Operating Rooms

Comments:

Trauma/Burn Exclusion and Tiered Data

Carolinas HealthCare System

August 1, 2008

Ms. Victoria McClanahan
Planner
Medical Facilities Planning Section
North Carolina Division of Health Service Regulation
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

RE: Comments Regarding Operating Room Need Methodology in the Proposed 2009 State Medical Facilities Plan

Dear Ms. McClanahan:

On behalf of Carolinas HealthCare System (CHS), I am providing comments on the operating room need methodology included in the Proposed 2009 State Medical Facilities Plan (SMFP).

Level I, II and III Trauma Centers

On page 58 you requested comments regarding the exclusion of one operating room for each Level I, II or III trauma center. The trauma center rules require Level I and II trauma centers to have an operating room available immediately at all times with in-house staff availability. We agree with the current methodology that excludes one operating room for each Level I and II trauma center.

The rules for Level III trauma centers require an operating room be available within 30 minutes. CHS operates a Level III trauma center at Cleveland Regional Medical Center (CRMC) in Shelby. CRMC is able to effectively manage their surgical cases to accommodate a trauma case within the allowed time frames without holding an operating room vacant. In addition, with the exception of CRMC and High Point Regional Medical Center (the State's only other Level III center), all the designated trauma centers in the state are large regional referral medical centers (see Attachment 1). These facilities,

based on their roles in their service areas, have greater operating room capacity to accommodate the trauma rule in question. We believe as additional hospitals in North Carolina seek Level III designation these facilities will likely be similar in size to CRMC and not have the operating room capacity as the larger Level I and Level II centers. In light of our experience at CRMC and the likelihood that future Level III trauma centers will not have substantial operating room capacity, we recommend that an operating room not be subtracted from the operating room inventory of Level III trauma centers.

Tiered Operating Room Methodology

On page 80 of the Proposed 2009 SMFP you requested comments on the tiered operating room methodology. CHS attended the operating room work group meetings that resulted in the tiered methodology presented in Table 6D. Overall, we believe the tiered approach provides a more accurate view of operating room need in the State. The tiered approach also factors in actual reported data for case times and operating room hours of operation rather than statewide averages applied to a wide range of facility types. We support the tiered approach contained in the Proposed 2009 SMFP.

If we can be of any assistance to the Medical Facilities Planning Section in the coming months as the development of the final 2009 SMFP continues, please do not hesitate to contact us.

Sincerely,

F. Del Murphy, Jr.
Vice President

Attachment 1

North Carolina Designated Trauma Hospitals

Trauma Centers	Location
Level I	
UNC Health Care System	Chapel Hill
Duke University Medical Center	Durham
Wake Forest University Baptist Medical Center	Winston-Salem
University Health Systems of Eastern North Carolina	Greenville
Carolinas Medical Center	Charlotte
Wake Med	Raleigh
Level II	
New Hanover Health System	Wilmington
Mission St. Joseph's Health System	Asheville
Moses Cone Health System	Greensboro
Level III	
Cleveland Regional Medical Center	Shelby
High Point Regional Health System	High Point

Wake Forest University Baptist
MEDICAL CENTER

Michael L. Freeman
Vice President
Strategic Planning

Telephone: (336) 716-5097
Fax: (336) 716-2879
freeman@wfubmc.edu

August 1, 2008

Dr. Dan A. Myers, Chairman
State Health Coordinating Council
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-214

RE: Comments Regarding Trauma/Burn Center Operation Room Exclusion

Dear Dr. Myers,

I would like to take this opportunity on behalf of Wake Forest University Baptist Medical Center to continue thank the SHCC and State Medical Facilities Planners for all their time and effort in continuing to advance the OR Workgroup recommendation adopted in 2007. It is important for all hospitals to continue to work with the State to provide the most accurate and credible data in all areas to ensure that appropriate planning takes place and that the healthcare needs of the citizens of North Carolina are met. I am respectfully submitting comments regarding the exclusion of one OR for each Level I, II, and III Trauma Center and one additional operating room or each designated Burn Intensive Care Unit.

NCBH believes that the State Medical Facilities Plan should continue to exclude one OR for each designated Trauma Center and one OR for each designated Burn Intensive Care Unit. It is important the State to understand that if they choose to segment out and report trauma and burn cases then the current definition of capacity and resource hours would not be applicable. Trauma and burn surgeries are more complex and can often take several hours rather than the typical 3 hours designated for inpatient OR cases. In addition case times vary from a Level I to a Level III trauma facility. It would be NCBH's recommendation for the State Medical Facilities Plan to come up with a different formula to account for these cases when taking into account an OR need in a Service Area with an excluded trauma and/or burn OR.

In conclusion, Wake Forest University Baptist Medical Center welcomes the prospect of continuing to revise the current operating room need methodology. We want the data to accurately reflect true utilization and resources for all North Carolina designated Trauma Centers and Burn Intensive Care Units. Thank you for the opportunity to voice my concerns through these comments.

Sincerely,

Michael L. Freeman

Michael L. Freeman
Vice President, Medical Center Strategic Planning
Wake Forest University Baptist Medical Center

Novant HEALTH®

Remarkable People. Remarkable Medicine.

August 1, 2008

Victoria McClanahan
Planner
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

RE: 2009 Proposed State Medical Facilities Plan Request for Comments – Trauma Center OR Exclusions; Comment from Novant Health, Inc.

Dear Ms. McClanahan:

In response to the request for comments regarding the exclusion of one operating room for each North Carolina designated Trauma Center and each designated Burn Intensive Care Unit, on page 58 of the Proposed 2009 State Medical Hospitals Plan, Novant Health submits the following comments.

OR Exclusions for Trauma Centers

Novant Health supports the exclusion for Level I and Level II Trauma Centers. To receive designation as a Level I or Level II Trauma Center, an operating room and available staffing must be available 24 hours per day. The following nine hospitals are currently designated as either Level I or Level II trauma centers: ECU/Pitt County Memorial Hospital, Wake Medical Center, Duke University Medical Center, UNC Hospital at Chapel Hill, Wake Forest University/Baptist Medical Center, Carolinas Medical Center, Moses Cone Hospital, New Hanover Regional Medical Center, and Mission Hospital. See Attachment 1.

However, the requirement for Level III Trauma Centers does not require "immediate" availability of an operating room, 24 hours per day, seven days per week as is the case for Level I and II trauma centers. The rules for Level III Trauma Centers allow a 30 minute lead time for an available OR and trauma team, which is a standard for many hospitals, including Novant in emergency cases.

Requirements for designation as a Trauma Center are included in the North Carolina Administrative Code in Chapter 10, subchapter 13P. Currently, eleven of North Carolina's 122 acute care hospitals are designated as Level I, II, or III trauma centers. Operating room requirements are as follows:

10A NCAC 13P .0901 LEVEL I TRAUMA CENTER CRITERIA *(EMPHASIS ADDED)*
To receive designation as a Level I Trauma Center, a hospital shall have the following:

(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 to include:

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(i) Cardiopulmonary bypass capability;
(ii) Operating microscope;
(iii) Thermal control equipment for patients
(iv) Thermal control equipment for blood and fluids;
(v) 24-hour-per-day x-ray capability including c-arm image intensifier;
(vi) Endoscopes and bronchoscopes;
(vii) Craniotomy instruments;
(viii) Capability of fixation of long-bone and pelvic fractures; and
(ix) Rapid infuser system.

10A NCAC 13P .0902 LEVEL II TRAUMA CENTER CRITERIA *(EMPHASIS ADDED)*

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

(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 to include:
  - (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) Capability of fixation of long-bone and pelvic fractures; and
  - (vii) Rapid infuser system.

10A NCAC 13P .0903 LEVEL III TRAUMA CENTER CRITERIA

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

(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 to include:
  - (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) Rapid infuser system.

See Attachment 2 for a copy of the North Carolina Office of Emergency Medical Services Trauma Center regulations.

The North Carolina Trauma Program is well developed and well coordinated. There are seventeen Emergency Medical Services Regions which make up eight Regional Advisory Committees (RAC). Each RAC includes at least one Level I or Level II Trauma Center. There are very few differences between the Level I and Level II Trauma Center Criteria and both

require substantial resources. Requirements for the Level III program are not as extensive. For designation at all three levels a hospital has to develop a designated trauma program (administrative department) and a designated trauma service (clinical service) for trauma care. In addition, all trauma centers must participate in the trauma registry. As a result of participation in the trauma registry, annual data should be available regarding the number of trauma cases, including surgical OR cases, treated at designated Trauma Centers.

As reflected in the North Carolina Administrative Code for designation as a Trauma Center, Level I and Level II Trauma Centers are required to provide immediate availability to an operating room as part of their Trauma Center designation. These hospitals must participate in and report trauma case data to the NC Trauma Registry as part of the Trauma Center designation. Therefore, Novant Health supports the exclusion of one operating room for each Level I and Level II Trauma Center from the annual State Medical Facilities Plan operating room planning inventory, *provided associated annual Trauma surgical cases/procedures performed at the hospital also are excluded for the same time period.* It would be inconsistent to exclude the Operating Room from the inventory used for the SMFP OR need methodology without also requiring the exclusion of the trauma OR cases/surgical procedures. Over time, if such Trauma Operating Rooms are excluded from the Operating Room inventory used for the SMFP OR need determination in a county and the associated trauma OR cases are not excluded, then the county's need for new ORs will be overstated or the surplus of existing ORs would be understated.

Since an operating room is not required to be immediately available for Level III Trauma Centers per the state's Level III Trauma Center designation regulations, Novant Health does not support the exclusion of an operating room from the planning inventory for operating rooms for these Level III Trauma Center hospitals. According to the North Carolina Trauma Center web site, there are currently two Level III Trauma-Center designated hospitals in North Carolina: High Point Regional Medical Center and CMC-Cleveland Regional Medical Center. See Attachment 1.

OR Exclusions for Hospitals with Designated Burn Intensive Care Units

There are currently two North Carolina Hospital with Burn Intensive Care Units: UNC Hospitals at Chapel Hill has a 21-bed burn ICU and WFU/Baptist Medical Center as an 8-bed burn ICU. On average, the combined utilization for these two burn ICUs is 69.4%. See Table 7C, page 120 of the Proposed 2009 SMFP. According to the Certificate of Need Criteria and Standards, 10 NCAC 14C .3400, for development of a new designated Burn Intensive Care Unit, an operating room shall be available to the burn intensive care unit 24 hours per day, 7 days per week as reflected in the following citation:

10A NCAC 14C .3404 SUPPORT SERVICES

(a) An applicant proposing to develop a new burn intensive care unit or to add a bed to an existing or approved burn intensive care unit shall demonstrate that the following services, equipment and supplies shall be available to the burn intensive care unit 24 hours per day, 7 days per week:

(6) an operating room;

Novant Health supports the exclusion of one operating room for each hospital with a designated Burn ICU from the State Medical Facilities Plan operating room planning inventory, *provided the hospital can document that the operating room is used solely for burn patients and provided associated burn surgical procedures performed in the OR also are excluded from the surgical volume for the hospital for the same time period.* It would be inconsistent to exclude the Operating Room from the inventory used for the SMFP OR need determination without also requiring the exclusion of the burn OR cases/surgical procedures for the same time period. Over time, if such burn ORs are excluded from the Operating Room inventory used for the SMFP OR need determination in a county and the associated burn cases are not excluded, then the need for new ORs will be overstated or the surplus of existing ORs would be understated.

Thank you for consideration of these comments.

Sincerely,

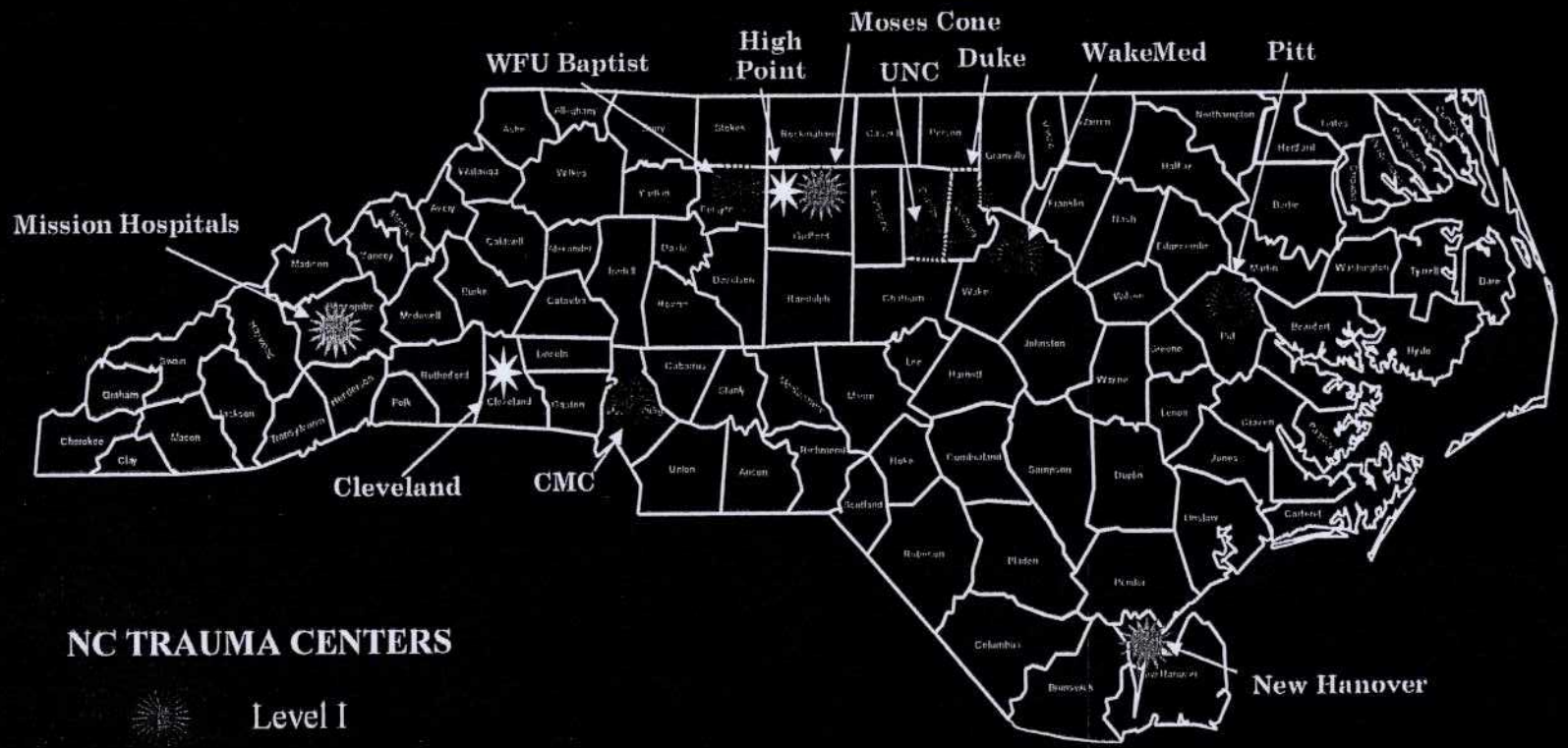
Barbara L. Freedy

Barbara L. Freedy
Director, Certificate of Need
Novant Health, Inc.

