

Proposed

**State of Kansas
Department of Health and Environment**

Notice of Hearing on Proposed Administrative Regulations

The Kansas Department of Health and Environment, Division of Health, Bureau of Community Health Systems, will conduct a public hearing at 10:00 a.m. Thursday, July 6, 2017, in the Flint Hills Conference Room, third floor, Curtis State Office Building, 1000 SW Jackson, Topeka, to consider the adoption of proposed amended regulations K.A.R. 28-54-1, 28-54-2, 28-54-3, 28-54-4 and 28-54-5 regarding designation of a hospital trauma center.

A summary of the proposed regulations and the estimated economic impact follows:

Summary of Regulations

K.A.R. 28-54-1. Definitions.

Amendments change the definition of a level IV trauma center to remove the limitation of only being able to transfer to a level I, level II or level III through the addition of language that allows the level IV trauma center to transfer to any trauma facility capable of providing care necessary to treat a patient's injuries. Amendments also define "on-site survey" and the criteria for successful completion of the secretary's on-site survey process and revise the definition of "verification" to reference the American College of Surgeons level I, level II and level III evaluation process.

K.A.R. 28-54-2. Standards for designation.

Amendments clarify the standards for designation for each of the four different trauma center designation levels.

K.A.R. 28-54-3. Application for designation.

Amendments clarify the processes associated with the application for designation for all four trauma center designation levels and the fees associated with each.

RECEIVED

APR 12 2017

**KRIS W. KOBACH
SECRETARY OF STATE**

K.A.R. 28-54-4. Application for change of designation.

Amendments clarify the processes associated with the application for change in trauma center designation for all four trauma center designation levels, keeping processes consistent with changes made to other trauma center designation processes.

K.A.R. 28-54-5. Certificate of designation; renewal.

Amendments clarify the processes associated with the trauma center designation renewal for all four trauma center designation levels, keeping processes consistent with changes made to other trauma center designation processes.

Economic Impact

Costs to the agency: It is anticipated that costs incurred by KDHE to implement the changes in the proposed regulations will be minimal. Current trauma program staff will be utilized to process and review level IV applications and coordinate on-site surveys.

Costs to consumers: There is no increase in costs to consumers.

Costs to other governmental agencies or units: There is no increase in costs to other governmental agencies or units.

The time period between the publication of this notice and the scheduled hearing serves as the required public comment period of at least 60 days for the purpose of receiving written public comments on the proposed amended regulations. All interested parties may submit written comments to Carman Allen, KDHE, Preparedness and Trauma, Bureau of Community Health Systems, Curtis States Office Bldg., 1000 SW Jackson, Suite 340, Topeka, 66612, by email to Carman.Allen@ks.gov, or by fax to 785-296-1210. During the hearing, all interested parties will be given a reasonable opportunity to present their views orally on the proposed regulations as well as an opportunity to submit their written comments. In order to give each

RECEIVED

APR 12 2017

KRIS W. KOBACH

individual an opportunity to present their views, it may be necessary for the hearing officer to request that each presenter limit an oral presentation to an appropriate time frame.

Complete copies of the proposed amended regulations and the corresponding economic impact statement may be obtained from the KDHE Trauma Program website at www.kansastrama.org or by contacting Nancy.Akin@ks.gov, 785-296-3180 or by fax at 785-296-2625. Questions pertaining to the proposed amended regulations should be directed to Carman Allen at the contact information for Carman Allen above.

Any individual with a disability may request accommodation in order to participate in the public hearing and may request the proposed regulations and the economic impact statement in an accessible format. Requests for accommodation should be made at least five working days in advance of the hearing by contacting Nancy Akin at 785-296-3180.

Susan Mosier, M.D.
Secretary

RECEIVED

APR 12 2017

KRIS W. KOBACH
SECRETARY OF STATE

28-54-1. Definitions. Each of the following terms used in this article shall have the meaning specified in this regulation:

(a) "ACS" means American college of surgeons.

(b) "Department" means Kansas department of health and environment.

