CABINET FOR HEALTH AND FAMILY SERVICES

Department for Public Health

Office of the Commissioner

(Amendment)

902 KAR 28:010. Definitions for 902 KAR Chapter 28.

RELATES TO: KRS 211.490, 211.492, 211.494, 211.496, 311A.010, 45 C.F.R. Parts 160, 162, 164

STATUTORY AUTHORITY: KRS 211.494(8)

CERTIFICATION STATEMENT:

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 definitions for 902 KAR Chapter 28 pertaining to the statewide trauma care system.

Section 1. Definitions.

(1) "ABEM" means the American Board of Emergency Medicine.

(2) "ACS COT" means the American College of Surgeons Committee on Trauma.

(3) "Adult" means an individual who has attained eighteen (18) years of age.

(4) "AOBEM" means the American Osteopathic Board of Emergency Medicine.

(5) "ATCN" means the Advanced Trauma Care for Nurses course for registered nurses of the American College of Surgeons Society of Trauma Nurses.

(6) "ATLS" means the Advanced Trauma Life Support course of the American College of Surgeons.

(7) "Board certified" means the physician has been certified by the appropriate specialty board recognized by the American Board of Medical Specialties.

(8) "Commissioner" means the commissioner of the Kentucky Department for Public Health.

(9) "Consultation" means the peer review process that:

(a) A hospital may request prior to verification to assess the hospital's system of trauma care, [~~its~~ ]institutional capabilities, and preparedness for verification; and

(b) Is conducted in accordance with 902 KAR 28:030, Section 2(1)(a).

(10) "Department" means the Department for Public Health, Cabinet for Health and Family Services.

(11) "Designation" means the process established in 902 KAR 28:020 by which a hospital is identified by the department as an appropriate facility to receive traumatically injured patients.

(12) "Emergency medical services" or "EMS" is defined by KRS 311A.010(9).[~~(5)~~]

(13) "Health Insurance Portability and Accountability Act of 1996" or "HIPAA" means the federal law codified at 45 C.F.R. Parts 160, 162, and 164 that covers the use of a patient's protected health information.

(14) "ITLS" or "International Trauma Life Support" means an international standard training course for pre-hospital trauma care designed by the American College of Surgeons.

(15) "Kentucky Trauma Advisory Committee" or "KyTAC" means the advisory committee established by KRS 211.494(3).

(16) "Kentucky Trauma Data Bank[~~Registry~~ ]"or "KTDB[~~KTR~~]" means a database of information submitted by designated trauma centers on the operation, quality, and services provided to patients, consistent with the standards of the National Trauma Data Bank (NTDB) as established by the American College of Surgeons Committee on Trauma (ASC COT).

(17) "Kentucky Trauma Hospital Reference[~~Resource~~] Manual" means the detailed reference document that:

(a) Provides guidance, information, references, and resources to assist hospital facilities:

1. Seeking designation as a trauma center pursuant to 902 KAR 28:020 or 28:030; or

2. Designated as a trauma center pursuant to 902 KAR 28:020 or 28:030;

(b) Is published by the Kentucky Trauma Advisory Committee and available on the Kentucky Hospital Association Web site at https://www.kyha.com/kentucky-trauma-system[~~http://www.kyha.com/home/kentucky-trauma-care-system~~]; and

(c) Is incorporated by reference in 902 KAR 28:030, Section 3.

(18) "Level I trauma center" means a regional trauma center that:

(a) Provides total care of every aspect of injury from prevention through rehabilitation; and

(b) Meets the requirements for a Level I trauma center established in 902 KAR 28:020.

(19) "Level II trauma center" means a regional trauma center that:

(a) Provides screening and initial trauma care of the injured patient regardless of the severity of injury; and

(b) Meets the requirements for a Level II trauma center established in 902 KAR 28:020.

(20) "Level III trauma center" means a regional trauma center that:

(a) Provides prompt assessment, resuscitation, emergency operations, and stabilization;

(b) Arranges for transfer, if warranted, to a facility that can provide trauma care at a higher level;

(c) Serves communities that do not have immediate access to a Level I or Level II trauma center; and

(d) Meets the requirements for a Level III trauma center established in 902 KAR 28:020.

(21) "Level IV trauma center" means a regional trauma center that:

(a) Provides advanced trauma life support before a patient is transferred to a higher level of care;

(b) Is located in a hospital emergency department; and

(c) Meets the requirements for a Level IV trauma center established in 902 KAR 28:030.

(22) "Multidisciplinary trauma review committee" means a committee composed of the facility's trauma services medical director and other members of the facility trauma team that reviews trauma related morbidity and mortality in a hospital.

(23) "NTDB" or "National Trauma Data Bank" means the national repository of trauma registry data established by the ACS COT and found at https://www.facs.org/quality-programs/trauma/quality/national-trauma-data-bank/[~~http://www.facs.org/trauma/ntdb/index.html~~].

(24) "Prehospital care provider" means an individual or organization certified or licensed by the Kentucky Board of Emergency Medical Services to provide out-of-hospital emergency medical services.

(25) "Process improvement program" means a quality assurance program established by a trauma center in accordance with the requirements of the ACS COT or the KyTAC[~~,~~] that:

(a) Continually evaluates the performance and quality of care provided by a trauma center; and

(b) Recommends quality improvements to the trauma care program of the center.

