

**Technology and Equipment Committee
Agency Report
Petition Related to Adding Clarifying Language to the
Fixed Cardiac Catherization Methodology for the
Proposed 2015 State Medical Facilities Plan**

Petitioner:

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Request:

The petitioner requests “to create language in the 2015 State Medical Facilities Plan that would clarify that fixed cardiac-catherization equipment at hospitals should be able to perform both diagnostic and interventional procedures.”

Background Information:

Chapter 2 of the State Medical Facilities Plan (SMFP) describes the purpose and process for submitting petitions to amend the SMFP during its development. Petitions may be sent to the Medical Facilities Planning Branch twice during the course of plan development. Early in the planning year petitions related to basic SMFP policies and methodologies that have a statewide impact may be submitted. The SMFP defines changes with the potential for a statewide impact as “*the addition, deletion, and revision of policies and revision of the projection methodologies.*” The review requested by this petitioner could affect a methodology and/or policies in the SMFP and should be considered before publication of the Proposed 2015 SMFP. This petition would have a statewide impact.

Later in the planning cycle when need projections are identified in the Proposed SMFP, petitions may be submitted seeking adjustments to the projected need determination in any service area if the petitioner believes the needs of a service area are not fully addressed by the standard methodology.

The Proposed 2015 State Medical Facilities Plan (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.

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 the 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. Consequently, a provider’s ability to provide interventional cardiac catheterization services is based upon the timing of its acquisition of the equipment.

In August 2012, Johnston Health petitioned the State Health Coordinating Council (SHCC) 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.” The petition was denied since the requested change would have impacted CON administrative rules and was beyond the purview of the SHCC. However, the SHCC suggested that Johnston Health work with the CON Section of the Division of Health Service Regulation to resolve the issue.

Analysis/Implications:

The CON Section has begun the process of petitioning for a change in the administrative rules related to this subject and continues to work with Johnston Health and other stakeholders in North Carolina to achieve consensus on the content of the petition.

Given that the issues raised are related to administrative rules that are beyond the purview of the SHCC, adding language to the cardiac catheterization methodology would not allow a facility still subject to 10A NCAC 14C .1604(a) to perform both diagnostic and interventional procedures if that facility does not provide open heart surgery on site. The SHCC has not historically taken positions on issues, such as the one raised by petitioner, that are beyond the SHCC’s scope of authority.

Agency Recommendation:

Given available information and comments submitted by the March 5, 2014 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the agency recommends denial of the petition. The proposed change would not impact the CON rule at issue and is beyond the purview of the SHCC.