For Consideration by the North Carolina Medical Care Commission

Office of Emergency Medical Services
Request to Initiate Rulemaking Process
For Revisions to the EMS and Trauma Rules 10A NCAC 13P
August 13, 2010

Proposed effective date: April 1, 2011

Section .0200 – EMS Systems

.0201 The agency determined this rule is in need of revision after issues were identified by the EMSAC Education Task Force that pertain to communications centers utilizing emergency medical dispatch priority reference system (EMDPRS) protocols. Specifically, language is being added that require the EMS system to have a defined service area for each communications center providing pre-arrival medical instructions, to require that each center the service 24-7, and for the EMS system providing these services to develop plans for the continued delivery of these services during disaster conditions, during mass casualty incidents, or situations requiring referral to specialty hotlines.

Section .0500 – EMS Personnel

The changes to this section are proposed for revision separate from issues being addressed by the EMSAC Education Task Force.

.0511 This revision is necessary to address the shift from paper fingerprint cards to an electronic scan of an applicants fingerprints. The authority to obtain the fingerprints and criminal background histories is already in statute. This is needed to address changes in technology only and does not expand the agency's authority to gather any additional criminal background history. This revision also addresses the collection of processing fees from the applicant prior to conducting the criminal background history check. There is no increase in background check processing fees and this is already authorized in statute.

Section .0700 – Enforcement

This entire section is being repealed and moved to a new Section .1500 – Denial, Suspension, Amendment, and Revocation. This is considered necessary to make the enforcement rules easier to read and use. Also, the agency will use this opportunity to update criteria within each area of enforcement. A more detailed review will be addressed later on in Section .1500 of this summary document.

Section .0900 – Trauma Center Standards and Approval

This entire section is being reformatted to make it easier to locate the various components and standards for the initial and renewal designation of trauma centers. Currently every aspect of the designation process was contained in five lengthy and difficult to use rules. This reformatting

now expands the criteria for the three levels of trauma centers into 47 focused and specific rules. Furthermore, some of the criteria addressing continuing education, research, and performance improvement are in need of updating. A document that addresses each of these topics is being incorporated by reference into rule that will enable the agency to ensure these standards are kept contemporary and specific to the needs of the healthcare industry as technology and practices continue to advance.

Section .1100 – Trauma System Design

Rules .1101 and .1102 only have minor revisions that reflect current practices on the process for RAC affiliation and how RAC affiliation membership changes should be reported to the OEMS.

Section 1500 – Denial, Suspension, Amendment, or Revocation

This is the new enforcement section. Where the old .0700 sections consisted of two rules, this new section is being expanded to 10 rules. The agency's approach to enforcement is being changed to provide options currently unavailable for EMS systems, educational institutions, and specialty care providers to undergo a focused review when it is determined that an application for designation fails to meet the criteria at the time of designation, but as with trauma centers, utilizing an expanded process enables the applicant to function pending resolution of any noted deficiencies. Also, the criteria warranting administrative sanctions is being expanded to include failures to report, fraudulent representations, or refusal to provide information necessary to verify compliance. There is also additional language that is being included for credentialed personnel to address the new chemical dependency rules to be codified effective January 1, 2011.

10A NCAC 13P .0201 is proposed for amendment as follows:

10A NCAC 13P .0201 EMS SYSTEM REQUIREMENTS

(a) County governments shall establish EMS Systems. Each EMS System shall have:

(1) a defined geographical service area for the EMS System. The minimum service area for an EMS System shall be one county. There may be multiple EMS Provider service areas within the service area of an EMS System. The highest level of care offered within any EMS Provider service area must be available to the citizens within that service area 24 hours per day;

(2) a defined scope of practice for all EMS personnel, functioning in the EMS System, within the parameters set forth by the North Carolina Medical Board pursuant to G.S. 143-514;

(3) written policies and procedures describing the dispatch, coordination and oversight of all responders that provide EMS care, specialty patient care skills and procedures as defined in Rule .0301(a)(4) of this Subchapter, and ambulance transport within the system;

(4) at least one licensed EMS Provider;

(5) a listing of permitted ambulances to provide coverage to the service area 24 hours per day;

(6) personnel credentialed to perform within the scope of practice of the system and to staff the ambulance vehicles as required by G.S. 131E-158. There shall be a written plan for the use of credentialed EMS personnel for all practice settings used within the system;

(7) written policies and procedures specific to the utilization of the EMS System's EMS Care data for the daily and on-going management of all EMS System resources;

(8) a written Infectious Disease Control Policy as defined in Rule .0102(33) of this Subchapter and written procedures which are approved by the EMS System medical director that address the cleansing and disinfecting of vehicles and equipment that are used to treat or transport patients;

(9) a listing of facilities that will provide online medical direction for all EMS Providers operating within the EMS System;

(10) an EMS communication system that provides for:

(A) public access ~~using the emergency telephone number~~ to emergency services by dialing 9-1-1 within the public dial telephone network as the primary method for the public to request emergency assistance. This number shall be connected to the ~~emergency communications center or~~ PSAP with immediate assistance available such that no caller will be instructed to hang up the telephone and dial another telephone number. A person calling for emergency assistance shall not be required to speak with more than two persons to request emergency medical assistance;

(B) ~~an emergency communications system~~ a PSAP operated by public safety telecommunicators with training in the management of calls for medical assistance available 24 hours per day;

(C) dispatch of the most appropriate emergency medical response unit or units to any caller's request for assistance. The dispatch of all response vehicles shall be in accordance with a written EMS System plan for the management and deployment of response vehicles including requests for mutual aid; and

(D) two-way radio voice communications from within the defined service area to the ~~emergency communications center or~~ PSAP and to facilities where patients are routinely transported. The ~~emergency communications system~~ PSAP shall maintain all required FCC radio licenses or authorizations;

(11) written policies and procedures for addressing the use of SCTP and Air Medical Programs within the system;

(12) a written continuing education program for all credentialed EMS personnel, under the direction of a System Continuing Education Coordinator, developed and modified based on feedback from system EMS Care data, review, and evaluation of patient outcomes and quality management peer reviews, that follows the guidelines of the:

(A) "US DOT NHTSA First Responder Refresher: National Standard Curriculum" for MR personnel;

(B) "US DOT NHTSA EMT-Basic Refresher: National Standard Curriculum" for EMT personnel;

(C) "EMT-P and EMT-I Continuing Education National Guidelines" for EMT-I and EMT-P personnel; and

(D) "US DOT NHTSA Emergency Medical Dispatcher: National Standard Curriculum" for EMD personnel.

These documents are incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and additions. These documents are available from NHTSA, 400 7th Street, SW, Washington, D.C. 20590, at no cost;

(13) written policies and procedures to address management of the EMS System that includes:

(A) triage and transport of all acutely ill and injured patients with time-dependent or other specialized care issues including trauma, stroke, STEMI, burn, and pediatric patients that may require the by-pass of other licensed health care facilities and which are based upon the expanded clinical capabilities of the selected healthcare facilities;

(B) triage and transport of patients to facilities outside of the system;

(C) arrangements for transporting patients to appropriate facilities when diversion or bypass plans are activated;

(D) reporting, monitoring, and establishing standards for system response times using data provided by the OEMS;

(E) weekly updating of the SMARTT EMS Provider information;

(F) a disaster plan; and

(G) a mass-gathering plan;

(14) affiliation as defined in Rule .0102(4) of this Subchapter with the trauma RAC as required by Rule .1101(b) of this Subchapter; and

(15) medical oversight as required by Section .0400 of this Subchapter.

(b) Each EMS System that utilizes emergency medical dispatching agencies applying the principles of EMD or offering EMD services, procedures, or programs to the public shall have:

(1) a defined service area for each agency;

(2) adequate personnel within each agency, credentialed in accordance with the requirements of Section .0500 of this Subchapter, to ensure continuous EMD services to the citizens within that service area are available 24 hours per day; and

(3) EMD responsibilities in special situations, such as disasters, multi-casualty incidents, or situations requiring referral to specialty hotlines.

~~(b)~~ (c) An application to establish an EMS System shall be submitted by the county to the OEMS for review. When the system is comprised of more than one county, only one application shall be submitted. The proposal shall demonstrate that the system meets the requirements in Paragraph (a) of this Rule. System approval shall be granted for a period of six years. Systems shall apply to OEMS for reapproval.

History Note: *Authority G.S. 131E-155(1), (6), (8), (9), (15);143-508(b), (d)(1), (d)(2), (d)(3), (d)(5), (d)(8), (d)(9), (d)(10), (d)(13); 143-509(1), (3), (4), (5);143-517; 143-518;*
Temporary Adoption Eff. January 1, 2002;
Eff. August 1, 2004;
Amended Eff. April 1, 2011; January 1, 2009.

10A NCAC 13P .0511 is proposed for amendment as follows:

10A NCAC 13P .0511 CRIMINAL HISTORIES

(a) The criminal background histories for all individuals who apply for EMS credentials, seek to renew EMS credentials, or hold EMS credentials shall be reviewed pursuant to G.S. 131E-159(g).

(b) In addition to Paragraph (a) of this Rule, the OEMS shall carry out the following for all EMS Personnel whose primary residence is outside North Carolina, individuals who have resided in North Carolina for 60 months or less, and individuals under investigation that may be subject to administrative enforcement action by the Department under the provisions of Rule ~~.0701(e)~~ .1508 of this Subchapter:

(1) obtain a signed consent form for a criminal history check;

(2) obtain fingerprints on an SBI identification ~~card; and~~ card or live scan electronic fingerprinting system at an agency approved by the North Carolina Department of Justice, State Bureau of Investigation;

(3) obtain the criminal history from the Department of ~~Justice.~~ Justice; and

(4) collect any processing fees from the individual identified in Paragraph (a) or (b) of this Rule as required by the Department of Justice pursuant to G.S. 114-19.21 prior to conducting the criminal history background check.

(c) An individual is not eligible for initial or renewal of EMS credentials if the applicant refuses to consent to any criminal history check required by G.S. 131E-159(g).

History Note: *Authority G.S. 143-508(d)(3),(10); 131E-159(g); 114-19.21;*
Eff. January 1, ~~2009.~~ 2009;
Amended Eff. April 1, 2011.

10A NCAC 13P .0701 is proposed for repeal as follows:

10A NCAC 13P .0701 DENIAL, SUSPENSION, AMENDMENT OR REVOCATION

History Note: *Authority G.S. 131E-155.1(d); 131E-157(c); 131E-159(a),(f); 131E-162; 143-508(d)(10);*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004;
Amended Eff. January 1, ~~2009.~~ <u>2009;</u>
<u>Repealed Eff. April 1, 2011.</u>

10A NCAC 13P .0702 is proposed for repeal as follows:

10A NCAC 13P .0702 PROCEDURES FOR DENIAL, SUSPENSION, AMENDMENT, OR REVOCATION

History Note: Authority G.S. 143-508(d)(10);
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, ~~2003.~~ 2003;
Repealed Eff. April 1, 2011.

10A NCAC 13P .0901 is proposed for amendment as follows:

SECTION .0900 – TRAUMA CENTER STANDARDS AND APPROVAL

10A NCAC 13P .0901 LEVEL I TRAUMA CENTER APPLICATION CRITERIA

To receive designation as a Level I Trauma Center, a hospital shall ~~have the following:~~ have:

(1) ~~A~~ a trauma program and a trauma service that have been operational for at least 12 months prior to application for designation; and

(2) for at least 12 months prior to submitting a Request for Proposal, ~~Membership~~ membership in and inclusion of all trauma patient records in the North Carolina Trauma ~~Registry for at least 12 months prior to submitting a Request for Proposal;~~ Registry, in accordance with the North Carolina Trauma Registry Data Dictionary, which is incorporated by reference, including subsequent amendments and editions. This document is available online at www.traumaregistry.ncdhhs.gov or by contacting the OEMS at 2707 Mail Service Center, Raleigh, NC 27699-2707, at no cost.

~~(3) A trauma medical director who is a board-certified general surgeon. The trauma medical director must:~~

~~(a) Have a minimum of three years clinical experience on a trauma service or trauma fellowship training;~~

~~(b) Serve on the center's trauma service;~~

~~(c) Participate in providing care to patients with life-threatening or urgent injuries;~~

~~(d) Participate in the North Carolina Chapter of the ACS Committee on Trauma as well as other regional and national trauma organizations;~~

~~(e) Remain a provider in the ACS' ATLS Course and in the provision of trauma-related instruction to other health care personnel; and~~

~~(f) Be involved with trauma research and the publication of results and presentations;~~

~~(4) A full-time TNC/TPM who is a registered nurse, licensed by the North Carolina Board of Nursing;~~

~~(5) A full-time TR who has a working knowledge of medical terminology, is able to operate a personal computer, and has the ability to extract data from the medical record;~~

~~(6) A hospital department/division/section for general surgery, neurological surgery, emergency medicine, anesthesiology, and orthopaedic surgery, with designated chair or physician liaison to the trauma program for each;~~

~~(7) Clinical capabilities in general surgery with separate posted call schedules. One shall be for trauma, one for general surgery and one back-up call schedule for trauma. In those instances where a physician may simultaneously be listed on more than one schedule,~~

~~there must be a defined back-up surgeon listed on the schedule to allow the trauma surgeon to provide care for the trauma patient. If a trauma surgeon is simultaneously on call at more than one hospital, there shall be a defined, posted trauma surgery back up call schedule composed of surgeons credentialed to serve on the trauma panel;~~

~~(8) A trauma team to provide evaluation and treatment of a trauma patient 24 hours per day that includes:~~

~~(a) An in-house trauma attending or PGY4 or senior general surgical resident. The trauma attending participates in therapeutic decisions and is present at all operative procedures.~~

~~(b) An emergency physician who is present in the Emergency Department 24 hours per day who is either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine). Emergency physicians caring only for pediatric patients may, as an alternative, be boarded or prepared in pediatric emergency medicine. Emergency physicians must be board certified within five years after successful completion of a residency in emergency medicine and serve as a designated member of the trauma team to ensure immediate care for the injured patient until the arrival of the trauma surgeon;~~

~~(c) Neurosurgery specialists who are never simultaneously on-call at another Level II or higher trauma center, who are promptly available, if requested by the trauma team leader, unless there is either an in-house attending neurosurgeon, a PGY2 or higher in-house neurosurgery resident or an in-house trauma surgeon or emergency physician as long as the institution can document management guidelines and annual continuing medical education for neurosurgical emergencies. There must be a specified back-up on the call schedule whenever the neurosurgeon is simultaneously on-call at a hospital other than the trauma center;~~

~~(d) Orthopaedic surgery specialists who are never simultaneously on-call at another Level II or higher trauma center, who are promptly available, if requested by the trauma team leader, unless there is either an in-house attending orthopaedic surgeon, a PGY2 or higher in-house orthopaedic surgery resident or an in-house trauma surgeon or emergency physician as long as the institution can document management guidelines and annual continuing medical education for orthopaedic emergencies. There must be a specified written back-up on the call schedule whenever the orthopaedist is simultaneously on-call at a hospital other than the trauma center;~~

1 (e) An in-house anesthesiologist or a CA3 resident as long as an anesthesiologist
2 on-call is advised and promptly available if requested by the trauma team leader;
3 and
4 (f) Registered nursing personnel trained in the care of trauma patients;
5 (9) A written credentialing process established by the Department of Surgery to approve
6 mid-level practitioners and attending general surgeons covering the trauma service. The
7 surgeons must have board certification in general surgery within five years of completing
8 residency;
9 (10) Neurosurgeons and orthopaedists serving the trauma service who are board certified or
10 eligible. Those who are eligible must be board certified within five years after successful
11 completion of the residency;
12 (11) Written protocols relating to trauma management formulated and updated to remain
13 current;
14 (12) Criteria to ensure team activation prior to arrival, and trauma attending arrival within 15
15 minutes of the arrival of trauma and burn patients that include the following conditions:
16 (a) Shock;
17 (b) Respiratory distress;
18 (c) Airway compromise;
19 (d) Unresponsiveness (GSC less than nine) with potential for multiple injuries;
20 (e) Gunshot wound to neck, chest or abdomen;
21 (f) Patients receiving blood to maintain vital signs; and
22 (g) ED physician's decision to activate;
23 (13) Surgical evaluation, based upon the following criteria, by the trauma attending surgeon
24 who is promptly available:
25 (a) Proximal amputations;
26 (b) Burns meeting institutional transfer criteria;
27 (c) Vascular compromise;
28 (d) Crush to chest or pelvis;
29 (e) Two or more proximal long bone fractures; and
30 (f) Spinal cord injury.
31 A PGY4 or higher surgical resident, a PGY3 or higher emergency medicine resident, a
32 nurse practitioner or physician's assistant, who is a member of the designated surgical
33 response team, may initiate the evaluation;
34 (14) Surgical consults for patients with traumatic injuries, at the request of the ED physician,
35 will conducted by a member of the trauma surgical team. Criteria for the consults
36 include:
37 (a) Falls greater than 20 feet;

~~(b) Pedestrian struck by motor vehicle;~~

~~(c) Motor vehicle crash with:~~

~~(i) Ejection (includes motorcycle);~~

~~(ii) Rollover;~~

~~(iii) Speed greater than 40 mph; or~~

~~(iv) Death of another individual in the same vehicle; and~~

~~(d) Extremes of age, less than five or greater than 70 years.~~

~~A senior surgical resident may initiate the evaluation;~~

~~(15) Clinical capabilities (promptly available if requested by the trauma team leader, with a posted on-call schedule), that include individuals credentialed in the following:~~

~~(a) Cardiac surgery;~~

~~(b) Critical care;~~

~~(c) Hand surgery;~~

~~(d) Microvascular/replant surgery, or if service is not available, a transfer agreement must exist;~~

~~(e) Neurosurgery (The neurosurgeon must be dedicated to one hospital or a back-up call schedule must be available. If fewer than 25 emergency neurosurgical trauma operations are done in a year, and the neurosurgeon is dedicated only to that hospital, then a published back-up call list is not necessary);~~

~~(f) Obstetrics/gynecologic surgery;~~

~~(g) Opthalmic surgery;~~

~~(h) Oral maxillofacial surgery;~~

~~(i) Orthopaedics (dedicated to one hospital or a back-up call schedule must be available);~~

~~(j) Pediatric surgery;~~

~~(k) Plastic surgery;~~

~~(l) Radiology;~~

~~(m) Thoracic surgery; and~~

~~(n) Urologic surgery;~~

~~(16) An Emergency Department that has:~~

~~(a) A designated physician director who is board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine);~~

~~(b) 24 hour-per-day staffing by physicians physically present in the ED such that:~~

~~(i) At least one physician on every shift in the ED is either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of~~

~~Emergency Medicine) to serve as the designated member of the trauma team to ensure immediate care until the arrival of the trauma surgeon. Emergency physicians caring only for pediatric patients may, as an alternative, be boarded in pediatric emergency medicine. All emergency physicians must be board certified within five years after successful completion of the residency;~~

~~(ii) All remaining emergency physicians, if not board certified or prepared in emergency medicine as outlined in Subitem (16)(b)(i) of this Rule, are board certified, or eligible by the American Board of Surgery, American Board of Family Practice, or American Board of Internal Medicine, with each being board certified within five years after successful completion of a residency; and~~

~~(iii) All emergency physicians practice emergency medicine as their primary specialty.~~

~~(c) Nursing personnel with experience in trauma care who continually monitor the trauma patient from hospital arrival to disposition to an intensive care unit, operating room, or patient care unit;~~

~~(d) Equipment for patients of all ages to include:~~

~~(i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, pocket masks, and oxygen);~~

~~(ii) Pulse oximetry;~~

~~(iii) End-tidal carbon dioxide determination equipment;~~

~~(iv) Suction devices;~~

~~(v) Electrocardiograph-oscilloscope-defibrillator with internal paddles;~~

~~(vi) Apparatus to establish central venous pressure monitoring;~~

~~(vii) Intravenous fluids and administration devices that include large bore catheters and intraosseous infusion devices;~~

~~(viii) Sterile surgical sets for airway control/cricothyrotomy, thoracotomy, vascular access, thoracostomy, peritoneal lavage, and central line insertion;~~

~~(ix) Apparatus for gastric decompression;~~

~~(x) 24-hour-per-day x-ray capability;~~

~~(xi) Two-way communication equipment for communication with the emergency transport system;~~

~~(xii) Skeletal traction devices, including capability for cervical traction;~~

~~(xiii) Arterial catheters;~~

~~(xiv) Thermal control equipment for patients;~~

~~(xv) Thermal control equipment for blood and fluids;~~

~~(xvi) A rapid infuser system;~~

~~(xvii) A dosing reference and measurement system to ensure appropriate age related medical care;~~

