ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DATE: September 25, 2009

PROJECT ANALYST: Michael J. McKillip
ASSISTANT SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: J-8329-09/University of North Carolina Hospitals at Chapel Hill /Acquire a linear accelerator and develop a multidisciplinary prostate health center in Chapel Hill/Orange County

J-8331-09/Parkway Urology, PA, d/b/a Cary Urology, PA/Acquire a linear accelerator and develop a multidisciplinary prostate health center in Raleigh/Wake County

F-8333-09/Carolinas Prostate Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a CMC-University/Acquire a linear accelerator and develop a multidisciplinary prostate health center in Charlotte/Mecklenburg County

J-8336-09/Wake-Prostate Center of Excellence, LLC and Cancer Centers of North Carolina, P.C./Acquire a linear accelerator and develop a multidisciplinary prostate health center in Raleigh/Wake County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C
UNCH-CH
Cary Urology
CPC

NC
WPCOE

On page 121 of the 2009 State Medical Facilities Plan (SMFP), it states:

"In response to a petition, there is included in this North Carolina 2009 State Medical Facilities Plan a statewide need determination for one dedicated linear accelerator that shall be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men.

The Linear Accelerator Demonstration Project shall include the following components:

- *Development of a multidisciplinary prostate health center to provide urology services, medical oncology services, biofeedback therapy, chemotherapy, brachytherapy and living skills counseling and therapy in the same building.*
- *Location of the prostate health center in close proximity to minorities communities.*
- *A medical director who shall be 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.*
- *Commitment to sponsor regular case conferences and tumor boards.*
- *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.*
- *Written strategies that include specific activities designed to assure the services will be accessible by indigent patients without regard to their ability to pay.*
- *Written description of patient selection criteria, including referral arrangements for high-risk patients.*
- *An organized African American Prostate Cancer Education/Outreach Program that partners with and complements existing initiatives, such as the NC Minority Prostate Cancer Awareness Action Team.*
- *An Advisory Board composed of representatives of prostate cancer advocacy groups, prostate cancer patients and survivors that meets regularly and provides feedback about effective practices or changes that need to be made.*
- *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:*
    - *The total number of patients treated;*
    - *The number of African-Americans treated;*
    - *The number of other minorities treated; and*
    - *The number of insured, underinsured and uninsured patients served by type of payment category.*
- *Documentation of arrangements made with a third party researcher (preferable a historically black university) to evaluate the efficacy of the mode during the fourth operating year of the Center and develop recommendations whether or not the model should be replicated in other parts of the State. The report and recommendations of the researcher shall be provided to the Medical Facilities Planning Section and the Certificate of Need Section in the first quarter of the fifth operating year of the project."*

Also, Policy GEN-3 in the 2009 State Medical Facilities Plan is applicable to the review of each application. Policy GEN-3 states:

"A CON 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 (SMFP) 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 CON 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 SMFP as well as addressing the needs of all residents in the proposed service area."

The 2009 SMFP identifies one statewide need determination for a dedicated linear accelerator to be part of a

demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer. Four applications were submitted to the Certificate of Need Section to acquire a linear accelerator and develop a multidisciplinary prostate health center. Each application is discussed below.

University of North Carolina Hospitals at Chapel Hill [UNCH-CH] proposes to acquire a linear accelerator and develop a multidisciplinary prostate health center in Chapel Hill. The applicant proposes to acquire no more than one linear accelerator. The applicant provides adequate documentation to demonstrate that its proposed project will meet the requirements for the Linear Accelerator Demonstration Project in the 2009 SMFP. See 10A NCAC 14C .1900 for discussion.

With regard to Policy GEN-3, in Section III.2, pages 195-196, the applicant provides the following information:

"UNC Hospitals maintains that the development of this model demonstration project will promote cost-effectiveness, quality, and access to services in the proposed service area. The proposed demonstration project promotes:

- *Cost-effectiveness: Cost effectiveness will be realized through the addition of radiation oncology capacity in an existing facility adjacent to the existing linear accelerators. In this way, staffing, supplies, and support services will be used jointly and therefore more cost-effectively than if the services were located elsewhere. Further, cost effectiveness will also be realized through the development of the multidisciplinary prostate health center in an existing facility with all project components, which equates to low capital costs for the proposed project.*
- *Quality: UNC Hospitals believes that the proposed multidisciplinary prostate health center will promote the provision of quality health care services to patients in the service area. Not only is UNC Hospitals known for high quality services and expects the proposed project to produce a high quality service, but the demonstrated benefits of multidisciplinary care to prostate cancer patients are overwhelming. Multidisciplinary care has been shown to improve the clinical quality of, care and improve patient satisfaction with prostate cancer programs. Prostate cancer and its treatments impact all elements of a man's life, not just his physical wellbeing. The proposed project will address the impact of this disease with a holistic approach to its treatment and management. Furthermore, the acquisition of the proposed new linear accelerator will provide UNC Hospitals with the capacity necessary to create a focal point for its ongoing research efforts in prostate cancer health disparities while the development of the new N.C. Cancer Hospital will provide the cohesive environment necessary for development of the multidisciplinary prostate health center. The creation of a multidisciplinary prostate health center housed in the same facility—the new N.C. Cancer Hospital—will enable physicians to work directly with physicians from other specialties, which will in turn enable the physicians to provide their patients with the opportunity to receive a balanced perspective on treatment options and expected outcomes that is based on the patients' individual needs. In addition, this collaborative approach will enable physicians to optimize the use of all available treatments and therapies.*
- *Access: The proposed multidisciplinary prostate health center will also promote access to health care services in the service area. The demonstration project as proposed is a model that is not currently formalized in the State of North Carolina. In some communities, patients being treated for prostate cancer often receive fragmented services. Increasing access to multidisciplinary prostate cancer care will improve patient satisfaction and patient outcomes. The model demonstration project proposed in this application will enable patients throughout the State of North Carolina to access these services at the facility most centrally located to the population."*

UNCH-CH adequately demonstrates that its projected volumes for the proposed multidisciplinary prostate health center incorporate these basic principles in meeting the needs of patients to be served. See Criterion (3) for additional discussion.

In summary, the application is conforming to Policy GEN-3. Consequently, the application is conforming with this criterion.

Parkway Urology, PA, d/b/a Cary Urology, PA [Cary Urology] proposes to acquire a linear accelerator and develop a multidisciplinary prostate health center in Raleigh. The applicant proposes to acquire no more than one linear accelerator. The applicant provides adequate documentation to demonstrate that its proposed project will meet the requirements for the Linear Accelerator Demonstration Project in the 2009 SMFP. See 10A NCAC 14C .1900 for discussion.

With regard to Policy GEN-3, in Section III.2, pages 147-151, the applicant provides the following information:

"The applicant, Cary Urology, currently delivers high-quality prostate cancer care at its Cary office location. Cary Urology will strive to deliver the same high-quality services at The Prostate Health Center. … Specializing in one disease process will enable The Prostate Health Center to concentrate on providing high quality prostate cancer services. … The proposed project offers prostate cancer service access to patients with limited financial resources and will be readily accessible to the medically underserved. In this case, some medically underserved persons may be underserved for lack of awareness or access to screening. The proposed services will be made available to all service area persons. The Prostate Health Center will not discriminate on the basis of income, race, color, national origin, age, sex, religious belief, handicap or other categories that would classify a person as underserved. Services will not be denied because of inability to pay. The facility will be developed in compliance with standards set by the Americans with Disabilities Act….

The proposal maximizes the healthcare value for resources expended by the prostate cancer patient. The patient and his third party payor will not pay for duplicative testing and consultation. The patient will also save on [sic] *because excessive travel from one specialist to the next will be minimized. Specialists will schedule patient visits at The Prostate Health Center. Patient charges will be based on the Medicare freestanding center fee schedules, which are lower than hospital-based fee schedules. Providers will be united by electronic medical records and Tumor Board information.*

…Cary Urology currently operates a multidisciplinary model of care. Integrating medical oncology and external beam radiation into its model will maximize the value and benefit of coordinated prostate cancer care to the patient. With radiation oncologists, medical oncologists and urologists working separately, each may order the same lab or imaging studies to measures outcomes associated with therapy. In the proposed Prostate Health Center, radiation oncologists, medical oncologists and urologists will share one medical record containing the same set of laboratory and imaging data. Savings on diagnostic testing resulting from the proposed organization of care delivery can be significant. Shared consult using exactly the same data will enhance clarity of communication among clinicians and between clinician and patient, thereby maximizing healthcare value….

The Prostate Health Center has reasonably projected volumes based on service area population, need for prostate cancer services, commitment of referrals and the superior capabilities of a multidisciplinary model of care for a site-specific disease. The projected volumes are commensurate with The Prostate Health Center's pledge to offer high-quality, value-added services in a safe and equitable manner to all service area prostate cancer patients."

Cary Urology adequately demonstrates that its projected volumes for the proposed multidisciplinary prostate health center incorporate these basic principles in meeting the needs of patients to be served. See Criterion (3) for additional discussion.

In summary, the application is conforming to Policy GEN-3. Consequently, the application is conforming with this criterion.

Carolinas Prostate Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a CMC-University [CPC] propose to acquire a linear accelerator and develop a multidisciplinary prostate health center in Charlotte. The applicants propose to acquire no more than one linear accelerator. The applicants provide adequate documentation to demonstrate that their proposed project will meet the requirements for the Linear Accelerator Demonstration Project in the 2009 SMFP. See 10A NCAC 14C .1900 for discussion.

With regard to Policy GEN-3, in Section III.2, pages 103-107, the applicants provide the following information:

"As discussed in Section III.3, CPC has selected the most cost effective alternative for the proposed project. CPC will offer a competitive charge structure. In addition, as a licensed [sic] *freestanding facility, CPC will be more economical for patients. Patients often benefit from third-party payor incentives to utilize freestanding services. … The proposed project also promotes cost effectiveness by coordinating patient care across multiple disciplines. This is consistent with the aim of the TOM Crossing the Quality Chasm report. Most cancer patients do not receive care from multidisciplinary care teams in which providers plan and coordinate care together. The proposed coordinate approach to treating prostate cancer will promote cost effectiveness with the objective of improving patient outcomes. In addition, CPC has planned several initiatives to reduce costs:*

- *Overhead administration will be provided (via management agreement) by CHS system administration saving the cost of hiring multiple disciplines to stay current with information technology support, and obtain maintenance and biomedical support.*
- *The new facility will use supplies and equipment from the same vendors as CHS providing standardization in use, training and repair.*
- *Training and continuing education will take advantage of the CHS system educational opportunities lowering the individual facility cost of providing such opportunities.*

All individuals will have access to CPC's services. CPC will not deny services to anyone due to economic status, race, gender, age, or handicap, as stated more fully in Section VI. As a center focused on access to prostate cancer treatment, particularly for African American patients, the proposed project will promote equitable access to health care services, particularly the medically underserved. Although African Americans only comprise 13 percent of the U.S. population, they account for the highest percentage of people living under the poverty level. In comparison, whites comprise approximately 80% of the U.S. population and have the lowest percentage of people living below the poverty line. African Americans comprise 15 percent of the uninsured in this country and are significantly less likely to obtain health insurance coverage through employer sponsored health insurance. Additionally, African Americans are more likely to obtain coverage through publicly funded programs like Medicaid, Medicare and SCHIP.

CPC will ensure that the proposed prostate cancer treatment services are available to the medically underserved. CHS, CPC's member, has a long history of being a good corporate citizen, providing access to hospital care to all patients, regardless of social or economic background. As CHS has evolved and grown over the years, so has its commitment to the communities its serves. In fact, CHS not only serves as significant engine of economic growth, but also takes a leadership role in providing a wide variety of safety net services. CHS also

provides comprehensive research and educational endeavors that advance the frontiers of medical knowledge and supply the region with needed health care professionals….

CHS recognizes the need to render medical care to patients at a reasonable cost. In accordance with CHS' mission to render medical care to all persons in need, regardless of their ability to pay, a Charity Care policy has been established to provide uncompensated services to families lacking adequate financial resources. … As noted in Section VI of this application, CHS has an excellent track record of providing care to persons covered by government insurance, and to persons dependent upon charity care. CPC projects 1.0% charity care and a combined Medicare and Medicaid payor mix of 73%.

CPC will utilize the quality-related policies and procedures currently in place at its proposed manager CHS. Excelling at quality care is at the core of CHS' mission. CHS continues to make tremendous gains in the quality of care provided to patients. CHS currently outperforms expected rates, as benchmarked by Solucient, the vendor that collects and reports mandatory hospital data for the State of North Carolina. … CHS has been internally focusing on outcomes for years. CHS constantly reviews its data and processes to determine how it can improve the services it provides. CHS also participates in a variety of external projects focusing on quality outcomes by submitting data to regional or national databases for comparative analysis. This form of benchmarking - or determining best practices based on outcomes information - allows CHS to continuously improve the care it delivers. Because the facility will be located at CMC-University, CPC will utilize the Quality Assessment and Performance Improvement Plan, Risk Management Plan and Utilization Management Plan currently in place at CMC-University."

CPC adequately demonstrates that their projected volumes for the proposed multidisciplinary prostate health center incorporate these basic principles in meeting the needs of patients to be served. See Criterion (3) for additional discussion.

In summary, the application is conforming to Policy GEN-3. Consequently, the application is conforming with this criterion.

Wake-Prostate Center of Excellence, LLC and Cancer Centers of North Carolina, P.C. [WPCOE] propose to acquire a linear accelerator and develop a multidisciplinary prostate health center in Raleigh. The applicants propose to acquire no more than one linear accelerator. However, the applicant did not adequately demonstrate the need the population proposed to be served has for the proposed project. Therefore, the applicant did not adequately demonstrate the project is a cost-effective approach. See Criterion (3) for discussion.

With regard to Policy GEN-3, in Section III.2, pages 99-100, the applicants provide the following information:

"The proposed project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing health care value for resources expended. WPCOE will enhance the continuum of care for oncology services by developing a multidisciplinary approach to the treatment of prostate cancer. The joint expertise of WakeMed and US Oncology as owners and CCNC as operators of the proposed facility will improve the care and treatment of prostate cancer patients, which disproportionately affects African American men. WPCOE has developed programs that will reach out to minority patients as well as those patients who qualify for charity and indigent care and has proposed to locate its facility in a portion of Raleigh that is approximately 80 percent African American and is readily accessible by public transportation.

In Section VI of this application, WPCOE provides documentation regarding the projected level of care provided to residents of the service area as a function of payor mix. The proposed

project will result in improved geographic access and, as a result, expanded access to all residents of the service area. The WPCOE joint venture partners have a history of providing care to all patients, regardless of their ability to pay. WakeMed is the largest provider of charity care services in Wake County. Please see Attachment 33 for the Indigent and Charity Care Policy that will be used by WPCOE."

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However, WPCOE did not adequately demonstrate that their projected volumes for the proposed multidisciplinary prostate health center incorporate these basic principles in meeting the needs of patients to be served. In summary, the applicants failed to adequately demonstrate the need for the project, and therefore, failed to adequately demonstrate the proposed project is a cost-effective approach. Consequently, the application is not conforming to Policy Gen-3 and is not conforming with this criterion. See Criterion (3) for additional discussion.

(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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University of North Carolina Hospitals at Chapel Hill **[UNCH-CH]** proposes to acquire a linear accelerator and develop a multidisciplinary prostate health center in the North Carolina Cancer Hospital on the hospital's main campus in Chapel Hill. In Section II.1, pages 27-28, the applicant describes the components of the project as follows:

"The proposed project will formalize many existing collaborations within the N.C. Cancer Hospital into a multidisciplinary prostate health center. Although all of the services included in the proposed project are currently provided at UNC Hospitals by a team dedicated to urologic cancer, these have not been formalized to the degree described below. This project is ideally timed with the opening of the state-of-the-art N.C. Cancer Hospital in September 2009. Because the new cancer hospital has been designed to best support providing multidisciplinary patient care and research under one roof', UNC Hospitals now has the opportunity to create teams, such as the one proposed in this project, with ease of access for patients, physicians and staff.

Further, the addition of one linear accelerator will allow UNC Hospitals to meet the demands of its increasing radiation oncology utilization as described in Section III.1(b). At present, the department has little capacity to increase its volume, including for prostate patients. The addition of a new linear accelerator will create that needed capacity.

The center will include the following services within the UNC Hospitals building:

- *Radiation oncology services (external beam)**
- *Urology services**
- *Medical oncology services**
- *Biofeedback therapy**

- *Chemotherapy**
- *Brachytherapy**
- *Living skills counseling and therapy**
- *Nurse navigators**

[Note: Applicant states, *"Each item denoted with an asterisk is located within the N.C. Cancer Hospital."*]

Please also note that the following services will likely be used by patients of the prostate center and support its mission. However, as they are not included as components of the prostate center as defined in the 2009 SMFP, UNC Hospitals has not provided any additional information, including volume and financial projections, for these services.

- *Genetics counseling**
- *Nanotechnology clinical research**
- *Inpatient oncology services**
- *da Vinci surgery system*

[Note: Applicant states, *"Each item denoted with an asterisk is located within the N.C. Cancer Hospital."*]

In addition, UNC Hospitals will work with Shaw University in Raleigh to collect and analyze data related to the patients utilizing the prostate health center for submission to the Medical Facilities Planning Section and the Certificate of Need Section."

Population to Be Served

In Application Section III.5(c), the applicant provides projected patient origin for prostate cancer patients and for linear accelerator patients for UNCH-CH's proposed multidisciplinary prostate health center in the second year of operation, as shown in the table below.

UNC Hospital's Prostate Cancer Patients by County – Year 2

County	Total Patients	Percent of Total
Orange	261	22.4%
Wake	138	11.8%
Chatham	104	8.9%
Alamance	71	6.1%
Durham	66	5.7%
Cumberland	43	3.7%
Lee	31	2.7%
Granville	29	2.5%
New Hanover	24	2.0%
Other NC counties*	348	29.9%
Other States & Countries	50	4.2%
Total	**1,165**	**100.0%**

*The applicant lists the counties included in the *"Other NC counties"* category on pages 211-213 of the application.

UNC Hospital's Linear Accelerator Patients by County – Year 2

County	Total Patients	Percent of Total

Wake	197	16.3%
Orange	187	15.5%
Durham	84	6.9%
Alamance	68	5.6%
Chatham	68	5.6%
Lee	59	4.9%
Cumberland	43	3.5%
Johnston	37	3.1%
Harnett	33	2.7%
New Hanover	25	2.0%
Other NC counties*	383	31.6%
Other States	29	2.4%
Total	**1,213**	**100.0%**

*The applicant lists the counties included in the *"Other NC counties"* category on pages 214-216 of the application.

In Section III.5(d), page 216, the applicant states projected patient origin for prostate cancer patients and linear accelerator patients is based on its historical patient origin for these patients in FY2008. The applicant adequately identified the population proposed to be served.

NEED ANALYSIS

In Section III.1(b), pages 176-185 of the application, the applicant provides tables showing the projected utilization of the proposed multidisciplinary prostate health center by program component in the first three years of the project, which are summarized in the following table.

Multidisciplinary Prostate Health Center Utilization Projections by Program Component	**Year 1 4/10-3/11**	**Year 2 4/11-3/12**	**Year 3 4/12-3/13**
Urology Service Encounters	403	416	428
Medical Oncology Service	376	388	399
Chemotherapy Patients	66	68	70
Brachytherapy Encounters	10	10	10
Biofeedback Encounters	1,130	1,165	1,201
Living Skills Counseling Encounters	678	699	720
Linear Accelerator Treatments	3,236	4,169	5,156

In Section III.1(b) of the application, the applicant describes its assumptions and methodology for the utilization projections for urology, medical oncology, chemotherapy, brachytherapy, biofeedback and living skills counseling services as follows:

> *"In order to project the number of prostate cancer patients to be served by the proposed multidisciplinary prostate center, UNC Hospitals examined its historical utilization, specifically the data for all patients with a primary diagnosis of prostate cancer. UNC Hospitals also provides services to patients with a secondary diagnosis of prostate cancer but has chosen not to include those patients in order to remain conservative. Please note that prostate cancer patients are often treated over many years and thus UNC Hospitals' annual utilization exceeds the number of prostate cases provided in its Tumor Registry reports. … According to its internal data, UNC Hospitals historically served the following number of prostate cancer patients:*

UNC Hospitals Prostate Cancer Patients

Year	***Patients Served***
FY2006	*966*
FY2007	*1,052*

FY2008	*1,040*
*CAGR**	*3.8%*

**Compound annual growth rate (CAGR).*
Source: UNC internal data.

As demonstrated UNC Hospitals served 1,040 prostate cancer patients in FY 2008 (July 1, 2007 to June 30, 2008) which represents 3.8 percent compound annual growth from FY 2006. While these patient volumes declined slightly from FY 2007, UNC Hospitals believes the growth from FY 2006 is more suggestive of future volumes; however, it is not basing its future patient volume on this growth rate. … In addition to examining its historical growth, UNC Hospitals reviewed the growth in new prostate cancer cases for its home county and four adjacent counties from 2006 to 2008. … In FY 2008, over 54 percent of prostate cancer patients at UNC Hospitals originated from the five counties listed in table [on page 178 of the application]*. As shown, new prostate cancer cases for those five counties grew 3.07 percent annually from 2006 to 2008. … UNC Hospitals projected that its prostate cancer patients will grow 3.07 percent annually, based on the CAGR from FY 2006 to 2008 of new prostate cancer cases in its home county and four adjacent counties. UNC Hospitals believes this projected growth rate is conservative given that it relies solely on market growth of prostate cancer cases and does not assume that the development of the proposed multidisciplinary prostate center will result in market share increases. Moreover, the projected growth rate of 3.07 percent annually is below UNC Hospitals' FY 2006 to 2008 3.8 percent CAGR.*

The table below demonstrates projected prostate cancer patients at UNC Hospitals when the 3.07 CAGR is applied to historical volume.

UNC Hospitals Projected Prostate Cancer Patients

Year	***Patients Served***
FY2008	*1,040*
FY2009	*1,072*
FY2010	*1,105*
FY2011	*1,139*
FY2012	*1,174*
FY2013	*1,210*
*CAGR**	*3.7%*

The proposed project is scheduled to begin operation on April 1, 2010; therefore, project year one begins April 1, 2010. Project year two begins April 1, 2011, and projectyear three begins April 1, 2012. To adjust for project years, utilization at the proposed multidisciplinary prostate center for project year one is calculated as 25 percent of FY 2010 projected volume and 75 percent of 2011 projected volume. Project year two utilization is calculated as 25 percent of 2011 projected volume and 75 percent of 2012 projected volume, and project year three utilization is calculated as 25 percent of 2012 projected volume and 75 percent of 2013 projected volume. The resulting project year volume is shown below.

UNC Hospitals Projected Prostate Cancer Patients

County	***Patients Served***
Project Year 1	*1,130*
Project Year 2	*1,165*
Project Year 3	*1,201*

…UNC Hospitals projected urology, medical oncology, and chemotherapy encounters during the

three project years based on its historical encounters per patient for each service. … In order to determine brachytherapy utilization for its projected prostate cancer patients, UNC Hospitals examined the historical utilization for prostate cancer patients.

UNC Hospitals Brachytherapy Encounters for Prostate Cancer Patients

Year	***Encounters***
FY2006	*24*
FY2007	*5*
FY2008	*0*
3-Year Average	***10***

Source: UNC internal data.

As demonstrated, UNC Hospitals had a vibrant brachytherapy program in 2006. The decline in volumes in FY 2007 and FY 2008 corresponds to changes in staffing. No implants were performed in 2008, in part, due to the lack of faculty with expertise in this area. During the last few years, UNC Health Care System provided brachytherapy services at UNC Hospitals' affiliated center at Rex. At Rex, Dr. Hoffman performs roughly 40 implants per year. … UNC Hospitals has added two physicians, Drs. Ron Chen and Andy Wang, who will begin practicing in the summer of 2009 and will assist in the care of patients with prostate cancer, including brachytherapy. In fact, one of Dr. Chen's priorities as a new facility member at UNC Hospitals will be the expansion of prostate brachytherapy services.

UNC Hospitals believes its brachytherapy utilization is result of the particular characteristics of its patient population in any given year. The selection of optimal therapy for patients with prostate cancer is a complex issue. … Given these factors, UNC Hospitals has conservatively projected that brachytherapy encounters for prostate cancer patients based on the three-year average of encounters from FY 2006 to 2008, or 10 encounters per year. UNC Hospitals will have the capacity to treat a large number of patients with brachytherapy if clinically indicated….

UNC Hospitals currently provides biofeedback and living skills services to all cancer patients; however, the utilization by prostate cancer patients is not currently tracked. Under the proposed prostate health center, UNC Hospitals will offer these services to all prostate cancer patients as a part of its comprehensive multidisciplinary approach. … UNC Hospitals conservatively assumes that only 20 percent of its patients will choose to utilize biofeedback services and that it will provide five encounters for each biofeedback patient, based on its expectation for patients accepting biofeedback services. … UNC Hospitals will offer each of its prostate cancer patients psychological counseling with its living skills staff and conservatively assumes that only 30 percent of its patients will choose to utilize these services. UNC Hospitals assumes that it will provide two encounters, an initial diagnostic and follow-up interview, for each psychological counseling patient. In addition, group therapy services will be available to prostate center patients."

Need for Linear Accelerator

On pages 185-188 of the application, the applicant describes its assumptions and methodology for projecting the utilization of the proposed linear accelerator at the multidisciplinary prostate health center as follows:

"In FY 2008, UNC Hospitals provided linear accelerator treatments to the following number of prostate cancer patients:

	All Prostate Cancer Patients	***Prostate Cancer Patients-Linear***	***Percent of Prostate Cancer Patients***

		Accelerator Services	*Receiving Linear Accelerator Treatment*
FY 2008	*1,040*	*65*	*6.25%*

UNC Hospitals believes that its current percentage of prostate cancer patients that receive linear accelerator treatments will increase as a result of the development of the proposed prostate center. Under the relatively new leadership of Dr. Marks, the radiation oncology department at UNC Hospitals has recognized that it has underutilized linear accelerator treatment for prostate cancer patients. The hiring of two physicians to focus on prostate cancer will help address this issue. Moreover, the availability of IMRT and IGRT will allow much more effective linear accelerator treatment options for prostate cancer patients. Finally, the development of the proposed prostate center will result in a more broadly representative prostate cancer patient population at UNC Hospitals who would be typically treated more frequently with linear accelerators. As noted in the 2009 SMFP, 'radiation therapy is used in the treatment of about half of all cancers' (page 118). … UNC Hospitals conservatively projects that the percentage of prostate cancer patients that receive linear accelerator treatments will double by the third year of the proposed project and that the growth from year to year will be one third of total growth as demonstrated below.

	All Prostate Cancer Patients	*Percent of Prostate Cancer Patients Receiving Linear Accelerator Services*	*Prostate Cancer Patients-Linear Accelerator Services*
FY 2008	*1,040*	*6.25%*	*65*
Project Year 1	*1,130*	*8.33%*	*94*
Project Year 2	*1,165*	*10.42%*	*121*
Project Year 3	*1,201*	*12.50%*	*150*

UNC Hospitals believes these projections are conservative as typically 50 percent of all cancers are treated with radiation therapy, per the 2009 SMFP. Note that the percent of patients receiving linear accelerator services noted in the above table are the percent of prostate cancer patients that will receive radiation therapy. As explained in the following section, UNC Hospitals projects its total linear accelerator volume to grow based on its historical growth rate. Thus, the projected increase in the percentage of prostate patients receiving linear accelerator services will increase this patient cohort as a percentage of overall linear accelerator patients. However, this will only have a modest effect on the total number of linear accelerator patients as most of the patients treated on linear accelerators at UNC Hospitals have non-prostate cancers.

In FY 2008, UNC Hospitals provided 2,233 total linear accelerator treatments to its 65 prostate cancer patients who received linear accelerator treatment, or 34.4 treatments per patient. UNC Hospitals projected linear accelerator treatments during the three project years based on its FY 2008 treatments per patient.

UNC Hospitals Prostate Cancer Patients and Linear Accelerator Treatments

	Project Year 1	*Project Year 2*	*Project Year 3*
Total Prostate Patients Receiving Linear Accelerator Treatments	*94*	*121*	*150*
Treatments per Patient	*34.4*	*34.4*	*34.4*
Linear Accelerator Treatments	***3,236***	***4,169***	***5,156***

On pages 188-191 of the application, the applicant describes its assumptions and methodology for projecting UNC Hospitals' total linear accelerator utilization as follows:

"To project total linear accelerator utilization during the third year of operation of the new equipment, UNC Hospitals examined its historical utilization using an April 1 to March 31 time period, which matches the project year time period for the proposed project. … According to its internal data, UNC Hospitals served historically the following number of patients on its linear accelerators:

UNC Hospitals Linear Accelerator Patients

Time Period	*Patients Served*
4/1/04 to 3/31/05	*878*
4/1/05 to 3/31/06	*884*
4/1/06 to 3/31/07	*902*
4/1/07 to 3/31/08	*980*
*4/1/08 to 3/31/09**	*1,056*

**April 1, 2008 to March 3, 31, 2009 data annualized based on 10 months of data (1,056 annualized patients 880 patients from April 1, 2008 to January 31, 2009 ÷ 10 months x 12 months).*
Source: UNC internal data.

As demonstrated, UNC Hospitals has experienced significant growth in its linear accelerator patients over time. From the 12 month period ending March 31, 2005 to the 12 month period ending March 31, 2009, linear accelerator patients grew at a 4.72 percent compound annual growth rate (CAGR). Over shorter historical time frames, the growth in patients has been even more significant, as shown below.

UNC Hospitals
Growth in Linear Accelerator Patients

Time Period	*Compound Annual Growth Rate*
4/1/04 to 3/31/09	*4.72%*
4/1/05 to 3/31/09	*6.11%*
4/1/06 to 3/31/09	*8.20%*
4/1/07 to 3/31/09	*7.76%*

In order to remain conservative, UNC Hospitals projected that its linear accelerator patients will grow 4.72 percent annually, based on its CAGR from April 1, 2004 to March 31, 2009. The table below demonstrates projected linear accelerator patients at UNC Hospitals when the 4.72 percent CAGR is applied to historical volume.

UNC Hospitals Linear Accelerator Patients

Time Period	*Patients Served*
*Historical: 4/1/04 to 3/31/05**	*1,056*
Interim: 4/1/09 to 3/31/10	*1,106*
Project Year 1: 4/1/10 to 3/31/11	*1,158*
Project Year 2: 4/1/11 to 3/31/12	*1,213*
Project Year 3: 4/1/12 to 3/31/13	*1,270*

**April 1, 2008 to March 3, 31, 2009 data annualized based on 10 months of data (1,056 annualized patients 880 patients from April 1, 2008 to January 31, 2009 ÷ 10 months x 12 months).*

The proposed project will begin operation on April 1, 2010 and thus the third year of operation will be from April 1, 2012 to March 31, 2013. During project year three, UNC Hospitals will serve 1,270 linear accelerator patients. According to 10A NCAC 14C .1903(a)(2), the performance standard for linear accelerators is an annual rate of 250 patients. Using this standard, UNC Hospitals requires five linear accelerators to treat the projected 1,270 patients (1,270 patients ÷ 250 patients per linac = 5.1 linear accelerators needed). It is important to note that this growth is based on the conservative methodology explained above and is based on the historical growth in patients needing linear accelerator treatments. Thus, the historical growth of the service, even without any impact of the proposed project, shows the need for an additional linear accelerator at UNC Hospitals to treat the growing number of patients. Moreover, the limited capacity of the existing linear accelerators is further indication of the need for an additional linear accelerator in order to effectively implement the proposed multidisciplinary prostate center.

UNC Hospitals also projected linear accelerator treatments for all radiation oncology patients through the project years, in order to provide comparable data to the linear accelerator treatments for prostate cancer patients provided above. … From April 1, 2008 to January 31, 2009, the time period which serves as the base of the patient projections, UNC Hospitals provided [19.4] *treatments per patient as shown* [in the table on page 191 of the application]. … *UNC Hospitals' historical number of 19.4 treatments per patient reflects a mix of palliative patients which receive approximately ten to 15 treatments and curative patients which receive approximately 25 to 35 treatments. UNC Hospitals projected patient treatments based on the historical ratio of 19.4 treatments per patient."*

On page 191 of the application, the applicant provides the following table showing the applicant's utilization projections for all radiation oncology patients through the first three years of the proposed project.

Time Period	Patients Served	Treatments per Patient	Total Treatments
Interim: 4/1/09 to 3/31/10	1,106	19.4	21,463
Project Year 1: 4/1/10 to 3/31/11	1,158	19.4	22,476
Project Year 2: 4/1/11 to 3/31/12	1,213	19.4	23,538
Project Year 3: 4/1/12 to 3/31/13	1,270	19.4	24,650

As shown above, the applicant projects to treat 150 patients and perform 5,156 linear accelerator treatments with the linear accelerator at the proposed multidisciplinary prostate health center in the third year of operation. Also, based on the historical utilization of UNC Hospitals' four existing linear accelerators, the applicant projects to treat 1,270 patients and perform 24,650 linear accelerator treatments with its existing and proposed linear accelerator in the third year of operation of the project, which exceeds the utilization threshold of 250 patients per linear accelerator [1,270/5 = 254 patient per linear accelerator] in the third operating year as required in 10A NCAC 14 .1903(a)(2) and (3). The applicant's utilization projections are based on the historical volumes and growth rates for prostate cancer patients treated at UNCH-CH, and the historical growth rates in new prostate cancer cases in Orange, Alamance, Chatham, Durham, and Wake Counties, from 2006 to 2008, based North Carolina Central Cancer Registry data. Also, the applicant's utilization projections are supported by UNCH-CH's historical linear accelerator utilization experience in the treatment of prostate cancer patients, and its historical growth in utilization for its linear accelerator services, overall. Exhibit II-16 contains letters from physicians expressing support for the proposed project. The applicant demonstrated that its projections are based on reasonable assumptions.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need the population to be served has for the proposed project. Consequently, the application is conforming with this criterion.

Parkway Urology, PA, d/b/a Cary Urology, PA [Cary Urology] proposes to acquire one linear accelerator, one computed tomography (CT) simulator, one digital ultrasound unit, and one brachytherapy unit, and to develop a multidisciplinary prostate health center off of New Bern Avenue and near Yonkers Road and Interstate 440 in Raleigh. In Section II.1, pages 27-28, the applicant describes the project as follows:

> *"Cary Urology is proposing to expand its urological health services by development of The Prostate Health Center. The Prostate Health Center will involve medical, research, therapy and social service disciplines in detection, treatment and aftercare management of people with or at risk of prostate cancer. Cary Urology proposes to house the multidisciplinary services in a newly constructed 12,315 square foot facility located in Raleigh, North Carolina. … The Prostate Health Center will be a state-of-the art ambulatory care facility primarily for treatment of men with prostate cancer. The center will also treat some patients who have urologic cancers. Male urologic cancers include prostate, bladder, kidney and male sexual organs. … The multidisciplinary Prostate Health Center will include programs designed to increase awareness about factors associated with maintaining healthy prostate organs, cancer prevention, early detection and post-treatment lifestyle management. It will also include cancer staging, prostate treatment, and continuing care. Clinicians from the fields of urology, medical oncology, radiation oncology and counseling/therapy will collaborate, bringing patients the most promising advances in medical, radiation and surgical treatments, including targeted therapies, chemotherapy, hormone therapy, radiation therapy and minimally invasive and ablative surgery. … Treatment of prostate cancer can involve brachytherapy, hormone therapy with testosterone suppression, surgical removal of the prostate, external beam radiation and chemotherapy, or combinations of these treatments."*

On pages 35-50 of the application, the applicant identifies the program components as urology, radiation oncology, brachytherapy, medical oncology, chemotherapy, biofeedback, and living skills counseling.

Population to Be Served

In Application Section III.5(c), the applicant provides projected patient origin for Cary Urology's proposed multidisciplinary prostate health center in the second year of operation (CY2013), as shown in the table below.

Cary Urology's Prostate Health Center Patients by County – Year 2

County	Total Patients	Percent of Total
Wake	273	85.1%
Sampson	2	0.5%
Harnett	14	4.3%
Franklin	6	1.8%
Durham	2	0.5%
Lee	6	1.8%
Johnston	3	0.9%
Duplin	1	0.2%
Chatham	2	0.7%
Out of Area*	13	4.2%
Total	**321**	**100.0%**

*The applicant lists the counties and states included in the "*Out of Area*" category on page 163 of the application.

In Section III.5(d), page 164, the applicant states projected patient origin for prostate health center patients is based on its proposed health screening activities and the geographic proximity of proposed multidisciplinary prostate health center to these counties. The applicant adequately identified the population proposed to be served.

NEED ANALYSIS

In Section IV.1(c), pages 179-181 of the application, the applicant provides tables showing the projected utilization of the proposed multidisciplinary prostate health center by program component in the first three years of the project, which are summarized in the following table.

Multidisciplinary Prostate Health Center Utilization Projections by Program Component	**Year 1 2012**	**Year 2 2013**	**Year 3 2014**
Prostate Cancer Screenings*	2,514	2,739	3,154
Biopsies	67	67	67
Ultrasound Procedures	134	134	134
Brachytherapy Procedures	378	462	616
Medical Oncology Chemotherapy Sessions	35	40	45
Biofeedback Sessions	141	171	228
Living Skills Counseling Sessions	141	171	228
Linear Accelerator ESTV**	4,781	6,109	8,024

*Combines all of the applicant's proposed cancer screening programs listed on page 179 of the application.
**ESTV = Equivalent simple treatment visit

In Section IV.1(d) of the application, the applicant describes its assumptions and methodology for the utilization projections for cancer screenings, biopsies, ultrasound procedures, medical oncology chemotherapy, brachytherapy, biofeedback, and living skills counseling services. With regard to the cancer screening program, the applicant states:

> *"The applicant estimates that every new prostate cancer patient treated at The Prostate Health Center will receive four PSA screens, during the treatment year, as follow-up. … The Action Team will hold two education sessions per month, and will offer vouchers for free PSA/DRE exams. The applicant estimates 25 persons at each event will use vouchers (12 * 2 * 25 = 600). … The Prostate Health Center expects to participate in the outreach events listed on page 89. The applicant assumes 25 screens per event (17 * 25 = 425). … The applicant will hold two free screening events yearly. The applicant estimates screening 100 persons at each event (2*100 = 200). … The applicant estimates six walk in screenings per week (6*52 = 312)."*

With regard to the biopsies and ultrasound procedures, the applicant states:

> *"The applicant estimates an approximate four percent biopsy rate based on a study done by the National Cancer Institute's ongoing multicenter Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. Over 40,000 men were screened in the trial. Of the 40,000 men, 2,717 had abnormal PSA levels (4ng/ml and above). Of the 2,717 men, 64 percent received a biopsy. Therefore, four percent of the men screened had a biopsy. … All persons who undergo a biopsy will receive two ultrasound procedures prior to the actual biopsy; one to examine the prostate and one for needle placement guidance."*

On pages 185-202, the applicant describes it assumptions and methodology for projecting patients to be treated at the proposed health center by treatment modality and county of origin as follows:

> *"Estimate the number of new prostate cancer patients, in each service area county* [as shown on pages 137-138 of the application]. … *Determine Cary Urology's annual market share, for each service area county. The proposed project will begin in January 2012.*

PHC Proposed New Prostate Cancer Market Share

County	***2012***	***2013***	***20i4***
Wake	*30.0%*	*35.0%*	*44.5%*

Sampson	*5.8%*	*5.8%*	*5.8%*
Hamett	*22.7%*	*22.7%*	*22.7%*
Franklin	*21.2%*	*21.2%*	*21.2%*
Durham	*0.6%*	*0.6%*	*0.6%*
Lee	*9.3%*	*9.3%*	*9.3%*
Johnston	*2.7%*	*2.7%*	*2.7%*
Duplin	*1.7%*	*1.7%*	*1.7%*
Chatham	*4.8%*	*4.8%*	*4.8%*

Develop an algorithm for estimating share by county:

a. *Determine the percentage of county radiation therapy patients who sought radiation therapy care in Wake County in 2007 from 2008 Hospital Licensure renewals and patients who came to freestanding center database provided by NC DHSR Planning Section.*
   Assumption: Radiation Oncology Wake County destination measures the extent to which distance from origin county to Wake County is a factor in patient decision to obtain care in Wake County.
b. *Determine percentage of county urologists proposing to refer patients to The Prostate Health Center.*
   Assumption: This represents the percentage of prostate cancer patients who could be referred to The Prostate Health Center.
c. *Determine the historical patient origin of Cary Urology from each county.*
   Assumption: Cary Urology history in 2008 is a relative measure of patient willingness to seek care from Cary Urology.
d. *Determine the number of existing linear accelerators in each county.*
   Assumption: Availability of alternative linear accelerators may cause patients to choose other than The Prostate Health Center, regardless of referral.
e. *Multiply step a times step b.*
   Assumption: This conservatively adjusts commitment of referring urologists to distance from the proposed project.
f *For Wake County, which has eight existing linear accelerators, subtract 20 percent from the result.*
   Assumption: This is an additional reduction of market share that allows for the presence of multiple linear accelerators.
g. *If there are no urologists in the county, determine if referring urologists or other referring physicians are located in or have patients from the county.*
   Assumption/Supporting Information: Referring physicians will be the source of patients from these counties. Cary Urology serves patients from Duplin and Chatham Counties and the four referring urologists from Durham County also serve patients from Chatham County. Cary Urology received a letter of support from Duplin County
h. *For Duplin and Chatham Counties, market share equals step a.*
i. *For Johnston County, multiply step a times step c.*
   Assumption/Supporting Information: Johnston County has part time urologists, including Cary Urology. Patients are served by Cary Urology and other Wake County urologists. Applying Cary Urology patient origin to the Johnston patients, who seek care in Wake County, produces a conservative market share. Cary Urology alone served over 500 total patients from Johnston County in 2008.
j. *To allow for start up, reduce market share in Wake County to 30 percent in 2012 and 35 percent in 2013.*

… The Prostate Health Center will be in one of the most densely populated areas of Wake County. The Center will be in close proximity to Interstates 40 and 440 and easily accessible for all patients who reside in Wake County. Please also see Exhibit 27 for letters of support and referrals from Wake County urologists and Exhibit 63 for letters of support from other Wake

County physicians. Together, these physicians promise to refer more patients than the projected market share of Wake County yields. Clearly, it is reasonable for The Prostate Health Center to attract at least 44.5 percent of the new prostate cancer cases in Wake County by the third project year. …

It is reasonable for The Prostate Health Center to attract 5.8 percent of the new prostate cancer cases in Sampson County for full treatment at The Prostate Health Center. Cary Urology physicians are currently the only urologists practicing in Sampson County, and have offices in Lillington. Currently, more than 14 percent of all the patients served by Cary Urology reside in Sampson County. … Northern Sampson County is only ten miles from Lillington. According to Claritas, nine percent of Sampson County lives in this Newton Grove zip code. While it is conceivable that Cary Urology urologists might serve a large percentage of the County's new prostate cancer cases, the applicant conservatively projects only 5.8 percent. Sampson County residents will have excellent access to the proposed Prostate Health Center through highway 701 and Interstate 40. Clinton, the major population center of Sampson County is located less than one hour's drive from the proposed Center. Finally, support letters from urologists and other physicians in Sampson County, located in Exhibits 27 and 63, promise to refer more patients than a 5.8 percent market share yields. … It is reasonable for The Prostate Health Center to attract 22.7 percent of the Harnett County new prostate cancer cases. Currently, Harnett County residents make up nearly 7 percent of all Cary Urology patients, and Cary Urology currently maintains an office in Lillington. Data from the 2008 Hospital License Renewal Applications and the DHSR Planning Section radiation oncology database show that 45.4 percent of Harnett County cancer patients sought their radiation oncology care in Wake County. Residents from Harnett County will have excellent access to the proposed site through highway 401 and Interstate 40. Additionally, letters from Harnett County physicians in Exhibit 63 promise to refer more patients than a 22.7 percent market share yields. … Currently, Dr. Norm Goldbach is the only urologist practicing in Franklin County, and he has agreed to send more patients to The Prostate Health Center than a 21.2 percent market share yields; please see Exhibit 27. In addition, The Prostate Health Center will work with Dr. Goldbach to conduct regular prostate cancer screenings; please see Exhibit 17. Finally, patients from Franklin County will have excellent access to The Prostate Health Center. Highway US 1, 401, and Interstate 440 will provide residents in Louisburg, Franklinton and Youngsville with a direct route to The Prostate Health Center. … Residents from Durham will have excellent access to The Prostate Health Center via Interstates 40, 440, and 85 and highway 70. The proposed Prostate Health Center will be less than a 30 minute drive from most of Durham County. Additionally, Exhibit 27 contains letters of support from four Durham urologists promising to refer more patients that a 0.6 percent market share yields. … Lee County has no linear accelerator. Sanford, the major population center of Lee County can be reached from Wake County in less than 45 minutes. Lee County residents will have excellent access to the proposed Center via US 1 and Interstate 440. Additionally, The Prostate Health Center will work with Lee County urologist William Purvis to conduct prostate cancer screening clinics in Sanford. Please see Exhibit 17. Finally, support letters from Lee County urologists in Exhibit 27 promise to refer more patients than a 9.3 percent market share yields. ... Johnston County is located directly adjacent to Wake County and residents will have excellent access to the proposed Center via highway 70 and Interstate 440. Communities like Clayton and Smithfield are located within a 30 minute drive the proposed Center. Analysis of 2008 Hospital Licensure Renewal and DHSR freestanding planning data shows that 51 percent of Johnston County linear accelerator patients sought their radiation oncology care in Wake County. Cary Urology maintains and office in Clayton and most Wake County urologists serve Johnston County patients. Finally, letters of support from Johnston County physicians promise to refer more patients than a 2.7 percent market share yields. … Current patient origin shows more than 5 percent of all Cary Urology patients reside in Duplin County. Most of the Duplin County residents seen by Cary Urology are treated in the Sampson County office, as there is currently no urologist in Duplin County. It is possible that Cary Urology physicians will treat a much larger percentage of the Duplin County cases. Duplin County residents in communities like Faison and Warsaw will have direct access

to Wake County via interstate 40. The proposed Center could be reached by these patients in less than one hour. Finally, letters of support from Duplin County physicians promise to refer more patients than a 1.7 percent market share yields. Please see Exhibit 86. It is reasonable for The Prostate Health Center to attract 4.8 percent of the new prostate cancer cases in Chatham County. Chatham County is located directly southeast of Wake County. Areas of Chatham County could be reached from the proposed Center in less than 30 minutes. Residents of Chatham County will have excellent access to The Center via highway 64 and US 1. Additionally, historical internal data shows that Cary Urology physicians treated over 80 patients from Chatham County in 2008. Finally, letters of support from Chatham County physicians promise to refer more patients than a 4.8 percent market share yields.

… Apply the market shares determined in Step 2 to the projected service area prostate cancer cases in Step 1.

New Prostate Cancer Cases Referred to PHC from Service Area Counties

County	***2012***	***2013***	***2014***
Wake	*198*	*242*	*322*
Sampson	*1*	*1*	*1*
Hamett	*12*	*12*	*12*
Franklin	*5*	*5*	*5*
Durham	*1*	*1*	*1*
Lee	*5*	*5*	*5*
Johnston	*2*	*2*	*3*
Duplin	*1*	*1*	*1*
Chatham	*2*	*2*	*2*
Total	***227***	***272***	***352***

As noted in Section II, prostate cancers are treated differently from other types of cancers. Treatment involves both different forms of radiation therapy and typically higher doses of radiation. Based on the applicant's experience, of patients who will be referred for treatment, 50 percent of new prostate cancers will receive radiation therapy.

Based on the applicant's experience, of prostate cancer patients who undergo radiation therapies:

- *75 percent receive external beam radiation therapy (EBRT),*
- *20 percent receive brachytherapy, and*
- *5 percent receive a combination of EBRT and brachytherapy.*

Based on the applicant's experience, another 48 percent of treated patients receive surgery or watchful waiting. However, 20 percent of those patients who undergo surgery or watchful waiting will need post-op EBRT to complete their treatment. The remaining 2 percent of prostate cancer patients, who are not appropriate for radiation therapy or surgery, will receive medical oncology treatment, known as chemotherapy. … Using this profile of patient treatment, the following table will be used to project the number of new prostate cancer cases needing EBRT, brachytherapy, and medical oncology, in the service area.

Projected Cancer Treatment Profile New Prostate Cancers at PHC

	Percent Eligible	***Percent in Subset***	***Percent of Treated Cancer Cases***
Radiation Candidates	*50%*		
Brachytherapy		*20%*	*10.0%*
EBRT		*75%*	*37.5%*
Combo (Brachytherapy & IMRT)		*5%*	*2.5%*
Surgery Candidates	*48%*		

Surgery / Watchful Waiting		*80%*	*38.4%*
Post-op EBRT		*20%*	*9.6%*
Medical Oncology Candidates	*2%*		*2.0%*

Use the patient treatment profile from in Step B-4 to determine the number of new prostate cancer cases, by treatment.

Total Service Area New Prostate Cancer Patients by Treatment at The Prostate Health Center

Entire Service Area	***2012***	***2013***	***2014***
Radiation Candidates			
Brachytherapy	*23*	*27*	*35*
EBRT	*85*	*102*	*132*
Combo (Brachytherapy & IMRT)	*6*	*7*	*9*
Surgery Candidates			
Surgery / Watchful Waiting	*87*	*104*	*135*
Post-op EBRT	*22*	*26*	*34*
Medical Oncology Candidates	*5*	*5*	*7*

Determine the percentage of Palliative prostate cancer patients at The Prostate Health Center.

Palliative New Prostate Cancer Percentages

2012	***2013***	***2014***
3.0%	*6.0%*	*10.0%*

Based on Dr. Khoudary and Dr. Leung's professional experience, the number of prostate patients who will get palliative prostate treatment at The Prostate Health Center could be as high as 10 percent of the new prostate cancer patients, increasing as the Center's patient population grows…

Apply the palliative percentages determined in Step 6 above to the total new prostate cancer patients from each service area county in Step 3.

Total PHC Prostate Cancer Palliative Patients from Service Area by Modality

Modality	***2012***	***2013***	***2014***
EBRT	*7*	*16*	*35*

Estimate the number of new non-prostate GU cancer patients, in each service area county; [as shown in the table on page 143 of the application].

Determine Cary Urology's annual market share of non-prostate urological cancer (new GU cancers), for each service area county. The proposed project will begin in January 2012.

PHC Proposed New GU Cancer Market Share

County	***2012***	***2013***	***2014***
Wake	*6.0%*	*6.0%*	*6.0%*
Sampson	*0.8%*	*0.8%*	*0.8%*
Harnett	*3.1%*	*3.1%*	*3.1%*
Franklin	*2.9%*	*2.9%*	*2.9%*
Durham	*0.8%*	*0.8%*	*0.8%*
Lee	*1.3%*	*1.3%*	*1.3%*
Johnston	*0.4%*	*0.4%*	*0.4%*

Duplin	*0.2%*	*0.2%*	*0.2%*
Chatham	*0.6%*	*0.6%*	*0.6%*

Set Wake County at 6 percent market share.

Divide GU market share by new prostate market share for Wake County to get a GU factor. (0.06 / .445 = 13.48 percent).

Multiply the new prostate cancer patient market share for each service area county in Step B-2 by the GU factor.

Assumptions:

These new GU patients have primarily bladder and testicular cancer. All are surgery candidates. Based on Dr. Khoudary's experience and knowledge, half can definitively be treated with surgery. For the remaining half, 70 percent will have clearly defined algorithms for post operative care and 30 percent will have complex issues that require the attention of a multidisciplinary team. Assume only 40 percent of these select the Prostate Health Center. (0.5 times 0.3 times 0.4 = .06). … A consistent methodology applies this factor proportionately to all service area counties.

Apply the market shares determined in Step B-2 to the projected prostate cancer cases in Step B-8.

