DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Chapter 97, §9706 (g)(2) (16 **Del.C.** Ch 97, §9706 (g)(2))
16 **DE Admin. Code** 4305

PROPOSED

4305 Trauma System

PUBLIC NOTICE

Office of Emergency Medical Services & Preparedness Section, Division of Public Health, Department of Health and Social Services (Department), has proposed amendments to the State of Delaware Trauma System Regulations. The proposed revisions to the Trauma System regulations bring the Delaware Statewide Trauma System and its components into alignment with the current revision of the American College of Surgeons' Committee on Trauma's Resources for Optimal Care of the Injured Patient 2006. The revisions were developed and recommended by the stakeholders who serve on the state Trauma System Committee and primarily are related to documentation of the requirements for Trauma System Participating Hospitals, modification of the Trauma Registry inclusion criteria to be in alignment with the National Trauma Data Bank criteria, updating of the Trauma Center Designation Process, and relocation of the Prehospital Trauma Triage Scheme to the Advanced and Basic Life Support Standing Orders.

On September 1, 2013, the Department plans to publish proposed amendments to the State of Delaware Trauma System Regulations and hold them out for public comment per Delaware law.

Copies of the proposed regulations are available for review in the September 1, 2013 edition of the Delaware *Register of Regulations*, accessible online at: http://regulations.delaware.gov or by calling the Office of Emergency Medical Services at (302) 223-1789.

Any person who wishes to make written suggestions, testimony, briefs or other written materials concerning the proposed regulations must submit same to Deborah Harvey by 4:30 p.m. on Tuesday, October 3, 2013 at:

Deborah Harvey
Division of Public Health
417 Federal Street
Dover, DE 19901
Email: Deborah.Harvey@state.de.us
Phone: (302) 744-4700

4305 Trauma System

1.0 Purpose

The purpose of these Rules and Regulations 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.

2.0 Authority

These Rules and Regulations are promulgated pursuant to the authority of Title 16 **Del.C.** Ch. 97. Emergency Medical Services Systems.

3.0 Definitions

"ACLS" The Advanced Cardiac Life Support Course of the American Heart Association.

"Attending" A physician with practice privileges delineated by the hospital's medical staff.

"ATLS" The Advanced Trauma Life Support Course of the American College of Surgeons.

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

"Bypass" A request by a hospital to an Emergency Medical Service that patient (s) be directed to another hospital's Emergency Department due to a shortage or unavailability of beds, equipment, personnel, or other essential resource.

"Classification of Injuries"

“Minor injuries” Those patients with an Injury Severity Score less than 9.

“Moderate injuries” Those patients with an Injury Severity Score between 9 and 15.

“Major (severe) injuries” Those patients with an Injury Severity Score greater than 15.

“**Community Trauma Center”** An acute care hospital 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 (CME) Credit” Educational hours for physicians approved by the Accreditation Council of Continuing Medical Education or an agency recognized by this council.

“Credentialing Process” A hospital's procedure for granting practice privileges to healthcare providers.

"D" Desirable requirement for trauma facilities; encouraged but not required for designation.

“**Dedicated”** A resource used solely for a specific program.

“**Definitive Care”** A level of medical intervention capable of providing comprehensive services for a patient's injuries and associated conditions.

“**Demonstrated Commitment”** Provision of evidence (visible and written) that demonstrates clearly an institution-wide commitment to trauma care.

“**Designation”** A process through which a hospital is confirmed by the Division of Public Health 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.

"E" Essential requirement for trauma facilities.

“**EMS”** Emergency Medical Services. 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.

“**Hospital Trauma Quality Management Program”** 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.

“Immediately Available” This implies the physical presence of a resource in a stated location at the time it is needed by the trauma patient.

“Inclusive Trauma Care System” A Trauma Care System which incorporates every acute care facility in the defined region into a system in order to provide a continuum of services for all injured persons who require medical care; in such a system, the injured patient's needs are matched to the appropriate hospital resources.

“In-house” Physically present in the hospital.

“Injury Control” Methodologies designed for the purpose of preventing and eliminating injuries.

“Injury Severity Score (ISS)” 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” The transfer of a patient from one hospital to another hospital.

“**Interpretations to Standards”** Information issued by the Division of Public Health defining acceptable methods for hospitals to demonstrate compliance with the Trauma Center Standards.

“n/a” A standard which is not applicable to a particular level of trauma facility or participating hospital.

“On-call” Committed for a specific time period to be available and respond within an agreed amount of time to provide care for a patient in the hospital.

“PALS” The *Pediatric Advanced Life Support Course* of the American Heart Association.

“Participating Hospital” 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 hospitals contribute data to the Delaware Trauma System Registry and Quality Improvement Program.

“Pediatric Specialists” Certified pediatric specialists with a commitment to trauma or certified general practitioners with special training, experience, and continuing education relevant to pediatric trauma care.

“Pediatric Trauma Centers” Children's hospitals 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.*

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

“Promptly Available” Implies the physical presence of health professionals in a stated location within a short period of time, which is defined by the Trauma Director, incorporated into the written protocols of the Trauma Service, and continuously monitored by the Quality Improvement Program.

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

“Regional Level 1 Trauma Center” 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 2 Trauma Center” 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 which would require transfer for the depth of services of a Regional Level 1 or Specialty Center.

“Response Time” Time interval between notification and arrival of the general surgeon or surgical specialist in the Emergency Department or Operating Room.

“Transfer Agreement” A formal written agreement between hospitals which provides for the acceptance of patients in transfer.

“Trauma” A term derived from the Greek for "wound", it refers to 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” A specialized hospital 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”** An acute care hospital which has received and maintains current State designation as a Trauma Center.

“Trauma Registry” A data base 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 hospital's Trauma Quality Program; the 'Minimal' data set collects largely demographic information.

“Trauma System Quality Management Program” 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 Care System are functioning optimally.

“Trauma Team” A team approach is required for the optimal care of patients with multiple-system injuries. The composition of the trauma team and roles of the members are to be defined by the Trauma Director. The Trauma Surgeon Team Leader is responsible for overseeing and coordinating the operation of the Trauma Team to provide optimal patient care throughout hospitalization.

“Triage” 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” A process in which the trauma care capability and performance of an institution are evaluated by experienced on-site reviewers.

