

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: November 20, 2014

PROJECT ANALYST: Michael J. McKillip

INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: J-10300-14 / Parkway Urology, PA / Acquire a second linear accelerator to be located at The Prostate Health Center in Raleigh / Wake County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (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, or home health offices that may be approved.

NC

Parkway Urology, PA [**Parkway**] proposes to acquire a second linear accelerator to be located in a 1,088 square foot addition to its existing facility, The Prostate Health Center, which is located at 117 Sunnybrook Road in Raleigh. On February 23, 2011, the applicant received a certificate of need (Project I.D. # J-8331-09) to acquire a linear accelerator and develop a multidisciplinary prostate health center demonstration project in Raleigh. On page 126, the 2014 SMFP states,

“The North Carolina 2009 State Medical Facilities Plan included a statewide need determination for one dedicated linear accelerator to 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. In response to that need determination, a certificate of need was issued to Parkway Urology, PA d/b/a Cary Urology, PA on 2/23/2011 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.”

In Section III.1, page 71 of the application, the applicant states,

“The 2014 SMFP notes that ‘The linear accelerator is not counted in the regular inventory of linear accelerators.’ The Plan 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. This issue was acknowledged at a meeting with the DHSR Division Director on December 20, 2013. Services provided on the linear accelerator at The Prostate Health Center are excluded from the inventory in Table 9G of the 2014 SMFP. The 2014 SMFP includes neither the inventory nor the productivity of The Prostate Health Center linear accelerator in its need tables or planning methodology for linear accelerators; hence its contributions to the state health care delivery system are not acknowledged in the 2014 SMFP.

Moreover, both the 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. With the demonstration clearly needed, it is reasonable to conclude that a successful demonstration should be permitted to have capacity to meet the needs of its intended service population. Unlike a staff-dependent service, The Prostate Health Center requires specific equipment in order to expand capacity, specifically an additional linear accelerator.”

However, as noted in the 2014 SMFP, *“The North Carolina 2009 State Medical Facilities Plan included a statewide need determination for one [Emphasis added] dedicated linear accelerator to 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.”* The 2014 SMFP does not include a need determination for any additional dedicated linear accelerators to be part of the demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer. Moreover, on page 135, the 2014 SMFP identifies a need in Areas 20 and 21 and states, *“There is no need anywhere else in the state and no other reviews are scheduled.”* This application was not submitted in response to the adjusted need determination for Area 20. Therefore, this application for an additional linear accelerator to be part of the previously approved demonstration project is not consistent with the need determinations in the 2014 State Medical Facilities Plan.

Policy GEN-4 is applicable to this review. *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities* states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the

applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section III.2, page 89, the applicant states,

"The applicant understands that it will be required to develop a plan to assure improved energy efficiency and water conservation.... The proposed linear accelerator involves little or no water consumption and the site changes involve no changes in water run-off because the area is already paved. ... Please see letter from the architect in Exhibit 56 for the proposed energy and water conservation plan."

Exhibit 56 contains a copy of a letter from the applicant's architect describing the strategies it will employ to improve energy efficiency and conserve water. The application is consistent with Policy GEN-4.

In summary, the application is consistent with Policy GEN-4, but is not consistent with the need determination in the 2014 SMFP. Therefore, the application is not conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

Parkway proposes to acquire a second linear accelerator to be located in a 1,088 square foot addition to its existing facility, The Prostate Health Center. On February 23, 2011, the applicant received a certificate of need (Project I.D. # J-8331-09) to acquire one linear accelerator and develop a multidisciplinary prostate health center demonstration project in

Raleigh. The applicant’s existing linear accelerator has been operational since May 2013. In Section II.1, pages 25-27, the applicant describes the project as follows:

“The project involves construction of a second linear accelerator vault in a patio area of The Prostate Health Center and acquisition of a second linear accelerator. It will result in the expansion of The Prostate Health Center by 1,088 square feet. The Prostate Health Center is a demonstration model multi-disciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men. ... The project will involve contracting for an additional radiation oncologist and additional radiation therapy staff members. ... The other components of The Prostate Health Center’s multidisciplinary offering will remain: Urology, Radiation Oncology Brachytherapy, Medical Oncology and Chemotherapy, Biofeedback Therapy, Living Skills Counseling, Research, and outreach education.”

Population to be Served

In Sections III.4 and III.5, pages 95-96, the applicant provides the current and projected patient origin for linear accelerator services at The Prostate Health Center, as shown in the table below.

**The Prostate Health Center
 Linear Accelerator Services Patient Origin**

County	Current (2013-2014) Percent of Total Patients	FY2016 Percent of Total Patients	FY2017 Percent of Total Patients
Wake	51.7%	56.6%	57.6%
Harnett	12.7%	10.5%	9.7%
Johnston	11.2%	9.3%	8.6%
Sampson	8.3%	6.3%	5.7%
Franklin	3.4%	2.9%	2.7%
Lee	2.4%	2.1%	2.0%
Duplin	2.0%	1.8%	1.7%
Wayne	2.0%	1.9%	2.0%
Durham	1.5%	2.2%	2.6%
Chatham	1.0%	1.2%	1.3%
Other*	3.8%	5.2%	6.1%
TOTAL	100.0%	100.0%	100.0%

*The applicant identifies the counties included in the “Other” category on pages 95-96 of the application.

On page 97, the applicant states, “The forecast follows historical patient origin with market share and population changes that are explained in Section IV.1(d) Steps 1 through 9.” The applicant adequately identified the population proposed to be served.

Need Analysis

In Section III.1(a) of the application, the applicant describes the factors which it states support the need for the proposed project, including the utilization of the existing linear accelerator (pages 72-73), the incidence and prevalence of prostate cancer (pages 74-77), projected population in the proposed service area (pages 78-79), and support from referring physicians (page 79).

