

ATTACHMENT – REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA – Conditional

NC – Nonconforming

NA = Not Applicable

Decision Date: January 28, 2015

Findings Date: January 30, 2015

Project Analyst: Michael J. McKillip

Assistant Chief: Martha J. Frisone

COMPETITIVE REVIEW

Project ID #: J-10318-14

Facility: UNC Hospitals Radiation Oncology, Holly Springs Campus

FID #: 140331

County: Wake

Applicant(s): University of North Carolina Hospitals at Chapel Hill (UNCH-CH)

Project: Acquire a linear accelerator to be located on Avent Ferry Road in Holly Springs

Project ID #: J-10320-14

Facility: The Prostate Health Center (TPHC)

FID #: 090277

County: Wake

Applicant(s): Parkway Urology, PA (Parkway)

Project: Acquire a second linear accelerator to be located at The Prostate Health Center in Raleigh

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.

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The 2014 State Medical Facilities Plan (2014 SMFP) includes a need determination for one linear accelerator for Service Area 20 (Wake and Franklin counties) as a result of a petition for an adjusted need determination. Three applications were submitted to the Certificate of Need Section, each proposing to acquire one linear accelerator to be located in Wake County. However, one of the applicants, Duke Raleigh Hospital, subsequently withdrew its application on January 8, 2015. Therefore, only two applications are considered in this review. However, pursuant to the need determination, only one linear accelerator may be approved in this review for Linear Accelerator Service Area 20. See the Summary following the Comparative Analysis for the decision.

Policy GEN-3 and Policy GEN-4 of the 2014 SMFP are applicable to this review.

Policy GEN-3: Basic Principles, states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

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."

UNCH-CH. University of North Carolina Hospitals at Chapel Hill [**UNCH-CH**] proposes to acquire a linear accelerator to be located in a medical office building on Avent Ferry Road in Holly Springs (Wake County).

Need Determination – UNCH-CH does not propose to acquire more than one linear accelerator in Service Area 20. Therefore, the application is conforming to the 2014 SMFP need determination for one additional linear accelerator in Service Area 20.

Policy GEN-3 – In Section III.2, page 99, UNCH-CH describes how it believes the project conforms with Policy GEN-3. UNCH-CH describes how it believes its proposal would promote safety and quality in Section II.6, pages 37-38, Section II.7, pages 38-40, Exhibits 10-13, and Section V.7, pages 130-132. The information provided by the applicant is reasonable, credible and supports the determination that the applicant's proposal would promote safety and quality.

UNCH-CH describes how it believes its proposal would promote equitable access in Section V.7, pages 130-132, Exhibit 23, and Section VI, pages 134-145. The information provided by the applicant is reasonable, credible and supports the determination that the applicant's proposal would promote equitable access.

UNCH-CH describes how it believes its proposal would maximize health care value for resources expended in Section III.2, page 99, Section V.7, pages 130-132, Section X, pages 163-165, and the applicant's pro forma financial statements, pages 176-186. However, the applicant does not adequately demonstrate that the proposal would maximize health care value for resources expended. The discussions regarding analysis of need, alternatives, and duplication found in Criteria (3), (4) and (6), respectively, are incorporated herein by reference. Therefore, the applicant does not adequately document that its projected volumes incorporate the concept of maximizing healthcare value for resources expended in meeting the need identified in the 2014 SMFP.

Therefore, the application is not consistent with Policy GEN-3.

Policy GEN-4 – The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section III.2, page 100, the applicant states,

“UNC Hospitals will develop and implement an Energy Efficiency and Sustainability plan for the proposed project that conforms to or exceeds the energy efficiency and water conservation standards incorporated in the latest editions of the NC State Building Codes. The plan shall not adversely affect patient or resident health, safety, or infection control.”

The applicant describes the strategies it will employ to improve energy efficiency and conserve water in Section III.2, pages 100-101, and Section XI.7, pages 171-172. The application is consistent with Policy GEN-4.

In summary, the application is consistent with Policy GEN-4 and with the 2014 SMFP need determination for one additional linear accelerator in Service Area 20. However, the application is not consistent with Policy GEN-3. Therefore, the application is not conforming to this criterion.

Parkway. 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 (Wake County).

Need Determination – Parkway does not propose to acquire more than one linear accelerator in Service Area 20. Therefore, the application is conforming to the 2014 SMFP need determination for one additional linear accelerator in Service Area 20.

Policy GEN-3 – In Section III.2, pages 104-106, Parkway describes how it believes the project conforms with Policy GEN-3. Parkway describes how it believes its proposal would promote safety and quality in Section II.6, page 44, Section II.7, pages 45-49, Exhibits 21 and 24, and Section V.7, pages 214-217. The information provided by the applicant is reasonable, credible and supports the determination that the applicant’s proposal will promote safety and quality.

Parkway describes how it believes its proposal would promote equitable access in Section V.7, pages 214-217, Exhibits 33 and 34, and Section VI, pages 219-230. The information provided by the applicant is reasonable, credible and supports the determination that the applicant’s proposal will promote equitable access.

Parkway describes how it believes its proposal would maximize health care value for resources expended in Section III.2, pages 104-106, Section V.7, pages 214-217, Section X, pages 255-258, and the applicant’s pro forma financial statements, pages 268-279. The discussions regarding analysis of need, alternatives, and duplication found in Criteria (3), (4) and (6), respectively, are incorporated herein by reference. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will maximize health care value for resources expended.

Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4 – The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section III.2, page 107, 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 62 for the proposed energy and water conservation plan.”

Exhibit 62 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-3, Policy GEN-4, and with the 2014 SMFP need determination for one additional linear accelerator in Service Area 20. Therefore, the application is conforming to this criterion.

Summary

Both applications are consistent with Policy GEN-4 and with the 2014 SMFP need determination for one additional linear accelerator in Service Area 20. However, UNCH-CH’s application is not consistent with Policy GEN-3. Parkway’s application is consistent with Policy GEN-3. Therefore, only Parkway’s application is conforming to this criterion.

Moreover, the limit on the number of linear accelerators that may be approved in this review is one. Therefore, both applications cannot be approved. See the Summary following the Comparative Analysis for the decision.

- (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.

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UNCH-CH. The applicant proposes to acquire a linear accelerator to be located in a medical office building on Avent Ferry Road in Holly Springs. In Section II.1, page 31-34, the applicant describes the project, which is summarized below:

“In order to ensure that adequate radiation therapy services are available for the residents of southern Wake County and surrounding communities, UNC Hospitals proposes to acquire a linear accelerator in Service Area 20 pursuant to a need determination in the 2014 State Medical Facilities Plan. UNC Hospitals proposes to acquire an Elekta Versa HD linear accelerator which will be developed in Holly Springs. The location of the proposed service will be 781 Avent Ferry Road in 4,165 square feet of leased space on the first floor of a medical office building to be constructed and owned by Duke Realty. ... The proposed project will be provider-based to UNC Hospitals, operated as part of the existing UNC Hospitals Department of Radiation Oncology under the Business Occupancy Exception, as permitted under NCGS 131E-76(3). As such, it will be seamlessly integrated with UNC Hospitals’ existing radiation oncology services....

The location of the proposed hospital-based outpatient linear accelerator will allow UNC Hospitals and Rex Healthcare, facilities operating under the broader UNC Health Care System umbrella, to strengthen their working relationship. The proposed project, which will be located on the same campus as Rex’s existing services, together with a planned medical oncology clinic on the same site, will allow for enhanced coordination of care....

UNC Hospitals does not anticipate needing simulator support at the proposed Holly Springs linear accelerator at this time. Rather, patients will have their initial treatment planning and simulation at either UNC Hospitals or Rex Healthcare, depending on patient convenience and preference....

In addition to the vault for the linear accelerator, the proposed facility includes a waiting area, a sub-waiting room, a dressing room, three exam rooms, physician and administration offices, a staff lounge, a control area, equipment and storage rooms, clean and soiled laundry rooms, a control area [sic], and a nurses station all related to the provision of radiation therapy services, as shown in the proposed line drawings in Exhibit 35.”

Population to be Served

In Section III.5, page 110, the applicant provides projected patient origin for the proposed Holly Springs linear accelerator in the first two years of operation (FY2017-FY2018), as shown in the table below.

**UNCH-CH
Holly Springs Linear Accelerator Services
Projected Patient Origin, FY2017 and FY2018**

County	FY2017 Percent of Total Patients	FY2018 Percent of Total Patients
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Wake	61%	61%
Harnett	28%	28%
Lee	11%	11%
TOTAL	100.0%	100.0%

In Section III.1(b), pages 81-83, the applicant describes its assumptions regarding the patient origin projections. The applicant adequately identified the population proposed to be served.

Analysis of Need

In Section III.1(a) and (b) of the application, the applicant describes the factors which it states support the need for the proposed project, including:

- The adjusted need determination in the 2014 SMFP (pages 59-62).
- The current concentration of linear accelerator capacity in Raleigh and the lack of linear accelerators in southern Wake County, Harnett County or Lee County (pages 62-70).
- The projected population growth and aging in the proposed service area (pages 70-78).

In Section IV.1 of the application, page 118, the applicant provides a table showing the projected utilization for the proposed Holly Springs linear accelerator in the first three years of operation following completion of the project (FY2017-FY2019), which is summarized below.

**UNCH-CH, Holly Springs Linear Accelerator
Projected Linear Accelerator Utilization, FY2017-FY2019**

Year	Patients	ESTV* Procedures	Percent Increase (Patients and ESTVs)	Percent of Minimum Performance Standard**
FY2017 (PY 1)	132	3,321	---	53%
FY2018 (PY 2)	202	5,090	53%	81%
FY2019 (PY 3)	275	6,934	36%	110%

*ESTVs = equivalent simple treatment visits.

**Based on minimum performance standard of 250 patients per linear accelerator per year.

As indicated in the table above, the applicant projects it will perform 6,934 ESTVs on its proposed Holly Springs linear accelerator 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 III.1(b), pages 78-97, the applicant describes its assumptions and methodology for projecting utilization of the proposed Holly Springs linear accelerator. On pages 79-83, the applicant identifies its proposed service area as southern Wake County, Harnett County, and Lee County, as summarized in the following table:

**UNCH-CH, Holly Springs
Linear Accelerator Service Area**

Service Area (Zip Code)
Holly Springs Service Area
Holly Springs (27540)
Apex (27502, 27539)
Fuquay-Varina (27526)
New Hill (27562)
Willow Springs (27592)
Raleigh (27603, 27606)*
Other Counties
Harnett
Lee

Source: Map on page 80.

*Includes those parts of the Raleigh Zip Codes that are within 10 miles of the proposed site.

On page 83, the applicant states:

“In Fiscal Year 2014, UNC Hospitals’ linear accelerators served 249 patients from the Holly Springs Service Area, Harnett County, and Lee County combined, which represented a 38 percent increase over the prior year.

UNC Hospitals’ Linear Accelerator Patients

	<i>FY11</i>	<i>FY12</i>	<i>FY13</i>	<i>FY14[^]</i>	<i>CAGR</i>
<i>Holly Springs Service Area</i>	77	31	39	77	0.0%
<i>Harnett County</i>	42	48	57	78	23.0%
<i>Lee County</i>	80	75	84	93	5.2%
<i>Total</i>	199	154	180	249	7.6%

[^]FY14 estimated based on nine months of data annualized.

Source: UNC Hospitals internal data.

Although the total growth from these areas has exceeded seven percent in the last four years, UNC Hospitals projected future growth by balancing the impact of expanded access through the development of the project in Holly Springs with a conservative approach to future growth. This analysis resulted in growth rates of

2.5 percent, 1.7 percent, and 1.4 percent for Holly Springs Service Area, Harnett County, and Lee County respectively, from the FY 2014 base year, as shown below.

