

# Regulation 61-116

## South Carolina Trauma Care Systems

### Disclaimer

DHEC provides this copy of the regulation for the convenience of the public and makes every effort to ensure its accuracy. However, this is an unofficial version of the regulation. The regulation's most recent final publication in the *South Carolina State Register* presents the official, legal version of the regulation.

Regulation History as Published in State Register			
Date	Document Number	Volume	Issue
April 24, 2009	3199	33	4
May 27, 2016	4578	40	5

## Table of Contents

<b>SECTION 100.</b>	<b>DEFINITIONS</b>	1
<b>SECTION 200.</b>	<b>DESIGNATION PROCESS</b>	4
201.	Eligibility for Designation	4
202.	Application Process	4
203.	Designation Renewal	4
204.	Categories of Designation	5
205.	Designation	5
206.	Site Review	5
207.	Review Team Composition	6
208.	Protocol for Inspections	6
209.	Content of Inspection	7
210.	Designation Criteria	7
211.	Designation Process	7
212.	Process of Re-designation	8
213.	Change in Trauma Center Designation Status	8
214.	Public Notification of Trauma Center Designation Status	9
<b>SECTION 300.</b>	<b>CERTIFICATE OF DESIGNATION REQUIREMENTS</b>	9
301.	Certification Requirements	9
302.	Issuance and Terms of the Certificate of Designation	9
303.	Exceptions to the Standards	10
<b>SECTION 400.</b>	<b>ENFORCEMENT OF REGULATIONS</b>	10
401.	General	10
402.	Inspections and Investigations	10
403.	Investigation Procedures	11
<b>SECTION 500.</b>	<b>ENFORCEMENT ACTIONS</b>	11
501.	General	11
502.	Violation Classifications	11

<b>SECTION 600. STAFFING</b>	13
<b>SECTION 700. FACILITY, EQUIPMENT, AND CARE REQUIREMENTS</b>	13
701. Physical Facilities	13
702. Trauma Care of the Patient (Transfers)	13
703. Trauma Care Services	14
<b>SECTION 800. TRAUMA TRIAGE AND TRANSPORT GUIDELINES</b>	14
801. Purpose	14
802. Required Participation	14
803. Required Transport	14
804. Triage Tag System	15
<b>SECTION 900. PATIENT RIGHTS</b>	15
901. General	15
902. Grievances and Complaints	15
<b>SECTION 1000. STATEWIDE TRAUMA REGISTRY</b>	16
1001. Purpose of Trauma Registry	16
1002. Requirement to Submit Data	16
1003. Inclusion and Exclusion Criteria	16
1004. Confidentiality Protection of Data and Reports	17
<b>SECTION 1100. HOSPITAL RESOURCES DATA BASE</b>	17
1101. Purpose	17
1102. Required Participation	17
<b>SECTION 1200. TRAUMA CARD FUND</b>	17
1201. Eligible Recipients of Fund	17
1202. Allocation of Fund	17
<b>SECTION 1300. PERFORMANCE IMPROVEMENT PROGRAMS</b>	18
1301. General	18
1302. Statewide Trauma System Performance Improvement Plan	18
1303. Trauma Center Performance Improvement Plan	18
1304. Performance Improvement and Feedback	18
<b>SECTION 1400. ADVISORY COMMITTEES</b>	18
1401. State Trauma Advisory Council	18
1402. Medical Control Committee	19
<b>SECTION 1500. TRAUMA SYSTEM PLANS</b>	19
1501. General	19

1502. Trauma Center Internal Disaster Plan	19
<b>SECTION 1600. SEVERABILITY</b>	19
<b>SECTION 1700. GENERAL</b>	20

## **SECTION 100**

### **DEFINITIONS**

A. Bypass. A medical protocol or request for the transport of an EMS patient past a normally used EMS receiving facility to an alternate medical facility for the purpose of accessing more readily available or appropriate medical care.

B. Certificate. A document issued by the Department to a hospital that denotes the trauma designation level thereof, as determined by the Department subject to the provisions of this regulation.

C. Certificate Holder. The hospital that has received a certificate to provide trauma care from the Department and with whom rests the ultimate responsibility for compliance with this regulation.

D. Department. The South Carolina Department of Health and Environmental Control (DHEC).

E. Designation. The formal determination by the Department that a hospital is capable of providing a specified level of trauma care services.

F. Emergency Department. The area of a licensed general acute care hospital that customarily receives patients in need of emergency medical evaluation and/or care.

G. Emergency Medical Services (EMS). The treatment and transport of patients in crisis health situations, occurring from a medical emergency or from an accident, natural disaster, or similar situation, that may be life threatening, through a system of coordinated response and emergency medical care.

H. Emergency Medical Services Advisory Council. Emergency Medical Services council created pursuant to S.C. Code Section 44-61-30(C).

I. Facility. A trauma center having a certificate of designation by the Department.

J. Field Triage. Classification of patients according to medical need at the scene of an injury or onset of an illness.

K. Glasgow Coma Scale. A standardized system for assessing response to stimuli in a neurologically impaired patient by assessing eye opening, verbal responsiveness, and motor ability.

