

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

Petitioner:

Duke University Health System
d/b/a Duke University Hospital
2301 Erwin Road
Box 3708 DUMC
Durham NC 27710
Catharine W. Cummer, Strategic and Regulatory Planning

Request:

As stated by the petitioner, “Duke requests that the need methodologies for open heart surgery services and heart-lung bypass equipment be modified... 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.”

Background Information:

Inventory and utilization information about open heart surgery appeared first in the 1993 North Carolina State Medical Facilities Plan (SMFP). Need was determined on a statewide basis, and calculated by multiplying the number of open heart surgery operating rooms times the capacity of 400 procedures per operating room. Next, the total number of procedures performed, with pediatric procedures being counted as two adult procedures, were summed. The difference between capacity and utilization indicated the need for new open heart surgery services. Starting with the 1996 SMFP, the number of heart-lung bypass machines instead of open heart surgery operating rooms began to be used in need determination calculations, along with the number of adult and pediatric procedures performed.

Currently, need for heart-lung bypass machines “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* (emphasis added) 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” (2011 SMFP, page 103).

As described in Section 131E-176 of the Certificate of Need statute, “Heart-lung bypass machine’ means the equipment used to perform extra-corporeal circulation and oxygenation during surgical procedures” (paragraph 10a). Uses for heart-lung bypass machines extend beyond open-heart surgery procedures.

Analysis/Implications:

Given that open-heart bypass machines are used for numerous purposes, the petitioner requests that the methodology include non-open heart surgical procedures. For Duke Hospital, “[n]on 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.” With a state inventory of 73 heart-lung bypass machines at 22 programs across the state, other facilities are likely to be experiencing higher utilization than is being captured on current data collection instruments.

Agency Recommendation:

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 Agency recommends that a workgroup be formed to develop recommendations regarding what additional utilization data should be incorporated into the need determination methodology for heart-lung bypass machines.