

NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL

PETITION REGARDING HEART-LUNG BYPASS EQUIPMENT

AND FOR ADJUSTMENT TO NEED DETERMINATION IN DURHAM COUNTY

Petitioner Duke University Health System, Inc. d/b/a Duke University Hospital (“Duke”) hereby submits this petition regarding the need determination for heart-lung bypass equipment in the 2012 State Medical Facilities Plan.

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Statement of the Proposed Change

Duke proposes that the State Health Coordinating Council (SHCC) amend the Proposed 2012 State Medical Facilities Plan to:

- Eliminate the need determination for heart-lung bypass machines in Chapter 7 (Exhibit A) or

- In the alternative, find need for 3 additional machines in Durham County (Exhibit B)

Background

In February 2011 Duke proposed a change to the need methodology for heart-lung bypass machines to reflect their use for procedures other than those defined by regulation as open heart surgery procedures. The Agency Report on the petition stated that “The Agency recognizes the need to incorporate data from other uses of heart-lung bypass machines and is in agreement with concepts brought forth in this petition; however, at this point, the Hospital License Renewal Application does not include questions related to other uses of the machines.”

The Acute Care Services Committee then discussed the collection of the data necessary to evaluate the petition and the appointment of a work group to consider the data. Several speakers expressed concern about the burden that the collection and analysis of additional data would entail. The Chief of the Planning Section said that no additional work groups could be appointed in the current cycle. The Acute Care Services Committee discussed the reason for regulating heart-lung machines under the CON Law and heard that the need determinations for the equipment predated operating rooms being placed under CON; at the time, regulation of bypass equipment served as a way of controlling the unnecessary growth of open heart surgery programs. After members expressed the view that it would be helpful to receive comments on the issue during the summer hearings, the Committee deferred further action on the petition.

Further consideration of the issues raised by the original petition leads to the conclusion that the anticipated burden and delay of data gathering and analysis could be eliminated entirely if the Committee and the SHCC concluded that need determinations for heart-lung bypass machines were no longer necessary, leaving the evaluation of need for such equipment to the CON Section similar to the procedures in place for other kinds of equipment such as CT scanners.

Alternative 1 – Eliminate the Need Determination for Bypass Machines

If the SHCC agrees with the Agency that the use of bypass equipment for all procedures, including both Open Heart Surgery (OHS) procedures and other procedures, should be considered in evaluating the need for additional machines, the SHCC could simply amend the Proposed 2012 Plan to eliminate the need determination for bypass machines. That action is made even more compelling if the SHCC agrees that need determinations for heart-lung machines are no longer needed to control the growth of open heart surgery programs due to the fact that operating rooms are now regulated by the CON Law. The risk that open heart surgery providers could unnecessarily expand their capacity unnecessarily is mitigated by the state’s regulation of additional operating rooms in which to perform those procedures. The elimination of a need determination for the machines would not affect the need methodology for open heart surgery services or the need methodology for operating rooms. The SHCC could simply develop a general policy and leave it to the CON Section to determine the specific requirements to be used in evaluating an applicant’s need for additional equipment. This treatment would be

consistent with that of simulators, which are also subject to CON review without need determinations.

Eliminating the need methodology and determination for bypass machines would preclude the need to:

- Amend the Hospital License Renewal Application form
- Collect and analyze the data required to assess the utilization of the State's 79 existing machines
- Appoint and staff a work group to consider the data and develop a recommendation to the SHCC
- Evaluate and act on the work group's recommendation
- Develop and adopt a need methodology reflecting the use of machines for both OHS and non-OHS procedures
- Develop new need determinations each year

The CON Section would be required to develop Criteria and Standards for Heart Lung Bypass Machines to establish the capacity of the machines and the utilization required to demonstrate need for another machine. Applicants seeking a machine would then document need based on those requirements. But that would be all.

This change would have no effect on the plan's need determination for new open heart surgery services. Open heart surgery and heart-lung bypass equipment are independently identified as new institutional health services requiring a certificate of need, and may be treated separately in the planning process.

Reasons for the Proposed Change

1) The existing methodology is fatally flawed. It is built on two assumptions that are no longer true:

A. Heart-Lung bypass machines are used only to support OHS procedures. In fact, over the years surgeons have come to rely on bypass machines to support a wide variety of non-OHS procedures, including:

- Organ transplants
- Trauma resuscitations
- Nephrectomies and other tumor cases
- Closed heart valve replacements
- Stent repairs
- Pacemaker implants
- Convergence procedures to treat atrial fibrillation

- High risk obstetric procedures

None of these procedures fall into the DRGs which the existing regulations categorize as OHS cases, and yet they account for 39% to 48% of all the perfusion cases at Duke in recent years:

Fiscal Year	Total Cases	OHS Cases	OHS as % of Total Perfusion Cases
2007	1,674	981	58.6%
2008	1,817	945	52.0%
2009	2,062	1,089	52.8%
2010	1,828	1,123	61.4%

B. “Research indicates that one heart-lung bypass machine can be utilized for two scheduled open heart surgical procedures per day.” (2011 State Plan, page 101). In fact, in FY2010, perfusion cases at Duke required an average of 7 hours 36 minutes, and the average non-OHS procedure lasted 70 minutes longer than the average OHS procedure.