~~(xviii) Sonography; and~~

~~(xix) A doppler;~~

~~(17) An operating suite that is immediately available 24 hours per day and has:~~

~~(a) 24-hour-per-day immediate availability of in-house staffing;~~

~~(b) Equipment for patients of all ages that includes:~~

~~(i) Cardiopulmonary bypass capability;~~

~~(ii) Thermal control equipment for patients;~~

~~(iii) Thermal control equipment for blood and fluids;~~

~~(iv) 24-hour-per-day x-ray capability including c-arm image intensifier;~~

~~(v) Endoscopes and bronchoscopes;~~

~~(vi) Craniotomy instruments;~~

~~(vii) The capability of fixation of long-bone and pelvic fractures; and~~

~~(viii) A rapid infuser system;~~

~~(18) A postanesthetic recovery room or surgical intensive care unit that has:~~

~~(a) 24-hour-per-day in-house staffing by registered nurses;~~

~~(b) Equipment for patients of all ages that includes:~~

~~(i) The capability for resuscitation and continuous monitoring of temperature, hemodynamics, and gas exchange;~~

~~(ii) The capability for continuous monitoring of intracranial pressure;~~

~~(iii) Pulse oximetry;~~

~~(iv) End tidal carbon dioxide determination capability;~~

~~(v) Thermal control equipment for patients; and~~

~~(vi) Thermal control equipment for blood and fluids;~~

~~(19) An intensive care unit for trauma patients that has:~~

~~(a) A designated surgical director for trauma patients;~~

~~(b) A physician on duty in the intensive care unit 24 hours per day or immediately available from within the hospital as long as this physician is not the sole physician on-call for the Emergency Department;~~

~~(c) Ratio of one nurse per two patients on each shift;~~

~~(d) Equipment for patients of all ages that includes:~~

~~(i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, and pocket masks);~~

~~(ii) An oxygen source with concentration controls;~~

~~(iii) A cardiac emergency cart;~~

~~(iv) A temporary transvenous pacemaker;~~

~~(v) Electrocardiograph-oscilloscope-defibrillator;~~

~~(vi) Cardiac output monitoring capability;~~

~~(vii) Electronic pressure monitoring capability;~~

~~(viii) A mechanical ventilator;~~

~~(ix) Patient weighing devices;~~

~~(x) Pulmonary function measuring devices;~~

~~(xi) Temperature control devices; and~~

~~(xii) Intracranial pressure monitoring devices.~~

~~(c) Within 30 minutes of request, the ability to perform blood gas measurements, hematocrit level, and chest x-ray studies;~~

~~(20) Acute hemodialysis capability;~~

~~(21) Physician-directed burn center staffed by nursing personnel trained in burn care or a transfer agreement with a burn center;~~

~~(22) Acute spinal cord management capability or transfer agreement with a hospital capable of caring for a spinal cord injured patient;~~

~~(23) Radiological capabilities that include:~~

~~(a) 24-hour-per-day in-house radiology technologist;~~

~~(b) 24-hour-per-day in-house computerized tomography technologist;~~

~~(c) Sonography;~~

~~(d) Computed tomography;~~

~~(e) Angiography;~~

~~(f) Magnetic resonance imaging; and~~

~~(g) Resuscitation equipment that includes airway management and IV therapy;~~

~~(24) Respiratory therapy services available in-house 24 hours per day;~~

~~(25) 24-hour-per-day clinical laboratory service that must include:~~

~~(a) Analysis of blood, urine, and other body fluids, including micro-sampling when appropriate;~~

~~(b) Blood typing and cross-matching;~~

~~(c) Coagulation studies;~~

~~(d) Comprehensive blood bank or access to community central blood bank with storage facilities;~~

~~(e) Blood gases and pH determination; and~~

~~(f) Microbiology;~~

~~(26) A rehabilitation service that provides:~~

~~(a) A staff trained in rehabilitation care of critically injured patients;~~

~~(b) Functional assessment and recommendations regarding short- and long-term rehabilitation needs within one week of the patient's admission to the hospital or as soon as hemodynamically stable;~~

~~(c) In-house rehabilitation service or a transfer agreement with a rehabilitation facility accredited by the Commission on Accreditation of Rehabilitation Facilities;~~

~~(d) Physical, occupational, speech therapies, and social services; and~~

~~(e) Substance abuse evaluation and counseling capability;~~

~~(27) A performance improvement program, as outlined in the North Carolina Chapter of the American College of Surgeons Committee on Trauma document "Performance Improvement Guidelines for North Carolina Trauma Centers," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. This performance improvement program must include:~~

~~(a) The state Trauma Registry whose data is submitted to the OEMS at least weekly and includes all the center's trauma patients as defined in Rule .0102(68) of this Subchapter who are either diverted to an affiliated hospital, admitted to the trauma center for greater than 24 hours from an ED or hospital, die in the ED, are DOA or are transferred from the ED to the OR, ICU, or another hospital (including transfer to any affiliated hospital);~~

~~(b) Morbidity and mortality reviews including all trauma deaths;~~

~~(c) Trauma performance committee that meets at least quarterly and includes physicians, nurses, pre-hospital personnel, and a variety of other healthcare providers, and reviews policies, procedures, and system issues and whose members or designee attends at least 50 percent of the regular meetings;~~

~~(d) Multidisciplinary peer review committee that meets at least quarterly and includes physicians from trauma, neurosurgery, orthopaedics, emergency medicine, anesthesiology, and other specialty physicians, as needed, specific to the case, and the trauma nurse coordinator/program manager and whose members or designee attends at least 50 percent of the regular meetings;~~

~~(e) Identification of discretionary and non-discretionary audit filters;~~

~~(f) Documentation and review of times and reasons for trauma-related diversion of patients from the scene or referring hospital;~~

~~(g) Documentation and review of response times for trauma surgeons, neurosurgeons, anesthesiologists or airway managers, and orthopaedists. All must demonstrate 80 percent compliance.~~

~~(h) Monitoring of trauma team notification times;~~

~~(i) Review of pre-hospital trauma care that includes dead-on-arrivals; and~~

~~(j) Review of times and reasons for transfer of injured patients;~~

~~(28) An outreach program that includes:~~

~~(a) Transfer agreements to address the transfer and receipt of trauma patients;~~

~~(b) Programs for physicians within the community and within the referral area (that include telephone and on-site consultations) about how to access the trauma center resources and refer patients within the system;~~

~~(c) Development of a Regional Advisory Committee as specified in Rule .1102 of this Subchapter;~~

~~(d) Development of regional criteria for coordination of trauma care;~~

~~(e) Assessment of trauma system operations at the regional level; and~~

~~(f) ATLS;~~

~~(29) A program of injury prevention and public education that includes:~~

~~(a) Epidemiology research that includes studies in injury control, collaboration with other institutions on research, monitoring progress of prevention programs, and consultation with researchers on evaluation measures;~~

~~(b) Surveillance methods that includes trauma registry data, special Emergency Department and field collection projects;~~

~~(c) Designation of a injury prevention coordinator; and~~

~~(d) Outreach activities, program development, information resources, and collaboration with existing national, regional, and state trauma programs.~~

~~(30) A trauma research program designed to produce new knowledge applicable to the care of injured patients that includes:~~

~~(a) An identifiable institutional review board process;~~

~~(b) Educational presentations that must include 12 education/outreach presentations offered outside the trauma center over a three-year period; and~~

~~(c) 10 peer-reviewed publications over a three-year period that could come from any aspect of the trauma program; and~~

~~(31) A written continuing education program for staff physicians, nurses, allied health personnel, and community physicians that includes:~~

~~(a) A general surgery residency program;~~

~~(b) 20 hours of Category I or II trauma-related continuing medical education (as approved by the Accreditation Council for Continuing Medical Education) every two years for all attending general surgeons on the trauma service, orthopedists, and neurosurgeons, with at least 50 percent of this being external education including conferences and meetings outside of the trauma center. Continuing education based on the reading of content such as journals or other continuing~~

~~medical education documents is not considered education outside of the trauma center;~~

~~(c) 20 hours of Category I or II trauma-related continuing medical education (as approved by the Accreditation Council for Continuing Medical Education) every two years for all emergency physicians, with at least 50 percent of this being external education including conferences and meetings outside of the trauma center or visiting lecturers or speakers from outside the trauma center. Continuing education based on the reading of content such as journals or other continuing medical education documents is not considered education outside of the trauma center;~~

~~(d) ATLS completion for general surgeons on the trauma service and emergency physicians. Emergency physicians, if not boarded in emergency medicine, must be current in ATLS;~~

~~(e) 20 contact hours of trauma-related continuing education (beyond in-house in-services) every two years for the TNC/TPM;~~

~~(f) 16 hours of trauma-registry-related or trauma-related continuing education every two years, as deemed appropriate by the trauma nurse coordinator/program manager for the trauma registrar;~~

~~(g) At least an 80 percent compliance rate for 16 hours of trauma-related continuing education (as approved by the TNC/TPM)every two years related to trauma care for RN's and LPN's in transport programs, Emergency Departments, primary intensive care units, primary trauma floors, and other areas deemed appropriate by the TNC/TPM; and~~

~~(h) 16 hours of trauma-related continuing education every two years for mid-level practitioners routinely caring for trauma patients.~~

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. April 1, 2011; January 1, 2009; January 1, 2004.

10A NCAC 13P .0902 is proposed for amendment as follows:

10A NCAC 13P .0902 ~~LEVEL II TRAUMA CENTER CRITERIA~~ LEVEL I TRAUMA CENTER ADMINISTRATION

(a) A Level I Trauma Center shall designate a trauma medical director who is a board-certified general surgeon. The trauma medical director must:

(1) have a minimum of three years clinical experience on a trauma service or trauma fellowship training;

(2) serve on the center's trauma service;

(3) participate in providing care to patients with life-threatening or urgent injuries;

(4) participate in the North Carolina Chapter of the ACS Committee on Trauma as well as other regional and national trauma organizations;

(5) remain a provider in the ACS' ATLS Course and in the provision of trauma-related instruction to other health care personnel; and

(6) be involved with trauma research and the publication of results and presentations.

(b) A Level I Trauma Center shall designate a full-time TNC/TPM who is a registered nurse and licensed by the North Carolina Board of Nursing.

(c) A Level I Trauma Center shall designate a full-time TR who has a working knowledge of medical terminology, is able to operate a personal computer and has the ability to extract data from the medical record.

~~To receive designation as a Level II Trauma Center, a hospital shall have the following:~~

~~(1) A trauma program and a trauma service that have been operational for at least 12 months prior to application for designation;~~

~~(2) Membership in and inclusion of all trauma patient records in the North Carolina Trauma Registry for at least 12 months prior to submitting a Request for Proposal;~~

~~(3) A trauma medical director who is a board-certified general surgeon. The trauma medical director must:~~

~~(a) Have at least three years clinical experience on a trauma service or trauma fellowship training;~~

~~(b) Serve on the center's trauma service;~~

~~(c) Participate in providing care to patients with life-threatening urgent injuries;~~

~~(d) Participate in the North Carolina Chapter of the ACS' Committee on Trauma as well as other regional and national trauma organizations; and~~

~~(e) Remain a provider in the ACS' ATLS and in the provision of trauma related instruction to other health care personnel;~~

~~(4) A full-time trauma nurse coordinator TNC/TPM who is a registered nurse, licensed by the North Carolina Board of Nursing;~~

~~(5) A full-time TR who has a working knowledge of medical terminology, is able to operate a personal computer, and has the ability to extract data from the medical record;~~

~~(6) A hospital department/division/section for general surgery, neurological surgery, emergency medicine, anesthesiology, and orthopedic surgery, with designated chair or physician liaison to the trauma program for each;~~

~~(7) Clinical capabilities in general surgery with separate posted call schedules. One shall be for trauma, one for general surgery and one back-up call schedule for trauma. In those instances where a physician may simultaneously be listed on more than one schedule, there must be a defined back-up surgeon listed on the schedule to allow the trauma surgeon to provide care for the trauma patient. If a trauma surgeon is simultaneously on call at more than one hospital, there shall be a defined, posted trauma surgery back-up call schedule composed of surgeons credentialed to serve on the trauma panel;~~

~~(8) A trauma team to provide evaluation and treatment of a trauma patient 24 hours per day that includes:~~

~~(a) A trauma attending or PGY4 or senior general surgical resident. The trauma attending participates in therapeutic decisions and is present at all operative procedures.~~

~~(b) An emergency physician who is present in the Emergency Department 24 hours per day who is either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine) or board certified or eligible by the American Board of Surgery, American Board of Family Practice, or American Board of Internal Medicine and practices emergency medicine as his primary specialty. This emergency physician if prepared or eligible must be board-certified within five years after successful completion of the residency and serves as a designated member of the trauma team to ensure immediate care for the injured patient until the arrival of the trauma surgeon;~~

~~(c) Neurosurgery specialists who are never simultaneously on-call at another Level II or higher trauma center, who are promptly available, if requested by the trauma team leader, as long as there is either an in-house attending neurosurgeon; a PGY2 or higher in-house neurosurgery resident; or in-house emergency physician or the on-call trauma surgeon as long as the institution can document management guidelines and annual continuing medical education for neurosurgical emergencies. There must be a specified back-up on the call schedule whenever the neurosurgeon is simultaneously on-call at a hospital other than the trauma center;~~

~~(d) Orthopaedic surgery specialists who are never simultaneously on-call at another Level II or higher trauma center, who are promptly available, if requested by the trauma team leader, as long as there is either an in-house attending orthopaedic surgeon; a PGY2 or higher in-house orthopaedic surgery resident; or in-house emergency physician or the on-~~

1 ~~call trauma surgeon as long as the institution can document management guidelines and~~
2 ~~annual continuing medical education for orthopaedic emergencies. There must be a~~
3 ~~specified back-up on the call schedule whenever the orthopaedic surgeon is~~
4 ~~simultaneously on call at a hospital other than the trauma center; and~~
5 ~~(e) An in-house anesthesiologist or a CA3 resident unless an anesthesiologist on-call is~~
6 ~~advised and promptly available after notification or an in-house CRNA under physician~~
7 ~~supervision, practicing in accordance with G.S. 90-171.20(7)e, pending the arrival of the~~
8 ~~anesthesiologist;~~
9 ~~(9) A credentialing process established by the Department of Surgery to approve mid-level~~
10 ~~practitioners and attending general surgeons covering the trauma service. The surgeons must have~~
11 ~~board certification in general surgery within five years of completing residency;~~
12 ~~(10) Neurosurgeons and orthopaedists serving the trauma service who are board certified or eligible.~~
13 ~~Those who are eligible must be board certified within five years after successful completion of the~~
14 ~~residency;~~
15 ~~(11) Written protocols relating to trauma care management formulated and updated to remain current;~~
16 ~~(12) Criteria to ensure team activation prior to arrival, and attending arrival within 20 minutes of the~~
17 ~~arrival of trauma and burn patients that include the following conditions:~~
18 ~~(a) Shock;~~
19 ~~(b) Respiratory distress;~~
20 ~~(c) Airway compromise;~~
21 ~~(d) Unresponsiveness (GCS less than nine with potential for multiple injuries;~~
22 ~~(e) Gunshot wound to neck, chest or abdomen;~~
23 ~~(f) Patients receiving blood to maintain vital signs; and~~
24 ~~(g) ED physician's decision to activate;~~
25 ~~(13) Surgical evaluation, based upon the following criteria, by the health professional who is promptly~~
26 ~~available:~~
27 ~~(a) Proximal amputations;~~
28 ~~(b) Burns meeting institutional transfer criteria;~~
29 ~~(c) Vascular compromise;~~
30 ~~(d) Crush to chest or pelvis;~~
31 ~~(e) Two or more proximal long bone fractures; and~~
32 ~~(f) Spinal cord injury;~~
33 ~~(14) Surgical consults, based upon the following criteria, by the health professional who is promptly~~
34 ~~available:~~
35 ~~(a) Falls greater than 20 feet;~~
36 ~~(b) Pedestrian struck by motor vehicle;~~
37 ~~(c) Motor vehicle crash with:~~

1 ~~(i) Ejection (includes motorcycle);~~
2 ~~(ii) Rollover;~~
3 ~~(iii) Speed greater than 40 mph; or~~
4 ~~(iv) Death of another individual in the same vehicle; or~~
5 ~~(d) Extremes of age, less than five or greater than 70 years;~~
6 ~~(15) Clinical capabilities (promptly available if requested by the trauma team leader, with a posted on-~~
7 ~~call schedule), that include individuals credentialed in the following:~~
8 ~~(a) Critical care;~~
9 ~~(b) Hand surgery;~~
10 ~~(c) Neurosurgery (The neurosurgeon must be dedicated to one hospital or a back-up call~~
11 ~~schedule must be available. If fewer than 25 emergency neurosurgical trauma operations~~
12 ~~are done in a year, and the neurosurgeon is dedicated only to that hospital, then a~~
13 ~~published back-up call list is not necessary.);~~
14 ~~(d) Obstetrics/gynecologic surgery;~~
15 ~~(e) Opthalmic surgery;~~
16 ~~(f) Oral maxillofacial surgery;~~
17 ~~(g) Orthopaedics (dedicated to one hospital or a back-up call schedule must be available);~~
18 ~~(h) Plastic surgery;~~
19 ~~(i) Radiology;~~
20 ~~(j) Thoracic surgery; and~~
21 ~~(k) Urologic surgery;~~
22 ~~(16) An Emergency Department that has:~~
23 ~~(a) A physician director who is board-certified or prepared in emergency medicine (by the~~
24 ~~American Board of Emergency Medicine or the American Osteopathic Board of~~
25 ~~Emergency Medicine);~~
26 ~~(b) 24-hour-per-day staffing by physicians physically present in the Emergency Department~~
27 ~~who:~~
28 ~~(i) Are either board-certified or prepared in emergency medicine (by the American~~
29 ~~Board of Emergency Medicine or the American Osteopathic Board of~~
30 ~~Emergency Medicine or board-certified or eligible by the American Board of~~
31 ~~Surgery, American Board of Family Practice, or American Board of Internal~~
32 ~~Medicine). These emergency physicians must be board-certified within five~~
33 ~~years after successful completion of a residency;~~
34 ~~(ii) Are hospital designated members of the trauma team; and~~
35 ~~(iii) Practice emergency medicine as their primary specialty;~~

~~(c) Nursing personnel with experience in trauma care who continually monitor the trauma patient from hospital arrival to disposition to an intensive care unit, operating room, or patient care unit;~~

~~(d) Equipment for patients of all ages that includes:~~

~~(i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, pocket masks, and oxygen);~~

~~(ii) Pulse oximetry;~~

~~(iii) End-tidal carbon dioxide determination equipment;~~

~~(iv) Suction devices;~~

~~(v) An electrocardiograph-oscilloscope-defibrillator with internal paddles;~~

~~(vi) An apparatus to establish central venous pressure monitoring;~~

~~(vii) Intravenous fluids and administration devices that include large bore catheters and intraosseous infusion devices;~~

~~(viii) Sterile surgical sets for airway control/cricothyrotomy, thoracotomy, vascular access, thoracostomy, peritoneal lavage, and central line insertion;~~

~~(ix) An apparatus for gastric decompression;~~

~~(x) 24-hour-per-day x-ray capability;~~

~~(xi) Two-way communication equipment for communication with the emergency transport system;~~

~~(xii) Skeletal traction devices, including capability for cervical traction;~~

~~(xiii) Arterial catheters;~~

~~(xiv) Thermal control equipment for patients;~~

~~(xv) Thermal control equipment for blood and fluids;~~

~~(xvi) A rapid infuser system;~~

~~(xvii) A dosing reference and measurement system to ensure appropriate age related medical care;~~

~~(xviii) Sonography; and~~

~~(xix) A Doppler;~~

~~(17) An operating suite that is immediately available 24 hours per day and has:~~

~~(a) 24-hour-per-day immediate availability of in-house staffing;~~

~~(b) Equipment for patients of all ages that includes:~~

~~(i) Thermal control equipment for patients;~~

~~(ii) Thermal control equipment for blood and fluids;~~

~~(iii) 24-hour-per-day x-ray capability, including c-arm image intensifier;~~

~~(iv) Endoscopes and bronchoscopes;~~

~~(v) Craniotomy instruments;~~

~~(vi) The capability of fixation of long-bone and pelvic fractures; and~~

~~(vii) A rapid infuser system;~~

~~(18) A postanesthetic recovery room or surgical intensive care unit that has:~~

