

**SECTION .1700 - CRITERIA AND STANDARDS FOR OPEN-HEART SURGERY  
SERVICES AND HEART-LUNG BYPASS MACHINES**

**10A NCAC 14C .1701 DEFINITIONS**

The following definitions shall apply to all rules in this Section:

- (1) "Capacity" of a heart-lung bypass machine means 400 adult-equivalent open heart surgical procedures per year or 1800 [or 1872?] hours in use or staffed on standby for all procedures per year. One open heart surgical procedure on persons age 14 and under is valued at two adult open heart surgical procedures. For purposes of determining capacity, one open heart surgical procedure is defined to be one visit or trip by a patient to an operating room for an open heart operation.
- (2) "Cardiac Surgical Intensive Care Unit" means an intensive care unit as defined in 10A NCAC 14C .1201(2) and which is for exclusive use by post-surgical open heart patients.
- (3) "Heart-lung bypass machine" shall have the same meaning as defined in G.S. 131E-176(10a).
- (4) "Open heart surgery service area" means a geographical area defined by the applicant, which has boundaries that are not farther than 90 road miles from the facility, except that the open heart surgery service area of an academic medical center teaching hospital designated in the State Medical Facilities Plan shall not be limited to 90 road miles.
- (5) "Open heart surgery services" shall have the same meaning as defined in G.S. 131E-176(18b).
- (6) "Open heart surgical procedures" means specialized surgical procedures which:
  - (a) utilize a heart-lung bypass machine (the "pump");
  - (b) are designed to correct congenital or acquired cardiac and coronary disease; and
  - (c) are identified by Medicare Diagnostic Related Group ("DRG") numbers ~~104, 105, 106, 108, 547, 548, 549, and 550~~216 through 221 and 228 through 236.
- (7) "Primary open heart surgery service area" means a geographical area defined by the applicant, which has boundaries that are not farther than 45 road miles from the facility, except that the primary open heart surgery service area of an academic medical center teaching hospital designated in the State Medical Facilities Plan shall not be limited to 45 road miles.

*History Note: Authority G.S. 131E-177(1); 131E-183;  
Eff. January 1, 1987;  
Amended Eff. November 1, 1989;  
Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;  
Amended Eff. November 1, 1996; January 4, 1994;  
Temporary Amendment Eff. January 1, 1999;  
Temporary Eff. January 1, 1999 Expired on October 12, 1999;*

*Temporary Amendment Eff. January 1, 2000 and shall expire on the date on which the permanent amendment to this Rule, approved by the Rules Review Commission on November 17, 1999, becomes effective;*  
*Amended Eff. July 1, 2000;*  
*Temporary Amendment Eff. March 1, 2010;*  
*Amended Eff. November 1, 2010.*

**10A NCAC 14C .1702 INFORMATION REQUIRED OF APPLICANT**

(a) An applicant that proposes to to develop open heart surgery services ~~add an open heart surgery room~~ or to acquire a heart-lung bypass machine shall use the acute care facility/medical equipment application form.

(b) An applicant that proposes to develop open heart surgery services ~~applicant~~ shall also provide the following additional information:

- (1) the projected number of open heart surgical procedures to be performed on each heart-lung bypass machine owned by or operated in the facility for each of the first 12 calendar quarters following completion of the proposed project, including the methodology and assumptions used to make these projections;
- (2) the projected number of cardiac catheterization procedures to be completed in the facility for each of the first 12 calendar quarters following completion of the proposed project, including the methodology and assumptions used for these projections;
- (3) the applicant's experience in treating cardiovascular patients at the facility during the past 12 months, including:
  - (A) the number of patients receiving stress tests;
  - (B) the number of patients receiving intravenous thrombolytic therapies;
  - (C) the number of patients presenting in the Emergency Room or admitted to the hospital with suspected or diagnosed acute myocardial infarction;
  - (D) the number of cardiac catheterization procedures performed, by type of procedure;
  - (E) the number of patients referred to other facilities for cardiac catheterization or open heart surgical procedures, by type of procedure;
  - (F) the number of patients referred to the applicant's facility for cardiac catheterization or open heart surgical procedures, by type of procedure; and
  - (G) the number of open heart surgery procedures performed by type of procedure during the twelve month period reflected in the most recent licensure form on file with the Division of Health Service Regulation;
- (4) the number of patients from the proposed open heart surgery service area who are projected to receive open heart surgical procedures by patient's county of residence in each of the first 12 quarters of operation including the methodology and assumptions used to make the projections;
- (5) the number of patients from the proposed primary open heart surgery service area who are projected to receive open heart surgical procedures by patient's county of residence in each of the first 12 quarters, including the methodology and assumptions used to make these projections;
- (6) the projected patient referral sources;