(c) "Designation" means a determination by the secretary that a hospital shall provide the trauma care required of a level I trauma center, level II trauma center, level III trauma center, or level IV trauma center.

(d) "Level I trauma center" means a hospital that has the capability to provide the highest level of trauma care for every aspect of injury, from prevention through rehabilitation.

(e) "Level II trauma center" means a hospital that meets the following conditions:

(1) Provides initial trauma care, regardless of the severity of the injury;

(2) is not necessarily able to provide the same comprehensive care as that provided by a level I trauma center; and

(3) does not have trauma research as a primary objective.

(f) "Level III trauma center" means a hospital that provides initial trauma care or arranges for the appropriate transfer of trauma patients to a level I trauma center or a level II trauma center.

(g) "Level IV trauma center" means a hospital that provides urgent care for injured persons and the timely transfer of the seriously injured to a ~~level I trauma center, level II trauma center, or level III trauma center as appropriate~~ trauma facility capable of providing care necessary for the treatment of the patients' injuries.

(h)(1) "On-site survey" means the secretary's evaluation of a hospital's compliance with

RECEIVED

APR 12 2017

KRIS W. KOBACH
SECRETARY OF STATE

ATTORNEY GENERAL

JAN 25 2017

APPROVED BY 

APPROVED

MAR 07 2016

DEPT. OF ADMINISTRATION

the following:

(A) The level IV trauma center type I designation criteria and type II designation criteria identified in the department's document titled "Kansas level IV criteria quick reference," dated November 4, 2015, which is hereby adopted by reference; and

(B) all standards specified on pages eight through 31 in the department's document titled "pre-review questionnaire (PRQ) guidance for Kansas level IV trauma center designation," dated November 4, 2015. Pages eight through 33 of this document are hereby adopted by reference, excluding all sections titled "reference" or "rationale."

(2) Each hospital's successful completion of the on-site survey shall require compliance with the following:

(A) All type I designation criteria;

(B) all type II designation criteria, except that a hospital may have no more than three type II critical deficiencies; and

(C) reporting trauma registry data and information pursuant to K.S.A. 75-5666, and amendments thereto.

(i) "Regional trauma council" means one of the six councils, as defined in K.S.A. 75-5663 and amendments thereto, in the state established to address trauma and emergency medical care issues within a specific geographic area and to coordinate services to meet the needs of trauma patients injured within that area.


(j) "Trauma" means any of the following:

(1) Any injury to a person that results from acute exposure to mechanical, thermal,



ATTORNEY GENERAL

JAN 25 2017

APPROVED BY 

APPROVED

JAN 24 2017

DEPT. OF ADMINISTRATION

electrical, or chemical energy;

(2) any injury to a person that is caused by the absence of heat or oxygen and that requires immediate medical intervention; or

(3) any injury to a person that requires surgical intervention or treatment to prevent death or permanent disability.

(+) (k) "Trauma facility" means a hospital distinguished by the availability of surgeons, physician specialists, anesthesiology services, nurses, and resuscitation and life-support equipment on a 24-hour basis to care for persons with trauma. This term shall include the following:

(1) Level I trauma centers;

(2) level II trauma centers;

(3) level III trauma centers; and

(4) level IV trauma centers.

(+) (l) "Trauma registry" means the database maintained by the department to collect and analyze reportable patient data on the incidence, severity, and causes of trauma.

(+) (m) "Verification" means the ~~process by which the American college of surgeons confirms~~ evaluation and confirmation by the ACS of a hospital's trauma care capability and performance to operate as a level I trauma center, level II trauma center, or level III trauma center. (Authorized by K.S.A. 2011 2016 Supp. 75-5665; implementing K.S.A. 2011 2016 Supp. 75-5665 and K.S.A. 2011 2016 Supp. 75-5666; effective Nov. 2, 2007; amended March 16, 2012; amended P-_____.)

