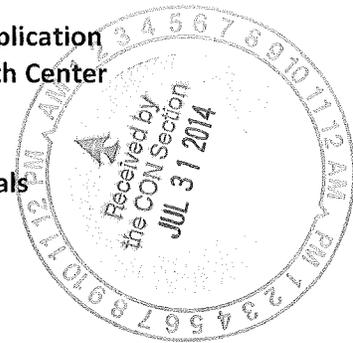


**Comments Regarding the Certificate of Need Application
Filed by Parkway Urology, PA/The Prostate Health Center
Project No. J-10300-14**

**Submitted by: WakeMed Health & Hospitals
July 31, 2014**



Overview

A certificate of need application was filed for the July 1, 2014 review cycle to develop a second linear accelerator at Parkway Urology, PA/The Prostate Health Center ("Parkway") in Raleigh, which was originally approved to develop a prostate health demonstration project pursuant to the 2009 State Medical Facilities Plan. According to Parkway, this CON application would provide additional radiation therapy capacity at The Prostate Health Center, which opened in 2013.

WakeMed is supportive of the overall mission of The Prostate Health Center demonstration project and believes that the Center provides valuable and needed services to the community and region. However, WakeMed is concerned that approval of Project No. J-10300-14 would circumvent the State Health Planning process, and could set a precedent that may allow other demonstration projects to expand their services outside the need determinations set forth in annual State Medical Facilities Plans.

The following comments will demonstrate that the Parkway application should not be approved, as it does not conform to all applicable certificate of need Review Criteria found in G.S. §131E-183, namely Criteria 1 and 4, as discussed below.

CON Review Criterion 1

The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, home health office that may be approved.

Parkway seeks to acquire a second linear accelerator to expand its demonstration project for its multidisciplinary prostate health center, which received approval for its linear accelerator via a statewide demonstration project need determination in the 2009 State Medical Facilities Plan (SMFP). Page 121 of the 2009 SMFP contains the following statement:

"In 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 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."

Pages 127 and 134 of the 2014 SMFP include the following notation regarding the 2009 demonstration project need determination:

“[A] certificate of need was issued to Parkway Prology, PA dba Cary Prology, PA on 2/22/2009 to acquire one dedicated linear accelerator for a model multidisciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men. The linear accelerator is not counted in the regular inventory of linear accelerators.”

The Prostate Health Center was approved in February 2011 and opened in May 2013. According to Parkway, patient volumes during the first year of operation at The Prostate Health Center demonstration project were sufficiently high to warrant acquisition of a second unit. However, since 2009, no subsequent SMFP has contained a need determination for either a second statewide linear accelerator demonstration project or for additional equipment for the existing demonstration project.

Despite Parkway’s claims that its application is an expansion of the statewide linear accelerator demonstration project, there have been no provisions made by the State Health Coordinating Council to permit the development of additional linear accelerator capacity to the demonstration project initially allocated in the 2009 SMFP and awarded to Parkway in 2011. Parkway is applying for a linear accelerator for which no need determination has been made in the current SMFP. The CON Section considers the Parkway application to fall under Review Category D while applications for the upcoming linear accelerator need determination for Service Area 20 will be reviewed under Category H. Clearly, Parkway did not intend for its application to be reviewed with potential competing applications.

Parkway states, on Application page 11, that “[t]he Plan neither provides nor prohibits a specific mechanism by which The Prostate Health Center can accommodate the needs of intended beneficiaries when the linear accelerator reaches capacity.” However, during meetings of the State Health Coordinating Council and its committees held in 2014 to develop the Draft 2014 SMFP, there was no correspondence or communication to the SHCC from Parkway describing the need to consider additional linear accelerator capacity for its statewide demonstration project.

For these reasons, the Parkway application does not conform to Review Criterion 1.

CON Review Criterion 4

D here alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

In its response to Application Question #3, Parkway discusses several alternatives to the proposal to expand The Prostate Health Center, including status quo, pursuit of a joint venture, consideration of alternative locations, development of alternative equipment or services, and project delay.

Missing from these alternatives is any discussion of applying for the need determination in the 2014 SMFP for one linear accelerator in Service Area 20, which includes Wake County, scheduled for the September 1, 2014 review cycle. It is certainly possible that Parkway could apply for this linear accelerator allocation to expand The Prostate Health Center. There would be nothing to prohibit Parkway from doing so. Likewise, Parkway is not precluded from petitioning the State Health Coordinating Council for an adjusted need determination to expand its demonstration project.

Given that there is no need determination in the 2014 SMFP for a linear accelerator dedicated to prostate health, the most effective alternatives for Parkway are: 1) status quo, 2) project delay, or 3) applying for the linear accelerator need determination for Service Area 20. Without a discussion as to why the alternatives of either applying for the linear accelerator for Service Area 20 or petitioning the SHCC to expand The Prostate Health Center are not viable, the Parkway application is not conforming with Criterion 4.

Summary

For the reasons described above, WakeMed respectfully requests that the CON Section deny the Parkway application. Approval of Parkway's proposal would set a precedent that would allow any approved demonstration project a mechanism by which to expand its capacity outside the need determinations set forth in the annual State Medical Facilities Plan. If the CON Section does approve the Parkway application, The Prostate Health Center should be conditioned to use its linear accelerator to treat only patients with prostate cancer, in keeping with the spirit of the original 2009 need determination for a statewide demonstration project for a multidisciplinary prostate health center.