UNC Hospitals' Projected Linear Accelerator Patients

	FY15	FY16	FY17	FY18	FY19	CAGR
<i>Holly Springs Service Area</i>	79	81	83	85	88	2.5%
<i>Harnett County</i>	79	81	82	84	85	1.7%
<i>Lee County</i>	94	96	97	99	100	1.4%

Although the most recent year of growth for the Holly Springs Service Area was nearly 100 percent, the four-year trend has been more modest; however, the proposed location of the linear accelerator will enhance geographic access for those in the Holly Springs Service Area. Thus, for that area, UNC Hospitals projected its future patients to grow at 2.5 percent, which is equal to the projected population growth for that area. For Lee and Harnett counties, UNC Hospitals also projected growth rates equal to their respective projected population growth rates.”

The applicant projects that 50 percent of patients from the Holly Springs Service Area and Harnett County, and 25 percent of the Lee County patients, will be served at the proposed Holly Springs linear accelerator, based on factors such as proximity of the communities to UNC Hospitals in Chapel Hill, and the availability of specialized services such as stereotactic radiosurgery, pediatric services, and irradiation. On page 85, the applicant provides a table showing its projected patients by service area to be served at the proposed Holly Springs linear accelerator in the first three operating years, which is summarized below:

**UNCH-CH, Holly Springs Linear Accelerator
Projected Linear Accelerator Patients by Service Area, FY2017-FY2019**

Service Area	FY2017	FY2018	FY2019
Holly Springs Service Area	42	43	44
Harnett County	41	42	43
Lee County	24	25	25
Total	107	109	111

In addition to linear accelerator patient volume projections above, which are based on service area patients historically served by UNC Hospitals in Chapel Hill, the applicant projects additional new linear accelerator patients at the proposed Holly Springs linear accelerator based on the addition of six Wake County medical oncologists to its medical staff who had previously been on the staff at Cancer Centers of North Carolina (CCNC). On pages 86-90, the applicant describes its assumptions as follows:

“As discussed in Section III.1(a), six former CCNC medical oncologists have decided to join the UNC Health Care System. These physicians have historically referred their patients in need of radiation therapy services to CCNC’s linear accelerators. ... In the future, these six medical oncologists will refer patients in

need of radiation therapy to linear accelerators operated by the UNC Health Care System.

According to CCNC internal data, these six medical oncologists made 278 radiation therapy referrals in FY 2014 YTD annualized. While their referral volume has decreased slightly since its peak in FY 2012, the trend is significantly positive overall.

**Linear Accelerator Referrals
From UNC Health Care System CCNC Medical Oncologists**

	Linear Accelerator Referrals
<i>FY 2010</i>	190
<i>FY 2011</i>	230
<i>FY 2012</i>	325
<i>FY 2013</i>	302
<i>FY 2014^</i>	278
CAGR	10.0%

^FY14 estimated based on 11 months of data annualized.

Source: CCNC internal data.

“...Based on the proposed development of a new linear accelerator facility in Holly Springs within the UNC Health Care System, as proposed in this application, UNC Hospitals expects that patients will seek care at different facilities that they may have historically chosen. With the new affiliation of physicians from CCNC to UNC Health Care System, and the closing of the CCNC practice, those physicians will no longer refer to CCNC, but to the UNC Health Care System. Patients of these physicians that originate from the Holly Springs Service Area, Harnett County, and Lee County are expected to be referred to the proposed facility for care....

...UNC Hospitals estimated the patient origin for the radiation therapy referrals from these physicians by applying the patient origin for their total patient panel to the number of radiation therapy referrals. Based on this approach, UNC Hospitals estimates that the six former CCNC medical oncologists that are newly affiliated with the UNC Health Care System referred 83 patients for radiation therapy in total in FY 2014 from the Holly Springs Service Area, Harnett County, and Lee County.

**Linear Accelerator Referrals
from UNC HCS CCNC Medical Oncologists**

	FY14^
<i>Holly Springs Service Area</i>	60

<i>Harnett County</i>	22
<i>Lee County</i>	1
TOTAL	83

*^FY14 estimated based on 11 months of data annualized.
Source: CCNC internal data.*

In order to estimate projected linear accelerator patients from these areas, UNC Hospitals grew the FY 2014 linear accelerator referrals from the UNC Health Care System CCNC medical oncologists by 2.5 percent, 1.7 percent, and 1.4 percent for Holly Springs Service Area, Harnett County, and Lee County respectively.

***UNC Health Care System CCNC Medical Oncologist
Projected Linear Accelerator Patients***

	FY15	FY16	FY17	FY18	FY19	CAGR
<i>Holly Springs Service Area</i>	62	63	65	66	68	2.5%
<i>Harnett County</i>	22	23	23	23	24	1.7%
<i>Lee County</i>	1	1	1	1	1	1.4%

As noted above, these assumed growth rates are equivalent to the projected population growth rates for each geography....

...UNC Hospitals estimates that 90 percent of the six medical oncologists' linear accelerator patients from these areas would be referred to the Holly Springs linear accelerator. UNC Hospitals believes this estimate is reasonable for numerous reasons. The proposed linear accelerator will be closer to these patients than any other linear accelerator in the UNC Health Care System and for many it will be the closest linear accelerator operated by any provider. As linear accelerator patients receive care on a daily or weekly basis, the convenience of the location is paramount. The linear accelerator patients of these six medical oncologists have historically traveled to CCNC's linear accelerators; thus the proposed location represents a more convenient alternative. ... The following table demonstrates the projected referrals for linear accelerator services at the Holly Springs location based on the historic linear accelerator patient volume from the UNC Health Care System's former CCNC medical oncologists.

***UNC Health Care System CCNC Medical Oncologist
Projected Linear Accelerator Patients
Referred to Holly Springs Location***

	FY17	FY18	FY19
<i>Holly Springs Service Area</i>	58	60	61
<i>Harnett County</i>	21	21	21

<i>Lee County</i>	<i>1</i>	<i>1</i>	<i>1</i>
Total	80	82	83

In addition to linear accelerator patient volume projections above, which are based on service area patients historically served by UNC Hospitals in Chapel Hill, and additional new linear accelerator patients projected based on the addition of six Wake County medical oncologists to its medical staff who had previously been on the staff at CCNC, the applicant projects additional linear accelerator patients at the proposed Holly Springs linear accelerator based on the service area patients historically served by Rex Healthcare. On pages 90-92, the applicant describes its assumptions as follows:

“As noted above, UNC Hospitals expects that patients will seek care at different facilities than they may have historically chosen as a result of the proposed project. As part of the UNC Health Care System, patients that historically were referred to Rex Healthcare for linear accelerator services that originate from the Holly Springs Service Area, Harnett County, and Lee County are expected to be referred to the proposed facility for care. As discussed above, the rationale for the change in this utilization pattern is the reduced travel burden on patients who may be traveling to the facility daily. The development of the proposed facility will reduce patient travel time and promote more time for patients to heal.

In Fiscal Year 2014, Rex Healthcare’s linear accelerators served 79 patients from the Holly Springs Service Area, Harnett County, and Lee County combined, which represented 12 percent of its total linear accelerator patients.

Rex Healthcare Linear Accelerator Patients

	<i>FY 2014</i>	<i>Percent of Total</i>
<i>Holly Springs Service Area</i>	<i>63</i>	<i>9%</i>
<i>Harnett County</i>	<i>13</i>	<i>2%</i>
<i>Lee County</i>	<i>3</i>	<i>0%</i>
<i>Subtotal</i>	<i>79</i>	<i>12%</i>
<i>Other Areas</i>	<i>595</i>	<i>88%</i>
<i>Total Linear Accelerator Patients</i>	<i>674</i>	<i>100%</i>

Source: Rex Healthcare internal data. FY 2014 is based on 11 months of data annualized.

In order to estimate projected Rex linear accelerator patients from these areas, UNC Hospitals grew the FY 2014 volume by 2.5 percent, 1.7 percent, and 1.4 percent for Holly Springs Service Area, Harnett County, and Lee County respectively, using the same rationale described above.

Rex Healthcare Projected Linear Accelerator Patients

	<i>FY15</i>	<i>FY16</i>	<i>FY17</i>	<i>FY18</i>	<i>FY19</i>	<i>CAGR</i>
<i>Holly Springs Service Area</i>	<i>64</i>	<i>66</i>	<i>68</i>	<i>69</i>	<i>71</i>	<i>2.5%</i>

<i>Harnett County</i>	<i>13</i>	<i>14</i>	<i>14</i>	<i>14</i>	<i>14</i>	<i>1.7%</i>
<i>Lee County</i>	<i>3</i>	<i>3</i>	<i>3</i>	<i>3</i>	<i>4</i>	<i>1.4%</i>

As noted above, these assumed growth rates are equivalent to the projected population growth rates for each geography....

...UNC Hospitals estimates that 90 percent of Rex’s linear accelerator patients from these areas would be referred to the Holly Springs linear accelerator. UNC Hospitals believes this estimate is reasonable for the same reason elucidated above in explaining the percent referral estimate for the UNC Health Care System’s former CCNC medical oncologists. The following table demonstrates the projected referrals for linear accelerator services at the Holly Springs location based on Rex’s historic linear accelerator patient volume.

***Projected Rex Linear Accelerator Patients
Referred to Holly Springs Location***

	<i>FY17</i>	<i>FY18</i>	<i>FY19</i>
<i>Holly Springs Service Area</i>	<i>61</i>	<i>62</i>	<i>64</i>
<i>Harnett County</i>	<i>12</i>	<i>13</i>	<i>13</i>
<i>Lee County</i>	<i>3</i>	<i>3</i>	<i>3</i>
<i>Total</i>	<i>76</i>	<i>78</i>	<i>80</i>

The applicant projects a “ramp-up” period during the first two operating years. In the first operating year the applicant assumes that 50 percent of its projected patients will utilize the proposed Holly Springs linear accelerator, and that 75 percent and 100 percent of the projected patients will utilize the proposed Holly Springs linear accelerator in operating years two and three, respectively. The applicant’s total projected linear accelerator patients for the first three operating years is summarized in the table below:

Projected Holly Springs Linear Accelerator Patients by Referral Source

<i>Referral Sources</i>	<i>FY17</i>	<i>FY18</i>	<i>FY19</i>
UNC Hospitals-Chapel Hill	107	109	111
Former CCNC Oncologists	80	82	83
Rex Healthcare	76	78	80
Total Prior to Ramp-up	263	269	275
Ramp-up Percentage	50%	75%	100%
Total Patients to be Served	132	202	275

Source: Table on application page 93.

On pages 94-96, the applicant describes its assumptions regarding the projected number of ESTV procedures per patients as follows:

“In order to project the number of treatments that the proposed linear accelerator will perform, UNC Hospitals considered the historical experience of the linear accelerators at UNC Hospitals, CCNC, and Rex Healthcare. The table [on page 95 of the application] summarizes 2014 licensure data for each operator. ... The proposed facility is expected to offer services similar to CCNC and Rex Healthcare. As such, projected treatments at the proposed facility are based on the average experience of CCNC and Rex Healthcare. The table below shows the average number of treatments by patients for these two facilities and the average experience.

Linear Accelerator Treatments and AFCRs per Patient

	<i>CCNC</i>	<i>Rex Healthcare</i>	<i>Average</i>
<i>Simple, Intermediate, & Complex</i>	16.2	18.8	17.5
<i>Intensity Modulated Radiation Therapy (IMRT)</i>	5.0	6.9	6.0
<i>Additional Field Check Radiographs (AFCRs)</i>	4.0	3.1	3.5

Using the average experience of CCNC and Rex Healthcare, the following number of treatments and AFCRs are projected for the proposed facility based on the projected number of patients determined above. Please note that UNC Hospitals does not assume that patients will have both IMRT and non-IMRT treatments; these calculations are performed simply to determine the appropriate ratio for projecting treatments.

Linear Accelerator Treatments and AFCRs

	<i>Ratio to Patients</i>	<i>FY17</i>	<i>FY18</i>	<i>FY19</i>
<i>Patients</i>		132	202	275
<i>Simple, Intermediate, & Complex</i>	17.5	2,303	3,530	4,809
<i>IMRT</i>	6.0	784	1,202	1,638
<i>Total Treatments</i>	23.5	3,087	4,732	6,447
<i>AFCRs</i>	3.5	467	715	974
<i>ESTVs</i>		3,321	5,090	6,934

As discussed above, the applicant’s utilization projections for the proposed Holly Springs linear are based on historical utilization of linear accelerator services by patients from the proposed service area from three existing referrals sources: UNC Hospitals in Chapel Hill, former CCNC medical oncologists, and Rex Healthcare. The applicant’s assumptions regarding the number linear accelerator treatments and ESTVs per patient are based on the historical experience of CCNC and Rex Healthcare. Exhibit 37 contains letters from physicians and surgeons in the proposed service area expressing support for the proposed

project. The projected utilization of the proposed Holly Springs linear accelerator is based on reasonable and adequately supported assumptions.