L. Hospital. A facility licensed by the Department and organized and administered to provide medical or surgical care or nursing care of illness, injury, or infirmity and in which all diagnoses, treatment, or care is administered by or under the direction of persons currently licensed to practice medicine, surgery, or osteopathy.

M. Injury. The result of an act that damages, harms, or hurts; unintentional or intentional damage to the body resulting from acute exposure to thermal, mechanical, electrical or chemical energy or from the absence of such essentials as heat or oxygen.

N. Injury Prevention. Efforts to reduce or prevent incidents that might result in injuries.

O. Level I. Hospitals that have met the requirements for Level I as stated in Section 204 of this regulation and are designated by the Department.

P. Level I Pediatric. Hospitals that have met the Level I criteria along with the required pediatric criteria, and are designated as “Level I Pediatric” by the Department.

Q. Level II. Hospitals that have met the requirements for Level II as stated in Section 204 of this regulation and are designated by the Department.

R. Level II Pediatric. Hospitals that have met the Level II criteria along with the required pediatric criteria, and are designated as “Level II Pediatric” by the Department.

S. Level III. Hospitals that have met the requirements for Level III as stated in Section 204 of this regulation and are designated as “Level III” by the Department.

T. Level IV. Hospitals that have met the requirements for Level IV and are designated as “Level IV” by the Department.

U. Licensed Nurse. An individual licensed by the South Carolina Board of Nursing as a registered nurse or licensed practical nurse.

V. Medical Control. On-line or off-line physician direction over pre-hospital activities to ensure efficient and proficient trauma triage, transportation, and care, as well as ongoing quality assurance.

W. Participating Providers. Those providers who have been approved by the Department for participation in the trauma system and include, but are not limited to, designated trauma centers, designated rehabilitation facilities, and designated fee-for-service physicians who provide trauma care within a designated facility.

X. Performance Improvement (PI) Programs. A method of monitoring, evaluating and improving processes of patient care that emphasizes a multidisciplinary approach to problem solving. These activities are concordant with the Institute of Medicines six (6) quality aims for patient care: safe, effective, patient-centered, timely, efficient, and equitable. (ACS P.114).

Y. Physician. An individual currently licensed as such by the South Carolina Board of Medical Examiners.

Z. Rehabilitation. Services that seek to return a trauma patient to the fullest physical, psychological, social, vocational, and educational level of functioning of which he or she is capable, consistent with physiological or anatomical impairments and environmental limitations.

AA. Repeat Violation. The recurrence of any violation cited under the same section of the regulation.

BB. Revocation of Certificate and Designation. An action by the Department to cancel or annul a certificate and designation by recalling, withdrawing, or rescinding its authority to operate.

CC. South Carolina Trauma Plan. An organized plan developed by the Department pursuant to legislative directive that sets out a comprehensive system of prevention, management, and rehabilitation of traumatic injuries.

DD. State Medical Director (or “State Medical Control Physician”). A South Carolina board-certified physician responsible for providing medical oversight to the Department.

EE. State Trauma Advisory Council (or “TAC”). The Department’s advisory committee regarding trauma related issues.

FF. State Trauma Registry. A statewide database of information collected by the Department including, but not limited to, the incidence, severity, and causes of trauma and the care and outcomes.

GG. Suspension of Certificate and Designation. An action by the Department terminating the certificate holder’s authority to provide trauma care services for a period of time until such time as the Department rescinds that restriction.

HH. Traumatic Injury. Injury or wound to a person caused by the application of an external force or by violence and requiring medical or surgical intervention to prevent death or disability. For the purposes of this regulation, the definition of “trauma” shall be determined by current national medical standards including, but not limited to, injury severity scales.

II. Trauma Care Facility (or “trauma center”). A hospital designated by the Department to provide trauma care services at a particular level.

JJ. Trauma Care Region. A geographic area of the state formally organized in accordance with standards promulgated by the Department and is coterminous with the Department EMS regions.

KK. Trauma Care System. An organized statewide and regional system of care for the trauma patient, including the Department, emergency medical service providers, hospitals, in-patient rehabilitation providers, and other providers who have agreed to participate in and coordinate with and who have been accepted by the Department in an organized statewide system.

LL. Trauma Patient. A patient who presents with acute bodily injuries secondary to an external force requiring immediate intervention deemed necessary to preserve life and limb.

MM. Trauma Program. An administrative unit that includes the trauma service and coordinates other trauma-related activities, including, but not limited to, injury prevention and public education.

NN. Trauma Program Manager. A designated individual with responsibility for coordination of all activities of the trauma program who works in collaboration with the trauma medical director.

OO. Trauma Medical Director. A physician designated by the facility and medical staff to coordinate trauma care.

PP. Trauma System Fund. The separate fund established pursuant to this regulation for the Department to create and administer the State Trauma System.

QQ. Trauma Team. A group of health care professionals organized to provide coordinated and timely care to the trauma patient.

RR. Triage. The process of sorting injured patients on the basis of the actual or perceived degree of injury and assigning them to the most effective and efficient regional care resources in order to insure optimal care and the best chance of survival.

SS. Verification. The inspection of a participating facility in order to determine whether the facility is capable of providing a designated level of trauma care.

## SECTION 200

### DESIGNATION PROCESS

#### 201. Eligibility for Designation (II)

A. Any South Carolina licensed hospital with a functioning emergency service may apply for trauma center designation.

B. Any South Carolina licensed hospital applying for initial designation or renewal designation after July 1, 2018, shall obtain an American College of Surgeons (ACS) verification.