File: Draft09SMFPTraumaCenterORExclusionPetition.07.31.08.doc

North Carolina Trauma Centers

March 2008



NC TRAUMA CENTERS

- Level I
- Level II
- Level III

Counties:	100
Medical Schools:	4
Acute Care Hospitals:	122

Attachment #1

Attachment #2

(4) obtained or attempted to obtain an ambulance permit, EMS nontransporting vehicle permit, or EMS provider license through fraud or misrepresentation.

(j) The issuance of a provisional EMS provider license is not a procedural prerequisite to the revocation or suspension of a license pursuant to Paragraph (i) of this Rule.

(k) The Department may amend, deny, suspend, or revoke the credential of an EMS educational institution for any of the following reasons:

(1) failure to substantially comply with the requirements of Section .0600 of this Subchapter; or

(2) obtaining or attempting to obtain a credential through fraud or misrepresentation.

(l) The Department may amend, deny, suspend, or revoke the approval of an EMS System or designation of a Model EMS System for any of the following reasons:

(1) failure to substantially comply with the requirements of Section .0300 of this Subchapter; or

(2) obtaining or attempting to obtain designation through fraud or misrepresentation.

(m) The Department may amend, deny, suspend, or revoke the designation of a Specialty Care Transport Program for any of the following reasons:

(1) failure to substantially comply with the requirements of Section .0300 of this Subchapter; or

(2) obtaining or attempting to obtain designation through fraud or misrepresentation.

History Note: *Authority G.S. 131E-155.1(d); 131E-157(c); 131E-159(a); 143-508(d)(10);*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004.

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

Denial, suspension, amendment or revocation of credentials, licenses, permits, approvals, or designations shall follow the law regarding contested cases found in G.S. 150B.

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

SECTION .0800 – TRAUMA SYSTEM DEFINITIONS

10A NCAC 13P .0801 TRAUMA SYSTEM DEFINITIONS

The following definitions apply throughout this Subchapter:

(1) "ACS" stands for the American College of Surgeons.

(2) "Advanced Trauma Life Support (ATLS)" refers to the course sponsored by the American College of Surgeons.

(3) "Affiliated Hospital" means a non-trauma center hospital that is owned by the trauma center such that a contract or other agreement exists between these facilities to allow for the diversion or transfer of the trauma center's patient population to this non-trauma center hospital.

(4) "Attending" is a physician who has completed medical or surgical residency and is either eligible to take boards in a specialty area or is boarded in a specialty.

(5) "Board Certified, Board Certification, Board Eligible, Board Prepared, or Boarded" means approval by the American Board of Medical Specialties, the Advisory Board for Osteopathic Specialties, or the Royal College of Physicians and Surgeons of Canada unless a further sub-specialty such as the American Board of Surgery or Emergency Medicine is specified.

(6) "Bypass" means the transport of an emergency medical services patient past an emergency medical services receiving facility for the purposes of accessing a designated trauma center or a higher-level trauma center.

(7) "Contingencies" are conditions placed on a trauma center's designation that, if unmet, can result in the loss or amendment of a hospital's designation.

(8) "Deficiency" is the failure to meet essential criteria for a trauma center's designation as specified in Section .0900 of this Subchapter, that can serve as the basis for a focused review or denial of a trauma center designation.

(9) "Department" means the North Carolina Department of Health and Human Services.

(10) "Diversion" means that a hospital of its own volition reroutes a trauma patient to a trauma center from the scene or referring hospital.

(11) "E-Code" is a numeric identifier that defines the cause of injury, taken from the International Classification of Diseases (ICD).

(12) "Essential Criteria" means those items listed in Rules .0901, .0902, and .0903 of this Section that are the minimum requirements in staffing, equipment, services, etc., for the respective level of trauma center designation (I, II, or III).

(13) "Focused Review" is an evaluation of the trauma center's corrective actions to remove contingencies (as the result of deficiencies) placed upon it following a renewal site visit.

(14) "Hospital" means a licensed facility as defined in G.S. 131E-176.

(15) "Immediately Available" means the physical presence of the health professional in a location in the trauma center as defined by the needs of the trauma patient.

(16) "Lead RAC Agency" is the agency (comprised of one or more Level I or II trauma centers) that provides staff support and serves as the coordinating entity for trauma planning in a region.

(17) "Level I Trauma Center" is a regional resource trauma center that has the capability of providing leadership, research, and total care for every aspect of injury from prevention to rehabilitation.

(18) "Level II Trauma Center" is a hospital that provides definitive trauma care regardless of the severity of the injury but may not be able to provide the same comprehensive care as a Level I trauma center and does not have trauma research as a primary objective.

(19) "Level III Trauma Center" is a hospital that provides prompt assessment, resuscitation, emergency operations, and stabilization, and arranges for hospital transfer as needed to a Level I or II trauma center.

(20) "Mid-level Practitioner means a physician assistant or nurse practitioner who routinely cares for trauma patients."

(21) "OEMS" means the Office of Emergency Medical Services.

(22) "Post Graduate Year Four (PGY4)" means any surgery resident having completed three clinical years of general surgical training. A pure laboratory year shall not constitute a clinical year.

(23) "Promptly Available" means the physical presence of health professionals in a location in the trauma center within a short period of time, that is defined by the trauma system (director) and continuously monitored by the performance improvement program.

(24) "RAC" stands for "Regional Advisory Committee" which is comprised of a lead RAC agency and a group representing trauma care providers and the community, for the purpose of regional trauma planning, establishing, and maintaining a coordinated trauma system.

(25) "Revocation" means the removal of a trauma center designation for concerns related to patient morbidity or mortality or failure to meet essential criteria or recurrent contingencies.

(26) "RFP" stands for "Request for Proposal" and is a standardized state document that must be completed by each hospital seeking initial or renewal trauma center designation.

(27) "Transfer Agreement" means a formal written agreement between two agencies specifying the appropriate transfer of patient populations delineating the conditions and methods of transfer.

(28) "Trauma Center" is a hospital facility designated by the State of North Carolina and distinguished by its ability to immediately manage, on a 24-hour basis, the severely injured patient or those at risk for severe injury.

(29) "Trauma Center Criteria" means essential criteria to define Level I, II, or III trauma centers.

(30) "Trauma Center Designation" means a formalized process of approval in which a hospital voluntarily seeks to have its trauma care capabilities and performance evaluated by experienced on-site reviewers.

(31) "Trauma Guidelines" are suggested standards for practice in a variety of situations within the trauma system.

(32) "Trauma Minimum Data Set" means the basic data required of all hospitals for submission to the trauma statewide database.

(33) "Trauma Patient" is any patient with an ICD-9-CM discharge diagnosis 800.00-959.9 excluding 905-909 (late effects of injury), 910.0-924 (blisters, contusions, abrasions, and insect bites), and 930-939 (foreign bodies).

(34) "Trauma Performance Improvement Program (TPIP)" means a system in which outcome data is used to modify the process of patient care and prevent repetition of adverse events.

(35) "Trauma Program" means an administrative entity that includes the trauma service and coordinates other trauma related activities. It must also include, at a minimum, the trauma medical director, trauma program manager/trauma coordinator, and trauma registrar. This program's reporting structure shall give it the ability to interact with at least equal authority with other departments providing patient care.

(36) "Trauma Protocols" are standards for practice in a variety of situations within the trauma system.

(37) "Trauma Registry" is an OEMS-maintained database to provide information for analysis and evaluation of the quality of patient care, including epidemiological and demographic characteristics of trauma patients.

(38) "Trauma Service" means a clinical service established by the medical staff that has oversight of and responsibility for the care of the trauma patient.

(39) "Trauma System" means an integrated network that ensures that acutely injured patients are expeditiously taken to hospitals appropriate for their level of injury.

(40) "Trauma Team" means a group of health care professionals organized to provide coordinated and timely care to the trauma patient.

(41) "Triage" is a predetermined schematic for patient distribution based upon established medical needs.

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

SECTION .0900 – TRAUMA CENTER STANDARDS AND APPROVAL

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

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

(1) A trauma program and a trauma service that have been operational for at least six 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 six months prior to submitting a Request for Proposal;

(3) 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 current provider in the ACS' Advanced Trauma Life Support 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 trauma nurse coordinator (TNC)/program manager (TPM) who is a registered nurse, licensed by the North Carolina Board of Nursing;

(5) A full-time trauma registrar (TR) who has a working knowledge of medical terminology, is able to operate a personal computer, and has demonstrated 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 two separate posted call schedules. One shall be for trauma, one for general surgery. In those instances where a physician may simultaneously be listed on both schedules, there must be a defined back-up surgeon listed on the schedule to allow the trauma surgeon to provide care for the trauma patient. 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). 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) Response of a trauma team to provide evaluation and treatment of a trauma patient 24 hours per day that includes:

(a) An in-house Post Graduate Year 4 (PGY4) or senior general surgical resident, at a minimum, who is a member of that hospital's surgical residency program and responds within 20 minutes of notification;

(b) A trauma attending whose presence at the patient's bedside within 20 minutes of notification is documented and who participates in therapeutic decisions and is present at all operative procedures;

(c) 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 until the arrival of the trauma surgeon;

(d) 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 Post Graduate Year 2 (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 written back-up on the call schedule whenever the neurosurgeon is simultaneously on-call at a hospital other than the trauma center;

(e) 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 Post Graduate Year 2 (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;

(f) An in-house anesthesiologist or a Clinical Anesthesiology Year 3 (CA3) resident as long as an anesthesiologist on-call is advised and promptly available if requested by the trauma team leader, and

(g) Registered nursing personnel trained in the care of trauma patients.

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

(11) Standard written protocols relating to trauma management formulated and routinely updated;

(12) Criteria to ensure team activation prior to arrival of trauma/burn patients to include the following:

(a) Shock;

(b) Respiratory distress;

(c) Airway compromise;

(d) Unresponsiveness (Glasgow Coma Scale less than 8) with potential for multiple injuries; and

(e) Gunshot wound to head, neck, or torso.

(13) Surgical evaluation, 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; and

(f) Spinal cord injury.

(14) Surgical consults, 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 at the scene;

(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), to include individuals credentialed in the following:

(a) Cardiac surgery;

(b) Critical care;

(c) Hand surgery;

(d) Microvascular/replant surgery;

(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 Emergency Department such that:

(i) At least one physician on every shift in the Emergency Department 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 at least 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 Item (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 to 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) Rapid infuser system;
(xvii) Broselow tape;
(xviii) Sonography; and
(xix) 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 to include:
(i) Cardiopulmonary bypass capability;
(ii) Operating microscope;
(iii) Thermal control equipment for patients
(iv) Thermal control equipment for blood and fluids;
(v) 24-hour-per-day x-ray capability including c-arm image intensifier;
(vi) Endoscopes and bronchoscopes;
(vii) Craniotomy instruments;
(viii) Capability of fixation of long-bone and pelvic fractures; and
(ix) 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 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 to include:
(i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, and pocket masks);
(ii) Oxygen source with concentration controls;

(iii) Cardiac emergency cart;
(iv) Temporary, transvenous pacemaker;
(v) Electrocardiograph-oscilloscope-defibrillator with internal paddles;
(vi) Cardiac output monitoring capability;
(vii) Electronic pressure monitoring capability;
(viii) Mechanical ventilator;
(ix) Patient weighing devices;
(x) Pulmonary function measuring devices;
(xi) Temperature control devices; and
(xii) Intracranial pressure monitoring devices.

(e) 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 written transfer agreement with a burn center;

(22) Acute spinal cord management capability or written 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 to include: 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) Standard 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) For major trauma patients, 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) Full in-house rehabilitation service or a written 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 trauma registry agreed to by the North Carolina State Trauma Advisory Committee and OEMS, whose data is submitted to the OEMS at least quarterly and includes all the center's trauma patients as defined in Rule .0801(33) who are either diverted to an affiliated hospital, admitted to the trauma center for greater than 23:59 hours (24 hours or more) 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 to include all trauma deaths;

(c) Trauma performance committee that meets at least quarterly, to include 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% 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% 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% compliance.

(h) Monitoring of trauma team notification times;

(i) Review of pre-hospital trauma care to include dead-on-arrivals; and

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

(28) An outreach program to include:

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

(b) Programs for physicians within the community and within the referral area (to 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 (RAC) 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 to include:

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

(b) Surveillance methods to include 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 to include:

(a) Identifiable institutional review board process;

(b) Extramural educational presentations that must include 12 education/outreach presentations 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.

(31) A documented continuing education program for staff physicians, nurses, allied health personnel, and community physicians to include:

(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, orthopaedists, and neurosurgeons, with at least 50% of this being extramural;

(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% of this being extramural;

(d) Advanced Trauma Life Support (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 trauma nurse coordinator/program manager;

(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% 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

(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. January 1, 2004.