Rex Healthcare Linear Accelerators

Rex Healthcare, which is part of the UNC Health Care System, currently operates four linear accelerators in Wake County, including three units located at Rex Hospital and one unit located at Rex Healthcare at Wakefield. See Section I, pages 8-9, 25, 29-30, Section II, pages 31-34, Exhibit 5, Exhibit 7, and Exhibit 32. See also the documents for Rex Hospital, Inc. which show Rex Hospital is part of the UNC Healthcare System along with UNCH-CH. Copies are included in the Staff Notes or Working Papers. In Exhibit 24, the applicant provides utilization projections for the four existing Rex Healthcare linear accelerators through the first three operating years of the project, which is summarized in the following table:

**Rex Healthcare Linear Accelerators
Projected Linear Accelerator Utilization, FY2015-FY2019**

Year	Linear Accelerator Units	Total Linear Accelerator Patients	Patients Per Linear Accelerator	Percent of Minimum Performance Standard**
FY2015	4	972	243	97%
FY2016	4	993	248	99%
FY2017 (PY 1)	4	937	234	94%
FY2018 (PY 2)	4	919	230	92%
FY2019 (PY 3)	4	901	225	90%

*ESTVs = equivalent simple treatment visits.

**Based on minimum performance standard of 250 patients per linear accelerator per year.

As indicated in the table above, the applicant projects Rex Healthcare will serve 901 patients on its four existing linear accelerators in the third operating year following completion of the proposed project, which is below the minimum performance standard of 250 patients required in 10A NCAC 14C .1903(a)(2). The applicant was informed at the pre-application meeting on August 11, 2014 that the Agency considered the four linear accelerators at Rex Hospital to be under the control of the applicant’s parent and that the applicant should provide historical and projected utilization for those units, as utilization of those units would be considered in reviewing its proposal.

In Exhibit 24, pages 566-570, the applicant describes its assumptions and methodology for projecting utilization of the four Rex Healthcare linear accelerators. The applicant states,

“In FY 2014, Rex Healthcare treated 674 linear accelerator patients on its four linear accelerators. Rex Healthcare’s volume has fluctuated from year to year but overall has shown a 0.3 percent growth rate since 2011. Over the past year, linear accelerator patients treated by Rex Healthcare grew by 6.0 percent.

Rex Historical Linear Accelerator Utilization

	<i>Linear Accelerator Patients</i>
<i>FY11</i>	669
<i>FY12</i>	720
<i>FY13</i>	636
<i>FY14*</i>	674
<i>CAGR</i>	<i>0.3%</i>

**FY14 data is based on 11 months annualized.
Source: Rex internal data.*

Conservatively, Rex’s linear accelerator volume is projected to grow into the future at its historical annual growth rate of 0.3 percent, prior to any impact from the proposed Holly Springs linear accelerator. This assumed growth rate is less than the projected population growth of Wake County and less than Rex’s FY13 to FY14 growth of 6.0 percent. The following table shows Rex’s projected volume through FY 2019 prior to the impact of the proposed Holly Springs linear accelerator.

***Rex Projected Linear Accelerator Utilization
Prior to Impact of Holly Springs Linear Accelerator***

	<i>Linear Accelerator Patients</i>
<i>FY15</i>	676
<i>FY16</i>	678
<i>FY17</i>	680
<i>FY18</i>	682
<i>FY19</i>	684
<i>CAGR</i>	<i>0.3%</i>

As discussed above, the applicant assumes some future Rex Healthcare patients will be referred to the proposed Holly Springs linear accelerator. On page 568 of Exhibit 24, the applicant provides the following table showing the effect of that assumption on the projections.

***Rex Projected Linear Accelerator Utilization
After Impact of Holly Springs Linear Accelerator***

	<i>Linear Accelerator Patients Prior to Impact</i>	<i>Referrals to Holly Springs</i>	<i>Rex After Holly Springs Referrals</i>

<i>FY15</i>	676	0	676
<i>FY16</i>	678	0	678
<i>FY17</i>	680	38	642
<i>FY18</i>	682	59	623
<i>FY19</i>	684	80	604

As discussed above, the applicant assumes six former CCNC medical oncologists who are now affiliated with the UNC Health Care System will refer their future linear accelerator patients to UNC Health Care System linear accelerators in Wake County, including the existing Rex Healthcare linear accelerators and the proposed Holly Springs linear accelerator. On page 568 of Exhibit 24, the applicant states,

“In FY 2014, the UNC Health Care System CCNC medical oncologists referred 278 patients to linear accelerators. Since 2011, the referral volume for these six medical oncologists has grown 6.5 percent annually.

***UNC HCS CCNC Medical Oncologists
Historical Linear Accelerator Referrals***

	<i>Linear Accelerator Referrals</i>
<i>FY 2011</i>	230
<i>FY 2012</i>	325
<i>FY 2013</i>	302
<i>FY 2014*</i>	278
<i>CAGR</i>	6.5%

**FY14 data is based on 11 months annualized.*

Source: Rex [sic] internal data.

The applicant assumes that linear accelerator referrals from these six former CCNC medical oncologists will continue to increase at an annual rate of 6.5 percent from FY2014 through FY2019. As discussed above, the applicant assumes some future referrals to linear accelerator services from these physicians will be directed to the proposed Holly Springs facility, and that the remainder will be referred to the four existing Rex Healthcare linear accelerators. On page 569 of Exhibit 24, the applicant provides the following table showing its projections of referrals by these physicians to Holly Springs and the existing Rex Healthcare linear accelerators through the third operating year of the proposed project.

**UNC HCS CCNC Medical Oncologists
Projected Linear Accelerator Referrals by Location**

	Total Linear Accelerator Referrals	Referrals to Holly Springs	Referrals to Rex
<i>FY15</i>	296	0	296
<i>FY16</i>	315	0	315
<i>FY17</i>	336	40	296
<i>FY18</i>	357	61	296
<i>FY19</i>	381	83	297

On page 570 of Exhibit 24, the applicant provides a table showing the total projected linear accelerator patients for the four existing Rex Healthcare linear accelerators through the first three operating years of the project, after adjusting the projection for patients to be referred from Rex Healthcare to the proposed Holly Springs facility, which is shown below:

Rex Projected Linear Accelerator Utilization

Year	Rex After Holly Springs Referrals	UNCHCS CCNC Med Onc Referrals to Rex	Total Rex Patients	Linacs Needed (Patients / 250 per Linac)
<i>FY15</i>	676	296	972	3.9
<i>FY16</i>	678	315	993	4.0
<i>FY17</i>	642	296	937	3.7
<i>FY18</i>	623	296	919	3.7
<i>FY19</i>	604	297	901	3.6

On page 570 of Exhibit 24, the applicant states,

“As the table demonstrates, Rex Healthcare shows a need for four linear accelerators throughout the time period from FY 2015 to FY 2019; in every year, Rex Healthcare patients far exceed the patient-equivalent capacity of three units, 750 patients, based on the assumed capacity of 250 patients per linear accelerator. Given that Rex Healthcare far exceeds the need for three units of equipment, it is clear that its four existing units of equipment are needed.”

On page 571 of Exhibit 24, the applicant provides a table showing its projections of linear accelerator patients at both the proposed Holly Springs facility and the four existing Rex Healthcare through FY2022. The projections for FY2015 to FY2019 are summarized below:

**Projected Linear Accelerator Utilization for Existing Rex Healthcare
Linear Accelerators and the Proposed Holly Springs Linear Accelerator**

Year	Total Rex Healthcare Patients	Total Holly Springs Patients	Total Linear Accelerator Patients	Total Linear Accelerators	Linear Accelerator Patients Per Linear Accelerator	Percent of Minimum Performance Standard*
FY2015	972	0	972	4	243	97%

FY2016	993	0	993	4	248	99%
FY2017 (PY 1)	937	132	1,069	5	214	86%
FY2018 (PY 2)	919	202	1,121	5	224	90%
FY2019 (PY 3)	901	275	1,176	5	235	94%

*Based on minimum performance standard of 250 patients per linear accelerator per year.

As indicated in the table above, the applicant projects the linear accelerators at Rex Healthcare and the proposed Holly Springs facility will serve 1,176 patients, or 235 patients per linear accelerator (1,176 patients / 5 linear accelerators = 235 patients/unit), in the third operating year following completion of the proposed project, which is below the minimum performance standard of 250 patients required by 10A NCAC 14C .1903(a)(2). Also, the applicant reports the four existing linear accelerators at Rex Healthcare served 674 patients, or 169 patients per linear accelerator (674 patients / 4 linear accelerators = 169 patients/unit), in FY2014, which is below the minimum performance standard of 250 patients required by 10A NCAC 14C .1903(a)(1). Therefore, the applicant did not demonstrate the need to acquire a new linear accelerator.

Access

The applicant projects 53.7% of the patients will be covered by Medicare (41.5%) and Medicaid (12.2%). The discussion regarding access found in Criterion (13c) is incorporated herein by reference. The applicant adequately demonstrates the extent to which all residents of the area, including medically underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identified the population to be served and the extent to which all residents of the area, including medically underserved groups, are likely to have access to the proposed services. However, the applicant did not adequately demonstrate the need the population projected to be served has for the proposed project. Therefore, the application is not conforming to this criterion.

Parkway. The applicant proposes to acquire a second linear accelerator to be located in a 1,100 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, page 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 began as a demonstration model multi-disciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men. Approval of this project will enable it to add a second linear accelerator and add services to support treatment of other cancers. The second linear accelerator would increase capacity at The Center and be used to provide treatment for lung, ear, nose and throat, breast, and colorectal cancer, as well as prostate and genitourinary (GU) cancers.

...Approval of the proposed project would result in two linear accelerators at The Prostate Health Center. Approval of this project would replace approval of a request to expand the demonstration capability of The Prostate Health Center by one linear accelerator. That Certificate of Need application [Project I.D. # J-10300-14] was submitted in June 2014. Equipment and accessories proposed in this application include elements that are necessary to treat a wider scope of cancers. ... The project is intended to permit The Prostate Health Center to meet demand for services, and grow to an efficient operating size while continuing with its demonstration mission. The Center may adapt its name, following approval and development of additional cancer capabilities.”

On November 20, 2014, the proposal (Project I.D. J-10300-14) to acquire a second linear accelerator pursuant to the need determination in the 2009 SMFP was denied. That denial is under appeal at OAH as of the date of this decision.

Population to be Served

In Section III.5, page 114, the applicant provides projected patient origin for its linear accelerator services in the first two years of operation (CY2016-CY2017), as shown in the table below.

**Parkway Linear Accelerator Services
Projected Patient Origin, CY2016-CY2017**

County	CY2016 Percent of Total Patients	CY2017 Percent of Total Patients
Wake	57.0%	58.2%
Harnett	9.8%	9.2%
Johnston	9.4%	9.0%
Sampson	6.0%	5.6%
Franklin	3.1%	3.0%
Lee	2.5%	2.4%
Duplin	2.2%	2.2%
Wayne	2.4%	2.4%
Durham	2.9%	3.2%
Other*	4.9%	4.9%

TOTAL	100.0%	100.0%
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*The applicant identifies the counties included in the "Other" category on page 114 of the application.

On page 114, the applicant states, "The service area includes nine counties, the historical origin of the Center's current patients." The applicant adequately identified the population proposed to be served.

Analysis of Need

In Section III.1(a) of the application, the applicant describes the factors which it states supports the need for the proposed project, including:

- The utilization of the applicant's existing linear accelerator (pages 86-88).
- The incidence and prevalence of prostate cancer and other types of cancer (pages 89-94).
- The projected population growth in the proposed service area (pages 95-97).
- The support from referring physicians (page 97).

