DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
Emergency Medical Services

4305 Trauma System

1.0 Purpose

The purpose of this regulation is to establish and define the conditions under which the Delaware Statewide Trauma System functions. The goal of this Trauma System is to assure that every person injured in Delaware receives the same high quality care, thus decreasing morbidity and mortality from injury.

27 DE Reg. 529 (01/01/24)

2.0 Authority

This regulation is promulgated pursuant to the authority of Title 16 **Del.C.** Ch. 97. Emergency Medical Services Systems.

27 DE Reg. 529 (01/01/24)

3.0 Definitions

The following words and terms, when used in this regulation, should have the following meaning:

"**ACS**" means the American College of Surgeons.

"Attending" means a physician with practice privileges delineated by the facility's medical staff.

"Board certified" means a physician certified by an appropriate specialty board recognized by the American Board of Medical Specialties or the American Osteopathic Association.

"Bypass" means a request by a facility to an Emergency Medical Service that patients be directed to another facility's Emergency Department due to a shortage or unavailability of beds, equipment, personnel, or other essential resource.

"Classification of injuries" include the following:

"Minor injuries" means those patients with an Injury Severity Score less than 9.

"Moderate injuries" means those patients with an Injury Severity Score between 9 and 15.

"Major (severe) injuries" means those patients with an Injury Severity Score greater than 15.

"**Community trauma center**" or "**Level III**" means an acute care facility that provides assessment, resuscitation, stabilization, and triage of all trauma patients, arranging for timely transfer of those patients requiring the additional resources of a regional trauma or specialty center and delivering definitive care to those whose needs match the resources of the community trauma center.

"Continuing Medical Education credit" or "**CME credit**" means educational hours for physicians approved by the Accreditation Council of Continuing Medical Education or an agency recognized by this council.

"Credentialing process" means a facility's procedure for granting practice privileges to healthcare providers.

"**Definitive care**" means a level of medical intervention capable of providing comprehensive services for a patient's injuries and associated conditions.

"**Demonstrated commitment**" means provision of evidence (visible and written) that demonstrates clearly an institution-wide commitment to trauma care.

"**Designation"** means a process through which a facility is confirmed by the Division to have the appropriate resources to manage patients with injuries of particular degrees of severity, and is granted the authorization to function as a Delaware trauma center.

"**Division**" means the Delaware Division of Public Health.

"**Division Director**" means the Director of the Delaware Division of Public Health.

"**Emergency Medical Services**" or "**EMS**" means the arrangement of personnel, facilities, equipment, transportation, and communication to provide for the effective and coordinated delivery of medical care in emergency situations resulting from accidents, illnesses, or natural disasters.

“**Facility Trauma Quality Management Program”** means the review program within each trauma center which monitors such aspects of the trauma program as adherence to policies and patient outcome with the goal of assuring that optimal care is continuously provided.

“In-house” means physically present in the facility.

“Injury control" means methodologies designed for the purpose of preventing and eliminating injuries.

“Injury Severity Score” means a retrospective summary score derived by applying a prescribed scoring system and mathematical formula to a listing of a trauma patient's injuries. Use of this scoring system allows objective comparisons of trauma patients based on their injuries.

“Interfacility transfer" means the transfer of a patient from 1 facility to another facility.

"**Level III**" see definition for "community trauma center".

"**Level IV**" see definition for "participating facility".

“Participating facility" or "**Level IV"** means an acute care facility which transfers trauma patients with moderate or severe injuries to trauma centers after initial resuscitation. When necessary, this facility may provide care to trauma patients with minor injuries. Participating facilities contribute data to the Delaware Trauma System Registry and Quality Improvement Program.

“Pediatric trauma centers" means children's facilities which meet the standards for a particular classification of trauma center within Delaware's *Pediatric Trauma Standards* and the corresponding classification in Delaware's *Adult Trauma Standards.*

"**Performance improvement**" or "**PI**" means a process of measuring the outcome of a particular component, process, procedure, or treatment within the trauma care continuum, then modifying the process or procedure to improve patient care. PI is often interchanged with the term "quality improvement" or "QI".

"**Performance Improvement and Patient Safety**" or "**PIPS**" means processes for identifying adverse events and implementing subsequent corrective action plans.

“Prevention” means efforts to decrease the numbers and severity of traumatic injuries.

“Protocols” means written standards for clinical practice in a variety of situations within the Trauma System.

"**Quality improvement**" or "**QI**" see definition for "performance improvement".

“Regional Level I Trauma Center” means a regional resource trauma center that has the capability of providing leadership and comprehensive, definitive care for every aspect of injury from prevention through rehabilitation.

“Regional Level II Trauma Center” means a regional trauma center with the capability to provide initial care for all trauma patients. Most patients would continue to be cared for in this center; there may be some complex cases requiring transfer for the depth of services of a Regional Level I or specialty center.

“Response time" means the time interval between notification and arrival of the general surgeon or surgical specialist at the patient's bedside.

"**Specialty center**" means a facility and staff that meet minimum standards established under the program and are designated by the board for program use in the comprehensive diagnostic and treatment services for a specific medical condition. This may include pediatric centers, burn centers, and others.

“Transfer agreement" means a formal written agreement between hospitals which provides for the acceptance of patients in transfer.

“Trauma” means any bodily injury. Injury is the result of an act that damages, harms, or hurts; unintentional or intentional damage to the body resulting from acute exposure to mechanical, thermal, electrical, or chemical energy or from the absence of such essentials as heat or oxygen.

“Trauma center" means a specialized facility distinguished by the immediate availability of specialized surgeons, physician specialists, anesthesiologists, nurses, and resuscitation and life support equipment on a 24-hour basis to care for severely injured patients or those at risk for severe injury.

“**Trauma facility**" means an acute care facility which has received and maintains current State designation as a trauma center.

"**Trauma Medical Director**" or "**TMD**" means the physician responsible for and has the authority to develop and enforce policies and procedures relevant to the care of the injured patient and to oversee the structure and process of the trauma PIPS program. Each trauma center is required by the ACS to have a TMD.

"**Trauma Program Manager**" or "**TPM**" means the individual with the daily responsibility for process and performance improvement activities as they relate to nursing and ancillary personnel involved in the care of

trauma patients. The TPM's role includes partnering with the TMD in the development of policies and oversight of the program. Each trauma center is required by ACS to have a TPM.

"Trauma registry" means a database to provide information for analysis and evaluation of the quality of patient care, including epidemiological and demographic characteristics of trauma patients. The 'Expanded' data set provides a basis for the facility's Trauma Quality Program; the 'Minimal' data set collects largely demographic information.

"**Trauma System Medical Advisor**" means an advisor on both specific and general trauma clinical and patient care issues which are brought to the Trauma System Committee or its subcommittees.

"Trauma System Quality Management Program" means the program which reviews aspects of the Trauma System such as interfacility transfers and triage decisions with the goal of assuring that the various components of the Trauma System are functioning optimally.

"Triage" means the sorting of patients in terms of priority need for care, so that appropriate treatment, transportation, and destination decisions can be made according to predetermined protocols.