#### 202. Application Process

A. A facility seeking designation shall submit to the Department a completed application and Pre-Review Questionnaire (PRQ). The application shall include the applicant's oath assuring that the contents of the application and PRQ are accurate and true and that the applicant will comply with this regulation. The application shall be authenticated as follows:

1. The application shall be signed by the owner(s) if an individual or partnership;
2. If the applicant is a corporation, the application shall be signed by two (2) of its officers;

3. If the applicant is a governmental unit, the application shall be signed by the head of the governmental unit having jurisdiction.

B. The application shall set forth the full name and address of the facility for which the designation is sought, the name and address of the owner of the facility in the event that his or her address is different from that of the facility, and a list of essential program personnel. In the event of a change in the owner of the facility and/or essential program personnel, the Department shall be notified in writing within forty-eight (48) hours of the change.

C. The Department may require additional information evidencing the applicant's ability to comply with this regulation. Corporations or partnerships shall be registered with the South Carolina Office of the Secretary of State. Other required information may also include, but is not limited to, written affirmation of compliance with all applicable federal Occupational Safety and Health Association (OSHA) requirements or guidelines.

D. The application shall be property of the Department and shall be considered public information at the end of the designation process, subject to state and federal laws. The PRQ shall be confidential in accordance with S.C. Code Section 44-61-520.

E. All applicants prior to July 1, 2018, shall select either a state or ACS site visit. All applicants after July 1, 2018, shall undergo a site visit by an ACS team accompanied by a Department representative.

#### 203. Designation Renewal

A. Prior to July 1, 2018, unless directed otherwise by the Department, all designations shall be renewed every five (5) years by application in accordance with Section 202.

B. After July 1, 2018, the trauma center shall renew their designation requirements at timeframes as required by the ACS and in accordance with Section 202.

C. Any facility designated prior to July 1, 2018, shall be designated for a period of five (5) years.

#### **204. Categories of Designation**

A. The designations available are the adult and pediatric designations listed in Chapter 2 of the 2014 ACS “Resources for Optimal Care of the Injured Patient.”

B. Until July 1, 2018, a trauma center may be granted full designation or provisional designation. Designation levels are granted based on the factors prescribed in the 2014 ACS “Resources for Optimal Care of the Injured Patient.”

C. Prior to July 1, 2018, applicants may obtain provisional designation at any of the levels prescribed in Section 204.A. To receive provisional designation status, a hospital shall have no more than one (1) Type I deficiency and/or no more than five (5) Type II deficiencies.

1. Provisional designation may be granted for a period not to exceed one (1) year except as granted by the Department. The Trauma Advisory Council shall provide oversight during the provisional period.

2. Provisional trauma centers shall have a written work plan of objectives to rectify deficiencies and to demonstrate progress on the work plan throughout the one (1) year designation period.

3. At the end of the provisional designation period, the Department may grant full designation, extend the provisional period, or suspend the trauma center for cause.

D. A hospital may submit an Application for Request of a Waiver prior to the state site visit.

#### **205. Designation**

The designation processes delineated herein are the same regardless of designation level sought, including pediatric.

A. Prior to July 1, 2018, after receipt and acceptance of the application, the Department shall provide a Pre-Review Questionnaire (PRQ) to the hospital seeking designation which shall be completed and returned to the Department in accordance with Section 205.C. The information in the PRQ shall be reviewed by the Department and team prior to the site visit, and the information provided in the PRQ by the hospital shall be verified by the site review team. Any misrepresentation and/or false information provided by the hospital in the PRQ is grounds for denial of designation.

B. After July 1, 2018, any new hospital that wishes to become a trauma center, and any existing trauma center wishing to renew its designation, shall be required to provide to the Department an American College of Surgeons (ACS) verification notice. The hospital shall notify the Department prior to the associated ACS visit. A Department representative shall conduct a state verification simultaneously.

C. The PRQ shall be submitted no later than thirty (30) days prior to the scheduled site visit.

#### **206. Site Review**

A. The Department will work with the hospital requesting designation to establish a date for a designation site visit. All costs associated with the site visit and team expenses, excluding costs associated with Department personnel, are the responsibility of the applicant.

B. The onsite review for designation shall be conducted by the review team verifying the requirements for designation.

C. Any facility wishing to become a trauma center, or remain a trauma center after July 1, 2018, shall undergo the ACS verification process. Centers current as of July 1, 2018, shall obtain ACS verification prior to the expiration of their state designation. No extensions shall be granted for failure to schedule appropriately.

## **207. Review Team Composition**

A. The review team shall include, but not be limited to:

1. Two (2) general surgeons (at least one (1) pediatric surgeon for pediatric facilities), who do not live or work in the same state as the applicant and who currently work in a designated trauma center and who are a FACS or member of the ACS; and

2. A Department representative.

3. Prior to July 1, 2018, additional members may be assigned at the discretion of the Department or request of the facility. Any additional cost(s), with the exception of costs for Department representative(s), shall be the responsibility of the facility.

B. The composition of site visit teams, if required for follow up on facilities with provisional designation, shall be determined by the Department with consideration of recommendations made by the TAC.