In Section IV.2 of the application, page 195, the applicant provides a table showing the projected utilization for Parkway's existing and proposed linear accelerators in the first three years of operation following completion of the project (CY2016-CY2018), which is summarized below.

Parkway Linear Accelerator Utilization, CY2016-CY2018

Year	ESTV* Procedures	Percent Increase	ESTVs Per Linear Accelerator	Percent of Minimum Performance Standard**
CY2016 (PY 1)	12,302	---	6,150	91%
CY2017 (PY 2)	13,981	13.6%	6,991	104%
CY2018 (PY 3)	14,481	3.6%	7,241	107%

*ESTVs = equivalent simple treatment visits.

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

As indicated in the table above, the applicant projects it will perform an average of 7,241 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 125-196, 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 service area as Wake, Harnett, Johnston Sampson, Franklin, Lee, Duplin, Wayne, and Durham counties (See pages 125-127). 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 TPHC 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:

**The Prostate Health Center (TPHC) New Patients
as Percent of New Prostate Cancer Cases in 2013**

Service Area County	TPHC Percent of Total New Prostate Cancer Cases
Wake	16.3%
Harnett	28.7%
Johnston	16.7%
Sampson	29.2%
Franklin	11.8%
Lee	9.6%
Duplin	7.0%
Wayne	3.7%
Durham	1.6%

Source: Table IV.6, page 132.

Based on the annual growth rates in new prostate cancer cases by county from 2012 to 2014 as estimated by NCCCR (Table IV.4, page 130), the applicant projects new prostate cancer cases by county for the proposed service area from 2014 through 2018, which is summarized in the table below:

Projected New Prostate Cancer Cases by County

County	2014	2015	2016	2017	2018
Wake	649	659	669	679	690
Harnett	90	91	92	93	94
Johnston	134	135	135	136	136
Sampson	57	57	57	57	57
Franklin	57	57	57	57	57
Lee	51	51	51	51	51
Duplin	56	56	57	57	57
Wayne	104	104	104	104	104
Durham	190	193	195	198	201
TOTAL	1,388	1,402	1,417	1,432	1,447

Source: Table IV.8, page 134 of the application.

The applicant projects market share increases in a range from less than one to three percent per year (Wake County only) for each of the counties in its proposed service area for the years 2014 through 2017, as shown in the table on page 135. The applicant provides adequate support for its projected market shares on pages 135-136 and Exhibit 10. Based on those projected annual increases in market share by county (Table IV.9, page 135), 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.10 – The Prostate Health Center New Cancer Cases as Percent of New Prostate Cancer Cases by County, FY 2014 through FY2018

County	2014	2015	PY 1 2016	PY 2 2017	PY 3 2018
<i>Wake</i>	16.8%	19.8%	22.8%	25.8%	25.8%
<i>Harnett</i>	28.7%	29.7%	30.7%	31.7%	31.7%
<i>Johnston</i>	16.7%	17.7%	18.7%	19.7%	19.7%
<i>Sampson</i>	29.2%	29.2%	30.2%	31.2%	31.2%
<i>Franklin</i>	11.8%	12.8%	13.8%	14.8%	14.8%
<i>Lee</i>	9.6%	10.6%	11.6%	12.6%	12.6%
<i>Duplin</i>	7.0%	7.0%	8.5%	9.5%	9.5%
<i>Wayne</i>	3.7%	4.2%	5.2%	6.2%	6.2%
<i>Durham</i>	1.6%	2.1%	3.1%	4.1%	4.1%

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 IV.8, page 134). 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	109	130	152	175	178
Harnett	26	27	28	30	30
Johnston	22	24	25	27	27
Sampson	17	17	17	18	18
Franklin	7	7	8	8	8
Lee	5	5	6	6	6
Duplin	4	4	5	5	5
Wayne	4	4	5	6	6
Durham	3	4	6	8	8
TOTAL*	196	223	253	284	287

Source: Table IV.11, page 137 of the application.

*Applicant states total may not foot due to rounding.

On pages 138-145, the applicant describes a similar process for projecting breast cancer cases to be treated with external beam radiation treatment (EBRT) at TPHC. Specifically, the applicant projects total new breast cancer cases by county based on the NCCCR data (Tables IV.12 and IV.13, pages 138-139), then projects the total new breast cancer cases that will require EBRT (Tables IV.15-IV.20, page 140-143), which results in the applicant's projection of breast cancer cases requiring EBRT by county, as summarized below:

Projected Breast Cancer Cases Requiring EBRT by County

County	2014	2015	2016	2017	2018
Wake	476	498	521	545	570
Harnett	60	62	64	67	69
Johnston	92	94	97	99	101
Sampson	38	39	40	41	43
Franklin	36	37	38	38	39
Lee	34	35	37	38	39
Duplin	35	36	37	38	39
Wayne	70	74	79	84	89
Durham	144	151	158	166	173
Total Cases	986	1,027	1,070	1,115	1,162

Source: Table IV.21, page 144 of the application.

The applicant projects it will have a 2.5 percent market share for all of counties in the service area except Wayne and Durham, for which it projects a one percent market share, in each of the first three operating years. The applicant provides adequate support for its projected market shares on page 144 and Exhibit 10. Based on those market share projections, the applicant projects it will treat the following number of breast cancer cases in the first three operating years:

Projected TPHC Breast Cancer Cases by County

County	2014	2015	2016	2017	2018
Wake	0	0	13	14	14
Harnett	0	0	2	2	2
Johnston	0	0	2	2	3
Sampson	0	0	1	1	1
Franklin	0	0	1	1	1
Lee	0	0	1	1	1
Duplin	0	0	1	1	1
Wayne	0	0	1	1	1
Durham	0	0	2	2	2
Total Cases*	0	0	23	24	25

Source: Table IV.23, page 145 of the application.

*Applicant states totals may not foot due to rounding.

On pages 146-145, the applicant describes a similar process for projecting lung cancer cases to be treated with EBRT at TPHC. Specifically, the applicant projects total new lung cancer cases by county based on the NCCCR data (Tables IV.24 and IV.25, pages 146-147), then projects the total new lung cancer cases that will require EBRT (Tables IV.26-IV.33, pages 148-152), which results in the applicant's projection of lung cancer cases requiring EBRT by county, as summarized below:

Projected Lung Cancer Cases Requiring EBRT by County

County	2014	2015	2016	2017	2018
Wake	265	272	280	288	296
Harnett	37	38	38	39	40
Johnston	55	55	55	56	56
Sampson	24	24	24	24	25
Franklin	23	23	23	23	23
Lee	21	21	21	20	20
Duplin	23	24	24	25	25
Wayne	44	44	45	45	46
Durham	81	83	85	87	90
Total Cases*	573	584	596	608	620

Source: Table IV.34, page 152 of the application.

*Applicant states totals may not foot due to rounding.

The applicant projects it will have a five percent market share in Wake County in each of the first three operating years, and a 2.5 percent market share for all of the remaining counties in the service area except Wayne and Durham, for which it projects a one percent market share over that time period. The applicant provides adequate support for its projected market shares on page 153 and Exhibit 10. Based on those market share projections, the applicant projects it will treat the following number of lung cancer cases in the first three operating years:

Projected TPHC Lung Cancer Cases by County

County	2014	2015	2016	2017	2018
Wake	0	0	14	14	15
Harnett	0	0	1	1	1
Johnston	0	0	1	1	1
Sampson	0	0	1	1	1
Franklin	0	0	1	1	1
Lee	0	0	1	1	0
Duplin	0	0	1	1	1
Wayne	0	0	0	0	0
Durham	0	0	1	1	1
Total Cases*	0	0	20	20	21

Source: Table IV.36, page 154 of the application.

*Applicant states totals may not foot due to rounding.

On pages 155-170, the applicant describes a similar process for projecting colorectal cancer cases to be treated with EBRT at TPHC. Specifically, the applicant projects total new colorectal cancer cases by county based on the NCCCR data (Tables IV.37 and IV.38, pages 155-156), then projects the total new colorectal cancer cases that will require EBRT (Tables IV.39-IV.60, pages 157-167), which results in the applicant's projection of colorectal cancer cases requiring EBRT by county, as summarized below:

Projected Colorectal Cancer Cases Requiring EBRT by County

County	2014	2015	2016	2017	2018
Wake	86	85	85	85	84
Harnett	11	11	11	11	11
Johnston	17	17	16	16	15
Sampson	8	7	7	7	7
Franklin	7	7	7	6	6
Lee	7	6	6	6	6
Duplin	7	7	7	6	6
Wayne	14	13	13	13	12
Durham	26	26	26	26	26
Total Cases	182	180	178	176	174

Source: Table IV.61, page 168 of the application.

The applicant projects it will have a five percent market share in Wake County, a four percent market share for Wayne County, and a two percent market share for Durham County, in each of the first three operating years. The applicant provides adequate support for its projected market shares on page 169 and Exhibit 10. Based on those market share projections, the applicant projects it will treat the following number of lung cancer cases in the first three operating years:

Projected TPHC Colorectal Cancer Cases by County

County	2014	2015	2016	2017	2018
Wake	0	0	4	4	4
Harnett	0	0	1	1	1
Johnston	0	0	1	1	1
Sampson	0	0	0	0	0
Franklin	0	0	0	0	0
Lee	0	0	0	0	0
Duplin	0	0	0	0	0
Wayne	0	0	1	1	0
Durham	0	0	1	1	1
Total Cases*	0	0	8	8	8

Source: Table IV.36, page 154 of the application.
*Applicant states totals may not foot due to rounding.

On pages 171-175, the applicant describes a similar process for projecting ENT (“*mouth, oral cavity, esophagus, and larynx*”) cancer cases to be treated with EBRT at TPHC. Specifically, the applicant projects total new ENT cancer cases by county based on the NCCCR data (Tables IV.64 and IV.65, pages 171-172). The applicant projects it will have a five percent market share in Wake County, a four percent market share for Wayne County, and a two percent market share for Durham County, in each of the first three operating years. The applicant provides adequate support for its projected market shares on page 173 and Exhibit 10. Based on those market share projections, the applicant projects it will treat the following number of ENT cancer cases with EBRT in the first three operating years:

Projected TPHC ENT Cancer Cases by County

County	2014	2015	2016	2017	2018
Wake	0	0	6	6	6
Harnett	0	0	1	1	1
Johnston	0	0	1	1	1
Sampson	0	0	1	1	1
Franklin	0	0	1	1	1
Lee	0	0	1	1	1
Duplin	0	0	1	1	1
Wayne	0	0	1	1	1
Durham	0	0	1	1	1
Total Cases*	0	0	12	12	12

Source: Table IV.68, page 175 of the application.
*Applicant states totals may not foot due to rounding.

On pages 176-180, the applicant describes a similar process for projecting genitourinary (GU) cancer cases to be treated with EBRT at TPHC. Specifically, the applicant projects total new GU cancer cases by county based on the NCCCR data (Tables IV.69 and IV.70, pages 176-177). Based on the TPHC’s experience treating prostate cancer cases, the applicant projects it will have the following market share percentages for new GU cancer cases through the first three operating years:

Projected TPHC Market Shares for New GU Cancer Cases by County

County	2014	2015	2016	2017	2018
Wake	8.1%	8.1%	8.1%	8.1%	8.1%
Harnett	14.4%	14.4%	14.4%	14.4%	14.4%
Johnston	8.4%	8.4%	8.4%	8.4%	8.4%
Sampson	14.6%	14.6%	14.6%	14.6%	14.6%
Franklin	5.9%	5.9%	5.9%	5.9%	5.9%
Lee	4.8%	4.8%	4.8%	4.8%	4.8%
Duplin	3.5%	3.5%	3.5%	3.5%	3.5%
Wayne	1.8%	1.8%	1.8%	1.8%	1.8%
Durham	0.8%	0.8%	0.8%	0.8%	0.8%

Source: Table IV.71, page 178 of the application.