At Duke, at least, the bypass machines are capable of supporting no more than one scheduled procedure per day.

- 2) The second reason for the change is that application of the existing methodology prevents the finding of need for additional machines, even where they are required to assure patient safety.

During FY2010, Duke operated 6 machines during the first 3 quarters and 7 machines during the last quarter, for an average of 6.25 machines for the year. Those machines provided a total of 834,230 minutes of perfusion, for an average of 523 minutes (8.7 hours) per day on each of the 255 days surgery was scheduled. (In addition, staffed machines were available on standby for 198 other procedures, leaving those machines unavailable for other procedures, but those minutes were not counted, so they are excluded here.)

With all its machines used an average of more than 8 hours per day, it is safe to say that utilization of the Hospital’s machines was at least 100% of capacity. Nonetheless, the existing methodology would artificially rate the utilization of the Duke machines at only 50.6% of capacity. Here is why:

As the Hospital’s 2011 Hospital Licensure Renewal Application reports, the Hospital provided a total of 1,266 weighted OHS procedures during FY2010. The methodology

would say that the 6.25 machines then in use at Duke could have supported 2,500 weighted procedures. (400 procedures / machine x 6.25 = 2,500). As they provided only 1,266 procedures, they were used at 50.6% of capacity.

- 3) A facility might also need additional machines to increase efficiency of hospital operations or to reduce costs. If some of the procedures for which the machines are used occur outside the operating suite it may become time consuming or cumbersome to move them back and forth. In addition, if a hospital is leasing machines and the lease cost exceeds the cost of purchasing machines, health care costs could be lowered by allowing the hospital to purchase machines.
- 4) There is no reason to think that hospitals would seek to acquire heart-lung bypass machines for which they have no genuine need. The machines cost nearly \$200,000 each. The use of machines for procedures is not diagnostic, and there is no incentive to use them for procedures other than those for which they are needed.

For all these reasons, eliminating a need determination for heart-lung bypass machines and allowing the CON Section instead to evaluate applications on a case-by-case basis would be appropriate and consistent both with Duke's original petition and the Agency's report.

Alternative 2 – A Special Need Determination for Durham County

In the event that the SHCC decides not to eliminate the need determinations for heart-lung bypass machines in the 2012 Plan, Duke proposes that the need determination in the 2012 Plan be modified to find need for three additional heart-lung bypass machines in Durham County.

The special need determination would enable Duke to apply for three machines, including a second pediatric machine to backstop the pediatric machine acquired pursuant to the approval of Project ID# J-8385-09 and two additional adult machines. The acquisition of those machines would provide an added measure of safety for patients undergoing procedures requiring the support of perfusion services. Currently, all of Duke's machines are fully utilized at all times, leaving very little capacity for backup in the event of emergencies.

During FY2010, Duke operated 6 machines during the first 3 quarters and 7 machines during the last quarter, for an average of 6.25 machines for the year. Those machines provided a total of 834,230 minutes of perfusion. In addition, staffed machines were available on standby for 198 other procedures, leaving those machines unavailable for other procedures; assuming those cases take the same average length of time as those for which the machines are utilized, the machines were utilized and/or staffed on standby for a total of 924,590 minutes, or 15,410 hours. The existing State Medical Facilities Plan methodology currently assumes that the capacity of a heart-lung bypass machine is 1,800 hours per year, based on a capacity of 400 procedures and

the assumption that each procedure lasts 270 minutes each (2 procedures per day in operating rooms staffed 9 hours per day). Using a capacity of 1,800 hours per year, Duke would have needed 8.56 machines in use full time in 2010 just to accommodate the actual time heart-lung equipment was used or staffed on standby for procedures, without even taking into consideration the need for backup capacity for emergencies. (Duke provided this service on its existing machines only by running them well in excess of the assumed capacity of an operating room.)

Duke would also note that under existing CON regulations, an applicant must only project utilization at an annual rate of 200 open heart surgical procedures per machine, or 50% of assumed capacity, to justify an increase in machines. 14C NCAC .1703. Duke would easily be able to project utilization well in excess of 50% of the capacity of 10 machines based on time rather than procedures. In fact, to be conservative, Duke has proposed a utilization requirement of 80% for proposed equipment in its proposed adjustment to the need determination set forth in Exhibit B.