4.0 Delaware Trauma Center Designation Process

4.1 Responsibilities- Division of Public Health

4.1.1 Preparation for verification visits

4.1.1.1 Provide staff support for the Trauma Center Designation Process.

4.1.1.2 ~~Make~~ Assist with making verification visit arrangements with the American College of Surgeons (ACS) upon hospital request.

4.1.1.3 Develop and disseminate a timeline for the designation process.

4.1.1.4 Hold educational and informational forums about the verification process and hospital role, including mock surveys for hospitals desiring them.

4.1.2 ~~Contract~~ Work with American College of Surgeons for verification visits

4.1.2.1 Team composition and requirements

4.1.2.1.1 Familiarity with similar size geographical region and facilities

4.1.2.1.2 No conflicts of interest

4.1.2.1.3 Regional Trauma Centers Levels 1 and 2:

4.1.2.1.3.1 2 Trauma Surgeons

4.1.2.1.3.2 1 trauma RN

~~1 Neurosurgeon~~

4.1.2.1.3.3 1 ~~E.M.~~ Emergency Medicine physician

4.1.2.1.3.4 A Neurosurgeon will 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.

4.1.2.1.3.5 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 Director of the Division of Public Health. Movement to a new level of designation is considered an initial review visit.

4.1.2.1.4 Community Trauma Centers (Level 3):

4.1.2.1.4.1 2 Trauma Surgeons

4.1.2.1.4.2 1 ~~E. M.~~ Emergency Medicine physician

4.1.2.1.5 Participating Hospitals (Level 4):

4.1.2.1.5.1 Division of Public Health designees

4.1.2.1.6 Pediatric Trauma Centers

4.1.2.1.6.1 Pediatric Trauma Centers will have equivalent teams to the corresponding level of adult Trauma Center.

4.1.2.2 Timeframe

4.1.2.2.1 ~~ACS administrative costs decrease when multiple hospitals within one state are visited during the same time period.~~

~~4.1.2.2.2~~ It will be the individual hospital's decision as to when it is adequately prepared to begin the verification process. The Division of Public Health will hold periodic designation cycles for hospitals to apply for Trauma Center ~~status~~ designation.

4.1.2.3 Cost

4.1.2.3.1 Hospital fees for verification visits will include all ACS and surveyor fees.

4.1.2.4 Application form

4.1.2.4.1 ~~The ACS requires a detailed application form. This form will be supplied to requesting hospitals by the Division of Public Health and forwarded to the ACS by the Division upon receipt of the completed applications.~~ A completed ACS application must be submitted to ACS and the Division of Public Health by the hospital.

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

4.1.3 Coordinate site visits, surveyor accommodations, transportation, preparatory information to hospitals as needed.

4.2 Designation

4.2.1 The Director of the Division of Public Health will, under State of Delaware authority, establish an impartial Trauma Center Designation Committee by requesting the names of two nominees from each of the following Delaware organizations or chapters:

4.2.1.1 ~~Association of Delaware Hospitals~~ Delaware Healthcare Association

4.2.1.2 American Neurosurgery Association, Delaware Chapter (advisory role)

4.2.1.3 Delaware Organization of Nurse Executives

4.2.1.4 ~~Delaware Medical Society~~ Medical Society of Delaware (request an anesthesiologist or intensivist)

4.2.1.5 American College of Surgeons, Delaware Chapter, Committee on Trauma

4.2.1.6 American College of Emergency Physicians, Delaware Chapter

4.2.1.7 Delaware Emergency Nurse Association ~~and Critical Care Nurse Association~~

4.2.1.8 Delaware ~~Orthopedic Surgeon~~ Society of Orthopedic Surgeons

4.2.1.9 Representative of pediatric care.

4.2.1.10 American Association of Critical Care Nurses, Delaware Chapter

4.2.2 The Director will appoint ~~nine~~ committee members who will provide geographic and institutional diversity from the nominations received ~~for initial terms of one (three members), two (three members), or three (three members) years. Terms thereafter will be three years; committee members may be invited to serve~~

~~up to two subsequent terms providing the Committee's diversity is maintained~~. Members will serve at the pleasure of the Director of Public Health, until they submit a letter of resignation, their organization requests to replace them, or they are absent from meetings for a period of one year, which will be cause for dismissal.

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

4.2.3 The Designation Committee will develop a template outlining the correlation between the ACS verification report and State of Delaware Trauma Center designation in terms of 'Essential' and 'Desirable' criteria. This template will be presented to the Delaware Trauma System Committee for review and recommendation to the Division of Public Health for approval.

4.2.4 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 will be required to sign confidentiality statements and all written information distributed during the meetings will be collected prior to adjournment. Any documented breach of confidentiality will be referred to the Division of Public Health for appropriate action.

4.2.5 The ACS report on all verification visits will be received by the Division of Public Health, which will forward the information to the Trauma Center Designation Committee. The Designation Committee will make recommendations to the Division on the category of Trauma Center designation for which each hospital has qualified, based on its review of the ACS site visit report and application of Delaware's correlational template. Any hospital not receiving the full ACS verification will be offered the opportunity for a representative to address the Designation Committee for no more than ten minutes prior to their deliberation. The Division Director will then designate the state's Trauma Centers based on these recommendations.

4.2.5.1 Categories of designation and timeframes

4.2.5.1.1 Full designation - 3 years

4.2.5.1.2 State Provisional designation- 1 year; deficient areas must be corrected and verified by the ACS within this period.

4.2.5.1.3 Nondesignation

4.2.5.1.4 Hospitals 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 level designation 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.

4.2.5.1.5 Hospitals not receiving full designation must notify the Division of Public Health within 30 days of status notification of their intent to correct deficiencies or to accept nondesignation. A written plan of correction including timeframes must be submitted if the hospital chooses to pursue designation. All corrections must be completed and verified within one year from the date of status notification. Hospitals will be informed whether or not their plan for correction is acceptable. The Division may require interim reports or on-site progress evaluations as a condition of approval of the written plan of correction.

4.2.5.1.6 A hospital seeking to be designated at a higher level will:

4.2.5.1.6.1 Meet with the Trauma System Coordinator to review compliance with the standards of the higher level Trauma Center

4.2.5.1.6.2 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.

4.2.5.1.6.3 If approved, the Office of EMS will notify prehospital and hospital agencies of the change in status after a start date has been agreed upon.