The applicant provides adequate support for its projected market shares on page 178 and Exhibit 10. Based on those market share projections, the applicant projects it will treat the following number of ENT cancer cases with EBRT in the first three operating years:

Projected TPHC GU Cancer Cases by County

County	2014	2015	2016	2017	2018
Wake	5	5	5	6	6
Harnett	1	1	1	1	1
Johnston	1	1	1	1	1
Sampson	1	1	1	1	1
Franklin	0	0	0	0	0
Lee	0	0	0	0	0
Duplin	0	0	0	0	0
Wayne	0	0	0	0	0
Durham	0	0	0	0	0
Total Cases*	9	9	9	10	10

Source: Table IV.68, page 175 of the application.

*Applicant states totals may not foot due to rounding.

On page 180, the applicant provides a table showing the total number of cancer cases by type projected to be treated with the linear accelerators at TPHC through the first three operating years, which is summarized below:

Projected TPHC Linear Accelerator Cases by Cancer Type

Type	2014	2015	2016	2017	2018
Prostate	196	223	253	284	287
Breast	0	0	23	24	25
Lung	0	0	20	20	21
Colorectal	0	0	8	8	8
ENT	0	0	12	12	12
Genitourinary	9	9	9	10	10
Total Cases	205	232	325	358	363

Source: Table IV.74, page 180 of the application.

On pages 181-182, the applicant provides tables showing the projected number of “non-service area cases” and “cases requiring palliation” and adds those projections to the projected linear accelerator cases from the service area counties to calculate total projected linear accelerator cases to be treated at TPHC through the first three operating years, which is summarized in the table below:

Total Projected TPHC Linear Accelerator Cases

	2014	2015	2016	2017	2018
Service Area	205	232	325	358	363
Non-Service Area*	11	12	17	18	19
Palliative**	2	2	12	25	41

Total Cases	218	247	354	401	423
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Source: Table IV.74, page 180 of the application. Applicant states totals may not foot due to rounding.

*The applicant projects that approximately 5 percent of its linear accelerator cases will originate from outside the proposed service area (Table IV.75, page 181).

**The applicant projects that between zero and 15 percent of cancer patients will require palliative care, depending on the cancer type (Tables IV.76 and IV.77, pages 181-182).

The applicant's assumptions regarding projected percentages for each case type by cancer type and the applicant's projected number of linear accelerator treatments by case type are shown in Tables IV.78 and IV.79, pages 183-185, and the total projected linear accelerator treatments by cancer type and case type are shown in the Table IV.80, page 186, which is shown below.

Table IV.80 Linear Accelerator Treatments by Treatment Protocol and Year

Treatment Protocol	2014	2015	2016	2017	2018
<i>Prostate</i>	8,310	9,452	10,724	12,027	12,165
<i>IMRT only</i>	6,213	7,067	8,018	8,992	9,095
<i>EBRT + Surgery Post Op</i>	1,704	1,939	2,200	2,467	2,495
<i>EBRT+Brachy</i>	393	447	507	568	575
<i>Breast</i>	0	0	817	851	885
<i>3D Tangents</i>	0	0	498	518	539
<i>3D Tangents & Supraclav</i>	0	0	121	126	131
<i>IMRT: Tangents w Electron Boost</i>	0	0	199	207	215

<i>Lung</i>	0	0	734	750	768
<i>3D Boost</i>	0	0	561	574	587
<i>IMRT with Boost</i>	0	0	173	177	181
<i>Colorectal</i>	0	0	260	257	254
<i>All</i>	0	0	260	257	254
<i>ENT</i>	0	0	394	406	419
<i>Esophagus</i>	0	0	63	64	66
<i>Head and Neck + Surgery</i>	0	0	215	221	228
<i>Head and Neck Arcs</i>	0	0	117	121	125
<i>Genital/Urinary</i>	277	284	291	299	307
<i>GYN</i>	132	135	139	142	146
<i>Male GU (Non Prostate) Complex</i>	120	123	126	129	133
<i>Male GU (Non Prostate) IMRT</i>	25	26	27	27	28
<i>Palliation</i>	26	29	139	298	492
<i>All</i>	26	29	139	298	492
Total	8,613	9,766	13,360	14,888	15,289

On pages 187-190, the applicant makes adjustments to the projections, including a 5 percent reduction in total projected treatments for “*uncompleted treatment protocols*” and an adjustment for “*treatments not completed within the year of diagnosis.*” On page 190, the applicant provides a table showing the total projected ESTV treatments for the existing and proposed linear accelerator combined in the first three operating years, which is summarized below:

Parkway’s Total Projected ESTV Treatments

	CY2016	CY2017	CY2018
Total ESTV Procedures	12,286	13,946	14,431

Source: Table IV.86, page 190.

On page 195, the applicant provides a table showing the total projected linear accelerator treatments for the existing and proposed linear accelerator in the first three operating years, which is summarized below:

Parkway’s Projected Treatments by Linear Accelerator

	CY2016	CY2017	CY2018
Existing Linear Accelerator	7,243	7,243	7,243
Proposed Linear Accelerator	5,065	6,753	7,238
Total Treatments	12,308	13,981	14,481

Source: Table IV.91, page 195.

On page 196, the applicant states,

“The Trilogy [existing linear accelerator] remains dedicated to a demonstrations function and will have the same distribution of procedures as in the period August 1, 2013 through July 31, 2014. The remaining procedures will be conducted on the second [proposed] linear accelerator.”

As discussed above, the applicant projects new 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 2012 to 2014 or, in some cases, from 2011 to 2014. For prostate cancer cases, the applicant estimated its historical (2014) market shares for new prostate cancer cases by county and projected those forward through 2018. For the other types of cancer cases, the applicant assumes service area market shares for new breast cancer cases from 1.0% to 2.5%, market shares for new lung cancer cases from 1.0% to 5.0%, market shares for new colorectal cancer cases from 2.0% to 5.0%, market shares for new ENT cancer cases from 2.0% to 5.0%, and market shares for new GU cancer cases from 0.8% to 14.4%, in the first three operating years. Based on these assumptions, the applicant projects the total number of new cancer cases that it will treat through the third year of operation of the project. Based on the applicant’s historical experience, and a report from a consulting firm (Exhibit 49), the applicant 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 (2018). Exhibit 10 contains letters from physicians and surgeons in the proposed service area expressing support for the proposed project and their intention to refer patients. The projected utilization of the linear accelerators at Parkway is based on reasonable and adequately supported assumptions. Parkway adequately demonstrates the need for the proposed linear accelerator.

Access

The applicant projects 60.18% of the patients will be covered by Medicare (58.62%) and Medicaid (1.56%). The discussion regarding access found in Criterion (13c) is incorporated herein by reference. The applicant adequately demonstrates the extent to which all residents of the area, including medically underserved groups, are likely to have access to the proposed services.

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 demonstrated the extent to which all residents of the area, including medically 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.

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Parkway

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UNCH-CH. In Section III.3, pages 101-103, the applicant discusses the alternatives considered prior to the submission of this application, which include:

1. Maintaining the status quo, which the applicant rejected because it does not improve accessibility for the residents of the proposed service area who would continue to be required to travel outside their home counties to UNC Hospitals in Chapel Hill.
2. Relocate an existing linear accelerator from Rex Healthcare to Holly Springs, which the applicant rejected because it states the existing linear accelerators at Rex Hospital and Rex Healthcare of Wakefield are needed to meet the projected utilization at those locations, particularly with the addition to UNC Health Care System of the medical oncologists formerly associated with CCNC.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative.

The applicant states that relocating an existing linear accelerator to Holly Springs is not the least costly or most effective alternative to meet the identified need because all of the existing linear accelerators are needed in their current locations based on the projected utilization. However, the applicant does not project sufficient utilization to adequately demonstrate that it requires a fifth linear accelerator for the volume of patients it projects to serve. Specifically, the applicant projects to serve a total of 1,176 patients at all locations (see page 118 and Exhibit 24), which is 235 patients per linear accelerator per year assuming five units ($1,176 / 5 = 235.2$) and 294 patients per linear accelerator per year assuming four units ($1,176 / 4 = 294$).

Assuming the applicant served an average of 294 patients per linear accelerator per year, that would be only 44 more patients per unit per year than the minimum performance threshold of

250 patients per unit per year ($294 - 250 = 44$). The applicant does not provide sufficient information in the application to adequately demonstrate that the four existing units would not be able to serve an average of 294 patients per unit per year.

Furthermore, the application is not conforming with all other statutory and regulatory review criteria, and, thus, cannot be approved. A project that cannot be approved cannot be an effective alternative.

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.

Parkway. In Section III.3, pages 108-112, the applicant discusses the alternatives it considered prior to submitting this application, which include:

1. 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.
2. 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.
3. Restricting services to the treatment of prostate cancer only, which the applicant states was rejected because the treatment model and equipment are well-suited to treat other patients.
4. 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 and cost-effective site for the addition of a second linear accelerator.
5. 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 represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion.

- (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
Both Applicants

UNCH-CH. In Section VIII.1, pages 156-157, the applicant projects the capital cost for the project will be \$4,384,019. In Section VIII.3, the applicant states it will finance the capital costs with accumulated reserves. In Section IX.1, page 162, the applicant projects no start-up expenses or initial operating expenses. In Exhibit 30, the applicant provides an August 13, 2014 letter from the President for UNC Hospitals, which states

“As the President, I am responsible for all operations of UNC Hospital. As such, I am very familiar with the organization’s financial position. The total capital expenditure for this project is estimated to be \$4,384,019. There are no start-up costs related to this project.

This letter is to confirm the availability of funding in excess of \$4,384,019 specifically for use for the capital costs associated with the development of the above referenced project. Attached is a copy of our most recent audited financial statement for the fiscal year ending June 30, 2013. You can find disclosed in the ‘Current Assets’ section of the Statement of Net Assets” in the fiscal year 2013 audited financial statement, listed as line item ‘Cash and Cash Equivalents’ in the statement’s Exhibit A-1, funds in excess of this amount which are available for the project.”

Note: There is a watermark printed on page 162 which consists of the word “draft.” Whether this page is really a draft is unknown to the Agency. It does appear unusual that a new location (not a new service) would have no start-up costs at all (these costs would include inventory, salaries, training, etc.).

Exhibit 31 of the application contains the “*Financial Statement Audit Report*” for the University of North Carolina Hospitals at Chapel Hill for the year ended June 30, 2013, which indicates the applicant had \$142 million in cash and cash equivalents. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the proposal.

In the pro forma financial statements for the Radiation Oncology Services of UNC Hospitals, the applicant projects revenues will exceed expenses in each of the first three full fiscal years, as shown below:

UNC Hospitals, Radiation Oncology Services			
	FY2017	FY2018	FY2019

	Year 1	Year 2	Year 3
Total Revenue	\$38,186,377	\$42,006,174	\$46,185,128
Total Expenses	\$20,043,326	\$21,239,490	\$21,859,380
Net Income (Loss)	\$18,143,052	\$20,766,684	\$24,325,749

Source: Applicant's Form C on page 180 of the application.

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 projected utilization 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.

Parkway. In Section VIII.1, pages 249-250, the applicant projects the capital cost for the project will be \$3,794,262. In Section VIII.3, the applicant states Parkway will finance the capital costs with conventional loans. In Section IX.1, the applicant projects no start-up expenses or initial operating expenses. In Exhibit 53, the applicant provides an August 11, 2014 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 Parkway Urology's TPHC (Form B), the applicant projects revenues will exceed expenses in each of the first three full fiscal years of operations, as shown below:

Parkway Urology, The Prostate Health Center

	CY2016 Year 1	CY2017 Year 2	CY2018 Year 3
Total Revenue	\$7,269,026	\$8,007,455	\$8,006,199
Total Expenses	\$7,203,488	\$7,658,252	\$7,767,589
Net Income (Loss)	\$65,538	\$349,203	\$238,610

Source: Applicant's Form B on page 269 of the application.

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 projected utilization 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.

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Parkway

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The following table shows the utilization of the existing linear accelerators in Service Area 20, which includes Franklin and Wake counties, in FY2013.

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

Facility Name	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2012 – 9/30/2013	Average 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.