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

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 six 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 six 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 current provider in the ACS' Advanced Trauma Life Support Course and in the provision of trauma-related instruction to other health care personnel.

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

(5) A full-time trauma registrar (TR) who has a working knowledge of medical terminology, is able to operate a personal computer, and has demonstrated 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 two separate posted call schedules. One shall be for trauma, one for general surgery. In those instances where a physician may simultaneously be listed on both schedules, there must be a defined back-up surgeon listed on the schedule to allow the trauma surgeon to provide care for the trauma patient. 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). 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) 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 20 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 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 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 Post Graduate Year 2 (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 written back-up on the call schedule whenever the neurosurgeon is simultaneously on-call at a hospital other than the trauma center; and

(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 Post Graduate Year 2 (PGY2) or higher in-house orthopaedic surgery 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 orthopaedic emergencies. There must be a specified written back-up on the call schedule whenever the orthopaedic surgeon is simultaneously on-call at a hospital other than the trauma center; and

(e) An in-house anesthesiologist or a Clinical Anesthesiology Year 3 (CA3) resident unless an anesthesiologist on-call is advised and promptly available after notification 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.

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

(11) Standard written protocols relating to trauma care management formulated and routinely updated;

(12) Criteria to ensure team activation prior to arrival of trauma/burn patients to include the following:

(a) Shock;

(b) Respiratory distress;

(c) Airway compromise;

(d) Unresponsiveness (Glasgow Coma Scale less than eight with potential for multiple injuries; and

(e) Gunshot wound to head, neck, or torso.

(13) Surgical evaluation, 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; and

(f) Spinal cord injury.

(14) Surgical consults, 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 at the scene;
- (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), to include individuals credentialed in the following:
- (a) Critical care;
- (b) Hand surgery;
- (c) 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.);
- (d) Obstetrics/gynecologic surgery;
- (e) Opthalmic surgery;
- (f) Oral maxillofacial surgery;
- (g) Orthopaedics (dedicated to one hospital or a back-up call schedule must be available);
- (h) Plastic surgery;
- (i) Radiology;
- (j) Thoracic surgery; and
- (k) 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 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; 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) 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 to 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) Rapid infuser system;
(xvii) Broselow tape;
(xviii) Sonography; and
(xix) 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 to include:
(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) Capability of fixation of long-bone and pelvic fractures; and
(vii) 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 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 to include:
(i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, and pocket masks);
(ii) Oxygen source with concentration controls;
(iii) Cardiac emergency cart;
(iv) Temporary transvenous pacemaker;
(v) Electrocardiograph-oscilloscope-defibrillator with internal paddles;
(vi) Cardiac output monitoring capability;
(vii) Electronic pressure monitoring capability;
(viii) Mechanical ventilator;
(ix) Patient weighing devices;
(x) Pulmonary function measuring devices;
(xi) Temperature control devices; and
(xii) Intracranial pressure monitoring devices.
(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 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 written 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 to include 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) Standard 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 major 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) Full in-house rehabilitation service or a written 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 trauma registry agreed to by the North Carolina State Trauma Advisory Committee and OEMS whose data is submitted to the OEMS at least quarterly and includes all the center's trauma patients as defined in Rule .0801(33) who are either diverted to an affiliated hospital, admitted to the trauma center for greater than 23:59 hours (24 hours or more) 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 to include all trauma deaths;

(c) Trauma performance committee that meets at least quarterly, to include 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% 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% 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% compliance;
(h) Monitoring of trauma team notification times;
(i) Review of pre-hospital trauma care to include dead-on-arrivals; and
(j) Review of times and reasons for transfer of injured patients.

(28) An outreach program to include:
(a) Written transfer agreements to address the transfer and receipt of trauma patients;
(b) Programs for physicians within the community and within the referral area (to 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 (RAC) as specified in Rule .1102 of this Subchapter;
(d) Development of regional criteria for coordination of trauma care; and
(e) Assessment of trauma system operations at the regional level.

(29) A program of injury prevention and public education to include:
(a) Designation of an injury prevention coordinator; and
(b) Outreach activities, program development, information resources, and collaboration with existing national, regional, and state trauma programs.

(30) A documented continuing education program for staff physicians, nurses, allied health personnel, and community physicians to include:
(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% of this being extramural;
(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% of this being extramural;
(c) Advanced Trauma Life Support (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 trauma nurse coordinator/program manager;
(e) 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;
(f) at least 80% 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 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. January 1, 2004.

10A NCAC 13P .0903 LEVEL III TRAUMA CENTER CRITERIA

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

(1) A trauma program and a trauma service that have been operational for at least six 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 six 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;
   (d) Remain a current provider in the ACS' Advanced Trauma Life Support Course in the provision of trauma-related instruction to other health care personnel.

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

(5) A trauma registrar (TR) who has a working knowledge of medical terminology, is able to operate a personal computer, and has demonstrated 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 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 serve as a designated member of the trauma team until the arrival of the trauma surgeon;
   (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 20 minutes of notification.

(9) A written 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) Current board certification or eligibility of orthopaedists, with board certification within five years after successful completion of residency;

(11) Standard written protocols relating to trauma care management formulated and routinely updated;

(12) Criteria to ensure team activation prior to arrival of trauma/burn patients to include the following:
   (a) Shock;
   (b) Respiratory distress;
   (c) Airway compromise;
   (d) Unresponsiveness (Glasgow Coma Scale less than eight) with potential for multiple injuries; and
   (e) Gunshot wound to head, neck, or torso.

(13) Surgical evaluation, 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; and
(f) Spinal cord injury.

(14) Surgical consults, 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 at the scene;
(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) to include individuals credentialed in the following:
(a) Orthopaedics; and
(b) Radiology.

(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 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; 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 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 to 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; and
(xiv) Thermal control equipment for blood and fluids;
(xv) Rapid infuser system;
(xvi) Broselow tape; and
(xvii) 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 to include:
  - (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) 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 to include:
  - (i) 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 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 (which may be a physician who is the sole physician on-call for the Emergency Department);
- (c) Equipment for patients of all ages to include:
  - (i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators and pocket masks);
  - (ii) Oxygen source with concentration controls;
  - (iii) Cardiac emergency cart;
  - (iv) Temporary transvenous pacemaker;
  - (v) Electrocardiograph-oscilloscope-defibrillator;
  - (vi) Cardiac output monitoring capability;
  - (vii) Electronic pressure monitoring capability;
  - (viii) Mechanical ventilator;
  - (ix) Patient weighing devices;
  - (x) Pulmonary function measuring devices; and
  - (xi) Temperature control devices.
- (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 written transfer agreement with a hospital capable of caring for a spinal cord injured patient;

(23) Acute head injury management capability or written 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 to include 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) Standard 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) Full in-house rehabilitation service or written 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 trauma registry agreed to by the North Carolina State Trauma Advisory Committee and OEMS, whose data is submitted to the OEMS at least quarterly and includes all the center's trauma patients as defined in Rule .0801(33) who are either diverted to an affiliated hospital, admitted to the trauma center for greater than 23:59 hours (24 hours or more) 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 to include all trauma deaths;
(c) Trauma performance committee that meets at least quarterly, to include 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% of the regular meetings;
(d) Multidisciplinary peer review committee that meets at least quarterly and includes physicians from trauma, emergency medicine, 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% 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, airway managers, and orthopaedists. All must demonstrate 80% compliance;
(h) Monitoring of trauma team notification times;
(i) Documentation (unless in-house) and review of Emergency Department response times for anesthesiologists or airway managers and computerized tomography technologist;
(j) Documentation of availability of the surgeon on-call for trauma, such that compliance is 90% or greater where there is no trauma surgeon back-up call schedule;
(k) Trauma performance and multidisciplinary peer review committees may be incorporated together or included in other staff meetings as appropriate for the facility performance improvement rules;
(l) Review of pre-hospital trauma care to include dead-on-arrivals; and
(m) Review of times and reasons for transfer of injured patients.

(30) An outreach program to include:
(a) Written transfer agreements to address the transfer and receipt of trauma patients;
(b) Participation in a Regional Advisory Committee (RAC).

(31) Coordination or participation in community prevention activities;

(32) A documented continuing education program for staff physicians, nurses, allied health personnel, and community physicians to include:

(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, with at least 50% of this being extramural;

(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% of this being extramural;

(c) Advanced Trauma Life Support (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 trauma nurse coordinator/program manager;

(e) 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;

(f) At least an 80% 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. January 1, 2004.

10A NCAC 13P .0904 INITIAL DESIGNATION PROCESS

(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.

(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 also 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 at a minimum:

(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;

(2) Geographic considerations to include trauma primary and secondary catchment area and distance from other trauma centers; and

(3) Trauma patient volume and severity of injury for the facility for the 24-month period of time preceding the application. The trauma center shall show that its trauma service will be taking care of at least 200 trauma patients with an Injury Severity Score (ISS) greater than or equal to 15 during the first 2-year period of its designation. 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 200-patient minimum.

(c) Following receipt of the letter of intent by OEMS, any designated Level I or II trauma center(s) sharing all or part of the applicant's catchment area must provide to OEMS a trauma registry download for the same two-year period used by the applicant. This download shall be provided within 30 days of the request of OEMS.

(d) OEMS shall review the regional 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 Paragraphs (b)(1) – (3) of this Rule. Simultaneously, the applicant's primary RAC shall be notified of the application and be provided the regional data as required in Paragraphs (b)(1) – (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 so that any necessary changes in protocols can be considered.

(f) OEMS shall also 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 an original and five copies of bound, page-numbered 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) – (h) of this Rule.
(j) If the OEMS recommends the hospital for a site visit, the hospital shall be notified within 30 days and the site visit shall be conducted within six months of the recommendation. The site visit shall be scheduled on a date 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 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 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;
(5) The medical director of the OEMS; and
(6) The Hospitals Specialist of the OEMS.

(l) All site team members for a Level III visit shall be from in-state, and all (except for the OEMS representatives) shall be from outside the planning region in which the hospital is located. The composition of a Level III state 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) A trauma nurse coordinator/program manager;
(4) The medical director of the OEMS; and
(5) The Hospitals Specialist of the OEMS.

(m) On the day of the site visit the hospital shall make available all requested patient medical charts.
(n) A post-conference report based on the consensus of the site review team shall be given verbally during a summary conference. A written consensus report will be completed, to include a peer review report, by the primary reviewer and submitted to OEMS within 30 days of the site visit.
(o) The report of the site survey team and the staff recommendations shall be reviewed by the State Emergency Medical Services Advisory Council at its next regularly scheduled meeting which is more than 45 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 designation be approved or denied.
(p) All criteria defined in Rule .0901, .0902, or .0903 of this Section shall be met for initial designation at the level requested. Initial designation shall not be granted if deficiencies exist.
(q) Hospitals with a deficiency(ies) may be given up to 12 months to demonstrate compliance. Satisfaction of deficiency(ies) may require an additional site visit. If compliance is not demonstrated within the time period, to be defined by OEMS, the hospital shall be required to submit a new application and updated RFP and follow the process outlined in Paragraphs (a) – (h) of this Rule.
(r) The final decision regarding trauma center designation shall be rendered by the OEMS.
(s) The hospital shall be notified, in writing, of the State Emergency Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the Advisory Council meeting.

(t) If a trauma center changes its trauma program administrative structure (such that the trauma service, trauma medical director, trauma nurse coordinator/program manager and/or trauma registrar are relocated on the hospital's organizational chart) at any time, it shall notify OEMS of this change in writing within 30 days of the occurrence.
(u) Initial designation as a trauma center is valid for a period of three years.

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

10A NCAC 13P .0905 RENEWAL DESIGNATION PROCESS

(a) One of two options may be utilized 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 three- 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 seeking a renewal of trauma center designation shall complete and submit an original and five copies of a bound, page-numbered RFP as directed by the OEMS 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) A post-conference report based on consensus of the site review team shall be given verbally during 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); 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, may be given a time period (up to 12 months) 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 be required to 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 hospital shall be notified in writing 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.

(14) Hospitals in the process of satisfying contingencies placed on them prior to December 31, 2001, shall be evaluated based on the rules that were in effect at the time of their renewal visit.

(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) 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.

(3) When completing the ACS' documentation for verification, the trauma center must simultaneously submit two identical copies 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.

(4) 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.

(5) 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.

(6) 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 shall be required of the surgeons or emergency physician, respectively, if from out-of-state.

(7) 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 shall be required of the surgeon or emergency physician, respectively, if from out-of-state.

(8) All state trauma center criteria must be met as defined in Rules .0901, .0902, and 0903, for renewal of state designation. An ACS' verification is not required for state designation. An ACS' verification does not ensure a state designation.

(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 written reports from the ACS and the OEMS staff recommendation shall be reviewed by the State Emergency Medical Services Advisory Council at its next regularly scheduled meeting. The State EMS Advisory Council shall recommend to 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 hospital shall be notified 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 may be given up to 12 months 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 be required to submit a new RFP and follow the initial applicant process outlined in Rule .0904 of this Section.

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

SECTION .1000 – TRAUMA CENTER DESIGNATION ENFORCEMENT

10A NCAC 13P .1001 DENIAL, FOCUSED REVIEW, VOLUNTARY WITHDRAWAL, OR REVOCATION OF TRAUMA CENTER DESIGNATION

(a) The OEMS may deny the initial or renewal designation (without first allowing a focused review) of a trauma center for any of the following reasons:

(1) Failure to comply with G.S. 131E-162 and the rules adopted under that article; or
(2) Attempting to obtain a trauma center designation through fraud or misrepresentation; or
(3) Endangerment to the health, safety, or welfare of patients cared for in the hospital; or
(4) Repetition of contingencies placed on the trauma center in previous site visits.

(b) When a trauma center is required to have a focused review, an option only for a trauma center seeking renewal, it must be able to demonstrate compliance with the provisions of G.S.131E-162 and the rules adopted under that article within one year or less as required and delineated in writing by OEMS.

