

**North Carolina State Health Coordinating Council**

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**Petition**

**Endorsing Duke University Health System's Petition  
Regarding Heart-Lung Bypass Machines**

Petitioner WakeMed Health & Hospitals submits this petition requesting an adjustment regarding the need determination for heart-lung bypass machines in the 2012 Proposed State Medical Facilities Plan.

Petitioner:

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Statement of Proposed Change

WakeMed joins Duke University Health System (Duke) in proposing that the North Carolina Health Coordinating Council (SHCC) adjust the need determination for heart-lung bypass machines by eliminating any specific need determination in the 2012 State Medical Facilities Plan (SMFP).

Background

In 1993 the Certificate of Need (CON) statute was amended to require a CON for the acquisition of heart-lung bypass machines, regardless of cost. The reason for this change was that the cost of the machines did not exceed the threshold for major medical equipment, and controlling the number of heart-lung machines would serve as a means of regulating the expansion of open heart surgery programs. This amendment

occurred at a time when there were fewer open heart surgery programs in operation statewide, and unregulated expansion of existing programs would preclude the opportunity for new providers to be approved.

Since that time, six additional providers have been approved for open heart surgery programs, making it available in all regions of the state. The number of open heart surgery cases, however has been declining. In 1997 there were 13,498 cases in North Carolina and by 2010 there were only 8,075. There is no longer any pressure to expand existing programs, nor any impetus to develop new ones.

Earlier this year Duke petitioned the SHCC for the need methodology for heart-lung machines to be changed to include all procedures which involved the use of the equipment, rather than limiting it only to open heart surgery cases. Staff expressed support for the concept at the Acute Care Committee meeting, but explained that the data is not available to make the calculations. Discussion at the Committee meeting included a questioning of the need for a need determination and an invitation for input during the summer hearings.

#### Reasons for the Proposed Change

Limits on the acquisition of heart-lung machines are no longer necessary to control expansion of open heart surgery programs. New programs would still require a CON and because there currently is no need methodology, the SHCC would need to allocate a new program in the SMFP in order for an applicant to be approved for one. Since 2001, an expansion of an existing program would require a CON for any new operating rooms; thus effective control would continue to exist without limitations on heart-lung machines. The methodology used to make need determinations for heart-lung machines is based on the number of open heart surgery cases performed in the facility. However, as Duke's petition makes clear, the machines are used for many other procedures. Since those other procedures are not taken into account in making need projections, providers who use them for other procedures cannot obtain them because of the need determinations in the SMFP.

Because heart-lung machines are used only in open heart surgery and other procedures performed on critically ill patients during extremely invasive treatment, they are not used unnecessarily. More machines do not result in their overuse. The cost, while well below the \$750,000 threshold for major medical equipment, is at \$150,000 – \$200,000, high enough to discourage acquiring more than are needed

Because the original purpose of limiting heart-lung machines has been accomplished, and there is no reason to believe providers would spend money to stockpile them and

create an unnecessary inventory of them, there is no longer a rationale for a specific need determination to be made, particularly one based on an outdated methodology.

Adjusting the SMFP to eliminate the need determination would solve the problem presented in both of Duke's petitions and would avoid the necessity of appointing a study group and placing extra duties on an already overburdened medical facilities planning staff.

Without the requested adjustment the only alternative for providers is to petition the SHCC whenever they have need for an additional machine. This is an unnecessary regulatory burden on both the providers and the SHCC that in the end does not result in any known benefit.

#### Evidence the Change is Consistent With the Basic Principles of the SMFP

Allowing providers to apply for a CON to acquire additional heart-lung machines so they can meet demand for procedures requiring them, provide appropriate safety back-up, or improve the cost effectiveness or efficiency of their operations are all entirely consistent with the principles of safety and quality, access and value.

#### Proposed Text for the Revised SMFP

WakeMed fully supports the adjustment to the wording in the SMFP attached to the Duke petition and is attaching a slightly revised version, updated based on the language in the Proposed 2012 Plan, as an exhibit to this petition. In addition WakeMed believes that the list of bases that applicants may use to justify the need for additional machines should be included, however, the list should not be meant to exclude other bases which are not specifically enumerated.

## EXHIBIT A

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

#### 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 2010, with a total planning inventory of 72 heart-lung bypass machines. Data reported for 2010 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 1996-2010 are shown on the following graph and the reported numbers of procedures for years ending 9/30/96 through 9/30/10 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 an existing open-heart provider did wish to expand, it would need a CON to add any operating rooms to accommodate an expanded program. New programs would still be prohibited from developing open-heart programs unless they petitioned to have a need recognized in the SMFP.

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.~~