

Acute Care Services Committee
Agency Report for Petitions Regarding
Heart-Lung Bypass Equipment
in the Proposed 2012 State Medical Facilities Plan

Petitioners:

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Request:

Duke requests that the need methodology for heart-lung bypass equipment be eliminated from the North Carolina 2012 State Medical Facilities Plan (SMFP or “Plan”). If removal of the methodology is not approved, Duke asks for an adjusted need determination for three additional heart-lung bypass machines in the Durham County service area.. The WakeMed petition also requests removing the heart-lung bypass machine need determination methodology from the 2012 Plan. Because of the similarities between the two petitions, this report will cover both petitions.

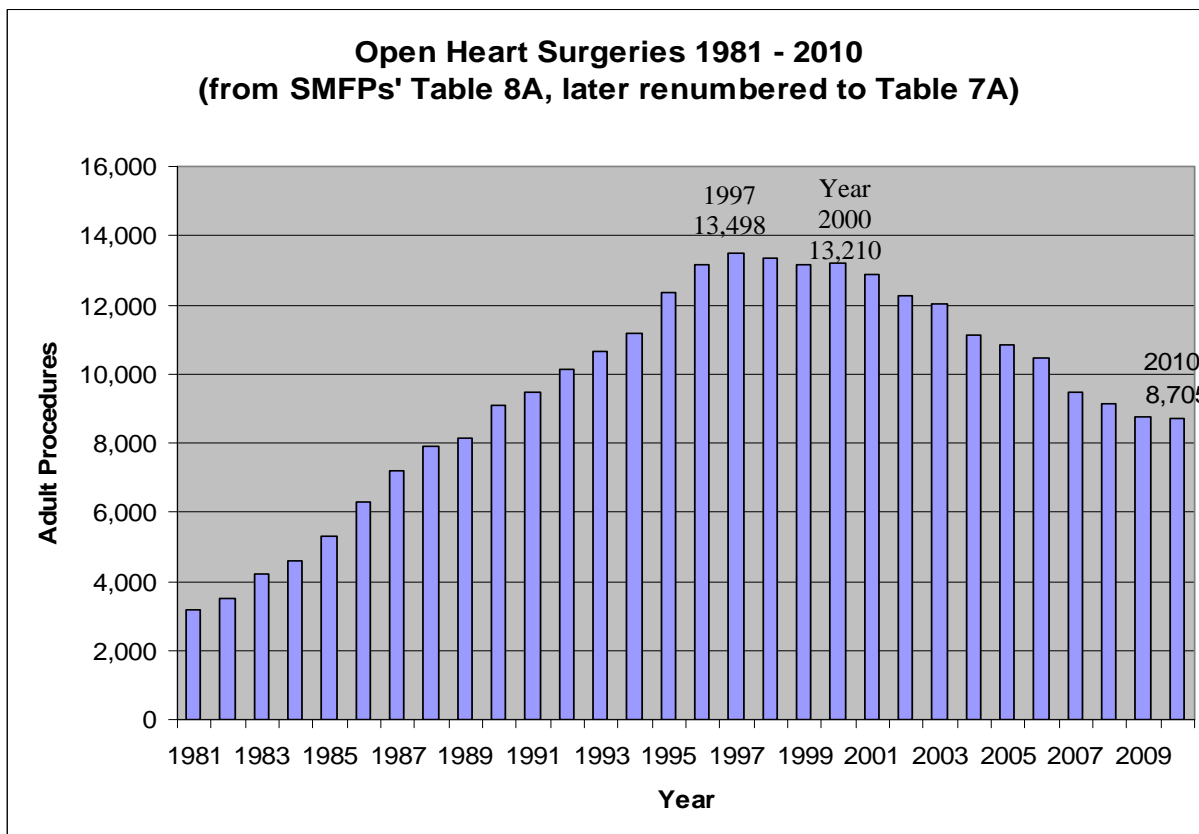
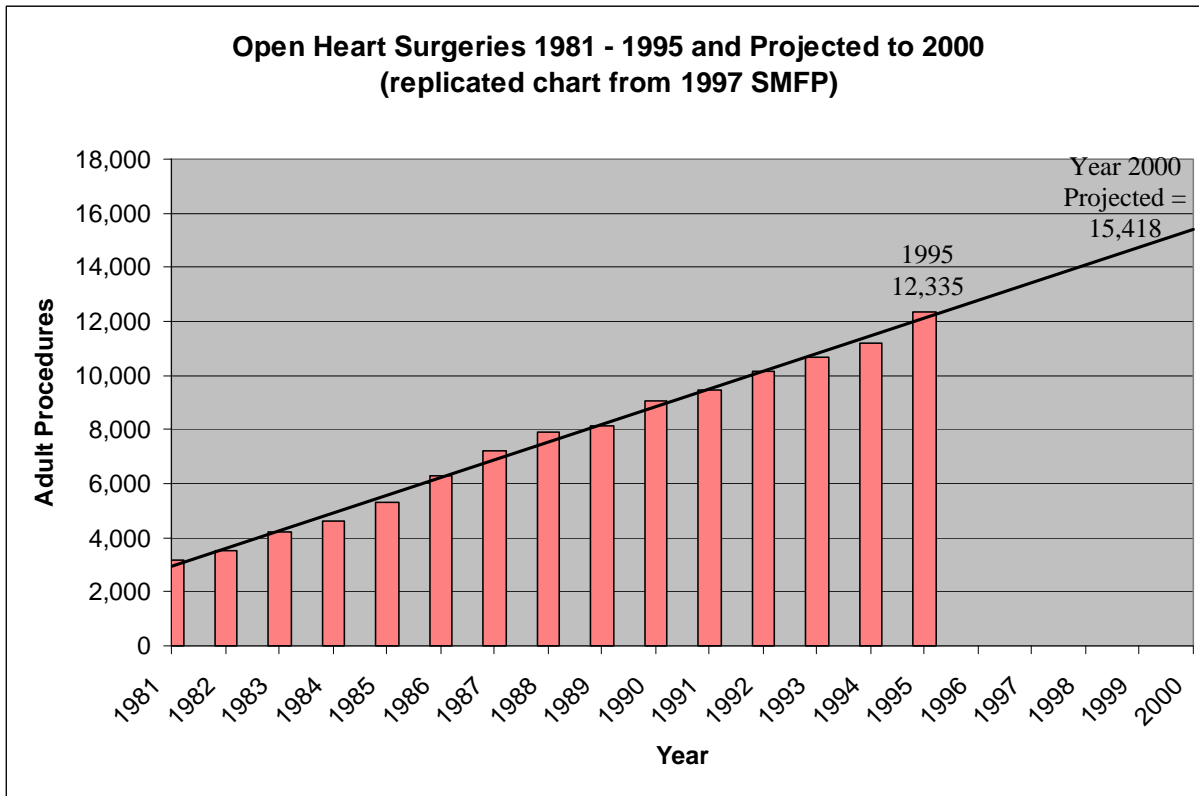
Background Information:

In March 1993, the Certificate of Need statute (G.S 131E-175) was amended to require additional equipment and health care services to be covered by the statute. As explained in the 1994 SMFP, “[the North Carolina] General Assembly in responding to concerns regarding the proliferation of high-cost services and equipment, listed specific items which are subject to certificate of need review. These include the following five services: 1) bone marrow transplantation; 2) burn intensive care; 3) neonatal intensive care; 4) open-heart surgery; and 5) solid organ transplantation. In addition the following eight types of equipment are covered: 1) air ambulances; 2) cardiac angioplasty; 3) cardiac catheterization; 4) gamma knives; 5) heart-lung by-pass machines; 6) lithotriptors; 7) magnetic resonance imaging scanners; and 8) positron emission tomography scanners” (page 62).

The North Carolina 1993 State Medical Facilities Plan was the first SMFP to contain inventories and need projections for “high technology programs” (page 69) in a new chapter dedicated to technology. The 1993 and 1994 SMFPs both included open-heart operating room capacity and volumes for North Carolina hospitals. The 1993 SMFP listed the 16 North Carolina hospitals that provided open-heart surgery procedures in 1991, along with the number of open heart surgery rooms (42) and their capacity, assuming 400 procedures a year per operating room. The 1993 Plan noted that certificates of need were awarded in early 1992 for four new open heart surgery rooms at four hospitals, and that there was no need for additional open heart operating rooms in the 1993 Plan.

The 1994 SMFP contained significant information about technology services and continued listing North Carolina hospitals providing open heart surgery, as well as open-heart surgery room capacity and volumes. The 1995 Plan, for the first time, provided an inventory of 74 heart-lung bypass machines at the 20 North Carolina hospitals with open-heart surgery programs at the time. The 1995, 1996 and 1997 Plans included a graph showing the growth in open-heart surgeries from 1981 through the Plan’s data and projecting the number of open-heart surgical procedures into the year 2000.

As shown below, the expected growth in adult open-heart surgeries was not realized. Instead, there has been a steady decline in the number of adult open-heart surgeries since 2000.



Starting with the 1998 SMFP, Table 8B, which includes adult and pediatric weighted procedures, changed from a focus on open heart surgery rooms to heart-lung bypass machines. The table continues to report heart-lung bypass machine inventory, capacity (400 procedures per machine, per year), procedures performed and machine utilization. Twenty North Carolina hospitals had open heart surgery programs in 1996 as reported in the 1998 Plan. In the 14 years since that Plan, the number of programs has changed to 22, but the number of open-heart surgeries has decreased substantially. As shown in the 2012 SMFP, 73 heart-lung bypass machines are operating in 22 hospitals with seven backup machines, reporting 9,861 procedures and a statewide utilization rate of 34.2 percent for 2010.

