

**Technology and Equipment
Committee Meeting**

**Petition from Daniel Carter,
Health Planning Source**

April 29, 2009



PETITION

TO: NORTH CAROLINA DIVISION OF HEALTH SERVICE
REGULATION
MEDICAL FACILITIES PLANNING SECTION
2714 MAIL SERVICE CENTER
RALEIGH, NC 27699-2714

PETITIONER: DANIEL CARTER
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SUBJECT: SMFP TECHNOLOGY METHODOLOGIES

DATE: MARCH 4, 2009

REQUESTED CHANGE

This Petition respectfully requests the inclusion of clarifying language in the SMFP relative to its impact and use in the subsequent development of performance standards for the technology methodologies. As discussed in detail below, performance standards in the regulatory criteria (“rules”) find their origin in the utilization standards developed by the SHCC in the SMFP. This Petition will demonstrate that while such a method is warranted for those services utilizing projected need methodologies, such a method is counterintuitive and impractical for those services utilizing historical need methodologies.

The requested clarifying language would directly address the disconnect between the SMFP technology methodologies and the required performance standards in the rules by permitting the SHCC to establish target utilization recommendations for applicants that could be different from the historical utilization required to generate need determinations. Given that the current rules mirror the language in the SMFP need

methodology, the inclusion of such clarifying language and accompanying recommendations would enable the Certificate of Need Section to update the rules to reflect the SHCC's recommendations, which while they may differ from the historical utilization which generated the need, will address the impracticality of using the SMFP technology methodologies to dictate the required performance standards in the rules.

REASONS FOR THE REQUESTED CHANGE

Over the past several months, we (HPS) have reviewed the various methodologies in the SMFP to discover both similarities and differences to help us assess how differences in the methodologies translate into different standards in the rules. The current methodologies in the SMFP, while different for each service, fall into two primary categories: projected need and historical need. The projected need methodologies take historical utilization, project it forward based on the methodology's assumptions, then compare the projected future need with the current capacity to assess any additional capacity that may be needed. Two examples are the acute care bed and operating room methodologies. While the respective methodologies differ considerably, both take historical utilization and project it forward to calculate the need for those services in the future. The second category of methodology is based on historical need. Unlike the projected need methodologies, these methodologies do not project future need; rather, they base the need determination on a threshold that has been met historically. For example, the MRI methodology examines the average historical utilization in a given service area (using weighted procedures); once a service area has hit the target utilization, a need for an additional MRI scanner is generated. In the historical need methodologies, no consideration is given for the projected utilization of the additional unit of equipment, and therefore no utilization is projected for those units in the future.

The different approach used by these two primary types of methodologies is certainly warranted, given the evolution of the methodologies over the past several years and the considerable differences among the services represented. The different approaches have a substantial impact on the rules for each service, however, which is the focus of this discussion. For the projected methodologies, specifically acute care beds and operating rooms, the performance standards in the rules, particularly the required projected utilization, mirror the methodology and the projected need. For example, the operating room rules require an applicant to project future utilization that corresponds with the SMFP-projected need. Thus, an SMFP need determination in a county with fewer than five operating rooms that resulted in a need determination based on a projected deficit of 0.2 operating rooms corresponds with a requirement in the CON rules than an applicant project utilization of a minimum of 0.2 operating rooms. Because the methodology contemplates future need based on projected utilization, the CON rules can reasonably require applicants to also meet that future need.

For the historical need methodologies, however, the SMFP does not contemplate the future volume of the service, but only looks at the historical volume generated by the service. As a result, the performance standards in the rules are based on the historical

volume thresholds, but require applicants to project this volume in the future for the proposed service. While this situation has existed for some time, as the SMFP methodologies have been refined, the threshold utilization required to generate a need determination has generally increased. As a result, the utilization required by the performance standards in the rules has also increased. The performance standards in the rules place a disproportional burden on providers in less populated service areas. Applicants in areas with one piece of equipment are the most disadvantaged, in some cases needing to project as much as a 100 percent increase in volume by the third project year.

ADVERSE EFFECTS ON PROVIDERS IF THE CHANGE IS NOT MADE

Consider the following example using MRI.

