

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

Petitioner:

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Request:

The petitioner requests changes to steps 5 and 6 of the Cardiac Catheterization Methodology One so that “the threshold for additional cardiac catheterization equipment be applied to each hospital, or in the case of hospitals under common ownership in the same service area, to each group of hospitals.” The change would also generate a need determination any time a facility exceeds the 80% utilization threshold without regard to the utilization of other facilities in the service area. Additionally, the petitioner requests the addition of new language to the methodology regarding qualified applicants for certificates of need for cardiac catheterization equipment.

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. The petition’s requested change 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. The petition requests a change to Methodology One.

Analysis/Implications:

The proposed change would have a far-reaching negative impact and would result in an over-projection of need over time in multiple avenues. Firstly, the petitioner did not take into account the effect of this proposed change on the process of assigning Certificate of Need (CON) placeholders. While the petitioner's proposed methodology change did not make specific changes to Step 1 of the methodology, the proposal would have an impact on pending CONS. Step 1 calculates the total number of machines for the service area. This includes existing machines currently in operation, those that have been awarded a CON but are under development, and those for which no CON has been awarded, but are pending. Under the suggested methodology change it would be possible for a need determination to be generated without regard to a pending CON review. Secondly, there is the potential for one facility in a service area to generate a need but the CON is awarded to a different facility in the service area. Thus, additional need determinations for the service area could again be generated the next year due to the procedures performed at the facility that initially generated the need. This would increase the service area's capacity unnecessarily but would not benefit the facility that triggered the need. Seven service areas in the state have multiple cardiac catheterization service providers that could create this scenario.

The petition indicates a facility specific approach is used in the need determination calculations in acute care beds and for PET scanners. It is true that a facility specific calculation is used for acute care bed needs. However, in determining need for acute care beds (both licensed and pending) all projected deficits and surpluses for each facility are totaled for the service area and can offset each other. The PET methodology does use a facility specific calculation and does not calculate a total for the service area. It too, would be subject to the aforementioned calculation issues with pending CONs. However, this hasn't been a significant issue since many of the facilities have much lower utilization rates and could be considered underutilized.

The petition sets an annual threshold of 0.1 above the current 1200 procedure capacity for one facility in order to generate a need. Thus, any facility which performs 120 more procedures (weighted) more than the 1200 capacity, it would generate a need. This standard could potentially be sensitive to changes in the data.

The petition suggests altering the rounding in step 5. In this scenario need is generated at a considerably lower threshold than with the current methodology. Presently, facilities within a service area would need to collectively reach the 80% utilization threshold (1,200 procedures) plus .5% (600 additional procedures) to generate a need determination. This is 300 procedures above the maximum capacity of a cardiac catheterization unit. In the proposed methodology, only one facility would need to reach a much lower threshold of 1,320 procedures- 180 below the maximum capacity- in order to generate a need determination. Generating a need determination using this standard rather than the higher threshold currently employed could result in over-capacity in a service area. The total volume of cardiac catheterization procedures

performed with fixed equipment in North Carolina has declined steadily since 2005, as shown in Table 1 below. Consequently, only three need determinations have been generated under Methodology One for new equipment in the last five years.

Table 1: Procedures Using Fixed Cardiac Catheterization Equipment by Year

| Year | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
|------------|--------|--------|--------|--------|--------|--------|--------|--------|
| Procedures | 80,305 | 69,589 | 65,335 | 68,182 | 64,847 | 63,138 | 62,519 | 60,836 |

Applying the proposed methodology to data drawn from the 2014 SMFP (the most recent dataset available) generates need determinations in two service areas, as shown in Table 2 below. Last year, the one and only need determination for cardiac catheterization equipment was removed from the 2014 SMFP. The only provider in the service area, New Hanover Regional Medical Center, petitioned the State Health Coordinating Council to have the need determination removed, stating that it was unnecessary. Lowering the threshold by 780 procedures when these procedures are on the decline would result in an over-projection of need.

Table 2: Need Determinations Using the Proposed Methodology

| Service Area | Cardiac Caths Needed |
|--------------|----------------------|
| Cumberland | 1 |
| New Hanover | 1 |

The petition also requests that hospitals under common ownership in the same service area be combined and that language be added to the methodology defining qualified applicants for cardiac catheterization equipment. Given the previously addressed problems with the proposed changes to the methodology and the fact that the current methodology defines need by service area rather than by facility, combining data from hospitals under common ownership would have no impact on the current methodology. Additionally, in order to generate a need determination any given service area would have to reach a threshold of at least 1,800 procedures under the current methodology, well above the petitioner’s suggested minimum of 1,200 procedures.

Given the decline in cardiac catheterization procedures, the Agency believes adding the suggested language is unnecessary and would potentially over-project the need.

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 result in unnecessary duplication of services given the construction of the proposed changes and the current utilization patterns for cardiac catheterization equipment in North Carolina. The Agency supports the standard methodology for fixed cardiac catheterization equipment.