"Verification" means a process in which the trauma care capability and performance of a facility are evaluated by experienced on-site reviewers.

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4.0 Trauma System Committee ("TSC")

4.1 Membership. The minimum membership requirements of the Trauma System Committee membership are defined by 16 **Del.C.** §9704(f).

4.2 Purpose. The TSC shall act as an advisory group to the Division Director pursuant to 16 **Del.C.** §9704(g) and shall:

4.2.1 Maintain a system-wide perspective and communicate with other committees to encourage open dialogue and problem-solving system-wide;

4.2.2 Model a collaborative approach between Committee members and Division of Public Health/Office of Emergency Medical Services (OEMS) personnel; and

4.2.3 Provide coordination, oversight, and guidance for all components of the Trauma System in Delaware and with the support of the Trauma System of Care Coordinator, and shall be responsible for the development and maintenance of the Trauma System Plan.

4.3 Committee Leadership. The Division Director shall appoint Committee and, as necessary, Subcommittee chairpersons for 4-year terms. Chairpersons may be appointed to subsequent terms and shall:

4.3.1 Collaborate with the Office of EMS or OEMS contractors to develop meeting agendas, presentations, and minutes; and

4.3.2 Preside at respective committee meetings and perform related administrative duties according to Roberts' Rules of Order.

4.4 Trauma System of Care Medical Advisor

4.4.1 The Trauma System of Care Medical Advisor shall serve as a non-voting member of the TSC and must have the following qualifications:

4.4.1.1 Have a minimum of 1 year of active involvement in state Trauma System development or management;

4.4.1.2 Be a Board certified trauma or trauma subspecialty surgeon or Emergency Medicine physician; and

4.4.1.3 Have experience in medical leadership in a role such as physician chairperson or medical director.

4.4.2 The Trauma System of Care Medical Advisor shall:

4.4.2.1 Serve as an advisor on both specific and general trauma clinical and patient care issues which are brought to the TSC or its subcommittees;

4.4.2.2 Assist the TSC and its subcommittees in developing clinical-oriented trauma system policies and protocols;

4.4.2.3 Serve as a leader in injury prevention and injury control activities;

4.4.2.4 Serve as a liaison to the Trauma System Quality Evaluation Committee for medical issues requiring physician input; and

4.4.2.5 Serve as moderator of the Trauma System Quality Educational Forum.

4.5 Standing Committees and Subcommittees. The TSC's standing committees and subcommittees include the following:

4.5.1 Trauma System Quality Evaluation Committee ("Quality Committee")

4.5.1.1 The Quality Committee is a standing subcommittee of the TSC and shall focus on trauma system performance improvement.

4.5.1.2 Membership consists of representatives from each component of the statewide Trauma System.

4.5.1.2.1 Standing members shall be available for frequent working meetings and have access to the Quality Management Process of the agency which they represent. The Committee and Division may designate ad hoc Quality Management project members as needed.

4.5.1.2.2 After 3 unexcused absences in a calendar year, a member will be automatically terminated from the Committee and the Division will name a replacement.

4.5.1.3 Specific tasks and duties of the Quality Committee are as listed in subsection 8.8.

4.5.2 Trauma Center Designation Subcommittee ("Designation Committee"). The Designation Committee shall review reports of Trauma Center site visits and make recommendations through the Trauma System Coordinator to the Division Director on state Trauma Center designation.

4.5.3 Trauma Registrar Network

4.5.3.1 The Trauma Registrar Network is a standing committee of the TSC and its membership consists of Trauma Registrars from designated Trauma Centers in Delaware.

4.5.3.2 The Trauma Registrar Network shall:

4.5.3.2.1 Ensure timely and accurate trauma registry data submissions;

4.5.3.2.2 Provide trauma registry-related education to the Registrars; and

4.5.3.2.3 Refer trauma registry data and quality issues identified through this Network to the Quality Committee for consideration and potential action.

4.5.4 Delaware Coalition for Injury Prevention ("Coalition")

4.5.4.1 The Delaware Coalition for Injury Prevention is a standing committee of the TSC and its membership consists of volunteers from agencies involved with injury prevention.

4.5.4.2 The Coalition's primary purpose is to decrease death and disability from injury through public education.

4.5.4.3 The Coalition shall support statewide injury prevention efforts and develop the prevention component of the Delaware State Trauma System Plan.

4.5.5 Ad hoc subcommittees and work groups.

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5.0 Delaware Trauma Center Designation Process

5.1 Trauma System Participation

5.1.1 To be considered a participant in Delaware's Prehospital Trauma Triage Scheme and receive injured and trauma patients, an acute care facility must be designated as a trauma center by the Division Director.

5.1.2 To be considered a participant in Delaware's Prehospital Trauma Triage Scheme, an out-of-state facility must receive Delaware reciprocity as a trauma center by demonstrating current trauma center designation status and adherence to equivalent trauma standards.

5.1.3 All acute care in-patient facilities in Delaware which receive traumatically injured patients shall be required to contribute to the State Trauma Registry program by collecting and recording electronic data into the facility Registry system, following the patient criteria described in the Delaware System Trauma Plan, July 2023 Version, and any subsequent revisions. All designated trauma facilities must use the complete trauma registry form, which includes patient information and facility-specific quality assurance and financial data elements.

5.1.4 Each designated trauma center shall have a contractual agreement with the Division.

5.1.4.1 In the contract, the trauma center agrees to maintain commitment and resources commensurate with the standards of its designation level and to notify the Division in writing of intent to function at any other level of designation, no less than 30 days prior to that change becoming effective.

5.1.4.2 This contract shall also serve as the mechanism by which a facility receives permission to publicly refer to itself as a Delaware trauma center.

5.2 Responsibilities of the Division of Public Health. The Division shall:

5.2.1 Prepare for verification visits;

5.2.2 Provide staff support for the trauma center designation process;

5.2.3 Coordinate and provide staff for Level IV verification visits;

5.2.4 Develop and disseminate a timeline for the designation process;

5.2.5 Establish partnerships to hold educational and informational forums about the verification process and facility role, including mock surveys upon request or as necessary.

5.3 Responsibilities of Delaware Facilities

5.3.1 Cost. Facility fees for verification visits shall include all ACS and surveyor fees.

5.3.2 Application form. The facility must submit a completed ACS application to ACS and the Division.

5.3.3 The facility shall coordinate site visits, surveyor accommodations, transportation, and preparatory information to facilities as needed.

5.4 Verification Process

5.4.1 All Level I, Level II, and Level III trauma centers must be verified by the ACS Committee on Trauma prior to being designated as a Delaware trauma center.

5.4.2 Level IV (Participating Facility) trauma centers shall be verified by designees appointed by the Division Director as detailed in subsection 5.4.3.4.