4.2.6 The Delaware Division of Public Health will have a contractual agreement with each designated Trauma Center whereby 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 ~~lower~~ other level of designation. This contract will also serve as the mechanism by which a hospital receives permission to publicly refer to itself as a Delaware Trauma Center.

4.3 Trauma System

4.3.1 Initial implementation of the Prehospital Triage Scheme will not occur until all Delaware hospitals have had a reasonable opportunity to have consultation visits, if desired, and verification visits from the American College of Surgeons.

4.3.1.1 Initial Trauma Center/Division of Public Health contracts will take effect at this time.

4.3.2 In order 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.

4.4 Redesignation

4.4.1 ACS reverification visits ~~will~~ must be scheduled ~~by the Division of Public Health~~ every three years for those hospitals wishing to continue their Trauma Center status.

4.4.2 Subsequent site visits will focus heavily on quality management and patient care issues.

4.4.3 Re-designation categories and timeframes will be the same as those for initial designation.

4.5 Initiation of Revocation of Trauma Center Designation Process

4.5.1 Consideration of revocation of a Trauma Center's state designation will be initiated when a documented violation of an applicable Essential Delaware Trauma Center Standard is identified.

4.5.2 Identification may occur through one of the following mechanisms:

4.5.2.1 Expiration of a Trauma Center's designation period with failure of the hospital to successfully complete an American College of Surgeons (ACS) reverification visit,

4.5.2.2 An interim Quality Improvement site visit,

4.5.2.3 A Trauma System Quality Evaluation Committee recommendation.

4.5.2.3.1 Any written complaint will prompt investigation by the hospital and the Trauma System Quality Evaluation Committee. The hospital will be asked to report the findings of its investigation to the Quality Evaluation Committee.

4.6 Investigation of Identified Violation of Standard

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

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

4.6.2.1 The involved Trauma Center will be notified of the investigation in writing with a request for its written response.

4.6.2.2 The assigned investigation committee will conduct an appropriate follow-up investigation.

4.6.3 The Designation Committee taskforce will submit its report and recommendation for one of the following to the Director of the Division of Public Health:

4.6.3.1 Probation until the deficiency is remedied and accepted by DPH. The Designation taskforce will include a timeframe and method by which the hospital must demonstrate compliance with the standard.

4.6.3.2 Status change to Participating Hospital until the deficiency is remedied and accepted by DPH (revocation of Trauma Center designation).

4.6.3.3 Continuation of current Trauma Center designation.

4.6.4 If probation or revocation of designation is recommended, the Designation Committee report will include recommended steps necessary for reinstatement. This will 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 American College of Surgeons site visit may be recommended.

4.6.5 If probation or revocation of designation is not recommended, the Designation Committee may recommend follow-up monitoring or reporting.

4.6.6 The Director, Division of Public Health, will make a decision on the action to be taken after consideration of the investigation committee's report. Written notification of the action will be forwarded to the hospital.

4.6.7 If a hospital is unable to demonstrate compliance in the specified timeframe it must submit a written progress report and request for a deadline extension to the Director of Public Health. Failure to comply within the specified timeframe without requesting such an extension will result in change of status from probationary to Participating Hospital.

4.6.7.1 A hospital may relinquish its Trauma Center designation through written notification of the Director of Public Health if it chooses not to pursue correction of ~~the~~ a deficiency.

4.6.7.2 If a hospital fails to comply with an extended timeframe, the Director of Public Health may require a full American College of Surgeons verification site visit in order for a hospital to be reinstated at its former level of designation.

4.7 Appeal Process

4.7.1 The involved Trauma Center will have the right to appeal any decision of the Division of Public Health regarding initial or subsequent designation or a change in designation status.

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

4.7.1.2 The Director of the Division of Public Health will name an impartial panel to hear the hospital's case and make recommendations. The panel will consist of three members of the Trauma System Committee who have no relationship with the appealing hospital and have not been involved in the case in any way. At least one of these will be affiliated with a Delaware Trauma Center in a different county from the appealing hospital.

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

4.7.1.4 Information pertinent to the case will 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 hospital. The presentations will be audio-recorded and transcribed by DPH staff.

4.7.1.5 The hearing panel will make a recommendation to the Director of the Division of Public Health that the original decision stand, be reversed, or be modified (specific recommendations for the modification should be outlined).

4.7.1.6 The Director of Public Health will make a decision based on the hearing panel's recommendation within thirty days of the hearing's conclusion and will provide written notification of the action to the hospital.

4.8 Reinstatement Process

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

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

4.8.3 Outcomes of the review may be:

4.8.3.1 Return to previous level of designation or end of probation.

4.8.3.2 Designate at lower level until reverified by ACS.

4.8.3.3 Remain at Participating Hospital level until reverified by ACS.

5.0 State of Delaware Trauma Center Standards

5.1 Delaware Adult and Pediatric Trauma Center and Participating Hospital Standards will be those of the current American College of Surgeons' Committee on Trauma Verification/Consultation Program for Hospitals as published in their *Resources for Optimal Care of the Injured Patient:~~1999~~* ~~(Chapter 23 pages 99-102 and Chapter 10, Table 1, page 40)~~ *2006* and subsequent revisions.

5.1.1 Delaware may modify existing American College of Surgeons' Committee on Trauma Standards to increase the level of the requirement.

5.1.2 Because American College of Surgeons verification is a requirement for designation as a Delaware Trauma Center, no American College of Surgeons Trauma Standard may be modified so as to decrease the level of the requirement.

5.1.3 The process for modifying an existing American College of Surgeons Standard is:

5.1.3.1 The Trauma System Committee will discuss and vote to recommend to the Director of the Division of Public Health that a modification be made.

5.1.3.2 If approved by the Director, the existing Delaware Trauma System regulations will be revised following the usual promulgation of regulations procedures of Delaware Health and Social Services and the Division of Public Health.

5.1.4 Copies of the current American College of Surgeons' *Resources for Optimal Care of the Injured Patient:~~1999~~* may be obtained by contacting the American College of Surgeons' Publication Orders Department at 633 N. Saint Clair Street in Chicago, IL, 60611 or by telephone at (312) 202-5000.

5.1.4.1 Additionally, The Office of Emergency Medical Services (~~Blue Hen Corporate Center Suite 4H, Dover (302) 739-6637~~ 100 Sunnyside Road, Smyrna, DE. 19977, (302)223-1350) and Division of Public Health Director's Office (Jesse Cooper Building, Dover, (302) 739-4701) will each have a copy of this document available on site for public reference.