- (7) evidence of the applicant's capability to communicate efficiently with emergency transportation agencies and with all hospitals serving the proposed service area;
- (8) the number and composition of open heart surgical teams available to the applicant;
- (9) a brief description of the applicant's in-service training or continuing education programs for open heart surgical team members; and
- (10) evidence of the applicant's capability to perform both cardiac catheterization and open heart surgical procedures 24 hours per day, 7 days per week.

*History Note: Filed as Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Authority G.S. 131E-177(1); 131E-183; Eff. January 1, 1987; Amended Eff. November 1, 1996; January 4, 1994; November 1, 1989; Temporary Amendment January 1, 1999; Temporary Eff. January 1, 1999 Expired on October 12, 1999; Temporary Amendment Eff. January 1, 2000; Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 2000; Amended Eff. April 1, 2001.*

#### **10A NCAC 14C .1703 PERFORMANCE STANDARDS**

(a) An applicant that proposes to develop open-heart surgery services shall demonstrate that the proposed project is capable of meeting the following standards:

~~The applicant shall demonstrate that the proposed project is capable of meeting the following standards:~~

- ~~(1) an applicant's existing and new or additional heart-lung bypass machines shall be utilized at an annual rate of 200 open heart surgical procedures per machine, measured during the twelfth quarter following completion of the project;~~
- ~~(2) at least 50 percent of the projected open heart surgical procedures shall be performed on patients residing within the primary open heart surgery service area;~~
- ~~(3) the applicant's projected utilization and proposed staffing patterns are such that each open heart surgical team shall perform at least 150 open heart surgical procedures in the third year following completion of the project;~~
- ~~(4) the applicant shall document the assumptions and provide data supporting the methodology used to make these projections; and~~
- ~~(5) heart-lung bypass machines that have been acquired for non-surgical use or for non-heart surgical procedure use shall not be utilized in the performance of open heart surgical procedures.~~

(c) An applicant that proposes to acquire an additional heart-lung bypass machine shall demonstrate either:

(i) that the applicant's existing and new or additional heart-lung bypass machines shall be utilized at an annual rate of 200 open heart surgical procedures per machine, measured during the twelfth quarter following completion of the project; or

- (ii) that the annual utilization of its existing and proposed heart-lung bypass machines as measured in minutes in use or staffed on standby for all procedures shall be at or above 900 [or 936?] hours per year during the twelfth quarter following completion of the project; or
- (iii) that the applicant currently operates an open heart surgery program with only one heart-lung bypass machine, and that the additional machine is to be used to assure appropriate coverage for emergencies and in no instance shall be scheduled for use at the same time as the machine used to support scheduled open heart surgery procedures; or
- (iv) that the applicant will reduce costs by acquiring a heart-lung bypass machine and discontinue use of an existing heart-lung bypass machine that it does not own; or
- (v) that the applicant has need for a heart-lung bypass machine outside the area used for open heart surgery and that acquiring an additional machine will improve efficiencies of the applicant or the safety of its patients.
- (d) Heart-lung bypass machines that have been acquired for non-surgical use or for non-heart surgical procedure use shall not be utilized in the performance of open heart surgical procedures.