5.4.3 Requirements of Verification Team Composition

5.4.3.1 For all Levels:

5.4.3.1.1 Familiarity with similar size geographical region and facilities; and

5.4.3.1.2 No conflicts of interest.

5.4.3.2 For Regional Trauma Centers Levels 1 and 2:

5.4.3.2.1 Two trauma surgeons;

5.4.3.2.2 One trauma registered nurse;

5.4.3.2.3 One Emergency Medicine physician;

5.4.3.2.4 A neurosurgeon shall be utilized for all initial verification visits and for reverification of facilities where there has been a documented neurosurgical care or coverage issue since the last site visit; and

5.4.3.2.5 Subspecialty reviewers may be added to any review on request of the American College of Surgeons, the Trauma System Designation Committee, the facility, or the Division Director. Movement to a new level of designation is considered an initial review visit.

5.4.3.3 For Community Trauma Centers (Level III):

5.4.3.3.1 One Trauma Surgeons; and

5.4.3.3.2 One Emergency Medicine physician.

5.4.3.3.3 In addition, for first-time Level III verification, or an increase to Level III from a Level IV, one trauma registered nurse from the ACS Committee on Trauma's Verification, Review and Consultation (VRC) Committee.

5.4.3.4 Participating Facilities (Level IV) Trauma Centers shall be verified and designated by Division-appointed designees, including:

5.4.3.4.1 One Delaware Trauma System Coordinator;

5.4.3.4.2 One out-of-state Emergency Department Physician;

5.4.3.4.3 One trauma registered nurse; and

5.4.3.4.4 The Delaware Trauma System of Care Medical Advisor.

5.4.3.5 Pediatric Trauma Centers. Pediatric trauma centers shall have equivalent verification teams to the corresponding level of adult trauma center.

5.4.4 In any case where the ACS does not provide the scope necessary to include a particular facility in its verification process, the Division Director may decide to allow that facility to participate in the Delaware Trauma System under special circumstances. In this case, that facility is encouraged to utilize the ACS to the extent to which applicable services are available, and the Division shall arrange for a comparable verification visit by national trauma experts under individual contract with the Division. Fees and site visit reports of this team shall be handled in the same manner as those of the ACS.

5.5 Timeframe

5.5.1 The facility shall determine when it is adequately prepared to begin the verification process.

5.5.2 The Division shall hold periodic designation cycles for facilities to apply for trauma center designation.

5.6 Designation Process

5.6.1 The Designation Committee shall make recommendations to the Division on the category of trauma center designation for which each facility has qualified, based on its review of the ACS site visit report and application of Delaware's correlational template.

5.6.1.1 Any facility not receiving the full ACS verification shall be offered the opportunity for a representative to address the Designation Committee for no more than 10 minutes prior to their deliberation.

5.6.1.2 The Division Director shall designate a trauma center based on the Designation Committee's recommendations.

5.6.2 Categories of State Designation and Timeframes

5.6.2.1 Full designation may be awarded for 3 years.

5.6.2.2 Provisional designation may be awarded for 1 year.

5.6.2.2.1 Deficiencies defined by ACS must be corrected and verified by the ACS within this period.

5.6.2.2.2 All corrections must be completed and verified within 1 year from the date of status notification. Facilities shall be informed whether their plan for correction is acceptable.

5.6.2.2.3 The Division may require interim reports or on-site progress evaluations as a condition of approval of the written plan of correction 1 year after the provisional designation has been awarded.

5.6.2.3 Non-designation

5.6.2.3.1 Facilities not receiving full designation must notify the Division within 30 days of status notification of their intent to correct deficiencies or to accept non-designation. A written plan of correction including timeframes must be submitted to the Division if the facility chooses to pursue designation.

5.6.2.3.2 All corrections must be completed and verified within 1 year from the date of status notification. Facilities shall be informed whether their plan for correction is acceptable.

5.6.2.4 Lower Designation

5.6.2.4.1 Facilities may be offered a lower designation level than originally applied for if they do not qualify for the higher level. If they accept the lower designation level, they may apply again for a verification visit at the higher level at any time that they are ready or may elect to remain at the designated level.

5.6.2.4.2 A facility seeking to be designated at a higher level shall:

5.6.2.4.2.1 Meet with the Trauma System Coordinator to review compliance with the standards of the higher-level trauma center.

5.6.2.4.2.2 Request provisional designation in writing from the Division of Public Health, providing documentation of intent to obtain ACS verification within the year of provisional designation.

5.6.2.4.2.3 If approved, the Office of EMS shall notify prehospital and facility agencies of the change in status after a start date has been agreed upon.

5.7 Designation Committee

5.7.1 The Division Director shall maintain an impartial Trauma Center Designation Committee. The Designation Committee members are appointed from each of the following Delaware organizations or chapters as follows:

5.7.1.1 One member from the Delaware Healthcare Association;

5.7.1.2 One member from the Delaware Organization of Nurse Leaders;

5.7.1.3 One anesthesiologist or intensivist from the Medical Society of Delaware;

5.7.1.4 One member from the American College of Surgeons, Delaware Chapter, Committee on Trauma;

5.7.1.5 One member from the American College of Emergency Physicians, Delaware Chapter;

5.7.1.6 One member from the Delaware Emergency Nurse Association;

5.7.1.7 One member from the Delaware Society of Orthopedic Surgeons

5.7.1.8 One member from American Association of Critical Care Nurses, Delaware Chapter;

5.7.1.9 One member who shall be a pediatric care specialist; and

5.7.1.10 One member from the American Neurosurgery Association, Delaware Chapter who shall serve in advisory, non-voting role.

5.7.2 The Division Director shall make an effort to appoint committee members who provide geographic and institutional diversity. Members shall serve at the pleasure of the Division Director, until they submit a letter of resignation, their organization requests to replace them, or they are absent from meetings for a period of 1 year, which shall be cause for dismissal.

5.7.3 Committee members shall be chosen by the Division Director to participate in each Designation Committee assignment, with the selections designed to optimize impartiality and avoid conflict of interest related to the current action.

5.7.4 In the event a committee member retires, resigns, or is removed, the nominating committee shall request 2 names from the appropriate Delaware organization or chapters and submit those names to the Division Director for consideration of appointment.

5.7.5 All Designation Committee proceedings shall be confidential. Information discussed at meetings and the records thereof shall be confidential and privileged and shall be protected from direct or indirect means of discovery, subpoena, or admission into evidence in any judicial or administrative proceeding. All meeting attendees shall be required to sign confidentiality statements and all written information distributed during the meetings shall be collected prior to adjournment. Any documented breach of confidentiality shall be referred to the Division of Public Health for appropriate action.

5.8 Redesignation

5.8.1 ACS reverification visits must be scheduled every three years for facilities wishing to continue their trauma center status.

5.8.2 Subsequent site visits shall focus heavily on quality management and patient care issues.

5.8.3 Re-designation categories and timeframes shall be the same as those for initial designation.

5.9 Initiation of Revocation of Trauma Center Designation Process

5.9.1 Consideration of revocation of a trauma center's designation shall be initiated when a documented violation of an applicable Delaware Trauma Center Standard is identified.