5.1.4.2 Each County Library System will also have a copy of this document available for public reference (New Castle County (302) 395-~~5680~~5555, Kent County (302) 698-6440, Sussex County (302) 855-7890).

5.2 The modifications to the current American College of Surgeons Standards in effect for Delaware Trauma System facilities are:

Regional Trauma Center		Community	Participating
Level 1	Level 2	Trauma Center	Hospital

5.2.1 Clinical Capabilities

5.2.1.1 Trauma surgeons~~, neurosurgeons, and orthopedic surgeons~~ must be dedicated to one hospital when on call (taking call at only one institution at a time) or there must be a physician on back-up call at each institution he/she is covering.

Essential

5.2.2 Clinical Qualifications

5.2.2.1 Trauma ~~surgeons~~ medical directors and physician liaisons to the trauma program from, neurosurge~~ons~~ry, Emergency Medicine ~~department physicians~~, and orthopedics ~~surgeons~~ must obtain 16 hours of verifiable, external trauma or trauma-related Continuing Medical Education credits per year, or 48 hours in 3 years.

Essential

5.2.2.2 Other trauma surgeons who take trauma call must have the documented 16 hours annually or 48 hours in 3 years of trauma-related CME or participate in an internal educational process conducted by the trauma program based on the principles of practice-based learning and the PIPS program.

Essential

5.2.2.3 Other neurosurgery, Emergency Medicine, and orthopedic physicians who take trauma call must have the documented 16 hours annually or 48 hours in 3 years of trauma-related CME or participate in an internal educational process conducted by the trauma program based on the principles of practice-based learning and the PIPS program.

Desirable

5.2.2.~~2~~4 Emergency Medicine department physicians, orthopedic surgeons, and neurosurgeons taking trauma call must be Board certified or eligible.

(NOTE: Non-boarded physicians in these specialty areas who have active privileges at a designated Trauma System facility at the time of promulgation of these revisions will be grandfathered.)

Essential

5.2.3 Collaborative Clinical Services – Radiology

5.2.3.1 Board certified or board eligible attending radiologists with privileges in diagnostic radiology are available 24/7, in person or by teleradiology, for the interpretation of radiographs, performance of complex imaging studies, and interventional procedures.

Essential

5.2.4 Trauma System Participating Hospital Essential Criteria

5.2.4.1 Institutional Organization

5.2.4.1.1 Trauma program

5.2.4.1.2 Trauma Director

5.2.4.1.3 Trauma team/activation procedure

5.2.4.1.4 Trauma coordinator, may be part-time

5.2.4.2 Clinical Capabilities

5.2.4.2.1 Published on-call schedule

5.2.4.3 Clinical Qualifications

5.2.4.3.1 General/trauma surgeon – ATLS completion

5.2.4.3.2 Emergency Medicine physician – ATLS completion

5.2.4.4 Facilities/Resources/Capabilities

5.2.4.4.1 Presence of surgeon at operative procedures

5.2.4.4.2 24 hour Emergency Medicine physician coverage

5.2.4.5 Emergency Department

5.2.4.5.1 Equipment for resuscitation for patients of all ages:

5.2.4.5.1.1 Airway control and ventilation equipment

5.2.4.5.1.2 Pulse oximetry

5.2.4.5.1.3 Suction devices

5.2.4.5.1.4 Electrocardiograph-cardiac monitor-defibrillator

5.2.4.5.1.5 Standard intravenous fluids and administration sets

5.2.4.5.1.6 Large-bore intravenous catheters

5.2.4.5.1.7 Sterile surgical sets for airway control/cricothyrotomy, thoracostomy, venous cutdown

5.2.4.5.1.8 Drugs necessary for emergency care

5.2.4.5.1.9 Broselow tape

5.2.4.5.1.10 Thermal control equipment for patient

5.2.4.5.1.11 Qualitative end-tidal carbon dioxide determination

5.2.4.5.1.12 Communication with emergency vehicles

5.2.4.6 Operating Room

5.2.4.6.1 Personnel available 24 hours a day

5.2.4.6.2 Thermal control equipment for patient, fluids, and blood

5.2.4.6.3 Xray capability, including c-arm image intensifier

5.2.4.7 Postanesthetic Recovery Room

5.2.4.7.1 Equipment for monitoring and resuscitation

5.2.4.7.2 Pulse oximetry

5.2.4.7.3 Thermal control

5.2.4.8 Clinical Laboratory Service (available 24 hours/day)

5.2.4.8.1 Standard analyses of blood, urine, other body fluids, and microsampling when appropriate

5.2.4.8.2 Blood typing and cross-matching

5.2.4.8.3 Coagulation studies

5.2.4.8.4 Comprehensive blood bank or access to community/central blood bank and adequate storage facilities

5.2.4.8.5 Blood gases and pH determinations

5.2.4.8.6 Microbiology

5.2.4.9 Trauma Transfer Agreements including hemodialysis, burn care, acute spinal cord management, and rehabilitation, approved by the Trauma Medical Director and monitored by the Performance Improvement program, that define appropriate patients for transfer and retention.

5.2.4.10 Performance Improvement Programs

5.2.4.10.1 Trauma Registry participation in state, local, or regional registry

5.2.4.10.2 Audit of all trauma deaths

5.2.4.10.3 Morbidity and mortality review

5.2.4.10.4 Medical nursing audit

5.3 Designated Trauma System facilities will continue to function in accordance with the Trauma Facility – Division of Public Health Memoranda of Agreement signed upon designation.

5 DE Reg. 632 (9/1/01)

6.0 State of Delaware Triage, Transport and Transfer Protocols

~~Prehospital Trauma Triage Scheme Implementation Guidelines~~ Due to the dynamic nature of identification and evolution of best practices in prehospital care, the prehospital trauma triage guidance will 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 will ask for input by the State EMS Medical Director through the Trauma System Manager during every Standing Orders revision process.