~~(a) 24 hour per day in house staffing by registered nurses;~~

~~(b) Equipment for patients of all ages to include:~~

~~(i) Capability for resuscitation and continuous monitoring of temperature, hemodynamics, and gas exchange;~~

~~(ii) Capability for continuous monitoring of intracranial pressure;~~

~~(iii) Pulse oximetry;~~

~~(iv) End tidal carbon dioxide determination capability;~~

~~(v) Thermal control equipment for patients; and~~

~~(vi) Thermal control equipment for blood and fluids;~~

~~(19) An intensive care unit for trauma patients that has:~~

~~(a) A hospital designated surgical director of trauma patients;~~

~~(b) A physician on duty in the intensive care unit 24 hours per day or immediately available from within the hospital as long as this physician is not the sole physician on call for the Emergency Department;~~

~~(c) Ratio of one nurse per two patients on each shift;~~

~~(d) Equipment for patients of all ages that includes:~~

~~(i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, and pocket masks);~~

~~(ii) An oxygen source with concentration controls;~~

~~(iii) A cardiac emergency cart;~~

~~(iv) A temporary transvenous pacemaker;~~

~~(v) Electrocardiograph-oscilloscope-defibrillator;~~

~~(vi) Cardiac output monitoring capability;~~

~~(vii) Electronic pressure monitoring capability;~~

~~(viii) A mechanical ventilator;~~

~~(ix) Patient weighing devices;~~

~~(x) Pulmonary function measuring devices;~~

~~(xi) Temperature control devices; and~~

~~(xii) Intracranial pressure monitoring devices; and~~

~~(e) Within 30 minutes of request, the ability to perform blood gas measurements, hematocrit level, and chest x-ray studies;~~

~~(20) Acute hemodialysis capability or utilization of a transfer agreement;~~

~~(21) Physician-directed burn center staffed by nursing personnel trained in burn care or a transfer agreement with a burn center;~~

~~(22) Acute spinal cord management capability or transfer agreement with a hospital capable of caring for a spinal cord injured patient;~~

~~(23) Radiological capabilities that include:~~

~~(a) 24-hour-per-day in-house radiology technologist;~~

~~(b) 24-hour-per-day in-house computerized tomography technologist;~~

~~(c) Sonography;~~

~~(d) Computed tomography;~~

~~(e) Angiography; and~~

~~(f) Resuscitation equipment that includes airway management and IV therapy;~~

~~(24) Respiratory therapy services available in-house 24 hours per day;~~

~~(25) 24 hour-per-day clinical laboratory service that must include:~~

~~(a) Analysis of blood, urine, and other body fluids, including micro-sampling when appropriate;~~

~~(b) Blood-typing and cross-matching;~~

~~(c) Coagulation studies;~~

~~(d) Comprehensive blood bank or access to a community central blood bank with storage facilities;~~

~~(e) Blood gases and pH determination; and~~

~~(f) Microbiology;~~

~~(26) A rehabilitation service that provides:~~

~~(a) A staff trained in rehabilitation care of critically injured patients;~~

~~(b) For trauma patients, functional assessment and recommendation regarding short- and long-term rehabilitation needs within one week of the patient's admission to the hospital or as soon as hemodynamically stable;~~

~~(c) In-house rehabilitation service or a transfer agreement with a rehabilitation facility accredited by the Commission on Accreditation of Rehabilitation Facilities;~~

~~(d) Physical, occupational, speech therapies, and social services; and~~

~~(e) Substance abuse evaluation and counseling capability;~~

~~(27) A performance improvement program, as outlined in the North Carolina Chapter of the American College of Surgeons Committee on Trauma document "Performance Improvement Guidelines for North Carolina Trauma Centers," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. This performance improvement program must include:~~

~~(a) The state Trauma Registry whose data is submitted to the OEMS at least weekly and includes all the center's trauma patients as defined in Rule .0102(68) of this Subchapter who are either diverted to an affiliated hospital, admitted to the trauma center for greater~~

1 than 24 hours from an ED or hospital, die in the ED, are DOA or are transferred from the
2 ED to the OR, ICU, or another hospital (including transfer to any affiliated hospital);
3 (b) Morbidity and mortality reviews that include all trauma deaths;
4 (c) Trauma performance committee that meets at least quarterly and includes physicians,
5 nurses, pre hospital personnel, and a variety of other healthcare providers, and reviews
6 policies, procedures, and system issues and whose members or designee attends at least
7 50 percent of the regular meetings;
8 (d) Multidisciplinary peer review committee that meets at least quarterly and includes
9 physicians from trauma, neurosurgery, orthopaedics, emergency medicine,
10 anesthesiology, and other specialty physicians, as needed, specific to the case, and the
11 TNC/TPM and whose members or designee attends at least 50 percent of the regular
12 meetings;
13 (e) Identification of discretionary and non-discretionary audit filters;
14 (f) Documentation and review of times and reasons for trauma-related diversion of patients
15 from the scene or referring hospital;
16 (g) Documentation and review of response times for trauma surgeons, neurosurgeons,
17 anesthesiologists or airway managers, and orthopaedists. All must demonstrate 80
18 percent compliance;
19 (h) Monitoring of trauma team notification times;
20 (i) Review of pre-hospital trauma care to include dead-on-arrivals; and
21 (j) Review of times and reasons for transfer of injured patients;
22 (28) An outreach program that includes:
23 (a) Transfer agreements to address the transfer and receipt of trauma patients;
24 (b) Programs for physicians within the community and within the referral area (that include
25 telephone and on-site consultations) about how to access the trauma center resources and
26 refer patients within the system;
27 (c) Development of a Regional Advisory Committee as specified in Rule .1102 of this
28 Subchapter;
29 (d) Development of regional criteria for coordination of trauma care; and
30 (e) Assessment of trauma system operations at the regional level;
31 (29) A program of injury prevention and public education that includes:
32 (a) Designation of an injury prevention coordinator; and
33 (b) Outreach activities, program development, information resources, and collaboration with
34 existing national, regional, and state trauma programs; and
35 (30) A written continuing education program for staff physicians, nurses, allied health personnel, and
36 community physicians that includes:

~~(a) 20 hours of Category I or II trauma-related continuing medical education (as approved by the Accreditation Council for Continuing Medical Education) every two years for all attending general surgeons on the trauma service, orthopaedics, and neurosurgeons, with at least 50 percent of this being external education including conferences and meetings outside of the trauma center or visiting lecturers or speakers from outside the trauma center. Continuing education based on the reading of content such as journals or other continuing medical education documents is not considered education outside of the trauma center;~~

~~(b) 20 hours of Category I or II trauma-related continuing medical education (as approved by the Accreditation Council for Continuing Medical Education) every two years for all emergency physicians, with at least 50 percent of this being external education including conferences and meetings outside of the trauma center or visiting lecturers or speakers from outside the trauma center. Continuing education based on the reading of content such as journals or other continuing medical education documents is not considered education outside of the trauma center;~~

~~(c) ATLS completion for general surgeons on the trauma service and emergency physicians. Emergency physicians, if not boarded in emergency medicine, must be current in ATLS.~~

~~(d) 20 contact hours of trauma-related continuing education (beyond in-house in-services) every two years for the TNC/TPM;~~

~~(e) 16 hours of trauma registry-related or trauma-related continuing education every two years, as deemed appropriate by the TNC/TPM, for the trauma registrar;~~

~~(f) at least 80 percent compliance rate for 16 hours of trauma-related continuing education (as approved by the TNC/TPM)every two years related to trauma care for RN's and LPN's in transport programs, Emergency Departments, primary intensive care units, primary trauma floors, and other areas deemed appropriate by the trauma nurse coordinator/program manager; and~~

~~(g) 16 contact hours of trauma-related continuing education every two years for mid-level practitioners routinely caring for trauma patients.~~

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. April 1, 2011; January 1, 2009; January 1, 2004.

10A NCAC 13P .0903 is proposed for amendment as follows:

10A NCAC 13P .0903 ~~LEVEL III TRAUMA CENTER CRITERIA~~ LEVEL I TRAUMA CENTER PHYSICIAN AND TRAUMA TEAM SERVICES

(a) A Level I Trauma Center shall ensure there is a department/division/section for general surgery, neurological surgery, emergency medicine, anesthesiology, and orthopaedic surgery, with a designated chair or physician liaison to the trauma program for each.

(b) Clinical capabilities in general surgery must be posted with separate call schedules. One shall be for trauma, one shall be for general surgery and one shall be a back-up call schedule for trauma. In those instances where a physician may simultaneously be listed on more than one schedule, there must be a defined back-up surgeon listed on the schedule to allow the trauma surgeon to provide care for the trauma patient. If a trauma surgeon is simultaneously on call at more than one hospital, there shall be a defined, posted trauma surgery back-up call schedule composed of surgeons credentialed to serve on the trauma panel.

(c) A Level I Trauma Center shall ensure the availability of a trauma team to provide evaluation and treatment of a trauma patient 24 hours per day that includes:

(1) an in-house trauma attending or PGY4 or senior general surgical resident whose presence at the patients bedside within 15 minutes of notification is documented and who participates in therapeutic decisions and is present at all operative procedures;

(2) an emergency physician who is present in the Emergency Department 24 hours per day who is either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine). Emergency physicians caring only for pediatric patients may, as an alternative, be boarded or prepared in pediatric emergency medicine. Emergency physicians must be board-certified within five years after successful completion of a residency in emergency medicine and serve as a designated member of the trauma team to ensure immediate care for the injured patient until the arrival of the trauma surgeon;

(3) neurosurgery specialists who are never simultaneously on-call at another Level II or higher trauma center, who are promptly available, if requested by the trauma team leader, unless there is either an in-house attending neurosurgeon, a PGY2 or higher in-house neurosurgery resident or an in-house trauma surgeon or emergency physician as long as the institution can document management guidelines and annual continuing medical education for neurosurgical emergencies. There must be a specified back-up on the call schedule whenever the neurosurgeon is simultaneously on-call at a hospital other than the trauma center;

(4) orthopaedic surgery specialists who are never simultaneously on-call at another Level II or higher trauma center, who are promptly available, if requested by the trauma team leader, unless there is either an in-house attending orthopaedic surgeon, a PGY2 or higher in-house orthopaedic surgery resident or an in-house trauma surgeon or emergency physician as long as the institution can

document management guidelines and annual continuing medical education for orthopaedic emergencies. There must be a specified written back-up on the call schedule whenever the orthopaedist is simultaneously on-call at a hospital other than the trauma center;

(5) an in-house anesthesiologist or a CA3 resident as long as an anesthesiologist on-call is advised and promptly available if requested by the trauma team leader; and

(6) registered nursing personnel trained in the care of trauma patients.

(d) A written credentialing process shall be established by the Department of Surgery to approve mid-level practitioners and attending general surgeons covering the trauma service. The surgeons must have board certification in general surgery within five years of completing residency.

(e) Neurosurgeons and orthopaedists serving the trauma service must be board certified or eligible. Those who are eligible must be board certified within five years after successful completion of the residency.

~~To receive designation as a Level III Trauma Center, a hospital shall have:~~

~~(1) A trauma program and a trauma service that have been operational for at least 12 months prior to application for designation;~~

~~(2) Membership in and inclusion of all trauma patient records in the North Carolina Trauma Registry for at least 12 months prior to submitting a Request for Proposal application;~~

~~(3) A trauma medical director who is a board-certified general surgeon. The trauma medical director must:~~

~~(a) Serve on the center's trauma service;~~

~~(b) Participate in providing care to patients with life-threatening or urgent injuries;~~

~~(c) Participate in the North Carolina Chapter of the ACS' Committee on Trauma; and~~

~~(d) Remain a provider in the ACS' ATLS Course in the provision of trauma-related instruction to other health care personnel;~~

~~(4) A hospital-designated trauma nurse coordinator TNC/TPM who is a registered nurse, licensed by the North Carolina Board of Nursing;~~

~~(5) A TR who has a working knowledge of medical terminology, is able to operate a personal computer, and has the ability to extract data from the medical record;~~

~~(6) A hospital department/division/section for general surgery, emergency medicine, anesthesiology, and orthopaedic surgery, with designated chair or physician liaison to the trauma program for each;~~

~~(7) Clinical capabilities in general surgery with a written posted call schedule that indicates who is on call for both trauma and general surgery. If a trauma surgeon is simultaneously on call at more than one hospital, there must be a defined, posted trauma surgery back-up call schedule composed of surgeons credentialed to serve on the trauma panel. The trauma service director shall specify, in writing, the specific credentials that each back-up surgeon must have. These must state that the back-up surgeon has surgical privileges at the trauma center and is boarded or eligible in general surgery (with board certification in general surgery within five years of completing residency);~~

~~(8) Response of a trauma team to provide evaluation and treatment of a trauma patient 24 hours per day that includes:~~

~~(a) A trauma attending whose presence at the patient's bedside within 30 minutes of notification is documented and who participates in therapeutic decisions and is present at all operative procedures;~~

~~(b) An emergency physician who is present in the ED 24 hours per day who is either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine) or board-certified or eligible by the American Board of Surgery, American Board of Family Practice, or American Board of Internal Medicine and practices emergency medicine as his primary specialty. This emergency physician if prepared or eligible must be board-certified within five years after successful completion of the residency and serve as a hospital designated member of the trauma team to ensure immediate care for the trauma patient until the arrival of the trauma surgeon; and~~

~~(c) An anesthesiologist who is on-call and promptly available after notification by the trauma team leader or an in-house CRNA under physician supervision, practicing in accordance with G.S. 90-171.20(7)e, pending the arrival of the anesthesiologist within 30 minutes of notification;~~

~~(9) A credentialing process established by the Department of Surgery to approve mid-level practitioners and attending general surgeons covering the trauma service. The surgeons must have board certification in general surgery within five years of completing residency;~~

~~(10) Board certification or eligibility of orthopaedists and neurosurgeons (if participating),with board certification within five years after successful completion of residency;~~

~~(11) Written protocols relating to trauma care management formulated and updated. Activation guidelines shall reflect criteria that ensures patients receive timely and appropriate treatment including stabilization, intervention and transfer. Documentation of effectiveness of variances from activation criteria addressed in Items (12), (13), and (14) of this Rule must be available for review;~~

~~(12) Criteria to ensure team activation prior to arrival of trauma and burn patients that include the following conditions:~~

~~(a) Shock;~~

~~(b) Respiratory distress;~~

~~(c) Airway compromise;~~

~~(d) Unresponsiveness (GSC less than nine) with evidence for multiple injuries;~~

~~(e) Gunshot wound to neck, or torso; or~~

~~(f) ED physician's decision to activate;~~

~~(13) Trauma Treatment Guidelines based on facility capabilities that ensure surgical evaluation or appropriate transfer, based upon the following criteria, by the health professional who is promptly available:~~

~~(a) Proximal amputations;~~

~~(b) Burns meeting institutional transfer criteria;~~

~~(c) Vascular compromise;~~

~~(d) Crush to chest or pelvis;~~

~~(e) Two or more proximal long bone fractures;~~

~~(f) Spinal cord injury; and~~

~~(g) Gunshot wound to the head;~~

~~(14) Surgical consults or appropriate transfers determined by Trauma Treatment Guidelines based on facility capabilities, based upon the following criteria, by the health professional who is promptly available:~~

~~(a) Falls greater than 20 feet;~~

~~(b) Pedestrian struck by motor vehicle;~~

~~(c) Motor vehicle crash with:~~

~~(i) Ejection (includes motorcycle);~~

~~(ii) Rollover;~~

~~(iii) Speed greater than 40 mph; or~~

~~(iv) Death of another individual in the same vehicle; and~~

~~(d) Extremes of age, less than five or greater than 70 years;~~

~~(15) Clinical capabilities (promptly available if requested by the trauma team leader, with a posted on-call schedule) that include individuals credentialed in the following:~~

~~(a) Orthopaedics;~~

~~(b) Radiology; and~~

~~(c) Neurosurgery, if actively participating in the acute resuscitation and operative management of patients managed by the trauma team;~~

~~(16) An Emergency Department that has:~~

~~(a) A physician director who is board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine);~~

~~(b) 24-hour-per-day staffing by physicians physically present in the Emergency Department who:~~

~~(i) Are either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine) or board-certified or eligible by the American Board of Surgery, American Board of Family Practice, or American Board of Internal~~

~~Medicine. These emergency physicians must be board-certified within five years after successful completion of a residency;~~

~~(ii) Are designated members of the trauma team to ensure immediate care to the trauma patient; and~~

~~(iii) Practice emergency medicine as their primary specialty;~~

~~(c) Nursing personnel with experience in trauma care who continually monitor the trauma patient from hospital arrival to disposition to an intensive care unit, operating room, or patient care unit;~~

~~(d) Resuscitation equipment for patients of all ages that includes:~~

~~(i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, pocket masks, and oxygen);~~

~~(ii) Pulse oximetry;~~

~~(iii) End-tidal carbon dioxide determination equipment;~~

~~(iv) Suction devices;~~

~~(v) An Electrocardiograph-oscilloscope-defibrillator with internal paddles;~~

~~(vi) Apparatus to establish central venous pressure monitoring;~~

~~(vii) Intravenous fluids and administration devices that include large bore catheters and intraosseous infusion devices;~~

~~(viii) Sterile surgical sets for airway control/cricothyrotomy, thoracotomy, vascular access, thoracostomy, peritoneal lavage, and central line insertion;~~

~~(ix) Apparatus for gastric decompression;~~

~~(x) 24-hour-per-day x-ray capability;~~

~~(xi) Two-way communication equipment for communication with the emergency transport system;~~

~~(xii) Skeletal traction devices;~~

~~(xiii) Thermal control equipment for patients;~~

~~(xiv) Thermal control equipment for blood and fluids;~~

~~(xv) A rapid infuser system;~~

~~(xvi) A dosing reference and measurement system to ensure appropriate age-related medical care; and~~

~~(xvii) A Doppler;~~

~~(17) An operating suite that has:~~

~~(a) Personnel available 24 hours a day, on-call, and available within 30 minutes of notification unless in-house;~~

~~(b) Age-specific equipment that includes:~~

~~(i) Thermal control equipment for patients;~~

~~(ii) Thermal control equipment for blood and fluids;~~

~~(iii) 24-hour-per-day x-ray capability, including c-arm image intensifier;~~

~~(iv) Endoscopes and bronchoscopes;~~

~~(v) Equipment for long bone and pelvic fracture fixation; and~~

~~(vi) A rapid infuser system;~~

~~(18) A postanesthetic recovery room or surgical intensive care unit that has:~~

~~(a) 24-hour-per-day availability of registered nurses within 30 minutes from inside or outside the hospital;~~

~~(b) Equipment for patients of all ages that includes:~~

~~(i) The capability for resuscitation and continuous monitoring of temperature, hemodynamics, and gas exchange;~~

~~(ii) Pulse oximetry;~~

~~(iii) End-tidal carbon dioxide determination;~~

~~(iv) Thermal control equipment for patients; and~~

~~(v) Thermal control equipment for blood and fluids;~~

~~(19) An intensive care unit for trauma patients that has:~~

~~(a) A trauma surgeon who actively participates in the committee overseeing the ICU;~~

~~(b) A physician on duty in the intensive care unit 24-hours-per-day or immediately available from within the hospital (which may be a physician who is the sole physician on-call for the ED);~~

~~(c) Equipment for patients of all ages that includes:~~

~~(i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators and pocket masks);~~

~~(ii) An oxygen source with concentration controls;~~

~~(iii) A cardiac emergency cart;~~

~~(iv) A temporary transvenous pacemaker;~~

~~(v) An electrocardiograph-oscilloscope-defibrillator;~~

~~(vi) Cardiac output monitoring capability;~~

~~(vii) Electronic pressure monitoring capability;~~

~~(viii) A mechanical ventilator;~~

~~(ix) Patient weighing devices;~~

~~(x) Pulmonary function measuring devices; and~~

~~(xi) Temperature control devices; and~~

~~(d) Within 30 minutes of request, the ability to perform blood gas measurements, hematocrit level, and chest x-ray studies;~~

~~(20) Acute hemodialysis capability or utilization of a written transfer agreement;~~

~~(21) Physician-directed burn center staffed by nursing personnel trained in burn care or a written transfer agreement with a burn center;~~

~~(22) Acute spinal cord management capability or transfer agreement with a hospital capable of caring for a spinal cord injured patient;~~

~~(23) Acute head injury management capability or transfer agreement with a hospital capable of caring for a head injury;~~

~~(24) Radiological capabilities that include:~~

~~(a) Radiology technologist and computer tomography technologist available within 30 minutes of notification or documentation that procedures are available within 30 minutes;~~