5.9.2 Identification may occur through one of the following mechanisms:

5.9.2.1 Expiration of a trauma center's designation period with failure of the facility to successfully complete an American College of Surgeons (ACS) reverification visit;

5.9.2.2 An interim quality improvement site visit;

5.9.2.3 A Trauma System Quality Evaluation Committee recommendation; or

5.9.2.4 A written complaint that prompts investigation by the facility and the Trauma System Quality Evaluation Committee. The facility must report the findings of its investigation to the Quality Evaluation Committee.

5.10 Investigation of Identified Violation of Standard

5.10.1 The identifying agent (report of site visit or Quality Evaluation Committee) shall provide written notification of the violation to the Division of Public Health, including supporting documentation.

5.10.2 The Division Director shall select the Designation Committee members to be assigned to the ad hoc investigation committee.

5.10.3 The involved trauma center shall be notified of the investigation in writing with a request for its written response.

5.10.4 The assigned investigation committee shall conduct an appropriate follow-up investigation.

5.10.5 The investigation committee shall submit its report and recommendation for 1 of the following to the Division Director:

5.10.5.1 Probation until the deficiency is remedied and accepted by the Division. The investigation committee shall include a timeframe and method by which the facility must demonstrate compliance with the standard.

5.10.5.2 Status change to Participating Facility until the deficiency is remedied and accepted by the Division (revocation of trauma center designation).

5.10.5.3 Continuation of current trauma center designation.

5.10.6 If probation or revocation of designation is recommended, the investigation committee report shall include recommended steps necessary for reinstatement. This shall include verification of adequate correction by an in-state or out-of-state review team and may include interim reports or on-site progress evaluations. In cases of revocation, a full or focused ACS site visit may be recommended.

5.10.7 If probation or revocation of designation is not recommended, the investigation committee may recommend follow-up monitoring or reporting.

5.10.8 The Division Director shall make a decision on the action to be taken after consideration of the investigation committee's report. Written notification of the action shall be forwarded to the facility.

5.10.9 If a facility is unable to demonstrate compliance in the specified timeframe it must submit a written progress report and request for a deadline extension to the Division Director. Failure to comply within the specified timeframe without requesting such an extension shall result in change of status from probationary status to a level that is commensurate with verified resource capabilities, which may include a change in designation level or the loss of designation.

5.10.9.1 If a facility fails to comply with an extended timeframe, the Division Director may require a full American College of Surgeons verification site visit for a facility to be reinstated at its former level of designation.

5.10.9.2 A facility may relinquish its trauma center designation through written notification to the Division Director if it chooses not to pursue correction of a deficiency.

5.11 Appeal Process

5.11.1 The involved trauma center shall have the right to appeal any decision of the Division of Public Health regarding initial or subsequent designation or a change in designation status.

5.11.2 Written notification of the intent to appeal must be made to the Division Director within 30 days of notification of action. Written notice shall comply with 29 **Del.C.** §10122, as far as practicable.

5.11.3 The Division Director shall name an impartial panel to hear the facility's case and make recommendations. The panel shall consist of 3 members of the Trauma System Committee who have no relationship with the appealing facility and have not been involved in the case. At least 1 of these members shall be affiliated with a Delaware trauma center in a different county from the appealing facility.

5.11.4 The appeal hearing shall be scheduled to occur no later than 45 days following receipt of the facility's request for appeal by the Division of Public Health.

5.11.5 Information pertinent to the case shall be presented to the panel by a member of the ad hoc investigation committee (or assigned Designation Committee taskforce in the case of appeal of a designation decision following site visit) and a representative of the facility. The presentations shall be audio-recorded and transcribed by the Division.

5.11.6 The panel shall make a recommendation to the Division Director that the original decision stand, be reversed, or be modified, and specific recommendations for the modification shall be outlined.

5.11.7 The Division Director shall make a decision based on the panel's recommendation within 30 days of the hearing's conclusion and shall provide written notification of the action to the facility.

5.12 Reinstatement Process

5.12.1 When a facility has corrected a problem which resulted in probation or revocation of designation, it shall notify the Division of Public Health in writing, requesting reinstatement.

5.12.2 Based on the reinstatement steps recommended by the Designation Committee, the Division shall arrange a review to verify resolution of the problem.

5.12.3 Outcomes of the review are for the facility to:

5.12.3.1 Return to previous level of designation or end of probation;

5.12.3.2 Designate at lower level until reverified by ACS; or

5.12.3.3 Remain at Participating Facility level until reverified by ACS.

5.13 A facility may relinquish its trauma center designation through written notification of their intent to the Division Director no less than 30 days prior to the effective date.

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6.0 State of Delaware Trauma Center Standards

6.1 At a minimum, Delaware Trauma Center Standards must meet the requirements and trauma standards set forth in the ACS Committee on Trauma's Verification, Review and Consultation (VRC) Committee Resources

for Optimal Care of the Injured Patient, 2006 Standards and all subsequent updates for verification and designation.

6.1.1 The Division may modify existing American College of Surgeons' Committee on Trauma Standards to increase the level of the requirement.

6.1.2 American College of Surgeons Trauma Standards may not be modified so as to decrease the level of the requirement.

6.1.3 The process for modifying an existing American College of Surgeons Standard is as follows:

6.1.3.1 The Trauma System Committee shall discuss and vote to recommend to the Division Director that a modification should be made.

6.1.3.2 If approved by the Division Director, the existing Delaware Trauma System regulations shall be revised pursuant to 29 **Del.C.** Ch. 101.

6.1.4 Copies of the current ACS Resources for Optimal Care of the Injured Patient may be obtained by contacting the ASC Publication Orders Department at 633 N. Saint Clair Street in Chicago, IL, 60611 or by telephone at (312) 202-5000. Copies can also be found at https://www.facs.org/quality-programs/trauma/quality/verification-review-and-consultation-program/.

6.2 Facility Requirements

6.2.1 Facility administration and medical staff must demonstrate commitment to the trauma program, including:

6.2.1.1 Development and adoption of written resolution of support from both the facility Board of Trustees and the medical staff;

6.2.1.2 Establishment of written policies and procedures to provide and maintain the services for trauma patients as outlined in Delaware's Trauma Center Standards;

6.2.1.3 Demonstrated evidence of budgetary support of the facility's trauma program such as facility-funded positions for Trauma Medical Director (TMD), Trauma Program Manager (TPM), trauma registry personnel or Trauma Quality Improvement Program personnel;

6.2.1.4 Active participation and attendance of trauma leadership staff in the Delaware Trauma System Committee and Trauma Quality Evaluation Committee;

6.2.1.5 Adherence to State Trauma Registry guidelines for providing facility trauma registry data to the State Trauma Registry for utilization in trauma system management and quality improvement activities;

6.2.1.6 Establishment and maintenance of written transfer procedures and agreements with appropriate trauma centers, specialty centers, and facilities, providing for movement of both critical and convalescing patients within the trauma system. Compliance with these procedures is to be monitored by the quality improvement process in each facility. It is the responsibility of each receiving facility to provide timely feedback to transferring facilities on the status and outcome of all patients received.

6.2.1.7 Designated trauma system facilities shall continue to function in accordance with the Trauma Facility - Division of Public Health Memoranda of Agreement signed upon designation.