(c) The OEMS may revoke a trauma center designation at any time or deny a request for renewal of designation, whenever the OEMS finds that the trauma center has failed to comply with the provisions of G.S. 131E-162 and the rules adopted under that article; and

(1) It is not probable that the trauma center can remedy the deficiencies within one year or less; or
(2) Although the trauma center may be able to remedy the deficiencies within a reasonable period of time, it is not probable that the trauma center shall be able to remain in compliance with designation rules for the foreseeable future; or
(3) The trauma center fails to meet the requirements of a focused review; or
(4) Failure to comply endangers the health, safety, or welfare of patients cared for in the trauma center.

(d) The OEMS shall give the trauma center 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 hospital'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 (d) of this Rule.

(f) With the OEMS' approval, a trauma center 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 facility shall provide written documentation of compliance that is acceptable to the OEMS. Voluntary withdrawal shall not affect the original expiration date of the trauma center's designation.

(g) If the trauma center fails to resolve the issues which resulted in a voluntary withdrawal within the specified time period for resolution, the OEMS may revoke the trauma center designation.

(h) In the event of a revocation or voluntary withdrawal, the OEMS shall provide written notification to all hospitals and emergency medical services providers within the trauma center's defined trauma primary catchment area. The OEMS shall provide written notification to same if, and when, the voluntary withdrawal reactivates to full designation.

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

10A NCAC 13P .1002 PROCEDURES FOR APPEAL OF DENIAL, FOCUSED REVIEW, OR REVOCATION

Appeal of denial or revocation of a trauma center designation shall follow the law regarding contested cases found in G.S. 150B.

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

10A NCAC 13P .1003 MISREPRESENTATION OF DESIGNATION

(a) Hospitals shall not represent themselves as trauma centers unless they are currently designated by the Department pursuant to Section .0900 of this Subchapter.

(b) Designation applies only to the hospital that submitted the RFP and underwent the formal site survey and does not extend to its satellite facilities or affiliates.

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

SECTION .1100 – TRAUMA SYSTEM DESIGN

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 and monitored by the OEMS.

(b) The OEMS shall require that each hospital select a Regional Advisory Committee (RAC). If a hospital does not exist in a given county, the EMS System for the county shall select the RAC. Each RAC shall include at least one Level I or II trauma center. Any hospital changing its affiliation shall report the change in writing to the OEMS within 30 days of the date of the change.

(c) The OEMS shall notify each RAC of its hospital and county membership.

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

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 shall include, at a minimum, 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.

(b) The RAC membership shall include, at a minimum, 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) or designee(s), as well as an identified RAC registrar or designee(s) from the lead RAC agency;
(3) A senior level hospital administrator;
(4) An emergency physician;
(5) An Emergency Medical Services representative;
(6) A representative from each hospital participating in the RAC;
(7) Community representatives;
(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 containing at a minimum:

(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 the RAC Registry.

(d) The RAC shall submit to the OEMS an annual progress report that assesses compliance with the regional trauma system plan and specifies any updates to the plan.

(e) Upon OEMS' receipt of a letter of intent for initial Level I or II trauma center designation pursuant to Rule .0904 (b) of this Subchapter, the applicant's RAC shall be provided the applicant's data from OEMS to review and comment. This data which should demonstrate the need for the trauma center designation must include at a minimum:

(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;
(2) Geographic considerations to include trauma primary and secondary catchment area and distance from other trauma centers; and
(3) Trauma patient volume and severity of injury for the facility for the 24-month period of time preceding the application. The trauma center shall show that its trauma service will be taking care of at least 200 trauma patients with an Injury Severity Score (ISS) greater than or equal to 15 during the first two-year period of its designation. 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 200-patient minimum.

(f) The RAC has 30 days to comment on the request for initial designation.

(g) The RAC shall also be notified of the OEMS approval to submit an RFP so that necessary changes in protocols can be considered.

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

10A NCAC 13P .1103 REGIONAL TRAUMA SYSTEM POLICY DEVELOPMENT

The RAC shall oversee the development, implementation, and evaluation of the regional trauma system to include:

(1) Public information and education programs to include system access and injury prevention;
(2) Written trauma system guidelines to address the following:
    (a) Regional communications;
    (b) Triage;
    (c) Treatment at the scene and in the pre-hospital, inter-hospital, and Emergency Department to include guidelines to facilitate the rapid assessment and initial resuscitation of the severely injured patient, including primary and secondary survey. Criteria addressing management during transport shall include continued assessment and management of airway, cervical spine, breathing, circulation, neurologic and secondary parameters, communication, and documentation.
    (d) Transport to determine the appropriate mode of transport and level of care required to transport, considering patient condition, requirement for trauma center resources, family requests, and capability of transferring entity.
    (e) Bypass procedures that define:
        (i) circumstances and criteria for bypass decisions;
        (ii) time and distance criteria; and
        (iii) mode of transport which bypasses closer facilities.
    (f) Scene and inter-hospital diversion procedures that shall include delineation of specific factors such as hospital census or acuity, physician availability, staffing issues, disaster status, or transportation which would require routing of a patient to another trauma center.
(3) Transfer agreements (to include those with other hospitals, as well as specialty care facilities such as burn, pediatrics, spinal cord, and rehabilitation) which shall outline mutual understandings between

facilities to transfer/accept certain patients. These shall specify responsible parties, documentation requirements, and minimum care requirements.

(4) A performance improvement plan that includes:

(a) A regional trauma peer review committee of the RAC;

(i) whose membership and responsibilities are defined in G.S. 131E-162; and

(ii) continuously evaluates the regional trauma system through structured review of process of care and outcomes; and

(b) The existing trauma registry database and the RAC registry database, once operational, that report quarterly or as requested by the OEMS.

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

SECTION .1200 - TRAUMA SYSTEM DESIGN

10A NCAC 13P .1201 STATE TRAUMA SYSTEM PLAN
10A NCAC 13P .1202 REGIONAL TRAUMA SYSTEM PLAN
10A NCAC 13P .1203 REGIONAL TRAUMA SYSTEM POLICY DEVELOPMENT

History Note: *Authority G.S. 131E-162;*
Eff. August 1, 1998;
Repealed Eff. January 1, 2004.

SECTION .1300 - FORMS

10A NCAC 13P .1301 SOURCE OF FORMS AND DOCUMENTS

History Note: *Authority G.S. 131E-162;*
Eff. August 1, 1998;
Repealed Eff. January 1, 2004.

UNIVERSITY HEALTH SYSTEMS
of Eastern Carolina

DFS Health Planning
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AUG 01 2008
Medical Facilities
Planning Section

August 1, 2008

State Health Coordinating Council
Dr. Dan Myers, Chair
c/o Medical Facilities Planning Section
North Carolina Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

RE: RESPONSE TO REQUEST FOR COMMENTS – PROPOSED 2009 SMFP

Comments on behalf of:
Pitt County Memorial Hospital, Greenville
Bertie Memorial Hospital, Windsor
Chowan Hospital, Edenton
Duplin General Hospital, Kenansville
Heritage Hospital, Tarboro
Roanoke-Chowan Hospital, Ahoskie
The Outer Banks Hospital, Nags Head

Dear Council Members:

Thank you for requesting feedback on the basic principles and on several changes outlined in the proposed 2009 State Medical Facilities Plan (SMFP). The comments below are made on behalf of the seven hospitals in the University Health Systems' Corporation. These comments support the concerns of not only our system hospitals but of the people living in the communities within our 29-county service area.

Basic Principles Governing the Development of the SMFP (pp. 2-5 of proposed 2009 SMFP)

The work group did an exceptional job of tackling a very challenging task -- the restatement of the basic principles on quality, access and value. While the updated principles are thorough and timely, we believe there is a need for more clarity if these principles are to be used as a reference for policy or methodology changes or as a means by which to evaluate competing certificate of need applications. Overall, the restatement supports the following:

- The need to define and track evidence-based, standardized, measurable, and consistent quality metrics,
- The importance of using rational criteria to compare the value of supporting existing providers who offer comprehensive services to a disproportionate share of the medically underserved and the value of encouraging new providers who may wish to provide a specialty service to a disproportionate share of well-funded patients, and
- An expanded view of the impact of the principles beyond the local level or in the short-term view, especially when the state must compare the cost-effectiveness and benefits of programs designed to meet the needs defined in the SMFP.

We encourage you to support the following action steps, many of which are embedded in the restatement of basic principles. In fact, in order to give these action items appropriate emphasis, we suggest revising the restatement to include only the core value statements for each principle in the SMFP. We believe the action items should be listed separately and provided to the small work group that will be appointed to help create a more concrete implementation plan.

- Establish the small workgroup as soon as possible to develop the implementation plan. Include in this workgroup members from DHSR, experts in the area of healthcare quality measurements, and providers who can appropriately represent the needs of the medically underserved. Balance rural and urban market representatives on the small group.
- Provide the opportunity for public comment at public hearings once an implementation plan is developed.
- Recommend changes to CON special rules, applications and review criteria to assure these tools are integrated with, and support, implementation of the basic principles.
- Define the publicly available, standardized measures for quality and safety that should be reported at least annually by any service provider approved by CON. Strongly consider implementing measures that would require current holders of regulated services to report similar data. Defined metrics must support comparisons among providers in order to evaluate, track and sustain compliance.
- Define publicly available and standardized measures for patient satisfaction that should be reported at least annually by any service provider approved by CON. Strongly consider implementing measures that would require current holders of regulated services to report similar data. Defined metrics must support comparisons among providers in order to evaluate, track and sustain compliance.
- Identify standard definitions and quantifiable economic measures for charity and under-compensated care and the medically under-served. Any measures of access used to secure CON approval should be reported annually and tracked against generally accepted standards and definitions for these measures.
- Continue to acknowledge the special needs and circumstances of rural community providers who are the sole providers of comprehensive care and emergency services when evaluating costs and value.
- All required public reporting by providers should be readily available to the general public (e.g. website postings, public notices, etc.).

Step 4 – Inventory of Operating Rooms (pg. 58 of proposed 2009 SMFP)

We strongly support continuing to exclude one operating room for Trauma Centers when determining operating room need in an OR Service Area with a state-designated Level I, II, or III Trauma Center. Pitt County Memorial Hospital (PCMH), the only Level I Trauma Center in eastern NC, has at least one operating room readily available at any given time to serve trauma patients. However, this does not mean there is only one distinct room that is always used or available for trauma patients. Because PCMH must routinely have one operating room (or the equivalent capacity) available for trauma patients, the hospital cannot use this available operating room capacity for other patients. This requirement limits the overall

operating room capacity for PCMH. The exclusion of one "trauma" operating room when determining operating room need is essentially diluted when the hospital must also exclude trauma cases.

For that reason, we request the SHCC consider not excluding the trauma cases if there is need for additional operating rooms in an OR Service Area with a state-designated Level I, II, or III Trauma Center. If the state desires to continue to exclude trauma cases in this situation, we propose using a standard definition for calculating excluded cases. One recommendation is to define excluded trauma cases as follows: Patients that are defined as a "trauma patient" by the state Trauma Registry who are sent to a hospital operating room directly from the hospital's Emergency Department for life or limb-saving surgical intervention.

Tiered Operating Room Data (pp. 79-102 of proposed 2009 SMFP)

We support the use of a tiered approach to evaluate operating room need across the state. We support a small group revisiting this and the remaining recommendations made by the last OR Work Group. In concept, if the tiered approach is designed to group like institutions and allow calculation of median resource hours and case time, then we suggest the state consider creating an academic medical center tier. These facilities are unique in terms of the types and complexity of patients each center serves, variables that significantly impact the use and need for operating rooms. The current Tier 1 contains a number of hospitals that vary substantially in terms of beds, services and complexity. An analysis of the resource hours and case time specific to academic medical centers is needed to determine if different resource hours and case time are needed for these institutions.

Please feel free to call me if you have questions or need additional information concerning our healthcare system's comments. Thank you in advance for your careful consideration of our input.

Sincerely,

Sue Collier

Sue Collier, Vice President, Planning & Strategic Development
University Health Systems of Eastern Carolina
P. O. Box 6028
Greenville, NC 27835-6028
scollier@pcmh.com
Phone: 252-847-2222

UNC HEALTH CARE

August 1, 2008

Dr. Dan Meyers, Chair
State Health Coordinating Council
c/o Medical Facilities Planning Section
North Carolina Division of Health Services Regulation
Raleigh, N.C. 27699-2714

Re: UNC Health Care System's Comments on the Proposed 2009 State Medical Facilities Plan

The UNC Health Care System appreciates the opportunity to provide comments on the proposed 2009 State Medical Facilities Plan. We will be commenting on several things today: I) the quality, access and value principles; II) the operating room methodology; III) the cardiac catheterization equipment section; and, IV) the heart lung bypass machine section.

I. Quality, Access, and Value Principles

UNC Health Care supports the concept of relating quality, access, and value to the State Medical Facilities Planning Process. For clarity and implementation we have several suggestions: 1) the principles should be equitable and enforceable; 2) quality reporting should be consistent across provider types; 3) a history of providing access to medically underserved patients should be considered when evaluating applicants; and 4) the contributions of Academic Medical Centers should be reflected in the principles. We support the concept of a working group continuing to work on this initiative to ensure that these elements are presented in a fair and consistent manner. Specific comments for each of these suggestions follow.

1. The Principles should be Enforceable & Equitable

On page 2 of the proposed SMFP, the Basic Principles that are proposed to govern the development of the North Carolina State Medical Facilities Plan are presented. These Basic Principles are to "reliably serve as reference guidelines for the SHCC when it considers any policy or methodology inclusion, elimination, and/or modification." That concept is an excellent idea for overall policy making. The SHCC needs to clarify its intentions depending on its goals. If the SHCC wants to use this only as a guiding principal, what is in the SMFP is adequate. However, unless there are clear and equitable requirements that can be compared across CON applications, then they cannot be effectively utilized in the regulatory process.