C. There shall be no demonstrable conflict of interest between any inspection team member and the hospital for which the team member has been selected. The hospital applying for designation shall be provided with the reviewer's information. The hospital shall notify the Department in writing within three (3) business days of any conflict or if they wish to reject a reviewer. After 5:00 p.m. on the third (3rd) day, the team shall be secured and no objections may be submitted.

D. The cost of the team shall be the responsibility of the applying facility and includes meals, lodging, transportation, and honorarium.

E. Prior to July 1, 2018, hospitals applying for designation may, at its own discretion and its own expense, request a verification site inspection by representatives of the American College of Surgeons or any other national organization having standards that are, at a minimum, equal to the criteria set forth in this regulation. The composition of the site visit team, if other than the state, shall be subject to the discretion of the entity utilized. If a hospital wishes to use an outside agency and intends to submit their recommendation to the state for designation, a Department representative shall be present for the entire visit. The Department may accept the findings of the verification site visit or may request additional information as necessary to ensure that the hospital meets the criteria set forth in this regulation.

## **208. Protocol for Inspections**

The applicant's administration, faculty, medical staff, employees and representatives shall not have any contact with any onsite review team member in regards to the designation process after the announcement

of the team members and prior to the onsite review, except as authorized by the Department. A violation of this provision may be grounds for denying the applicant's proposal as determined by the Department. If a review team member contacts the facility representative directly for information, the facility may respond as requested and shall notify the Department.

### **209. Content of Inspection**

The onsite review team shall evaluate the appropriateness and capabilities of the applicant to provide trauma care services and validate the hospital's ability to meet the responsibilities, equipment, and performance standards for the level of designation sought and to meet the overall needs of the trauma system in that region. Any evidence of inadequate performance or trauma patient care shall be presented to the TAC and this alone is grounds for denial of designation or re-designation.

### **210. Designation Criteria**

A. The Department shall use the designation criteria of the 2014 ACS "Resources for Optimal Care of the Injured Patient" for each trauma center level. These provisions apply to all designation levels, including pediatric.

B. As part of the designation process and site review, the review team shall perform a comprehensive chart review. At least ten (10) charts shall be reviewed by the site review team. All site team members shall review charts.

C. The charts reviewed by the review team shall be in accordance with the latest ACS Review Agenda.

### **211. Designation Process**

A. Prior to completion of the site visit, the team shall meet and develop a draft report and provide feedback to the facility. The format shall be the same as the official written report.

B. On completion of the site visit, the team shall have ninety (90) days to submit a written report of their recommendation to the Department. The report shall include deficiencies listed by criteria number, opportunities (shall not be counted as deficiencies and shall not be used in consideration of designation status), strengths, and recommendations.

C. Within thirty (30) days of receipt of the written report from the site review team, the report shall be forwarded to the TAC, or appropriate subcommittee, to review for the purpose of providing the Department a recommendation. The final report shall also be forward to the facility at the same time. The report shall be sent to the hospital Trauma Program Manager, Trauma Medical Director, and Administrator as identified on the application.

D. As soon as practical, but no later than ninety (90) days after receipt of the onsite report document, the TAC, or subcommittee of the TAC, shall make written recommendations to the Department regarding trauma center designation based on:

1. Evaluation of the pre-review questionnaire;
2. Evaluation of deficiencies, including deficiencies in trauma patient care, and supporting statements from the onsite review team; and

3. The ability of each hospital to demonstrate compliance with the designation criteria at the level of designation they are seeking.

E. The Department shall make the final determination of designation regarding each application and shall consider all pertinent facts, the final survey report, and the recommendation of the TAC.

F. After July 1, 2018, a hospital requesting designation shall submit to the Department a letter of verification from the American College of Surgeons. Any hospital not obtaining ACS verification shall be denied South Carolina designation. Hospitals denied designation or whose designation was suspended or revoked shall wait a period of no less than six (6) months after the written decision prior to resubmitting an application. However, there is no waiting period if the hospital seeks a designation level lower than the denied, suspended, or revoked designation.

G. With the recommendation of the State Trauma Advisory Council, the Department shall notify the hospital of its decision regarding designation at the level requested by the hospital.

H. Prior to July 1, 2018, trauma centers requesting an ACS consultation or verification visit shall include a Department representative to participate in the site visit, as written in this regulation. The Department may utilize the visit and final report to designate the trauma center based on these regulations for state designation.

## **212. Process of Re-designation**

A. Scheduled re-designation inspections of currently designated trauma centers shall occur in an interval no greater than five (5) years. After July 1, 2018, the designation interval shall coincide with the ACS verification cycle and shall not exceed three (3) years.

B. Designated trauma centers shall be notified by the Department within six (6) months of the trauma center's scheduled date for the submission of the application for re-designation.

C. The hospital shall follow the application procedure outlined in Section 202.

D. All hospitals requesting re-designation shall follow the designation procedures outlined in Section 211.

E. If a change in the designated trauma center's staffing or resource capabilities occurs at any time during the trauma center's designation period, an inspection may be conducted by the Department as needed to ensure compliance with the regulatory requirements. If such inspection reveals that the trauma center may not be meeting regulatory requirements, the Department may require that the trauma center undergo a complete trauma center re-designation verification inspection prior to the next scheduled re-designation date.