~~(b) Computed Tomography;~~

~~(c) Sonography; and~~

~~(d) Resuscitation equipment that includes airway management and IV therapy;~~

~~(25) Respiratory therapy services on-call 24 hours per day;~~

~~(26) 24-hour-per-day clinical laboratory service that must include:~~

~~(a) Analysis of blood, urine, and other body fluids, including micro-sampling when appropriate;~~

~~(b) Blood-typing and cross-matching;~~

~~(c) Coagulation studies;~~

~~(d) Comprehensive blood bank or access to a community central blood bank with storage facilities;~~

~~(e) Blood gases and pH determination; and~~

~~(f) Microbiology;~~

~~(27) In-house rehabilitation service or transfer agreement with a rehabilitation facility accredited by the Commission on Accreditation of Rehabilitation Facilities;~~

~~(28) Physical therapy and social services;~~

~~(29) A performance improvement program, as outlined in the North Carolina Chapter of the American College of Surgeons Committee on Trauma document "Performance Improvement Guidelines for North Carolina Trauma Centers," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. This performance improvement program must include:~~

~~(a) The state Trauma Registry whose data is submitted to the OEMS at least weekly and includes all the center's trauma patients as defined in Rule .0102(68) of this Subchapter who are either diverted to an affiliated hospital, admitted to the trauma center for greater than 24 hours from an ED or hospital, die in the ED, are DOA or are transferred from the ED to the OR, ICU, or another hospital (including transfer to any affiliated hospital);~~

~~(b) Morbidity and mortality reviews including all trauma deaths;~~

~~(c) Trauma performance committee that meets at least quarterly and includes physicians, orthopaedics and neurosurgery if participating in trauma service, nurses, pre-hospital~~

1 personnel, and a variety of other healthcare providers, and reviews policies, procedures,
2 and system issues and whose members or designee attends at least 50 percent of the
3 regular meetings;
4 (d) Multidisciplinary peer review committee that meets at least quarterly and includes
5 physicians from trauma, emergency medicine, and other specialty physicians as needed
6 specific to the case, and the trauma nurse coordinator/program manager and whose
7 members or designee attends at least 50 percent of the regular meetings;
8 (e) Identification of discretionary and non-discretionary audit filters;
9 (f) Documentation and review of times and reasons for trauma related diversion of patients
10 from the scene or referring hospital;
11 (g) Documentation and review of response times for trauma surgeons, airway managers, and
12 orthopaedists. All must demonstrate 80 percent compliance;
13 (h) Monitoring of trauma team notification times;
14 (i) Documentation (unless in house) and review of Emergency Department response times
15 for anesthesiologists or airway managers and computerized tomography technologist;
16 (j) Documentation of availability of the surgeon on call for trauma, such that compliance is
17 90 percent or greater where there is no trauma surgeon back-up call schedule;
18 (k) Trauma performance and multidisciplinary peer review committees may be incorporated
19 together or included in other staff meetings as appropriate for the facility performance
20 improvement rules;
21 (l) Review of pre-hospital trauma care including dead-on-arrivals; and
22 (m) Review of times and reasons for transfer of injured patients;
23 (30) An outreach program that includes:
24 (a) Transfer agreements to address the transfer and receipt of trauma patients; and
25 (b) Participation in a RAC;
26 (31) Coordination or participation in community prevention activities; and
27 (32) A written continuing education program for staff physicians, nurses, allied health personnel, and
28 community physicians that includes:
29 (a) 20 hours of Category I or II trauma-related continuing medical education (as approved by
30 the Accreditation Council for Continuing Medical Education) every two years for all
31 attending general surgeons on the trauma service, orthopaedists, and neurosurgeons if
32 participating in trauma service, with at least 50 percent of this being external education
33 including conferences and meetings outside of the trauma center or visiting lecturers or
34 speakers from outside the trauma center. Continuing education based on the reading of
35 content such as journals or other continuing medical education documents is not
36 considered education outside of the trauma center;

~~(b) 20 hours of Category I or II trauma-related continuing medical education (as approved by the Accreditation Council for Continuing Medical Education)every two years for all emergency physicians, with at least 50 percent of this being external education including conferences and meetings outside of the trauma center or visiting lecturers or speakers from outside the trauma center. Continuing education based on the reading of content such as journals or other continuing medical education documents is not considered education outside of the trauma center;~~

~~(c) ATLS completion for general surgeons on the trauma service and emergency physicians. Emergency physicians, if not boarded in emergency medicine, must be current in ATLS;~~

~~(d) 20 contact hours of trauma-related continuing education (beyond in-house in- services) every two years for the TNC/TPM;~~

~~(e) 16 hours of trauma registry-related or trauma-related continuing education every two years, as deemed appropriate by the TNC/TPM, for the trauma registrar;~~

~~(f) At least an 80 percent compliance rate for 16 hours of trauma-related continuing education (as approved by the trauma nurse coordinator/program manager) every two years related to trauma care for RN's and LPN's in transport programs, Emergency Departments, primary intensive care units, primary trauma floors, and other areas deemed appropriate by the trauma nurse coordinator/program manager; and~~

~~(g) 16 hours of trauma-related continuing education every two years for mid-level practitioners routinely caring for trauma patients.~~

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. April 1, 2011; January 1, 2009; January 1, 2004.

1 10A NCAC 13P .0904 is proposed for amendment as follows:
2
3 **10A NCAC 13P .0904 ~~INITIAL DESIGNATION~~ LEVEL I TRAUMA CENTER TRAUMA TEAM**
4 **ACTIVATION**
5 To ensure activation of the trauma team for a Level I Trauma Center, the trauma center shall:
6 (1) have written protocols relating to trauma management formulated and updated to remain current;
7 (2) have criteria established to ensure team activation prior to arrival, and trauma attending arrival
8 within 15 minutes of the arrival of trauma and burn patients that include the following conditions:
9 (a) shock;
10 (b) respiratory distress;
11 (c) airway compromise;
12 (d) unresponsiveness (GSC less than nine) with potential for multiple injuries;
13 (e) gunshot wound to neck, chest or abdomen;
14 (f) patients receiving blood to maintain vital signs; and
15 (g) ED physician's decision to activate.
16 (3) ensure performance of a surgical evaluation, based upon the following criteria, by the trauma
17 attending surgeon who is promptly available for the following conditions:
18 (a) proximal amputations;
19 (b) burns meeting institutional transfer criteria;
20 (c) vascular compromise;
21 (d) crush to chest or pelvis;
22 (e) two or more proximal long bone fractures; and
23 (f) spinal cord injury.
24 A PGY4 or higher surgical resident, a PGY3 or higher emergency medicine resident, a nurse
25 practitioner or physician's assistant, who is a member of the designated surgical response team,
26 may initiate the evaluation.
27 (4) ensure surgical consults for patients with traumatic injuries, at the request of the ED physician, be
28 conducted by a member of the trauma surgical team. Criteria for the consults include:
29 (a) falls greater than 20 feet;
30 (b) pedestrian struck by motor vehicle;
31 (c) motor vehicle crash with:
32 (i) ejection (includes motorcycle);
33 (ii) rollover;
34 (iii) speed greater than 40 mph; or
35 (iv) death of another individual in the same vehicle; and
36 (d) extremes of age, less than five or greater than 70 years.
37 A senior surgical resident may initiate the evaluation; and

1. (5) ensure clinical capabilities are available, (promptly available if requested by the trauma team leader, with a posted on-call schedule), that include individuals credentialed in the following:
3. (a) cardiac surgery;
4. (b) critical care;
5. (c) hand surgery;
6. (d) microvascular/replant surgery, or if service is not available, a transfer agreement must exist;
8. (e) neurosurgery (The neurosurgeon must be dedicated to one hospital or a back-up call schedule must be available. If fewer than 25 emergency neurosurgical trauma operations are done in a year, and the neurosurgeon is dedicated only to that hospital, then a published back-up call list is not necessary);
12. (f) obstetrics/gynecologic surgery;
13. (g) opthalmic surgery;
14. (h) oral maxillofacial surgery;
15. (i) orthopaedics (dedicated to one hospital or a back-up call schedule must be available);
16. (j) pediatric surgery;
17. (k) plastic surgery;
18. (l) radiology;
19. (m) thoracic surgery; and
20. (n) urologic surgery.

21. ~~(a) For initial Trauma Center designation, the hospital shall request a consult visit by OEMS and have the consult within one year prior to submission of the RFP.~~

23. ~~(b) A hospital interested in pursuing Trauma Center designation shall submit a letter of intent 180 days prior to the submission of an RFP to the OEMS. The letter shall define the hospital's primary trauma catchment area. Simultaneously, Level I or II applicants shall also demonstrate the need for the Trauma Center designation by submitting one original and three copies of documents that include:~~

27. ~~(1) The population to be served and the extent to which the population is underserved for trauma care with the methodology used to reach this conclusion;~~
29. ~~(2) Geographic considerations to include trauma primary and secondary catchment area and distance from other Trauma Centers; and~~
31. ~~(3) Evidence the Trauma Center will admit at least 1200 trauma patients yearly or show that its trauma service will be taking care of at least 240 trauma patients with an Injury Severity Score (ISS) greater than or equal to 15 yearly. This criteria shall be met without compromising the quality of care or cost effectiveness of any other designated Level I or II Trauma Center sharing all or part of its catchment area or by jeopardizing the existing Trauma Center's ability to meet this same 240 patient minimum.~~

~~(c) The hospital must be actively participating in the state Trauma Registry and submit data to the OEMS at least weekly and include all the Trauma Center's trauma patients as defined in Rule .0102(68) of this Subchapter who are either diverted to an affiliated hospital, admitted to the Trauma Center for greater than 24 hours from an ED or hospital, die in the ED, are DOA or are transferred from the ED to the OR, ICU, or another hospital (including transfer to any affiliated hospital) a minimum of 12 months prior to application.~~

~~(d) OEMS shall review the regional Trauma Registry data, from both the applicant and the existing trauma center(s), and ascertain the applicant's ability to satisfy the justification of need information required in Subparagraphs (b)(1) through (3) of this Rule. Simultaneously, the applicant's primary RAC shall be notified by the OEMS of the application and be provided the regional data as required in Subparagraphs (b)(1) through (3) of this Rule submitted by the applicant for review and comment. The RAC shall be given a minimum of 30 days to submit any concerns in writing for OEMS' consideration. If no comments are received, OEMS shall proceed.~~

~~(e) OEMS shall notify the hospital in writing of its decision to allow submission of an RFP. The RAC shall also be notified by the OEMS so that any necessary changes in protocols can be considered.~~

~~(f) OEMS shall notify the respective Board of County Commissioners in the applicant's trauma primary catchment area of the request for initial designation to allow for comment.~~

~~(g) Hospitals desiring to be considered for initial trauma center designation shall complete and submit one paper copy with signatures and an electronic copy of the RFP to the OEMS at least 90 days prior to the proposed site visit date.~~

~~(h) For Level I, II, and III applicants, the RFP shall demonstrate that the hospital meets the standards for the designation level applied for as found in Rules .0901, .0902, or .0903 of this Section.~~

~~(i) If OEMS does not recommend a site visit based upon failure to comply with Rules .0901, .0902, or .0903, the reasons shall be forwarded to the hospital in writing within 30 days of the decision. The hospital may reapply for designation within six months following the submission of an updated RFP. If the hospital fails to respond within six months, the hospital shall reapply following the process outlined in Paragraphs (a) through (h) of this Rule.~~

~~(j) If the OEMS recommends the hospital for a site visit, the OEMS shall notify the hospital within 30 days and the site visit shall be conducted within six months of the recommendation. The site visit date shall be mutually agreeable to the hospital and the OEMS.~~

~~(k) Any in-state reviewer for a Level I or II visit (except the OEMS representatives) shall be from outside the planning region in which the hospital is located. The composition of a Level I or II state site survey team shall be as follows:~~

~~(1) One out-of-state Fellow of the ACS, experienced as a site surveyor, who shall be designated the primary reviewer;~~

~~(2) One emergency physician who works in a trauma center, is a member of the American College of Emergency Physicians, and is boarded in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine);~~

~~(3) One in-state trauma surgeon who is a member of the North Carolina Committee on Trauma;~~

1 (4) One out-of-state trauma nurse coordinator/program manager and one in-state trauma nurse coordinator/program manager; and
2
3 (5) OEMS Staff.
4 (l) All site team members for a Level III visit shall be from in-state, and all (except for the OEMS representatives)
5 shall be from outside the planning region in which the hospital is located. The composition of a Level III state site
6 survey team shall be as follows:
7 (1) One Fellow of the ACS, who is a member of the North Carolina Committee on Trauma and shall
8 be designated the primary reviewer;
9 (2) One emergency physician who currently works in a designated trauma center, is a member of the
10 North Carolina College of Emergency Physicians, and is boarded in emergency medicine (by the
11 American Board of Emergency Medicine or the American Osteopathic Board of Emergency
12 Medicine);
13 (3) A trauma nurse coordinator/program manager; and
14 (4) OEMS Staff.
15 (m) On the day of the site visit the hospital shall make available all requested patient medical charts.
16 (n) The lead researcher of the site review team shall give a verbal post-conference report representing a consensus
17 of the site review team at the summary conference. A written consensus report shall be completed, to include a peer
18 review report, by the primary reviewer and submitted to OEMS within 30 days of the site visit.
19 (o) The report of the site survey team and the staff recommendations shall be reviewed by the State Emergency
20 Medical Services Advisory Council at its next regularly scheduled meeting which is more than 45 days following
21 the site visit. Based upon the site visit report and the staff recommendation, the State Emergency Medical Services
22 Advisory Council shall recommend to the OEMS that the request for Trauma Center designation be approved or
23 denied.
24 (p) All criteria defined in Rule .0901, .0902, or .0903 of this Section shall be met for initial designation at the level
25 requested. Initial designation shall not be granted if deficiencies exist.
26 (q) Hospitals with a deficiency(ies) shall be given up to 12 months to demonstrate compliance. Satisfaction of
27 deficiency(ies) may require an additional site visit. If compliance is not demonstrated within the time period, to be
28 defined by OEMS, the hospital shall submit a new application and updated RFP and follow the process outlined in
29 Paragraphs (a) through (h) of this Rule.
30 (r) The final decision regarding Trauma Center designation shall be rendered by the OEMS.
31 (s) The OEMS shall notify the hospital in writing, of the State Emergency Medical Services Advisory Council's and
32 OEMS' final recommendation within 30 days of the Advisory Council meeting.
33 (t) If a trauma center changes its trauma program administrative structure (such that the trauma service, trauma
34 medical director, trauma nurse coordinator/program manager or trauma registrar are relocated on the hospital's
35 organizational chart) at any time, it shall notify OEMS of this change in writing within 30 days of the occurrence.
36 (u) Initial designation as a trauma center is valid for a period of three years.
37

1 *History Note:* *Authority G.S. 131E-162; 143-509(3);*
2 *Temporary Adoption Eff. January 1, 2002;*
3 *Eff. April 1, 2003;*
4 *Amended Eff. April 1, 2011; January 1, 2009.*

1 10A NCAC 13P .0905 is proposed for amendment as follows:

2

3 **10A NCAC 13P .0905 ~~RENEWAL DESIGNATION PROCESS~~ LEVEL I TRAUMA CENTER**
4 **EMERGENCY DEPARTMENT CRITERIA**

5 The emergency department of a Level I Trauma Center shall:

6 (1) have a designated physician director who is board-certified or prepared in emergency medicine
7 (by the American Board of Emergency Medicine or the American Osteopathic Board of
8 Emergency Medicine);

9 (2) ensure 24-hour-per-day staffing by physicians physically present in the ED such that:

10 (a) at least one physician on every shift in the ED is either board-certified or prepared in
11 emergency medicine (by the American Board of Emergency Medicine or the American
12 Osteopathic Board of Emergency Medicine) to serve as the designated member of the
13 trauma team to ensure immediate care until the arrival of the trauma surgeon. Emergency
14 physicians caring only for pediatric patients may, as an alternative, be boarded in
15 pediatric emergency medicine. All emergency physicians must be board-certified within
16 five years after successful completion of the residency;

17 (b) all remaining emergency physicians, if not board-certified or prepared in emergency
18 medicine as outlined in Subitem (2)(a) of this Rule, are board-certified, or eligible by the
19 American Board of Surgery, American Board of Family Practice, or American Board of
20 Internal Medicine, with each being board-certified within five years after successful
21 completion of a residency; and

22 (c) all emergency physicians practice emergency medicine as their primary specialty;

23 (3) have nursing personnel with experience in trauma care who continually monitor the trauma patient
24 from hospital arrival to disposition to an intensive care unit, operating room, or patient care unit;
25 and

26 (4) have equipment for patients of all ages to include:

27 (a) airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask
28 resuscitators, pocket masks, and oxygen);

29 (b) pulse oximetry;

30 (c) end-tidal carbon dioxide determination equipment;

31 (d) suction devices;

32 (e) electrocardiograph-oscilloscope-defibrillator with internal paddles;

33 (f) apparatus to establish central venous pressure monitoring;

34 (g) intravenous fluids and administration devices that include large bore catheters and
35 intraosseous infusion devices;

36 (h) sterile surgical sets for airway control/cricothyrotomy, thoracotomy, vascular access,
37 thoracostomy, peritoneal lavage, and central line insertion;

(i) apparatus for gastric decompression;

(j) 24-hour-per-day x-ray capability;

(k) two-way communication equipment for communication with the emergency transport system;

(l) skeletal traction devices, including capability for cervical traction;

(m) arterial catheters;

(n) thermal control equipment for patients;

(o) thermal control equipment for blood and fluids;

(p) a rapid infuser system;

(q) a dosing reference and measurement system to ensure appropriate age related medical care;

(r) sonography; and

(s) a doppler.