As an example, consider the following Basic Principle: "When performance data on established quality and safety metrics as identified by the SHCC are available for a CON applicant, they should be required and considered by the CON Section in

evaluating the quality of service provided by that applicant." This statement is not enforceable by CON as presently stated and should be removed from the Basic Principles and addressed in the specific Policies within the SMFP or within specific rules in the CON Criteria and Standards. Another example under the Access Principle is the statement "The first priority is to ameliorate economic barriers and the second priority is to mitigate time and distance barriers, but CON applicants should address how their proposal will reduce all access barriers." Unless this is an action item that is moved to a Policy that an applicant must respond to, or to a Criteria and Standard that an applicant must respond to, we do not believe that the regulators can enforce the intent of this statement in reviewing Certificate of Need applications.

In addition, if rules are developed, they must apply equally to all applicants but in reality not all applicants have quality metrics or data. If one applicant has developed data, but another has not, is it fair to apply a required data reporting standard to the first applicant and not the other? We believe that the SHCC has a responsibility for assuring equal and consistent applicability of any metrics and data used in the regulatory process.

In summary, instructions and action steps for the SHCC in development of the SMFP are different than policies and rules that can be applied in making decisions in reviewing CON applications. Therefore we recommend that the two be separated with the Basic Principles stated in the annual SMFP and the action steps addressed through the SHCC's annual planning process, perhaps at the subcommittee or workgroup level.

2. Quality Data Reporting should be Consistent

With respect to quality, the SHCC has a responsibility to assure that any reporting mechanism the SHCC proposes is comparable, consistent, and measurable across all provider types. Currently, there is no data collection or reporting system that meets this standard. In addition, some providers do not currently collect quality data. It is not evident how providers who do not currently have quality data will be fairly evaluated against providers who do have that data. Just having one provider say it supports the quality principle while another is required to provide data proving it supports the principle does not lead to a fair comparison. It should be recognized that there is a cost to acquire and provide data on quality and value, and this needs to be considered as well.

In addition, we wholeheartedly agree that patient satisfaction is vital to helping us evaluate our success as an institution. However, we also know that providers are using very different patient satisfaction surveys and changing surveys has the potential to affect results. How will you create consistency in patient satisfaction data collection across all provider types?

In sum, if data is requested for the quality, access and value principles, then there should be a framework and rules developed for consistently providing that data across providers regardless of licensure status. The rule must apply to hospitals, physicians, physician groups, for-profit and not-for-profit entities equally.

Additional work is required if the SHCC is to implement the quality, access and value principles beyond a basic philosophy.

3. A History of Access for Medically Underserved Patients should be assessed

UNC Health Care is particularly interested in making sure patients have access to necessary health care services and that access issues are adequately reflected in the quality, access and value principles. We agree with the North Carolina Hospital Association's position statement that CON applicants with a documented history of service accessibility to the medically underserved patients should not be penalized if higher costs resulting from the services they provide are evident in a CON application.

4. ***The Value of Academic Medical Center's should be reflected***

As an academic medical center, we have an important charge of educating future health professionals and advancing the field of medicine through research. Like other Academic Medical Centers (AMCs), the costs and charges we have may be higher than our non-teaching hospital counterparts that do not have this societal contribution as part of their Mission and responsibilities. However, penalizing AMCs because of their higher costs has serious implications for our ability to continue educating and training physicians throughout the State? The SHCC needs to directly incorporate the importance of teaching and research in the value statement, and recognize the significant contributions of Academic Medical Centers to the health care system in North Carolina.

II. Operating Room Methodology

The proposed 2009 SMFP (and earlier SMFPs) incorporates excluding 1 Operating Room for each Level I, II, and III Trauma Center and 1 additional Operating Room for each designated Burn Intensive Care Unit. In the Draft SMFP, there is a request for comments on this part of the methodology. Because of the impact and importance of Level I Trauma Centers and the N.C. Jaycee Burn Center to the care of patients from across the State, we support the methodology as presently configured to provide these excluded Operating Rooms. Furthermore while the cases should be counted in the existing methodology, we believe there would be significant issues isolating these cases for reporting purposes routinely. Therefore we support the current operating room methodology regarding the Trauma/Burn Intensive Care exclusion criteria as reflected in the proposed 2009 SMFP.

III. Cardiac Catheterization Equipment

Table 9Q (pg. 187) of the proposed 2009 SMFP gives both pediatric and adult cardiac catheterization volumes. However, the table only lists UNC as having 3 catheterization labs. UNC Health Care operates a fourth cardiac catheterization laboratory that is dedicated to pediatric heart catheterizations. The volume from this fourth lab was included in the table; however, the lab itself was not included in the table. We request that table 9Q be footnoted to indicate that we have 1 pediatric catheterization lab in addition to the 3 adult catheterization labs already reflected in the table.

IV. HEART LUNG BYPASS MACHINES

Table 7B (pg 117) is designed to account for the fact that certain facilities (UNC and 4 others) provide heart lung bypass procedures on children under the age of 14. The table is supposed to multiply the number of procedures performed on children age 14 and under by two before adding it to the number of procedures performed on adults (reflected in table 7A). This is to account for the weighting for all procedures performed on young children.

Currently, table 7B reflects all procedures listed in table 7A and the number of procedures performed on children 14 and under has been added to that total. However, the table does not have the increased weight for the procedures performed on children under the age of 14 included. We believe this is true for all providers that perform these special procedures – not just UNC.

We request that table 7B be modified such that UNC has a total of 595 procedures listed.

- Current table 7B justification: 375 + 110 = 485
- Corrected table 7B justification: 375 + 110 (multiplied by 2) = 595

Thank you for this opportunity to comment.

Sincerely and on behalf of the UNC Health Care System,

Mary A. Beck, MPH, FACHE
Senior Vice President for System Affiliations
3rd Floor, Med Wing E
Chapel Hill, NC 27514
Work: (919) 966-4038
Fax: (919) 966-5001
mbeck@unch.unc.edu

Wake Forest University Baptist
MEDICAL CENTER

Michael L. Freeman
Vice President
Strategic Planning

Telephone: (336) 716-5097
Fax: (336) 716-2879
freeman@wfubmc.edu

August 1, 2008

Dr. Dan A. Myers, Chairman
State Health Coordinating Council
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-214

RE: Comments Regarding Table 6D Discussion Table for Operating Room Need Projections Using Tiered Data

Dear Dr. Myers,

I would like to take this opportunity on behalf of Wake Forest University Baptist Medical Center to thank the SHCC and State Medical Facilities Planners for all their time and effort in continuing to advance the OR Workgroup recommendation adopted in 2007. It is important for hospitals, physicians and other providers to work with the State to provide the most accurate and credible data in all areas to ensure that appropriate planning takes place and that the healthcare needs of the citizens of North Carolina are met. However, for many reasons, I believe that the OR Workgroup recommendation for the 2009 State Medical Facilities Plan continues to need further refinement. A summary of the original recommendation is provided below:

> *Recommendation 2 – Hospital tiers: Recommend DFS develop capacity to further refine the OR methodology incorporating all three Basic Principles governing the development of the State Medical Facilities Plan using facility specific total surgical hours, as reported in the license renewal data, to develop tiers of like institutions. This would allow calculation of median resource hours per day and case times per tier group, to be considered by the Acute Care Services Committee, for replacing the current use of 9 hours of OR availability, 3 hours for inpatient cases, and 1.5 hours for outpatient cases.*

I am respectfully submitting comments concerning the tiering methodology described above. My concerns are outlined in the following comments:

First, NCBH proposes the tiers be reorganized to allow for a separate recognition of the Academic Medical Centers (AMC) in North Carolina. By proposing to currently group the AMCs along with large community hospitals, the median number of resource hours and inpatient and ambulatory case times do not accurately reflect the true level of case times utilized by AMCs.

The methodology should be revised to recognize the unique characteristics of surgery patients treated at Academic Medical Centers. These characteristics include the following: AMC patients have a higher acuity index, AMC patients are non-typical due to the investigational nature of their care, AMC patient complexity equates to higher throughput times, and other factors such as the fact that many AMCs are also Level I trauma centers, two of which are also designated burn centers. All of these characteristics create a unique set characteristics associated with AMCs.

A detailed look at the data further reflects the difference between AMCs and larger community hospitals in North Carolina. A calculation of median resource hours as well as inpatient and ambulatory case times using the 2008 License Renewal Application data was performed to identify the differences as depicted below:

Second, the overall tiering methodology as it is currently calculated actually reduces the projected OR need in 2011 for all Tier 1 hospitals. I believe this speaks to that fact that the State Planning methodology needs to place more focus on the different characteristic of hospital and ambulatory surgery centers. As stated above, calculating the median case time for a larger group of facilities that are very different from one another in terms of the types and complexity of patients treated undermines the original intent and purpose of the tiering methodology, which was to better reflect true surgical utilization.

In conclusion, Wake Forest University Baptist Medical Center welcomes the prospect of continuing to revise the current operating room need methodology, but we are concerned with the integrity of the current proposed tiering methodology. We want the data to accurately reflect true utilization and resources for all North Carolina hospitals and ambulatory surgical centers. At a minimum, these discussions should address the issues raised in my comments to assure the appropriateness of any revised operating room need methodology data. Thank you for the opportunity to voice my concerns through these comments.

Sincerely,

Michael L. Freeman

Michael L. Freeman
Vice President, Medical Center Strategic Planning
Wake Forest University Baptist Medical Center

Table 1- AMC OR Tier Calculations

Facility	County	Resource Hours	2007 Inpatient Cases	Inpatient Case Time	Estimated Inpatient Hours	2007 ambulatory cases	ambulatory case time	estimated ambulatory hours	total estimated hours
NCBH	Forsyth	9.40	12208.00	4.43	54122.13	16717.00	2.27	37891.87	92014.00
Duke	Durham	11.50	16131.00	4.27	68825.60	18694.00	2.62	48915.97	117741.57
UNC	Orange	10.60	11105.00	4.83	53674.17	13525.00	3.33	45083.33	98757.50
CMC	Mecklenburg	11.50	17293.00	3.48	60237.28	12300.00	2.20	27060.00	87297.28
Pitt County Memorial Hospital	Pitt	10.50	10336.00	2.70	27907.20	9302.00	2.12	19689.23	47596.43
MEDIAN		**10.60**		**4.27**			**2.27**		

Median Hours per OR per Year Calculation:
Capacity = Median # of resource hours (10.6) x 260 days of availability x 80% capacity (.8) = 2204.8

Table 20 – Remaining Tier 1 (Large Community Hospital) OR Calculations

Facility	County	Resource Hours	2007 Inpatient Cases	Inpatient Case Time	Estimated Inpatient Hours	2007 ambulatory cases	ambulatory case time	estimated ambulatory hours	total estimated hours
Rex	Wake	10	9096	2.7	24559.2	17767	2	27835	52394
Mission	Buncombe	10	13384	2.82	37,698	19947	1.43	35738	73771
Moses Cone	Guilford	9.6	13263	2.38	31,610	17872	1.55	32021	69710
WakeMed Raleigh	Wake	11.1	8198	2.93	24,047	13407	1.83	24021	47317
New Hanover	New Hanover	10.1	9258	2.50	23,145	18782	1.28	33651	59959
FMC	Forsyth	9.5	10424	2.87	29,882	6298	1.75	11284	40905
Presby	Mecklenburg	8.4	5562	2.28	12,700	14405	1.75	25809	41614
Cape Fear Valley	Cumberland	9.5	7261	2.68	19,484	7199	1.67	12898	33532
CMC-Mercy,Pineville	Mecklenburg	9.8	3066	3.23	9,913	10460	2.03	18741	27453
MEDIAN		**9.8**		**2.7**			**1.67**		

Median Hours per OR per Year Calculation:
Capacity = Median # of resource hours (9.8) x 260 days of availability x 80% capacity (.8) = 2038.4

The data above shows that AMCs have significantly higher inpatient and ambulatory case times, especially for inpatient surgeries. In fact, by separating Tier 1 into two tiers, an AMC Tier and a Tier 1comprised of only large community hospitals, both sets of OR Need projections for 2011 are adjusted to be more in line with actual utilization. In addition Table 6E in the draft 2009 SMFP, also depicts a higher room utilization percentage for 2007 and actual room utilization for AMCs, further supporting the difference between AMCs and large community hospitals.

A detailed set of comparative data tables are attached as Exhibit 1 to demonstrate the calculations for the current OR methodology, 'he proposed methodology set forth in Discussion Tables 6D and an alternative methodology separating out AMCs from Tier 1.