## **213. Change in Trauma Center Designation Status**

A. A designated trauma center shall have the right to withdraw as a trauma center or to request a designation lower than its current designation level by giving a ninety (90) day written notice to the Department.

B. A designated trauma center shall: (II)

1. Notify the Department within ten (10) calendar days if it is unable to provide the level of care or services for its level of designation, the reasons, and plans to correct;

2. Notify the Department if it chooses to no longer provide trauma services commensurate with its designation level.

C. If the trauma center chooses to apply for a lower level of designation, they shall follow the procedures listed in the application and designation process in accordance with this regulation, and may have an onsite visit upon recommendation by the TAC.

#### **214. Public Notification of Trauma Center Designation Status**

A. At the time of designation, revocation of designation, or of any change in the status of a hospital's designation as a trauma center, the Department shall report such changes to the public by means of public record within thirty (30) days of the change of said hospital's trauma center designation status. The Department shall also notify licensed emergency medical service providers of the change of trauma center designation status.

B. The Department, Trauma Advisory Council, and the members of the onsite inspection team shall maintain confidentiality of information, records, and reports developed pursuant to onsite reviews as permitted by state and federal laws.

### **SECTION 300**

#### **CERTIFICATE OF DESIGNATION REQUIREMENTS**

##### **301. Certification Requirements (II)**

A. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or market itself or represent itself as a trauma center or use similar terminology, for example, "trauma hospital" or "trauma facility," in South Carolina without first obtaining a certificate of designation from the Department. When it has been determined by the Department that an entity claims, advertises, or represents itself as a trauma center and is not designated by the Department, the entity shall be ordered by the Department to cease operation immediately. False representation as a trauma center may result in monetary penalties as determined by the Department.

B. A certificate of designation shall not be issued to an entity until the owner and/or operator of that entity has demonstrated to the Department that the facility is in substantial compliance with these standards through the designation process.

C. No provider that has been issued a certificate for a trauma center at a specific address shall relocate or establish a new trauma center without first obtaining authorization from the Department.

D. No trauma center shall, in any manner, advertise or publicly assert that its trauma designation affects the hospital's care for non-trauma patients or that the designation would influence the referral of non-trauma system patients.

##### **302. Issuance and Terms of the Certificate of Designation (II)**

A. A certificate shall be issued by the Department and shall be displayed in a conspicuous place in a public area in the trauma center.

B. The issuance of a certificate does not guarantee adequacy of individual care, treatment, procedures, and/or services, personal safety, fire safety or the well-being of any patient.

C. A certificate is not assignable or transferable and is subject to revocation at any time by the Department for the provider's failure to comply with the laws and regulations of this State.

D. A certificate shall be effective for a specific trauma center, at a specific physical location, for a period of up to five (5) years following the date of issue. A certificate shall remain in effect until the Department notifies the certificate holder of a change in that status or until the expiration of such certificate. Certificates issued after July 1, 2018, shall expire on the date of expiration of the ACS verification.

### **Section 303. Exceptions to the Standards**

The Department has the authority to make exceptions to these standards when it is determined that the health, safety, and well-being of the patients will not be compromised and provided such standard is not specifically required by statute.

## **SECTION 400**

### **ENFORCEMENT OF REGULATIONS**

#### **401. General**

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a hospital trauma center in order to enforce this regulation. Such areas of review may include, but not be limited to, trauma patient records, hospital trauma registry data, trauma process improvement plans, educational records, committee minutes, and physical facilities.

#### **402. Inspections and Investigations**

A. An onsite inspection shall be conducted prior to designation of a hospital trauma center in accordance with Sections 207 and 208. Subsequent inspections may be conducted as deemed appropriate by the Department.

B. All facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by the Department.

C. Individuals authorized by the Department shall be granted unobstructed access to all properties and areas, objects, and records. If photocopies are made for the Department, they shall be used only for purposes of enforcement of regulations and/or ensuring compliance with designation criteria, and confidentiality shall be maintained as permitted by state and federal laws. The physical area of inspections shall be determined by the extent to which there is potential impact or effect upon patients as determined by the Department.

D. A facility found noncompliant with this regulation shall submit a written plan of correction to the Department, signed by the administrator and returned by the date specified on the report of inspection or investigation. The written plan of correction shall describe:

1. The actions to correct each cited deficiency;
2. The proposed actions to prevent similar recurrences; and

3. The actual or expected completion dates of those actions.

E. Information received by the Department through filed reports, inspections, or as otherwise authorized under this regulation shall not be disclosed publicly in such a manner as to identify hospitals or other participating providers except in proceedings involving the denial, change, or revocation of a trauma center designation or type.

F. The Department, members of the onsite inspection team, and the TAC shall maintain confidentiality of information, records, and reports developed pursuant to onsite reviews as permitted by state and federal laws.

### **403. Investigation Procedures**

A. Any person or entity may communicate a complaint or knowledge of an incident of any alleged violation of these regulations to the Department. Complaints shall be submitted in written form to the Department. The Department may begin an investigation without a written complaint if there is sufficient cause.

B. All designated trauma centers and EMS providers are subject to investigation at any time without prior notice by individuals authorized by the Department.