6.2.2 Facilities must incorporate the following trauma services procedures:

6.2.2.1 Written protocols and standards of care for the major trauma patient, including definitions of response and turnaround times as well as team participant roles; and

6.2.2.2 Written trauma activation procedures.

6.2.3 Facilities must retain a Trauma Program Manager (TPM). The TPM shall have the following qualifications and responsibilities:

6.2.3.1 The TPM shall work with the Trauma Medical Director (TMD) and shall be responsible for the organization of services and systems necessary for a multidisciplinary approach throughout the continuum of trauma care. The TPM role has the following components: clinical, educational, registry/quality improvement/research, administrative, and liaison.

6.2.3.2 In Level I, II, and III trauma centers, the TPM must have 1 full-time equivalent (FTE) commitment to the trauma program.

6.2.3.3 The TPM is not required to be a full-time (1 FTE) position for Level IV centers.

6.2.3.4 The TPM must be certified in Trauma Nursing Core Course (TNCC).

6.2.3.5 The TPM must attend a minimum of 36 hours of trauma-related continuing education during the verification cycle, and records must be available documenting these trauma-specific continuing education hours.

6.2.3.6 The TPM must actively participate in and attend meetings of the Delaware Trauma System Committee and Trauma Quality Evaluation Committee.

6.2.4 Facilities must retain a Trauma Medical Director (TMD). The TMD shall have the following qualifications and responsibilities:

6.2.4.1 The TMD shall be a board-certified or board-eligible surgeon or emergency department physician.

6.2.4.2 Through the quality improvement process, the TMD shall have responsibility for all trauma patients and administrative authority for the facility's Trauma Program.

6.2.4.3 The TMD must attend a minimum of 8 trauma-related hours of continuing education annually and records must be available documenting these trauma-specific continuing education hours.

6.2.4.4 Additional qualifications for the TMD shall include regular involvement in the care of injured patients and participation in trauma-related educational activities.

6.2.4.5 The TMD shall maintain current Advanced Trauma Life Support certification.

6.2.4.6 The TMD must actively participate in and attend meetings of the Delaware Trauma System Committee and Trauma Quality Evaluation Committee.

6.2.5 Each facility must have a Performance Improvement and Patient Safety (PIPS) Program that conducts the following:

6.2.5.1 In accordance with Section 9.0, provide facility trauma registry data to the State Trauma Registry for utilization in trauma system management and quality improvement activities;

6.2.5.2 Special audits for all trauma deaths;

6.2.5.3 Morbidity and mortality reviews;

6.2.5.4 Nursing performance improvement reviews;

6.2.5.5 Reviews of prehospital trauma care;

6.2.5.6 Documentation of times of and reasons for trauma-related bypass;

6.2.5.7 Reviews of trauma patients admitted to medical services (non-surgical service admissions); and

6.2.5.8 Establishment of a Trauma Program Performance Improvement Committee, which shall:

6.2.5.8.1 Meet regularly for the purpose of peer-review and trauma center performance;

6.2.5.8.2 Be chaired by the Trauma Medical Director;

6.2.5.8.3 Have representation from the major services and applicable specialists that were involved in the treatment of the reviewed trauma patient with membership including the Trauma Program Manager, emergency medicine physician, and if applicable the surgeon and anesthesiologist; and

6.2.5.8.4 Conduct the following tasks: critically review, evaluate, and discuss the quality and appropriateness of care in cases of adverse outcome (complications and deaths, particularly unexpected deaths), monitor complication trends, identify well-managed cases which can be utilized as teaching cases, and designate focused audits.

6.3 Transfer Agreements

6.3.1 Written transfer procedures and agreements with appropriate trauma centers, specialty centers, and facilities, providing for timely movement of both critical and convalescing patients within the Trauma System, must be established and maintained. Compliance with these procedures is to be monitored by each facility's PIPS program.

6.3.2 Transfer agreements are required for the following:

6.3.2.1 Regional trauma resources/capabilities, or specialty centers;

6.3.2.2 Recognized burn centers; and

6.3.2.3 Tertiary pediatric referral center with critical care capabilities.

6.4 Rehabilitative Services

6.4.1 Consultation with appropriate rehabilitative services shall be made early in the patient's hospitalization. Patients with rehabilitative needs shall have access to early rehabilitative evaluation and bedside therapy during the acute phase of their care. Optimal time for rehabilitation consult is within 72 hours of admission.

6.4.2 There must be identifiable evidence of early and adequate discharge planning for patients, including assessment of function to assure that all trauma patients have access to the inpatient or outpatient services that may be required post-acute care discharge.

6.4.3 Facilities that do not have in-house trauma rehabilitation services must have a transfer agreement with a rehabilitation facility.

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7.0 State of Delaware Triage, Transport, and Transfer Protocols

7.1 Due to the dynamic nature of identification and evolution of best practices in prehospital care, the prehospital trauma triage guidance shall be found solely in the current State of Delaware, Department of Health and Social Services, Division of Public Health, Office of Emergency Medical Services, Statewide Standard Treatment Protocols, Guidelines, Policies, and Paramedic Standing Orders and Statewide Standard Treatment Protocols and Basic Life Support Standing Orders. The Trauma System Committee shall be asked for input by the State EMS Medical Director through the Trauma System Manager during every Standing Orders revision process.

7.2 If transport time between 2 trauma centers is relatively equal, critically injured trauma patients should be transported directly to the higher-level trauma center. Patients with significant head trauma as evidenced by a Glasgow Coma Score of 8 or less, or spinal cord trauma as evidenced by new onset limb paralysis or weakness should be transported directly to a Level I or Level II Trauma Center with an available neurosurgeon when possible. Availability of air transport will impact these time and distance decisions and may potentially save the patient the time required for later interfacility transfer as well as keep the helicopter available for scene medevac work.

7.3 In order to be considered a participant in Delaware's Trauma System, an out-of-state facility must receive Delaware reciprocity as a trauma center by demonstrating current trauma center designation status and adherence to equivalent trauma standards.

7.4 Air Transport Guidelines

7.4.1 Utilization of aeromedical services has become a nationally accepted standard for the rapid evacuation and transportation of critically injured patients to the most appropriate medical facility for definitive medical care. In order to make the best decisions about the most appropriate mode of transport for a particular patient, multiple factors must be considered. Clinical factors relate to the patient and are described in the Delaware Paramedic and Basic Life Support Standing Orders. Operational factors relate to the transport process and include helicopter availability and location measured against ground transport time. Weather, traffic, ground unit availability, and scene accessibility are other operational factors which must be considered on a case-by-case basis.

7.4.2 Air transportation from the scene is appropriate for a seriously injured trauma patient. These decisions shall be based on current State of Delaware, Department of Health and Social Services, Division of Public Health, Office of Emergency Medical Services, Statewide Standard Treatment Protocols, Guidelines, Policies, and Paramedic Standing Orders and Statewide Standard Treatment Protocols and Basic Life Support Standing Orders.

