Fiscal Impact Analysis of Proposed Rule Change
10A NCAC 14C .1700
Criteria and Standards for Open Heart Surgery
and Heart-Lung Bypass Machines

Agency	Division of Health Service Regulation Division Director
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Rule Titles	10A NCAC 14C .1701 Definitions 10A NCAC 14C .1702 Information Required of Applicant 10A NCAC 14C .1703 Performance Standards 10A NCAC 14C .1704 Support Services 10A NCAC 14C .1705 Staffing
Statutory Authority:	G.S. 131E-177(1); 131E-183;

Federal Impact	NO
State Impact	YES
Local Impact	NO
Substantial Economic Impact	NO

Purpose of the Proposed Revisions

Since 1993, the development of open-heart surgery programs and the acquisition of heart-lung bypass machines have been regulated by the Certificate of Need Law (G.S. 131E-175 et seq.). Specifically, both are defined as new institutional health services in G.S. 131E-176(16). The authority for the Certificate of Need (CON) Section to develop rules is found in G.S. 131E-177(1) and G.S. 131E-183(b). These rules were initially developed for open-heart surgery, effective January 1, 1987, and were amended for heart-lung bypass machines, effective November 1, 1993.

The annual state medical facilities plan (SMFP) provided a methodology that developed need determinations that controlled both the number of open-heart surgery programs and the number of heart-lung bypass machines needed at each program.

In 2011, the State Health Coordinating Council, an advisory committee that develops the SMFP for the governor's approval, accepted a petition at the request of Duke University Medical Center that proposed uncoupling the need for open-heart surgery programs and heart-lung bypass machines, effective with the 2012 SMFP. (Copy of Duke's petition included in Appendix 3).

Chapter 7 of the 2012 SMFP includes the following:

Changes from the Previous Plan

Two substantive changes have been incorporated into Chapter 7 of the North Carolina 2012 State Medical Facilities Plan, one related to heart-lung bypass machines and the other related to burn intensive care services.

The first change is the elimination of the need determination methodology for heart-lung bypass equipment. The absence of need determinations in the State Medical Facilities Plan does not change the requirement to obtain a certificate of need for heart-lung bypass equipment. This change will allow interested parties, including those using heart-lung bypass machines for purposes other than or in addition to open-heart surgery services, to apply directly to the Certificate of Need Section for needed capacity, documenting the requested equipment's anticipated utilization (i.e., type of utilization, utilization rates, and anticipated service area, etc.) in their certificate of need applications.

Need Determination for Open-Heart Surgery Services

It is determined that there is no need for additional open-heart surgery services anywhere in the state and no reviews are scheduled.

Notice Regarding Heart-Lung Bypass Machines

Prior to the North Carolina 2012 State Medical Facilities Plan, a section detailing the heart-lung bypass machine need determination methodology and its results for the year followed the open-heart surgery services section. In 2011, the State Health Coordinating Council recommended removal of the heart-lung bypass machine need determination methodology. The primary reason for creating the need determination methodology for heart-lung bypass equipment was to control the expansion of open-heart surgery programs. When the North Carolina certificate of need statute was amended in 1993 to include open-heart surgery programs, there was no requirement to obtain a certificate of need for new operating rooms. Limiting the number of heart-lung bypass machines was determined to be the most effective means of controlling open-heart surgery expansions; however, since 2000, the number of adult open-heart surgeries has dropped steadily. At the same time that open-heart surgery procedures declined, the use of heart-lung bypass machines for other procedures increased across the state. Other procedures include organ transplants, stent repairs, trauma resuscitations, and pacemaker implants. Also, a certificate of need now is required for new operating rooms.

Because limiting the number of heart-lung bypass machines is no longer necessary to control unneeded growth in open-heart surgery programs, and since the machines are used for procedures other than open-heart surgery, the need determination methodology for heart-lung bypass machines has been taken out of the State Medical Facilities Plan. Heart-lung bypass machines are still regulated by the certificate of need statutes, and acquisition of a new or replacement heart-lung bypass machine must be reviewed by the Certificate of Need Section.

As a result of this change, the CON Section has been working with the petitioner to amend the rules at 10A NCAC 14C .1700 to address the performance standards for heart-lung bypass machines when they are not operated specifically to provide open-heart surgery. Additionally, the petitioner has also informed us of technical changes that require modification of some parts of the rules.

