

Comments on Proposed Rules Relating to
Certificate of Need Review of Applications
For Heart-Lung Bypass Machines

In the summer of 2011 Duke University Health Service (DUHS) and WakeMed each petitioned the State Health Coordinating Council (SHCC) to eliminate the specific need determination for heart-lung machines and allow applicants to apply for a Certificate of Need (CON) for a machine and document the need for it according to criteria included as proposed language for the State Medical Facilities Plan (SMFP) in both petitions. The DUHS petition also asked that in the alternative an adjusted need determination for heart-lung machines for Durham County be added to the 2012 SMFP.

The SHCC approved both petitions – the WakeMed petition in whole and the portion of the DUHS petition requesting the elimination of a need determination for heart-lung bypass machines.

While both petitions included identical criteria to be used to determine need for new machines, the petitioners had specific interest in different portions of the criteria. DUHS was most interested in the portion allowing applicants to demonstrate that the use of heart-lung machines for procedures other than open heart surgery requires additional machines, while WakeMed was primarily interested in the portion allowing the purchase of new machines by documenting that doing so would lower operational costs of the facility.

Following approval of the petitions by the SHCC, WakeMed and DUHS provided the CON Section a draft of proposed CON rules for review of applications for heart-lung machines. The draft rules conformed to the language of the petitions approved by the SHCC and included all of the criteria included within them.

The proposed rules published in the North Carolina Register on September 4, 2012, make several changes and updates that are not specifically related to the changes made by the SHCC last year, but are generally improvements to rules that have not

been modified in nearly 20 years. However, in the parts of the published proposed rules that do address the changes adopted by the SHCC (10A NCAC 14C .1703) some of the criteria for demonstrating need for new machines included in the petitions are inexplicably left out. Specifically, the following criteria included in the petitions are not reflected in the published proposed rules:

- Demonstration that the operational efficiencies or patient safety can be improved by the addition of one or more machines
- Demonstration that the purchase of new machines would be a cost effective means of lowering operational costs of the facility

Since the approval of the petitions in 2011, WakeMed and Rex Healthcare have negotiated an arrangement with the CON Section that allowed each institution to purchase heart-lung machines that have been used in their respective hospitals but were owned by physician practices. This action did obviate the immediate problem faced by WakeMed which was the primary reason for it submitting the petition. Whether there is another provider currently facing the problem WakeMed and Rex faced is not known.

However, the petitions were not specific to WakeMed and DUHS, and they generated a change in policy that should apply to other providers. The fact that no other providers have indicated a need for these changes does not mean that there are not any who may in the future. If such a provider does exist it would not be able to be approved for a new machine if the proposed rules are not changed to include the criteria contained in the petitions, but left out of the rules.

It is important for the integrity of the process for the rules to reflect the policy changes specifically approved. These changes should not be dependent upon another provider expressing a need for them, but because the changes were approved through the process that has been established for making them. Reflecting all the actual changes in the rules is simply the right thing to do.

Attached is a copy of the WakeMed petition to the SHCC including Exhibit A which was a part of both the WakeMed and DUHS petitions, and a copy of the proposed CON rules jointly submitted to the CON Section by WakeMed and DUHS.