C. An authorized representative of the Department, upon presentation of valid identification, shall be permitted to examine equipment, vehicles, physical plant, and records. Any other requests shall be complied with so long as it is pertinent to the care of trauma patients and consistent with the requirements within the applicable regulations.

D. At the conclusion of the Department's investigation, the Department shall report its findings to the trauma center in writing, including any requirements for corrective action.

## **SECTION 500**

### **ENFORCEMENT ACTIONS**

#### **501. General**

A. When the Department determines that a designated trauma center is in violation of any statutory provision, rule, or regulation relating to the duties therein, the Department may, upon proper notice to that entity, impose a monetary penalty and/or deny, suspend, and/or revoke its certificate of designation. This includes failure to comply with designation criteria and/or failing to comply with previously approved corrective plans.

B. The Department may impose monetary penalties on any licensed emergency medical service provider found noncompliant with this or other related statute or regulations.

#### **502. Violation Classifications**

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of any persons or a substantial probability that death or serious physical harm could

result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of this time may be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health, safety or well-being of persons in the facility. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations. The citation of a Class III violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

D. In arriving at a decision to take enforcement action, the Department will consider the following factors:

1. The number and classification of violations, including repeat violations;
2. The specific conditions and their impact or potential impact on health, safety or well-being of the patients;
3. The efforts by the facility to correct cited violations;
4. The overall conditions of the facility;
5. The failure or refusal to comply with the provisions or requirements of this regulation;
6. The misrepresentation of a material fact about facility capabilities or other pertinent circumstances in any record or in a matter under investigation for any purposes connected with this chapter;
7. The prevention, interference with, or any attempts to impede the work of a representative of the Department in implementing or enforcing these regulations or the statute;
8. The use of false, fraudulent, or misleading advertising, or any public claims regarding the hospital's ability to care for non-trauma patients based on its trauma center designation status;
9. The misrepresentation of the facility's ability to care for trauma patients based on its designation status;
10. The failure to provide data to the Trauma Registry;
11. Any other pertinent conditions that may be applicable to statutes and regulations.

E. When a decision is made to impose monetary penalties, the Department may utilize the following schedule as a guide to determine the dollar amount:

**Frequency of violation of standard within a thirty-six (36) month period:**

**MONETARY PENALTY RANGES**

<b>FREQUENCY</b>	<b>CLASS I</b>	<b>CLASS II</b>	<b>CLASS III</b>
1st	\$500-1500	\$300-800	\$100-300
2nd	1000-3000	500-1500	300-800
3rd	2000-5000	1000-3000	500-1500
4th	5000	2000-5000	1000-3000
5th	7500	5000	2000-5000
6th and more	10000	7500	5000

**SECTION 600**

**STAFFING (I)**

A. Trauma centers shall have adequate staff, to include physicians, a Trauma Program Manager, Registrar, and other staff necessary to meet criteria for designation as outlined in the 2014 edition of “Resources for Optimal Care of the Injured Patient,” by the American College of Surgeons.

B. Detailed components of support services and medical, nursing, and ancillary staffing for each level shall, at a minimum, meet the criteria for the applicable designation as outlined in the 2014 edition of “Resources for Optimal Care of the Injured Patient,” by the American College of Surgeons.

**SECTION 700**

**FACILITY, EQUIPMENT, AND CARE REQUIREMENTS**

**701. Physical Facilities (II)**

Environment, equipment, supplies, and procedures utilized in the care of trauma patients shall meet the criteria outlined in the 2014 edition of “Resources for Optimal Care of the Injured Patient,” by the American College of Surgeons unless required otherwise by these regulations.

**702. Trauma Care of the Patient (Transfers) (II)**

Trauma patients arriving at non-designated trauma centers shall be transferred to the appropriate level of trauma center. Patients arriving at a designated trauma center and having care needs exceeding the capabilities of that center shall be transferred to a higher level of care. Each hospital providing trauma care

services shall establish and implement a written plan that outlines the process, providers, and methods of providing risk-appropriate stabilization and transfer of any patient requiring specialized services as well as reciprocal transfer of those patients when specialized services are no longer required. These plans shall be developed in collaboration with the receiving trauma centers and may include specific crew configuration for transport. The plan shall outline the following:

A. Communication between referring hospitals (must be physician to physician), transport teams, medical control, patients, and families;

B. Indications for both acute phase and reciprocal transfer between trauma centers, to include essential contact persons and telephone numbers for referrals and transfers; and

C. A list of all medical record copies and additional materials to accompany each patient in transport.

### **703. Trauma Care Services (I)**

A. Each trauma care facility shall provide adequate staffing and equipment to meet criteria established by the Department, guided by the recommendations outlined in the 2014 edition of “Resources for Optimal Care of the Injured Patient,” by the American College of Surgeons.

B. No person, regardless of his ability to pay or location of residence, may be denied trauma care if a member of the admitting hospital’s medical staff or, in the case of a transfer, a member of the accepting hospital’s staff determines that the person is in need of trauma care services.

C. If the care required for any patient is not available at the facility, arrangements shall be made for transfer to a more appropriate facility. Prior to the transfer of a patient to another facility, the receiving trauma center shall be notified of the impending transfer.

