

DUKE UNIVERSITY HOSPITAL'S PUBLIC HEARING COMMENTS
IN SUPPORT OF PETITION REGARDING HEART-LUNG BYPASS EQUIPMENT

Presented by Catharine W. Cummer
Regulatory Counsel, Strategic Planning
Duke University Health System
3100 Tower Blvd.
Box 3229
Durham, NC 27707
(919) 668-0857
catharine.cummer@duke.edu

DFS Health Planning
RECEIVED

AUG 01 2011

Medical Facilities
PLANNING SECTION

Duke University Hospital is the largest provider of open heart surgery services in the state. Duke's surgeons also, however, use its bypass machines for procedures that are not reported in the Plan as open heart 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, and high risk obstetric procedures. Because these procedures are not counted in the existing methodology, Duke's machines do not appear in the Plan to be utilized as fully as they are in practice, and no need appears in the draft Plan pursuant to which Duke could apply for additional machines.

Duke previously petitioned the SHCC for a change in methodology to allow utilization of equipment to reflect time in use, rather than simply the number of open-heart procedures. No negative comments were made against this petition. The Agency Report on this petition agreed that a genuine need was identified, but concluded that because other providers were not currently required to report the time in use of their machines, it would not be possible to implement the proposed methodology until additional data were collected.

At the Acute Care Committee meeting at which this petition was discussed, various members expressed interest in updating the Plan's regulation of bypass machines and receiving comments about this issue. Accordingly, Duke has made a further submission this summer that includes 1) comments in response to the Agency's report with a proposal on how to deal with the need methodology for heart-lung bypass equipment; and 2) a petition for a special need determination in Durham County in the event the SHCC does not pursue the proposed change in methodology.

Duke's primary proposal is to eliminate the need methodology and determination solely for heart-lung bypass equipment from the Plan.

What would stay the same as a result of this proposal:

1. No change to SHCC's regulation of open-heart surgery services

This petition would have no effect on the need determination for new open-heart surgery services. Open-heart surgery and heart-lung bypass machines are two separate new institutional health services under the CON Law. The current Plan language lists open-heart surgery volumes on the Bar Graph in Chapter 7, and Table 7A, which lists "open-heart surgery procedures." We would note that where Table 7A also refers to "procedures utilizing heart-lung bypass machines," that is somewhat misleading. Open-heart surgery procedures are only a subset of the procedures using bypass equipment, and include only specific DRG codes identified by regulation. Those specified open-heart surgery volumes would continue to be reported, and the SHCC could continue to use them in the same way to evaluate the need for additional surgery providers, although we would recommend that the table headings be modified to be more precise about the procedures they reflect.

2. Providers must still apply for a CON for new bypass equipment

The statutory requirement for a CON for bypass equipment would remain unchanged. The CON Section would evaluate applications against its regulations, as it currently does with simulators, diagnostic centers, endoscopy rooms, neonatal intensive care services, major medical equipment and any other new institutional health services on which the Plan is silent. In each case, an applicant files an application which is judged against applicable regulations, but which is not limited by a need determination in the Plan.

What would change:

There would no longer be a need determination each year for bypass equipment. This would preclude the need to amend the Hospital License Renewal Application form, collect additional data, appoint a work group, and develop and adopt a new need methodology reflecting the use of machines for both open-heart and non-open-heart procedures.

Reasons for the Proposed Change

Several factors support the proposed change:

- 1) The existing methodology is fatally flawed. It is built on two assumptions that are no longer true, including both that heart-lung bypass machines are used only to support open-heart procedures, and that the machines can be used for 2 open heart procedures per day. At Duke, at least, cases requiring bypass equipment, which include transplants, for example, last 7 or more hours each on average.
- 2) The existing methodology prevents the finding of need for additional machines, even where they are necessary to provide capacity for emergencies or mechanical backup.

- 3) A facility might also need additional machines to increase efficiency of hospital operations or to reduce costs.
- 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.

Alternative: 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 be modified to find need for 3 additional heart-lung bypass machines in Durham County. Based on time, assuming a capacity of 1800 hours per year, Duke would have needed 8.56 machines in use full time in 2010 just to accommodate the actual time its heart-lung equipment was used or staffed on standby for procedures, without even taking into consideration the need for backup capacity for emergencies. It had 6.25 machines. Duke provided this service on its existing machines only by running them all well in excess of the assumed capacity of an operating room. 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.