RECEIVED

APR 12 2017

KRIS W. KOBACH
SECRETARY OF STATE

ATTORNEY GENERAL

JAN 25 2017

APPROVED BY *SY*

APPROVED

JAN 24 2017

DEPT. OF ADMINISTRATION

28-54-2. Standards for designation. The designation of a hospital as a level I trauma center, level II trauma center, level III trauma center, or level IV trauma center shall be made by the secretary based on ~~the capability of the hospital to meet the requirements of the requested designation, as specified in this regulation~~ the following:

(a) For level I trauma centers ~~and, level II trauma centers, and level III trauma centers,~~ verification by ~~the American college of surgeons that the hospital meets the standards specified in the "resources for optimal care of the injured patient: 2006," excluding the appendices, published by the American college of surgeons, which is adopted by reference, or a determination by the secretary that the hospital meets equivalent standards; and~~

(b) ~~for level III trauma centers, the "Kansas trauma care facility categorization criteria for level III trauma center," published by the Kansas advisory committee on trauma and dated April 6, 2007, which is adopted by reference; and~~

(c) for each level IV trauma centers center, the ~~"Kansas trauma care facility categorization criteria for level IV trauma center," published by the Kansas advisory committee on trauma and dated August 25, 2010, which is adopted by reference~~ successful completion of an on-site survey. (Authorized by and implementing K.S.A. 2011 2016 Supp. 75-5665; effective Nov. 2, 2007; amended March 16, 2012; amended P-_____.)

RECEIVED

APR 12 2017

KRIS W. KOBACH
SECRETARY OF STATE

ATTORNEY GENERAL

JAN 25 2017

APPROVED BY 

APPROVED

JAN 24 2017

DEPT. OF ADMINISTRATION

28-54-3. Application for designation. (a)(1) Each hospital administrator that seeks a certificate of designation for its hospital as a level I trauma care center, level II trauma care center, or level III trauma care center shall submit a designation application on a form provided by the department and the following to the secretary:

(A) ~~A designation application on a form provided by the department. Each applicant seeking designation as a level I trauma center, level II trauma center, or level III trauma center shall include one of the following:~~

(i) ~~(1) A copy of the applicant's current ACS one-year or three-year verification certificate; or and~~

~~(ii) documentation of successful completion of the secretary's on-site survey; and~~

~~(B) one of the following nonrefundable application fees:~~

~~(i) \$500 for designation as a level I trauma center, level II trauma center, or level III trauma center; or~~

~~(ii) \$250 for designation as a level IV trauma center.~~

~~(2) An application shall not be deemed complete until all of the required materials have been received. Each applicant shall be notified by the department of the completeness of the application within 30 calendar days after the application is submitted to the department a nonrefundable application fee of \$500.~~

~~(b) Any applicant seeking designation of its hospital as a level III trauma center may request an on-site survey from the department by submitting a request with the application. The applicant shall be notified by the department of the date on which the on-site survey is scheduled and the amount of the nonrefundable fee for the on-site survey, which shall not exceed \$15,000.~~

RECEIVED

APR 12 2017

KRIS W. KOBACH
SECRETARY OF STATE

ATTORNEY GENERAL

JAN 25 2017

APPROVED BY *SK*

APPROVED

MAR 07 2016

DEPT. OF ADMINISTRATION

The applicant shall submit this fee at least 30 calendar days before the date of the on-site survey. Each hospital administrator who seeks a certificate of designation for its hospital as a level IV trauma center shall submit a designation application on a form provided by the department and the following to the secretary:

(1) Documentation of successful completion of an on-site survey that occurred after submission of the application; and

(2) a nonrefundable application fee of \$250.

(c) ~~For each hospital seeking a level IV designation, a site visit may be arranged before the three-year designation period, within the three-year designation period, and every three years thereafter to coincide with the three-year designation process.~~ Each hospital administrator specified in subsection (b) who receives notice that the initial designation as a level IV trauma center is denied shall comply with one of the following before submitting a subsequent application for designation:

(1) Allow at least six months after the date of the notice; or

(2) submit a written request for reevaluation to the advisory committee on trauma that is subsequently approved.