Allowing an increase in capacity of 3 machines, for a total of 10, would allow Duke to accommodate its existing utilization and to have at least one machine available for backup. Duke may seek specifically to acquire an additional pediatric heart-lung bypass machine as one of the three proposed machines to ensure backup capacity for pediatric procedures in particular.

Adverse effect on providers and consumers without change:

Without the proposed modification, the actual need for heart-lung machines is artificially deflated. Machines that are in fact fully clinically utilized and not practically available for additional procedures appear to be underutilized when only a fraction of the procedures they perform is counted.

Therefore, the current regime prevents providers from acquiring new equipment when there is need for it based on actual utilization, inhibits access of consumers to these life-saving procedures, and makes it problematic to keep machines in reserve for use in emergency situations.

Alternatives considered:

As set forth above, Duke considered the following alternatives:

1. A change in methodology. The Agency responded that it does not have sufficient information from existing hospital license renewal applications to change the methodology as proposed for the 2012 Plan.
2. Eliminating any need methodology or determination for heart-lung bypass machines from the State Medical Facilities Plan. Duke supports this alternative.

3. Adjusting the need determination for Durham County. In the event that 2012 Plan continues to include a need determination for heart-lung bypass machines, Duke requests an adjustment to the need in Durham County where Duke has already provided the data reflecting the actual utilization in time of its existing equipment.

Evidence that the proposed change would not result in unnecessary duplication of health resources in the area:

Eliminating the need methodology for heart-lung bypass equipment would still require providers to apply for a certificate of need and demonstrate appropriate utilization in conformance with any regulations promulgated by the CON Section.

In Durham in particular, either of the proposed alternatives acknowledges that the Duke's equipment is regularly used for non-open heart surgery procedures and that as a result Duke has reached its existing equipment's capacity. Duke would note that although Durham Regional Hospital has two heart-lung bypass machines, those machines are not available as a practical matter to ease capacity at Duke University Hospital. Durham Regional Hospital offers open-heart surgery services, and accordingly needs one machine available for such surgery, and another as a backup in the event its first machine has a malfunction.

Evidence that the requested change is consistent with the Basic Principles of Safety and Quality, Access, and Value:

As set forth above, at Duke University Hospital, heart-lung bypass equipment is frequently used for non-open heart procedures. The requested change will allow providers to respond to the need for such procedures while continuing to have appropriate equipment available for open-heart surgical procedures as well and to have sufficient capacity to provide backup in the event of any equipment breakdown, including backup for pediatric procedures. In reflecting current uses of this equipment beyond traditional open-heart procedures, the proposed adjustment furthers the safety and quality of health care, access to equipment necessary for life-saving procedures, and value.

EXHIBIT A

Proposed Changes to the State Medical Facilities Plan Need Determination and Methodology for Heart-lung Bypass Equipment

Duke proposes the following amendments to the Open-Heart Surgery Services and Heart-Lung Bypass Machine section of the Plan (located in Chapter 7):

Open Heart Surgery Services and Heart-Lung Bypass Machines

Definitions

“Open heart surgery services,” as defined in G.S. 131E-176(18b), “means the provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects.”

“Heart-lung bypass machine,” as defined in G.S. 131E-176(10a), “means the equipment used to perform extra-corporeal circulation and oxygenation during surgical procedures.”

Facility Inventory - Service Volume

As the following Tables 7A and ~~7B~~ indicates, there were 22 open-heart surgery programs in North Carolina in 2009, with a total ~~planning~~ inventory of 72 heart-lung bypass machines. Data reported for 2009 indicate that these 72 machines were utilized at an average annual rate of X percent, a decrease from the previous year’s utilization at X percent of capacity. In addition, seven programs have “back-up” heart-lung bypass machines, which by law can only be used for emergency back-up of their other heart-lung machines. Total open-heart surgery procedures for 1995-2009 are shown on the following graph and the reported numbers of procedures for years ending 9/30/95 through 9/30/09 appear in the following Table 7A.

[TABLE A]

Open Heart Surgery Services and Heart-Lung Bypass Machine Need Determination

~~The capacity of a heart lung bypass machine has been defined as 400 adult equivalent open heart surgical procedures per year. For purposes of determining capacity, one open heart~~

surgical procedure is defined to be the single utilization of a heart-lung bypass machine for openheart surgery by a patient in a surgical operating room. Research indicates that one heart-lung bypass machine can be utilized for two scheduled open heart surgical procedures per day. Because of additional time often incurred during procedures on patients age 14 and under, one procedure is valued at two adult equivalent open heart surgical procedures. The following Table 7B displays 2009 heart-lung bypass machine capacity and utilization as reported on the 2010 Hospital License Renewal Applications on file with the Division of Health Service Regulation:

~~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.