~~(a) Hospitals may utilize one of two options to achieve Trauma Center renewal:~~

~~(1) Undergo a site visit conducted by OEMS to obtain a four-year renewal designation; or~~

~~(2) Undergo a verification visit arranged by the ACS, in conjunction with OEMS, to obtain a four-year renewal designation.~~

~~(b) For hospitals choosing Subparagraph (a)(1) of this Rule:~~

~~(1) Prior to the end of the designation period, the OEMS shall forward to the hospital an RFP for completion. The hospital shall, within 10 days of receipt of the RFP, define for OEMS the Trauma Center's trauma primary catchment area. Upon this notification, OEMS shall notify the respective Board of County Commissioners in the applicant's trauma primary catchment area of the request for renewal to allow for comment.~~

~~(2) Hospitals shall complete and submit one paper copy and an electronic copy of the RFP to the OEMS and the specified site surveyors at least 30 days prior to the site visit. The RFP shall include information that supports compliance with the criteria contained in Rule .0901, .0902, or .0903 of this Section as it relates to the Trauma Center's level of designation.~~

~~(3) All criteria defined in Rule .0901, .0902, or .0903 of this Section, as relates to the Trauma Center's level of designation, shall be met for renewal designation.~~

~~(4) A site visit shall be conducted within 120 days prior to the end of the designation period. The site visit shall be scheduled on a date mutually agreeable to the hospital and the OEMS.~~

~~(5) The composition of a Level I or II site survey team shall be the same as that specified in Rule .0904(k) of this Section.~~

~~(6) The composition of a Level III site survey team shall be the same as that specified in Rule .0904(l) of this Section.~~

~~(7) On the day of the site visit the hospital shall make available all requested patient medical charts.~~

~~(8) The primary reviewer of the site review team shall give a verbal post conference report representing a consensus of the site review team at the summary conference. A written consensus report shall be completed, to include a peer review report, by the primary reviewer and submitted to OEMS within 30 days of the site visit.~~

~~(9) The report of the site survey team and a staff recommendation shall be reviewed by the State Emergency Medical Services Advisory Council at its next regularly scheduled meeting which is more than 30 days following the site visit. Based upon the site visit report and the staff recommendation, the State Emergency Medical Services Advisory Council shall recommend to the OEMS that the request for Trauma Center renewal be approved; approved with a contingency(ies) due to a deficiency(ies) requiring a focused review; approved with a contingency(ies) not due to a deficiency(ies) requiring a consultative visit; or denied.~~

~~(10) Hospitals with a deficiency(ies) have up to 10 working days prior to the State EMS Advisory Council meeting to provide documentation to demonstrate compliance. If the hospital has a deficiency that cannot be corrected in this period prior to the State EMS Advisory Council meeting, the hospital, instead of a four-year renewal, shall be given 12 months by the OEMS to demonstrate compliance and undergo a focused review, that may require an additional site visit. The hospital shall retain its Trauma Center designation during the focused review period. If compliance is demonstrated within the prescribed time period, the hospital shall be granted its designation for the four year period from the previous designation's expiration date. If compliance is not demonstrated within the time period, as specified by OEMS, the Trauma Center designation shall not be renewed. To become redesignated, the hospital shall submit an updated RFP and follow the initial applicant process outlined in Rule .0904 of this Section.~~

~~(11) The final decision regarding trauma center renewal shall be rendered by the OEMS.~~

~~(12) The OEMS shall notify the hospital of the State Emergency Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the Advisory Council meeting.~~

~~(13) The four-year renewal date that may be eventually granted shall not be extended due to the focused review period.~~

~~(c) For hospitals choosing Subparagraph (a)(2) of this Rule:~~

~~(1) At least six months prior to the end of the Trauma Center's designation period, the trauma center must notify the OEMS of its intent to undergo an ACS verification visit. It must simultaneously define in writing to the OEMS its trauma primary catchment area. Trauma Centers choosing this option must then comply with all the ACS' verification procedures, as well as any additional state criteria as outlined in Rule .0901, .0902, or .0903, as apply to their level of designation.~~

~~(2) When completing the ACS' documentation for verification, the Trauma Center must ensure access to the ACS on-line PRQ (pre-review questionnaire) to OEMS. The Trauma Center must simultaneously complete documents supplied by OEMS to verify compliance with additional~~

~~North Carolina criteria (i.e., criteria that exceed the ACS criteria) and forward these to OEMS and the ACS.~~

~~(3) The OEMS shall notify the Board of County Commissioners within the trauma center's trauma primary catchment area of the Trauma Center's request for renewal to allow for comments.~~

~~(4) The Trauma Center must make sure the site visit is scheduled to ensure that the ACS' final written report, accompanying medical record reviews and cover letter are received by OEMS at least 30 days prior to a regularly scheduled State Emergency Medical Services Advisory Council meeting to ensure that the Trauma Center's state designation period does not terminate without consideration by the State Emergency Medical Services Advisory Council.~~

~~(5) The composition of the Level I or Level II site team must be as specified in Rule .0904(k) of this Section, except that both the required trauma surgeons and the emergency physician may be from out of state. Neither North Carolina Committee on Trauma nor North Carolina College of Emergency Physician membership is required of the surgeons or emergency physician, respectively, if from out of state. The date, time, and all proposed site team members of the site visit team must be submitted to the OEMS for review at least 45 days prior to the site visit. The OEMS shall approve the site visit schedule if the schedule does not conflict with the ability of attendance by required OEMS staff. The OEMS shall approve the proposed site team members if the OEMS determines there is no conflict of interest, such as previous employment, by any site team member associated with the site visit.~~

~~(6) The composition of the Level III site team must be as specified in Rule .0904(l) of this Section, except that the trauma surgeon, emergency physician, and trauma nurse coordinator/program manager may be from out of state. Neither North Carolina Committee on Trauma nor North Carolina College of Emergency Physician membership is required of the surgeon or emergency physician, respectively, if from out of state. The date, time, and all proposed site team members of the site visit team must be submitted to the OEMS for review at least 45 days prior to the site visit. The OEMS shall approve the site visit schedule if the schedule does not conflict with the ability of attendance by required OEMS staff. The OEMS shall approve the proposed site team members if the OEMS determines there is no conflict of interest, such as previous employment, by any site team member associated with the site visit.~~

~~(7) All state Trauma Center criteria must be met as defined in Rules .0901, .0902, and .0903 of this Section, for renewal of state designation. An ACS' verification is not required for state designation. An ACS' verification does not ensure a state designation.~~

~~(8) ACS reviewers shall complete the state designation preliminary reporting form immediately prior to the post conference meeting. This document and the ACS final written report and supporting documentation described in Subparagraph (c)(4) of this Rule shall be used to generate a staff summary of findings report following the post conference meeting for presentation to the NC EMS Advisory Council for redesignation.~~

~~(9) The final written report issued by the ACS' verification review committee, the accompanying medical record reviews (from which all identifiers may be removed), and cover letter must be forwarded to OEMS within 10 working days of its receipt by the Trauma Center seeking renewal.~~

~~(10) The OEMS shall present its summary of findings report to the State Emergency Medical Services Advisory Council at its next regularly scheduled meeting. The State EMS Advisory Council shall recommend to the Chief of the OEMS that the request for Trauma Center renewal be approved; approved with a contingency(ies) due to a deficiency(ies) requiring a focused review; approved with a contingency(ies) not due to a deficiency(ies); or denied.~~

~~(11) The OEMS shall notify the hospital in writing of the State Emergency Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the Advisory Council meeting.~~

~~(12) Hospitals with contingencies, as the result of a deficiency(ies), as determined by OEMS, have up to 10 working days prior to the State EMS Advisory Council meeting to provide documentation to demonstrate compliance. If the hospital has a deficiency that cannot be corrected in this time period prior to the State EMS Advisory Council meeting, the hospital, instead of a four-year renewal, may undergo a focused review (to be conducted by the OEMS) whereby the Trauma Center is given 12 months by the OEMS to demonstrate compliance. Satisfaction of contingency(ies) may require an additional site visit. The hospital shall retain its Trauma Center designation during the focused review period. If compliance is demonstrated within the prescribed time period, the hospital shall be granted its designation for the four-year period from the previous designation's expiration date. If compliance is not demonstrated within the time period, as specified by OEMS, the Trauma Center designation shall not be renewed. To become redesignated, the hospital shall submit a new RFP and follow the initial applicant process outlined in Rule .0904 of this Section.~~

~~(d) If a Trauma Center currently using the ACS' verification process chooses not to renew using this process, it must notify the OEMS at least six months prior to the end of its state trauma center designation period of its intention to exercise the option in Subparagraph (a)(1) of this Rule.~~

History Note: *Authority G.S. 131E-162; 143-509(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. April 1, 2011; April 1, 2009; January 1, 2009; January 1, 2004.

1 10A NCAC 13P .0906 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0906 LEVEL I TRAUMA CENTER OPERATING ROOM, POST ANESTHESIA CARE**
4 **UNIT AND SURGICAL INTENSIVE CARE UNIT CRITERIA**

5 (a) The operating room of a Level I Trauma Center shall ensure an operating suite is immediately available 24
6 hours per day and has the following:
7 (1) 24-hour-per-day immediate availability of in-house staffing; and
8 (2) equipment for patients of all ages that includes:
9 (A) cardiopulmonary bypass capability;
10 (B) thermal control equipment for patients;
11 (C) thermal control equipment for blood and fluids;
12 (D) 24-hour-per-day x-ray capability including c-arm image intensifier;
13 (E) endoscopes and bronchoscopes;
14 (F) craniotomy instruments;
15 (G) the capability of fixation of long-bone and pelvic fractures; and
16 (H) a rapid infuser system.
17 (b) The post anesthesia care unit or surgical intensive care unit of a Level I Trauma Center shall have:
18 (1) 24-hour-per-day in-house staffing by registered nurses; and
19 (2) equipment for patients of all ages that includes:
20 (A) the capability for resuscitation and continuous monitoring of temperature,
21 hemodynamics, and gas exchange;
22 (B) the capability for continuous monitoring of intracranial pressure;
23 (C) pulse oximetry;
24 (D) end-tidal carbon dioxide determination capability;
25 (E) thermal control equipment for patients; and
26 (F) thermal control equipment for blood and fluids.

27

28 *History Note: Authority G.S. 131E-162;*
29 *Eff. April 1, 2011.*

1 10A NCAC 13P .0907 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0907 LEVEL I TRAUMA CENTER INTENSIVE CARE UNIT AND**

4 **CRITICAL CARE MANAGEMENT CRITERIA**

5 (a) The intensive care unit for trauma patients for a Level I Trauma Center shall have:

6 (1) a designated surgical director for trauma patients;

7 (2) a physician on duty in the intensive care unit 24 hours per day or immediately available

8 from within the hospital as long as this physician is not the sole physician on-call for the

9 emergency department;

10 (3) a ratio of one nurse per two patients on each shift;

11 (4) equipment for patients of all ages that includes:

12 (A) airway control and ventilation equipment (laryngoscopes, endotracheal tubes,

13 bag-mask resuscitators, and pocket masks);

14 (B) an oxygen source with concentration controls;

15 (C) a cardiac emergency cart;

16 (D) a temporary transvenous pacemaker;

17 (E) electrocardiograph-oscilloscope-defibrillator;

18 (F) cardiac output monitoring capability;

19 (G) electronic pressure monitoring capability;

20 (H) a mechanical ventilator;

21 (I) patient weighing devices;

22 (J) pulmonary function measuring devices;

23 (K) temperature control devices; and

24 (L) intracranial pressure monitoring devices; and

25 (5) within 30 minutes of request, the ability to perform blood gas measurements, hematocrit

26 level, and chest x-ray studies.

27 (b) A Level I Trauma Center shall have acute hemodialysis capability.

28 (c) A Level I Trauma Center shall have a physician-directed burn center staffed by nursing personnel

29 trained in burn care or a transfer agreement with a burn center.

30 (d) A Level I Trauma Center shall have an acute spinal cord management capability or transfer agreement

31 with a hospital capable of caring for a spinal cord injured patient.

32

33 *History Note:* *Authority G.S. 131E-162;*

34 *Eff. April 1, 2011.*

1 10A NCAC 13P .0908 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0908 LEVEL I TRAUMA CENTER RADIOLOGY SERVICES CRITERIA**

4 The radiology services for a Level I Trauma Center shall have:

5 (1) a 24-hour-per-day in-house radiology technologist;

6 (2) a 24-hour-per-day in-house computerized tomography technologist;

7 (3) the ability to provide sonography;

8 (4) the ability to provide computed tomography;

9 (5) the ability to provide angiography;

10 (6) the ability to provide magnetic resonance imaging; and

11 (7) resuscitation equipment that includes airway management and IV therapy.

12

13 *History Note: Authority G.S. 131E-162;*

14 *Eff. April 1, 2011.*

1 10A NCAC 13P .0908 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0908 LEVEL I TRAUMA CENTER RADIOLOGY SERVICES CRITERIA**

4 The radiology services for a Level I Trauma Center shall have:

5 (1) a 24-hour-per-day in-house radiology technologist;

6 (2) a 24-hour-per-day in-house computerized tomography technologist;

7 (3) the ability to provide sonography;

8 (4) the ability to provide computed tomography;

9 (5) the ability to provide angiography;

10 (6) the ability to provide magnetic resonance imaging; and

11 (7) resuscitation equipment that includes airway management and IV therapy.

12

13 *History Note: Authority G.S. 131E-162;*

14 *Eff. April 1, 2011.*

1 10A NCAC 13P .0909 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0909 LEVEL I TRAUMA CENTER RESPIRATORY THERAPY AND CLINICAL**

4 **LABORATORY CRITERIA**

5 (a) A Level I Trauma Center shall ensure respiratory therapy services are available in-house 24 hours per day.

6 (b) A Level I Trauma Center shall have a 24-hour-per-day clinical laboratory service that includes:

7 (1) analysis of blood, urine, and other body fluids, including micro-sampling when appropriate;

8 (2) blood-typing and cross-matching;

9 (3) coagulation studies;

10 (4) comprehensive blood bank or access to community central blood bank with storage facilities;

11 (5) blood gases and pH determination; and

12 (6) microbiology.

13

14 *History Note:* *Authority G.S. 131E-162;*

15 *Eff. April 1, 2011.*

1 10A NCAC 13P .0910 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0910 LEVEL I TRAUMA CENTER REHABILITATION SERVICES CRITERIA**

4 The rehabilitation services for a Level I Trauma Center shall:

5 (1) provide a staff trained in rehabilitation care of critically injured patients;

6 (2) for trauma patients, provide a functional assessment with recommendations regarding short- and

7 long-term rehabilitation needs within one week of the patient's admission to the hospital or as soon

8 as hemodynamically stable;

9 (3) provide in-house rehabilitation service or a transfer agreement with a rehabilitation facility

10 accredited by the Commission on Accreditation of Rehabilitation Facilities;

11 (4) provide physical, occupational, speech therapies, and social services; and

12 (5) have substance abuse evaluation and counseling capability.

13

14 *History Note:* *Authority G.S. 131E-162;*

15 *Eff. April 1, 2011.*

1 10A NCAC 13P .0911 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0911 LEVEL I TRAUMA CENTER PERFORMANCE IMPROVEMENT CRITERIA**

4 A Level I Trauma Center shall participate in a performance improvement program, as outlined in the "North
5 Carolina Committee on Trauma, Performance Improvement/Outcomes Subcommittee of the American College of
6 Surgeons: Performance Improvement, Research, and Continuing Education Standards for the North Carolina
7 Trauma System," which is incorporated by reference, including subsequent amendments and editions. This
8 document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost.

9

10 *History Note:* *Authority G.S. 131E-162;*
11 *Eff. April 1, 2011.*

1 10A NCAC 13P .0912 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0912 LEVEL I TRAUMA CENTER OUTREACH PROGRAM, PUBLIC EDUCATION**
4 **AND INJURY PREVENTION CRITERIA**

5 A Level I Trauma Center shall participate in:

6 (1) an outreach program that includes:

7 (a) transfer agreements to address the transfer and receipt of trauma patients;

8 (b) programs for physicians within the community and within the referral area (that include
9 telephone and on-site consultations) about how to access the trauma center resources and
10 refer patients within the system;

11 (c) development of a Regional Advisory Committee as specified in Rule .1102 of this
12 Subchapter;

13 (d) development of regional criteria for coordination of trauma care;

14 (e) assessment of trauma system operations at the regional level; and

15 (f) ATLS.

16 (2) a program of injury prevention and public education that includes:

17 (a) epidemiology research that includes studies in injury control, collaboration with other
18 institutions on research, monitoring progress of prevention programs, and consultation
19 with researchers on evaluation measures;

20 (b) surveillance methods that includes trauma registry data, special emergency department
21 and field collection projects;

22 (c) designation of an injury prevention coordinator; and

23 (d) outreach activities, program development, information resources, and collaboration with
24 existing national, regional, and state trauma programs.

25

26 *History Note:* *Authority G.S. 131E-162;*
27 *Eff. April 1, 2011.*

1 10A NCAC 13P .0913 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0913 LEVEL I TRAUMA CENTER RESEARCH CRITERIA**

4 A Level I Trauma Center shall participate in a trauma research program, as outlined in the "North Carolina

5 Committee on Trauma, Performance Improvement/Outcomes Subcommittee of the American College of Surgeons:

6 Performance Improvement, Research, and Continuing Education Standards for the North Carolina Trauma System,"

7 which is incorporated by reference, including subsequent amendments and editions. This document is available

8 from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost.

9

10 *History Note: Authority G.S. 131E-162;*

11 *Eff. April 1, 2011.*

1 10A NCAC 13P .0918 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0918 LEVEL II TRAUMA CENTER TRAUMA TEAM ACTIVATION**

4 To ensure activation of the trauma team for a Level II Trauma Center, the trauma center shall:

5 (1) have written protocols relating to trauma care management formulated and updated to remain
6 current;

7 (2) have criteria established to ensure team activation prior to arrival, and trauma attending arrival
8 within 20 minutes of the arrival of trauma and burn patients that include the following conditions:

9 (a) shock;

10 (b) respiratory distress;

11 (c) airway compromise;

12 (d) unresponsiveness (GCS less than nine) with potential for multiple injuries;

13 (e) gunshot wound to neck, chest or abdomen;

14 (f) patients receiving blood to maintain vital signs; and

15 (g) ED physician's decision to activate.

16 (3) ensure performance of a surgical evaluation, based upon the following criteria, by the health
17 professional who is promptly available for the following conditions:

18 (a) proximal amputations;

19 (b) burns meeting institutional transfer criteria;

20 (c) vascular compromise;

21 (d) crush to chest or pelvis;

22 (e) two or more proximal long bone fractures; and

23 (f) spinal cord injury;

24 (4) ensure surgical consults, based upon the following criteria, by the health professional who is
25 promptly available for the following:

26 (a) falls greater than 20 feet;

27 (b) pedestrian struck by motor vehicle;

28 (c) motor vehicle crash with:

29 (i) ejection (includes motorcycle);

30 (ii) rollover;

31 (iii) speed greater than 40 mph; or

32 (iv) death of another individual in the same vehicle; or

33 (d) extremes of age, less than five or greater than 70 years;

34 (5) ensure clinical capabilities (promptly available if requested by the trauma team leader, with a
35 posted on-call schedule), that include individuals credentialed in the following:

36 (a) critical care;

37 (b) hand surgery;

1 (c) neurosurgery (The neurosurgeon must be dedicated to one hospital or a back-up call
2 schedule must be available. If fewer than 25 emergency neurosurgical trauma operations
3 are done in a year, and the neurosurgeon is dedicated only to that hospital, then a
4 published back-up call list is not necessary.);
5 (d) obstetrics/gynecologic surgery;
6 (e) opthalmic surgery;
7 (f) oral maxillofacial surgery;
8 (g) orthopaedics (dedicated to one hospital or a back-up call schedule must be available);
9 (h) plastic surgery;
10 (i) radiology;
11 (j) thoracic surgery; and
12 (k) urologic surgery.
13
14 *History Note:* *Authority G.S. 131E-162;*
15 *Eff. April 1, 2011.*

1 10A NCAC 13P .0919 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0919 LEVEL II TRAUMA CENTER EMERGENCY DEPARTMENT CRITERIA**

4 The emergency department of a Level II Trauma Center shall:

5 (1) have a designated physician director who is board-certified or prepared in emergency medicine
6 (by the American Board of Emergency Medicine or the American Osteopathic Board of
7 Emergency Medicine);

8 (2) ensure 24-hour-per-day staffing by physicians physically present in the Emergency Department
9 who:

10 (a) are either board-certified or prepared in emergency medicine (by the American Board of
11 Emergency Medicine or the American Osteopathic Board of Emergency Medicine or
12 board-certified or eligible by the American Board of Surgery, American Board of Family
13 Practice, or American Board of Internal Medicine). These emergency physicians must be
14 board-certified within five years after successful completion of a residency;

15 (b) are hospital designated members of the trauma team; and

16 (c) practice emergency medicine as their primary specialty;

17 (3) have nursing personnel with experience in trauma care who continually monitor the trauma patient
18 from hospital arrival to disposition to an intensive care unit, operating room, or patient care unit;
19 and

20 (4) have equipment for patients of all ages that includes:

21 (a) airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask
22 resuscitators, pocket masks, and oxygen);

23 (b) pulse oximetry;

24 (c) end-tidal carbon dioxide determination equipment;

25 (d) suction devices;

26 (e) an electrocardiograph-oscilloscope-defibrillator with internal paddles;

27 (f) an apparatus to establish central venous pressure monitoring;

28 (g) intravenous fluids and administration devices that include large bore catheters and
29 intraosseous infusion devices;

30 (h) sterile surgical sets for airway control/cricothyrotomy, thoracotomy, vascular access,
31 thoracostomy, peritoneal lavage, and central line insertion;

32 (i) an apparatus for gastric decompression;

33 (j) 24-hour-per-day x-ray capability;

34 (k) two-way communication equipment for communication with the emergency transport
35 system;

36 (l) skeletal traction devices, including capability for cervical traction;

37 (m) arterial catheters;

1 (n) thermal control equipment for patients;

2 (o) thermal control equipment for blood and fluids;

3 (p) a rapid infuser system;

4 (q) a dosing reference and measurement system to ensure appropriate age related medical

5 care;

6 (r) sonography; and

7 (s) a doppler.