An existing provider of MRI services in a small county operates the only fixed MRI unit in the county, which is the only MRI service in the county. Based on its 2008 utilization of 3,775 weighted procedures, the 2010 SMFP allocates a second MRI scanner in the county. The provider files a certificate of need application in 2010, projecting to begin operating the second scanner in 2011. The third project year for the project is 2013, five years from the data that generated the allocation in the 2010 SMFP. The performance standards in the MRI rules require the applicant's two MRI scanners to perform a total of two times the 3,775 weighted procedures that generated the need, or 7,550 weighted procedures. Thus, in a five year period, the applicant must project (reasonably) to double its volume, which translates into 20 percent growth each year for five years. This sustained rate of growth for several years is unlikely under most circumstances and the applicant's ability to be found conforming with the MRI rules for certificate of need is doubtful. If the applicant in this scenario had two MRI scanners and a need was generated for a third based on the average volume of 4,118 weighted procedures (or a total of 8,236 weighted procedures), then the performance standards would require the applicant to project a total of three times 4,118 or 12,354 weighted procedures by the third project year. This would equate to a total growth of 50 percent, which translates into 10 percent growth each year for five years. While this growth may be more easily achieved than 20 percent per year, it is still higher than the current statewide growth rate in MRI procedures. As a final MRI example, an applicant operating the sole mobile MRI service in a county with no fixed scanners would generate a need at 1,716 weighted procedures, which also serves as the required performance standard for the third year. Thus, this applicant would not need to project any growth to be conforming with the rules. While this is certainly much easier to achieve, it is considerably different from the requirement once the need is generated for a second MRI in the service area.

A similar situation exists for other modalities as well. Providers of radiation oncology services must project the same volume on the proposed linear accelerator as what was required to generate a need. As a result, applicants with one existing linear accelerator must double their volume; applicants with two existing linear accelerators must increase by 50 percent, etc. Even more concerning is that applicants with no linear accelerators,

even in counties without any existing linear accelerators, must project to achieve the 6,750 ESTVs necessary to show need for another linear accelerator by the third project year, even though the need determination is generated because of the need for at least one linear accelerator in that service area, without consideration of any specific projected volume.

The same challenge exists for the other technology modalities as well, including PET and cardiac catheterization equipment in particular. While these modalities generate need determinations less frequently of late, applicants are required to project similar increases in volume, and applicants with more units of existing equipment can project lower growth rates than those with fewer units of existing equipment. Because the required utilization is more easily achieved by providers with multiple pieces of existing equipment, the growth rates required differ considerably, as shown in the following tables.

Volume requirements for applicants with one existing unit

<i>Modality</i>	<i>Applicant volume to generate need</i>	<i>Applicant projected volume to meet rules</i>	<i>Incremental growth required</i>	<i>Per year growth (assumed 5 years)</i>
PET	2,080	4,160	100%	20.0%
MRI	3,775	7,550	100%	20.0%
Cardiac Cath	1,200	2,100	75%	15.0%
Linear Accelerator	6,750	13,500	100%	20.0%

Volume requirements for applicants with four existing units

<i>Modality</i>	<i>Applicant volume to generate need</i>	<i>Applicant projected volume to meet rules</i>	<i>Incremental growth</i>	<i>Per year growth (assumed 5 years)</i>
PET	8,320	10,400	25%	5.0%
MRI	19,219	24,024	25%	5.0%
Cardiac Cath	4,800	5,700	19%	3.8%
Linear Accelerator	27,000	33,750	25%	5.0%

As the tables show, applicants with multiple units of equipment can more reasonably project to achieve the required utilization by the third project year. Please note that this analysis assumes for the sake of simplicity that the need was generated solely from the volume of the applicant with either one or four units of equipment, respectively.

ALTERNATIVES CONSIDERED AND REJECTED

Maintaining the status quo fails to address the disconnect between the SMFP technology methodologies and the required performance standards in the rules. Further, in considering maintaining the status quo, it is important to understand that the challenges described within this Petition are not just theory; in the past few years, several certificate of need reviews have denied all applicants for additional units of technology equipment, at least in part on the basis of unreasonable volume projections. Although some of these reviews have been settled and certificates of need issued, the initial findings have rejected the utilization projections in the applications, which, as explained above, must reach 20 percent per year in some cases.

THE PROPOSED CHANGE IS CONSISTENT WITH THE THREE BASIC PRINCIPLES AND WILL NOT RESULT IN UNNECESSARY DUPLICATION OF HEALTH RESOURCES IN THE AREA

The proposed clarifying language would neither involve nor result in the unnecessary duplication of health resources in the area. Rather, the proposed language would directly address current challenges faced by technology modalities. Further, the proposed change is consistent with the three basic principles governing the development of the SMFP: safety and quality, access, and value. It is important to note that this Petition does not question the technology methodologies themselves, but rather their direct translation into the performance standards in the CON rules. The current use of technology methodologies to develop performance standards that often act as insurmountable obstacles to prospective applicants is not in the spirit of improving quality, access or value. This Petition seeks to address this discrepancy by eliminating any unnecessary or unduly burdensome obstacles for potential applicants and thereby encouraging competition which will serve to improve overall quality, access, and value within the health care system.

CONCLUSION

The discussion at last year's PET workgroup meeting around this subject indicated that the SHCC could establish target utilization for applicants that could be different from the historical utilization required to generate need determinations. Given the situation described in this Petition, there are significant questions regarding the utilization required of applicants:

- If the SMFP methodology is based on historical volume reaching a threshold indicating more capacity is needed, does that not demonstrate that additional equipment is needed based on the existing equipment and regardless of the future utilization of the additional equipment?
- If a target utilization threshold is established, should it not be something considerably less than the volume required to generate the need determination?

