

TO: North Carolina State Health Coordinating Council
FROM: W. Stan Taylor *W. STAN TAYLOR*
Vice President, Corporate Planning
DATE: July 27, 2011
SUBJECT: Petition on Heart-Lung Bypass Machines

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WakeMed is submitting a petition to the State Health Coordinating Council supporting the Petition the Council has already received from the Duke University Health System. We believe that an adjustment to the need determination on Heart-Lung Bypass Machines which eliminates any specific need determination will remove a regulatory control that while necessary when implemented, is no longer needed.

Need determinations and policies in the State Medical Facilities Plan (SMFP) and Certificate of Need (CON) regulations, should like all regulatory activities be limited to those necessary and appropriate to accomplish an objective. The original purpose of limiting need determinations for heart-lung machines was to regulate the growth and expansion of open heart surgery programs. This was done at a time when there were fewer programs and unregulated expansion of existing programs would preclude the opportunity for other providers to be approved to develop one. We now have 22 open heart surgery programs in the state and the number of procedures performed in North Carolina has dropped for the tenth straight year. No new programs can develop without the Council putting a need for one in the SMFP, and existing programs cannot add operating rooms without a CON. The limitation on heart-lung machines is therefore not necessary. Even if it were, it is not appropriate to determine the need through a methodology that does not take into account all the uses of the machines.

We believe our petition and the one submitted by Duke make a convincing case for removing this unneeded regulatory requirement. The process will still be able to control expansion of open heart surgery programs. Providers who perform procedures other than open heart surgery, need to provide appropriate backup for all uses, or desire to improve cost-effectiveness or efficiencies will be able to acquire needed equipment.

As we know, both Governor Perdue and the General Assembly have placed a high priority on eliminating unnecessary regulations. We believe the Council can contribute to this effort by making this adjustment in the 2012 SMFP.