## **SECTION 800**

### **TRAUMA TRIAGE AND TRANSPORT GUIDELINES (I)**

#### **801. Purpose**

The Department, with the advice of the Trauma Advisory Council, shall establish Trauma Triage and Transport Guidelines to improve the quality of trauma care being provided to patients by ensuring that EMS providers transport patients to the appropriate level of trauma care. Such guidelines shall be established using the 2011 version of the Center for Disease Control’s “Guidelines for Field Triage of Injured Patients.”

#### **802. Required Participation**

All licensed Emergency Medical Services (EMS) providers shall, at a minimum, use the Department’s trauma triage and transport guidelines that shall be based on the guidelines established by the 2011 version of the Center for Disease Control’s “Guidelines for Field Triage of Injured Patients.” The EMS providers may edit the guidelines to identify the local trauma centers, but must use the Department-approved policy otherwise.

#### **803. Required Transport**

Emergency medical service personnel shall transport a trauma patient directly to a trauma center that is qualified to provide appropriate care, unless one (1) or more of the following exceptions apply:

A. It is medically necessary to transport the patient to another hospital for initial assessment and stabilization before transfer to a trauma center;

B. It is unsafe or medically inappropriate to transport the patient directly to a trauma center due to adverse weather or ground conditions;

C. Transporting the patient to a trauma center would cause a shortage of local emergency medical service resources (defined as no resources available for longer than thirty (30) minutes in a reasonable response area) and air transport is unavailable;

D. No appropriate trauma center is able to receive and provide trauma care to the trauma patient without undue delay; or

E. Before transport of a patient begins, the patient requests to be taken to a particular hospital that is not a trauma center or, if the patient is less than eighteen (18) years of age or is not able to communicate, such a request is made by an adult member of the patient's family or a legal representative of the patient.

#### **804. Triage Tag System**

All 911 EMS providers shall utilize a universal triage tag recommended by the Department. Such a tag shall have a barcode to scan for patient tracking and shall have the ability to show only one (1) color of triage category at any given time. The initial supply of these tags shall be provided by the Department and requests shall be granted on a first come first served basis. It shall be the responsibility of each agency to replenish their supply as necessary. Any other emergency response agencies, such as law enforcement, fire, and private EMS, may also request issuance of such tags to participate in the system and ensure consistency.

### **SECTION 900**

#### **PATIENT RIGHTS (III)**

##### **901. General**

The facility shall comply with all relevant federal, state, and local laws and regulations concerning discrimination, for example, Title VII, Section 601 of the Civil Rights Act of 1964.

##### **902. Grievances and Complaints**

A. The facility shall establish a written grievance and complaint procedure and make this procedure available to patients upon request.

B. Upon receipt of a complaint by the Department, the Department shall:

1. Notify the hospital of the complaint;
2. Initiate a review of the complaint which may consist of an onsite review by the Department;
3. Develop a written report of the review; and
4. Notify the hospital of the results and provide a copy of the final report.

**SECTION 1000**

**STATEWIDE TRAUMA REGISTRY (II)**

**1001. Purpose of Trauma Registry**

A. The Department shall establish a trauma data collection and evaluation system, known as the “Trauma Registry.” The Trauma Registry shall be designed to include, but not be limited to, trauma studies, patient care and outcomes, compliance with standards of verification, and types and severity of injuries in the state. The data elements collected in the state registry shall be determined by the Department with collaboration from the TAC and defined in the data dictionary.

B. The Department may collect, as considered necessary and appropriate, data and information regarding trauma patients admitted to a facility through the emergency service, through a trauma center, or directly to a special care unit. Data and information shall be collected in a manner that protects and maintains the confidential nature of patient and staff identifying information.

C. Any South Carolina hospital may participate in submitting to the Trauma Registry.

D. The Department shall establish and maintain a current data dictionary and provide it to all trauma centers to define required data points.

**1002. Requirement to Submit Data**

A. Each designated trauma center shall participate in the System Trauma Registry by:

1. Identifying a person to be responsible for coordination of trauma registry activities;
2. Participating in and submitting data to the National Trauma Data Bank (NTDB); and

3. Downloading required trauma data as stipulated by the Department in the state data dictionary. Each trauma center designated by the Department shall provide data to the Department at least quarterly as listed below. The trauma center shall provide the data to the Department no later than ninety (90) days following the end of each quarter. The trauma center shall establish measures to ensure that the data entered in the trauma registry is accurate and complete.

Admission Period	Due Date
January - March	July 1
April - June	October 1
July - September	January 1
October - December	April 1

B. Only patient care records that are included in the hospital’s trauma registry may be requested for review by site inspection teams at the time of initial designation and re-designation or by the Department for focused reviews during any time of the hospital’s designation period.

**1003. Inclusion and Exclusion Criteria**

Patient inclusion and exclusion criteria shall be established by the Department under the guidance of the Trauma Advisory Council and maintained in the state data dictionary. Such data shall include, at a minimum, the information and data points required by the National Trauma Data Bank.

#### **1004. Confidentiality Protection of Data and Reports**

Information that identifies individual patients shall not be disclosed publicly without the patient's consent. Reports that do not contain protected health information or any identifiable information may be generated and distributed. Such reports shall show only general information and shall not identify any protected information or hospital information.