8

9 *History Note:* *Authority G.S. 131E-162;*

10 *Eff. April 1, 2011.*

1 10A NCAC 13P .0920 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0920 LEVEL II TRAUMA CENTER OPERATING ROOM, POST ANESTHESIA**
4 **CARE UNIT AND SURGICAL INTENSIVE CARE UNIT CRITERIA**

5 (a) The operating room of a Level II Trauma Center shall ensure an operating suite that is immediately available 24
6 hours per day and has the following:
7 (1) 24-hour-per-day immediate availability of in-house staffing; and
8 (2) equipment for patients of all ages that includes:
9 (A) thermal control equipment for patients;
10 (B) thermal control equipment for blood and fluids;
11 (C) 24-hour-per-day x-ray capability, including c-arm image intensifier;
12 (D) endoscopes and bronchoscopes;
13 (E) craniotomy instruments;
14 (F) the capability of fixation of long-bone and pelvic fractures; and
15 (G) a rapid infuser system.
16 (b) The post anesthesia care unit or surgical intensive care unit of a Level II Trauma Center shall have:
17 (1) 24-hour-per-day in-house staffing by registered nurses; and
18 (2) equipment for patients of all ages to include:
19 (A) capability for resuscitation and continuous monitoring of temperature, hemodynamics,
20 and gas exchange;
21 (B) capability for continuous monitoring of intracranial pressure;
22 (C) pulse oximetry;
23 (D) end-tidal carbon dioxide determination capability;
24 (E) thermal control equipment for patients; and
25 (F) thermal control equipment for blood and fluids.
26
27 *History Note: Authority G.S. 131E-162;*
28 *Eff. April 1, 2011.*

1 10A NCAC 13P .0921 is proposed for adoption as follows:
2
3 **10A NCAC 13P .0921 LEVEL II TRAUMA CENTER INTENSIVE CARE AND CRITICAL CARE**
4 **MANAGEMENT CRITERIA**
5 (a) The intensive care unit for trauma patients for a Level II Trauma Center shall have:
6 (1) a hospital designated surgical director of trauma patients;
7 (2) a physician on duty in the intensive care unit 24 hours per day or immediately available from
8 within the hospital as long as this physician is not the sole physician on-call for the emergency
9 department;
10 (3) a ratio of one nurse per two patients on each shift;
11 (4) equipment for patients of all ages that includes:
12 (A) airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask
13 resuscitators, and pocket masks);
14 (B) an oxygen source with concentration controls;
15 (C) a cardiac emergency cart;
16 (D) a temporary transvenous pacemaker;
17 (E) electrocardiograph-oscilloscope-defibrillator;
18 (F) cardiac output monitoring capability;
19 (G) electronic pressure monitoring capability;
20 (H) a mechanical ventilator;
21 (I) patient weighing devices;
22 (J) pulmonary function measuring devices;
23 (K) temperature control devices; and
24 (L) intracranial pressure monitoring devices; and
25 (5) within 30 minutes of request, the ability to perform blood gas measurements, hematocrit level, and
26 chest x-ray studies.
27 (b) A Level II Trauma Center shall have acute hemodialysis capability or utilization of a transfer agreement.
28 (c) A Level II Trauma Center shall have a physician-directed burn center staffed by nursing personnel trained in
29 burn care or a transfer agreement with a burn center.
30 (d) A Level II Trauma Center shall have an acute spinal cord management capability or transfer agreement with a
31 hospital capable of caring for a spinal cord injured patient.
32
33 *History Note: Authority G.S. 131E-162;*
34 *Eff. April 1, 2011.*

1 10A NCAC 13P .0922 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0922 LEVEL II TRAUMA CENTER RADIOLOGY SERVICES CRITERIA**

4 The radiology services for a Level II Trauma Center shall have:

5 (1) a 24-hour-per-day in-house radiology technologist;

6 (2) a 24-hour-per-day in-house computerized tomography technologist;

7 (3) the ability to provide sonography;

8 (4) the ability to provide computed tomography;

9 (5) the ability to provide angiography; and

10 (6) resuscitation equipment that includes airway management and IV therapy.

11

12 *History Note:* *Authority G.S. 131E-162;*

13 *Eff. April 1, 2011.*

1 10A NCAC 13P .0923 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0923 LEVEL II TRAUMA CENTER RESPIRATORY THERAPY CLINICAL AND**
4 **LABORATORY CRITERIA**

5 (a) A Level II Trauma Center shall ensure respiratory therapy services are available in-house 24 hours per day.
6 (b) A Level II Trauma Center shall have a 24-hour-per-day clinical laboratory service that includes:
7 (1) analysis of blood, urine, and other body fluids, including micro-sampling when appropriate;
8 (2) blood-typing and cross-matching;
9 (3) coagulation studies;
10 (4) comprehensive blood bank or access to a community central blood bank with storage facilities;
11 (5) blood gases and pH determination; and
12 (6) microbiology.

13

14 *History Note: Authority G.S. 131E-162;*
15 *Eff. April 1, 2011.*

1 10A NCAC 13P .0924 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0924 LEVEL II TRAUMA CENTER REHABILITATION SERVICES CRITERIA**

4 The rehabilitation services for a Level II Trauma Center shall:

5 (1) provide a staff trained in rehabilitation care of critically injured patients;

6 (2) for trauma patients, provide a functional assessment with recommendations regarding short- and

7 long-term rehabilitation needs within one week of the patient's admission to the hospital or as soon

8 as hemodynamically stable;

9 (3) provide in-house rehabilitation service or a transfer agreement with a rehabilitation facility

10 accredited by the Commission on Accreditation of Rehabilitation Facilities;

11 (4) provide physical, occupational, speech therapies, and social services; and

12 (5) have substance abuse evaluation and counseling capability.

13

14 *History Note: Authority G.S. 131E-162;*

15 *Eff. April 1, 2011.*

1 10A NCAC 13P .0925 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0925 LEVEL II TRAUMA CENTER PERFORMANCE IMPROVEMENT CRITERIA**

4 A Level II Trauma Center shall participate in a performance improvement program, as outlined in the "North
5 Carolina Committee on Trauma, Performance Improvement/Outcomes Subcommittee of the American College of
6 Surgeons: Performance Improvement, Research, and Continuing Education Standards for the North Carolina
7 Trauma System," which are incorporated by reference, including subsequent amendments and editions. This
8 document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost.

9

10 *History Note: Authority G.S. 131E-162;*
11 *Eff. April 1, 2011.*

1 10A NCAC 13P .0926 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0926 LEVEL II TRAUMA CENTER OUTREACH PROGRAM, PUBLIC EDUCATION**
4 **AND INJURY PREVENTION CRITERIA**

5 A Level II Trauma Center shall participate in:

6 (1) an outreach program that includes:

7 (a) transfer agreements to address the transfer and receipt of trauma patients;

8 (b) programs for physicians within the community and within the referral area (that include
9 telephone and on-site consultations) about how to access the trauma center resources and
10 refer patients within the system;

11 (c) development of a Regional Advisory Committee as specified in Rule .1102 of this
12 Subchapter;

13 (d) development of regional criteria for coordination of trauma care; and

14 (e) assessment of trauma system operations at the regional level.

15 (2) a program of injury prevention and public education that includes:

16 (a) designation of an injury prevention coordinator; and

17 (b) outreach activities, program development, information resources, and collaboration with
18 existing national, regional, and state trauma programs.

19

20 *History Note: Authority G.S. 131E-162;*
21 *Eff. April 1, 2011.*

1 10A NCAC 13P .0927 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0927 LEVEL II TRAUMA CENTER CONTINUING EDUCATION CRITERIA**

4 A Level II Trauma Center shall participate in a written continuing education program, as outlined in the "North
5 Carolina Committee on Trauma, Performance Improvement/Outcomes Subcommittee of the American College of
6 Surgeons: Performance Improvement, Research, and Continuing Education Standards for the North Carolina
7 Trauma System," which is incorporated by reference, including subsequent amendments and editions. This
8 document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost.

9

10 *History Note:* *Authority G.S. 131E-162;*
11 *Eff. April 1, 2011.*

1 10A NCAC 13P .0928 is proposed for adoption as follows:
2
3 **10A NCAC 13P .0928 LEVEL III TRAUMA CENTER APPLICATION CRITERIA**
4 To receive designation as a Level III Trauma Center, a hospital shall have:
5 (1) a trauma program and a trauma service that have been operational for at least 12 months prior to
6 application for designation;
7 (2) for at least 12 months prior to submitting a Request for Proposal, membership in and inclusion of
8 all trauma patient records in the North Carolina Trauma Registry, in accordance with the North
9 Carolina Trauma Registry Data Dictionary, which is incorporated by reference, including
10 subsequent amendments and editions. This document is available online at
11 www.traumaregistry.ncdhhs.gov or by contacting the OEMS at 2707 Mail Service Center,
12 Raleigh, NC 27699-2707, at no cost.
13
14 *History Note:* *Authority G.S. 131E-162;*
15 *Eff. April 1, 2011.*

1 10A NCAC 13P .0929 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0929 LEVEL III TRAUMA CENTER ADMINISTRATION**

4 (a) A Level III Trauma Center shall designate a trauma medical director who is a board-certified general surgeon.

5 The trauma medical director must:

6 (1) serve on the center's trauma service;

7 (2) participate in providing care to patients with life-threatening or urgent injuries;

8 (3) participate in the North Carolina Chapter of the ACS' Committee on Trauma; and

9 (4) remain a provider in the ACS' ATLS Course in the provision of trauma-related instruction to other

10 health care personnel.

11 (b) A Level III Trauma Center shall designate a trauma nurse coordinator TNC/TPM who is a registered nurse and

12 licensed by the North Carolina Board of Nursing.

13 (c) A Level III Trauma Center shall designate a TR who has a working knowledge of medical terminology, is able

14 to operate a personal computer, and has the ability to extract data from the medical record.

15

16 *History Note:* *Authority G.S. 131E-162;*

17 *Eff. April 1, 2011.*

1 10A NCAC 13P .0930 is proposed for adoption as follows:
2
3 **10A NCAC 13P .0930 LEVEL III TRAUMA CENTER PHYSICIAN AND TRAUMA TEAM SERVICES**
4 (a) A Level III Trauma Center shall ensure there is a department/division/section for general surgery, emergency
5 medicine, anesthesiology, and orthopaedic surgery, with designated chair or physician liaison to the trauma program
6 for each.
7 (b) A Level III Trauma Center shall have clinical capabilities in general surgery with a written posted call schedule
8 that indicates who is on call for both trauma and general surgery. If a trauma surgeon is simultaneously on call at
9 more than one hospital, there must be a defined, posted trauma surgery back-up call schedule composed of surgeons
10 credentialed to serve on the trauma panel. The trauma service director shall specify, in writing, the specific
11 credentials that each back-up surgeon must have. These must state that the back-up surgeon has surgical privileges
12 at the trauma center and is boarded or eligible in general surgery (with board certification in general surgery within
13 five years of completing residency).
14 (c) A Level III Trauma Center shall ensure the availability of a trauma team to provide evaluation and treatment of
15 a trauma patient 24 hours per day that includes:
16 (1) a trauma attending whose presence at the patient's bedside within 30 minutes of notification is
17 documented and who participates in therapeutic decisions and is present at all operative
18 procedures;
19 (2) an emergency physician who is present in the ED 24 hours per day who is either board-certified or
20 prepared in emergency medicine (by the American Board of Emergency Medicine or the
21 American Osteopathic Board of Emergency Medicine) or board-certified or eligible by the
22 American Board of Surgery, American Board of Family Practice, or American Board of Internal
23 Medicine and practices emergency medicine as his primary specialty. This emergency physician if
24 prepared or eligible must be board-certified within five years after successful completion of the
25 residency and serve as a hospital designated member of the trauma team to ensure immediate care
26 for the trauma patient until the arrival of the trauma surgeon; and
27 (3) an anesthesiologist who is on-call and promptly available after notification by the trauma team
28 leader or an in-house CRNA under physician supervision, practicing in accordance with G.S. 90-
29 171.20(7)e, pending the arrival of the anesthesiologist within 30 minutes of notification.
30 (d) A written credentialing process shall be established by the Department of Surgery to approve mid-level
31 practitioners and attending general surgeons covering the trauma service. The surgeons must have board certification
32 in general surgery within five years of completing residency.
33 (e) Neurosurgeons (if participating) and orthopaedists serving the trauma service must be board certified or eligible.
34 Those who are eligible must be board certified within five years after successful completion of residency.
35
36 *History Note:* *Authority G.S. 131E-162;*
37 *Eff. April 1, 2011.*

10A NCAC 13P .0931 is proposed for adoption as follows:

10A NCAC 13P .0931 LEVEL III TRAUMA CENTER TRAUMA TEAM ACTIVATION

To ensure activation of the trauma team for a Level III Trauma Center, the trauma center shall:

(1) have written protocols relating to trauma care management formulated and updated. Activation guidelines shall reflect criteria that ensures patients receive timely and appropriate treatment including stabilization, intervention and transfer. Documentation of effectiveness of variances from activation criteria addressed in Items (2), (3), and (4) of this Rule must be available for review.

(2) have criteria established to ensure team activation prior to arrival, and trauma attending arrival within 30 minutes of the arrival of trauma and burn patients that include the following conditions:
  (a) shock;
  (b) respiratory distress;
  (c) airway compromise;
  (d) unresponsiveness (GSC less than nine) with evidence for multiple injuries;
  (e) gunshot wound to neck, or torso; or
  (f) ED physician's decision to activate.

(3) have trauma treatment guidelines based on facility capabilities that ensure surgical evaluation or appropriate transfer, based upon the following criteria, by the health professional who is promptly available:
  (a) proximal amputations;
  (b) burns meeting institutional transfer criteria;
  (c) vascular compromise;
  (d) crush to chest or pelvis;
  (e) two or more proximal long bone fractures;
  (f) spinal cord injury; and
  (g) gunshot wound to the head.

(4) ensure surgical consults or appropriate transfers determined by Trauma Treatment Guidelines based on facility capabilities, based upon the following criteria, by the health professional who is promptly available:
  (a) falls greater than 20 feet;
  (b) pedestrian struck by motor vehicle;
  (c) motor vehicle crash with:
    (i) ejection (includes motorcycle);
    (ii) rollover;
    (iii) speed greater than 40 mph; or
    (iv) death of another individual in the same vehicle; and

1 (d) extremes of age, less than five or greater than 70 years.
2 (5) ensure clinical capabilities (promptly available if requested by the trauma team leader, with a
3 posted on-call schedule) that include individuals credentialed in the following:
4 (a) orthopaedics;
5 (b) radiology; and
6 (c) neurosurgery, if actively participating in the acute resuscitation and operative
7 management of patients managed by the trauma team.
8
9 *History Note:* *Authority G.S. 131E-162;*
10 *Eff. April 1, 2011.*

1 10A NCAC 13P .0932 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0932 LEVEL III TRAUMA CENTER EMERGENCY DEPARTMENT CRITERIA**

4 The emergency department of a Level III Trauma Center shall:

5 (1) have a designated physician director who is board-certified or prepared in emergency medicine
6 (by the American Board of Emergency Medicine or the American Osteopathic Board of
7 Emergency Medicine);

8 (2) ensure 24-hour-per-day staffing by physicians physically present in the emergency department
9 who:

10 (a) are either board-certified or prepared in emergency medicine (by the American Board of
11 Emergency Medicine or the American Osteopathic Board of Emergency Medicine) or
12 board-certified or eligible by the American Board of Surgery, American Board of Family
13 Practice, or American Board of Internal Medicine. These emergency physicians must be
14 board-certified within five years after successful completion of a residency;

15 (b) are designated members of the trauma team to ensure immediate care to the trauma
16 patient; and

17 (c) practice emergency medicine as their primary specialty;

18 (3) have nursing personnel with experience in trauma care who continually monitor the trauma patient
19 from hospital arrival to disposition to an intensive care unit, operating room, or patient care unit;
20 and

21 (4) have resuscitation equipment for patients of all ages that includes:

22 (a) airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask
23 resuscitators, pocket masks, and oxygen);

24 (b) pulse oximetry;

25 (c) end-tidal carbon dioxide determination equipment;

26 (d) suction devices;

27 (e) an Electrocardiograph-oscilloscope-defibrillator with internal paddles;

28 (f) apparatus to establish central venous pressure monitoring;

29 (g) intravenous fluids and administration devices that include large bore catheters and
30 intraosseous infusion devices;

31 (h) sterile surgical sets for airway control/cricothyrotomy, thoracotomy, vascular access,
32 thoracostomy, peritoneal lavage, and central line insertion;

33 (i) apparatus for gastric decompression;

34 (j) 24-hour-per-day x-ray capability;

35 (k) two-way communication equipment for communication with the emergency transport
36 system;

37 (l) skeletal traction devices;

1 (m) thermal control equipment for patients;
2 (n) thermal control equipment for blood and fluids;
3 (o) a rapid infuser system;
4 (p) a dosing reference and measurement system to ensure appropriate age related medical
5 care; and
6 (q) a doppler.
7
8 *History Note:* *Authority G.S. 131E-162;*
9 *Eff. April 1, 2011.*

1 10A NCAC 13P .0933 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0933 LEVEL III TRAUMA CENTER OPERATING ROOM, POST ANESTHESIA**
4 **CARE UNIT AND SURGICAL CARE UNIT CRITERIA**

5 (a) The operating room of a Level III Trauma Center shall provide an operating suite that has the following:
6 (1) personnel available 24 hours a day, on-call, and available within 30 minutes of notification unless
7 in-house; and
8 (2) age-specific equipment that includes:
9 (A) thermal control equipment for patients;
10 (B) thermal control equipment for blood and fluids;
11 (C) 24-hour-per-day x-ray capability, including c-arm image intensifier;
12 (E) endoscopes and bronchoscopes;
13 (F) equipment for long bone and pelvic fracture fixation; and
14 (G) a rapid infuser system.
15 (b) The post anesthesia care unit or surgical intensive care unit of a Level III Trauma Center shall have:
16 (1) 24-hour-per-day availability of registered nurses within 30 minutes from inside or outside the
17 hospital; and
18 (2) equipment for patients of all ages that includes:
19 (A) the capability for resuscitation and continuous monitoring of temperature,
20 hemodynamics, and gas exchange;
21 (B) pulse oximetry;
22 (C) end-tidal carbon dioxide determination;
23 (D) thermal control equipment for patients; and
24 (E) thermal control equipment for blood and fluids.

25

26 *History Note:* *Authority G.S. 131E-162;*
27 *Eff. April 1, 2011.*

1 10A NCAC 13P .0934 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0934 LEVEL III TRAUMA CENTER INTENSIVE CARE UNIT AND CRITICAL**
4 **CARE MANAGEMENT CRITERIA**

5 (a) The intensive care unit for trauma patients for a Level III Trauma Center shall have:
6 (1) a trauma surgeon who actively participates in the committee overseeing the ICU;
7 (2) a physician on duty in the intensive care unit 24-hours-per-day or immediately available from
8 within the hospital (which may be a physician who is the sole physician on-call for the ED);
9 (3) equipment for patients of all ages that includes:
10 (A) airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask
11 resuscitators and pocket masks);
12 (B) an oxygen source with concentration controls;
13 (C) a cardiac emergency cart;
14 (D) a temporary transvenous pacemaker;
15 (E) an electrocardiograph-oscilloscope-defibrillator;
16 (F) cardiac output monitoring capability;
17 (G) electronic pressure monitoring capability;
18 (H) a mechanical ventilator;
19 (I) patient weighing devices;
20 (J) pulmonary function measuring devices; and
21 (K) temperature control devices; and
22 (4) within 30 minutes of request, the ability to perform blood gas measurements, hematocrit level, and
23 chest x-ray studies.

24 (b) A Level III Trauma Center shall have acute hemodialysis capability or utilization of a written transfer
25 agreement.

26 (c) A Level III Trauma Center shall have a physician-directed burn center staffed by nursing personnel trained in
27 burn care or a written transfer agreement with a burn center.

28 (d) A Level III Trauma Center shall have an acute spinal cord management capability or transfer agreement with a
29 hospital capable of caring for a spinal cord injured patient.

30 (e) A Level III Trauma Center shall have an acute head injury management capability or transfer agreement with a
31 hospital capable of caring for a head injury.

32

33 *History Note:* *Authority G.S. 131E-162;*
34 *Eff. April 1, 2011.*

1 10A NCAC 13P .0935 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0935 LEVEL III TRAUMA CENTER RADIOLOGY SERVICES CRITERIA**

4 The radiology services for a Level III Trauma Center shall have:

5 (1) a radiology technologist and computer tomography technologist available within 30 minutes of

6 notification or documentation that procedures are available within 30 minutes;

7 (2) the ability to provide computed tomography;

8 (3) the ability to provide sonography; and

9 (4) resuscitation equipment that includes airway management and IV therapy.

10

11 *History Note: Authority G.S. 131E-162;*

12 *Eff. April 1, 2011.*

1 10A NCAC 13P .0936 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0936 LEVEL III TRAUMA CENTER RESPIRATORY THERAPY AND CLINICAL**
4 **LABORATORY CRITERIA**

5 (a) A Level III Trauma Center shall ensure respiratory therapy services are on-call 24 hours per day.
6 (b) A Level III Trauma Center shall have a 24-hour-per-day clinical laboratory service that includes:
7 (1) analysis of blood, urine, and other body fluids, including micro-sampling when appropriate;
8 (2) blood-typing and cross-matching;
9 (3) coagulation studies;
10 (4) comprehensive blood bank or access to a community central blood bank with storage facilities;
11 (5) blood gases and pH determination; and
12 (6) microbiology.