Summary of Proposed Revisions

1. The changes in Rule 10A NCAC 14C .1701 Definitions, removes definitions for open-heart surgery service area and primary open-heart surgery service area that are based on concepts developed in 1986 that are no longer relevant today, as there are considerably more facilities providing this service than when these rules were originally developed. The current list of DRGs (diagnosis-related groups) that define open-heart surgery is obsolete. It has changed before and should not be codified in a rule.
2. The changes in rule 10A NCAC 14C .1702 Information Required of the Applicant were primarily for the purposes of reorganization and clarification to differentiate between heart-lung machines acquired to provide for open-heart surgery programs and those programs that used heart-lung machines for other types of procedures.
3. The changes in rule 10A NCAC 14C .1703 Performance Standards are designed to differentiate between open-heart surgery programs and heart-lung bypass machines
4. The changes in rule 10A NCAC 14C .1704 Support Services were primarily for the purposes of reorganization and clarification to differentiate heart-lung machines acquired to provide for open-heart surgery programs and those programs that used heart-lung machines for other types of procedures
5. The changes in rule 10A NCAC 14C .1705 Staffing and Staff Training were primarily for the purposes of reorganization and clarification to differentiate heart-lung machines acquired to provide for open-heart surgery programs and those programs that used heart-lung machines for other types of procedures.

Economic Impact of the Proposed Rule Revisions

Private Entities
The proposed rule changes will enable the implementation of the changes in the 2012 State Medical Facilities Plan, which eliminated the outdated need-determination methodology for obtaining a certificate of need for a heart-lung bypass machine. As a result, medical facilities will be better able to obtain a certificate of need for heart-lung bypass machines to use for procedures other than open-heart surgery.

Compared to a baseline scenario under the existing rules, medical facilities in the state are likely to obtain additional heart-lung bypass machines in the future under the proposed rules. However, in the course of the next few years, the Division expects only the petitioner (Duke University Health System) to obtain additional heart-lung bypass machines as a result of the proposed rule changes. Under the proposed rule, no medical facilities would be newly *required* to obtain and/or operate additional heart-lung bypass machines; the facilities would simply have additional methods to obtain and operate additional machines under the State's certificate of need requirements.

Costs associated with obtaining and operating a heart-lung bypass machines include capital costs (approximately $175,000), staffing (approximately $96,000 per year for a full-time perfusionist), maintenance and support services (approximately $7,200 per

year), and the application fee for the certificate of need ($5,000). Thus, expected costs to a medical facility to obtain and operate a single new heart-lung bypass machine would be under $300,000 in a given 12-month period. Medical facilities do not expect an increase in revenues associated with additional heart-lung bypass machines, as increasing the number of machines is not expected to increase the number of related medical procedures conducted using heart-lung bypass machines.

Discussions between Division staff and relevant medical facilities' stakeholders indicate that it is unlikely that medical facilities would obtain more than one additional heart-lung bypass machine in a given 12-month period. Thus, the proposed rules would not generate a substantial economic impact as defined in G.S. 150B-21.4.

State Government
The Certificate of Need (CON) section may experience a small increase in fee revenues associated with additional applications for heart-lung bypass machines over the course of the next several years. Reviewing the applications will also result in additional opportunity costs of for CON section staff. As the Division expects the number of additional applications to be no more than one per year, the associated additional fee revenues would be $0 or $5,000 per year in future years, and the opportunity costs of staff time to review each application would be approximately $9,200 based on an analysis of current budgeted positions and the workload during fiscal year 2011. (See Appendix 1 for detailed calculations.)

Benefits
As stated in the attached Duke petition (see Appendix 3), allowing medical facilities an alternative means of obtaining authorization for additional heart-lung bypass machines may reduce patient risk associated with overutilization of heart-lung bypass machines and may also improve the efficiency of hospital operations and reduce hospital costs.

Summary

The proposed rule revisions will benefit the public interest by implementing the elimination of an outdated need-determination methodology that understates the true demand for heart-lung bypass machines in the state.

The proposed rules will generate a small potential impact on State funds and demands on staff and a non-substantial economic impact associated with the costs to medical facilities for obtaining and operating heart-lung bypass machines that the facilities would likely not be able to obtain under the existing rules. The costs to facilities associated with the proposed rule revisions will be at the discretion of the facilities; the costs are not *required* by the proposed rule revisions.