### **SECTION 1100**

#### **HOSPITAL RESOURCES DATA BASE (II)**

##### **1101. Purpose**

A. The Hospital Resources Data Base shall be used to monitor hospital resources on a continuous basis, disseminate information throughout South Carolina's healthcare system, and inform users of the clinical services offered, laboratory capabilities, and bed capacity.

B. The Department shall manage the Hospital Resources Data Base for South Carolina participants.

##### **1102. Required Participation**

All trauma centers designated by the Department shall utilize the Hospital Resources Data Base. Information shall be updated on a daily basis, which shall include, but not be limited to: hospital bed availability, specialty service capability, and disaster resources.

### **SECTION 1200**

#### **TRAUMA CARE FUND**

##### **1201. Eligible Recipients of Fund**

Trauma centers, rehabilitation centers, physicians, Emergency Medical Services providers licensed by the Department, Regional EMS Councils, Regional Trauma Councils, and the Division of EMS and Trauma are eligible to receive trauma care funds appropriated by the South Carolina General Assembly.

##### **1202. Allocation of Fund**

The Department may authorize and allocate the distribution of funds as directed by the General Assembly in the Appropriations Act to trauma centers, rehabilitation centers, physicians, Emergency Medical Services providers licensed by the Department, air ambulance providers licensed by the Department that always use a certified paramedic on all flights and maintain a licensed South Carolina medical director on staff, Regional Trauma Councils, and Regional EMS Councils. The Department, with the advice of the Trauma Advisory Council and its subcommittees and/or workgroups, shall determine the priority of distributions after Department operating expenses, as well as a distribution formula.

## **SECTION 1300**

### **PERFORMANCE IMPROVEMENT PROGRAMS**

#### **1301. General**

Performance improvement (PI) programs shall be developed, maintained, and executed.

#### **1302. Statewide Trauma System Performance Improvement Plan**

The Department shall develop and maintain a Statewide Trauma System PI Plan with input from the state Trauma Advisory Council and its subcommittees or workgroups. This plan shall, at a minimum, report:

A. Summary statistics and trends for demographic and related information about trauma care for the state Trauma Advisory Council; and

B. Outcome measures for evaluation of clinical care and system-wide quality assurance and performance improvement programs.

#### **1303. Trauma Center Performance Improvement Plan (II)**

Each trauma center shall have in place an ongoing performance improvement process consistent with the designation requirements. Performance improvement records must be available for inspection by the Department upon request. Records shall include the process for identification and review, documentation or disposition of issues found, and summaries of changes implemented to include, but not be limited to, patient care practice, policies, and/or operating procedures.

#### **1304. Performance Improvement and Feedback**

Each trauma center shall develop functional relationships with all potential referring facilities and is required to provide feedback. Any process issues shall be identified and a written cooperative plan shall be established when needed. Sufficient documentation of other lesser process issues shall be maintained and available for review upon request.

## **SECTION 1400**

### **ADVISORY COMMITTEES**

#### **1401. State Trauma Advisory Council**

A. The State Trauma Advisory Council shall act as an advisory body for trauma care system development and provide technical support to the Department in areas of trauma care system design, trauma standards, data collection and evaluation, performance improvement, trauma system funding, and evaluation of the trauma care system and trauma care programs.

B. The State Trauma Advisory Council (TAC), the State EMS Advisory Council, and the Department shall adopt similar guidelines for its operations. These guidelines shall include attendance, maintenance of minutes, and other guidelines necessary to ensure the orderly conduct of business. The TAC shall have other functions as follows:

1. Review and comment on the Department's regulations, policies, and standards for trauma;

2. Advise the Department regarding trauma system needs and progress throughout the state;
3. Review state and local pre-hospital trauma triage guidelines; and
4. Advise the Department on injury prevention and public information and/or educational programs.

#### **1402. Medical Control Committee**

A. The Medical Control Committee is a subcommittee of the Trauma Advisory Council and the EMS Advisory Council composed of medical control physicians from each of the state's four (4) EMS regions, physician members of the EMS and Trauma Advisory Councils, and the State Medical Control Physician.

B. The Medical Control Committee is an advisory board responsible for the establishment of approved pre-hospital equipment and skills, the State EMS Formulary and other issues pertaining to EMS and trauma care.

### **SECTION 1500**

#### **TRAUMA SYSTEM PLANS**

##### **1501. General**

A. The Department shall establish and maintain a state trauma system plan with input from the TAC and its working groups.

B. The Department shall use the state trauma system plan as the basis for establishing a statewide inclusive trauma system.

C. In developing the state trauma system plan, the Department shall consider any available federal model trauma plans.

D. The Department shall provide technical assistance and support to the TAC, the Medical Control Committee, hospitals or other healthcare facilities, and EMS providers as necessary to carry out the State Trauma Plan.

##### **1502. Trauma Center Internal Disaster Plan (II)**

Each designated trauma center shall develop an internal disaster plan that is based on data supplied by the trauma registry and other sources and shall provide for the ongoing assessment and improvement of performances of the trauma center. Such plan shall be made available to the site survey team at the time of their visit.

### **SECTION 1600**

#### **SEVERABILITY**

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect, as if such invalid portions were not originally a part of these regulations.

## **SECTION 1700**

### **GENERAL**

Conditions which have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.