(d) ~~The findings of the on-site survey team shall be provided to each applicant within 60 calendar days after the date of each survey. If a hospital does not meet the requirements for the level of designation for which the hospital administrator has applied, the hospital administrator shall be notified of the requirements that the hospital is required to meet for designation at the requested level. The hospital administrator shall submit to the secretary a plan of the proposed~~

RECEIVED

APR 12 2017

KRIS W. KOBACH
SECRETARY OF STATE

ATTORNEY GENERAL

JAN 25 2017

APPROVED BY 

APPROVED

MAR 07 2016

DEPT. OF ADMINISTRATION

~~actions that the hospital will take to ensure compliance with the requirements. A second survey may be required by the secretary. The secretary's survey team shall make a recommendation for the designation to the secretary, based on the hospital's capability to meet the criteria for the requested level of designation.~~

~~(e) Each applicant specified in subsection (d) shall be notified by the secretary about the status of designation as a trauma facility within 90 calendar days after the applicant's last survey.~~

~~(f) Each applicant who submits a current ACS one-year or three-year verification certificate with an application and the required fee shall be notified by the secretary about the status of designation as a trauma facility within 30 calendar days after these required materials are submitted to the secretary.~~

(g) Each certificate of designation shall be valid from the date of issuance and for the period specified on the certificate. (Authorized by and implementing K.S.A. 2014 2016 Supp. 75-5665; effective Nov. 2, 2007; amended March 16, 2012; amended P-_____.)

RECEIVED

APR 12 2017

KRIS W. KOBACH
SECRETARY OF STATE

ATTORNEY GENERAL

JAN 25 2017

APPROVED BY *86*

APPROVED

JAN 24 2017

DEPT. OF ADMINISTRATION

28-54-4. Application for change of designation. (a) Any administrator of a designated trauma facility may request a change of designation by submitting an application for a change of designation on the form provided by the department and the following to the secretary:

(1) ~~An application for a change of designation on the form provided by the department.~~
Each applicant seeking a change of designation to a level I trauma center, level II trauma center, or level III trauma center shall ~~include one of~~ submit the following:

(A) A copy of the applicant's current ACS one-year or three-year verification certificate for the level of designation sought; or

(B) ~~documentation of successful completion of the secretary's on-site survey for the level of designation sought. The applicant may request an on-site survey from the department by submitting a request with the application; and~~

(2) (B) ~~one of the following a nonrefundable fees:~~

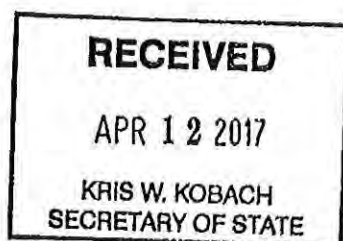
(A) fee of \$500 for designation as a level I trauma center, level II trauma center, or level III trauma center; or

(B) \$250 for designation as a level IV trauma center.

~~An application shall not be deemed complete until all of the required materials have been received. Each applicant shall be notified by the department of the completeness of the application within 30 calendar days after the application is submitted to the department.~~

(2) Each applicant seeking a change of designation to a level IV trauma center shall submit the following:

(A) Documentation of successful completion of an on-site survey that occurred after submission of the application; and



ATTORNEY GENERAL

JAN 25 2017

APPROVED BY 86

APPROVED

MAR 07 2016

DEPT. OF ADMINISTRATION

(B) a nonrefundable fee of \$250.

~~(b) If the applicant seeking designation of its hospital as a level III trauma center requests an on-site survey by the department, the applicant shall be notified by the department of the date on which the on-site survey is scheduled and the amount of the nonrefundable fee for the on-site survey, which shall not exceed \$15,000. The applicant shall submit this fee at least 30 calendar days before the date of the on-site survey.~~

~~(c) The findings of the secretary's on-site survey team shall be provided to the applicant within 60 calendar days after the date of the survey. The survey team shall make a recommendation for the designation to the secretary, based on the hospital's capability to meet the criteria for the requested level of designation.~~

~~(d) Each applicant specified in subsection (c) shall be notified by the secretary about the status of designation as a trauma facility within 90 calendar days after the applicant's on-site survey.~~

~~(e) Each applicant who submits a current ACS one-year or three-year verification certificate for the level of designation sought with an application and the required fee shall be notified by the secretary about the status of designation as a trauma facility within 30 calendar days after these required materials are submitted to the secretary.~~

~~(f) Each change of designation certificate shall be valid from the date of issuance and for the period specified on the certificate. (Authorized by and implementing K.S.A. 2011 2016 Supp. 75-5665; effective Nov. 2, 2007; amended March 16, 2012; amended~~

P- _____.)