- Should target utilization thresholds be tiered so that providers in smaller counties can more easily achieve them reasonably?

Since each of the technology need methodologies is based on the historical volume in a service area, the simplest conclusion is that the need was demonstrated in the past; therefore, an applicant would not be required to project any particular future volume. For example, if the MRI utilization in a service area with one MRI scanner reached 3,775 weighted procedures, does the SHCC not intend that the 3,775 warrants a second MRI scanner? Or is there some level of utilization that should be required by the second scanner? In any case, it seems appropriate that the Technology and Equipment Committee and the SHCC should identify what, if any, projected utilization should be required of an applicant, in order to ensure that the certificate of need performance standards and the SMFP need methodologies are consistent. Rather than suggest a specific solution in this Petition, we request that the SHCC begin a dialogue to discuss the most appropriate projected utilization targets for the respective technology modalities.

Technology & Equipment Committee
Technology Methodologies Petition
Regarding the Proposed 2010 SMFP

AGENCY ANALYSIS:

Petitioner:

Daniel Carter

Health Planning Source, Inc.

Durham, Durham County, North Carolina

Request

The petitioner requests inclusion of language in the Proposed 2010 State Medical Facilities Plan (SMFP) to “*address a disconnect between the SMFP technology methodologies and the required performance standards in the [CON] rules by permitting the SHCC to establish target utilization recommendations for applicants that could be different from the historical utilization required to generate need determinations.*” The petitioner also states “*Rather than suggest a specific solution in this Petition, we request that the SHCC begin a dialogue to discuss the most appropriate projected utilization targets for the respective technology modalities.*”

Background Information

Methodologies for need determinations for four of the six types of medical equipment in Chapter 9 of the SMFP are based on actual utilization of existing equipment for the operating year reported in the most recent license renewal applications and equipment inventories. Specifically, these methodologies do not include projections of need for a future date utilizing an assumed growth rate factor. The four types of equipment for which need methodologies are based on actual recent utilization and not on projected utilization include: linear accelerators, PET scanners, MRI scanners, and cardiac catheterization equipment. Other need determinations in the SMFP that also are based on actual recent utilization instead of projected utilization include: open heart surgery, burn intensive care, solid organ transplants, rehabilitation beds,

Examples of need methodologies that are based on applying projections for a future year include: acute care beds, operating rooms, nursing care beds, adult care home beds, home health agencies, hospices, psychiatric beds, and substance abuse beds.

In accordance with G. S. 131E-183(b) and 150B, Article 2A, the Certificate of Need Section adopts by rule criteria to be used in the review of certificate of need (CON) applications for specific services and equipment. The review criteria include standards for projected utilization of the proposed equipment, i.e. performance standards. The performance standards specify the number of procedures the applicant is required to project it will perform in the applicant’s third year of operation to be approved. The performance standards must be adopted as rules or administrative regulations in accordance with the Administrative Procedures Act.

Petitioner's Analysis/Implications

The petitioner characterizes the need determination methodologies in the SMFP as falling into two primary categories: projected need and historical need (i.e. need based on actual recent utilization). Projected need methodologies take historical utilization, project it forward based on the methodology's assumptions, then compare the projected future need with the current capacity to assess any additional capacity that may be needed. Unlike the projected need methodologies, historical need methodologies base the need determination on a threshold that has been met in the past. For example, the MRI methodology examines the average historical utilization in a given service area (using weighted procedures). Once a service area has hit the target utilization, a need for an additional MRI scanner is generated.

The petitioner continues that in the historical need methodologies, no consideration is given for the projected utilization of the additional unit of equipment, and therefore no utilization is projected for those units in the future. The petitioner contends that since each of the technology need methodologies is based on the historical volume in a service area, the conclusion is that the need was demonstrated in the past; therefore, an applicant would not be required to project any particular future volume. The petitioner further points out that providers with fewer pieces of equipment have a more difficult time achieving targeted utilization.

The petitioner states *“the Technology and Equipment Committee and the SHCC should identify what, if any, projected utilization should be required of an applicant, in order to ensure that the certificate of need performance standards and the SMFP need methodologies are consistent.”* The petitioner also states, *“It is important to note that this Petition does not question the technology methodologies themselves, but rather their direct translation into the performance standards in the CON rules.”*

Agency Recommendation

As explained in Chapter Two of the 2009 SMFP, “Anyone who finds that the SMFP's 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.” As the petitioner pointed out, the petitioner is not making any recommendations for changes to the technology and equipment methodologies. The petition instead requests changes to performance standards 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. Therefore, the Agency recommends denial of the petition. The Technology and Equipment Committee may wish to review the technology and equipment need determination methodologies in light of the petitioner's comments.