STEP 1- CURRENT OR METHODOLOGY

Facility Name	County	Inpatient Cases (exclude dedicated C-section room)	Inpatient Case Time	Total Inpatient Hours	Ambulatory Cases	Ambulatory Case Time	Total Amb Case Hours	Total Combined Hours	Growth Factor	Projected Hours	Hours per OR Per Year	Projected ORs needed in 2011	2009 Adjusted Planning Inventory
NCBH	Forsyth	12208	3	36624	16717	1.5	25075.5	61699.5	5.99	65395.30005	1872	34.93	38
Duke	Durham	16131	3	48393	18694	1.5	28041	76434	6.98	81769.0932	1872	43.68	48
UNC	Orange	11105	3	33315	13525	1.5	20287.5	53602.5	4.81	56180.78025	1872	30.01	38
CMC	Mecklenburg	17239	3	51717	12300	1.5	18450	70167	12.18	78713.3406	1872	42.05	38
Pitt County Memorial Hospital	Pitt	10336	3	31008	9302	1.5	13953	44961	7.49	48332.62539	1872	25.82	24
Rex	Wake	9096	3	27288	17767	1.5	26650.5	53938.5	15.07	62067.03195	1872	33.16	27
Mission	Buncombe	13384	3	40152	26583	1.5	39874.5	80026.5	5.55	84467.97075	1872	45.12	44
Moses Cone	Guilford	13263	3	39789	17872	1.5	26808	66597	5.76	70432.9872	1872	37.62	53
WakeMed Raleigh	Wake	8198	3	24594	13407	1.5	20110.5	44704.5	15.07	51441.46815	1872	27.48	25
New Hanover	New Hanover	9258	3	27774	18782	1.5	28173	55947	9.26	61127.6922	1872	32.65	28
FMC	Forsyth	10424	3	31272	6298	1.5	9447	40719	5.99	43158.0681	1872	23.05	27
Presby	Mecklenburg	5562	3	16686	14405	1.5	21607.5	38293.5	12.18	42957.6483	1872	22.95	29
Cape Fear Valley	Cumberland	7261	3	21783	7199	1.5	10798.5	32581.5	1.77	33158.19255	1872	17.71	15
CMC-Mercy,Pineville	Mecklenburg	3066	3	9198	10460	1.5	15690	24888	12.18	27919.3584	1872	14.91	19

STEP 2- PROPOSED METHODOLOGY AS SHOWN IN DISCUSSION TABLE 6D

Facility	County	2007 Inpatient Cases	Inpatient Case Time	Estimated Inpatient Hours	2007 ambulatory caes	ambulatory case time	estimated ambulatory hours	total estimated hours	growth factor 2007-2011	projected surgical hours: 2011	hours per OR per year	Projected ORs needed in 2011	2009 Adjusted Planning Inventory
NCBH	Forsyth	12208	2.84	34961	16717	1.79	29951	64642	5.99	68514	2080	32.94	38
Duke	Durham	16131	2.84	45,839	18,694	1.79	33493	79332	0.07	84867	2080	40.8	48
UNC	Orange	11105	2.84	31557	13525	1.79	24232	55789	4.81	58471	2080	28.11	38
CMC	Mecklenburg	17293	2.84	48987	12300	1.79	22038	71025	12.18	79674	2080	38.3	38
Pitt County Memorial Hospital	Pitt	10336	2.84	29371	9302	1.79	16666	46038	6.93	49228	2080	23.67	24
Rex	Wake	9096	2.84	25848	17767	1.79	31833	57680	15.07	66370	2080	31.91	27
Mission	Buncombe	13384	2.84	38,033	19947	1.79	35738	73771	5.13%	77559	2080	37.29	44
Moses Cone	Guilford	13263	2.84	37689	17872	1.79	32021	69710	5.76	73725	2080	35.44	53
WakeMed Raleigh	Wake	8198	2.84	23296	13407	1.79	24021	47317	15.07	54446	2080	26.18	25
New Hanover	New Hanover	9258	2.84	26308	18782	1.79	33651	59959	9.26	65512	2080	31.5	28
FMC	Forsyth	10424	2.84	29622	6298	1.79	11284	40905	5.99	43356	2080	20.84	27
Presby	Mecklenburg	5562	2.84	15805	14405	1.79	25809	41614	12.18	46682	2080	22.44	29
Cape Fear Valley	Cumberland	7261	2.84	20633	7199	1.79	12898	33532	1.77	34127	2080	16.41	15
CMC-Mercy,Pineville	Mecklenburg	3066	2.84	8713	10460	1.79	18741	27453	12.18	30796	2080	14.81	19

STEP 3- CALCULATION OF PROPOSED METHODOLOGY- BASED ON DISCUSSION TABLE 6D

Recommendation 2 – Hospital tiers: Recommend DFS develop capacity to further refine the OR methodology incorporating all three Basic Principles governing the development of the State Medical Facilities Plan using facility specific total surgical hours, as reported in the license renewal data, to develop tiers of like institutions. This would allow calculation of median resource hours per day and case times per tier group, to be considered by the Acute Care Services Committee, for replacing the current use of 9 hours of OR availability, 3 hours for inpatient cases, and 1.5 hours for outpatient cases.

Facility	County	Resource Hours	2007 Inpatient Cases	Inpatient Case Time	Estimated Inpatient Hours	2007 ambulatory caes	ambulatory case time	estimated ambulatory hours	total estimated hours
NCBH	Forsyth	9.4	12208	4.43	54122.13333	16717	2.27	37891.8667	92014
Duke	Durham	11.5	16131	4.27	68825.6	18,694	2.62	48915.9667	117741.57
UNC	Orange	10.6	11105	4.83	53674.16667	13525	3.33	45083.3333	98757.5
CMC	Mecklenburg	11.5	17293	3.48	60237.28333	12300	2.20	27060	87297.283
Pitt County Memorial Hospital	Pitt	10.5	10336	2.70	27907.2	9302	2.12	19689.2333	47596.433
Rex	Wake	10	9096	2.70	24559.2	17767	1.57	27834.9667	52394.167
Mission	Buncombe	10	13384	2.82	37,698	19947	1.43	35738	73771
Moses Cone	Guilford	9.6	13263	2.38	31,610	17872	1.55	32021	69710
WakeMed Raleigh	Wake	11.1	8198	2.93	24,047	13407	1.83	24021	47317
New Hanover	New Hanover	10.1	9258	2.50	23,145	18782	1.28	33651	59959
FMC	Forsyth	9.5	10424	2.87	29,882	6298	1.75	11284	40905
Presby	Mecklenburg	8.4	5562	2.28	12,700	14405	1.75	25809	41614
Cape Fear Valley	Cumberland	9.5	7261	2.68	19,484	7199	1.67	12898	33532
CMC-Mercy,Pineville	Mecklenburg	9.8	3066	3.23	9,913	10460	2.03	18741	27453
MEDIAN		10		2.841667			1.79166667		

Median Hours per OR per Year Calculation:
Capacity = Median # of resource hours (10) x 260 days of availability x 80% capacity (.8) = 2080

Facility	County	Resource Hours	2007 Inpatient Cases	Inpatient Case Time	Estimated Inpatient Hours	2007 ambulatory caes	ambulatory case time	estimated ambulatory hours	total estimated hours	growth factor 2007-2011	projected surgical hours: 2011	median hours per OR per year	Projected ORs needed in 2011	2009 Adjusted Planning Inventory
NCBH	Forsyth	9.4	12208	2.84	34670.72	16717	1.79	29923.43	64594.15	5.99	68463.33959	2080	32.92	38
Duke	Durham	11.5	16131	2.84	45812.04	18,694	1.79	33462.26	79274.3	6.98%	84807.64614	2080	40.77	48
UNC	Orange	10.6	11105	2.84	31538.2	13525	1.79	24209.75	55747.95	4.81	58429.4264	2080	28.09	38
CMC	Mecklenburg	11.5	17293	2.84	49112.12	12300	1.79	22017	71129.12	12.18	79792.64682	2080	38.36	38
Pitt County Memorial Hospital	Pitt	10.5	10336	2.84	29354.24	9302	1.79	16650.58	46004.82	6.93	49192.95403	2080	23.65	24
Rex	Wake	10	9096	2.84	25832.64	17767	1.79	31802.93	57635.57	15.07	66321.2504	2080	31.89	27
Mission	Buncombe	10	13384	2.84	38,011	19947	1.79	35738	73771	5.13%	77559	2080	37.29	44
Moses Cone	Guilford	9.6	13263	2.84	37,667	17872	1.79	32021	69710	5.76	73725	2080	35.44	53
WakeMed Raleigh	Wake	11.1	8198	2.84	23,282	13407	1.79	24021	47317	15.07	54446	2080	26.18	25
New Hanover	New Hanover	10.1	9258	2.84	26,293	18782	1.79	33651	59959	9.26	65512	2080	31.50	28
FMC	Forsyth	9.5	10424	2.84	29,604	6298	1.79	11284	40905	5.99	43356	2080	20.84	27
Presby	Mecklenburg	8.4	5562	2.84	15,796	14405	1.79	25809	41614	12.18	46682	2080	22.44	29
Cape Fear Valley	Cumberland	9.5	7261	2.84	20,621	7199	1.79	12898	33532	1.77	34127	2080	16.41	15
CMC-Mercy,Pineville	Mecklenburg	9.8	3066	2.84	8,707	10460	1.79	18741	27453	12.18	30796	2080	14.81	19
MEDIAN		10		2.84			1.79							

STEP 4- NEW AMC METHODOLOGY0 SEPARATE TIER 1 ACADEMIC MEDICAL CENTERS USING MEDIAN RESOURCE HOURS AND INPATIENT/AMBULATORY CASE TIMES

Facility	County	Resource Hours	2007 Inpatient Cases	Inpatient Case Time	Estimated Inpatient Hours	2007 ambulatory caes	ambulatory case time	estimated ambulatory hours	total estimated hours
NCBH	Forsyth	9.40	12208.00	4.43	54122.13	16717.00	2.27	37891.87	92014.00
Duke	Durham	11.50	16131.00	4.27	68825.60	18694.00	2.62	48915.97	117741.57
UNC	Orange	10.60	11105.00	4.83	53674.17	13525.00	3.33	45083.33	98757.50
CMC	Mecklenburg	11.50	17293.00	3.48	60237.28	12300.00	2.20	27060.00	87297.28
Pitt County Memorial Hospital	Pitt	10.50	10336.00	2.70	27907.20	9302.00	2.12	19689.23	47596.43
MEDIAN		10.60		4.27			2.27		

Median Hours per OR per Year Calculation:
Capacity = Median # of resource hours (10.6) x 260 days of availability x 80% capacity (.8) = 2204.8

Facility	County	Resource Hours	2007 Inpatient Cases	Inpatient Case Time	Estimated Inpatient Hours	2007 ambulatory caes	ambulatory case time	estimated ambulatory hours	total estimated hours	growth factor 2007-2011	projected surgical hours: 2011	median hours per OR per year	Projected ORs needed in 2011	2009 Adjusted Planning Inventory
NCBH	Forsyth	9.40	12208	4.27	52128.16	16717	2.27	37947.59	90075.75	5.99	95471.29	2204.8	43.30	38
Duke	Durham	11.50	16131	4.27	68879.37	18,694	2.27	42435.38	111314.75	0.07	119084.52	2204.8	54.01	48
UNC	Orange	10.60	11105	4.27	47418.35	13525	2.27	30701.75	78120.10	4.81	81877.68	2204.8	37.14	38
CMC	Mecklenburg	11.50	17293	4.27	73841.11	12300	2.27	27921.00	101762.11	12.18	114156.73	2204.8	51.78	38
Pitt County Memorial Hospital	Pitt	10.50	10336	4.27	44134.72	9302	2.27	21115.54	65250.26	6.93	69772.10	2204.8	31.65	24
MEDIAN		10.6		4.27			2.27							

STEP 5 SEPARATE NON -AMC TIER 1 HOSPITALS USING MEDIAN RESOURCE HOURS AND INPATIENT/AMBULATORY CASE TIMES

Facility	County	Resource Hours	2007 Inpatient Cases	Inpatient Case Time	Estimated Inpatient Hours	2007 ambulatory caes	ambulatory case time	estimated ambulatory hours	total estimated hours
Rex	Wake	10	9096	2.7	24559.2	17767	2	27835	52394
Mission	Buncombe	10	13384	2.82	37,698	19947	1.43	35738	73771
Moses Cone	Guilford	9.6	13263	2.38	31,610	17872	1.55	32021	69710
WakeMed Raleigh	Wake	11.1	8198	2.93	24,047	13407	1.83	24021	47317
New Hanover	New Hanover	10.1	9258	2.50	23,145	18782	1.28	33651	59959
FMC	Forsyth	9.5	10424	2.87	29,882	6298	1.75	11284	40905
Presby	Mecklenburg	8.4	5562	2.28	12,700	14405	1.75	25809	41614
Cape Fear Valley	Cumberland	9.5	7261	2.68	19,484	7199	1.67	12898	33532
CMC-Mercy,Pineville	Mecklenburg	9.8	3066	3.23	9,913	10460	2.03	18741	27453
MEDIAN		9.8		2.7			1.67		

Median Hours per OR per Year Calculation:
Capacity = Median # of resource hours (9.8) x 260 days of availability x 80% capacity (.8) = 2038.4

Facility	County	Resource Hours	2007 Inpatient Cases	Inpatient Case Time	Estimated Inpatient Hours	2007 ambulatory caes	ambulatory case time	estimated ambulatory hours	total estimated hours	growth factor 2007-2011	projected surgical hours: 2011	median hours per OR per year	Projected ORs needed in 2011	2009 Adjusted Planning Inventory
Rex	Wake	10	9096	2.7	24559.20	17767	1.67	29670.89	54230.09	15.07	62402.56	2038.4	30.61	27
Mission	Buncombe	10	13384	2.7	36,137	19947	1.67	35738	73771	5.13%	77559	2038.4	38.05	44
Moses Cone	Guilford	9.6	13263	2.7	35,810	17872	1.67	32021	69710	5.76	73725	2038.4	36.17	53
WakeMed Raleigh	Wake	11.1	8198	2.7	22,135	13407	1.67	24021	47317	15.07	54446	2038.4	26.71	25
New Hanover	New Hanover	10.1	9258	2.7	24,997	18782	1.67	33651	59959	9.26	65512	2038.4	32.14	28
FMC	Forsyth	9.5	10424	2.7	28,145	6298	1.67	11284	40905	5.99	43356	2038.4	21.27	27
Presby	Mecklenburg	8.4	5562	2.7	15,017	14405	1.67	25809	41614	12.18	46682	2038.4	22.90	29
Cape Fear Valley	Cumberland	9.5	7261	2.7	19,605	7199	1.67	12898	33532	1.77	34127	2038.4	16.74	15
CMC-Mercy,Pineville	Mecklenburg	9.8	3066	2.7	8,278	10460	1.67	18741	27453	12.18	30796	2038.4	15.11	19
MEDIAN		9.8		2.7			1.67							

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Remarkable People. Remarkable Medicine.

August 1, 2008

Victoria McClanahan, Planner
State Medical Facilities Planning Section
Division of Health Service Regulation
701 Barbour Dr.
Raleigh, NC 27603

RE: 2009 Proposed State Medical Facilities Plan; Request for Comments – OR Tiering Alternative Need Method; Comments of Novant Health, Inc.