ATTORNEY GENERAL

JAN 25 2017

APPROVED BY 

APPROVED

JAN 24 2017

DEPT. OF ADMINISTRATION

28-54-5. Certificate of designation; renewal. (a) ~~Each certificate of designation shall be valid for three years from the effective date specified on the certificate.~~

(b)(1) Each administrator of a designated trauma facility ~~that wants~~ wanting to renew the trauma facility's certificate of designation shall submit an application for renewal on a form provided by the department and either of the following at least six months before the expiration date specified on the certificate of designation:

(A) (1) ~~An application for renewal of the hospital's designation on a form provided by the department, which shall include~~ For a level I trauma center, level II trauma center, or level III trauma center, the following:

(i) (A) A copy of the applicant's current ACS one-year or three-year verification certificate; ~~or~~ and

(ii) ~~documentation of successful completion of the secretary's on-site survey. If an applicant for renewal wants to request an on-site survey from the department, the applicant shall meet the requirements specified in K.A.R. 28-54-3(b) or (c) and in K.A.R. 28-54-3(d); and~~

(B) ~~one of the following~~ a nonrefundable renewal fees:

(i) ~~fee of \$500 for designation as a level I trauma center, level II trauma center, or level III trauma center; or~~

(ii) ~~\$250 for designation as a level IV trauma center.~~

(2) ~~An application shall not be deemed complete until all of the required materials have been received. Each applicant for renewal shall be notified by the department of the completeness of the application within 30 calendar days after the application is submitted to the department. Except as otherwise provided in subsection (c), failure to renew the certificate of~~

RECEIVED

APR 12 2017

KRIS W. KOBACH
SECRETARY OF STATE

ATTORNEY GENERAL

JAN 25 2017

APPROVED BY *ST*

APPROVED

MAR 07 2016

DEPT. OF ADMINISTRATION

designation before the expiration date shall render the certificate invalid. for a level IV trauma center, the following:

(A) A nonrefundable renewal fee of \$250; and

(B) documentation of successful completion of an on-site survey that occurred after submission of the application.

(b) The renewal of a level IV trauma center designation may be denied for willful misrepresentation of information and documentation during the renewal application process.

(c) The certificate of designation shall not expire on the specified expiration date if all of the required materials specified in paragraph (b)(1) have been submitted to the secretary at least six months before the expiration date on the certificate of designation. In this case, the certificate of designation shall expire on the earlier of the following dates:

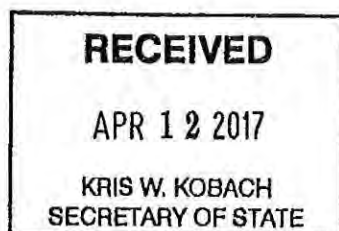
(1) The date on which the certificate of designation is renewed; or

(2) the date on which the secretary denies the renewal application. Each hospital administrator seeking designation as a level IV trauma center who receives notice that the renewal designation is denied shall comply with one of the following before submitting a subsequent application for renewal:

(1) Allow at least six months after the date of the notice; or


(2) submit a written request for reevaluation to the advisory committee on trauma that is subsequently approved.