Projected Utilization

In Section IV.2, page 121, the applicant provides historical and projected utilization for the existing and proposed linear accelerators at The Prostate Health Center (TPHC) through the first three years of operation following completion of the project (May 2013-CY2018), which is summarized below.

**The Prostate Health Center
 Linear Accelerator Utilization, May 2013-FY2018**

Year	ESTV* Treatments	Percent Increase	ESTVs Per Linear Accelerator	Percent of Minimum Performance Standard**
2013 Actual***	6,911	---	6,911	102%
CY2014 Projected	7,996	15.70%	7,996	118%
CY2015 Projected	9,231	15.45%	9,231	137%
CY2016 (PY 1)	10,680	15.70%	5,340	79%
CY2017 (PY 2)	12,212	14.34%	6,106	90%
CY2018 (PY 3)	13,854	13.45%	6,927	103%

*ESTVs = equivalent simple treatment visits.

**Minimum performance standard is 6,750 ESTVs per linear accelerator per year.

***The applicant states utilization data for 2013 is from May 1, 2013 – April 30, 2014, which was the first 12 months of operation for the existing linear accelerator.

As indicated in the table above, the applicant projects it will perform an average of 6,929 ESTVs on each of its two linear accelerators (one existing and one proposed) in the third year of operation following completion of the project, which exceeds the minimum performance standard of 6,750 ESTVs required in 10A NCAC 14C .1903(a)(2).

In Section IV.1, pages 103-126, the applicant describes its assumptions and methodology for projecting utilization of the linear accelerators. Based on the patient origin data from its first year of operation, the applicant identified the primary service area as Wake, Harnett, Johnston and Sampson counties, and the secondary service area was identified as Franklin, Lee, Duplin, Wayne, Chatham, and Durham counties (See pages 103-105). Based on the North Carolina Central Cancer Registry (NCCCR) forecast of new prostate cancer cases by county, and the number of new prostate cancer cases by county treated by The Prostate Health Center in its first operating year (May 1, 2013-April 30, 2014), the applicant calculated its 2013/2014 market share of new prostate cancer cases by county, which is shown in the table on page 109, and summarized below:

New Patients as Percent of New Prostate Cancer Cases in 2013

Service Area County	TPHC Percent of Total New Prostate Cancer Cases (Actual)
Primary Service Area	
Wake	16.9%
Harnett	29.9%
Johnston	17.4%
Sampson	30.4%
Secondary Service Area	
Franklin	12.3%
Lee	10.0%
Duplin	7.3%
Wayne	3.8%
Durham	1.7%
Chatham	2.6%
Other Counties	
Vance	5.1%
Alamance	0.8%
Guilford	0.3%
Lenoir	1.8%
Moore	0.9%
Wilson	1.4%

Source: Table IV.5, page 109.

Based on the annual growth rates in new prostate cancer cases by county from 2011 to 2014 as estimated by NCCCR (Table IV.3, page 107), the applicant projects new prostate cancer cases by county for the primary and secondary service area from 2015 through 2018, which is summarized in the table below:

Projected New Prostate Cancer Cases by County

	2013	2014	2015	2016	2017	2018

County						
Wake	626	649	669	689	710	732
Harnett	87	90	92	94	96	99
Johnston	132	134	135	136	137	138
Sampson	56	57	57	57	57	57
Franklin	57	57	57	57	57	57
Lee	50	51	51	51	51	51
Duplin	55	56	57	57	58	58
Wayne	104	104	104	104	104	104
Durham	180	190	195	201	206	212
Chatham	76	79	81	82	84	85
Vance	39	40	41	41	42	42
Alamance	133	132	130	128	126	124
Guilford	396	403	408	412	417	422
Lenoir	56	56	56	56	56	56
Moore	108	110	110	109	109	108
Wilson	73	74	74	74	74	74
Other	-	-	-	-	-	-
TOTAL	2,228	2,282	2,317	2,348	2,384	2,419

Source: Table III.8, page 111 of the application. [Note: The applicant's totals in the table on page 111 are incorrect. The corrected totals are shown above].

The applicant projects market share increases in a range from zero to three percent per year for each of the counties in its proposed primary and secondary service areas for years 2014 through 2018, as shown in the table on page 112. Based on those projected annual increases in market share by county (Table IV.6, page 112), the applicant projects its percentage of new prostate cancer cases (market share) by county for the years 2014 through 2018, as shown below:

Table IV.7 – The Prostate Health Center Cases as Percent of New Prostate Cancer Cases by County, FY2014 through FY2018

	2014	2015	PY 1	PY 2	PY 3
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County			2016	2017	2018
<i>Wake</i>	17.4%	20.4%	23.4%	26.4%	29.4%
<i>Harnett</i>	29.9%	30.9%	31.9%	32.9%	33.9%
<i>Johnston</i>	17.4%	18.4%	19.4%	20.4%	21.4%
<i>Sampson</i>	30.4%	30.4%	31.4%	32.4%	33.4%
<i>Franklin</i>	12.3%	13.3%	14.3%	15.3%	16.3%
<i>Lee</i>	10.0%	11.0%	12.0%	13.0%	15.0%
<i>Duplin</i>	7.3%	7.8%	8.8%	9.8%	10.8%
<i>Wayne</i>	3.8%	4.3%	5.3%	6.3%	7.3%
<i>Durham</i>	1.7%	2.2%	3.2%	4.2%	5.2%
<i>Chatham</i>	2.6%	3.1%	4.1%	5.1%	7.1%
<i>Vance</i>	5.1%	5.1%	5.4%	5.6%	5.9%
<i>Alamance</i>	0.8%	0.8%	1.0%	1.3%	1.5%
<i>Guilford</i>	0.3%	0.3%	0.5%	0.8%	1.0%
<i>Lenoir</i>	1.8%	1.8%	2.0%	2.3%	2.5%
<i>Moore</i>	0.9%	0.9%	1.2%	1.4%	1.7%
<i>Wilson</i>	1.4%	1.4%	1.6%	1.9%	2.1%
OTHER					

Note OTHER is excluded from this calculation.

