

## R. 61-116. SOUTH CAROLINA TRAUMA CARE SYSTEMS

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## SECTION 100. SCOPE

This regulation establishes standards for implementing provisions of Sections 44-61-510 through 44-61-550 of the South Carolina Code of Laws, 1976, as amended, regarding trauma care systems in South Carolina.

## SECTION 200. DEFINITIONS AND REFERENCES.

### 201. Definitions.

1. ACS: American College of Surgeons.
2. Bypass (diversion): 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.
3. Certificate: A printed document issued by the Department to a hospital that authorizes trauma services at designated levels, i.e., I, II, III, as determined by the Department subject to the provisions of this regulation.
4. Certificate Holder: The individual, corporation, organization, or public entity that has received a certificate to provide trauma care and with whom rests the ultimate responsibility for compliance with this regulation.
5. CRNA: Certified Registered Nurse Anesthetist.
6. Department: The South Carolina Department of Health and Environmental Control (DHEC).
7. Designation: The formal determination by the Department that a hospital or health care facility is capable of providing a specified level of trauma care services.
8. Diversion (see “bypass”).

9. Emergency Department: The area of a licensed general acute care hospital that customarily receives patients in need of emergency medical evaluation and/or care.
10. EMS: Emergency Medical Services – the arrangement of personnel, facilities, and equipment for the effective and coordinated delivery of emergency care required to prevent and manage incidents that occur from a medical emergency or from an accident, natural disaster, or similar situation.
11. Emergency Medical Services Advisory Council: Emergency Medical Services council created pursuant to S.C. Code of Law Section 44-61-30(c) (2002 and Supp. 2006).
12. Facility: A trauma center having a certificate of designation by the Department.
13. Field Triage: Classification of patients according to medical need at the scene of an injury or onset of an illness.
14. 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.
15. Injury Prevention: Efforts to forestall or prevent incidents that might result in injuries.
16. Level I: Hospitals that have met the requirements for Level I as stated in Section 303 of this regulation and are designated by the Department.
17. Level II: Hospitals that have met the requirements for level II as stated in Section 303 of this regulation and are designated by the Department.
18. Level III: Hospitals that have met the requirements for level III as stated in Section 303 of this regulation and are designated by the Department.
19. Licensed Nurse: An individual licensed by the South Carolina Board of Nursing as a registered nurse or licensed practical nurse.
20. 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 management.
21. 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.
22. Performance Improvement: A method of evaluating and improving processes of patient care that emphasizes a multidisciplinary approach to problem solving and focuses not on individuals, but systems of patient care that might cause variations in patient outcome.
23. Performance Improvement Program: The process used by a facility to examine its methods and practices of providing trauma care and services, identify the ways to improve its performance, and take actions that result in higher quality performance of trauma care and services for the facility's patients.
24. Physician: An individual currently licensed as such by the South Carolina Board of Medical Examiners.

25. 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.
26. Repeat Violation: The recurrence of any violation cited under the same section of the regulation.
27. Residency Program: A medical education and training program of the Trauma Center. Residency programs may be affiliated with the Trauma Center where residents can participate in educational rotations.
28. Revocation of Certificate: An action by the Department to cancel or annul a certificate by recalling, withdrawing, or rescinding its authority to operate.
29. South Carolina Trauma Plan: An organized plan developed by the Department pursuant to legislative directive that sets out a comprehensive system of prevention and management of major traumatic injuries.
30. State Medical Director (or “State Medical Control Physician”): A South Carolina board-certified physician responsible for providing medical oversight to the Department.
31. State Trauma Advisory Council (or “TAC”): The Department’s advisory committee regarding trauma related issues.
32. 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 for certain types of injuries.
33. Suspension of Certificate: 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.
34. TAC: (see “State Trauma Advisory Council”).
35. Trauma: Major injury or wound to a living person caused by the application of an external force or by violence and requiring immediate medical or surgical intervention to prevent death or permanent disability. For the purposes of this regulation, the definition of “trauma” shall be determined by current national medical standards including, but not limited to, trauma severity scales.
36. Trauma Care Facility (or “trauma center”): Trauma care facility or trauma center hospital that has been designated by the Department to provide trauma care services at a particular level.
37. Trauma Care Region: A geographic area of the state formally organized in accordance with standards promulgated by the Department.
38. 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.
39. Trauma Center: (see “Trauma Care Facility”).