7.4.3 To avoid excessive time spent on scene awaiting arrival of the aircraft, the helicopter should be dispatched at the time of initial ALS dispatch or immediately upon arrival of the first units on scene. It is in the patient's best interest for the aircraft to be dispatched early rather than to wait for ground unit request when available information suggests a major incident. When appropriate, consideration may be given to rendezvous.

7.5 Interfacility Transfer Decisions

7.5.1 The most appropriate mode of transportation to be utilized when an interfacility transfer is being arranged is a decision made by the referring physician. Operational factors as well as clinical factors must be considered in arriving at the best transport decision in each circumstance.

7.5.2 High-risk Criteria for Consideration of Early Transfer of Injured Patients: See A*ppendix C, Delaware System Trauma Plan, July 2023 Version*, and any subsequent revisions.

7.5.3 Interfacility Transfer Protocol: See *Appendix C Delaware System Trauma Plan, July 2023 Version*, and any subsequent revisions.

7.5.4 Interfacility transfer decisions must follow the Acceptance of Critically Injured Patients for Acute Tertiary Care, September 2019, See *Appendix C, Delaware System Trauma Plan, July 2023 Version* and any subsequent revisions.

7.5.5 Burn Center Referral Criteria: See *Appendix C, Delaware System Trauma Plan, July 2023 Version* and any subsequent revisions.

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8.0 State of Delaware Trauma System Performance Improvement Plan

8.1 The State of Delaware Trauma System is committed to provision of optimal care for all injured persons. In order to attain this goal, the Division of Public Health coordinates all medical services provided to trauma patients based on national standards for trauma care as set forth by the Joint Commission on Accreditation of Health Care Organizations (JCAHO), the ACS Committee on Trauma's Resources for Optimal Care of the Injured Patient: 1993, the American College of Emergency Physicians (ACEP)'s Trauma Care System Guidelines, 1992 and Health Resources and Services Administration's The Model Trauma Care System Plan, 1992 and subsequent revisions of these documents. This Performance Improvement Plan seeks to enable the Trauma System to meet and exceed these standards, both administratively and clinically, through promotion and achievement of continuous improvement in all aspects of the statewide trauma program's organization and associated activities.

8.2 Purpose

8.2.1 The State of Delaware Trauma System's Quality Improvement Plan describes the framework for designing, measuring, assessing, and improving the organizational functions related to provision of medical services to injured patients within the State. It promotes performance improvement through education, facilitation of inter- and intra-facility communication, and systems coordination. The plan integrates all prehospital, medical staff, nursing, ancillary services, and operational performance improvement activities through systematic monitoring and evaluation of the appropriateness of patient care, the measurement of outcomes, and the identification of opportunities for improvement.

8.2.2 The goals of the Trauma System's Quality Improvement Plan are "to monitor the process and outcome of patient care, to ensure the quality and timely provision of such care, to improve the knowledge and skills of trauma care providers, and to provide the structure and organization to promote quality improvement" (ACS, 1993, p. 78) within the state.

8.3 Objectives. Based on national standards for Facility Quality Improvement set forth in the ACS's Resources for Optimal Care of the Injured Patient and the JCAHO Recommendations for Improving Organizational Performance and for System Quality Improvement as outlined in the American College of Emergency Physician's Trauma Care System Guidelines, the Trauma System's Quality Improvement Plan describes the framework for use in designing, measuring, assessing, and improving the Delaware Trauma System's organization, functions, and services. This is accomplished by a collaborative approach with the appropriate facilities, services, and disciplines involved, utilizing the following objectives:

8.3.1 Systematic measurement on a continuing basis to understand and maintain the stability of systems and processes;

8.3.2 Measurement of patient and systems outcomes to help determine priorities for improving systems and processes; and

8.3.3 Assessment of system competence and performance.

8.4 Authority

8.4.1 The Division of Public Health has the ultimate authority and responsibility for assuring the delivery of quality trauma care throughout the state.

8.4.1.1 The Division has the authority for system data collection, review, and most importantly the authority to recommend corrective action in all aspects of trauma care throughout the continuum from injury to rehabilitation.

8.4.1.2 The Division shall provide guidance as needed to individual trauma facilities in the development and implementation of their Quality Improvement Programs.

8.4.2 The care of the trauma patient is monitored and evaluated at both the facility and Trauma System levels, and maintenance of patient confidentiality is the joint responsibility of evaluators at the both the facility and Trauma System levels.

8.5 Prehospital Evaluation

8.5.1 The Division of Public Health shall work with the State Fire Prevention Commission to address improvements regarding prehospital care of the injured patient. The American College of Emergency Physicians' Trauma Care System Guidelines shall provide a basis for prehospital trauma care evaluation.

There shall be an ongoing evaluation of all aspects of trauma care from the receipt of the call at central dispatch to the patient's arrival at the medical facility. Evaluation shall document quality of care provided and compliance with protocols.

8.5.2 Areas to be reviewed by the agency's PI staff include the following:

8.5.2.1 Access to the system;

8.5.2.2 Efficacy of field therapy;

8.5.2.3 Scene time;

8.5.2.4 Transport decisions;

8.5.2.5 Transport time;

8.5.2.6 Transport to the appropriate facility;

8.5.2.7 Under/over triage; and

8.5.2.8 Documentation.

8.5.3 Delaware shall follow national standards for prehospital data collection.

8.5.3.1 The Division of Public Health shall collaborate with the State Fire Prevention Commission to determine the minimum data sets to be collected by Basic and Advanced Life Support providers. Data used for evaluation of prehospital care must be consistent with the design of the Delaware Trauma Registry, as collected by the medical facilities and analyzed by the Division.

8.5.3.2 Data to be reviewed shall include:

8.5.3.2.1 Completion of primary patient assessment;

8.5.3.2.2 Appropriate care of life-threatening conditions;

8.5.3.2.3 Trip sheet completion and availability at facility;

8.5.3.2.4 Scene time within accepted guidelines;

8.5.3.2.5 Proper triage/determination of facility type needed by patient; and

8.5.3.2.6 Transportation to appropriate facility within an acceptable time frame.

8.5.4 Performance Improvement

8.5.4.1 PI measures shall be determined by the Trauma System Evaluation Committee based on Delaware prehospital protocols and national and Delaware standards of care.

8.5.4.2 A completed prehospital patient care record must be provided to the medical receiving facility for inclusion in the patient's emergency room or facility medical record. Facilities and prehospital providers are strongly encouraged to establish a mechanism for exchange of information, including provision of feedback to prehospital providers on triage decisions made. Additionally, the facility's Trauma Registrar shall include this record's data in the facility's trauma registry for outcome evaluation.

8.5.4.3 A PI program model shall be developed by the Division of Public Health or its designee for the use of Basic Life Support and Advanced Life Support agencies. Recommendations for changes in educational curricula, patient care protocols, etc. shall be based on analysis of information obtained through the prehospital evaluation process. The Division shall also develop a mechanism for prehospital providers to have input into quality assurance issues, including the identification of educational needs and methods of addressing them.