Heart-Lung Bypass Machines

Heart-lung bypass machines were previously subject to need determinations based solely on the number of open heart surgery procedures reported by the facility during the previous year. Statewide the number of open heart procedures dropped for the tenth consecutive year in 2010. It is now less than two-thirds of the number performed in 1997- the peak year.

The primary reason for creating need determinations for equipment was to control the expansion of open heart surgery programs, because approval for an open heart surgery program does not limit its subsequent expansion. When the CON law was amended to include open heart surgery programs there was no requirement to obtain a CON for new operating rooms, and limiting the number of heart-lung bypass machines was determined to be the most effective means of controlling open heart surgery expansions at the expense of potential new providers. The downward trend of open heart surgery cases has effectively ended the impetus for expansion of these programs in North Carolina. Moreover, if a provider did wish to expand, it would need a CON to add any operating rooms to accommodate an expanded program.

At the same time that open heart surgery procedures have been declining, the use of heart-lung bypass machines for other procedures has been increasing, at least in some facilities. Other procedures include organ transplants, heart valve replacement, stent repairs, trauma resuscitations, and pacemaker implants. Because not all facilities with open heart surgery programs perform some or all of the above procedures, many will have no need for additional heart - lung bypass machines for this purpose. However, so long as a need determination methodology was used based only on the number of open heart surgery procedures done, the need generated by other uses for the machines was not recognized and some facilities were not able to obtain approval for needed machines. Over time it is likely that additional providers will be using the machines more often for non-open heart surgery procedures.

Because regulation of heart-lung bypass machines is no longer necessary to control unneeded growth in open heart surgery programs, and because the machines are only used for life support

during highly complex procedures performed on critically ill patients, there is little likelihood that facilities will purchase more machines than they can usefully employ or that are not cost-effective. Therefore, in order to provide needed flexibility to facilities offering these complex procedures it is determined that no specific need determination using the current methodology is necessary. Rather, applicants should document their need for additional machines in a CON application to be reviewed against both statutory criteria and appropriate administrative rules.

Potential bases for an applicant to justify the need for additional heart-lung bypass machines could include the following:

1. Demonstration that increasing average time of open heart surgery cases precludes the ability of the provider to use the machines for two procedures per day.
2. Demonstration that the use of heart-lung bypass machines for procedures other than open heart surgery requires additional machines.
3. Demonstration that operational efficiencies or patient safety can be improved by the addition of one or more machines.
4. Demonstration that purchase of new machines would be a cost effective means of lowering operating costs of the facility.
5. Demonstration that increasing utilization of existing machines requires that one or more additional machines be available to assure appropriate back-up for all uses.

Heart-Lung Bypass Machine Need Determination Methodology

~~A need exists for an additional heart lung bypass machine when the utilization of a provider's existing and approved equipment is at or above 80 percent of capacity based on the number of open heart surgery procedures reported in the 2010 licensure application on file with the Division of Health Service Regulation, and after equipment, which is allocated in previous State Medical Facilities Plans but pending review or appeal, is subtracted from the equipment deficit. Any person may apply for a certificate of need to purchase an additional heart lung bypass machine for which a need is determined, provided the heart lung bypass machine will be located in the same county as the provider whose utilization was at or above 80 percent of capacity based on the number of open heart surgery procedures reported in the 2010 licensure application on file with the Division of Health Service Regulation. (Note: A heart lung bypass machine's service area is the heart lung bypass machine planning area in which the heart lung bypass machine is located. The heart lung bypass machine planning areas are the single and multi-county groupings shown in Figure 5.1.)~~

Need Determination for Heart-Lung Bypass Machines

~~Application of the standard methodology indicates no need for additional heart lung bypass machines anywhere in the state and no reviews are scheduled.~~

[In addition, Policy AC-6 could be deleted from the plan as unnecessary. This policy could be included in any promulgated CON regulations regarding applications for additional heart-lung machines.]

EXHIBIT B

Proposed Adjustment to the State Medical Facilities Plan Need Determination for Heart-Lung Bypass Equipment in Durham County

Duke proposes the following amendments to the Open-Heart Surgery Services and Heart-Lung Bypass Machine section of the Plan (located in Chapter 7):

A need exists for 3 additional heart-lung bypass machines in Durham County. Such machines may be used for open-heart and non-open-heart procedures. Any provider may apply when the utilization of the provider's existing and approved equipment as measured in minutes in use or staffed on standby is at or above 80 percent of capacity, which is defined as either 1800 hours per year or 400 procedures per year. The applicant shall demonstrate that the utilization of its existing and proposed heart-lung bypass machines as measured in minutes in use or staffed on standby shall be at or above 80 percent of capacity, which is defined as either 1800 hours per year or 400 procedures per year during the third year following completion of the project.