40. Trauma Center Designation: The process by which the Department identifies facilities within a Trauma Care Region.
41. Trauma Patient: An injured patient (see “Trauma”).
42. 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.
43. Trauma Program Manager: A designated individual with responsibility for coordination of all activities of the trauma service who works in collaboration with the trauma service director.
44. Trauma Service Director: A physician designated by the facility and medical staff to coordinate trauma care.
45. Trauma System Fund: The separate fund established pursuant to this regulation for the Department to create and administer the State Trauma System.
46. Trauma Team: A group of health care professionals organized to provide coordinated and timely care to the trauma patient.
47. 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.
48. Verification: The Department's inspection of a participating facility in order to determine whether the facility is capable of providing a designated level of trauma care.

## 202. References.

The following Non-Departmental standards, publications, or organizations are referenced in this regulation: “Resources for Optimal Care of the Injured Patient,” by the American College of Surgeons Committee on Trauma.

## SECTION 300. DESIGNATION PROCESS.

### 301. General.

The Department shall designate the level of trauma care a hospital is able to provide by the issuance of a certificate that shall be posted in a conspicuous location for public view in the hospital.

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

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

B. Requests for trauma center designation shall be accomplished by letter of intent to the Department and by submission of an application.

C. Within one year of the effective date of this regulation, a trauma center designated prior to the effective date of this regulation, which chooses to remain a designated trauma center, shall comply

with the provisions of this regulation as well as submit an application and obtain approval by the Department to maintain its status as a designated trauma center.

### 303. Levels of Trauma Centers.

The Department shall identify trauma centers by levels of care capability as defined in these regulations. The designations shall be Level I, Level II, and Level III with Level I being the highest level of capability available. Determination of designation level shall be made by the Department based upon a hospital's ability to meet regulatory requirements. Designation of level shall be determined by a special inspection by the Department following the initial request for designation and as an integral part of subsequent renewal procedures. Designation criteria for trauma centers shall be established by the Department, guided by the recommendations outlined in the current edition of "Resources for Optimal Care of the Injured Patient," by the American College of Surgeons.

### 304. Categories of Designation.

A. Provisional. The Department may initially designate a trauma center as "provisional" for a term not to exceed one year except as granted by the Department. Provisional trauma centers shall have a written work plan of objectives to rectify deficiencies and to demonstrate progress on the work plan throughout the twelve (12) month time period. The Trauma Advisory Council shall provide oversight during the provisional period. At the end of the provisional period the department shall grant full designation, extend the provisional period, or suspend the trauma center for cause.

B. Full Designation. The Department may grant full designation to any hospital in full compliance with these regulations, subject to the review process described, for a period not to exceed five (5) years.

### Section 305. Application Process. (II)

A. Applicants shall submit to the Department a letter of intent for initial designation as a hospital trauma center.

B. In addition to the letter of intent, applicants for designation shall submit to the Department a completed application on a form developed and furnished by the Department prior to initial designation and periodically thereafter at intervals determined by the Department. The application shall include the applicant's oath assuring that the contents of the application 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 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.

C. The application shall set forth the full name and address of the facility for which the designation is sought and 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.

D. The Department may require additional information, including affirmative evidence of 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 application information may include, but is not limited to:

1. System criteria for the level at which the hospital is applying together with the current status of each criteria standard and category of designation sought;

2. Written affirmation of compliance with all applicable federal Occupational Safety and Health Association (OSHA) requirements or guidelines.

E. The application shall become the property of the Department and shall be considered public information at the end of the designation process, subject to state and federal laws.

### 306. Designation.

A. As soon as practical, but no later than ninety (90) days after receipt of the on-site report inspection document, the State Trauma Advisory Council, or a subcommittee thereof, shall make written recommendations to the Department regarding trauma center designation based on:

1. The Department's evaluation of pre-review documentation submitted as part of the application;

2. The evaluation and recommendations from the Department's on-site review team;

3. The ability of each applicant to comply with goals of the State Trauma Plan.

B. If, after completion of the on-site review and after consideration of the application by the Trauma Advisory Council, the facility does not meet requirements for designation at the level requested, the hospital may submit a written request to be designated at a lower level based on the Department's findings of its original site visit and the facility's application.

C. 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.

### 307. 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.

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. If a significant 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 assure 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.

D. If the Department determines that a complete on-site inspection shall be conducted, the Department shall give the trauma center a minimum of thirty (30) days to prepare. If, prior to the trauma

center's scheduled re-designation inspection date, a focused inspection or unscheduled inspection by the Department has been conducted, this review will not change the scheduled re-designation inspection date.

#### 308. Appeals from Decision for Designation or Non-Designation.

Any Department decision involving the issuance, denial, renewal, suspension, or revocation of a certificate of designation may be appealed pursuant to applicable law, including S.C. Code Ann. Sections 44-1-50 and 44-1-60 (1976, as amended).

#### 309. 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 comply with any of the standards for its level of designation and its reasons for non-compliance;

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, the Department, at its discretion, may repeat all or part of the designation process in accordance with this regulation.