The applicant projects new prostate cancer cases that will be treated by TPHC by multiplying its projected market shares by county shown above by the projected new prostate cancer cases by county (Applicant’s Table III.8, page 111). The applicant’s projected new prostate cancer cases by county and by year are summarized in the table below:

TPHC’s Projected New Prostate Cancer Cases by County

County	2014	2015	2016	2017	2018
Wake	113	137	162	188	216

Harnett	27	28	30	32	33
Johnston	23	25	26	28	30
Sampson	17	17	18	18	19
Franklin	7	8	8	9	9
Lee	5	6	6	7	8
Duplin	4	4	5	6	6
Wayne	4	5	6	7	8
Durham	3	4	6	9	11
Chatham	2	3	3	4	6
Vance	2	2	2	2	2
Alamance	1	1	1	2	2
Guilford	1	1	2	3	4
Lenoir	1	1	1	1	1
Moore	1	1	1	2	2
Wilson	1	1	1	1	2
Other	1	4	6	9	11
TOTAL	214	247	286	326	370

Source: Table IV.8, page 115 of the application.

The applicant's assumptions regarding projected percentages for each case type and the applicant's projected number of linear accelerator treatments by case type are summarized in the following table:

**Distribution of The Prostate Health Center Cases By Type
 and Number of Linear Accelerator Treatments by Type**

Treatment Type	Percent of Total Cases	Expected Treatments per Case
Prostate		
IMRT only	67.3%	41
EBRT + surgery	21.5%	37
EBRT + brachytherapy	7.3%	25
GU (Non-prostate)	2.9%	17
Palliation	1.0%	10
Total EBRT	100.0%	

Source: Applicant's Table IV.10, page 117.

The applicant states the projected case type percentages and projected treatments per case type shown in the table above are based on utilization data from May 1, 2013 – April 30, 2014, which was the first 12 months of operation of the applicant's existing linear accelerator. On page 120 of the application, the applicant applies the percentages and treatments per case estimates to its total projected cases by year to project the number of external beam radiation treatments (EBRT) per year, as shown below:

Table IV.13 – Forecast EBRT Procedures without Field Checks

	2013/2014	2014	2015	2016	2017	2018
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<i>Prostate</i>						
<i>IMRT only</i>		5,912	6,810	7,883	9,001	10,205
<i>EBRT + surgery post op</i>		1,701	1,959	2,268	2,590	2,936
<i>EBRT+Brachy</i>		392	451	522	597	676
<i>GU – non prostate</i>		107	123	142	162	184
<i>Palliation</i>		21	24	28	32	36
<i>Total EBRT Expected without field checks</i>	6,908	8,133	9,368	10,844	12,382	14,037

On page 121, the applicant provides a table showing its projected number of EBRT and field checks by year and calculates projected total ESTVs by year, as shown below:

Table IV.14 – Forecast EBRT Procedures, Field Checks and ESTV’s by Year

	2013/2014	2014	2015	PY 1 2016	PY 2 2017	PY 3 2018
<i>EBRT completed</i>	6,908					
<i>Percent completed</i>	88.8%					
<i>Forecast EBRT procedures completed exclusive of field checks Table IV.13 (1)</i>	7,783	7,995	9,229	10,678	12,209	13,851
<i>Field Checks (2)</i>	3	4	3	5	5	6
<i>Total Procedures per SMFP</i>		7,998	9,233	10,682	12,214	13,857
<i>ESTV’s for Treatment Procedures</i>		7,995	9,229	10,678	12,209	13,851
<i>ESTV’s for Field Checks</i>		2	2	2	3	3
<i>Total ESTV’s</i>	6,911	7,996	9,231	10,680	12,212	13,854

Notes:

- (1) The applicant’s projections of “EBRT procedures completed exclusive of field checks” shown in Table IV.14 above are slightly lower than the projected “Total EBRT expected without field checks” shown on page 120, Table IV.13.
- (2) The applicant projects field checks as a percentage (0.04%) of other types of EBRT procedures based on its historical experience.

As discussed above, the applicant projects new prostate cancer cases in the proposed service area will increase from 2014 to 2018 at the same rate of increase estimated by the NCCCR for the time period from 2011 to 2014. Using its own internal data from the most recent year, which was also the applicant’s first year of operation, the applicant estimated its historical (2014) market shares for new prostate cancer cases by county and projected those forward through CY2018. Based on these assumptions, the applicant projects the total number of new prostate cancer cases that it will treat through the third year of operation of the project. Based on the applicant’s historical experience, it projects the number of cases by type and the number of treatments per case type. Finally, the applicant calculates the ESTV’s based on the weighting system in the 2014 SMFP to calculate the total ESTV’s per year through the third year of operation (CY2018). Exhibit 43 contains letters from the physicians and surgeons in the proposed service area expressing support for the proposed project and their intention to refer patients to TPHC. The projected utilization of the linear

accelerators at TPHC is based on reasonable and adequately supported assumptions. Parkway adequately demonstrates the need for the proposed linear accelerator.

Access

The applicant projects 59.5% of the patients will be covered by Medicare (59%) and Medicaid (0.5%). The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately identified the population to be served, adequately demonstrated the need the population projected to be served has for the proposed project, and adequately demonstrated the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (4) Where 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.

NC

In Section III.3, pages 90-94, the applicant discusses the alternatives it considered prior to submitting this application, which include:

- a) Maintaining the status quo, which the applicant states was rejected because it does not address the lack of capacity at TPHC to accommodate the growing demand for services.
- b) Developing a joint venture with an existing provider, which the applicant states was rejected because of the cost and complexity of such ventures due to legal, governance, and reimbursement differences among the different types of providers.
- c) Developing the project in an alternative location, which the applicant states was rejected because Raleigh and Wake County's location, population, and transportation systems make it the most appropriate site for a statewide demonstration project.

