PUBLIC COMMENTS REGARDING CHANGES TO CERTIFICATE OF NEED REGULATIONS GOVERNING ACQUISITION OF HEART-LUNG BYPASS EQUIPMENT

Submitted by DUKE UNIVERSITY HEALTH SYSTEM

Duke University Health System, Inc. d/b/a Duke University Hospital ("Duke") hereby submits these comments in support of the proposed changes to the certificate of need regulations governing the acquisition of heart-lung bypass equipment located at 10A NCAC 14C Section .1700 ("Criteria and standards for open-heart surgery services and heart-lung bypass machines").

Changes to performance standards at 10A NCAC 14C .1703

The existing regulation defines the performance standards for the proposed acquisition of new heart-lung bypass machines solely in terms of the number of open heart surgeries the provider projects:

> The applicant shall demonstrate that the proposed project is capable of meeting the following standards:
>
> (1) an applicant's existing and new or additional heart-lung bypass machines shall be utilized at an annual rate of 200 open heart surgical procedures per machine, measured during the twelfth quarter following completion of the project;

10A NCAC 14C .1703.

However, as the practice of medicine continues to advance at Duke and elsewhere, surgeons have come to rely on bypass machines to support not only open-heart surgery but also a wide variety of other kinds of procedures, including:

- Heart and lung transplants
- Trauma resuscitations
- Nephrectomies and other tumor cases
- Closed heart valve replacements
- Stent repairs
- Pacemaker implants
- Convergence procedures to treat atrial fibrillation
- High risk obstetric procedures

None of these procedures fall within the codes which the existing regulations categorize as open-heart surgery cases, and yet they have accounted for more than a third of all the cases in which bypass equipment is used at Duke in recent years:

Fiscal Year	Total Cases	Open-heart surgery ("OHS") Cases	Non OHS Cases	Non OHS as % of Total Perfusion Cases
2007	1,674	981	693	41%
2008	1,817	945	872	48%
2009	2,062	1,089	973	47%
2010	1,828	1,123	705	39%
2011	1695	1015	680	40%
2012	1661	974	687	41%

Therefore, Duke's actual utilization of its bypass equipment is much higher than it appears if only open-heart surgeries are considered. In FY2012, 7 machines provided a total of 818,955 minutes of perfusion, at an average of 493 minutes per case. The average non-OHS procedure lasted 99 minutes longer than the average OHS procedure. Duke's machines were in use an average of more than 7.6 hours per day (assuming a schedule of 255 days of surgery per year). In addition, machines were provided and staffed on "standby" basis for 221 other procedures, which added to the time that they were not available for other procedures. With all its machines used or staffed on standby at close to 8 hours per day or more, utilization of Duke's machines was at 100% of practical capacity in FY 2012. This can create scheduling and operational difficulties in the event of emergencies or equipment maintenance needs.

The proposed changes to the performance standards would enable providers such as Duke to demonstrate need for additional bypass equipment based on their actual utilization of the equipment for <u>all</u> procedures, not just for open-heart procedures. The proposed changes also reflect that the time of procedures can vary greatly, and that time in use or on standby may provide a more accurate reflection of actual utilization than procedure volumes alone.

<u>Other changes to CON regulations regarding bypass equipment.</u>

Duke supports the other proposed changes to the regulations as both providing more clarity to providers on the information to be provided in an application for bypass equipment and better reflecting the current provision of open-heart surgery services and bypass equipment.