~~6.1.1 The Triage Scheme is designed to serve as a tool for the prehospital provider to use in a step-by-step manner in order to arrive at appropriate triage decisions for trauma patients. Based on the American College of Surgeons' Committee on Trauma's *Resources for Optimal Care of the Injured Patient:1993* and the American College of Emergency Physicians' *Guidelines for Trauma Care Systems*, it is laid out to~~

~~follow the logical progression of assessment used when responding to a trauma call. Step 1 takes place as the responder approaches the scene and notes mechanism of injury, followed by the notation of obvious injuries (Step 2) observed as the provider approaches the patient. Step 3 criteria are vital sign parameters.~~

~~6.1.2 A patient who meets any one of the Step 1, 2 or 3 criteria needs to be triaged to a Regional Level 1 Trauma Center, Regional Level 2 Trauma Center, or Community Trauma Center. These patients are also appropriate candidates for air transport depending on scene location and aircraft availability.~~

~~6.1.3 All prehospital personnel who are caring for a patient meeting Triage Scheme criteria should alert the receiving hospital of this as early as possible so that the facility can assemble its trauma team prior to the patient's arrival.~~

~~6.1.4 Any patient with an unmanageable airway is to be transported to the closest hospital for definitive airway management and subsequent trauma triage.~~

~~6.1.5 All 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 triaged to a Trauma Center with an available neurosurgeon.~~

~~6.1.6 The most critical and unstable patients should be triaged to the higher level Trauma Center whenever transport time to two Trauma Centers is nearly the same. This will save the patient the time required for later interfacility transfer if a higher level of care or resources is needed.~~

~~6.1.7 **Major burns** (STEP 2) are defined as:~~

~~3rd degree burns > 5% BSA (Body Surface Area) - all ages,~~

~~2nd or 3rd degree burns > 10% BSA - patients < 10 or > 50 years of age,~~

~~2nd or 3rd degree burns> 20% BSA- all ages,~~

~~2nd or 3rd degree burns involving face, hands, feet, genitalia, perineum, or major joints - all ages,~~

~~Significant electrical burns including lightening injury - all ages,~~

~~Significant chemical burns - all ages,~~

~~Inhalation injury - all ages, and~~

~~Burn injury in patients with significant pre-existing illnesses, such as respiratory or cardiac disease.~~

~~6.1.8 If a patient fails to meet any of the criteria of Steps 1, 2 or 3, assessment should be made for the criteria listed in Step 4. The presence of one or more of these conditions should raise the index of suspicion for serious injury, and a triage decision should be made in consultation with Medical Control.~~

~~6.1.9 Patients who meet no criteria of the Triage Scheme may be transported to the closest hospital.~~

~~6.1.10 If there is any doubt about whether or not a patient needs to be in a Trauma Center, Medical Control should be consulted and consideration given to transporting the patient to a Trauma Center for evaluation.~~

~~6.1.11 The run sheet, with full documentation of the call, must be left at the hospital for inclusion in the patient's medical record and later use by the hospital's Trauma Registry.~~

6.1~~12~~ In order to be considered a participant in Delaware's ~~Prehospital~~ Trauma System ~~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.

~~6.1.13 The duPont Hospital for Children is prepared to accept and manage children and adolescents through the age of 18 years. However, any pregnant adolescent should be considered to be an adult and transported to an adult Trauma Center.~~

6.2 Air Transport Guidelines

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 ~~*Prehospital Trauma Triage Scheme*, Steps 1, 2, and 3~~ 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.

Air transport is appropriate for a seriously injured trauma patient (see ~~*Prehospital Trauma Triage Scheme, Steps 1, 2, 3*~~ Delaware Paramedic and Basic Life Support Standing Orders*)* when ground transport time to a Trauma Center will exceed 10 minutes. 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.

If transport time between two 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 1 or Level 2 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.

The most appropriate mode of transportation to be utilized when an interfacility transfer is being arranged is a decision to be made jointly by the receiving and transferring physicians. Again, operational factors as well as clinical factors need to be considered in arriving at the best transport decision in each circumstance.

6.3 High-risk Criteria For Consideration Of Early Transfer Of Injured Patients

These criteria are for use by Community Trauma Centers and Participating Trauma System Hospitals in identifying critical patients requiring early transfer to a higher or more specialized level of care. Their intent is to decrease the need for an extensive, time-consuming workup prior to transfer. (These guidelines are not intended to be hospital-specific.) PLANS FOR TRANSPORT SHOULD BE INITIATED IMMEDIATELY UPON RECOGNITION THAT A PATIENT MEETS ANY OF THE CRITERIA LISTED BELOW. PATIENTS WHO MEET EARLY TRANSFER CRITERIA SHOULD BE ENROUTE WITHIN ONE HOUR OF THIS DETERMINATION BEING MADE.

~~Central Nervous System:~~ Head, Neck

Carotid or vertebral arterial injury

Penetrating injury or open fracture (with or without cerebrospinal fluid leak)

Depressed skull fracture

Glasgow Coma Scale (GCS) <~~12~~14 or GCS deterioration

Lateralizing signs

~~Central Nervous System:~~ Spinal Cord

Spinal column injury or major vertebral injury *(limb paresis or paralysis)*

Chest

Major chest wall injury *(penetrating injuries to torso, flail chest)*

Wide mediastinum or other signs suggesting thoracic aorta or other great vessel injury

Cardiac rupture or other cardiac injury

Bilateral pulmonary contusion with PaO2 to FiO2 ratio < 200 >2 unilateral rib fractures, bilateral rib fractures with pulmonary contusion, or other ~~P~~patients who may require mechanical ventilation

Significant torso injury with advanced comorbid disease (see Comorbid Factors below)

Abdomen

Major abdominal vascular injury

Grade IV or V liver injuries requiring > 6 units red blood cell (RBC) transfusion in 6 hours

Pelvis

Unstable pelvic ring disruption

Unstable pelvic fracture with shock or other evidence of continuing hemorrhage requiring > 6 units RBC transfusion in 6 hours)

Open pelvic injury

Major Extremity Injuries

Fracture/dislocation with loss of distal pulses

Complex ~~O~~open or multiple long-bone fractures

Extremity ischemia

Amputation proximal to wrist or ankle

Multiple-system Injury

Head injury combined with face, chest, abdominal, or pelvic injury

Major burns *****, burns with associated injuries

Injury to more than two organ systems

Hemodynamic or respiratory instability

Severe facial fractures or neck injury with potential for airway instability

Secondary Deterioration

Sepsis

Major tissue necrosis

Single or multiple organ system failure (deterioration in central nervous, cardiac, pulmonary, hepatorenal, or coagulation systems)

Comorbid Factors (not stand alone criteria but should increase index of suspicion):

Age<~~12~~15 or>55 years

Pregnancy

Presence of intoxicants

Cardiac or respiratory disease

Insulin-dependent diabetes

Morbid obesity

Immunosuppression

6.4 Burn Center Referral Criteria

6.4.1 Major burns which usually require early referral to a Burn Center include the following:

6.4.1.1 3rd degree burns ~~involving more than 5% Body Surface Area (BSA~~) in all ages,

6.4.1.2 2nd ~~or 3rd~~ degree burns involving more than 10% BSA in patients ~~younger than 10 years or older than 50 years of age~~ of all ages,

~~2nd or 3rd degree burns involving more than 20% BSA in all ages,~~

6.4.1.3 ~~2nd or 3rd degree b~~Burns involving face, hands, feet, genitalia, perineum, or major joints in all ages,

6.4.1.4 ~~Significant e~~Electrical burns including lightening injury in all ages,

6.4.1.5 ~~Significant c~~Chemical burns in all ages,

6.4.1.6 Inhalation injury in all ages,

6.4.1.7 Burn injury in patients with pre-existing ~~illnesses~~ medical disorders that could complicate management, prolong recovery, or affect mortality, ~~and~~

6.4.1.8 Burn injury in patients who will require special social, emotional, or ~~long-term~~ rehabilitative ~~support, including cases involving suspected child abuse and neglect,~~ intervention,

6.4.1.9 Patients with burns and trauma where the burn injury poses the greatest risk of morbidity or mortality. If the trauma poses the greater immediate risk, the patient may be stabilized initially in the trauma center before transfer to a burn center,

6.4.1.10 Burned children in hospitals without qualified personnel or equipment,

~~6.4.2 A burn patient in whom concomitant trauma poses an increased risk of morbidity or mortality may be initially treated in a Trauma Center until stable before transfer to a Burn Center.~~

~~6.4.3 Children with burns should be transferred to a Burn Center with qualified personnel and proper equipment to care for the pediatric burn patient.~~

6.5 Interfacility Transfer Protocol

6.5.1 Rationale: Optimal outcome for the trauma patient is time-related. It is to the patient's advantage to receive definitive care as promptly as possible. In order to perform appropriate and timely hospital-based triage, candidates for interhospital transfer must be identified quickly and the transfer process carried out promptly.

6.5.2 Patient Identification: The physician should utilize the High-Risk Patient Criteria in conjunction with knowledge of available institutional resources to identify patients who would best be served by immediate transfer to a tertiary or specialty care center.

6.5.3 Initiation Of Transfer: Formal written transfer agreements and procedures must be established and made readily available to staff prior to the need for their implementation.

As soon as the need for interhospital transfer is identified, the responsible physician should initiate the transfer process by contacting the responsible physician at the receiving facility following established transfer agreements and procedures. Care of the patient while awaiting transfer will be determined by the referring and receiving physicians. It is NOT necessary to complete all diagnostic studies and/or minor procedures (such as suturing) prior to contacting the receiving facility or prior to transfer.

In physician to physician communication, patient condition and transfer options, including most appropriate mode of transportation and accompanying personnel shall be discussed. The physicians shall also reach an agreement on timeframe of transfer and treatment/diagnostic measures to be completed at transferring versus receiving facility.

6.5.4 Documentation: Full documentation of the patient's course, including initial and subsequent assessment findings, treatment, results of diagnostic studies including copies of x-rays whenever possible should be forwarded to the receiving hospital with or prior to the arrival of the patient (fax).

6.5.5 Quality Management: All transfers in or out will be reviewed as part of both the in-hospital and System Trauma Quality Management processes.

6.5.6 Follow-up: It is the responsibility of every receiving hospital to provide timely feedback to the transferring facility on the status and outcome of each patient received.

7.0 State of Delaware Trauma System Quality Management Plan

7.1 Philosophy

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 American College of Surgeons Committee on Trauma (ACS/COT)'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* <u>and subsequent revisions of these documents</u>. This Performance Improvement Plan seeks to enable this 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.

7.2 Purpose/goals

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-hospital communication, and systems coordination. The plan integrates all pre-hospital, 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.

The goals of the Trauma System's Performance 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." within the state (ACS, 1993, p. 78).

7.3 Objectives

7.3.1 Based on national standards for Facility Quality Improvement set forth in the American College of Surgeon's *Resources for Optimal Care of the Injured Patient* ~~(1993)~~ 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,* ~~*1992*,~~ 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:

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

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

7.3.1.3 Assessment of system competence and performance.

7.4 Authority

The Division of Public Health has the ultimate authority and responsibility for assuring the delivery of quality trauma care throughout the state. The care of the trauma patient is monitored and evaluated at both the Facility and System levels. 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. The Division will provide guidance as needed to individual trauma facilities in the development and implementation of their Trauma Quality Improvement Programs.

Maintenance of patient confidentiality is the joint responsibility of evaluators at the State and Facility levels.

7.5 Pre-hospital Evaluation

7.5.1 Objective

The Division of Public Health shall work with the Fire Prevention Commission to address improvements regarding pre-hospital care of the injured patient. The American College of Emergency Physicians' *Trauma Care System Guidelines* will provide a basis for pre-hospital trauma care evaluation. There will be an on-going 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 will document quality of care provided and compliance with protocols. Areas in need of improvement will be identified**.** Major areas of review are as follows:

Access to the system	Response time
Efficacy of field therapy	Scene time
Transport decisions	Transport time
Transport to the appropriate facility	
Under/over triage	
Documentation	

7.5.2 Data Collection

7.5.2.1 Delaware will follow national standards for pre-hospital data collection. The Division of Public Health will 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 pre-hospital care must be consistent with the design of the Delaware Trauma Registry, as collected by the medical facilities and analyzed by the Division of Public Health.

7.5.2.1.1 Data to be reviewed shall consist of, but not be limited to the following:

7.5.2.1.2 Initial response times

7.5.2.1.3 Completion of primary patient assessment

7.5.2.1.4 Appropriate care of life-threatening conditions

7.5.2.1.5 Trip sheet completion and availability at facility

7.5.2.1.6 Scene time within accepted guidelines

7.5.2.1.7 Proper triage/determination of facility type needed by patient

7.5.2.1.8 Transportation to appropriate facility within an acceptable time frame

7.5.2.2 Quality improvement indicators will be determined by the Trauma System Evaluation Committee based on Delaware pre-hospital protocols and national and Delaware standards of care.

7.5.3 Quality Improvement

A completed pre-hospital patient care record must be provided to the medical receiving facility for inclusion in the patient's emergency room or hospital medical record. Facilities and pre-hospital 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 hospital's Trauma Registrar will include this record's data in the facility's Trauma Registry for outcome evaluation.

A Quality Improvement 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 pre-hospital evaluation process. The Division shall also develop a mechanism for pre-hospital providers to have input into quality assurance issues, including the identification of educational needs and methods of addressing them.

7.6 Trauma Center Evaluation

7.6.1 All designated trauma facilities will design a performance improvement plan which meets the standards and requirements established by the Division of Public Health. The Division shall utilize as guidelines the American College of Surgeons' *Resources for Optimal Care of the Injured Patient: 1993* standards and subsequent revisions ~~(as described in Chapter 6, Section D, page 32, and Chapter 16, pages 77-83)~~. Hospital performance improvement plans will be verified during site survey and quality improvement visits.

7.6.2 Design

When new processes or systems are developed within an institution, the design will be based on the following:

7.6.2.1 Up-to-date sources of information about designing processes and systems including, but not limited to, practice guidelines, clinical pathways, professional standards, and regulatory standards;

7.6.2.2 The needs and expectations of internal and external consumers;

7.6.2.3 The performance of the processes and systems and their outcomes including, but not limited to, internal and external (benchmarking) comparison data.

7.6.3 Measure

Quality indicators (audit filters) will be based on nationally recognized guidelines set forth by the American College of Surgeons. They 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 will 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 will be included.

7.6.3.1 Data collection will be designed to:

7.6.3.1.1 Assess new or existing processes;

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

7.6.3.1.3 Set performance improvement priorities;

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

7.6.3.1.5 Identify patterns and trends that may require focused attention;

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

7.6.3.1.7 Evaluate whether changes have improved the processes.

7.6.3.2 Quality indicators (audit filters) may:

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

7.6.3.2.2 Relate data about either a process or an outcome;

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

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

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

7.6.3.3 Focused audits will be used to periodically examine the process of care as recommended by ACS and may include, but will not be limited to, the following:

7.6.3.3.1 Noncompliance with hospital criteria for trauma center designation

7.6.3.3.2 Trauma attending surgeon arrival times for Trauma Codes

7.6.3.3.3 The absence of documentation of required information/patient assessment findings on trauma care records

7.6.4 Assess

7.6.4.1 After collection the data will be analyzed to determine the following:

7.6.4.1.1 Whether design specifications for new processes were met;

7.6.4.1.2 The level of performance and stability of existing processes;

7.6.4.1.3 Priorities for possible improvement of existing processes;

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

7.6.4.1.5 Whether changes in the processes resulted in improvement.

7.6.4.2 This will be accomplished through the use of 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 will 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.

7.6.4.3 The assessment process will be interdisciplinary and interdepartmental depending upon the process or outcome under review.

7.6.5 Improve

7.6.5.1 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 recommended by the JCAHO, which currently uses the FOCUS-PDCA Model, will be implemented. This model is the ongoing process used to promote continuous improvement as described below:

7.6.5.1.1 Find Process Improvement Opportunity

7.6.5.1.1.1 Develop an opportunity statement

7.6.5.1.1.2 Identify the process

7.6.5.1.2 Organize A Team That Knows The Process

7.6.5.1.2.1 Identify employees who work closest with the process

7.6.5.1.2.2 Identify internal/external consumers and their expectations

7.6.5.1.3 Clarify Current Knowledge Of The Process

7.6.5.1.3.1 Identify sound areas of the process

7.6.5.1.3.2 Determine if team members are appropriate to assess the process

7.6.5.1.3.3 Identify the process flow

7.6.5.1.3.4 Identify problems/redundancies which can be eliminated to make the flow more efficient

7.6.5.1.4 Uncover Causes Of Process Variation

7.6.5.1.4.1 Identify variation in the process

7.6.5.1.4.2 Identify measurable process characteristics

7.6.5.1.4.3 Identify if the variation has a common or unique cause

7.6.5.1.4.4 Identify the effect the variation has on other hospital systems

7.6.5.1.5 Start The Improvement Cycle

7.6.5.1.5.1 Determine what changes can be made to improve the process

7.6.5.1.5.2 Start a description of the process to be improved

7.6.5.1.6 Plan The Improvement And Data Collection

7.6.5.1.6.1 Identify what improvements are to be made and in what order

7.6.5.1.6.2 Assign responsibility for making the change

7.6.5.1.6.3 Determine when the change will be effective

7.6.5.1.6.4 Determine what data will be collected to measure changes

7.6.5.1.7 Do The Improvement

7.6.5.1.7.1 Initiate the change (Pilot study period)

7.6.5.1.7.2 Collect data

7.6.5.1.8 Check The Results

7.6.5.1.8.1 Analyze the results of the data collection

7.6.5.1.8.2 Draw conclusions

7.6.5.1.9 Act In Process And Theory

7.6.5.1.9.1 Standardize the change

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

7.6.5.1.9.3 Policy and procedure development/revision

7.6.5.1.9.4 Education and communication of new process

7.6.5.1.10 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:

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

7.6.5.1.10.2 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

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

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

7.7 Delaware State Trauma Registry

7.7.1 Patient Criteria

In order to generate consistent Statewide data, all patients who meet the following criteria must be included in the hospital Trauma Registry <u>beginning with January 1, 2014 admissions</u>:

7.7.1.1 Patients with an ICD-9 CM N-code diagnosis between 800.00 and 959.9 plus any one or more of the following:

7.7.1.1.1 admission to the hospital ~~for greater than 2 calendar days,~~ or

~~7.7.1.1.2 inpatient operative procedure or~~

~~7.7.1.1.3 admission to the intensive care unit at any time, or~~

7.7.1.1.~~4~~2 transfer to a trauma center or acute care facility, or

7.7.1.1.~~5~~3 transfer from an acute care facility, or

7.7.1.1.~~6~~4 death, including Emergency Department deaths and patients who are dead on arrival.

7.7.1.2 ~~Exclusion: Patients over 55 years having the solitary diagnosis of closed fracture of neck of femur, ICD-9-CM-N-820.0 or 820.2 AND underlying cause of injury defined by E884.2, E885, or E888 (falls on same level, from bed or chair, other falls).~~ INCLUSIONS:

7.7.1.2.1 Drowning

7.7.1.2.2 Smoke Inhalation

7.7.1.2.3 Suffocation

7.7.1.3 EXCLUSIONS;

7.7.1.3.1 Injuries over 72 hours old without previous treatment

7.7.1.3.2 Readmissions for the same injury are added to the existing Registry record

7.7.1.3.3 Injury which is not the reason for hospital admissions

7.7.1.3.4 Exertional injuries particularly over time

7.7.1.3.5 Transfer to psychiatric facility as the only reason for inclusion

7.7.1.3.6 Foreign bodies without injury

7.7.1.3.7 Envenomation

7.7.1.3.8 Late effects of injury (ICD-9 905-909.9) – National Trauma Data Bank (NTDB) exclusion

7.7.1.3.9 Superficial injury codes (ICD-9 910-924.9) – NTDB exclusion

7.7.2 Data Set

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

7.7.2.2 Data collected from contributing acute care facilities will form the State's Trauma System Registry. System Registry data will then be used in the process of formulating System reports, for the purpose of System Quality Improvement, for data linkage, and for research/prevention activities. Researchers may request data for analysis by completing the Trauma System Registry Data Use Agreement.

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

7.7.3 Hospital Participation

7.7.3.1 All acute care in-patient facilities in Delaware which receive traumatically injured patients will be required to contribute to the State Trauma Registry program by collecting and recording electronic data into the hospital Registry system, following the patient criteria described in Section A. All designated trauma facilities must use the complete Trauma Registry form, which includes patient information and facility-specific quality assurance and financial data elements. Non-designated facilities may choose to use the abbreviated Trauma Registry format.

7.7.3.2 Each contributing facility will designate an individual who will have the authority, responsibility and accountability for directing and maintaining the hospital Trauma Registry and its data submission to the State.

7.7.3.3 Each contributing facility will identify a primary data entry person and allow them adequate time and resources 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 will facilitate communications among Registrars and provide educational information to improve data quality. All Registrars will be required to attend scheduled Network meetings and workshops.

7.7.3.4 Both the individual contributing facilities and the State will be responsible for data integrity and confidentiality.

7.8 Trauma System Evaluation

7.8.1 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.

7.8.2 Division Of Public Health Responsibilities

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

7.8.2.2 Appoint a qualified Trauma System Medical Advisor and Trauma System Committee Chairperson from candidates recommended by the Trauma System Committee members. Terms are for three years and successive terms are permissible.

7.8.3 Trauma System Registry Coordinator Responsibilities

7.8.3.1 Review Trauma Registry data submitted for completeness.

7.8.3.2 Provide educational support for Trauma Registrars.

7.8.3.3 Assure maintenance of all minutes and records related to System continuous improvement activities.

7.8.3.4 Function as staff for Evaluation Committee.

7.8.4 Delaware State Trauma System Evaluation Committee

7.8.4.1 The Trauma System Evaluation Committee will be a subcommittee of the Trauma System Committee.

7.8.4.2 Membership consists of representatives from each component of the statewide Trauma System. The Trauma System Medical Advisor will serve as Trauma System Quality Evaluation Committee Chairperson.

7.8.4.2.1 Standing members should 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.

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

7.8.4.3 Responsibilities of Evaluation Committee:

The Delaware Trauma System Quality Evaluation Committee is charged with providing recommendations, advice, and assistance to the Division of Public Health in its ongoing evaluation of the Delaware Trauma System based on American College of Emergency Physicians standards and nationally accepted Continuous Quality Improvement guidelines. Specific functions may include the following:

7.8.4.3.1 Assist the Trauma System Registry Coordinator in the supervision of the State Trauma Registry.

7.8.4.3.2 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.

7.8.4.3.3 Assess resources needed to support and sustain the Delaware State Trauma System.

7.8.4.3.4 Evaluate the coordination and integration of pre-hospital, inter-hospital, intra-hospital, and ancillary services.

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

7.8.4.3.6 Recommend action for identified problems or opportunities for improvement in patient care services.

7.8.4.3.7 Report Quality Improvement activities to the Division of Public Health on a regular basis.

7.8.4.3.8 Sponsor ongoing education regarding ACS, ACEP, and JCAHO standards and provide a multidisciplinary educational forum for presentation and discussion of interesting, difficult, and/or controversial trauma patient management cases.

7.8.4.3.9 Evaluate effectiveness of actions taken and determine follow-up.

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

7.8.4.3.11 Assess other sources of data to combine into a comprehensive database for evaluation of the continuum of trauma care in the State of Delaware.

7.8.4.3.12 Develop operational guidelines for the Committee's functioning.

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

7.8.4.4 Reports:

Report aggregate findings/activities of Evaluation Committee including, but not limited to:

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

7.8.4.4.2 Trend analyses of systems components;

7.8.4.4.3 Recommendations for action when opportunities for improvement are identified;

7.8.4.4.4 Evaluation of effectiveness of actions taken and methodologies for follow-up.

7.8.4.4.5 Support trauma prevention, research, and systems activities by publishing or helping others to publish reports

7.8.4.5 Major areas of Trauma System review will include:

Triage

Interhospital transfer

Facility performance

Impact of system

Integrity of Trauma Registry data

Prevention trends

7.9 Oversight

The Division of Public Health receives at least semi-annual reports of the Trauma System's Evaluation Committee activities. Minutes of each meeting will be forwarded to the Division in a timely manner.

7.10 Confidentiality

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 Evaluation Committee, its subcommittees, and the State Trauma Registry for the stated purpose of trauma system medical review or quality care review and audit.

All quality management proceedings shall be confidential. Records of the State Trauma Evaluation 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.

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.

7.11 Annual Review

This plan is reviewed at least annually by the Division of Public Health and the Quality Evaluation Committee.

~~8.0~~ ~~References~~

~~8.1 American College of Emergency Physicians: *Guidelines for Trauma Care Systems*. Dallas, Texas, ACEP, 1992.~~

~~8.2 American College of Surgeons Committee on Trauma: *Resources for Optimal Care of the Injured Patient:1993.* Chicago, Illinois, ACS, 1993.~~

~~8.3 U.S. Department of Health and Human Services: *Model Trauma Care System Plan.* Rockville, Maryland, DHSS, 1992.~~

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