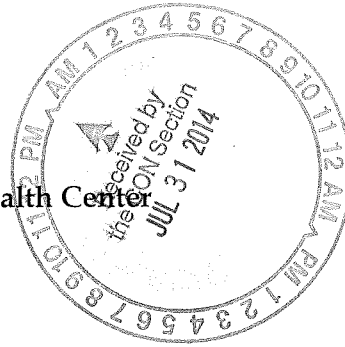


Comments on The Prostate Health Center

submitted by

Rex Hospital, Inc.



In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Rex Hospital, Inc. ("Rex") submits the following comments related to an application to acquire a second linear accelerator at its facility in Wake County. Rex's comments include "discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards." See N.C. GEN. STAT. § 131E-185(a1)(1)(c). In order to facilitate the Agency's review of these comments, Rex has organized its discussion by issue, noting some of the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity relative to each issue, as they relate to the following application:

- The Prostate Health Center, Project ID # J-10300-14

The Prostate Health Center's application should not be approved as proposed. Rex has identified the following specific issues, each of which contributes to the application's non-conformity:

- (1) Failure to Demonstrate that the Project is Not Subject to a Need Determination; and,
- (2) Failure to Demonstrate the Need for the Proposed Project;

Each of the issues listed above are discussed in turn below. Please note that relative to each issue, Rex has identified some of the statutory review criteria and specific regulatory criteria and standards creating the non-conformity.

Failure to Demonstrate that the Project is Not Subject to a Need Determination

The proposed project is flawed as the acquisition of a linear accelerator is the sole purpose of the application. Linear accelerators are per se reviewable, per NCGS 131E-176(f1)(5a). Need for linear accelerators are further restricted by and subject to need determinations in the *State Medical Facilities Plan (SMFP)*. The 2014 SMFP has a need determination for two additional linear accelerators: one for Service Area 20 (which includes Wake and Franklin counties) and one for Harnett County (Service Area 21, formerly part of Service Area 20). The date for the Harnett County review has passed; the review date for the Service Area 20 review is September 1, 2014. However, the application is clear that it is not intended for the September 1 review by stating in its request for an expedited

review, "I believe the application will not be competitive with other applications in this batch." On page 85, the application supports this fact by stating, "[t]he application is not for a new institutional health service for which there is a specific need determination in the 2014 State Medical Facilities Plan, other than the need for the demonstration project." Finally, while applications may be submitted prior to the application deadline date, since the Agency has accepted the application for the July 1 review cycle, as shown by its inclusion in the comments and public hearing page for July 1 reviews¹, then the application must be reviewed within 150 days by statute, and should not be reviewed competitively with any applications that might be filed for the September 1 cycle. Thus, the application requests the acquisition of per se reviewable equipment under the July 1 review cycle, for which there is no need determination.

It should also be noted that the statement in the application that there is a need in the 2014 SMFP for the demonstration project is incorrect; that need determination was in the 2009 SMFP, and was satisfied through the certificate of need awarded to the applicant, which included one linear accelerator. On page 71, the application refers to the nature of the Prostate Health Center as a demonstration project and the need for a linear accelerator as part of that demonstration project under the 2009 SMFP, with the expectation that a report will be provided in the fourth operating year. While these facts are true, they are neither relevant to the application for a second linear accelerator, nor do they obviate the requirement of a need determination under which the application must be reviewed and approved. On page 73, the application states that while the facility is meeting its intended goals, "[i]t is limited now by the capacity of the equipment." Even assuming the facility itself is limited by its capacity, the same can be said for any facility with well-utilized equipment; however, that does not enable it to escape the limitations imposed by the 2014 SMFP and the CON statute. In addition, despite the implication to the contrary, the application fails to establish that the demonstration project requires enough capacity to treat more patients than can be accommodated on one linear accelerator. Moreover, the applicant, who was also the petitioner for the Prostate Health Center and its one linear accelerator, requested one linear accelerator as part of the Prostate Health Center, not more than one, and certainly not an open-ended project under which multiple linear accelerators could be approved. If the State Health Coordinating Council (SHCC) had seen fit, it could have recommended that the SMFP include permissive language that allowed the development of multiple linear accelerators as part of the demonstration project. It did not, nor did the Governor include such language in the 2009 SMFP or the 2014 SMFP. The 2009 SMFP states "[i]n response to a petition, there is included in this North Carolina 2009 State Medical Facilities Plan a statewide need determination for one dedicated linear accelerator that

¹ Available at <http://ncdhhs.gov/dhsr/coneed/pdf/report/2014/0703comments.pdf>.

shall be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men" (emphasis added, page 121). The ability of the applicant to fulfill its obligations for the demonstration project and its material compliance requirements under the CON statute is not dependent on a second linear accelerator at the Prostate Health Center. None of those obligations requires a certain capacity at the facility; in fact, given the demonstration nature of the project, it is logical to assume that limited capacity would be expected, particularly prior to any positive outcomes being demonstrated. The facility has been operating just over one year and is not even halfway to its reporting deadline. Thus, the fact that the facility is a demonstration project supports limited capacity, not the unfettered capacity suggested by the applicant.