Dear Ms. McClanahan:

In response to the request for comments regarding the proposed OR Methodology including tiering surgical facilities based upon resource hours, on pages 81 through 102 of the Proposed 2009 State Medical Hospitals Plan, Novant Health submits the following comments.

Tiered OR Need Method Alternative

Novant Health does not support the proposed tiering methodology included in the Proposed 2009 State Medical Facilities Plan for the following reasons:

- The proposed methodology is considerably more complex, confusing than the existing OR need method which has been significantly updated within the past 3-5 years. And the application of the tiering approach has the potential to change significantly on an annual basis as it is based upon hours of operation and surgical hours per case at each existing surgical facility as reflected in the annual hospital and ambulatory surgical Licensure Renewal Applications. For operating rooms, both the hours of operation and the average surgical hours per case can change annually. No other methodology in the SMFP includes such an unknown or the potential for such a high level of variability on a year-to-year basis. It is challenging for those who deliver surgical services to plan, if there is a great deal of variability in the SMFP OR Need Determinations from year to year. The tiering approach would create more work for both the DHSR Medical Facilities Planning Section and for the CON Section, as well. This seems to have the potential to be a rather substantial and potentially disruptive approach to the annual process of planning for OR need. Novant believes it would be preferential to continue to make adjustments within the existing framework of the OR Need methodology.

- Surgical time per case is a very subjective measurement based upon operational efficiencies, block scheduling, physician expertise, and surgical mix. All of these variables can change on an annual basis, and all these variables impact the surgical hours of a facility.

- The current definitions utilized for inpatient and outpatient surgical case times are generous when compared to actual case times reported in the annual licensure renewal

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applications. However, the current defined times of 3.0 hours per inpatient and 1.5 hours per outpatient allow flexibility in OR scheduling. Surgical facilities can take advantage of the scheduling options such as block scheduling which encourages surgeon efficiency but also can result in greater cancellations and unfilled surgical times when block schedules are not 100% full.

- The Operating Room Work Group was developed to address the number of petitions submitted annually regarding the need for additional operating rooms across North Carolina among other reasons. One of the work products of the OR Work Group was included in the proposed 09 SMFP. The proposed 2009 SMFP includes for the first time, the Exclusions from OR Need Determinations of Underutilized Facilities. This new factor in the SMRP OR need method, resulted in the exclusion of 14 surgical programs in 10 North Carolina counties, with the stated goal being to ensure the need for new ORs in a given County was not artificially suppressed by underutilized ORs in that County.

- The proposed tiering methodology actually constricts the need for operating rooms in North Carolina and results in a greater surplus of operating rooms North Carolina. Surely, this was not the intended consequence for this valuable and necessary resource (ORs) for hospitals and ambulatory surgery centers:

  - The current OR methodology reflects a need for 996 operating rooms across the State as reflected on page 76 of the Proposed 2009 SMFP and a statewide surplus of 216 operating rooms.
  - The proposed tiering methodology reflects a need for only 863 operating rooms resulting in a surplus of 352 operating rooms as reflected in the attachment included with these comments.
  - Under the tiering method, the formula expresses a need for ORs that is 133 fewer ORs than the current SMFP OR need method and reflects a surplus of ORs that is 136 ORs greater than the estimate of surplus ORs under the current SMFP OR need method
  - In light of the OR need petitions presented to the Medical Facilities Planning Section and the SHCC in recent years, this is probably not the best direction for the revision of the OR need method at this time

- The current OR need methodology is functioning as it was designed to do and has generated the following need statewide for new ORs in the annual State Medical Facilities Plans:
  - Proposed 2009 SMFP: 3 new ORs
  - 2008 SFMP: 10 new ORs
  - 2007 SMFP: 0 new ORs
  - 2006 SMFP: 11 new ORs
  - 2005 SFMP: 4 new ORs
  - 2004 SMFP: 9 new ORs

  During the first six years of the operation of the updated OR need method the SMFPs have contained need determinations for 37 new ORs in North Carolina.

Application of the Alternative Tiered OR Need Method to Novant Health's Mecklenburg and Forsyth County Surgical Programs

Finally, Novant Health disagrees with the application of the tiered need analysis for its operating rooms in Forsyth and Mecklenburg Counties reflected in the tiering methodology, as well as in Brunswick and Davidson Counties. Within the last year, Novant has submitted Certificate of Need applications in both Forsyth County and Mecklenburg County which justify the need for all existing operating rooms. Relevant tables from these CON applications are attached.

While the existing operating room need methodology may not be perfect, Novant believes it is a reasonable planning methodology. Elements of the current methodology could clearly be updated to address concerns, but a wholesale overhaul of a need method that is generally working as intended seems unnecessary at this point in time. If the goal of the SHCC is to expand OR need rather than constrict OR need, other changes in the methodology should be considered such as decreasing the annual days of operation, decreasing daily hours of operation for all facilities for planning purposes, or expanding the planning horizon to a five or six year time frame.

Novant Health does not believe that the proposed tiering methodology adds any value to the current operating room methodology and in fact, may have the exact opposite impact. Thank you for consideration of these comments.

Sincerely,

Barbara L. Freedy

Barbara L. Freedy
Director, Certificate of Need
Novant Health, Inc.

File: Draft09SMFPORTierComments.07.31.08.doc

Comparison: Current OR Need Method & Tiering OR Need Method

County	Facility	County OR Need	OR Need/Surplus	County OR Need Tiered	OR Need/Surplus
Alamance	Alamance Regional Medical Center	9.37	-2.63	8.42	-3.58
Pasquotank	Albemarle Hospital	7.06	-0.94	6.13	-1.87
Alexander	Frye Regional Medical Center - Alexander Campus	0.00	-2.00	0.00	-2.00
Alleghany	Alleghany Memorial Hospital	0.26	-1.74	0.24	-1.78
Anson	Anson Community Hospital	0.61	-1.39	0.56	-1.44
Ashe	Ashe Memorial Hospital, Inc.	0.78	-1.22	0.66	-1.34
Avery	Charles A. Cannon, Jr. Memorial Hospital Incorporated	0.59	-1.41	0.50	-1.50
Beaufort	Beaufort County Hospital Association, Inc.	3.53	-1.47	3.07	-1.93
Beaufort	Pungo District Hospital				
Bertie	Bertie Memorial Hospital	0.74	-1.26	0.71	-1.29
Bladen	Bladen County Hospital	0.86	-1.14	0.72	-1.28
Brunswick	Brunswick Community Hospital	5.34	-0.66	4.75	-1.25
Brunswick	J. Arthur Dosher Memorial Hospital				
Buncombe	Asheville Eye Surgery Center				
Buncombe	Memorial Mission Hospital and Mission Surgicare Center (Mission Hospitals, Inc.)	44.94	-5.06	40.50	-9.50
Buncombe	Mission Family Medical Center Yancey County				
Buncombe	Orthopaedic Surgery Center of Asheville				
Buncombe	The Endoscopy Center (Asheville Gastroenterology Associates, P.A.)				
Burke	Grace Hospital, Inc.	9.83	-1.17	8.26	-2.74
Burke	Surgery Center of Morganton Eye Physicians				
Burke	Valdese General Hospital, Inc.				
Cabarrus	NorthEast Medical Center	23.25	-0.75	18.36	-5.64
Caldwell	Caldwell Memorial Hospital, Inc.	3.49	-3.51	3.11	-3.89
Carteret	Carteret County General Hospital	6.10	-0.90	4.65	-2.35
Carteret	Carteret Surgical Center				
Catawba	Catawba Valley Medical Center	25.21	-11.79	21.74	-15.26
Catawba	Frye Regional Medical Center				
Catawba	Healthsouth Hickory				
Chatham	Chatham Hospital, Inc.	0.18	-1.82	0.17	-1.83
Cherokee	Murphy Medical Center, Inc.	2.58	-1.42	2.33	-1.67
Chowan	Chowan Hospital	1.69	-1.31	1.47	-1.53
Cleveland	Cleveland Ambulatory Services				
Cleveland	Cleveland Regional Medical Center	9.21	0.21	7.45	-1.55
Cleveland	Crawley Memorial Hospital				
Cleveland	Eye Surgery Center of Shelby				
Cleveland	Kings Mountain Hospital				
Columbus	Columbus County Hospital, Inc.	5.02	0.02	4.31	-0.69
Craven	Craven Regional Medical Center	13.56	-3.44	12.00	-5.00
Cumberland	Cape Fear Valley Medical Center	29.31	-1.69	24.10	-6.90
Cumberland	Fayetteville Ambulatory Surgery Center				
Cumberland	Highsmith-Rainey Memorial Hospital				
Dare	RMS Surgery Center				
Dare	The Outer Banks Hospital, Inc.	2.81	-1.19	1.98	-2.02
Davidson	Lexington Memorial Hospital, Inc.				
Davidson	Thomasville Medical Center	6.34	-2.66	5.58	-3.42
Davie	Davie County Hospital	0.06	-1.94	0.05	-1.95
Duplin	Duplin General Hospital	2.19	-0.81	1.85	-1.15
Wake	Duke Health Raleigh Hospital				
Durham	Duke University Hospital - Duke North	64.61	-8.39	57.46	-15.54
Durham	Duke University Hospital - duke North Eye Center				
Durham	Duke University Hospital ASC				
Durham	Durham Regional Hospital				
Durham	James E. Davis Ambulatory Surgical Center (Associated Health Services, Inc.)				
Durham	North Carolina Specialty Hospital				
Edgecombe	Heritage Hospital	2.20	-2.80	1.89	-3.11
Forsyth	Forsyth Memorial Hospital, Inc.	74.58	-8.42	67.05	-15.95
Forsyth	Hawthorne Surgical Center				
Forsyth	Medical Park Hospital				
Forsyth	North Carolina Baptist Hospital				
Forsyth	Plastic Surgery Center of NC				
Franklin	Franklin Regional Medical Center	3.21	0.21	2.72	-0.28
Gaston	CaroMont Specialty Surgery				
Gaston	Gaston Memorial Hospital, Inc.- Oupt ORs	18.46	-5.54	15.36	-8.64
Gaston	Gaston Memorial Hospital, Inc.-main ORs				
Granville	Granville Medical Center	2.27	-0.73	1.99	-1.01
Guilford	Greensboro Center for Digestive Diseases				
Guilford	Healthsouth Greensboro Specialty				
Guilford	Healthsouth Greensboro Surgical				
Guilford	High Point Endoscopy Center, Inc.				
Guilford	High Point Regional Health System				
Guilford	High Point Surgery				
Guilford	Moses Cone Surgery Center				
Guilford	Moses H. Cone Memorial Hospital	67.46	-24.54	55.40	-36.60
Guilford	Piedmont Endoscopy Center, Inc.				
Guilford	Piedmont Surgical				
Guilford	Quadrangle Endoscopy Center				
Guilford	Surgical Eye Center (Greensboro)				
Guilford	Wesley Long				
Halifax	Halifax Regional Medical Center, Inc.	4.65	-1.35	3.88	-2.12
Halifax	Our Community Hospital				
Harnett	Betsy Johnson Regional Hospital	4.46	-5.54	3.88	-6.12
Harnett	Good Hope Hospital				
Haywood	Haywood Regional Medical Center, A NC Hospital Authority	4.75	-2.25	4.05	-2.95
Henderson	Margaret R. Pardee Memorial Hospital	13.22	-2.78	11.79	-4.21
Henderson	Park Ridge Hospital				
Hertford	Roanoke-Chowan Hospital	2.74	-2.26	2.37	-2.63