13

14 *History Note: Authority G.S. 131E-162;*
15 *Eff. April 1, 2011.*

1 10A NCAC 13P .0937 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0937 LEVEL III TRAUMA CENTER REHABILITATION SERVICES CRITERIA**

4 The rehabilitation services for a Level III Trauma Center shall:

5 (1) provide in-house rehabilitation service or a transfer agreement with a rehabilitation facility

6 accredited by the Commission on Accreditation of Rehabilitation Facilities; and

7 (2) provide physical therapy and social services.

8

9 *History Note:* *Authority G.S. 131E-162;*

10 *Eff. April 1, 2011.*

1 10A NCAC 13P .0942 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0942 DESIGNATED TRAUMA CENTER ADMINISTRATIVE STRUCTURE**

4 **CHANGES**

5 If a trauma center changes its trauma program administrative structure, such that the trauma service, trauma medical

6 director, trauma nurse coordinator/program manager or trauma registrar are relocated on the hospital's organizational

7 chart at any time, it shall notify the OEMS of this change in writing within 30 days of the occurrence.

8

9 *History Note:* *Authority G.S. 131E-162; 143-509(3);*

10 *Eff. April 1, 2011.*

1 10A NCAC 13P .0943 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0943 RENEWAL DESIGNATION OPTIONS**

4 Hospitals may utilize one of two options to achieve Trauma Center renewal designation:

5 (1) undergo a site visit conducted by OEMS to obtain a four-year renewal designation pursuant to

6 Rule .0944 of this Section; or

7 (2) undergo a verification visit arranged by the ACS, in conjunction with OEMS, to obtain a four-year

8 renewal designation pursuant to Rule .0945 of this Section.

9

10 *History Note:* *Authority G.S. 131E-162; 143-509(3);*

11 *Eff. April 1, 2011.*

1 10A NCAC 13P .0944 is proposed for adoption as follows:
2
3 **10A NCAC 13P .0944 STATE ONLY SITE VISIT RENEWAL DESIGNATION PROCESS**

4 For hospitals choosing to undergo a site visit conducted only by the OEMS, the following shall apply:

5 (1) Prior to the end of the designation period, the OEMS shall forward to the hospital an RFP for
6 completion. The hospital shall, within 10 days of receipt of the RFP, define for OEMS the Trauma
7 Center's trauma primary catchment area. Upon this notification, OEMS shall notify the respective
8 Board of County Commissioners in the applicant's trauma primary catchment area of the request
9 for renewal to allow for comment.

10 (2) Hospitals shall complete and submit to the OEMS one paper original RFP with signatures and the
11 number of copies of the RFP, as needed for the site team as determined by the OEMS, at least 30
12 days prior to the site visit. The RFP shall include information that supports compliance with the
13 criteria contained in Rules .0901 through .0940 of this Section as it relates to the Trauma Center's
14 level of designation.

15 (3) All criteria defined in Rules .0901 through .0940 of this Section, as it relates to the Trauma
16 Center's level of designation, shall be met for renewal designation.

17 (4) A site visit shall be conducted within 120 days prior to the end of the designation period. The site
18 visit shall be scheduled on a date mutually agreeable to the hospital and the OEMS.

19 (5) On the day of the site visit the hospital shall make available all requested patient medical charts.

20 (6) The primary reviewer of the site review team shall give a verbal post-conference report
21 representing a consensus of the site review team at the summary conference. A written consensus
22 report shall be completed, to include a peer review report, by the primary reviewer and submitted
23 to OEMS within 30 days of the site visit.

24 (7) The report of the site survey team and a staff recommendation shall be reviewed by the State
25 Emergency Medical Services Advisory Council at its next regularly scheduled meeting. Based
26 upon the site visit report and the staff recommendation, the State Emergency Medical Services
27 Advisory Council shall recommend to the OEMS that the request for Trauma Center renewal be
28 approved; approved with a deficiency(ies) requiring a focused review; approved with a
29 contingency(ies) not due to a deficiency(ies) recommending a consultative visit; or denied.

30 (8) Hospitals with a deficiency(ies) have up to 10 working days prior to the State EMS Advisory
31 Council meeting to provide documentation to demonstrate compliance. If the hospital has a
32 deficiency that cannot be corrected in this period prior to the State EMS Advisory Council
33 meeting, the hospital, instead of a four-year renewal, shall be given 12 months by the OEMS to
34 demonstrate compliance and undergo a focused review, that may require an additional site visit.
35 The hospital shall receive a 12 month Trauma Center designation during the focused review
36 period. If compliance is demonstrated within the 12 month time period, the hospital shall be
37 granted its designation for the four-year period from the previous designation's expiration date. If

1 compliance is not demonstrated within the time period, as specified by OEMS, the Trauma Center
2 designation shall not be renewed. To become redesignated, the hospital shall submit an updated
3 RFP and follow the initial applicant process outlined in Rule .0941 of this Section.
4 (9) The final decision regarding trauma center renewal shall be rendered by the OEMS.
5 (10) The OEMS shall notify the hospital of the State Emergency Medical Services Advisory Council's
6 and OEMS' final recommendation within 30 days of the Advisory Council meeting.
7 (11) Hospitals with a deficiency(ies) shall submit an action plan to the OEMS to address the
8 deficiency(ies) 10 days following the receipt of the written final decision on the trauma
9 recommendation.
10 (12) The four-year renewal date that may be eventually granted shall not be extended due to the
11 focused review period.
12
13 *History Note:* *Authority G.S. 131E-162; 143-509(3);*
14 *Eff. April 1, 2011.*

1 10A NCAC 13P .0945 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0945 STATE/ACS COMBINED SITE VISIT RENEWAL DESIGNATION PROCESS**

4 (a) To achieve Trauma Center renewal designation, hospitals may undergo a verification visit arranged by the ACS,
5 in conjunction with the OEMS, to obtain a four-year renewal designation.

6 (b) For hospitals choosing to undergo a site visit conducted by the ACS, in conjunction with the OEMS, the
7 following shall apply:

8 (1) At least six months prior to the end of the Trauma Center's designation period, the trauma center
9 must notify the OEMS of its intent to undergo an ACS verification visit. It must simultaneously
10 define in writing to the OEMS its trauma primary catchment area. Trauma Centers choosing this
11 option must then comply with all ACS' verification procedures, as well as any additional state
12 criteria as outlined in Rules .0901 through .0940 of this Section, as apply to their level of
13 designation.

14 (2) When completing the ACS' documentation for verification, the Trauma Center must ensure access
15 to the ACS on-line PRQ (pre-review questionnaire) to the OEMS. The Trauma Center must
16 simultaneously complete documents supplied by the OEMS to verify compliance with North
17 Carolina criteria and forward these to the OEMS and the ACS.

18 (3) The OEMS shall notify the Board of County Commissioners within the trauma center's trauma
19 primary catchment area of the Trauma Center's request for renewal to allow for comments.

20 (4) The Trauma Center must make sure the site visit is scheduled to ensure that the ACS' final written
21 report, accompanying medical record reviews and cover letter are received by the OEMS at least
22 30 days prior to a regularly scheduled State Emergency Medical Services Advisory Council
23 meeting to ensure that the Trauma Center's state designation period does not terminate without
24 consideration by the State Emergency Medical Services Advisory Council.

25 (5) The date and time of the site visit must be submitted to the OEMS for review at least 45 days prior
26 to the site visit. The OEMS shall approve the site visit schedule if the schedule does not conflict
27 with the ability of attendance by required OEMS staff.

28 (6) All state Trauma Center criteria must be met as defined in Rules .0901 through .0940 of this
29 Section, for renewal of state designation. An ACS' verification is not required for state
30 designation. An ACS' verification does not ensure a state designation.

31 (7) ACS reviewers shall complete the state designation preliminary reporting form immediately prior
32 to the post conference meeting. This document and the ACS final written report and supporting
33 documentation described in Subparagraph (b)(4) of this Rule shall be used to generate a staff
34 summary of findings report following the post conference meeting for presentation to the NC
35 EMS Advisory Council for redesignation.

1 (8) The final written report issued by the ACS' verification review committee, the accompanying
2 medical record reviews (from which all identifiers may be removed), and cover letter must be
3 forwarded to OEMS within 10 working days of its receipt by the Trauma Center seeking renewal.
4 (9) The OEMS shall present its summary of findings report to the State Emergency Medical Services
5 Advisory Council at its next regularly scheduled meeting. The State EMS Advisory Council shall
6 recommend to the Chief of the OEMS that the request for Trauma Center renewal be approved;
7 approved with a deficiency(ies) requiring a focused review; approved with a contingency(ies) not
8 due to a deficiency(ies) recommending a consultative visit; or denied.
9 (10) Hospitals with a deficiency(ies) have up to 10 working days prior to the State EMS Advisory
10 Council meeting to provide documentation to demonstrate compliance. If the hospital has a
11 deficiency that cannot be corrected in this period prior to the State EMS Advisory Council
12 meeting, the hospital, instead of a four-year renewal, shall be given 12 months by the OEMS to
13 demonstrate compliance and undergo a focused review, that may require an additional site visit to
14 be conducted by the OEMS. The hospital shall receive a 12 month Trauma Center designation
15 during the focused review period. If compliance is demonstrated within the 12 month time period,
16 the hospital shall be granted its designation for the four-year period from the pervious
17 designation's expiration date. If compliance is not demonstrated within the time period, as
18 specified by OEMS, the Trauma Center designation shall not be renewed. To become
19 redesignated, the hospital shall submit a new RFP and follow the initial applicant process outlined
20 in Rule .0941 of this Section.
21 (11) The final decision regarding trauma center designation shall be rendered by the OEMS.
22 (12) The OEMS shall notify the hospital in writing of the State Emergency Medical Services Advisory
23 Council's and OEMS' final recommendation within 30 days of the Advisory Council meeting.
24 (13) Hospitals with a deficiency(ies) shall submit an action plan to the OEMS to address the
25 deficiency(ies) 10 days following the receipt of the written final decision on the trauma
26 recommendation.
27 (14) The four-year renewal date that may be eventually granted shall not be extended due to the
28 focused review period.
29 (c) If a Trauma Center currently using the ACS' verification process chooses not to renew using this process, it must
30 notify the OEMS at least six months prior to the end of its state trauma center designation period of its intention to
31 exercise the option in Rule .0944 of this Section.
32
33 *History Note:* *Authority G.S. 131E-162; 143-509(3);*
34 *Eff. April 1, 2011.*

10A NCAC 13P .0946 is proposed for adoption as follows:

10A NCAC 13P .0946 STATE ONLY TRAUMA SITE SURVEY TEAM COMPOSITION

(a) Any in-state reviewer for a state only Level I or II visit, except for the OEMS representatives, shall be from outside the local or adjacent RAC in which the hospital is located. The composition of a Level I or II state only site survey team shall be as follows:

(1) one out-of-state Fellow of the ACS, experienced as a site surveyor, who shall be designated the primary reviewer;

(2) one emergency physician who currently works in a designated trauma center, is a member of the American College of Emergency Physicians, and is boarded in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine);

(3) one in-state trauma surgeon who is a member of the North Carolina Committee on Trauma;

(4) one out-of-state trauma nurse coordinator/program manager; and

(5) OEMS staff.

(b) All site team members for a state only Level III visit shall be from in-state and, except for the OEMS representatives, shall be from outside the local or adjacent RAC in which the hospital is located. The composition of a Level III state only site survey team shall be as follows:

(1) one Fellow of the ACS, who is a member of the North Carolina Committee on Trauma and shall be designated the primary reviewer;

(2) one emergency physician who currently works in a designated trauma center, is a member of the North Carolina College of Emergency Physicians, and is boarded in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine);

(3) one trauma nurse coordinator/program manager; and

(4) OEMS staff.

History Note: *Authority G.S. 131E-162; 143-509(3);*
Eff. April 1, 2011.

1 10A NCAC 13P .0947 is proposed for adoption as follows:

2

3 **10A NCAC 13P .0947 STATE/ACS COMBINED TRAUMA SITE SURVEY TEAM COMPOSITION**

4 (a) Any in-state review for a State/ACS combined Level I or II visit, except for the OEMS representatives, shall be
5 from outside the local or adjacent RAC in which the hospital is located. The composition of a Level I or II state site
6 survey team for a State/ACS combined visit shall be as follows:

7 (1) one out-of-state Fellow of the ACS, experienced as a site surveyor, who shall be designated the
8 primary reviewer;

9 (2) one in-state or out-of-state emergency physician who currently works in a designated trauma
10 center, is a member of the American College of Emergency Physicians, and is boarded in
11 emergency medicine (by the American Board of Emergency Medicine or the American
12 Osteopathic Board of Emergency Medicine), and has membership in the North Carolina College
13 of Emergency Physicians if from in-state only;

14 (3) one in-state or out-of-state trauma surgeon who is a member of the North Carolina Committee on
15 Trauma if from in-state only;

16 (4) one out-of-state trauma nurse coordinator/program manager; and

17 (5) OEMS staff.

18 (b) All site team members for a State/ACS combined Level III visit, except for the OEMS representatives, shall be
19 from outside the local or adjacent RAC in which the hospital is located. The composition of a Level III state site
20 survey team for a State/ACS combined visit shall be as follows:

21 (1) one in-state or out-of-state Fellow of the ACS, who is a member of the North Carolina Committee
22 if from in-state only, and shall be designated the primary reviewer;

23 (2) one in-state or out-of-state emergency physician who currently works in a designated trauma
24 center, is boarded in emergency medicine (by the American Board of Emergency Medicine or the
25 American Osteopathic Board of Emergency Medicine), and is a member of the North Carolina
26 College of Emergency Physicians if from in-state only;

27 (3) one trauma nurse coordinator/program manager; and

28 (4) OEMS staff.

29 (c) All proposed members of the site visit team must be submitted from the ACS to the OEMS for review at least 45
30 days prior to the site visit. The OEMS shall approve the proposed site team members if the OEMS determines there
31 is no conflict of interest, such as previous employment, by any site team member associated with the site visit.

32

33 *History Note:* *Authority G.S. 131E-162; 143-509(3);*
34 *Eff. April 1, 2011.*

10A NCAC 13P .1101 is proposed for amendment as follows:

10A NCAC 13P .1101 STATE TRAUMA SYSTEM

(a) The state trauma system consists of regional plans, policies, guidelines and performance improvement initiatives by the RACs to create an Inclusive Trauma System monitored by the OEMS.

(b) Each hospital and EMS System shall affiliate as defined in Rule .0102(4) of this Subchapter and participate with the RAC that includes the Level I or II Trauma Center in which the majority of trauma patient referrals and transports occur. Each hospital and EMS System shall submit to the OEMS upon request patient transfer patterns from data sources that support the choice of their primary RAC affiliation. Each RAC shall include at least one Level I or II Trauma Center.

(c) The OEMS shall notify each RAC of its hospital and EMS System membership.

(d) Each hospital and each EMS System must update and submit its RAC affiliation information to the OEMS no later than July 1 of each year. RAC affiliation may only be changed during this annual update and only if supported by a change in the majority of transfer ~~patterns.~~ patterns to a Level I or Level II Trauma Center. Documentation detailing these new transfer patterns must be included in the request to change affiliation. If no change is made in RAC affiliation, notification of continued affiliation shall be provided to the OEMS in writing.

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. April 1, 2011; January 1, 2009.

10A NCAC 13P .1102 is proposed for amendment as follows:

10A NCAC 13P .1102 REGIONAL TRAUMA SYSTEM PLAN

(a) A Level I or II Trauma Center shall facilitate development of and provide RAC staff support that includes the following:

(1) The trauma medical director(s) from the lead RAC agency;
(2) Trauma nurse coordinator(s) or program manager(s) from the lead RAC agency; and
(3) An individual to coordinate RAC activities.

(b) The RAC membership shall include the following:

(1) The trauma medical director(s) and the trauma nurse coordinator(s) or program manager(s) from the lead RAC agency;
(2) If on staff, an outreach coordinator(s), injury prevention coordinator(s) or designee(s), as well as a RAC registrar or designee(s) from the lead RAC agency;
(3) A senior level hospital administrator;
(4) An emergency physician;
(5) A representative from each EMS system participating in the RAC;
(6) A representative from each hospital participating in the RAC;
(7) Community representatives; and
(8) An EMS System physician involved in medical oversight.

(c) The RAC shall develop ~~and submit~~ a plan within one year of notification of the RAC ~~membership, or for existing RACs within six months of the implementation date of this rule, to the OEMS~~ membership containing:

(1) Organizational structure to include the roles of the members of the system;
(2) Goals and objectives to include the orientation of the providers to the regional system;
(3) RAC membership list, rules of order, terms of office, meeting schedule (held at a minimum of two times per year);
(4) Copies of documents and information required by the OEMS as defined in Rule .1103 of this Section;
(5) System evaluation tools to be utilized;
(6) Written documentation of regional support for the plan; and
(7) Performance improvement activities to include utilization of patient care data.

(d) The RAC shall ~~submit to the OEMS~~ prepare an annual progress report no later than July 1 of each year that assesses compliance with the regional trauma system plan and specifies any updates to the plan. This report shall be made available to the OEMS for review upon request.

(e) Upon OEMS' receipt of a letter of intent for initial Level I or II Trauma Center designation pursuant to Rule ~~.0904(b)~~ .0941(b) of this Subchapter, the applicant's RAC shall be provided the applicant's data from OEMS to review and comment.

(f) The RAC has 30 days to comment on the request for initial designation.

1 (g) The OEMS shall notify the RAC of the OEMS approval to submit an RFP so that necessary changes in
2 protocols can be considered.
3
4 *History Note:* *Authority G.S. 131E-162;*
5 *Temporary Adoption Eff. January 1, 2002;*
6 *Eff. April 1, 2003;*
7 *Amended Eff. April 1, 2011; January 1, 2009.*

1 10A NCAC 13P .1501 is proposed for adoption as follows:
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3 **SECTION .1500 - DENIAL, SUSPENSION, AMENDMENT, OR REVOCATION**
4
5 **10A NCAC 13P .1501 ENFORCEMENT DEFINITIONS**
6 Notwithstanding Section .0100 of this Subchapter, for the purpose of this Section, the following definitions apply to
7 Rules .1502, 1503, 1504, and .1506 for EMS Systems, Licensed EMS Providers, Specialty Care Transport
8 Programs, and EMS Educational Institutions:
9 (1) "Contingencies" mean conditions placed on an initial or renewal designation, approval or license
10 that, if unmet, can result in the loss or amendment of the designation, approval, or license.
11 (2) "Deficiency" means the failure to meet essential criteria for designation, approval, or licensing as
12 specified in Sections .0200, .0300 or .0600 of this Subchapter, that can serve as the basis for a
13 focused review or denial of a designation, approval or license.
14 (3) "Essential Criteria" means those items listed in Sections .0200, .0300 or .0600 of this Subchapter
15 that are the minimum requirements for the respective application for initial or renewal designation,
16 approval, or licensing.
17 (5) "Focused Review" means an evaluation by the OEMS of a regulated entity's corrective actions to
18 remove contingencies that are a result of deficiencies placed upon it following review of an
19 application for renewal.
20
21 *History Note: Authority G.S. 131E-155(13a); 143-508(b),(d)(1),(d)(4),(d)(13);*
22 *Eff. April 1, 2011.*

1 10A NCAC 13P .1502 is proposed for adoption as follows:

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3 **10A NCAC 13P .1502 EMS SYSTEMS**

4 (a) The OEMS may deny the initial or renewal designation, without first allowing a focused review, of an EMS
5 System for any of the following reasons:

6 (1) failure to comply with the requirements of Rule .0201 of this Subchapter;
7 (2) obtaining or attempting to obtain designation through fraud or misrepresentation.

8 (b) When an EMS System is required to have a focused review, it must demonstrate compliance with the provisions
9 of Rule .0201 of this Subchapter within one year or less.

10 (c) The OEMS may revoke an EMS System designation at any time or deny a request for renewal of designation,
11 whenever the OEMS finds that the EMS System has failed to comply with the provisions of Rule .0201 of this
12 Subchapter; and

13 (1) it is not probable that the EMS System can remedy the deficiencies within 12 months or less;
14 (2) although the EMS System may be able to remedy the deficiencies within a reasonable period of
15 time, it is not probable that the EMS System shall be able to remain in compliance with
16 designation rules for the foreseeable future;
17 (3) the EMS System fails to meet the requirements of a focused review;
18 (4) failure to comply endangers the health, safety, or welfare of the public;
19 (5) repetition of deficiencies placed on the EMS System in previous compliance site visits; or
20 (6) altering, destroying or attempting to destroy evidence needed for a complaint investigation.