8.6 Trauma Center Evaluation

8.6.1 All designated trauma facilities shall design a performance improvement plan which meets the standards and requirements established by the Division of Public Health. The Division shall utilize the ACS Resources for Optimal Care of the Injured Patient: 1993 standards and subsequent revisions as guidelines. Facility performance improvement plans shall be verified during site survey and quality improvement visits.

8.6.2 When new processes or systems are developed within a facility, the design shall be based on the following:

8.6.2.1 Up-to-date sources of information about designing processes and systems including practice guidelines, clinical pathways, professional standards, and regulatory standards;

8.6.2.2 The needs and expectations of internal and external consumers; and

8.6.2.3 The performance of the processes and systems and their outcomes including internal and external (benchmarking) comparison data.

8.6.3 Performance Measures

8.6.3.1 Performance measures (audit filters) shall be based on nationally recognized guidelines set forth by the ACS. Performance measures are established to evaluate process or outcome of the care or services provided or to determine the level of performance of existing processes and the outcomes resulting from these processes. Data collection and measurement shall be systematic, relate to relevant standards of care, and prioritized according to high volume, high risk, or problem-prone areas. In addition, the needs, expectations, and feedback from patients and their families, employees, results of ongoing monitoring activities (e.g., infection control), safety of the patient care environment, utilization, and risk management findings shall be included.

8.6.3.2 Specific response time performance measures include:

8.6.3.2.1 All trauma activation levels including consults;

8.6.3.2.2 Routine and STAT consultations for Orthopedics, Neurosurgery, and Interventional Radiology;

8.6.3.2.3 Radiological response times in terms of time from request to time of completion for diagnostic studies including X-ray, CT scan and MRI; and

8.6.3.2.4 Operating room response times from request to time of entry to the OR.

8.6.4 Data collection

8.6.4.1 Data collection shall be designed to:

8.6.4.1.1 Assess new or existing processes;

8.6.4.1.2 Measure the level of performance and stability of important existing processes;

8.6.4.1.3 Set performance improvement priorities;

8.6.4.1.4 Establish benchmarks of performance to identify potential opportunities for improvement;

8.6.4.1.5 Identify patterns and trends that may require focused attention;

8.6.4.1.6 Provide comparative performance data to use for performance improvements; and

8.6.4.1.7 Evaluate whether changes have improved the processes.

8.6.4.2 Performance measures (audit filters) may:

8.6.4.2.1 Measure events or phenomena that are expected to occur at some level of frequency;

8.6.4.2.2 Relate data about either a process or an outcome;

8.6.4.2.3 Relate data about occurrences that are either desirable or undesirable;

8.6.4.2.4 Relate data that guide the Trauma Program in improving norms of performance instead of focusing exclusively on censoring or eliminating individual outliers; and

8.6.4.2.5 Identify serious events which may trigger an opportunity for improvement and require further data collection.

8.6.5 Focused audits shall be used to periodically examine the process of care as recommended by ACS and may include the following:

8.6.5.1 Noncompliance with facility criteria for trauma center designation;

8.6.5.2 Trauma attending surgeon arrival times for Trauma Codes; and

8.6.5.3 The absence of documentation of required information or patient assessment findings on trauma care records.

8.6.6 After data collection, the data shall be analyzed to determine the following:

8.6.6.1 Whether design specifications for new processes were met;

8.6.6.2 The level of performance and stability of existing processes;

8.6.6.3 Priorities for possible improvement of existing processes;

8.6.6.4 Actions and strategies to improve the performance of processes; and

8.6.6.5 Whether changes in the processes resulted in improvement.

8.6.6.6 Data analysis shall be accomplished using statistical quality control techniques and tools, comparative benchmarking data such as TRISS, review of the Trauma Program's processes and outcomes over time, and other reference material as appropriate. Intensive assessment shall be used when measurement indicates that potential performance or system related opportunities for improvement exist, a single serious event occurs, the control limits are met, or when undesirable variation in performance has occurred or is occurring.

8.6.6.7 The data analysis process shall be interdisciplinary and interdepartmental depending upon the process or outcome under review.

8.6.7 When an opportunity for improvement is identified or when the measurement of an existing process identifies the need to redesign a process, a systematic approach, such as the FOCUS-PDCA Model, shall be implemented. This model is the ongoing process used to promote continuous improvement as described below:

8.6.7.1 Find process improvement opportunity:

8.6.7.1.1 Develop an opportunity statement; and

8.6.7.1.2 Identify the process.

8.6.7.2 Organize a team that knows the process:

8.6.7.2.1 Identify employees who work closest with the process; and

8.6.7.2.2 Identify internal and external consumers and their expectations.

8.6.7.3 Clarify current knowledge of the process:

8.6.7.3.1 Identify sound areas of the process;

8.6.7.3.2 Determine if team members are appropriate to assess the process;

8.6.7.3.3 Identify the process flow; and

8.6.7.3.4 Identify problems or redundancies which can be eliminated to make the flow more efficient.

8.6.7.4 Uncover causes of process variation:

8.6.7.4.1 Identify variation in the process;

8.6.7.4.2 Identify measurable process characteristics;

8.6.7.4.3 Identify if the variation has a common or unique cause; and

8.6.7.4.4 Identify the effect the variation has on other facility systems.

8.6.7.5 Start the improvement cycle:

8.6.7.5.1 Determine what changes can be made to improve the process; and

8.6.7.5.2 Start a description of the process to be improved.

8.6.7.6 Plan the improvement and data collection:

8.6.7.6.1 Identify what improvements are to be made and in what order;

8.6.7.6.2 Assign responsibility for making the change;

8.6.7.6.3 Determine when the change will be effective; and

8.6.7.6.4 Determine what data will be collected to measure changes.

8.6.7.7 Do the improvement:

8.6.7.7.1 Initiate the change (pilot study period); and

8.6.7.7.2 Collect data.

8.6.7.8 Check the results:

8.6.7.8.1 Analyze the results of the data collection; and

8.6.7.8.2 Draw conclusions.

8.6.7.9 Act in process and theory:

8.6.7.9.1 Standardize the change;

8.6.7.9.2 Determine ongoing measurement of the process and reevaluation of implemented changes (effectiveness monitored for a minimum of 3 months following corrective action);

8.6.7.9.3 Policy and procedure development/revision;

8.6.7.9.4 Education and communication of new process; and

8.6.7.9.5 Following identification and documentation of a specific problem in patient care or system performance by the peer-review process, corrective action is taken through one of the following mechanisms:

8.6.7.9.5.1 Change of existing policies and procedures that govern or define the standard of care;

8.6.7.9.5.2 Professional education: cases may be selected for discussion at the trauma service conferences; deficits in knowledge can be addressed through education of the whole group of providers or of specific providers;

8.6.7.9.5.3 Counseling: review of a specific case or cases is conducted by the Trauma Medical Director, chief of the service, or the supervisor, with the individual; or

8.6.7.9.5.4 Credentialing process: information from quality improvement activities may be reported through the facility's QI System for consideration at the time of credentialing, delineation of privileges, or evaluation.