#### 310. Public Notification of Trauma Center Designation Status.

A. At the time of designation, or 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 and the members of the on-site inspection team shall maintain confidentiality of information, records, and reports developed pursuant to on-site reviews as permitted by state and federal laws.

### SECTION 400. CERTIFICATE OF DESIGNATION REQUIREMENTS.

#### 401. 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, e.g., "trauma hospital", "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.

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.

C. A copy of the trauma center criteria standards and regulations shall be maintained by the provider to whom the certificate is issued and accessible to all staff members.

D. 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.

E. 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.

#### 402. 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 trauma center shall maintain a business address and telephone number at which the trauma center may be reached during business hours.

C. 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.

D. 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.

E. A certificate shall be effective for a specific trauma center, at a specific location(s), for a period of 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.

#### Section 403. 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 the standard is not specifically required by statute.

### SECTION 500. ENFORCING REGULATIONS.

#### 501. General.

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

#### 502. Inspections and Investigations.

A. An on-site inspection shall be conducted prior to initial designation of a hospital trauma center. 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 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 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 taken to correct each cited deficiency;
2. The actions taken to prevent recurrences;
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 and the members of the on-site inspection team shall maintain confidentiality of information, records, and reports developed pursuant to on-site reviews as permitted by state and federal laws.

G. The Department reserves the right to make exceptions to these regulations where it is determined that the health and welfare of those being served would be compromised.

#### 503. Inspection Report for Designation.

A. The inspection team shall provide the Department with the written inspection report of the on-site inspection.

B. Within thirty (30) days of receipt of the information from the site inspection team, the Department shall forward written findings and recommendations to the State Trauma Advisory Council.

C. The Trauma Advisory Council, or a subcommittee thereof, shall review the reports of the on-site inspection team and render a recommendation to the Department.

D. The Department shall make the final determination of designation regarding each application upon consideration of all pertinent facts, including the recommendation of the Trauma Advisory Council.

#### 504. Inspection Team Composition.

A. There shall be a multi-disciplinary on-site inspection team composed of individuals knowledgeable in trauma care and systems, appropriate to the level of designation requested.

B. For the initial inspection, the team shall include, but not be limited to:

1. A trauma surgeon;
2. An emergency physician;
3. A trauma nurse coordinator.

C. The composition of inspection teams subsequent to the initial inspection shall be determined by the Department. Such teams shall consist of professionals who:

1. Do not live or work in the same state as the applicant for the designation of Levels I and II trauma centers;
2. Have been employed in a state-designated or American College of Surgeons-verified trauma center within the past three calendar years;
3. Must have attended a Department-sponsored or approved site inspector training workshop if reviewing applicants for Level III designation; and
4. Do not live or work in the same region as the applicant for the designation of Level III trauma centers.

D. There shall be no conflict of interest between any inspection team member and the hospital for which the team member has been selected.

E. A hospital applying for a designation may, at its discretion, request a verification site inspection by representatives of the American College of Surgeons or any other national organization where its standards are, at a minimum, equal to the criteria set forth in this regulation. 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.

#### 505. Protocol for Inspections.

The applicant's administration, faculty, medical staff, employees and representatives are prohibited from having any contact with any on-site review team member in regards to the designation process after the announcement of the team members and before the on-site review, except as authorized by the Department. A violation of this provision may be grounds for denying that applicant's proposal as determined by the Department.

#### 506. Content of Inspection.

The on-site 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.

#### 507. 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 signed written form to the Department. The Department may begin an investigation without a signed written complaint if there is sufficient cause.

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

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

## SECTION 600. ENFORCEMENT ACTIONS.

### 601. Enforcement Actions.

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.

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

### 602. 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 occur. 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 established by the Department may be considered a subsequent violation.

B. Class II violations are those 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 may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time established by the Department may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in this regulation. 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 established by the Department 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 of the facility to comply with the provisions of Regulation 61-16;
  6. The failure or refusal to comply with the provisions or requirements of this regulation;
  7. 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;
  8. 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;
  9. 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;
  10. The misrepresentation of the facility's ability to care for trauma patients based on its designation status;
  11. The failure to provide data to the Trauma Registry;
  12. Any other pertinent conditions that may be applicable to statutes and regulations.
- E. Pursuant to S.C. Code Ann. Sections 44-61-520 (E) & (F) (1976, as amended) the Department may impose monetary penalties.