- d) Delaying the project, which the applicant states was rejected since the CON process is already lengthy and the need for the second linear accelerator is already apparent.

After considering those alternatives, the applicant states the alternative proposed in the application is the most effective alternative. However, the application is not conforming to all other statutory review criteria, and thus, is not approvable. A project that cannot be approved cannot be an effective alternative. Specifically, there is no need determination in the 2014 SMFP for a second linear accelerator as part of the 2009 demonstration project. The discussion regarding the need determination found in Criterion (3) is incorporated herein by reference.

In summary, the applicant did not adequately demonstrate that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is not conforming to this criterion and is not approved.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 173, the applicant projects the capital cost for the project will be \$3,743,461. In Section VIII.3, the applicant states Parkway will finance the capital costs with a conventional loan. In Section IX.1, the applicant projects no start-up expenses or initial operating expenses, as the facility is already providing radiation therapy services. In Exhibit 53, the applicant provides a letter from a Senior Vice President for North State Bank, which states

“We understand that Parkway Urology, PA is applying for a Certificate of Need to acquire a linear accelerator and to continue to develop external beam radiation therapy services at its existing center, The Prostate Health Center. Parkway Urology, PA reports the capital costs to be approximately \$4 million. Based on today’s conditions, terms for a loan to finance such capital costs include up to a 20 year amortization and an interest rate of approximately 4.50% per year for a term of up to ten years. ... This letter’s intent is to provide a general indication of the bank’s interest in providing financing for this project and is based on our current loan policy and financial market conditions at the time this letter was prepared. ... Having provided that necessary disclaimer, we clearly would welcome the opportunity to assist Parkway Urology, PA with this endeavor by potentially providing the financing for the capital costs. Please accept this letter as an indication of our willingness to assist with this project.”

The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the proposal.

In the pro forma financial statements for TPHC (Form B), the applicant projects revenues will exceed expenses in the second and third operating years, as shown below:

The Prostate Health Center

	CY2016 Year 1	CY2017 Year 2	CY2018 Year 3
Total Revenue	\$6,953,863	\$8,341,130	\$9,926,465
Total Expenses	\$7,354,881	\$7,870,987	\$8,596,467
Net Income (Loss)	(\$401,017)	\$470,143	\$1,329,998

Operating costs and revenues are based on reasonable assumptions including projected utilization. See the pro forma financial statements in the application for the assumptions. The discussion regarding utilization assumptions found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of operating costs and revenues, and the application is conforming with this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

NC

Parkway proposes to acquire a second linear accelerator to be located in a 1,088 square foot addition to its existing facility, The Prostate Health Center. On February 23, 2011, the applicant received a certificate of need (Project I.D. # J-8331-09) to acquire one linear accelerator and develop a multidisciplinary prostate health center demonstration project in Raleigh. The applicant’s existing linear accelerator has been operational since May 2013.

In Section IV.2, page 121, Parkway reported that its existing linear accelerator performed 6,911 ESTV’s in the most recent 12-month period, May 1, 2013 – April 30, 2013. However, Parkway’s existing linear accelerator is not listed in the inventory of linear accelerators in Service Area 20. The Proposed 2015 State Medical Plan, Table 9J, states,

“A certificate of need was issued to Parkway Urology, PA d/b/a Cary Urology, PA on 2/23/2011 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 following table shows the utilization of the existing linear accelerators in Service Area 20, Franklin and Wake counties, in FY2013.

**Service Area 20 – Franklin and Wake Counties
 Linear Accelerators and Radiation Oncology Procedures**

Facility Name	County	Number of	Number of	Average
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		Linear Accelerators	Procedures (ESTVs) 10/1/2012 – 9/30/2013	Number of Procedures Per Unit
Franklin County Cancer Center	Franklin	1	115	115
Cancer Centers of North Carolina	Wake	3	15,429	5,143
Duke Raleigh Hospital	Wake	1	9,526	9,526
Rex Hospital	Wake	4	18,118	4,530

Source: Proposed 2015 State Medical Facilities Plan, Table 9G.

As shown in the table above, only one provider, Duke Raleigh Hospital, reported that their existing linear accelerators performed an average of more than 6,750 ESTV’s per unit in FY2013. In Section III.6(b), page 99, the applicant states

“Although existing providers provide high quality service with good equipment, no current provider of linear accelerator services in the proposed service area offers the disease-specific dedicated services of The Prostate Health Center. The proposed project involves addition of a linear accelerator to the existing program of total care for prostate cancers at The Prostate Health Center, as part of a model multidisciplinary demonstration project. Radiation treatment is largely an outpatient service; hence organization of care conferences around specific diseases requires an intentional effort on the part of the providers. It requires an accessible location, a care delivery structure that supports collaborative care protocol development and sufficient organized volume to support a single disease-focused tumor board. These are very difficult to accomplish in a generalized radiation treatment linear accelerator service. The Prostate Health Center will be starting the tumor board, now that it is building a steady case load.

Because of the high risk of harmful side effects of treatments and the related compromises in quality of life associated with those side effects, patients who have prostate cancer particularly need structured multidisciplinary care. Estimates of incidence of new cases of these cancers in the service area are more than sufficient to justify and support such a focused program. The applicant is not aware that any of the existing or proposed linear accelerators are equipped with Rapid Arc technology. The Prostate Health Center is the only center in the service area organized around this service.”

However, the 2014 SMFP does not include a need determination for any additional dedicated linear accelerators to be part of the 2009 demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer. Consequently, the applicant did not adequately demonstrate the proposed project would not result in the unnecessary duplication of existing or approved linear accelerators as part of a model multidisciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men. Therefore, the application is not conforming with this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.1, pages 155-160, Parkway provides the current (CY2014) and proposed Year 2 (CY2017) staffing for TPHC, as shown below in the table.