21 (d) The OEMS shall give the Board of Commissioners in the county or counties of the EMS System written notice
22 of revocation. This notice shall be given personally or by certified mail and shall set forth:

23 (1) the factual allegations;
24 (2) the statutes or rules alleged to be violated; and
25 (3) notice of the county's right to a contested case hearing on the amendment of the designation.

26 (e) In the event of a revocation, the OEMS shall provide written notification to all hospitals and emergency medical
27 services providers within the EMS System's defined service area.

28 (f) Focused review is not a procedural prerequisite to the revocation of a designation pursuant to Paragraph (c) of
29 this Rule.

30

31 *History Note:* *Authority G.S. 143-508(d)(10), (d)(13);*
32 *Eff. April 1, 2011.*

1 10A NCAC 13P .1503 is proposed for adoption as follows:

2

3 **10A NCAC 13P .1503 LICENSED EMS PROVIDERS**

4 (a) The Department may amend any EMS Provider license by reducing it from a full license to a provisional license
5 whenever the Department finds that:

6 (1) the licensee has failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted
7 under that article;

8 (2) there is a reasonable probability that the licensee can remedy the licensure deficiencies within a
9 reasonable length of time; and

10 (3) there is a reasonable probability that the licensee will be able thereafter to remain in compliance
11 with the licensure rules for the foreseeable future.

12 (b) The Department shall give the licensee written notice of the amendment of the EMS Provider license. This
13 notice shall be given personally or by certified mail and shall set forth:

14 (1) the length of the provisional EMS Provider license;

15 (2) the factual allegations;

16 (3) the statutes or rules alleged to be violated; and

17 (4) notice to the EMS provider's right to a contested case hearing on the amendment of the EMS
18 Provider license.

19 (c) The provisional EMS Provider license is effective immediately upon its receipt by the licensee and shall be
20 posted in a prominent location at the primary business location of the EMS Provider, accessible to public view, in
21 lieu of the full license. The provisional license remains in effect until the Department:

22 (1) restores the licensee to full licensure status; or

23 (2) revokes the licensee's license.

24 (d) The Department may revoke or suspend an EMS Provider license whenever the Department finds that the
25 licensee:

26 (1) has failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted under that
27 article and it is not reasonably probable that the licensee can remedy the licensure deficiencies
28 within a reasonable length of time;

29 (2) has failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted under that
30 Article and, although the licensee may be able to remedy the deficiencies within a reasonable
31 period of time, it is not reasonably probable that the licensee will be able to remain in compliance
32 with licensure rules for the foreseeable future;

33 (3) has failed to comply with the provision of G.S. 131E, Article 7, and the rules adopted under that
34 article that endanger the health, safety or welfare of the patients cared for or transported by the
35 licensee;

36 (4) obtained or attempted to obtain an ambulance permit, EMS nontransporting vehicle permit, or
37 EMS Provider license through fraud or misrepresentation;

1 (5) repetition of deficiencies placed on the EMS Provider License in previous compliance site visits;
2 (6) fails to provide emergency medical care within the defined EMS service area in a timely manner
3 as determined by the EMS System;
4 (7) altering, destroying, attempting to destroy, withholding or delaying release of evidence, records, or
5 documents needed for a complaint investigation; or
6 (8) is continuing to operate within an EMS System after a Board of County Commissioners has
7 terminated its affiliation with the licensee.
8 (e) The issuance of a provisional EMS Provider license is not a procedural prerequisite to the revocation or
9 suspension of a license pursuant to Paragraph (d) of this Rule.
10
11 *History Note:* *Authority G.S. 131E-155.1(d); 143-508(d)(10);*
12 *Eff. April 1, 2011.*

1 10A NCAC 13P .1504 is proposed for adoption as follows:

2

3 **10A NCAC 13P .1504 SPECIALTY CARE TRANSPORT PROGRAMS**

4 (a) The Department may deny the initial or renewal designation, without first allowing a focused review, of a SCTP
5 for any of the following reasons:

6 (1) failure to comply with the provisions of G.S.131E, Article 7 and the rules adopted under that
7 Article;

8 (2) obtaining or attempting to obtain designation through fraud or misrepresentation;

9 (3) endangerment to the health, safety, or welfare of patients cared for by the SCTP; or

10 (4) repetition of deficiencies placed on the trauma center in previous site visits.

11 (b) When an SCTP is required to have a focused review, it must demonstrate compliance with the provisions of
12 G.S. 131E, Article 7 and the rules adopted under that Article within one year or less.

13 (c) The OEMS may revoke an SCTP designation at any time or deny a request for renewal of designation whenever
14 the OEMS finds that the SCTP has failed to comply with the provisions of G.S.131E, Article 7 and the rules adopted
15 under that Article; and

16 (1) it is not probable that the SCTP can remedy the deficiencies within one year or less;

17 (2) although the SCTP may be able to remedy the deficiencies within a reasonable period of time, it is
18 not probable that the SCTP shall be able to remain in compliance with designation rules for the
19 foreseeable future;

20 (3) the SCTP fails to meet the requirements of a focused review;

21 (4) endangerment to the health, safety, or welfare of patients cared for or transported by the SCTP;

22 (5) fails to provide SCTP services within the defined service area in a timely manner as determined by
23 the OEMS;

24 (6) is continuing to operate within an EMS System after a Board of County Commissioners has
25 terminated its affiliation with the SCTP; or

26 (7) altering, destroying or attempting to destroy evidence needed for a complaint investigation.

27 (d) The OEMS shall give the SCTP written notice of revocation. This notice shall be given personally or by
28 certified mail and shall set forth:

29 (1) the factual allegations;

30 (2) the statutes or rules alleged to be violated; and

31 (3) notice of the hospital's right to a contested case hearing on the amendment of the designation.

32 (e) Focused review is not a procedural prerequisite to the revocation of a designation pursuant to Paragraph (c) of
33 this Rule.

34

35 *History Note:* *Authority 143-508(d)(10), (d)(13);*
36 *Eff. April 1, 2011.*

1 10A NCAC 13P .1505 is proposed for adoption as follows:

2

3 **10A NCAC 13P .1505 TRAUMA CENTERS**

4 (a) The OEMS may deny the initial or renewal designation, without first allowing a focused review, of a trauma
5 center for any of the following reasons:
6 (1) failure to comply with G.S. 131E-162 and the rules adopted under that Statute;
7 (2) attempting to obtain a trauma center designation through fraud or misrepresentation;
8 (3) endangerment to the health, safety, or welfare of patients cared for in the hospital; or
9 (4) repetition of deficiencies placed on the trauma center in previous site visits.
10 (b) When a trauma center is required to have a focused review, it must demonstrate compliance with the provisions
11 of G.S.131E-162 and the rules adopted under that Statute within 12 months or less.
12 (c) The OEMS may revoke a trauma center designation at any time or deny a request for renewal of designation,
13 whenever the OEMS finds that the trauma center has failed to comply with the provisions of G.S. 131E-162 and the
14 rules adopted under that Statute; and
15 (1) it is not probable that the trauma center can remedy the deficiencies within 12 months or less;
16 (2) although the trauma center may be able to remedy the deficiencies within a reasonable period of
17 time, it is not probable that the trauma center shall be able to remain in compliance with
18 designation rules for the foreseeable future;
19 (3) the trauma center fails to meet the requirements of a focused review;
20 (4) failure to comply endangers the health, safety, or welfare of patients cared for in the trauma center;
21 or
22 (5) altering, destroying or attempting to destroy evidence needed for a complaint investigation.
23 (d) The OEMS shall give the trauma center written notice of revocation. This notice shall be given personally or by
24 certified mail and shall set forth:
25 (1) the factual allegations;
26 (2) the statutes or rules alleged to be violated; and
27 (3) notice of the hospital's right to a contested case hearing on the amendment of the designation.
28 (e) A focused review is not a procedural prerequisite to the revocation of a designation pursuant to Paragraph (c) of
29 this Rule.
30 (f) With the OEMS' approval, a trauma center may voluntarily withdraw its designation for a maximum of one year
31 by submitting a written request. This request shall include the reasons for withdrawal and a plan for resolution of the
32 issues. To reactivate the designation, the facility shall provide to the OEMS written documentation of compliance.
33 Voluntary withdrawal shall not affect the original expiration date of the trauma center's designation.
34 (g) If the trauma center fails to resolve the issues which resulted in a voluntary withdrawal within the specified time
35 period for resolution, the OEMS may revoke the trauma center designation.
36 (h) In the event of a revocation or voluntary withdrawal, the OEMS shall provide written notification to all hospitals
37 and emergency medical services providers within the trauma center's defined trauma primary catchment area. The

1 OEMS shall provide written notification to all hospitals and emergency medical services providers within the trauma
2 center's defined trauma primary catchment area if, and when, the voluntary withdrawal reactivates to full
3 designation.
4
5 *History Note:* *Authority G.S. 131E-162; 143-508(d)(10);*
6 *Eff. April 1, 2011.*

10A NCAC 13P .1506 is proposed for adoption as follows:

10A NCAC 13P .1506 EMS EDUCATIONAL INSTITUTIONS

(a) The OEMS may deny the initial or renewal designation, without first allowing a focused review, of an EMS Educational Institution for any of the following reasons:

(1) failure to comply with the provisions of Section .0600 of this Subchapter;
(2) attempting to obtain a EMS Educational Institution designation through fraud or misrepresentation;
(3) endangerment to the health, safety, or welfare of patients cared by students of the EMS Educational Institution; or
(4) repetition of deficiencies placed on the EMS Educational Institution in previous compliance site visits.

(b) When a EMS Educational Institution is required to have a focused review, it must demonstrate compliance with the provisions of Section .0600 of this Subchapter within 12 months or less.

(c) The OEMS may revoke a EMS Educational Institution designation at any time or deny a request for renewal of designation, whenever the OEMS finds that the EMS Educational Institution has failed to comply with the provisions of Section .0600 of this Subchapter; and:

(1) it is not probable that the EMS Educational Institution can remedy the deficiencies within 12 months or less;
(2) although the EMS Educational Institution may be able to remedy the deficiencies within a reasonable period of time, it is not probable that the EMS Educational Institution shall be able to remain in compliance with designation rules for the foreseeable future;
(3) the EMS Educational Institution fails to meet the requirements of a focused review;
(4) failure to comply endangers the health, safety, or welfare of patients cared for as part of an EMS educational program; or
(5) altering, destroying or attempting to destroy evidence needed for a complaint investigation.

(d) The OEMS shall give the EMS Educational Institution written notice of revocation. This notice shall be given personally or by certified mail and shall set forth:

(1) the factual allegations;
(2) the statutes or rules alleged to be violated; and
(3) notice of the EMS Educational Institution 's right to a contested case hearing on the amendment of the designation.

(e) Focused review is not a procedural prerequisite to the revocation of a designation pursuant to Paragraph (c) of this Rule.

(f) With the OEMS' approval, an EMS Educational Institution may voluntarily withdraw its designation for a maximum of one year by submitting a written request. This request shall include the reasons for withdrawal and a plan for resolution of the issues. To reactivate the designation, the institution shall provide to the OEMS written

1 documentation of compliance. Voluntary withdrawal shall not affect the original expiration date of the EMS
2 Educational Institution's designation.
3 (g) If the institution fails to resolve the issues which resulted in a voluntary withdrawal within the specified time
4 period for resolution, the OEMS may revoke the EMS Educational Institution designation.
5 (h) In the event of a revocation or voluntary withdrawal, the OEMS shall provide written notification to all EMS
6 Systems within the EMS Educational Institution's defined service area. The OEMS shall provide written notification
7 to all EMS Systems within the EMS Educational Institution's defined service area if, and when, the voluntary
8 withdrawal reactivates to full designation.
9
10 *History Note:* *143-508(d)(4), (d)(10);*
11 *Eff. April 1, 2011.*

1 10A NCAC 13P .1507 is proposed for adoption as follows:
2
3 **10A NCAC 13P .1507 EMS VEHICLE PERMITS**
4 (a) In lieu of suspension or revocation, the Department may issue a temporary permit for an ambulance or EMS
5 nontransporting vehicle whenever the Department finds that:
6 (1) the EMS Provider to which that vehicle is assigned has failed to comply with the provisions of
7 G.S. 131E, Article 7, and the rules adopted under that Article;
8 (2) there is a reasonable probability that the EMS Provider can remedy the permit deficiencies within
9 a length of time determined by the Department; and
10 (3) there is a reasonable probability that the EMS Provider will be willing and able to remain in
11 compliance with the rules regarding vehicle permits for the foreseeable future.
12 (b) The Department shall give the EMS Provider written notice of the temporary permit. This notice shall be given
13 personally or by certified mail and shall set forth:
14 (1) the duration of the temporary permit not to exceed 60 days;
15 (2) a copy of the vehicle inspection form;
16 (3) the statutes or rules alleged to be violated; and
17 (4) notice of the EMS Provider's right to a contested case hearing on the temporary permit.
18 (c) The temporary permit is effective immediately upon its receipt by the EMS Provider and remains in effect until
19 the earlier of the expiration date of the permit or until the Department:
20 (1) restores the vehicle to full permitted status; or
21 (2) suspends or revokes the vehicle permit.
22 (d) The Department may deny, suspend, or revoke the permit of an ambulance or EMS nontransporting vehicle if
23 the EMS Provider:
24 (1) has failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted under that
25 Article;
26 (2) obtains or attempts to obtain a permit through fraud or misrepresentation;
27 (3) has a repetition of contingencies in previous compliance site visits;
28 (4) fails to provide emergency medical care within the defined EMS service area in a timely manner
29 as determined by the EMS System;
30 (5) continues to operate the ambulance or nontransporting vehicle in a county after written
31 notification by a Board of Commissioners to cease operations in that county;
32 (6) altering, destroying or attempting to destroy evidence needed for a complaint investigation; or
33 (7) does not possess a valid EMS Provider License.
34
35 *History Note:* *Authority G.S. 131E-156(c),(d); 131E-157(c);*
36 *Eff. April 1, 2011.*

1 10A NCAC 13P .1508 is proposed for adoption as follows:

2

3 **10A NCAC 13P .1508 EMS PERSONNEL CREDENTIALS**

4 (a) Persons convicted of a felony forfeit all EMS credentials pursuant to G.S. 15A-1331A.

5 (b) An EMS credential which has been forfeited under G.S.15A-1331A may not be reinstated until the person has
6 successfully complied with the court's requirements, has petitioned the OEMS for reinstatement, has appeared
7 before the EMS Disciplinary Committee, and has had reinstatement approved. The EMS credential may initially be
8 reinstated with restrictions.

9 (c) The Department may amend, deny, suspend, or revoke the credentials of EMS personnel for any of the
10 following reasons:

11 (1) failure to comply with the applicable performance and credentialing requirements as found in this
12 Subchapter;

13 (2) making false statements or representations to the OEMS or willfully concealing information in
14 connection with an application for credentials;

15 (3) making false statements or representations, willfully concealing information, or failing to respond
16 within a reasonable period of time and in a reasonable manner to inquiries from the OEMS during
17 a complaint investigation;

18 (4) tampering with or falsifying any record used in the process of obtaining an initial EMS credential
19 or in the renewal of an EMS credential;

20 (5) in any manner or using any medium, engaging in the stealing, manipulating, copying, reproducing
21 or reconstructing of any written EMS credentialing examination questions or scenarios;

22 (6) cheating or assisting others to cheat while preparing to take or when taking a written EMS
23 credentialing examination;

24 (7) altering an EMS credential, using an EMS credential that has been altered or permitting or
25 allowing another person to use his or her EMS credential for the purpose of alteration. Altering
26 includes changing the name, expiration date or any other information appearing on the EMS
27 credential;

28 (8) unprofessional conduct, including a failure to comply with the rules relating to the proper function
29 of credentialed EMS personnel contained in this Subchapter or the performance of or attempt to
30 perform a procedure that is detrimental to the health and safety of any person or that is beyond the
31 scope of practice of credentialed EMS personnel or EMS instructors;

32 (9) being unable to perform as credentialed EMS personnel with reasonable skill and safety to patients
33 and the public by reason of illness, use of alcohol, drugs, chemicals, or any other type of material
34 or by reason of any physical or mental abnormality;

35 (10) conviction in any court of a crime involving moral turpitude, a conviction of a felony, or
36 conviction of a crime involving the scope of practice of credentialed EMS personnel;

37 (11) while under court ordered supervised probation;

1 (12) by false representations obtaining or attempting to obtain money or anything of value from a
2 patient;
3 (13) adjudication of mental incompetence;
4 (14) lack of competence to practice with a reasonable degree of skill and safety for patients including a
5 failure to perform a prescribed procedure, failure to perform a prescribed procedure competently
6 or performance of a procedure that is not within the scope of practice of credentialed EMS
7 personnel or EMS instructors;
8 (15) performing as an EMT-I, EMT-P, or EMD in any EMS System in which the individual is not
9 affiliated and authorized to function;
10 (16) testing positive for any substance, legal or illegal, that is likely to impair the physical or
11 psychological ability of the credentialed EMS personnel to perform all required or expected
12 functions while on duty;
13 (17) failure to comply with G.S. 143-518 regarding the use or disclosure of records or data associated
14 with EMS Systems, Specialty Care Transport Programs, or patients;
15 (18) refusing to consent to any criminal history check required by G.S. 131E-159;
16 (19) abandoning or neglecting a patient who is in need of care, without making reasonable
17 arrangements for the continuation of such care;
18 (20) harassing, abusing, or intimidating a patient either physically or verbally;
19 (21) falsifying a patient's record or any controlled substance records;
20 (22) engaging in any activities of a sexual nature with a patient including kissing, fondling or touching
21 while responsible for the care of that individual;
22 (23) any criminal arrests that involve charges which have been determined by the Department to
23 indicate a necessity to seek action in order to further protect the public pending adjudication by a
24 court;
25 (24) altering, destroying or attempting to destroy evidence needed for a complaint investigation;
26 (25) as a condition to the issuance of an encumbered EMS credential with limited and restricted
27 practices for persons in the chemical addiction or abuse treatment program; or
28 (26) representing or allowing others to represent that the credentialed EMS personnel has a credential
29 that the credentialed EMS personnel does not in fact have.
30 (d) When a person who is credentialed to practice as an EMS professional is also credentialed in another
31 jurisdiction and that other jurisdiction takes disciplinary action against the person, the Department may summarily
32 impose the same or lesser disciplinary action upon receipt of the other jurisdiction's action. The EMS professional
33 may request a hearing before the EMS Disciplinary Committee. At the hearing the issues will be limited to:
34 (1) whether the person against whom action was taken by the other jurisdiction and the Department
35 are the same person;
36 (2) whether the conduct found by the other jurisdiction also violates the rules of the Medical Care
37 Commission; and

1 (3) whether the sanction imposed by the other jurisdiction is lawful under North Carolina law.

2

3 *History Note:* *Authority G.S. 131E-159(f),(g); 143-508(d)(10);*

4 *Eff. April 1, 2011.*

1 10A NCAC 13P .1509 is proposed for adoption as follows:
2
3 **10A NCAC 13P. 1509 SUMMARY SUSPENSION**
4 In accordance with G.S. 150B-3(c) an EMS Provider License, EMS Vehicle Permit, or EMS credential may be
5 summarily suspended if the public health, safety, or welfare requires emergency action. This determination is
6 delegated to the Chief of the OEMS. For EMS credentials, this determination shall be made following review by the
7 EMS Disciplinary Committee pursuant to G.S. 131E-159(f). Such a finding shall be incorporated with the order of
8 the Department and the order is effective on the date specified in the order or on service of the certified copy of the
9 order at the last known address of the affected party, whichever is later, and continues to be effective during the
10 proceedings. Failure to receive the order because of refusal of service or unknown address does not invalidate the
11 order. Proceedings shall be commenced in a timely manner.
12
13 *History Note:* *Authority G.S. 131E-159(f); 150B-3(c);*
14 *Eff. April 1, 2011.*

1 10A NCAC 13P .1510 is proposed for adoption as follows:

2

3 **10A NCAC 13P .1510 PROCEDURES FOR DENIAL, SUSPENSION, AMENDMENT, OR**

4 **REVOCATION**

5 Denial, suspension, amendment or revocation of credentials, licenses, permits, approvals, or designations shall

6 follow the law regarding contested cases found in G.S. 150B.

7

8 *History Note:* *Authority G.S. 143-508(d)(10);*

9 *Eff. April 1, 2011.*