

**Technology and Equipment Committee
Agency Report
Change in Rules for
Cardiac Catheterization Equipment for the
Proposed 2013 State Medical Facilities Plan**

Petitioner:

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Request:

A petition was filed by Johnston Health requesting “the State Health Coordinating Council to create language in the 2013 State Medical Facilities Plan to enable a change in the Certificate of Need rules that would allow for the provision of interventional cardiac catheterization services in Johnston County.”

Background Information:

The Proposed 2013 State Medical Facilities Plan (SMFP) contains policies and methodologies used in determining need for new health care facilities and services in North Carolina. The purpose of the SMFP is to make an overall need assessment with the primary objective to provide individuals, institutions, state and local government agencies and community leadership with policies and projections of need to guide local planning for specific health care facilities. With regards to cardiac catheterization, the Proposed 2013 SMFP provides two standard need determination methodologies for cardiac catheterization equipment. Methodology One is the standard methodology for determining need for additional fixed cardiac catheterization equipment and Methodology Two is the need determination methodology for shared fixed cardiac catheterization equipment for service areas in which a unit of fixed cardiac catheterization equipment is not located.

Chapter Two of the Proposed 2013 SMFP explains that “Anyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections.” The Proposed 2013 SMFP further states that

petitions regarding basic policies and methodologies will be considered in the first four months of the calendar year. In deference to the standard methodology, the Proposed 2013 SMFP allows persons to petition for an adjusted need determination in consideration of "...unique or special attributes of a particular geographic area or institution..." if they believe their needs are not appropriately addressed by the standard methodology.

Analysis/Implications:

Johnston Health acquired a fixed cardiac catheterization laboratory through a 2001 Certificate of Need (CON) based upon an identified need for cardiac catheterization services. In accordance with G.S. 131E-183(b) and 150B, Article 2A, the CON Section adopts by rule criteria to be used in the review of CON applications for specific services and equipment to include performance standards and support services standards. Within the CON regulations for cardiac catheterization, 10A NCAC 14C .1604(a) states the following: "If the applicant proposes to perform therapeutic cardiac catheterization procedures, the applicant shall demonstrate that open heart surgery services are provided within the same facility." Cardiac catheterization laboratories that were in service prior to the implementation of the regulation are considered "grandfathered" and thus not subject to the CON regulation. Thus, a provider's ability to provide interventional cardiac catheterization services is based upon the timing of its acquisition of the equipment.

Johnston Health pointed out in their petition that in the summer of 2011 during petition review, the Technology and Equipment Committee discussed the "inconsistency of a situation that would allow a hospital with two identical, side-by-side cardiac cath labs to have to determine which patients could be treated in which lab based on when the equipment was first acquired". However, no petitions were filed and no work group was developed to study the cardiac catheterization methodology. Johnston Health has now petitioned to include language in the 2013 SMFP as follows: "It is further determined that fixed cardiac catheterization equipment shall not be limited to diagnostic procedures only." The desired outcome is to have this language enable the CON Section to change the rules.

The State Health Coordinating Council (SHCC) is charged with the duty to direct the development of the annual SMFP, which prescribes the policies and methodologies used in determining need for new health care facilities and services in North Carolina. The SMFP does not address the conditions of the Certificate of Need nor is it within the purview of the SHCC to change CON rules. The request in this petition exceeds the authority of the SHCC.

Agency Recommendation:

The petitioner is not requesting any changes to the policies or to the cardiac catheterization methodologies. This petition requests changes in the support services regulations in the CON administrative regulations. The appropriate mechanism for recommending changes in administrative rules is to submit a petition to the Director of the Division of Health Service Regulation in accordance with 10A NCAC 14A .0101. Given available information and comments submitted by the 8/17/12 deadline, and in consideration of factors discussed above the Agency recommends denial of the petition.