Position	Current Staffing	Proposed Staffing Year 2
Administrator	1.25	1.0
Assistant Administrator	1.0	1.0
Chief Radiation Technologist	1.0	1.0
Radiation Technologists	2.0	5.0
Dosimetrist	1.0	2.0
Registered Nurse	0.0	1.0
Medical Assistant	1.0	1.0
Physicist	Contract	Contract
Dieticians	Contract	Contract
Support Coordinator	1.0	1.0
Billing/Coding Specialist	1.0	2.0
Reception/Clerical	1.9	2.4
TOTAL	11.15	17.4

Source: Table VII.1, pages 155-160.

In Section VII.3, page 162, the applicant states it proposes to add 6.25 full-time equivalent (FTE) positions as part of the proposed project. In Section VII.3, page 162, and Section VII.6, page 166, the applicant describes its recruitment and retention procedures, and indicates that it does not anticipate any difficulties identifying, hiring, and retaining qualified staff for the proposed project. In Section VII.8, page 167, the applicant identifies John Leung, M.D. as the Medical Director. Exhibit 11 contains a copy of a letter from Dr. Leung expressing his support for the project and willingness to continue to provide professional services to TPHC. Exhibit 43 of the application contains copies of letters from area physicians and surgeons expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section II.2, pages 34-35, and Exhibit 3, the applicant documents that all of the necessary ancillary and support services for the proposed services will be provided by the applicant or through arrangements with another provider. Exhibits 16, 17, and 18 contains copies of letters of interest and service agreements between TPHC and providers of pharmacy, laboratory, pathology, social work, physical therapy, and dietician services. Exhibit 18 contains a letter from WakeMed expressing its willingness to enter into a transfer agreement between the hospital and TPHC. Exhibit 43 contains copies of letters from physicians and surgeons expressing support for the proposed project. The applicant adequately demonstrates that necessary ancillary and support services will be available and that the proposed project will be coordinated with the existing health care system. Therefore, the application is conforming with this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to locate the second linear accelerator in a 1,088 square foot addition to the existing TPHC facility. Exhibit 25 of the application contains a copy of a letter from an architect which projects the site preparation costs for the proposed addition will be \$10,000 and construction costs for the addition will be \$820,000, which is consistent with the capital cost projections provided by the applicant in Section VIII.1, pages 172-173. [Note: The applicant identifies site costs as \$10,500, rather than \$10,000, on page 172.]

In Section XI.7, page 187, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding Policy GEN-4 found in Criterion (4) is incorporated herein by reference.

The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, that the construction project will not unduly increase costs and charges for health services, and that applicable energy saving features have been incorporated into the construction plans. Therefore, the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.12, page 151 the applicant reports the payer mix for TPHC for the last year (May 2013 – April 2014), which is summarized in the following table:

TPHC Payer Category	2013-2014 Procedures as % of Total
Self Pay/Indigent	1.30%
Medicare	59.03%
Medicaid	0.46%
Commercial Insurance/Managed Care	11.90%
Other (BCBS/Other)	27.31%
Total	100.0%

With regard to the percentage of procedures provided to Medicaid recipients, the applicant states

“The 2009 CON application overestimated the percentage of men who would be eligible for Medicaid. First, North Carolina did not adopt Medicaid expansion. Remaining traditional Medicaid eligibility is determined by a number of social-economic factors. ... The applicant now realizes that less than three percent of Medicaid eligibles would be candidates for The Prostate Health Center services. This was determined by examining the number of state Medicaid eligibles by category, and excluding those who would not seek treatment for prostate or male genitourinary cancer. The remaining eligibles include men between the ages of 21 and 64, who are blind, have refugee or alien status or are possibly included in the Medicaid expansion for low income families, MCHIP. However, MCHIP includes children and women, so a large proportion of MCHIP would not be treated at The Prostate Health Center.”

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available.

County	Total # of Medicaid Eligibles as % of Total Population June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Wake	10%	3.3%	18.4%
Statewide	17%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the linear accelerator services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 151 the applicant states:

“The applicant does not have any obligation to provide uncompensated care under Federal regulations. Nonetheless, The Prostate Health Center provides substantial amounts of uncompensated care and community service. As indicated in Section VI.2, The Prostate Health Center ensures access to services by minorities and handicapped persons.”

In Section VI.10 (a), page 150, the applicant states that no Office of Civil Rights complaints have been filed against it in last five years. The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.14, page 153, the applicant provides the projected payer mix for the second full fiscal year of operation (CY2017) for TPHC, as shown in the table below.

TPHC Payer Category	CY2017 Procedures as % of Total
Self Pay/Indigent	1.30%
Medicare	59.03%
Medicaid	0.46%

Commercial Insurance/Managed Care	11.90%
Other (BCBS/Other)	27.31%
Total	100.0%

On page 154, the applicant states, “Payor mix is based on current Prostate Health Center data and is projected to remain constant through 2017.” With regard to the percentage of procedures to be provided to Medicaid recipients, the applicant states

“The 2009 CON application overestimated the percentage of men who would be eligible for Medicaid. First, North Carolina did not adopt Medicaid expansion. Remaining traditional Medicaid eligibility is determined by a number of social-economic factors. ... The applicant now realizes that less than three percent of Medicaid eligibles would be candidates for The Prostate Health Center services. This was determined by examining the number of state Medicaid eligibles by category, and excluding those who would not seek treatment for prostate or male genitourinary cancer. The remaining eligibles include men between the ages of 21 and 64, who are blind, have refugee or alien status or are possibly included in the Medicaid expansion for low income families, MCHIP. However, MCHIP includes children and women, so a large proportion of MCHIP would not be treated at The Prostate Health Center.”