*Cancer Centers of North Carolina (CCNC) currently operates only two linear accelerators. CCNC was approved for the third linear accelerator (Project I.D. #J-7941-07), but the project is not yet developed. Moreover, these linear accelerators were acquired by Duke Raleigh Hospital. The existing linear accelerator owned by Parkway is a demonstration project and is not included in the inventory in the SMFP by direction of the SHCC (See page 126 of the 2014 SMFP).

In response to a petition that was approved by the State Health Coordinating Council, the 2014 SMFP identifies a need determination for one additional linear accelerator for Service Area 20.

UNCH-CH. The applicant proposes to acquire a linear accelerator to be located in a medical office building on Avent Ferry Road in Holly Springs (Wake County). The applicant does not propose to acquire more than one additional linear accelerator in Service Area 20. However, the applicant did not adequately demonstrate the need to acquire one additional linear in Wake County. The discussion regarding need found in Criterion (3) is incorporated herein by reference. Therefore, the applicant did not adequately demonstrate that the proposed project will not result in unnecessary duplication of existing or approved linear accelerators. Consequently, the application is not conforming with this criterion.

Parkway. The applicant 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 (Wake County). The applicant does not propose to acquire more than one additional linear accelerator in Service Area 20. The applicant adequately demonstrates the need to acquire one additional linear in Wake County. The discussion regarding need found in Criterion (3) is incorporated herein by reference. Therefore, the applicant adequately demonstrates that the proposed project will not result in unnecessary duplication of existing or approved linear accelerators. Consequently, the application is 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
Both Applicants

UNCH-CH. In Section VII.1, pages 146-147, UNCH-CH provides the current (FY2014) and proposed Year 2 (FY2018) staffing for its radiation oncology services, as shown below in the table.

Position	Current Staffing	Proposed Staffing Year 2
Administrative Support	11.30	12.40
Clinical Support	1.11	1.11
Dosimetrist	6.93	7.48
Nurse	7.46	8.26
Tech	17.32	19.52
Tech Supervisor	1.00	1.00
Physicist	4.23	4.73
Manager	0.48	0.98
TOTAL	49.83	55.48

Source: Table VII.1, pages 146-147.

As shown in the table above, the applicant proposes to add 5.65 full-time equivalent (FTE) positions as part of the proposed project. In Section VII.3, page 148, and Section VII.6, pages 149-150, 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 151, the applicant identifies Lawrence Marks, M.D. as the Medical Director for the proposed project. Exhibit 26 contains a copy of a letter from Dr. Marks expressing his support for the project and willingness to serve as medical director. Exhibit 37 of the application contains copies of letters from 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.

Parkway. In Section VII.1, pages 231-237, 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	1.0	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	1.0	1.0
Medical Assistant	1.0	1.0
Physicist	Contract	Contract
Dieticians	Contract	Contract
Support Coordinator	1.0	1.0
Billing/Coding Specialist	1.2	2.0
Reception/Clerical	1.9	2.4
TOTAL	12.1	17.4

Source: Table VII.1, pages 231-237.

In Section VII.3, page 239, the applicant states it will add 5.6 full-time equivalent (FTE) positions as part of the proposed project. In Section VII.3, page 239, and Section VII.6, page 242, 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 243, the applicant identifies John Leung, M.D. as the Medical Director. Exhibit 12 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 10 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

Both Applicants

UNCH-CH. In Section II.2, page 36, and Exhibits 6 and 7, the applicant documents that all of the necessary ancillary and support services for the proposed services that are not available on-site will be provided by referral to UNC Hospitals or Rex Healthcare. In Section V.2, pages 123-126, the applicant states that, as part of UNCH-CH, no written transfer agreements between the facility and hospitals are necessary, and that UNC Hospitals already has many long-standing referral relationships with physicians and other health care providers. Exhibit 37 contains copies of letters from physician 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.

Parkway. In Section II.2, pages 40-41, and Exhibit 14, 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 17, 18 and 19 contain copies of letters of interest and service agreements between the applicant and providers of medical physics and dosimetry, pharmacy, laboratory, pathology, social work, physical therapy, and dietician services. Exhibit 19 contains a letter from WakeMed expressing its willingness to enter into a transfer agreement between the hospital and TPHC. Exhibit 10 contains copies of letters from physician 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

Both Applicants

UNCH-CH. The applicant proposes to locate the linear accelerator in 4,165 square feet of leased space on the first floor of a medical office building to be constructed by Duke Realty on the same site on which Rex Healthcare is developing its Holly Springs hospital (Project I.D. # J-8669-11). Exhibit 34 of the application contains a copy of a letter from an architect which estimates the up-fit costs for the proposed linear accelerator facility will be \$679,736, which is consistent with the capital cost projections provided by the applicant in Section VIII.1, page 156. In Section XI.7, pages 171-172, 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 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, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

Parkway. The applicant proposes to locate the second linear accelerator in a 1,088 square foot addition to the existing TPHC facility. Exhibit 28 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 249-250. [Note: The applicant identifies site costs as \$10,500, rather than \$10,000, on page 249.] In Section XI.7, page 264, 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 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, and that the construction cost will not unduly increase costs and charges for health services. 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
Both Applicants

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)
Franklin	18%	7.4%	19.7%
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.

UNCH-CH. In Section VI.13, page 142, the applicant reports the payer mix for linear accelerator services at UNC Hospitals for FY2014, which is summarized in the following table:

Linear Accelerator Services at UNCH-CH Payer Category	FY2014 Treatments as % of Total
Self-Pay/Indigent/Charity	7.2%
Medicare/Medicare Managed Care	41.5%
Medicaid	12.2%
Commercial Insurance/Managed Care	0.5%
Managed Care	32.0%
Other Government	6.6%
Total	100.0%

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

Parkway. In the applicant's pro forma financial statements (Form C), page 271, it reports the payer mix for linear accelerator services at TPHC for CY2014, which is summarized in the following table:

Linear Accelerator Services at TPHC Payer Category	CY2014 Procedures as % of Total
Charity Care	3.0%
Self-Pay	1.25%
Medicare	57.67%
Medicaid	0.44%
Commercial Insurance/Managed Care	11.42%
BCBS/Other	26.22%
Total	100.0%

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

Both Applicants

UNCH-CH. 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 141 the applicant states:

“UNC Hospitals has long since satisfied its ‘free care’ obligation under the Hill-Burton Act. Charity care provided by UNC Hospitals for Fiscal Year 2014 is estimated to be \$191 million (15.64 percent of Net Revenue). UNC Hospitals provides care to all persons based only on their need for care, and without regard to minority status or handicap/disability.”

In Section VI.10 (a), page 141, 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.

Parkway. 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 228 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 227, 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

Both Applicants

UNCH-CH. In Section VI.15, page 144, the applicant provides the projected payer mix for the second full fiscal year of operation (FY2018) for UNC Hospitals’ linear accelerator services, as shown in the table below.

UNC Hospitals’ Linear Accelerator Services Payer Category	FY2014 Treatments as % of Total
Self-Pay/Indigent/Charity	7.2%
Medicare/Medicare Managed Care	41.5%
Medicaid	12.2%
Commercial Insurance/Managed Care	0.5%
Managed Care	32.0%
Other Government	6.6%
Total	100.0%

On page 144, the applicant states, “*UNC Hospitals assumes its payor mix for radiation oncology will not change from its historical mix as shown in Section VI.12 [sic].*” The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

Parkway. In Section VI.15, page 230, the applicant provides the projected payer mix for the second full fiscal year of operation (CY2017) for linear accelerator services at TPHC, as shown in the table below.

Linear Accelerator Services at TPHC Payer Category	CY2017 Procedures as % of Total
Charity Care	4.0%
Self-Pay	1.22%
Medicare	58.62%
Medicaid	1.56%
Commercial Insurance/Managed Care	8.41%
BCBS/Other	26.18%
Total	100.0%

On page 230, the applicant states, “*Payor mix is based on current data from The Prostate Health Center, adjusted for the change in cancer types.*” 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

Both Applicants

UNCH-CH. In Section VI.9, page 140, 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.

Parkway. In Section VI.9, page 226, 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

Both Applicants

UNCH-CH. In Section V.1 of the application, the applicant states UNC Hospitals serves as a teaching site for a broad range of healthcare disciplines, and that the proposed project will be available as a clinical training site for health professional training programs. The information provided in Section V.1 is reasonable and credible and supports a finding of conformity to this criterion.

Parkway. 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 39 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, as well as a copy of a letter from a representative of Pitt Community College expressing interest in TPHC as a training site. 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.

C
Parkway

NC
UNCH-CH

The following table shows the utilization of the existing linear accelerators in Service Area 20, which includes Franklin and Wake counties, in FY2013.

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

Facility Name	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2012 – 9/30/2013	Average 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.

*Cancer Centers of North Carolina (CCNC) currently operates only two linear accelerators. CCNC was approved for the third linear accelerator (Project I.D. #J-7941-07), but the project is not yet developed. Moreover, these linear accelerators were acquired by Duke Raleigh Hospital. The existing linear accelerator owned by Parkway is a demonstration project and is not included in the inventory in the SMFP by direction of the SHCC (See page 126 of the 2014 SMFP).

In response to a petition that was approved by the State Health Coordinating Council, the 2014 SMFP identifies a need determination for one additional linear accelerator for Service Area 20.

UNCH-CH

The applicant proposes to acquire a linear accelerator to be located in a medical office building on Avent Ferry Road in Holly Springs. The applicant, UNCH-CH, does not currently operate any linear accelerators in the proposed service area. However, Rex Healthcare, which is part of the UNC Health Care System, operates four linear accelerators in Wake County.

In Section V.7, pages 130-132, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states,

“UNC Hospitals believes that the proposed project may foster some competition in the proposed service area, particularly as the only provider of radiation oncology services in the service area. UNC Hospitals maintains that the development of radiation oncology services in Wake County will promote cost-effectiveness, quality, and access to services in the proposed service area and will thus be in compliance with the spirit and legislative intent of the Certificate of Need Law.

UNC Hospitals, as a member of the larger UNC Health Care System, benefits from the significant cost saving measures through the consolidation of multiple services and large economies of scale. This efficiency results in lower costs that are passed to patients in the form of lower charges. Patients also benefit from the proposed project in terms of reduced out-of-pocket expenses related to traveling, such as gas and parking fees on the larger hospital campus....

UNC Hospitals also believes that the proposed project will promote the provision of quality healthcare services to patients in the service area. UNC Hospitals is known for high quality services and expects the proposed project to expand its radiation oncology program while bolstering its high quality reputation. The location of the proposed hospital-based outpatient linear accelerator alongside Rex’s existing services and a planned medical oncology clinic will allow for enhanced coordination of care....

The proposed project will also promote access to healthcare services in the service area. Given the nature of radiation oncology services, it is of the utmost importance that patients have access to a convenient location where they can receive reliable, continuous care. ... UNC Hospitals has a long and proud history of serving patients who require care, regardless of their ability to pay. ... UNC Hospitals expects that patients with limited financial resources will continue to access its services upon completion of the proposed project.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

However, the applicant did not adequately demonstrate that any enhanced competition in the service area includes a positive impact on cost-effectiveness of the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant did not adequately demonstrate the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

The application is not conforming to this criterion.

Parkway

The applicant 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 214-217, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states,

“The proposed project will foster competition in the service area by promoting cost effectiveness, quality and access. It will offer additional linear accelerator service in a freestanding center that is subject to a lower charge structure; provide a patient treatment program that involves active participation of the referring physician in the care plan; and its location is highly accessible to a broad cross section of the population.

The proposed project will enhance the cost effectiveness of the investment made to date in The Prostate Health Center. With a second linear accelerator, it will have the capacity to make more efficient use of the simulator, the support facilities, the teleconference, and the shared electronic records already available. ... 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 with a single linear accelerator....

The applicant will continue to submit the services of The Prostate Health Center to external quality oversight. ... If approved, the new linear accelerator will be held to those same standards....