*History Note: Authority G.S. 131E-177(1); 131E-183(b);  
Eff. January 1, 1987;  
Amended Eff. November 1, 1989;  
Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;  
Amended Eff. January 4, 1994;  
Temporary Amendment January 1, 1999;  
Temporary Eff. January 1, 1999 expired October 12, 1999;  
Temporary Amendment Eff. January 1, 2000 and shall expire on the date the permanent amendment to this rule, approved by the Rules Review Commission on November 17, 1999, becomes effective;  
Amended Eff. July 1, 2000;  
Temporary Amendment Eff. January 1, 2002;  
Amended Eff. April 1, 2003;  
Temporary Amendment Eff. February 1, 2010;  
Amended Eff. November 1, 2010.*

#### **10A NCAC 14C .1704 SUPPORT SERVICES**

(a) The applicant that proposes to develop open-heart surgery services shall demonstrate that the following services shall be available in the facility 24 hours per day, 7 days per week:

- (1) electrocardiography laboratory and testing services, including stress testing and continuous cardiogram monitoring;
- (2) echocardiography service;
- (3) blood gas laboratory;
- (4) nuclear medicine laboratory;
- (5) pulmonary function unit;
- (6) staffed blood bank;
- (7) hematology laboratory or coagulation laboratory;

- (8) microbiology laboratory;
- (9) clinical pathology laboratory with facilities for blood chemistry;
- (10) a dedicated cardiac surgical intensive care unit that shall be a distinct intensive care unit and shall meet the requirements of 10A NCAC 14C .1200;
- (11) for facilities performing pediatric open heart surgery services, a pediatric intensive care unit that shall be a distinct intensive care unit and shall meet the requirements of 10A NCAC 14C .1300;
- (12) emergency room with full-time director, staffed for cardiac emergencies with acute coronary suspect surveillance area and voice communication linkage to the ambulance service and the coronary care unit; and
- (13) cardiac catheterization services including both diagnostic and interventional cardiac catheterization capabilities.

(b) The applicant that proposes to develop open-heart surgery services shall demonstrate that the following services shall be available to the applicant:

- (1) a preventive maintenance program for all biomedical devices, electrical installations and environmental controls;
- (2) a cardiac rehabilitation program; and
- (3) a community outreach and education program.

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### **10A NCAC 14C .1705 STAFFING AND STAFF TRAINING**

(a) The applicant that proposes to develop open-heart surgery services shall demonstrate that it can meet the following staffing requirements:

- (1) one cardiovascular surgeon who has been designated to serve as director of the open heart surgery program and who has the following special qualifications:
  - (A) certification by the American Board of Thoracic Surgery; and
  - (B) thorough understanding of and experience in basic medical and surgical knowledge and techniques of cardiac surgery, cardiopulmonary bypass and methods of myocardial management;
- (2) at least one specialized open heart surgical team composed of at least the following professional and technical personnel:
  - (A) one cardiovascular surgeon board certified by the American Board of Thoracic Surgery;
  - (B) one assistant surgeon, preferably a cardiovascular or thoracic surgeon;
  - (C) one board certified anesthesiologist trained in open heart surgical procedures;
  - (D) one certified registered nurse anesthetist;
  - (E) one circulating nurse or scrub nurse, with recent specialized training in open heart surgical procedures;
  - (F) one operating room technician or nurse with recent specialized training in open heart surgical procedures;

- (G) one certified pump technician per operational heart lung bypass machine and an additional certified pump technician on standby;
  - (H) staff for the dedicated cardiac surgical intensive care unit to ensure the availability of 1 RN for every 2 patients during the first 48 hours of post-operative care;
  - (3) at least two fully-qualified cardiac surgeons on the staff, at least one of whom is board-certified; one of these surgeons shall be on-call at all times; if pediatric open heart surgical procedures are performed, one of these surgeons shall be specially trained and clinically competent to perform pediatric open heart surgical procedures.
- (b) The applicant that proposes to develop open-heart surgery services shall demonstrate that it can provide the following staff training for members of open heart surgical teams:
- (1) certification in cardiopulmonary resuscitation and advanced cardiac life support;
  - (2) an organized program of staff education and training which is integral to the open heart surgery program and which ensures improvements in technique and the proper training of new personnel.

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