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9(a), page 149, the applicant describes the range of means by which a person will have access to the proposed services. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1 of the application, the applicant states it has contacted several area health professional training programs, and that TPHC will continue to be available as a clinical training site to those programs. Exhibit 42 contains copies of letters to several health professional training programs, including University of North Carolina-Chapel Hill, Duke University, Wake Forest University and East Carolina University. The information provided

in Section V.1 is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

NC

Parkway proposes to acquire a second linear accelerator to be located in a 1,088 square foot addition to its existing facility, The Prostate Health Center. On February 23, 2011, the applicant received a certificate of need (Project I.D. # J-8331-09) to acquire one linear accelerator and develop a multidisciplinary prostate health center demonstration project in Raleigh.

In Section V.7, pages 139-140, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed linear accelerator services. The applicant states,

“The proposed project will foster competition in the service area by offering additional linear accelerator services from a provider that is experienced in and focused on the treatment of prostate and related urological cancers. ... The proposed project will add to the cost effectiveness of the investment made to date in The Prostate Health Center. It will make more efficient use of the simulator, the support facilities, the teleconference, and the shared electronic records already available. It will make it possible for The Prostate Health Center to respond to increasing demand for services and to meet more of the need for which the statewide model demonstration project was intended. The project makes use of existing staff and facilities, so capital and labor investments required for the project will be lower than for a new facility....

The Prostate Health Center provides a competitive alternative to residents of the service area. It offers access to comprehensive prostate cancer treatment services in one convenient location, allowing patients to continue to deal with familiar physicians, technologists, therapist and office staff throughout their treatment and follow-up care. The Center has a reasonable charity policy that assures that patients in need face minimal financial obstacles to needed care. The Prostate Health Center has developed

written strategies with specific activities designed to assure services will be accessible by indigent patients without regard to ability to pay.”

In Section III.6(b), page 99, the applicant states

“Although existing providers provide high quality service with good equipment, no current provider of linear accelerator services in the proposed service area offers the disease-specific dedicated services of The Prostate Health Center. The proposed project involves addition of a linear accelerator to the existing program of total care for prostate cancers at The Prostate Health Center, as part of a model multidisciplinary demonstration project. Radiation treatment is largely an outpatient service; hence organization of care conferences around specific diseases requires an intentional effort on the part of the providers. It requires an accessible location, a care delivery structure that supports collaborative care protocol development and sufficient organized volume to support a single disease-focused tumor board. These are very difficult to accomplish in a generalized radiation treatment linear accelerator service. The Prostate Health Center will be starting the tumor board, now that it is building a steady case load.

Because of the high risk of harmful side effects of treatments and the related compromises in quality of life associated with those side effects, patients who have prostate cancer particularly need structured multidisciplinary care. Estimates of incidence of new cases of these cancers in the service area are more than sufficient to justify and support such a focused program. The applicant is not aware that any of the existing or proposed linear accelerators are equipped with Rapid Arc technology. The Prostate Health Center is the only center in the service area organized around this service.”

However, the 2014 SMFP does not include a need determination for any additional dedicated linear accelerators to be part of the 2009 demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer. Consequently, the applicant did not adequately demonstrate how any enhanced competition will have a positive impact on the cost-effectiveness of the proposed services. Therefore, the application is not conforming with this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

NA

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and

may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

SECTION .1900 – CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT

10A NCAC 14C .1902 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire radiation therapy equipment shall use the Acute Care Facility/Medical Equipment application form.

-C- The applicant used the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing to acquire radiation therapy equipment shall provide the following information:

(1) a list of all the radiation therapy equipment to be acquired and documentation of the capabilities and capacities of each item of equipment;

-C- The applicant identified the radiation equipment to be acquired and documented its capabilities in Exhibit 7 of the application. In Section IV.2, page 127, the applicant states, “*The regulatory review criteria set the maximum capacity for the new linear accelerator at 6,750 ESTV.*”

(2) documentation of the purchase price and fair market value of each piece of radiation therapy equipment, each simulator, and any other related equipment proposed to be acquired;

-C- The applicant documented the purchase price of the equipment in Exhibit 7 of the application.

(3) the projected number of patient treatments by intensity modulated radiation treatment (IMRT); stereotactic radiosurgery; simple, intermediate and complex radiation treatments to be performed on each piece of radiation therapy equipment for each of the first three years of operation following the completion of the proposed project and documentation of all assumptions by which utilization is projected;

-C- In Section II.8, page 47, the applicant provided the projected number of patient treatments by type for each of the first three years of operation for both the existing and proposed linear accelerators. The applicant provided its assumptions for the projections in Section IV.1, pages 103-123. The applicant’s projections are summarized in the table below:

Projected Linear Accelerator Utilization by Treatment Type*

Type	Year 1 CY2016	Year 2 CY2017	Year 3 CY2018
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IMRT	10,681	12,214	13,858
Stereotactic Radiosurgery	0	0	0
Simple Radiation	16	18	20
Intermediate Radiation	0	0	0
Complex Radiation	100	114	130
Field Checks	4	6	6

Source: Applicant's Table II.3, page 47.

*Applicant assumes the procedures will be evenly divided between the two units of equipment.