Services at The Prostate Health Center have access features that are not found at all other competitors. ... Radiation treatment and most follow up support services are in one convenient location, allowing patients to continue to deal with familiar physicians, technologists, therapists, and office staff throughout their treatment and follow-up care. The access of The Center features can easily expand to other cancers because of the capability of the equipment and staff. ... The Prostate Health Center is located in and near minority communities. The Center has an organized outreach program that was designed in cooperation with local physicians, churches and clinics, and complements the work of the NC Minority Prostate Cancer Awareness Action Team and others to provide minorities with improved awareness of prostate cancer and treatment options. All of this should improve access to the proposed project.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it would continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20), respectively, are incorporated herein by reference.
- The applicant demonstrates it will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1) and (13), respectively, are incorporated herein by reference.

The application is conforming to 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.

C
UNCH-CH

NA
Parkway

UNCH-CH. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on the hospital. Therefore, the application is conforming with this criterion.

- (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
Parkway

NC
UNCH-CH

The application submitted by Parkway is conforming to all applicable Criteria and Standards for Radiation Therapy Equipment. The application submitted by UNCH-CH is not conforming to all applicable Criteria and Standards for Radiation Therapy Equipment. The specific criteria are discussed below.

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- **Both Applicants.** Both applicants 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- **UNCH-CH.** The applicant identified the radiation therapy equipment to be acquired and documented its capabilities in Section II.1 and Exhibit 14 of the application. With regard to the capacity of the equipment, in Section IV.2, page 119, the applicant states, “*The SMFP provides a standard for capacity of linear accelerators.*”

-C- **Parkway.** The applicant identified the radiation therapy equipment to be acquired and documented its capabilities in Exhibit 6 of the application. With regard to the capacity of the equipment, in Section II.8, page 53, the applicant states, “*State-determined capacity is set by regulation and documented in 10NCAC 1903(a)(1).*”

(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- **UNCH-CH.** The applicant documented the purchase price of the equipment in Exhibit 14 of the application.
- C- **Parkway.** The applicant documented the purchase price of the equipment in Exhibit 6 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- **UNCH-CH.** In Section II.8, page 44, the applicant provided the projected number of patient treatments by type for each of the first three years of operation for the proposed linear accelerator. The applicant provided its assumptions for the projections in Section III.1.(b). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant’s projections are summarized in the table below:

Projected Linear Accelerator Utilization by Treatment Type

Treatment Type	Year 1 FY2017	Year 2 FY2018	Year 3 FY2019
Simple, Intermed., Complex	2,303	3,530	4,809
IMRT	784	1,202	1,638
Total Treatments	3,087	4,732	6,447

Source: Application page 44.

- C- **Parkway.** In Section II.8, page 54, 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 of the application. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant’s projections are summarized in the table below:

Projected Linear Accelerator Utilization by Treatment Type

Treatment Type	Year 1 CY2016	Year 2 CY2017	Year 3 CY2018
IMRT	7,177	7,177	7,177
Simple Radiation	10	10	10
Complex Radiation	53	53	53
Field Checks	3	3	3
Subtotal – Existing Equipment	7,243	7,243	7,243
IMRT	3,458	4,781	5,056
Simple Radiation	90	212	362
Complex Radiation	1,475	1,676	1,720
Field Checks	41	66	67
Subtotal – Proposed Equipment	5,064	6,735	7,235

Total Treatments	12,307	13,978	14,478
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Source: Applicant's Table II.3, page 54.

- (4) *documentation that the proposed radiation therapy equipment shall be operational at least seven hours per day, five days a week;*
- C- **UNCH-CH.** In Section II.8, page 44, the applicant states the proposed Holly Springs linear accelerator will operate from 8:00 a.m. to 5:00 p.m., Monday through Friday.
- C- **Parkway.** In Section II.8, page 54, 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- **UNCH-CH.** In Section II.8, page 44, the applicant states UNC Hospitals currently operates five linear accelerators and two simulators, and that no additional simulators are proposed.
- C- **Parkway.** In Section II.8, page 55, 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- **UNCH-CH.** In Section II.8, page 45, the applicant states the proposed facility will conform to the requirements of federal, state and local regulatory bodies.
- C- **Parkway.** In Section II.8, page 55, 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- **UNCH-CH.** In Section II.8, page 45, the applicant provides a table showing the projected total number of radiation treatment patients by county to be treated at the proposed Holly Springs facility in each of the first three years of operation.
- C- **Parkway.** In Section II.8, page 56, the applicant provides a table (Table II.4) 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- **UNCH-CH.** In Section II.8, page 46, the applicant provides a table showing the projected total number of radiation treatment patients that will be treated for palliation at the proposed Holly Springs facility in each of the first three years of operation.
- C- **Parkway.** In Section IV.1, page 182, the applicant provides a table (Table IV.77) 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- **UNCH-CH.** In Section II.8, page 46, the applicant provides a table showing the projected total number of radiation treatment patients that will be treated for cure at the proposed Holly Springs facility in each of the first three years of operation.
- C- **Parkway.** In Section IV.1, page 181, the applicant provided a table (Table IV.75) 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- **Both Applicants.** Neither of the applicants propose 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.

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;*

- NC- **UNCH-CH.** In Section II.8, page 48, the applicant states, “*UNC Hospitals does not have any existing linear accelerators in the service area, which includes Wake and Franklin counties.*” However, Rex Healthcare, which is part of the UNC Health Care System, currently operates four linear accelerators in Wake County. In Table 9G of the Proposed 2015 SMFP, Rex Healthcare reported performing a total of 18,118 ESTV treatments in FY2013, or 4,530 ESTV treatments per linear accelerator (18,118 ESTVs / 4 linear accelerators = 4,530 ESTVs/unit), which is below the minimum performance standard of 6,750 EST treatments required in this Rule. In Exhibit 24, the applicant reports the four existing linear accelerators at Rex Healthcare served 674 patients, or 169 patients per linear accelerator (674 patients / 4 linear accelerators = 169 patients/unit), in FY2014, which is below the minimum performance standard of 250 patients required in this Rule. The application is not conforming with this Rule.

- C- **Parkway.** In Section II.8, page 69, the applicant reports the existing TPHC linear accelerator performed 7,242 ESTV treatments during the period from August 1, 2013 to July 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- **UNCH-CH.** In Section II.8, page 49, the applicant projects the new linear accelerator will perform 6,934 ESTV treatments and treat 275 patients during the third year of operation (FY2019).

- C- **Parkway.** In Section II.8, page 70, the applicant projects the new linear accelerator will perform 7,238 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.*

- NC- **UNCH-CH.** In Section II.8, page 49, the applicant states, “*UNC Hospitals does not have any existing linear accelerators in the service area.*” However, Rex Healthcare, which is part of the UNC Health Care System, currently operates four linear accelerators in Wake County. In Exhibit 24, the applicant projects the four existing linear accelerators at Rex Healthcare will serve 901 patients, or 225 patients per linear accelerator (901 patients / 4 linear accelerators = 225 patients/unit), in the third year of operation of the equipment (FY2019), which is below the minimum performance standard of 250 patients required in this Rule. The application is not conforming with this Rule.
- C- **Parkway.** In Section II.8, page 70, the applicant projects its existing linear accelerator will perform 7,242 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- **Both Applicants.** Neither of the applicants proposes to use the linear accelerator 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- **Both Applicants.** Neither of the applicants is proposing to acquire radiation therapy equipment other than the 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- **UNCH-CH.** In Section III.1(b), pages 78-96, the applicant documents its assumptions and provides data supporting the methodology used to determine its utilization projections. The discussion of projected utilization found in Criterion (3) is incorporated herein by reference.
- C- **Parkway.** In Section IV.1(d), pages 125-196, the applicant documents its assumptions and provides data supporting the methodology used to determine its utilization projections. The discussion of 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- **UNCH-CH.** In Section II.8, pages 50-51, and Exhibit 14, the applicant provides documentation regarding its program of continuing education.

-C- **Parkway.** In Section II.8, page 73, and Exhibits 7 and 21, 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- **UNCH-CH.** In Section II.8, page 51, the applicant states that it has a program for the collection of utilization data.

-C- **Parkway.** In Section II.8, page 73, the applicant states that it has a program for the collection of utilization data.

(3) *medical laboratory services;*

-C- **UNCH-CH.** In Section II.8, pages 51-52, the applicant states UNC Hospitals operates a full service clinical laboratory, and that laboratory services will also be available at Rex Hospital's Holly Springs facility, and other Rex Healthcare facilities. Exhibits 6 and 7 contain copies of letters from representatives of UNC Hospitals and Rex Healthcare stating that all the necessary ancillary and support services will be available either on-site or through referral to UNC Hospitals or Rex Healthcare.

-C- **Parkway.** In Section II.8, page 73, the applicant states that it has agreements with LabCorp and WakeMed for the provision of medical laboratory services. Exhibit 9 contains a copy of an agreement between TPHC and LabCorp, and Exhibit 19 contains a copy of a letter from WakeMed expressing its intention to provide medical laboratory services to TPHC.

(4) *pathology services; and*

-C- **UNCH-CH.** In Section II.8, pages 52-53, the applicant states UNC Hospitals offers a full range of pathology services, and that pathology services will also be available at Rex Hospital's Holly Springs facility, and other Rex Healthcare facilities. Exhibits 6 and 7 contain copies of letters from representatives of UNC Hospitals and Rex Healthcare stating that all the necessary ancillary and support services will be available either on-site or through referral to UNC Hospitals or Rex Healthcare.

-C- **Parkway.** In Section II.8, page 73, the applicant states that it has an agreement with LabCorp for the provision of pathology services. Exhibit 9 contains a copy of an agreement between TPHC and LabCorp.

(5) *pharmaceutical support services.*

- C- **UNCH-CH.** In Section II.8, page 53, the applicant states UNC Hospitals offers a comprehensive pharmaceutical service, and that these services will also be available at Rex Hospital. Exhibits 6 and 7 contain copies of letters from representatives of UNC Hospitals and Rex Healthcare stating that all the necessary ancillary and support services will be available either on-site or through referral to UNC Hospitals or Rex Healthcare.
- C- **Parkway.** In Section II.8, page 74, the applicant states that pharmaceutical support services are provided by local pharmacies, insurance plan pharmacies, and WakeMed. Exhibit 19 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- **Both Applicants.** Neither of the applicants is 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.

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- **UNCH-CH.** In Section II.8, pages 54-55, the applicant states that UNC Hospitals currently employs fifteen radiation oncologists, and that one “*will be staffed to the proposed facility through a rotation schedule.*”
- C- **Parkway.** In Section II.8, page 76, 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 12 and 13 contain copies of letters from the radiation oncologists expressing their willingness to provide services to TPHC.

(2) *Radiation Physicist;*

- C- **UNCH-CH.** In Section II.8, page 55, the applicant states UNC Hospitals employs four radiation physicists that will be available to provide services to the proposed Holly Springs facility.
- C- **Parkway.** In Section II.8, page 76, the applicant identifies the radiation physicist that provides services to TPHC. Exhibit 17 contains a letter from the radiation physicist and a copy of an agreement for radiation physics services.

(3) *Dosimetrist or Physics Assistant;*

- C- **UNCH-CH.** In Section II.8, page 55, the applicant states UNC Hospitals employs 6.93 full-time equivalent (FTE) clinical dosimetrists and will add 1.1 FTE clinical dosimetrists by the third year of operation of the proposed Holly Springs facility.
- C- **Parkway.** In Section II.8, page 76, the applicant identifies the dosimetrist that provides services to TPHC. Exhibit 14 contains a letter from the dosimetrist expressing his intention to continue to provide services to TPHC.

(4) *Radiation Therapist;*

- C- **UNCH-CH.** In Section II.8, page 55, the applicant states UNC Hospitals will employ 2.2 FTE radiation therapists by the third operating year at the proposed Holly Springs facility.
- C- **Parkway.** In Section II.8, page 77, the applicant states that it currently employs three radiation therapists.

(5) *Radiation-Oncology Administrator;*

- C- **UNCH-CH.** In Section II.8, page 56, the applicant states UNC Hospitals will employ 0.5 FTE Patient Services Manager and 1.1 FTE administrative support staff by the third operating year at the proposed Holly Springs facility.
- C- **Parkway.** In Section II.8, page 77, the applicant states that it currently employs one full-time radiation oncology administrator.

(6) *Registered Nurse or LPN;*

- C- **UNCH-CH.** In Section II.8, page 56, the applicant states UNC Hospitals will employ 1.1 FTE registered nurses by the third operating year at the proposed Holly Springs facility.

- C- **Parkway.** In Section II.8, page 77, 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- **UNCH-CH.** In Section II.8, page 56, the applicant states UNC Hospitals will provide physical therapy services through referral to the hospital's physical therapy department.

- C- **Parkway.** In Section II.8, page 77, the applicant states that physical therapy services will be provided by WakeMed or Duke Raleigh Hospital. Exhibit 19 contains a copy of a letter from WakeMed expressing its intention to provide physical therapy services to TPHC.

(8) *Dietician;*

- C- **UNCH-CH.** In Section II.8, page 56, the applicant states UNC Hospitals will provide dietitian services through referral to the hospital's dietary services department.

- C- **Parkway.** In Section II.8, page 77, the applicant states that dietitian services will be provided by WakeMed. Exhibit 19 contains a copy of a letter from WakeMed expressing its intention to provide dietitian services to TPHC. The applicant also states that an independent dietitian is available to TPHC patients.

(9) *Pharmacist;*

- C- **UNCH-CH.** In Section II.8, page 57, the applicant states UNC Hospitals will provide pharmacy services through referral to the hospital's pharmacy department.

- C- **Parkway.** In Section II.8, page 77, the applicant states that pharmacist services are provided by local pharmacies, insurance plan pharmacies, and WakeMed. Exhibit 19 contains a copy of a letter from WakeMed expressing its intention to provide pharmacy services to TPHC.

(10) *Social Worker; and*

- C- **UNCH-CH.** In Section II.8, page 57, the applicant states UNC Hospitals will provide social work services through referral to the hospital's Continuity of Care Department.

- C- **Parkway.** In Section II.8, page 78, the applicant states, "*The Prostate Health Center has found that its billing staff is 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 19 contains a copy of a letter from WakeMed expressing its intention to provide social work services to TPHC.

(11) *Maintenance Engineer.*

- C- **UNCH-CH.** In Section II.8, page 57, the applicant states UNC Hospitals' maintenance engineers will be available to the propose Holly Springs facility.
- C- **Parkway.** In Section II.8, page 78, 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- **Both Applicants.** Neither of the applicants is 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.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2014 SMFP, no more than one new linear accelerator may be approved in this review for one linear accelerator for Linear Accelerator Service Area 20, which includes Franklin and Wake counties. Because each applicant proposes to acquire one linear accelerator, both applications cannot be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals. For the reasons set forth below and in the remainder of the findings, the application submitted by Parkway Urology, PA (Project I.D. #J-10320-14) is approved and the other application is disapproved.

Geographic Accessibility

The 2014 SMFP identifies a need for one additional linear accelerator for Linear Accelerator Service Area 20, which includes Franklin and Wake counties. Both applicants propose to locate the new linear accelerator in Wake County. The following table identifies the location of the existing and approved linear accelerators in Wake County.

Facility	Linear Accelerators	City/Town	Location Within Wake County
Duke Raleigh Hospital	1	Raleigh	Central
Rex Hospital	3	Raleigh	Central
Rex Healthcare at Wakefield	1	Raleigh	Northern
The Prostate Health Center	1	Raleigh	Central
Cancer Centers of NC-Raleigh*	2	Raleigh	Central
Cancer Centers of NC-Cary	1	Cary	Southwestern

*Includes one existing and one approved linear accelerator.

One of the two applications proposes to locate the new linear accelerator at a location with an existing linear accelerator. Specifically, Parkway (TPHC) proposes to locate the linear accelerator at the site of its existing linear accelerator on Sunnybrook Road in Raleigh. UNCH-CH proposes to locate the new linear accelerator in a medical office building on Avent Ferry Road in Holly Springs in southern Wake County. Therefore, with regard to improving geographic access to the proposed services, the UNCH-CH application is determined to be more effective than the Parkway application.

Demonstration of Need

Parkway adequately demonstrated the need the population it proposes to serve has for the proposed linear accelerator. UNCH-CH did not adequately demonstrate the need the population they propose to serve has for the proposed linear accelerator. See Criterion (3) and 10A NCAC 14C .1903(a)(1) and (2) for discussion.

Access by Underserved Groups

The following table shows each applicant’s projected percentages of linear accelerator procedures to be provided to Medicaid and Medicare recipients in the second full fiscal year of operation following completion of the project, based on the information provided by the applicants in Section VI.15(a) of the applications. Generally, the application proposing to serve the higher percentages of Medicare and Medicaid patients is the more effective alternative with regard to this comparative factor.

APPLICANT	Projected Percentage of Total Procedures Provided to Medicare Recipients	Projected Percentage of Total Procedures Provided to Medicaid Recipients
UNCH-CH*	41.50%	12.2%
Parkway	58.62%	1.56%

*On page 144, the applicant states the projections are for “*UNC Hospitals’ radiation oncology department overall.*”

As shown in the table above, Parkway projects the highest percentage of services to be provided to Medicare recipients, and UNCH-CH projects the lowest percentage of services to be provided to Medicare recipients. Also, UNCH-CH projects the highest percentage of services to be provided to Medicaid recipients, and Parkway projects the lowest percentage of services to be provided to Medicaid recipients. However, differences in the type and level of services provided by the two applicants makes a direct comparison of questionable value. UNCH-CH’s payer mix is for all radiation oncology patients, not just those projected to utilize the Holly Springs facility. TPHC does not serve the exact same type of radiation oncology patients as does UNCH-CH. Moreover, the service areas are not the same, which could impact the payer mix percentages.

Projected Average Gross Revenue per ESTV Procedure

The following table shows the projected gross revenue per ESTV procedure in the third year of operation for each of the applicants. For UNCH-CH, gross revenue is from the applicant’s pro forma financial statements (“*Assumptions,*” page 186), and ESTV’s are from Section IV.1, page 118. For Parkway, gross revenue is from the applicant’s Form C (“*Statement of Revenues and Expenses for Service Component,*” page 270), and ESTV’s are from Section IV.1, page 190. Generally, the application proposing the lowest average gross revenue per ESTV procedure is the more effective alternative with regard to this comparative factor.

Third Operating Year	UNCH-CH*	Parkway
Gross Revenue	\$16,697,583	\$22,616,458
ESTVs	6,934	14,431
Gross Revenue/ESTV	\$2,408	\$1,562

*All projections are for the proposed Holly Springs linear accelerator only.

As shown in the table above, Parkway projects the lowest average gross revenue per ESTV procedure in the third operating year. The application submitted by Parkway is the most effective alternative with regard to projected average gross revenue per ESTV procedure. It should be noted that UNCH-CH states their financial projections do not include professional (physician) charges or expenses, and that Parkway states professional fees and expenses are included in its financial projections. Therefore, the extent to which Parkway’s projected gross revenue per ESTV is lower than UNCH-CH’s projected gross revenue per ESTV is understated.

Projected Average Net Revenue per ESTV Procedure

The following table shows the projected net revenue per ESTV procedure in the third year of operation for each of the applicants. For UNCH-CH, net revenue (estimated as 37.9% of gross revenues) is based on the applicant’s Form C (“*UNC Hospitals Radiation Oncology*,” page 180), and ESTV’s are from Section IV.1, page 118. For Parkway, net revenue is from the applicant’s Form C (“*Statement of Revenues and Expenses for Service Component*,” page 270), and ESTV’s are from Section IV.1, page 190. Generally, the application proposing the lowest average net revenue per ESTV procedure is the more effective alternative with regard to this comparative factor.

Third Operating Year	UNCH-CH*	Parkway
Net Revenue	\$6,328,384	\$7,966,467
ESTVs	6,934	14,431
Net Revenue/ESTV	\$913	\$552

*All projections are for the proposed Holly Springs linear accelerator only.

As shown in the table above, Parkway projects the lowest average net revenue per ESTV procedure in the third operating year. The application submitted by Parkway is the most effective alternative with regard to projected average net revenue per ESTV procedure. It should be noted that UNCH-CH states their financial projections do not include professional (physician) charges or expenses, and that Parkway states professional fees and expenses are included in its financial projections. Therefore, the extent to which Parkway’s projected net revenue per ESTV is lower than UNCH-CH’s projected net revenue per ESTV is understated.

Projected Average Operating Expenses per ESTV Procedure

The following table shows the projected operating expenses per ESTV procedure in the third year of operation for each of the applicants. For UNCH-CH, operating expenses are from the applicant’s Form C (“*UNC Hospitals, Radiation Oncology*,” page 180), and ESTV’s are from Section IV.1, page 118. For Parkway, operating expenses are from the applicant’s Form C (“*Statement of Revenues and Expenses for Service Component*,” page 270), and ESTV’s are from Section IV.1, page 190. Generally, the application proposing the lowest average operating expense per ESTV procedure is the more effective alternative with regard to this comparative factor.

Third Operating Year	UNCH-CH*	Parkway
Operating Expenses	\$21,859,380	\$7,525,750
ESTVs	33,990	14,431
Expenses Per ESTV	\$643	\$521

*Projections are for UNC Hospitals' Radiation Oncology Department, including the proposed Holly Springs linear accelerator. The applicant did not provide separate operating expense projections for the proposed Holly Springs linear accelerator only.

As shown in the table above, Parkway projects the lowest average operating expense per ESTV procedure in the third operating year. The application submitted by Parkway is the most effective alternative with regard to projected average operating expense per ESTV procedure. It should be noted that UNCH-CH states their financial projections do not include professional (physician) charges or expenses, and that Parkway states professional fees and expenses are included in its financial projections. Therefore, the extent to which Parkway's projected operating expenses per ESTV is lower than UNCH-CH's projected operating expenses per ESTV is understated.

SUMMARY

The following is a summary of the reasons the proposal submitted by Parkway is determined to be the most effective alternative in this review:

- Parkway adequately demonstrated the need the population to be served has for the proposed project. See Criterion (3) for discussion.
- Parkway projects the lowest average gross revenue per ESTV procedure in the third operating year. See Comparative Analysis for discussion.
- Parkway projects the lowest average net revenue per ESTV procedure in the third operating year. See Comparative Analysis for discussion.
- Parkway projects the lowest average operating cost per ESTV procedure in the third operating year. See Comparative Analysis for discussion.

The following is a summary of the reasons the proposal submitted by UNCH-CH is determined to be a less effective alternative in this review than the approved applicant.

- UNCH-CH did not adequately demonstrate the need the population to be served has for the proposed project. See Criterion (3) for discussion.
- UNCH-CH did not demonstrate that the existing linear accelerators, owned by a related entity and 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 of the application, as required by 10A NCAC 14C .1903(a)(1).
- UNCH-CH did not demonstrate that the existing linear accelerators, owned by a related entity and located in the proposed service area, will be utilized at an annual rate of at least 6,750 ESTV treatments per machine or serve at least 250 patients per machine during the third year of operation of the new equipment, as required by 10A NCAC 14C .1903(a)(3).
- UNCH-CH projects the highest average gross revenue per ESTV procedure in the third operating

year. See Comparative Analysis for discussion.

- UNCH-CH projects the highest average net revenue per ESTV procedure in the third operating year. See Comparative Analysis for discussion.
- UNCH-CH projects the highest average operating cost per ESTV procedure in the third operating year. See Comparative Analysis for discussion.

CONCLUSION

The Agency determined that the application submitted by Parkway, Project I.D. #J-10320-14, is the most effective alternative proposed in this review for the additional linear accelerator for Service Area 20 and is approved. The approval of the application submitted by UNCH-CH would result in linear accelerators in excess of the need determination for Service Area 20. Consequently, the application submitted by UNCH-CH is denied.

The application submitted by Parkway is approved subject to the following conditions.

- 1. Parkway Urology, PA shall materially comply with all representations made in the certificate of need application.**
- 2. Parkway Urology, PA shall acquire no more than one linear accelerator as part of this project.**
- 3. Parkway Urology, PA shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VII of the application or that would otherwise require a certificate of need.**
- 4. Parkway Urology, PA shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**