#### MONETARY PENALTY RANGES

FREQUENCY	CLASS I	CLASS II	CLASS III
1 <sup>st</sup>	\$500 - \$1,500	\$300 - \$800	\$100 - \$300
2 <sup>nd</sup>	\$1,000 - \$3,000	\$500 - \$1,500	\$300 - \$800
3 <sup>rd</sup>	\$2,000 - \$5,000	\$1,000 - \$3,000	\$500 - \$1,500
4 <sup>th</sup>	\$5,000	\$2,000 - \$5,000	\$1,000 - \$3,000
5 <sup>th</sup>	\$7,500	\$5,000	\$2,000 - \$5,000
6 <sup>th</sup> and more	\$10,000	\$7,500	\$5,000

F. Any Department decision involving the issuance, denial, renewal, suspension, or revocation of a certificate and/or the imposition of monetary penalties where an enforcement order has

been issued may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23.

#### SECTION 700. STAFFING. (I)

A. Trauma centers shall have adequate staff, to include physicians, to meet criteria established by the Department, guided by the recommendations outlined in the current 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 meet the criteria established by the Department which shall be guided by the recommendations outlined in the current edition of "Resources for Optimal Care of the Injured Patient," by the American College of Surgeons.

#### SECTION 800. GENERAL FACILITY, EQUIPMENT AND CARE REQUIREMENTS.

##### 801. Physical Facilities. (II)

Environment, equipment, supplies, and procedures utilized in the care of trauma patients shall meet the criteria established by the Department which shall be guided by the recommendations outlined in the current edition of "Resources for Optimal Care of the Injured Patient," by the American College of Surgeons.

##### 802. Trauma Care of the Patient (Transfers). (II)

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. This plan shall be updated on an annual basis and shall include, but not be limited to, procedures outlining:

A. Communication between referring hospitals, 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;

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

##### 803. 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 current 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 900. PATIENT RIGHTS. (III)

##### 901. General.

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

##### 902. Grievances and Complaints.

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

#### 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.

B. The Department may collect, as considered necessary and appropriate, data and information regarding trauma patients admitted to a facility through the emergency department, 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.

##### 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. Downloading required trauma data as stipulated by the Department.

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.

C. Each trauma center designated by the Department shall provide data to the Department at least quarterly (March, June, September, December). The data shall be received by 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.

##### 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 its subcommittees.

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

Records and reports created with the use of the trauma data collection and evaluation system shall be held confidential and privileged within the Department and shall not be available to the public, admissible as evidence, or subject to discovery by subpoena. Information that identifies individual patients shall not be disclosed publicly without the patient's consent.

#### 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, 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, and Regional EMS Councils. The Department, with the advice of the Trauma Advisory Council and its subcommittees shall determine the priority of distributions, as well as a distribution formula based on the following criteria:

A. Funds shall be distributed equally among the Emergency Medical Services providers in counties with the highest fatality rates per capita due to motor vehicle collisions.

1. The Department shall utilize statistics provided by the South Carolina Department of Public Safety and the National Highway Traffic Safety Administration to determine eligibility.

2. The number of providers receiving funds shall be determined based on the total appropriation for each year.

B. Funds shall be distributed equally to the Regional EMS Councils and shall be based on the total appropriation for each year.

C. The criteria for the distribution of hospital, physician, air ambulance provider, and rehabilitation facility funds shall be established by the Department with the advice of the Trauma Advisory Council and its subcommittees. Hospital and physician disbursements shall be based on unfunded patient days. Only hospitals that have received trauma center designation by the Department are eligible for available trauma funds.

#### 1301. General.

Performance improvement (PI) programs shall be developed at the state and trauma center levels.

#### 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. 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;

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 on-going performance improvement process consistent with the designation requirements. Performance improvement records must be available for inspection by the department 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 assure the orderly conduct of business. The TAC shall have other functions as follows:

1. Periodically 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. Periodically review state and local pre-hospital trauma triage guidelines;

4. Advise the Department on injury prevention and public information/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 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 TRIAGE AND TRANSPORT GUIDELINES. (I)

1501. 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.

1502. Required Participation.

All licensed Emergency Medical Services providers shall provide the Department and all trauma centers utilized by the EMS provider with a copy of their system's trauma triage and transport policy that shall be based on the guidelines established by the Department.

SECTION 1600. TRAUMA SYSTEM PLANS.

1601. General.

A. The Department shall establish a state trauma system plan.

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 develop and update the State Trauma System Plan periodically with advice from the Trauma Advisory Council.

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

1602. Trauma Regions.

A. As part of the state trauma system plan, the Department shall establish geographical trauma regions.

B. Regions shall cover all geographical areas of the state and have boundaries that are coterminous with the boundaries of the emergency medical service regional areas. These regions may serve as the basis for the development of Department-approved regional trauma plans. However, the delivery of trauma services by or in coordination with a trauma agency may extend beyond the geographic boundaries of the EMS or Trauma Regions.

#### 1603. Trauma Center Internal Trauma Plan. (II)

Each designated trauma center shall develop an internal trauma 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.

#### SECTION 1700. 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.