

NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL

PETITION

FOR CHANGE IN HEART-LUNG BYPASS EQUIPMENT METHDOLODGY

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

Petitioner:

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Statement of the Requested Change:

Duke requests that the need methodologies for open heart surgery services and heart-lung bypass equipment be modified as set forth in Exhibit A, to allow for determinations of need for bypass equipment based on the utilization of such equipment for all procedures including both those defined as open-heart and other procedures.

Reasons for the Proposed Change:

The Certificate of Need statute defines heart-lung bypass machines as “the equipment used to perform extracorporeal circulation and oxygenation during surgical procedures” (N.C.G.S. § 131E-176 (10a)), and not just open-heart surgery procedures. In fact, due to advances in treatment technology and methods, heart-lung bypass equipment is used increasingly for non-open heart procedures (as those procedures are currently defined by CON Criteria and Standards, limited to certain DRGs). Duke’s own experience is that non-open heart procedures and standby cases constitute a significant percentage of the procedures in which heart-lung bypass equipment is needed.

The development of open-heart surgery services and the acquisition of a heart-lung bypass machine are separately listed as new institutional health services in the CON Law. There is no reason they cannot be therefore treated separately in the Plan and the CON Section’s Criteria and Standards. However, the current methodology in the Plan calculates the existing utilization of, and future need for, heart-lung bypass machines based solely on the number of open-heart procedures, and does not reflect the time that the equipment is actually in use or required on standby for other kinds of procedures. Amending the methodology to take into account all kinds of procedures for which the equipment is used would permit and facilitate the acquisition of equipment necessary to support all the procedures in progress at any one time as well as to ensure necessary reserves are kept available at all times.

Duke currently has 7 heart-lung bypass machines, including one recently acquired for pediatric procedures. The number of procedures at Duke Hospital that require the use or availability of a perfusionist and a heart-lung machine has increased significantly over time:

Fiscal Year	Perfusion Cases	Standby Cases	Total Cases
2007	1508	166	1674
2008	1652	165	1817
2009	1895	167	2062
2010	1607	198	1805

(Standby cases are those in which the equipment must be staffed and available in the event that bypass is needed during the procedure.) The procedures requiring the use (or standby availability) of a perfusionist and a heart-lung machine last an average of 6 to 7 hours each:

Fiscal Year	Perfusion Cases	Perfusion Time	Time / Case
2007	1508	611,629	406 minutes
2008	1652	688,306	417 minutes
2009	1895	742,808	392 minutes

During FY2009, Duke's 6 available machines¹ were in use or required on standby (where they cannot be used for any other purpose) an average of 8.8 hours per surgical day. (The daily average was derived by multiplying the total cases by the average minutes per case to obtain the total minutes for all machines, and then dividing that total by 6 machines, by 60 minutes/hour, and by the 255 days/year that surgery is scheduled.)

Over the past several years, approximately 50-60% of procedures provided at Duke University Hospital that require the use or availability of a perfusionist and a heart-lung machine

¹ Duke has since acquired a seventh machine dedicated to neonatal and pediatric cases.

are traditional open-heart surgery procedures as defined in the Hospital License Renewal Application, including both adult and pediatric patients:

Fiscal Year	Total Cases	OHS Cases	OHS as % of total perfusion cases
2007	1674	981	58.6%
2008	1817	945	52.0%
2009	2062	1089	52.8%
2010	1805	1089	60.3%

The remainder are cases that do not fall into the regulatory definition of open-heart procedures and would therefore not be reflected in the current need determination. Non open-heart cases in which bypass equipment is used include such procedures as organ transplants, trauma resuscitations, tumor cases such as nephrectomies, and hyperthermic isolated limb perfusion cases, in which bypass equipment is used by surgical oncologists during removal of extremity tumors. In addition, Duke routinely needs bypass equipment on standby for certain closed-heart valve replacements, stent repairs, high-risk obstetric cases, and convergence procedures. When the equipment is staffed and needed on standby for such procedures, it is not available for other use, including for open-heart procedures.

Therefore, at Duke University Hospital at least, the number of open-heart surgery procedures alone no longer represents the actual utilization and availability of the equipment for additional procedures. The use of heart-lung bypass machines to support procedures other than open-heart surgery procedures should not be constrained by a Plan methodology that assumes that heart-lung bypass machines are used only to support open-heart surgery procedures.

Accordingly, Duke proposes amending the need methodology for heart-lung bypass machines to allow utilization to be measured either in the number of open-heart surgery procedures or in the minutes of use per year (where the machine is in use or staffed and available on standby). Capacity would be defined as either 400 open-heart surgery procedures per machine per year or 72,000 minutes (1200 hours) of use per machine per year. That change could be implemented by amending the need methodology for heart-lung bypass machines as set forth in Exhibit A.

This proposed change would not otherwise affect the need methodology for the development of open-heart surgery services, which are a separate category of new institutional health services under the CON Law.

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 are 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 an emergency.

Alternatives considered:

Policy AC-6 recognizes that there is a need for backup heart-lung machines to ensure clinical safety. Duke considered a proposed modification that would address the need through changes to this Policy. However, the fundamental problem is in the methodology itself, which is outdated because it relies solely on open-heart procedures to calculate utilization of the equipment. A change through Policy AC-6 alone would not provide a complete remedy.

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

The proposed revision still requires appropriate utilization of existing equipment in the service area before need for additional equipment is found. It simply acknowledges that the equipment may be utilized for non-open heart surgery procedures and therefore the provider may have reached the machine's capacity, as described in Duke's own experience. As a result, the proposed change would not result in unnecessary duplication of health resources in the area and simply ensures that such resources are in fact available for all the procedures in which they are needed.

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

As set forth above, heart-lung equipment is increasingly used for non-open heart procedures. The requested change will allow facilities to respond to the need for such procedures while continuing to have appropriate equipment available for open-heart surgical procedures as well. In reflecting current uses of this equipment beyond traditional open-heart

procedures, the proposed change 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):

1) **Open Heart Surgery Services and Heart-Lung Bypass Machine Need Determination (at page 101 of 2011 Plan)**

~~The capacity of a heart lung bypass machine has been defined as 400 adult equivalent open heart surgical procedures per year.~~ The capacity of a heart-lung machine is defined as either:

- 72,000 minutes per year during which the machine is either in use or staffed to be available on standby or
- 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 open-heart 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.1 displays 2010 heart-lung bypass machine capacity and utilization measured in adult equivalent procedures, and the following Table 7B.2 displays 2010 heart-lung bypass machine capacity and utilization measured in minutes, as reported on the 2011 Hospital License Renewal Applications on file with the Division of Health Service Regulation.

2) **Heart-Lung Bypass Machine Need Determination Methodology (at page 103 of 2011 Plan)**

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 or the number of minutes in use or staffed to be available on standby reported in the 2011 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 201 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.)*