The application continues the discussion of the *SMFP* on page 71 by noting that the linear accelerator is not counted in the regular inventory, and then asserts that the *SMFP* "neither provides nor prohibits a specific mechanism by which the Prostate Health Center can accommodate the needs of its intended beneficiaries when the linear accelerator reaches capacity." The application further states that this issue was acknowledged by the DHSR Director in December 2013. While the precise nature of the "acknowledgement" is not provided in the application, it is a fact that the DHSR Director, respectfully, cannot supersede the SHCC nor the Governor with respect to need determinations (or lack thereof) in the *SMFP*. The DHSR Director is not ignorant of this fact; therefore, the most likely scenario is that the Director agreed that the *SMFP* is silent regarding the need for additional capacity specifically for the Prostate Health Center, a fact which may be true, but is not relevant. The *SMFP* is not silent regarding the need for additional linear accelerator capacity. Indeed, as discussed above, the *SMFP* includes a need for two additional linear accelerators, one each in Service Areas 20 and 21, and states, "[t]here is no need anywhere else in the state and no other reviews are scheduled...." Clearly, the intent of the SHCC and the Governor, as expressed in the 2014 *SMFP*, is for one linear accelerator in Service Area 20, set for review in the September 1 review cycle, under which the Prostate Health Center has not applied.

Further, the notion that there is not a mechanism contemplated in the *SMFP* for the accommodation of the need of the facility's "intended beneficiaries" is inaccurate. First, the "intended beneficiaries" of the project are African American men, whose lower-than-average outcomes for prostate cancer are the subject of the demonstration. To the extent that the facility is treating patients outside of this patient population, it is arguably these other patients that are preventing the facility from treating more of its "intended beneficiaries," not the lack of a second linear accelerator. While the facility may not be precluded from serving non-African American men and women, it is also not required to serve those patients.

Thus, the facility's choice of serving patients outside of those for whom the demonstration is intended does not create a need for an additional linear accelerator to serve African American men with prostate cancer. Thus, the premise that the facility needs more capacity to serve these patients is incorrect. Second, the *SMFP* most certainly contains multiple mechanisms for expanding the capacity of the facility. As noted above, there is a need determination in the 2014 *SMFP* for an additional linear accelerator in Service Area 20. Nothing in that need determination precludes the Prostate Health Center from applying for that allocation and attempting to demonstrate why it would be the most effective alternative for the equipment. The *SMFP* also includes directions on how to petition the SHCC for a methodology change or a special need adjustment to enable the facility to apply for a certificate of need for a second linear accelerator. Yet the applicant has failed to pursue either of these alternatives, both of which have records of success in enabling applicants to expand their capacity.

The fact that the equipment is excluded from the inventory and the utilization is ignored in the *SMFP* is also not unprecedented. Table 6D in the 2014 *SMFP* shows the inventory of operating rooms for the Single Specialty Ambulatory Surgery Demonstration project with no utilization provided; Tables 9Q(4) and (6) show the inventory of MRI scanners used as part of demonstration projects, also with no utilization provided. In fact, none of the demonstration projects in the *SMFP* include the inventory of equipment or rooms with the standard inventory, and none of the utilization for these projects is included in the *SMFP*. Like all demonstration projects, their impact on the "state health care delivery system" is measured at the end of their demonstration, when the issue they were approved to demonstrate is considered by the SHCC and the Governor. Thus, the applicant is receiving no different treatment than any other demonstration project. Further, the "demonstration" portion of the project was essential to its approval as part of the 2009 *SMFP*.

The application also states on page 71 that "*both Planning Staff and the State Health Coordinating Council at its October 2013 meeting agreed that the exclusion was intentional, because of the demonstration nature of the project.*" As the discussion in the previous paragraph demonstrates this idea supports the notion that no additional capacity is intended for the demonstration project and not that the *SMFP* intends for demonstration projects to have no limits on the acquisition of additional capacity. In addition, the statement is appears to be inaccurate. The referenced meeting of the SHCC took place on October 2, 2013. At no time during that meeting was the treatment of the Prostate Health Center in the *SMFP* discussed. An audio/visual recording from the meeting² confirms that the statement in the application is inaccurate. In fact, the sole mention of the Prostate

² Available at <https://dhhs.ncgovconnect.com/p99729602/>.

Health Center during that meeting was by Dr. Khoudary, who was asked to discuss his opposition to a petition for an additional linear accelerator in Service Area 20. As part of his statement, which is found in the recording referenced above starting at 47'15", Dr. Khoudary voiced his opposition to an additional linear accelerator in Service Area 20 by stating the following:

"I'm Kevin Khoudary and I represent the Prostate Health Center...we opened in May [2013]. We feel that another linear accelerator to an oversaturated marketplace might be detrimental to our project."

The Agency report³ on the petition also does not reference the Prostate Health Center. The discussion at the SHCC meeting in October 2013 involving linear accelerators centered on the petition for a special need adjustment. The one additional linear accelerator that was mentioned by staff and the SHCC members as part of that discussion was the undeveloped linear accelerator in Service Area 20, which is owned by Cancer Centers of North Carolina (CCNC). In fact, the Prostate Health Center was not mentioned until Dr. Khoudary was recognized to comment on his opposition to the petition. The application's assertion that the intentional exclusion of the linear accelerator from the inventory was a point of discussion at the meeting, whether intentional or inadvertent is false. More importantly, even if true, it does not impact the determinative limitation on linear accelerators in the *SMFP*.

For these reasons, the application is non-conforming with Criteria 1, 3, and 6, and should be denied.

Failure to Demonstrate the Need for the Proposed Project

The application does not sufficiently demonstrate the need the population has for its project. The projected volume at their facility is based on only one year of operation and does not demonstrate need for additional linear accelerator capacity. In particular, The Prostate Health Center is applying to develop linear accelerator capacity over and above what has been determined to be needed by the Governor and the SHCC, either through a need determination or another demonstration project. As such, The Prostate Health Center should have demonstrated the need for its project in that context and it failed to do so.

As a result, the application is non-conforming with Criteria 3 and 6, and should be denied.

³ Available at http://ncdhhs.gov/dhsr/mfp/pdf/2013/tec/0910_la_agencyrep.pdf.