- (4) *documentation that the proposed radiation therapy equipment shall be operational at least seven hours per day, five days a week;*
- C- In Section II.8, page 47, the applicant states TPHC operates from 7:30 a.m. to 5:00 p.m., Monday through Friday.
- (5) *documentation that no more than one simulator is available for every two linear accelerators in the applicant's facility, except that an applicant that has only one linear accelerator may have one simulator;*
- C- In Section II.8, page 47, the applicant states TPHC currently operates one simulator, and does not propose to acquire another simulator as part of this project.
- (6) *documentation that the services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;*
- C- In Section II.8, page 47, the applicant states the existing facility and proposed addition will conform to the requirements of federal, state and local regulatory bodies.
- (7) *the projected total number of radiation treatment patients by county that will be treated in the facility in each of the first three years of operation following completion of the proposed project;*
- C- In Section IV.1, page 115, the applicant provided a table (Table IV.8) showing the projected total number of radiation treatment patients by county to be treated at TPHC in each of the first three years of operation.
- (8) *the projected number of radiation treatment patients that will be treated for palliation in each of the first three years of operation following completion of the proposed project; and*
- C- In Section IV.1, page 122, the applicant provided a table (Table IV.15) showing the projected total number of radiation treatment patients that will be treated for palliation at TPHC in each of the first three years of operation.
- (9) *the projected number of radiation treatment patients that will be treated for cure in each of the first three years of operation following completion of the proposed project.*

-C- In Section IV.1, page 122, the applicant provided a table (Table IV.15) showing the projected total number of radiation treatment patients that will be treated for cure at TPHC in each of the first three years of operation.

(c) An applicant proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan shall provide the following information:

- (1) description of all services to be provided by the proposed multidisciplinary prostate health center, including a description of each of the following services:
 - (A) urology services,*
 - (B) medical oncology services,*
 - (C) biofeedback therapy,*
 - (D) chemotherapy,*
 - (E) brachytherapy, and*
 - (F) living skills counseling and therapy;**
- (2) documentation that urology services, medical and radiation oncology services, biofeedback therapy, brachytherapy and post-treatment living skills counseling and therapy will be provided in the same building;*
- (3) description of any services that will be provided by other facilities or in different buildings;*
- (4) demographics of the population in the county in which the proposed multidisciplinary prostate health center will be located, including:
 - (A) percentage of the population in the county that is African American,*
 - (B) the percentage of the population in the county that is male,*
 - (C) the percentage of the population in the county that is African American male,*
 - (D) the incidence of prostate cancer for the African American male population in the county, and*
 - (E) the mortality rate from prostate cancer for the African American male population in the county;**
- (5) documentation that the proposed center is located within walking distance of an established bus route and within five miles of a minority community;*
- (6) documentation that the multiple medical disciplines in the center will collaborate to create and maintain a single or common medical record for each patient and conduct multidisciplinary conferences regarding each patient's treatment and follow-up care;*
- (7) documentation that the center will establish its own prostate/urological cancer tumor board for review of cases;*
- (8) copy of the center's written policies that prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay;*
- (9) copy of written strategies and activities the center will follow to assure its services will be accessible by patients without regard to their ability to pay;*
- (10) description of the center's outreach activities and the manner in which they complement existing outreach initiatives;*
- (11) documentation of number and type of clinics to be conducted to screen patients at risk for prostate cancer;*

- (12) *written description of patient selection criteria, including referral arrangements for high-risk patients;*
- (13) *commitment to prepare an annual report at the end of each of the first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that shall include:*
 - (A) *the total number of patients treated;*
 - (B) *the number of African American persons treated;*
 - (C) *the number of persons in other minority populations treated; and*
 - (D) *the number of insured, underinsured and uninsured patients served by type of payment category;*
- (14) *documentation of arrangements made with a third party researcher to evaluate, during the fourth operating year of the center, the efficacy of the clinical and outreach initiatives on prostate and urological cancer treatment, and develop recommendations regarding the advantages and disadvantages of replicating the project in other areas of the State. The results of the evaluation and recommendations shall be submitted in a report to the Medical Facilities Planning Section and Certificate of Need Section in the first quarter of the fifth operating year of the demonstration project; and*
- (15) *if the third party researcher is not a historically black university, document the reasons for using a different researcher for the project.*

-NA- The applicant is not proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the 2014 SMFP.

10A NCAC 14C .1903 PERFORMANCE STANDARDS

- (a) *An applicant proposing to acquire a linear accelerator shall demonstrate that each of the following standards will be met:*
 - (1) *an applicant's existing linear accelerators located in the proposed radiation therapy service area performed at least 6,750 ESTV treatments per machine or served at least 250 patients per machine in the twelve months prior to the date the application was submitted;*
- C- In Section II.8, page 59, the applicant reports the existing TPHC linear accelerator performed 7,314 ESTV treatments during the period from June 1, 2013 to May 31, 2014.
 - (2) *each proposed new linear accelerator will be utilized at an annual rate of 250 patients or 6,750 ESTV treatments during the third year of operation of the new equipment; and*
- C- In Section IV.1(d), page 121, the applicant projects the new linear accelerator will perform 6,927 ESTV treatments during the third year of operation (CY2018).
 - (3) *an applicant's existing linear accelerators located in the proposed radiation therapy service area are projected to be utilized at an annual rate of 6,750 ESTV treatments or 250 patients per machine during the third year of operation of the new equipment.*

- C- In Section IV.1(d), page 121, the applicant projects its existing linear accelerator will perform 6,927 ESTV treatments during the third year of operation (CY2018).
- (b) *A linear accelerator shall not be held to the standards in Paragraph (a) of this Rule if the applicant provides documentation that the linear accelerator has been or will be used exclusively for clinical research and teaching.*
- NA- In Section II.8, page 60, the applicant states the linear accelerator will not be used exclusively for clinical research and teaching.
- (c) *An applicant proposing to acquire radiation therapy equipment other than a linear accelerator shall provide the following information:*
 - (1) *the number of patients that are projected to receive treatment from the proposed radiation therapy equipment, classified by type of equipment, diagnosis, treatment procedure, and county of residence; and*
 - (2) *the maximum number and type of procedures that the proposed equipment is capable of performing.*
- NA- In Section II.8, page 60, the applicant states it is not proposing to acquire radiation therapy equipment other than the proposed linear accelerator.
- (d) *The applicant shall document all assumptions and provide data supporting the methodology used to determine projected utilization as required in this Rule.*
- C- In Section IV.1(d), pages 103-123, the applicant documents its assumptions and provides data supporting the methodology used to determine its utilization projections. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