(26) "Protected health information" means a patient's information as defined in the Health Insurance Portability and Accountability Act of 1996, or HIPAA, 45 C.F.R. Parts 160, 162, and 164.

(27) "Response time" means the interval between notification and arrival of the general surgeon, surgical specialist, or other medical professional in the emergency department or operating room.

(28) "RTTDC" or "Rural Trauma Team Development Course" means a course developed by ACS COT for rural hospitals to help a rural hospital develop its trauma team.

(29) "TNCC" or "Trauma Nursing Care Course" means a training course that focuses on trauma care for nurses developed by the Emergency Nurses Association.

(30) "Transfer agreement" means the formal, written agreement between hospitals for the transfer and acceptance of patients that meets the requirements established in 902 KAR 28:030.

(31) "Trauma" is defined by KRS 211.492(1) and 311A.010(23)[~~(17)~~].

(32) "Trauma center" is defined by KRS 211.492(2).

(33) "Trauma center verification" is defined by KRS 211.492(3).

(34) "Trauma coordinator" or "trauma services manager" means an individual:

(a) Designated by the hospital with responsibility for the coordination of all trauma care activities and who works in collaboration with the trauma services medical director; and

(b) Responsible for the requirements established in 902 KAR 28:030.

(35) "Trauma registry" means a database comprised of trauma center data that is submitted by a hospital[~~all hospitals~~] designated as a trauma center consistent with the standards of the National Trauma Data Bank (NTDB) as established by the American College of Surgeons Committee on Trauma (ASC COT).

(36) "Trauma services medical director" means the physician designated by the hospital to coordinate trauma care.

(37) "Trauma system" means the integrated network of hospitals and medical services including transportation[~~,~~] that strives to provide the timely and appropriate services relative to the degree of the patient's injury.

STEVEN J. STACK, MD, MBA, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: August 15, 2024

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

PUBLIC HEARING AND PUBLIC 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, KY 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 defines the terms used in 902 KAR Chapter 28 administrative regulations.

(b) The necessity of this administrative regulation:

This administrative regulation is necessary to ensure a consistent understanding of the defined terms.

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

KRS 211.490(8) notes that a well-coordinated statewide trauma care system is vital to the health and wellbeing of the citizens of the commonwealth. KRS 211.494(8) authorizes the department to promulgate administrative regulations to implement a statewide trauma care system.

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

This administrative regulation ensures a consistent understanding of the terms used in 902 KAR Chapter 28 administrative regulations.

(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 updates the defined terms for clarification, updates website citations, and makes other changes necessary for KRS Chapter 13A compliance.

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

The amendment to this administrative regulation is necessary to ensure hospitals have accurate information when seeking designation as a trauma center.

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

KRS 211.494(8) authorizes the department to promulgate administrative regulations to implement a statewide trauma care system.

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

The amendment to this administrative regulation will ensure hospitals have accurate information when seeking designation as a trauma care center.

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

The amendment to this administrative regulation impacts the twenty-one (21) hospitals currently designated as trauma centers and all hospitals that will apply for 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:

Hospitals will need to be aware of the changes to the defined terms.

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

There is no cost for hospitals to comply with this administrative regulation.

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

Hospitals will be aware of the requirements for trauma care center designation.

(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 this administrative regulation.

(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 as the requirements of this administrative regulation are equally applied to all regulated entities.

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: This administrative regulation does not impact program expenditures.

Revenues: This administrative regulation does not generate revenue.

Cost Savings: This administrative regulation does not result in cost savings.

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

Not applicable.

(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):

Additional regulated entities include the twenty-one (21) hospitals currently designated as trauma centers, all hospitals that will apply for designation, and the Kentucky Trauma Advisory Committee.

(a) Estimate the following for the first year:

Expenditures: This administrative regulation will not impact the expenditures of the additional regulated entities.

Revenues: This administrative regulation will not impact the revenues of the additional regulated entities.

Cost Savings: This administrative regulation will not result in cost savings for the additional regulated entities.

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

Not applicable.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:

This administrative regulation will have no fiscal impact.

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

This administrative regulation only establishes the definitions used throughout 902 KAR Chapter 28 administrative regulations. There is no fiscal impact related to the defined terms.

(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:

Not applicable.

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.

45 C.F.R. Parts 160, 162 and 164.

(2) State compliance standards.

KRS 211.494(6) requires that all data obtained through the trauma registry or other data collected shall be confidential. The personal identifying information that is collected through the trauma registry shall not be subject to discovery or introduction into evidence in any civil action.

(3) Minimum or uniform standards contained in the federal mandate.

45 C.F.R. Parts 160, 162, and 164 cover the administrative data standards and related requirements for electronic data submission of protected health information. 45 C.F.R. 164.302 requires that any covered entity or business associate comply with the applicable standards, implementation specifications, and requirements for the electronic submission of protected health information of the covered entity. All data shared through the Kentucky trauma system registry must comply with all applicable parts of 45 C.F.R. Parts 160, 162, and 164.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?

No, this administrative regulation does not impose any stricter requirements, or additional of different responsibilities or requirements.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.

Not applicable.