8.7 Trauma System Evaluation

8.7.1 Evaluation of the Delaware Trauma System encompasses the entire scope of care provided to injured patients within the State of Delaware from injury through rehabilitation.

8.7.2 Division of Public Health responsibilities are:

8.7.2.1 Implement and monitor the State Trauma System Quality Improvement Program.

8.7.2.2 Trauma System Registry Coordinator responsibilities are as follows:

8.7.2.2.1 Review Trauma Registry data submitted for completeness;

8.7.2.2.2 Provide educational support for Trauma Registrars;

8.7.2.2.3 Assure maintenance of all minutes and records related to Trauma System continuous improvement activities; and

8.7.2.2.4 Function as staff for Quality Evaluation Committee.

8.8 Trauma System Quality Evaluation Committee ("Quality Committee")

8.8.1 The Quality Committee is established under subsection 4.5.1.

8.8.2 The Quality Committee shall provide recommendations, advice, and assistance to the Division in its ongoing evaluation of the Delaware Trauma System based on ACS standards and nationally accepted Continuous Quality Improvement guidelines. Specific functions may include the following:

8.8.2.1 Assist the Trauma System Registry Coordinator in the supervision of the State Trauma Registry;

8.8.2.2 Assess trauma care standards and recommend actions for the development and implementation of statewide policies and procedures that guide and support the provision of trauma care or services;

8.8.2.3 Assess resources needed to support and sustain the Delaware State Trauma System;

8.8.2.4 Evaluate the coordination and integration of prehospital, inter-facility, intra-facility, and ancillary services;

8.8.2.5 Monitor the incidence of adverse outcomes on a regular basis with comparison to regional and national norms;

8.8.2.6 Recommend action for identified problems or opportunities for improvement in patient care services;

8.8.2.7 Report Quality Improvement activities to the Division of Public Health on a regular basis;

8.8.2.8 Sponsor ongoing education regarding ACS, ACEP, and TJC standards and provide a multidisciplinary educational forum for presentation and discussion of interesting, difficult, or controversial trauma patient management cases;

8.8.2.9 Evaluate effectiveness of actions taken and determine follow-up;

8.8.2.10 Meet a minimum of four times per year, and as determined by the Committee or the Division;

8.8.2.11 Assess other sources of data to combine into a comprehensive database for evaluation of the continuum of trauma care in Delaware;

8.8.2.12 Develop operational guidelines for the Committee's functioning; and

8.8.2.13 Perform any other function deemed necessary by the Division of Public Health.

8.8.3 The Quality Committee shall report aggregate findings and activities of the Quality Committee including:

8.8.3.1 The incidence of adverse or positive outcomes with comparison to regional and national norms;

8.8.3.2 Trend analyses of systems components;

8.8.3.3 Recommendations for action when opportunities for improvement are identified;

8.8.3.4 Evaluation of effectiveness of actions taken and methodologies for follow-up; and

8.8.3.5 Publication of reports to support trauma prevention, research, and systems activities, or helping others to publish reports.

8.9 Major areas of Trauma System review shall include:

8.9.1 Triage;

8.9.2 Inter-facility transfer;
8.9.3 Facility performance;
8.9.4 Impact of system;
8.9.5 Integrity of Trauma Registry data; and
8.9.6 Prevention trends.

8.10 The Quality Committee shall send quarterly reports to the Division outlining its activities. Minutes of each meeting shall be forwarded to the Division in a timely manner.

8.11 Confidentiality

8.11.1 As used in this section, "records" means the recordings of interviews and all oral or written reports, statements, minutes, memoranda, charts, data, statistics, and other documentation generated by the Quality Committee, its subcommittees, and the State Trauma Registry for the stated purpose of trauma system medical review or quality care review and audit.

8.11.2 All quality management proceedings shall be confidential. Records of the Quality Committee, its subcommittees, the State Trauma Registry, and attendees at meetings held for stated purposes of trauma system medical review or quality care review and audit shall be confidential and privileged and shall be protected from direct or indirect means of discovery, subpoena, or admission into evidence in any judicial or administrative proceeding.

8.11.3 All studies, reports, and minutes will include only the patient trauma registry number with all other identifying information encoded or kept in locked files. Access to qualified researchers may be granted based on state, federal, and municipal statutes, bylaws, rules, regulations, and policies. All meeting attendees will be required to sign confidentiality statements. Any documented breach of confidentiality will be referred to the Division of Public Health for appropriate action.

8.12 The Trauma System Performance Improvement Plan shall be reviewed at least annually by the Division and the Quality Committee.

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9.0 Delaware State Trauma Registry

9.1 Facility Participation

9.1.1 All acute care inpatient facilities in Delaware which receive traumatically injured patients shall be required to contribute to the State Trauma Registry program by collecting and recording electronic data into the facility registry system, following the patient criteria described in the *Delaware System Trauma Plan, July 2023 Version*, and any subsequent revisions.

9.1.2 See *Appendix B, Delaware System Trauma Plan, July 2023 Version*, and any subsequent revisions for patient inclusion requirements.

9.1.3 Each contributing facility shall designate an individual with the authority, responsibility, and accountability for directing and maintaining the facility trauma registry and its data submission to the State Trauma Registry.

9.1.4 Each contributing facility shall identify a primary data entry individual and allow adequate time and resources for this individual to perform their tasks. (Time commitment is estimated to be 60 minutes for a complete form and an additional 60 minutes for quality improvement activities per patient.) This individual shall be required to participate in a Delaware Trauma Registrars Network, which shall facilitate communications among Registrars and provide educational information to improve data quality. All Registrars must attend scheduled Network meetings and workshops.

9.1.5 Both the individual contributing facilities and the State shall be responsible for data integrity and confidentiality.

9.2 To ensure consistent data collection across Delaware, data is entered into the National Trauma Data Bank according to the National Trauma Data Standards. See the *Delaware Trauma System Data Dictionary, Delaware System Trauma Plan, July 2023 Version*, and any subsequent revisions for required data fields.

9.3 Data Set

9.3.1 The Trauma Registry software to be used by facilities shall be specified by the Division of Public Health in conjunction with the Trauma System Quality Evaluation Committee, with input from all data-contributing facilities. Technical support shall be provided to all Delaware acute care facilities by the Division or its

designee. Facilities shall collect the required data and submit it to the System Trauma Registry Coordinator as soon as possible, but no more than 90 days after the close of each quarter.

9.3.2 Data collected from contributing acute care facilities shall form the State's Trauma System Registry. Registry data shall be used in the process of formulating Trauma System reports for the purposes of quality improvement, data linkage, and research and prevention activities. Researchers may request data for analysis by completing the Trauma System Registry Data Use Agreement.

9.3.3 The Trauma Registry data set shall be reviewed annually by the Trauma System Quality Evaluation Committee and the Division of Public Health for any necessary additions, deletions, or modifications.

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10.0 Severability

In the event any particular clause or section of these regulations should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full effect.

5 DE Reg. 632 (09/01/01)

17 DE Reg. 523 (11/01/13)

27 DE Reg. 529 (01/01/24)