10A NCAC 14C .1904 SUPPORT SERVICES

- (a) *An applicant proposing to acquire radiation therapy equipment shall document that the following items shall be available; and if any item shall not be available, the applicant shall provide substantive information obviating the need for that item:*
 - (1) *an organized program of radiation therapy continuing education for radiation therapists, technologists and medical staff;*
- C- In Section II.8, page 62, and Exhibits 7 and 19, the applicant provides documentation regarding its program of continuing education.
 - (2) *a program for the collection of utilization data relative to the applicant's provision of radiation therapy services;*
- C- In Section II.8, page 62, the applicant states that it has a program for the collection of utilization data.
 - (3) *medical laboratory services;*

-C- In Section II.8, page 62, the applicant states that it has agreements with LabCorp and WakeMed for the provision of medical laboratory services. Exhibit 17 contains a copy of an agreement between TPHC and LabCorp, and Exhibit 18 contains a copy of a letter from WakeMed expressing its intention to provide medical laboratory services to TPHC.

(4) *pathology services; and*

-C- In Section II.8, page 63, the applicant states that it has an agreement with LabCorp for the provision of pathology services. Exhibit 17 contains a copy of an agreement between TPHC and LabCorp.

(5) *pharmaceutical support services.*

-C- In Section II.8, page 63, the applicant states that pharmaceutical support services are provided by local pharmacies, insurance plan pharmacies, and WakeMed. Exhibit 18 contains a copy of a letter from WakeMed expressing its intention to provide pharmacy services to TPHC.

(b) An applicant proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan shall provide a written description of the center's plans and strategies to establish:

(1) *an African American Prostate Cancer Education/Outreach Program that will partner with and complement existing support groups, such as the N.C. Minority Prostate Cancer Awareness Action Team; and*

(2) *an Advisory Board composed of representatives of prostate cancer advocacy groups, prostate cancer patients and survivors that will meet regularly to provide feedback to the center regarding outreach practices which are effective or which need to be changed.*

-NA- The applicant is not proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the 2014 SMFP.

10A NCAC 14C .1905 STAFFING AND STAFF TRAINING

(a) *An applicant proposing to acquire radiation therapy equipment shall document the number and availability of staff or provide evidence that obviates the need for staff in the following areas:*

(1) *Radiation Oncologist;*

-C- In Section II.8, page 65, the applicant states that currently two radiation oncologists provide services at the facility, and a third radiation oncologist has expressed his willingness to provide services. The applicant states a radiation oncologist is on-site at TPHC during the hours of operation. Exhibits 11 and 12 contain copies of letters from the radiation oncologists expressing their willingness to provide services to TPHC.

(2) *Radiation Physicist;*

- C- In Section II.8, page 65, the applicant identifies the radiation physicist that provides services to TPHC. Exhibit 15 contains a letter from the radiation physicist and a copy of an agreement for radiation physics services.

(3) *Dosimetrist or Physics Assistant;*

- C- In Section II.8, page 65, the applicant identifies the dosimetrist that provides services to TPHC. Exhibit 13 contains a letter from the dosimetrist expressing his intention to continue to provide services to TPHC.

(4) *Radiation Therapist;*

- C- In Section II.8, page 66, the applicant states that it currently employs three radiation therapists.

(5) *Radiation-Oncology Administrator;*

- C- In Section II.8, page 66, the applicant states that it currently employs one full-time radiation oncology administrator.

(6) *Registered Nurse or LPN;*

- C- In Section II.8, page 66, the applicant states that currently physicians and medical assistants cover the duties of a registered nurse or LPN, but that it plans to employ one registered nurse as part of the proposed project.

(7) *Physical Therapist;*

- C- In Section II.8, page 66, the applicant states that physical therapy services will be provided by WakeMed. Exhibit 18 contains a copy of a letter from WakeMed expressing its intention to provide physical therapy services to TPHC.

(8) *Dietician;*

- C- In Section II.8, page 66, the applicant states that dietician services will be provided by WakeMed. Exhibit 18 contains a copy of a letter from WakeMed expressing its intention to provide dietician services to TPHC. The applicant also states that an independent dietician is available to TPHC patients.

(9) *Pharmacist;*

- C- In Section II.8, page 66, the applicant states that pharmacist services are provided by local pharmacies, insurance plan pharmacies, and WakeMed. Exhibit 18 contains a copy of a letter from WakeMed expressing its intention to provide pharmacy services to TPHC.

(10) *Social Worker; and*

- C- In Section II.8, page 67, the applicant states, “*The Prostate Health Center has found that its billing staff are effective in the social assistance needed to enroll patients in the State Cancer Control Program and other medical insurance coverage. ... Parkway Urology nurses also work with County Department of Social Services to coordinate additional services its patients may need to support them during the course of their radiation treatment.*” The applicant states that social work services will also be provided by WakeMed. Exhibit 18 contains a copy of a letter from WakeMed expressing its intention to provide social work services to TPHC.

(11) *Maintenance Engineer.*

- C- In Section II.8, page 67, the applicant states, “*The Prostate Health Center will have maintenance contracts on each piece of equipment. It will not need a maintenance engineer. This service will be vendor-provided.*”
- (b) *An applicant proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan shall document that the center will have:*
- (1) *a medical director who is either a urologist certified by the American Board of Urology, a medical oncologist certified by the American Board of Internal Medicine, or a radiation oncologist certified by the American Board of Radiology; and*
 - (2) *a multidisciplinary team consisting of medical oncologists, radiation oncologists, urologists, urologic pharmacologists, pathologists and therapy specialists.*
- NA- The applicant is not proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the 2014 SMFP.