APPENDIX 1: STATE GOVERNMENT OPPORTUNITY COSTS

The calculation of opportunity cost is based on the following assumptions:				
		Hours	Hourly Rate	Cost
Number of reviews per year	144			
Number of Analysts#	12			
Number of reviews per analyst*	12			
Average analyst salary	$ 65,103	2080	$ 31.30	
Number of days per project	20			
Length of review [days]	15	120		$3,755.96
Monitoring [days]	5	40		$1,251.99
Overhead				
Support staff time in days	3	24		
for Processing				
Support rate	$ 34,537.67	2080	$ 16.60	$ 398.51
Management time in days	5	40		
for Oversight				
Manager rate	$ 77,775.33	2080	$ 37.39	$1,495.68
TOTAL SALARY				$6,902.14
Personnel Benefits @ 34%				$2,346.73
TOTAL PERSONNEL COST (Rounded)				$9,200.00

There are 3 vacant positions, all in active recruiting

*Equals 1 per month

APPENDIX 2: PROPOSED RULE CHANGES

10A NCAC 14C .1701 is proposed for amendment as follows:

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

10A NCAC 14C .1701 DEFINITIONS

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

(1) "Approved heart-lung bypass machine" means a heart-lung bypass machine that was not operational prior to the beginning of the review period.

~~(1)~~ (2) "Capacity" of a heart-lung bypass machine means 400 adult-equivalent open heart surgical 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)~~ (3) "Cardiac Surgical Intensive Care Unit" means an intensive care unit as defined in 10A NCAC 14C .1201(2) and ~~which~~ that is for exclusive use by post-surgical open heart patients.

(4) "Existing heart-lung bypass machine" means a heart-lung bypass machine in operation prior to the beginning of the review period.

~~(3)~~ (5) "Heart-lung bypass machine" ~~shall have~~ has 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)~~ (6) "Open heart surgery services" ~~shall have~~ has the same meaning as defined in G.S. 131E-176(18b).

~~(6)~~ (7) "Open heart surgical procedures" means specialized surgical procedures ~~which:~~ that:

(a) utilize a heart-lung bypass machine (the "pump"); and

(b) are designed to correct congenital or acquired cardiac and coronary disease ~~and;~~ by opening the chest for surgery on the heart muscle, valves, arteries, or other parts of the heart.

(c) ~~are identified by Medicare Diagnostic Related Group ("DRG") numbers 104, 105, 106, 108, 547, 548, 549, and 550~~.

~~(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, 2012; November 1, 2010.

10A NCAC 14C .1702 is proposed for amendment as follows:

10A NCAC 14C .1702 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to 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 shall define the service area for the proposed project which shall be like the applicant's service area for other health services, unless the applicant documents that other providers are expected to refer patients to the applicant, including the methodology and assumptions used to define the service area.

~~(b)~~ (c) ~~The~~ An 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;~~ during the 12-month period prior to the submission of the application, identified by ACD-9, ACD-10, or CPT code;

~~(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)~~ (2) a projection of 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~~ procedures using the applicant's existing, approved and proposed heart-lung bypass machines in each of the first ~~12 quarters of operation~~ three years following completion of

____ including the methodology and assumptions used to make the projections;

~~(5)~~ (3) the number of patients from the proposed ~~primary open heart surgery~~ service area who are projected to receive ~~open heart surgical~~ procedures using the applicant’s existing, approved, and proposed heart-lung bypass equipment by patient's county of residence in each of the first ~~12 quarters,~~ three years following completion of the proposed project, including the methodology and assumptions used to make these projections;

~~(6)~~ (4) the projected patient referral sources;

~~(7)~~ (5) evidence of the applicant's capability to communicate efficiently with emergency transportation agencies and with all hospitals serving the proposed service area;

~~(8)~~ (6) the number and composition of open heart surgical teams available to the ~~applicant;~~ applicant; and

~~(9) a brief description of the applicant's in-service training or continuing education programs for open heart surgical team members; and~~

~~(10)~~ (7) 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. November 1, 2012; April 1, 2001.

