficiencies from six (6) months to eight (8) months, revises the number of site visitors for the verification team, and updates the material incorporated by reference.

(b) The necessity of the amendment to this administrative regulation:

The amendment to this administrative regulation is necessary to ensure the emergency departments in Level IV trauma centers are adequately prepared to care for pediatric trauma patients, to give potential Level IV trauma centers sufficient time to correct identified deficiencies, and to simplify the Level IV trauma center designation process.

(c) How the amendment conforms to the content of the authorizing statutes:

KRS 211.494 establishes a comprehensive statewide trauma care program in the Department for Public Health to reduce or prevent death and disability from trauma, provide optimal care for trauma victims, and recognize levels of care for the appropriate delivery of a full range of medical services to all trauma patients in the commonwealth.

(d) How the amendment will assist in the effective administration of the statutes:

The amendment to this administrative regulation will help to ensure a statewide, coordinated trauma care system by providing a method for hospitals to receive designation as a Level IV trauma center.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

There are currently thirteen (13) hospitals designated as Level IV trauma centers and six (6) hospitals listed as in development for Level IV trauma center designation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

Current designated hospitals will need to be aware of the requirements upon their reverification. Hospitals seeking initial designation will need to be aware of the requirements.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

The cost associated with Level IV hospital verification includes the \$500 fee every three years and cover the costs of each site review team member.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

Hospitals that receive and maintain Level IV trauma center designation will be able to provide a needed service to the communities they serve.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

This is an ongoing program, there are no initial cost to implement.

(b) On a continuing basis:

There is no change in cost for the administrative body to implement the amendment to this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

This administrative regulation is supported by funds available through the trauma care system fund established by KRS 211.496.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

An increase in fees or funding is not necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

There are no fees established in this administrative regulation.

(9) TIERING: Is tiering applied?

Tiering is not applied. The requirements of this administrative regulation are equally applied to all hospitals seeking Level IV trauma center designation.

FISCAL IMPACT STATEMENT

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 211.494.

(2) Identify the promulgating agency and any other affected state units, parts, or divisions:

The Cabinet for Health and Family Services, Department for Public Health is the promulgating agency.

(a) Estimate the following for the first year:

Expenditures:The amendment to this administrative regulation will not impact expenditures of the department.

Revenues:The amendment to this administrative regulation will not generate revenue for the department.

Cost Savings:The amendment to this administrative regulation will not result in cost savings for the department.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

The expenditures, revenue, and cost savings for the department will not change in subsequent years.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts):

There are no affected local entities.

(a) Estimate the following for the first year:

Expenditures:Not applicable.

Revenues:Not applicable.

Cost Savings:Not applicable.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

Not applicable.

(4) Identify additional regulated entities not listed in questions (2) or (3):

The additional regulated entities include the thirteen (13) hospitals currently designated as Level IV trauma centers and the six (6) hospitals seeking designation.

(a) Estimate the following for the first year:

Expenditures:Level IV trauma centers are assessed a \$1,000 fee every three (3) years. There are also expenditures related to the cost for each verification site visitor.

Revenues:The amendment to this administrative regulation will not impact the revenues for the Level IV trauma centers.

Cost Savings:The amendment to this administrative regulation changes the number of site visitors from three in each category to two. This will result in minimal cost savings for the regulated entities as they are required to cover the expenses for each verification site visitor.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

There will be no change in expenditures, revenues, cost savings in subsequent years.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:

The amendment to this administrative regulation will have minimal fiscal impact on the department and regulated entities.

(b) Methodology and resources used to determine the fiscal impact:

Reducing the number of required site visitors will make it easier to recruit potential site visitors and will lower the cost for the regulated entities. The materials incorporated by reference are available online and therefore will be free of charge for hospitals to access.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). (\$500,000 or more, in aggregate)

This administrative regulation does not have an overall negative or adverse major economic impact.

(b) The methodology and resources used to reach this conclusion:

The costs to the department or regulated entities will not exceed \$500,000.