County	Facility	County OR Need	OR Need/Surplus	County OR Need Tiered	OR Need/Surplus
Iredell	Davis Regional Medical Center	19.46	-5.54	15.76	-9.24
Iredell	Iredell Head Neck and Ear				
Iredell	Iredell Memorial Hospital, Incorporated				
Iredell	Iredell Surgical				
Iredell	Lake Norman Regional Medical Center				
Iredell	The Surgery Center at Lake Norman				
Jackson	Harris Regional Hospital, Inc.	5.63	-0.37	4.99	-1.01
Johnston	Johnston Memorial Hospital	7.59	0.59	6.41	-0.59
Lee	Central Carolina Hospital	3.96	-3.04	3.48	-3.52
Lenoir	Goldsboro Endoscopy Center, Inc.				
Lenoir	Lenior Memorial Hospital	5.62	-3.38	4.76	-4.24
Lincoln	Lincoln Medical Center	2.87	-1.13	2.48	-1.52
Macon	Angel Medical Center, Inc.	1.88	-2.12	1.68	-2.32
Macon	Highlands-Cashiers Hospital, Inc.				
Martin	Martin General Hospital	1.53	-0.47	1.37	-0.63
McDowell	The McDowell Hospital, Inc.	1.18	-1.82	1.00	-2.00
Mecklenburg	Carolinas Medical Center/Center for Mental Health	130.26	-12.74	113.83	-32.17
Mecklenburg	CMC - University				
Mecklenburg	CMC Mercy/Pineville				
Mecklenburg	CSC Randolph				
Mecklenburg	Healthsouth Charlotte				
Mecklenburg	Presbyterian Huntersville				
Mecklenburg	Presbyterian Matthews				
Mecklenburg	Presbyterian Orthopaedic				
Mecklenburg	SameDay Surgery Center at Presbyterian				
Mecklenburg	SouthPark Surgery Center				
Mecklenburg	The Presbyterian Hospital				
Mecklenburg	Waveco, LLC				
Montgomery	FirstHealth Montgomery Memorial Hospital	0.51	-1.49	0.46	-1.54
Moore	FirstHealth Moore Reg. Hosp and Pinehurst Treatment Center (FirstHealth of the Carolinas, Inc.)	26.87	-0.13	19.55	-7.45
Moore	Healthsouth Southern Pines				
Moore	Southern Eye Associates				
Nash	Nash General Hospital	9.45	-3.55	8.47	-4.53
NewHanover	New Hanover Regional Medical Center	40.38	-0.62	35.94	-5.06
NewHanover	Wilmington Health Associates				
NewHanover	Wilmington SurgCare				
Onslow	Onslow Memorial Hospital, Inc.	6.19	-2.81	4.45	-4.55
Onslow	SurgiCare of Jacksonville				
Orange	Chapel Hill Surgery Center				
Orange	University of North Carolina Hospitals at Chapel Hill	30.01	-7.99	28.11	-9.89
Pender	Pender Memorial Hospital, Inc.	0.38	-1.62	0.33	-1.67
Person	Person Memorial Hospital	2.68	-1.32	2.36	-1.64
Pitt	Pitt County Memorial Hospital, Inc.	34.57	-3.43	28.78	-9.22
Pitt	Surgicenter Services of Pitt				
Polk	St. Lukes	1.53	-1.47	1.36	-1.64
Randolph	Asheboro Endoscopy Center, LLC				
Randolph	Randolph Hospital	4.50	-0.50	3.96	-1.04
Richmond	FirstHealth Richmond Memorial Hospital (FirstHealth of the Carolinas, Inc.)	3.60	-2.40	3.05	-2.95
Richmond	Sandhills Regional Medical Center				
Robeson	Southeastern Regional Medical Center	7.08	-2.92	6.24	-3.76
Rockingham	Annie Penn Hospital	6.18	-1.56	5.28	-3.72
Rockingham	Morehead Memorial Hospital				
Rowan	Rowan Regional Medical Center, Inc.	9.42	-1.58	8.40	-2.60
Rutherford	Rutherford Hospital, Inc.	3.58	-1.42	3.02	-1.98
Sampson	Sampson Regional Medical Center	2.75	-5.25	2.36	-5.64
Scotland	Scotland Memorial Hospital, Inc.	3.91	-1.09	3.38	-1.62
Stanly	Stanly Memorial Hospital, Inc.	4.10	-0.90	3.71	-1.29
Stokes	Stokes-Reynolds Memorial Hospital, Inc.	0.63	-3.37	0.61	-3.39
Surry	Hugh Chatham Hospital	7.54	-1.46	6.47	-2.53
Surry	Northern Hospital District of Surry County				
Swain	Swain County Hospital				
Transylvania	Transylvania Community Hospital, Inc.	2.31	-1.69	2.10	-1.90
Union	CMC - Union Memorial Regional Medical Center.	8.58	0.58	7.73	-0.27
Vance	Maria Parham Hospital Medical Center	3.12	-1.88	2.73	-2.27
Wake	Femcare	90.15	-3.85	82.29	-11.71
Wake	Healthsouth Blue Ridge				
Wake	Raleigh Endoscopy Center				
Wake	Raleigh Plastic Surgery				
Wake	Raleigh Women's Health Organization of Raleigh, Inc.				
Wake	Rex Hospital, Inc.				
Wake	WakeMed - Raleigh Campus				
Wake	WakeMed Cary Hospital				
Washington	Washington County Hospital	0.27	-1.73	0.25	-1.75
Watauga	Blowing Rock Hospital				
Watauga	Watauga Medical Center, Inc.	4.52	-0.48	3.94	-1.06
Wayne	Wayne Memorial Hospital, Inc.	12.28	-0.72	10.91	-2.09
Wilkes	Wilkes Regional	3.63	-1.37	3.09	-1.91
Wilkes	Wilkes Regional Medical Center				
Wilson	Healthsouth Wilson				
Wilson	Wilson Medical Center	6.63	-3.37	5.53	-4.47
Wilson	Wilson OB Gyn				
Yadkin	Hoots Memorial Hospital, Inc.	0.21	-1.79	0.20	-1.80
Mitchell	Spruce Pine Community Hospital	1.17	-1.83	1.01	-1.99
	Carolina Birth Center				
	Eye Surgery and Laser Clinic				
Total Need and Total Surplus		996.23	-215.89	863.34	-351.68
Difference Between Current Methodology and Tiered - Decrease in OR Need = Increase in Surplus # of ORs				132.89	135.79

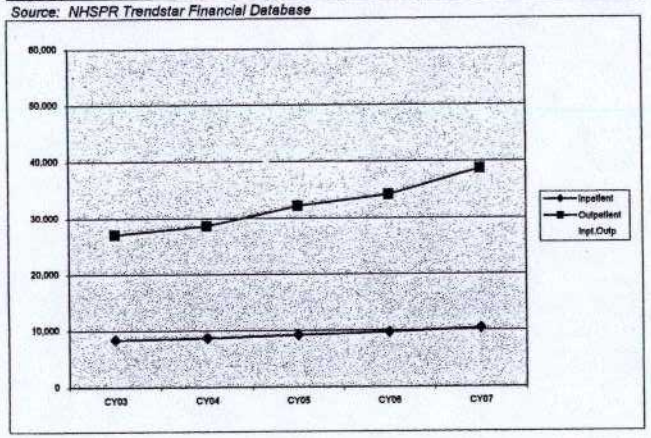
Attachment 1

Novant Health/Forsyth County OR Need Analysis - Included in Clemmons Medical Center CON App filed 7/2008									
MPH - With Proposed Project	**Apr07-Mar08**	**Apr08-Mar09**	**Apr09-Mar10**	**Apr10-Mar11**	**Apr11-Mar12**	**Apr12-Mar13**	**Apr13-Mar14**	**Apr14-Mar15**	**Facility OR Need**
Projected Inpatient Surgical Volume w.o Proposed Project	1,170	1,184	1,197	1,209	1,221	1,234	1,246	1,258	
Inpatient Surgery Shifted to CLMC						94	107	121	
Inpatient Surgery Shifted to FMC.WS - Additional volume from other zip codes and Clemmons zip code service area - volume not shifted too adjust to decrease in inpatient beds at MPH.Hawthorne Rd						553	585	650	
Projected Inpatient Surgical Volume - Adjusted	1,170	1,184	1,197	1,209	1,221	587	554	487	
Projected Outpatient Surgical Volume w.o Proposed Project	10,508	10,651	10,779	10,898	11,019	11,140	11,261	11,383	
Outpatient Surgery Shifted to CLMC						1,146	1,312	1,483	
Outpatient Surgery Shifted to FMC - Additional volume from other zip codes and Clemmons zip code service area - volume not shifted too adjust to decrease in operating rooms						1,530	1,620	1800	
Projected Outpatient Surgical Volume - Adjusted	10,508	10,651	10,779	10,898	11,019	8,464	8,329	8,100	
Weighted Surgical Hours	16,113	16,331	16,527	16,710	16,895	14,458	14,155	13,610	
ORs Needed at MPH	8.6	8.7	8.8	8.9	9.0	7.7	7.6	7.27	7
Clemmons Medical Center	**Apr07-Mar08**	**Apr08-Mar09**	**Apr09-Mar10**	**Apr10-Mar11**	**Apr11-Mar12**	**Apr12-Mar13**	**Apr13-Mar14**	**Apr14-Mar15**	
Projected Inpatient Surgical Volume						885	1,012	1,144	
Projected Outpatient Surgical Volume						2,578	2,951	3,336	
Weighted Surgical Hours						6,521	7,463	8,437	
ORs Needed at MPH						3.5	4.0	4.51	5
FMC w. FMC Kville AND Clemmons	**Apr07-Mar08**	**Apr08-Mar09**	**Apr09-Mar10**	**Apr10-Mar11**	**Apr11-Mar12**	**Apr12-Mar13**	**Apr13-Mar14**	**Apr14-Mar15**	
Projected Inpatient Surgical Volume	9,791	9,924	10,042	10,153	10,265	10,378	10,491	10,603	
Inpatient Volume Shifted to FMC Kernersville			359	531	603	629	641	653	
Inpatient Volume Shifted to CLMC						791	905	1,023	
Inpatient Volume Shifted to FMC from MPH						553	585	650	
Projected Inpatient Surgical Volume - Adjusted	9,791	9,924	9,683	9,622	9,663	9,510	9,530	9,577	
Projected Outpatient Surgical Volume	6,320	6,407	6,484	6,557	6,630	6,704	6,778	6,851	
Outpatient Volume Shifted to FMC Kernersville			529	775	810	826	843	948	
Outpatient Volume Shifted to CLMC						690	790	893	
Outpatient Volume Shifted From MPH						1,530	1,620	1,800	
Projected Outpatient Surgical Volume - Adjusted	6,320	6,407	5,956	5,782	5,820	6,718	6,765	6,810	
Weighted Surgical Hours	38,854	39,381	37,983	37,537	37,719	38,608	38,737	38,948	
ORs Needed at MPH	20.8	21.0	20.3	20.1	20.1	20.6	20.7	20.81	21
FMC-Kville	**Apr07-Mar08**	**Apr08-Mar09**	**Apr09-Mar10**	**Apr10-Mar11**	**Apr11-Mar12**	**Apr12-Mar13**	**Apr13-Mar14**	**Apr14-Mar15**	
Projected Inpatient Surgical Volume			575	904	1,092	1,156	1,180	1,204	
Projected Outpatient Surgical Volume			1,293	2,031	2,452	2,596	2,648	2,701	
Weighted Surgical Hours				5,758	6,954	7,364	7,512	7,663	
ORs Needed at FMC Kernersville				3.1	3.7	3.9	4.0	4.1	4
HSC	**Apr07-Mar08**	**Apr08-Mar09**	**Apr09-Mar10**	**Apr10-Mar11**	**Apr11-Mar12**	**Apr12-Mar13**	**Apr13-Mar14**	**Apr14-Mar15**	
Projected Outpatient Surgical Volume	6,784	6,879	6,965	7,044	7,125	7,206	7,288	7,369	
Outpatient Volume Shifted to CLMC						742	849	960	
Projected Outpatient Surgical Volume - Adjusted	6,784	6,879	6,965	7,044	7,125	6,465	6,438	6,409	
Weighted Surgical Hours	10,176	10,319	10,447	10,566	10,688	9,697	9,657	9,613	
ORs Needed at HSC	5.4	5.5	5.6	5.6	5.7	5.0	5.0	5.1	5
Total Novant Licensed Operating Rooms and Operating Room Need	**Apr07-Mar08**	**Apr08-Mar09**	**Apr09-Mar10**	**Apr10-Mar11**	**Apr11-Mar12**	**Apr12-Mar13**	**Apr13-Mar14**	**Apr14-Mar15**	**Sum Facility OR Need**
MPH Licensed ORs - Hawthorne Campus	13	13	12	12	12	7	7	7	
Clemmons Medical Center Licensed ORs	0	0	0	0	0	5	5	5	
FMC ORs - Operational and Approved; Does not include 5 OH/Csection Operating Rooms	23	23	23	20	20	20	20	20	
FMC Kville Licensed ORs	0	0	0	4	4	4	4	4	
Hawthorne Surgical Center	6	6	6	6	6	6	6	6	
Total Novant Licensed ORs	42	42	41	42	42	42	42	42.0	42.0

Novant Health Southern Piedmont Region OR Need

	CY03	CY04	CY05	CY06	CY07
Inpatient	8,368	8,670	9,212	9,668	10,352
Outpatient	27,042	28,636	32,191	34,115	38,672
Inpt.Outp	35,410	37,306	41,403	43,783	49,023

Source: NHSPR Trendstar Financial Database



NHSPR	CY03	CY04	CY05	CY06	CY07	CAGR CY03-CY07
Inpatient	8,368	8,670	9,212	9,668	10,352	5.5%
Annual Growth		3.6%	6.3%	5.0%	7.1%	
Outpatient	27,042	28,636	32,191	34,115	38,672	9.4%
Annual Growth		5.9%	12.4%	6.0%	13.4%	
Total (w.o C-Section ar	35,410	37,306	41,403	43,783	49,023	8.5%
Annual Growth		5.4%	11.0%	5.7%	12.0%	

Source: NHSPR Trendstar Financial Database

Total NHSPR OR Need - Projected Using NHSPR Five Year Surgical CAGR								
NHSPR	CY07	CY2008	CY2009	CY2010	CY2011	CY2012	CY2013	CY2014
Total Outpatient Surgery FFY Volu	38,672	42,289	46,245	50,571	55,302	60,476	66,133	72,320
Total Inpatient Surgery FFY Volum	10,352	10,917	11,513	12,142	12,805	13,505	14,242	15,020
Weighted Surgical Case Hours	89,062	96,184	103,907	112,283	121,369	131,227	141,926	153,540
SPR ORs Needed	47.6	51.4	55.5	60.0	64.8	70.1	75.8	82.0
SPR OR Inventory	71	71	71	71	71	71	71	71
OR Need	-23.4	-19.6	-15.5	-11.0	-6.2	-0.9	4.8	11.0

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3916 Ben Franklin Boulevard • Durham, NC 27704
P.O. Box 15819 • Durham, NC 27704

August 1, 2008

To the State Health Coordinating Counsel,

I would like to comment of the proposed Operating Room "tiers" methodology addressed in the 2009 State Facilities Plan.

I think we can all agree that there are specific procedures that fall into a complex procedure category, such as organ transplants or open heart surgeries. However, with advances in technology, many procedures once considered complex have become, over time, less invasive and less complex such as Laparoscopic Cholecystectomies. With that said, it makes sense to look at specific procedures and categorize them within a weighted tier system. The weighted procedural tier should be available to every hospital within the state. Providing a carve out for an entire hospital provides an unfair advantage in acquiring future operating rooms. Hospitals ranked in lower numerical tiers (2 through 4) will be at a disadvantage, even though they are providing many of the same services as provided by larger hospitals which fall under tier one (1) classification.

Hospitals need to be on an even playing field and needs determination should address the actual needs of individual facilities, efficiencies or lack of efficiencies within these facilities and should demonstrate fairness. Rewarding larger hospitals for increased length of procedures seems to be in direct conflict with quality and cost containment.

Respectfully submitted,

Randi L. Pisko
Chief Executive Officer
North Carolina Specialty Hospital