10A NCAC 14C .1703 is proposed for amendment as follows:

10A NCAC 14C .1703 PERFORMANCE STANDARDS

(a) An applicant that proposes to develop open-heart surgery services shall:

~~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)~~ (1) ~~the applicant's~~ demonstrate that the 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;~~ project; and

~~(4)~~ (2) ~~the applicant shall~~ document the assumptions and provide data supporting the methodology used to make these ~~projections; and~~ projections.

~~(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.~~

(b) An applicant that proposes to acquire a heart-lung bypass machine shall demonstrate either:

(1) that the applicant’s projected annual utilization of its existing, approved, and proposed heart-lung bypass machines (other than a machine acquired pursuant to 10A NCAC 14C.1703(b)(3)) will be at least 200 open-heart surgical procedures per machine during the third year following completion of the project;

(2) that the projected annual utilization of its existing, approved, and proposed heart-lung bypass machines (other than a machine acquired pursuant to 10A NCAC 14C.1703(b)(3)), will be at least 900 hours per year during the third year following completion of the project, as measured in minutes used or staffed on standby for all procedures; or

(3) that the proposed machine is needed to provide coverage for open-heart surgery emergencies and will not be scheduled for use at the same time as the applicant’s equipment used to support scheduled 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, 2012; November 1, 2010.

10A NCAC 14C .1704 is proposed for amendment as follows:

10A NCAC 14C .1704 SUPPORT SERVICES

(a) ~~The~~ An applicant that proposes to acquire a heart-lung bypass machine shall demonstrate that the following services ~~shall~~ will 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;~~ laboratory; and

(9) clinical pathology laboratory with facilities for blood ~~chemistry;~~ 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~~ An applicant that proposes to develop open-heart surgery services shall demonstrate that the following services ~~shall~~ will be available in the facility 24 hours per day, 7 days per week: ~~to the applicant:~~

(1) ~~a preventive maintenance program for all biomedical devices, electrical installations and environmental controls;~~ a dedicated cardiac surgical intensive care unit;

(2) ~~a cardiac rehabilitation program; and~~ for facilities performing pediatric open-heart surgery services, a pediatric intensive care unit that will be a distinct intensive care unit and will meet the requirements of 10A NCAC 14C .1300;

(3) ~~a community outreach and education program.~~ an emergency department 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

(4) cardiac catheterization services including both diagnostic and interventional cardiac catheterization capabilities.

History Note: *Filed as a 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(b);
Eff. January 1, 1987;
Amended Eff. November 1, 2012; January 4, 1994; November 1, 1989.

10A NCAC 14C .1705 is proposed for amendment as follows:

10A NCAC 14C .1705 STAFFING AND STAFF TRAINING

(a) An applicant that proposes to acquire a heart-lung bypass machine shall demonstrate that it can meet the following staffing requirements:

(1) at least two cardiovascular surgeons on the medical staff, at least one of whom is certified by the American Board of Thoracic Surgery; and

(2) one perfusionist certified by the American Board of Cardiovascular Perfusion and licensed by the North Carolina Medical Board per operational heart-lung bypass machine and an additional licensed, certified perfusionist on standby;

~~(a)~~ (b) ~~The~~ An 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;~~ licensed by the North Carolina Medical Board to practice medicine; and

(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 certified by The American Board of Anesthesiology and 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;~~ one licensed , certified perfusionist;

(H) staff for the dedicated cardiac surgical intensive care unit to ensure the availability of 1 ~~RN~~ registered nurse for every 2 patients during the first 48 hours of post-operative care;

(I) if pediatric open heart surgical procedures are performed, at least one cardiac surgeon trained to perform pediatric open heart surgical procedures.

(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) (c) The An applicant that proposes to acquire a heart-lung bypass machine or to develop open-heart surgery services shall demonstrate that it can provide the following staff training for members of open heart surgical teams: following:

(1) staff training for certification in cardiopulmonary resuscitation and advanced cardiac life support; and

(2) an organized a program of staff education and training which is integral to the open heart surgery program and which that ensures improvements in technique and the proper training of new personnel.

History Note: Filed as a 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(b);
Eff. January 1, 1987;
Amended Eff. November 1, 2012; January 4, 1994; November 1, 1989.

APPENDIX 3: DUKE UNIVERSITY HEALTH SYSTEM PETITION

[see pages below]