(d) Each renewed certificate of designation shall be valid from the date of issuance and for the period specified on the certificate. (Authorized by and implementing K.S.A. 2011 2016



ATTORNEY GENERAL

JAN 25 2017

APPROVED BY 

APPROVED

JAN 24 2017

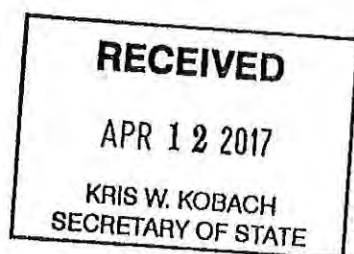
DEPT. OF ADMINISTRATION

Proposed

K.A.R. 28-54-5, Page 3


Supp. 75-5665; effective Nov. 2, 2007; amended March 16, 2012; amended

P-_____.)



ATTORNEY GENERAL

JAN 25 2017

APPROVED BY 

APPROVED

MAR 03 2016

DEPT. OF ADMINISTRATION

March 24, 2017

Kansas Department of Health and Environment
Economic Impact Statement

Pursuant to the requirements of KSA 2016 Supp. 77-416, the Kansas Department of Health and Environment submits the following economic impact statement.

1. Regulation(s):

K.A.R. 28-54-1
K.A.R. 28-54-2
K.A.R. 28-54-3
K.A.R. 28-54-4
K.A.R. 28-54-5

2. Brief description of each regulation(s) and what is intended to be accomplished by adoption.

28-54-1. Provides the definition of terms used in the trauma center regulations and updates the regulation regarding criteria for a level IV trauma center.

28-54-2. Specifies the requirements by which a hospital is designated as a level I, level II, level III or level IV trauma center. Defines the standards by which a hospital is designated as a trauma center.

28-54-3. Establishes the application process by which a hospital can apply for designation as a level I, level II, or level III trauma center and updates the regulation to include the process for level IV trauma center designation.

28-54-4. Defines the application process by which a hospital can request a change of designation for a level I, level II, or level III trauma center and updates the regulation to include the application process for change to designation as a level IV trauma center.

28-54-5. Specifies the period of time for which a certificate of designation as a trauma center is valid, provides for the process of renewal of a certificate of designation for a level I,

RECEIVED

APR 12 2017

KRIS W. KOBACH

level II, or level III trauma center and updates the regulation to include the process for renewal of a certificate of designation as a level IV trauma center.

3. Is this regulation(s) mandated by federal law as a requirement for participating in or implementing a federally subsidized or assisted program?

Yes _____

No x _____

If yes, please explain.

4. Do the proposed regulations exceed the requirements of applicable federal law?

Yes _____

No x _____

If yes, please explain.

5. Description of Costs:

a. Cost to the agency:

It is anticipated that the costs incurred by KDHE to implement these regulations will be minimal. Current staff within the trauma program will be utilized to process and review level IV applications and coordinate on-site surveys.

b. Cost to persons who will bear the costs and those who will be affected, (i.e. private citizens and consumers of the products or services) and are subject to the proposed rules and regulations or the enforcement:

There is no anticipated change in costs to the level IV trauma centers with these regulatory changes.

c. Costs to other governmental agencies or units:

There is no known increase in costs to other governmental agencies or units. Having designated trauma centers in Kansas would be of great benefit to other agencies such as disaster management/emergency preparedness. When an emergency response is needed, the trauma care resources in the state or region will help in triaging patients to the closest appropriate trauma center thereby reserving medical resources for those most in need and promoting efficient use of transportation resources.

6. Description of any less costly or less intrusive methods that were considered by the agency for the purpose of the rules and regulations and why such methods were rejected in favor of the proposed rules and regulations.



The regulations as written by KDHE are designed to be consistent with current state and national standards for trauma system care.

7. **Verification of economic impact statement with League of Kansas Municipalities, Kansas Association of Counties and the Kansas Association of School Boards.**

The above mentioned regulations were determined as appropriate for consultation as to the economic impact with the League of Kansas Municipalities, Kansas Association of Counties and the Kansas Association of School Boards, pursuant to KSA 2014 Supp. 77-416.

Yes _____

No x _____

If yes:

Date Contacted and by what means (i.e., letter, FAX, etc.):

Response and comments received by:

League of Kansas Municipalities:

Kansas Association of Counties:

Kansas Association of School Boards:

