

# Section 405.45 - Trauma Centers

## 405.45 Trauma Centers

(a) *Definitions.* The following terms when used in this section shall have the following meanings:

(1) “Trauma patient” means a patient at high risk of death or disability from multiple and severe injuries.

(2) “Trauma care” means health care provided to a trauma patient.

(3) “Level I trauma center” means a facility verified by the American College of Surgeons Committee on Trauma (ACS-COT), or other entity determined by the Department, and designated by the Department as a facility that is capable of providing the full range of services required of trauma patients; conducts trauma research; and provides training to surgical residents that comports with the ACS-COT’s publication entitled *Resources for Optimal Care of the Injured Patient* (2014). The standards set forth in the ACS-COT’s publication entitled *Resources for Optimal Care of the Injured Patient* (2014) are hereby incorporated by reference with the same force and effect as if fully set forth herein. A copy of *Resources for Optimal Care of the Injured Patient* (2014) is available for inspection and copying at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237. Copies are also available from the American College of Surgeons Committee on Trauma, 633 North Saint Clair Street, Chicago, Illinois 60611. A Level I trauma center shall have a transfer agreement with at least one pediatric trauma center for trauma patients whose needs exceed the clinical capabilities of the facility.

(4) “Level II trauma center” means a facility verified by the ACS-COT, or other entity determined by the Department, and designated by the Department as a facility that is capable of providing comprehensive trauma care. A Level II trauma center shall have a transfer agreement with at least one Level I trauma center and, unless otherwise designated, at least one pediatric trauma center for trauma patients whose needs exceed the clinical capabilities of the facility.

(5) “Level III trauma center” means a facility verified by the ACS-COT, or other entity determined by the Department, and designated by the Department to serve communities that do not have immediate access to a Level I or II trauma center that is capable of providing prompt assessment, resuscitation, emergency operations and stabilization of trauma patients. A Level III trauma center shall have a transfer agreement with at least one Level I or Level II trauma center, whichever is the most appropriate trauma center, and at least one pediatric trauma center for trauma patients whose needs exceed the clinical capabilities of the facility.

(6) “Level IV trauma center” means a facility located in a rural area verified by the ACS-COT, or other entity determined by the Department, and designated by the Department as a facility that is capable of providing initial evaluation and stabilization of trauma patients prior to transfer to a higher level trauma center. A Level IV trauma center shall have a transfer agreement with at

least one Level I, Level II, or Level III trauma center, whichever is the most appropriate trauma center, and at least one pediatric trauma center for trauma patients whose needs exceed the clinical capabilities of the facility.

(7) “Pediatric trauma center” means a facility verified by the ACS-COT, or other entity determined by the Department, and designated by the Department as a Level I or Level II trauma center and as a facility that is capable of providing comprehensive pediatric trauma care to pediatric trauma patients. A pediatric trauma center shall have a transfer agreement with at least one Level I or Level II trauma center, whichever is the most appropriate trauma center.

(8) “Region” means a defined geographic area of the state where a regional trauma advisory committee has been established pursuant to PHL § 3065.

(9) “Regional Trauma Center” means a Level I or Level II trauma center selected by the Department to coordinate regional trauma performance improvement activities in its region. The Regional Trauma Center will be selected from facilities in a region that have been successfully verified by ACS-COT, or other entity determined by the Department, and designated as a trauma center by the Department, with a history of leadership and commitment to the region.

(10) “Transfer agreement” means a written and fully executed agreement between a hospital that has limited capability to receive and treat trauma patients in need of specialized emergency care and a designated trauma center that is capable of providing such care, for the transfer of such patients, that is consistent with the criteria, policies and procedures set forth in the hospitals’ trauma affiliation agreement with the Regional Trauma Center.

(11) “Trauma affiliation agreement” means a written and fully executed agreement between the Regional Trauma Center and each of the Level I, Level II, Level III, and Level IV trauma centers and non-designated hospitals in the Regional Trauma Center’s region. A trauma affiliation agreement shall include provisions for:

(i) criteria, policies and procedures for the transfer of trauma patients to trauma centers and between levels of trauma center;

(ii) participation in the New York State Trauma Registry including the maintenance of confidentiality and protection of all data provided to the Registry;

(iii) cooperation in outreach, education, training and data collection activities; and

(iv) authority for a representative or representatives of the Regional Trauma Center to participate in and receive information from the affiliate hospital’s quality assurance committee, participate in other reviews of the quality of trauma care provided by the affiliate, and provide recommendations for quality improvement of trauma care.

(b) *General Provisions.*

(1) The Department may designate a hospital as a designated trauma center if the hospital demonstrates that it has met the requirements of section 3066 of the Public Health Law and this Part, to the Department's satisfaction.

(2) Only those hospitals designated as trauma centers by the Department shall admit and provide trauma care to trauma patients; provided, however, that if the existing designated trauma centers have exceeded their capacity during a state-declared disaster or an emergency surge, an undesignated hospital, upon approval by the commissioner, may temporarily provide trauma care.

(3) Any hospital not designated as a trauma center that receives a trauma patient shall transfer such patient to the most appropriate trauma center pursuant to a transfer agreement as required under section 405.19 of this Part. Trauma centers shall be consulted prior to transfer. Trauma patients requiring trauma care shall be transported to the most appropriate trauma centers in accordance with State Emergency Medical Advisory Committee (SEMAC) approved Emergency Medical Services (EMS) protocols developed and adopted pursuant to subdivision two of section 3002-a of the Public Health Law.

(4) No hospital shall state that it has trauma center status unless so designated by the Department.

(c) *Trauma Center Designation*

(1) A hospital seeking designation as a trauma center must receive verification by the American College of Surgeons, Committee on Trauma (ACS-COT), or other entity determined by the Department. To receive verification, the hospital must undergo a consultation site visit and verification site visit by the ACS-COT, or other entity determined by the Department. During the verification site visit, the hospital must exhibit that it is capable of providing Level I, Level II, Level III, Level IV or pediatric trauma care in accordance with the trauma care standards set forth in ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* (2014).

(i) Consultation site visits.

A hospital seeking designation as a trauma center shall request a consultation site visit by the ACS-COT, or other entity determined by the Department, for the purpose of providing recommendations and assistance in preparation for verification.

(a) The cost of the consultation site visit shall be at the facility's own expense.

(b) A hospital shall provide 30 days' notice to the Department prior to any and all consultation site visits.

(c) The Department may participate in any consultation site visits.

(ii) Verification site visit.

A hospital seeking designation as a trauma center shall request an official verification site visit by the ACS-COT, or other entity determined by the Department, no later than two years following a hospital's receipt of its consultation site visit report. The hospital must receive confirmation from the ACS-COT, or other entity determined by the Department, that the hospital meets the criteria for trauma center verification in accordance with the criteria outlined in the ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* (2014).

(a) The cost of any verification site visit shall be at the hospital's own expense.

(b) A hospital shall provide 30 days' notice to the Department prior to any and all verification site visits.

(c) The Department may participate in any verification site visits.

(d) A hospital seeking Level I, Level II, or Level III trauma center designation shall require that any verification review team, as provided by ACS-COT, or other entity determined by the Department, include a nurse reviewer. The hospital shall submit to the Department documentation confirming that a nurse reviewer was a member of the verification review team.

(e) A hospital shall submit to the Department a copy of all verification site visit reports and verification certificates issued by the ACS-COT, or other entity determined by the Department, within ten business days of receipt.

(f) A hospital shall submit to the Department immediately upon receipt any statement of deficiencies found or interim reports of focused surveys issued by the ACS-COT, or other entity determined by the Department, during a verification review.

(g) A hospital shall notify the Department immediately upon receipt of notice of failure to be verified by the ACS-COT, or other entity determined by the Department. Such notification must be made in writing to the Department by the hospital's chief administrative official.

(2) A hospital seeking designation as a trauma center must provide to the Department any additional materials received by the hospital from the ACS-COT, or other entity determined by the Department, upon the Department's request.

(3) A verified trauma center must be re-verified every three years by the ACS-COT, or other entity determined by the Department, and in accordance with subparagraph (ii) of paragraph (1) of subdivision (c) this section.

(d) *Requirements for Operating a Trauma Center.*

(1) Upon designation, a hospital operating a trauma center shall:

(i) remain subject to the provisions of this Part and all other applicable requirements of this Title and of the Public Health Law related to general hospitals;

(ii) comply with the trauma care standards set forth in ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* (2014);

(iii) have age and size appropriate resuscitation equipment consistent with section 405.19(b) and this Part;

(iv) participate and submit information to the New York State Trauma Registry as set forth in subdivision (f) of this section;

(v) maintain transfer agreements with non-designated hospitals and the nearest designated Level I, Level II, Level III and pediatric trauma center, as appropriate for the region, to assure the timely transfer of trauma patients to the appropriate level of trauma care;

(vi) participate in the performance improvement process as set forth in subdivision (g) of this section;

(vii) submit to the Department any notices of noncompliance issued by the ACS-COT, or other entity determined by the Department, within one business day of receipt;

(viii) provide to the Department any additional materials received by the hospital from the ACS-COT, or other entity determined by the Department, upon the Department's request; and

(ix) notify the Department immediately of any inability to meet the capabilities required by its current designation. Such notification must be made in writing to the Department by the hospital's chief administrative official.

(e) *Withdrawal of Designation*

(1) The Department may withdraw designation from a hospital if:

(i) the hospital's trauma center verification certificate lapses;

(ii) the hospital is not issued a certificate of trauma center verification after a reverification site visit; or

(iii) the hospital fails to comply with paragraph (1) of subdivision (d) of this section.

(2) Upon withdrawal of a trauma care designation, the hospital shall immediately take measures to notify affected parties and divert trauma patients to designated trauma centers, and within 30 days, provide to the Department a written plan describing the specific measures it has taken to notify affected parties and its process for diversion of trauma patients to designated trauma centers. In addition, the hospital shall ensure that it has a transfer agreement with at least one designated Level I, Level II or Level III trauma center, whichever is the most appropriate trauma center available, and at least one pediatric trauma center to assure the timely transfer of trauma patients in need of specialized emergency care, consistent with section 405.19 of this Part.

(f) *New York State Trauma Registry.*

Each designated trauma center, and every hospital that treats trauma patients prior to transferring them to a designated trauma center, shall submit information to the New York State Trauma Registry. The data elements that are required to be reported to the New York State Trauma Registry are set forth in the New York State Trauma Registry's data dictionary. Hospitals must submit data to the New York State Trauma Registry at least quarterly and at such other times as the Department may require. The hospital shall have in place appropriate measures to ensure the confidentiality of all information provided to the Registry.

(g) *Performance improvement.*

(1) Each designated trauma center shall participate with the coordinating Regional Trauma Center and other hospitals and healthcare facilities, EMS agencies and governmental disaster preparedness programs in regional trauma performance improvement activities that shall include:

(i) evaluation of the quality and appropriateness of care provided, including providing referring hospitals with information on trauma patient outcome;

(ii) analysis of data from the New York State Trauma Registry, Patient Care Report database and other sources to identify opportunities for improvement. The Regional Trauma Center shall have in place appropriate measures to ensure the confidentiality of all data utilized to conduct this analysis;

(iii) development of trauma protocols, procedures, guidelines and policies;

(iv) assessment of the regional trauma system;

(v) utilization of trauma and EMS data sources to guide public education and injury prevention efforts;

(vi) provision of trauma-related/injury prevention education to allied healthcare providers; and

(vii) participation in emergency and disaster planning including incorporation of resources and capabilities into plans to address mass casualty and other disaster events.

(2) The Regional Trauma Center in each region will coordinate with each hospital within its region to participate in regional trauma performance improvement activities.

(i) Each Regional Trauma Center shall enter into and comply with a trauma affiliation agreement with each hospital in its region. A representative of the Regional Trauma Center may participate in and receive information from the affiliate hospital's quality assurance committee, and may review other reviews of the quality of trauma care provided by the affiliate hospital, in order to make informed recommendations about improving trauma care and about the performance improvement process. Each Regional Trauma Center and each affiliate hospital shall take actions necessary, including but not limited to, incorporating necessary provisions in the trauma

affiliation agreement, to authorize such participation. For purposes of such participation, the Regional Trauma Center's representative(s) shall be deemed a member(s) of the affiliate hospital's quality assurance committee. The Regional Trauma Center's representative(s) shall only access confidential patient information for purposes of quality improvement of trauma care. Members of an affiliate hospital's quality assurance committee shall maintain the confidentiality of patient information and are subject to all applicable confidentiality laws and regulations, including subdivision three of section 3006 of the Public Health Law.

(ii) The Regional Trauma Center shall participate in the review of information and data for quality improvement purposes as described in the affiliation agreement, which shall include:

(a) a quarterly review of all pediatric trauma deaths, delays of three hours or more in transferring trauma patients to a higher level of trauma care, and any transport and/or admission of trauma patients to a non-trauma center;

(b) making quality improvement recommendations for trauma care for the hospitals in its region; and

(c) periodic review, at the Department's request, of potential issues with trauma care in its region identified by the Department during routine analysis of regional data in the New York State Trauma Registry; and

(d) any other activities required by the Department for quality improvement purposes.

(iii) The Regional Trauma Center shall submit to the Department on a quarterly basis a report, in a format determined by the Department, describing its quality improvement reviews of all pediatric trauma deaths, delays of three hours or more in transferring trauma patients to a higher level of trauma care, any transport and/or admission of trauma patients to a non-trauma center and any additional information requested by the Department, and a report, in a format determined by the Department, describing any quality improvement recommendations made to the hospitals in its region.

(iv) The Regional Trauma Center shall cooperate with the Department in regular reviews by the Department of the Regional Trauma Center's quality improvement activities, including providing medical records and other relevant documents and information on a timely basis when requested.

Effective Date:

Wednesday, May 16, 2018

Statutory Authority:

Public Health Law, Sections 2800, 2803, 3063, 3064, 3066, 3074 and 3075