Analysis/Implications:

As pointed out by petitioners, the impetus for a need determination methodology for heart-lung bypass machines in North Carolina was the expected continuing increase in open-heart surgeries and concurrent growth in hospital open-heart surgery programs, and the perceived direct link between open-heart surgery and heart-lung bypass machines. In 2000 and in prior years, limiting availability of heart-lung bypass machines was the primary method for controlling unnecessary growth in open-heart surgery programs. Now, uses of heart-lung bypass machines have expanded to where they are utilized during numerous types of procedures in addition to open-heart surgery. Maintaining a need determination methodology in the SMFP for heart-lung bypass machines continues to limit access to machines; however, the perceived one-to-one connection to open-heart surgical procedures is diminishing as the machines are needed for other procedures. Mechanisms other than heart-lung bypass machines exist to regulate growth of open-heart surgery programs, such as existing certificate of need rules concerning operating rooms. Furthermore, as indicated above, the number of adult open-heart surgeries is declining, thereby reducing the need for new open-heart surgery programs.

In lieu of changing the methodology to include machine utilization for non-open heart surgery procedures, the suggestion is to remove the need determination methodology for heart-lung bypass machines. Even with no need determination methodology in the SMFP, providers would still be required to apply for and obtain a certificate of need in order to acquire a heart-lung bypass machine, because the statute includes the machines on the list of equipment requiring a certificate of need (Sec. 131E-176 (16)f 1.5). There is precedent in that other equipment on the list, such as air ambulances, requires a certificate of need, and methodologies for projecting need are not included in the SMFP.

Agency Recommendation:

The Agency is in agreement with concepts brought forth in the two petitions. The Agency recommends approval of the part of the Duke petition and the WakeMed petition seeking to remove the need determination methodology for heart-lung bypass machines from the SMFP, but recommends denial of the portion of the Duke petition requesting an adjusted need determination for three additional heart-lung bypass machines in the Durham County service area. If this recommendation is approved, the Agency recommends the following language (found in the attached document) for the North Carolina 2012 State Medical Facilities Plan.

CHAPTER 7

OTHER ACUTE CARE SERVICES

Summary of Service Supply and Utilization

During FY 2009-2010, 22 hospitals ~~provided~~ offered open heart surgery services, providing a statewide total of 8,705 surgeries, a decline of 1% since the previous fiscal year. ~~The reported data indicate a statewide average annual utilization rate of 34.2 percent for the 72 heart lung bypass machines in the total planning inventory (excluding emergency backup machines).~~

There are two Burn Intensive Care Services located in North Carolina with a total of 29 Burn Intensive Care Unit beds. The reported days of care indicated an overall average annual occupancy rate of 91.7 percent in FY 2009-2010.

There are five hospitals approved to offer both Allogeneic and Autologous Bone Marrow Transplants, plus one hospital approved to offer only Autologous Bone Marrow Transplants. These facilities reported a total of 593 transplants performed during FY 2009-2010.

The Solid Organ Transplantation Services located at the five Academic Medical Center Teaching Hospitals reported a total of 1,060 transplants performed during FY 2009-2010.

Changes from the Previous Plan

One substantive change in the Burn Intensive Care Services Methodology has been recommended for incorporation into the North Carolina Proposed 2012 State Medical Facilities Plan. After many years of service, the existing Burn Intensive Care Services Units have reached the threshold for additional need (i.e., reported statewide utilization in excess of 80% for two fiscal years, prior to development of the North Carolina Proposed 2012 State Medical Facilities Plan). The recommended change is the addition of steps to the methodology indicating how many additional burn intensive care beds are needed. Alternatives are presented for public review and comment, based on the number of years for projection of future need (one, two, three or four years beyond the most current data). Details, including projections utilizing the four proposed “Alternatives,” can be found in the “Burn Intensive Care Services Need Determination Methodology” section of this chapter.

A second change in the North Carolina 2012 State Medical Facilities Plan is the elimination of the need determination methodology for heart-lung bypass equipment. The absence of need determinations in the State Medical Facilities Plan will allow providers 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.

Throughout the chapter, data have been revised to reflect services provided during FY 2009-2010, and dates have been advanced by one year, where appropriate.

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, providing a statewide total of 8,705 surgeries. The reported number of open-heart surgeries has declined significantly for the past 13 years, dropping 55% from the highest report of 13,498 surgeries in 1997. ~~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 34.2 percent, a slight increase from the previous year’s utilization at 34.0 percent of capacity, based on weighted totals which include pediatric cases. 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.~~ The following graph and Table 7A show reported numbers for 1996-2010 of adult open-heart surgery, performed using heart-lung bypass machines.

[\(Insert Graph and Table 7A Adult Open Heart Surgery Procedures\)](#)

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 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 for pediatric patients is valued at two adult equivalent open heart surgical procedures.~~

~~The following Table 7B displays 2010 heart lung bypass machine capacity and utilization, including pediatric surgical procedures, as reported on 2011 Hospital License Renewal Applications on file with the Division of Health Service Regulation.~~

[\(Insert Table 7B\)](#)

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

Prior to the North Carolina 2012 State Medical Facilities Plan, a section about heart-lung bypass machines need determination methodology and its results for the year followed open-heart surgery services. 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.

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 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 2011 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.~~

(This ends the portion of Chapter Seven dealing with heart-lung bypass equipment.)