PHC Proposed New GU Cancer Cases from Service Area

County	***2012***	***2013***	***2014***
Wake	*14*	*15*	*15*
Sampson	*0*	*0*	*0*
Hamett	*1*	*1*	*1*
Franklin	*0*	*0*	*0*
Durham	*1*	*1*	*1*
Lee	*0*	*0*	*0*
Johnston	*0*	*0*	*0*
Duplin	*0*	*0*	*0*
Chatham	*0*	*0*	*0*
Total	***17***	***18***	***18***

Note: numbers may not foot due to rounding

Determine the treatment modality distribution for new GU cancer cases. … Based on the applicant's clinical experience and knowledge, other male genital cancers (testicular, penile) and urinary cancers (kidney, bladder) receive far fewer EBRT treatments than prostate patients. Additionally, these patients are not appropriate for Brachytherapy. Most (80 percent) will be appropriate for surgery. The remaining 20 percent will split evenly between EBRT and medical oncology.

Projected PHC GU Cancer Treatment Profile

Treatment Modality	***Percent Eligible***	***Percent in Subset***	***Percent of all Cancer Cases***
Radiation	*10%*		
EBRT		*100%*	*10.0%*
Surgery	*80%*		
Surgery / Watchful Waiting		*100%*	*80.0%*
Medical Oncology	*10%*		*10.0%*

The Prostate Health Center further screens the referred GU patients and conservatively

eliminates all but 10 percent for EBRT.

Use the patient treatment profile from in Step B-11 and the cases in Step B-1 to determine the number of new GU cancer cases, by treatment. The table below summarizes new GU cancer patients at The Prostate Health Center.

Total PHC New GU Cancer Patients from Service Area by Modality

Treatment Modality	***2012***	***2013***	***2014***
Radiation			
EBRT	*2*	*2*	*2*
Surgery			
Surgery / Watchful Waiting	*14*	*14*	*14*
Medical Oncology	*2*	*2*	*2*

Determine the percentage of palliative GU cancer patients at The Prostate Health Center.

Palliative GU Cancer Percentage

2012	***2013***	***2014***
5.0%	*10.0%*	*15.0%*

Assumptions:

The GU cancer incidence rates and case projections include only new cancer patients. They do not include patients who will experience a recurrence of GU cancer. These patients are identified as 'palliative'. … Based on Dr. Khoudary and Dr. Leung's professional experience and knowledge, the number of patients that will be palliative patients at The Prostate Health Center could be as high as 15 percent of the new GU cancer patients, increasing as the Center's patient population grows. Conservative estimates show the number of palliative prostate patients at the Center will equal 5 percent of the new GU patients in year one, 10 percent of the new GU patients in year two, and 15 percent of the new GU patients in year three. … Apply the palliative GU cancer percentages determined in Step B- 13 above to the total new GU cancer patients county in Step B-10. The table below summarizes total GU cancer patients from all service area counties.

Total PHC GU Palliative Patients from Service Area

Modality	***2012***	***2013***	***2014***
EBRT	*1*	*2*	*3*

Assumptions:

In these calculations, palliative patients receive only EBRT treatments. At these small counts, the number receiving other therapies is negligible.

Summarize Service Area patients at PHC by treatment modality.

Service Area New Prostate Patients at PHC from Step B-5 and Step B-7.

Service Area Prostate Patients at PHC

Treatment Modality	***2012***	***2013***	***2014***
Radiation Candidates			
Brachytherapy	*23*	*27*	*35*
EBRT Only	*85*	*102*	*132*
Combo (Brachytherapy and IMRT)	*6*	*7*	*9*
Surgery Candidates			
Surgery / Watchful Waiting	*87*	*104*	*135*
Post-Op EBRT	*22*	*26*	*34*

Medical Oncology Candidates	*5*	*5*	*7*
Palliative Patients			
EBRT Only	*7*	*16*	*35*
Percent of Total	*95.8%*		

Service Area New GU Patients at PHC from Steps B-12 and B-14.

Service Area GU Patients at PHC

Treatment Modality	***2012***	***2013***	***2014***
Radiation Candidates			
EBRT Only	*2*	*2*	*2*
Surgery Candidates			
Surgery / Watchful Waiting	*14*	*14*	*14*
Medical Oncology	*2*	*2*	*2*
Palliative Patients			
EBRT Only	*1*	*2*	*3*
Percent of Total	*95.8%*		

Calculate total patients at PHC by dividing service area patients by percent of patients from the service area. (95.8 percent)

Total PHC Prostate Patients by Treatment Modality

Treatment Modality	***2012***	***2013***	***2014***
Radiation Candidates			
Brachytherapy	*24*	*28*	*37*
EBRT Only	*89*	*106*	*138*
Combo (Brachytherapy & IMRT)	*6*	*7*	*9*
Surgery Candidates			
Surgery / Watchful Waiting	*91*	*109*	*141*
Post-Op EBRT	*23*	*27*	*35*
Medical Oncology Candidates	*5*	*6*	*7*
Palliative Patients			
EBRT Only	*7*	*17*	*37*

Total PHC GU Patients by Treatment Modality

Treatment Modality	***2012***	***2013***	***2014***
Radiation Candidates			
EBRT Only	*2*	*2*	*2*
Surgery Candidates			
Surgery / Watchful Waiting	*14*	*15*	*15*
Medical Oncology	*2*	*2*	*2*
Palliative Patients			
EBRT Only	*1*	*2*	*3*

Assumptions:

Out of area patients represent 4.2 percent of all patients, following Cary Urology patient origin in Section III.4."

On pages 203-212 of the application, the applicant describes its assumptions and methodology for projecting utilization of the proposed linear accelerator as follows:

*"**Step C-1***

Determine the number of prostate and GU cancer EBRT patients, by county.

47Total PHC Linear Accelerator Patients by County

	2012	***2013***	***2014***
Wake	*106*	*138*	*196*
Sampson	*1*	*1*	*1*
Harnett	*6*	*7*	*8*
Franklin	*3*	*3*	*3*
Durham	*1*	*1*	*1*
Lee	*3*	*3*	*3*
Johnston	*1*	*1*	*2*
Duplin	*1*	*1*	*1*
Chatham	*1*	*1*	*1*
Out of Service Area Counties	*5*	*7*	*9*
Total	***129***	***163***	***225***

On page 204 of the application, the applicant describes the its assumptions for the above projections as follows:

a. *New prostate patients by county (Step B-3) times treatment profile (Step B-4) plus*
b. *New GU patients by county (Step B-10) times treatment profile (Step B-11) plus*
c. *The product of the palliative percentages from Steps B-6 and B- 13 times new prostate and new GU patients by county (Steps B-3 and B-10)*
d. *For other (out of area patients), sum results of each of steps a through c above, and divide by 0.958, the out of area factor.*
e. *Add patients from steps a through d and round to the nearest whole number in the summary table to get patients by county.*
   Assumption: This is a mathematical calculation and applying consistent mathematics will consistently reflect total patients by county.
f. *In Exhibit 90, if the above calculations produced only one patient in a county, that patient was assigned to New Prostate IMRT.*

Determine the treatment level (Simple, Intermediate, Complex, IMRT) for each type of patient at The Prostate Health Center that will receive EBRT. … From the methodology explained in Section B, there are six types of patients who will utilize the Linear Accelerator at the Center. … Based on Dr. Leung's experience treating these types of patients, and his review of RTOG standards and oncology literature, the aforementioned cancer patients will receive EBRT in the following manner.

Types of EBRT Treatments

	2012	***2013***	***2014***
New Prostate Cancer EBRT			
IMRT	*100%*	*100%*	*100%*
New Prostate Cancer Combo			
IMRT	*100%*	*100%*	*100%*
New Prostate Cancer Post-Op EBRT			
IMRT	*100%*	*100%*	*100%*
New GU Cancer EBRT			
Complex	*85%*	*85%*	*85%*
IMRT	*15%*	*15%*	*15%*
Palliative Cancer EBRT (Prostate and			

GU)			
Simple	*10%*	*10%*	*10%*
Intermediate	*15%*	*15%*	*15%*
Complex	*75%*	*75%*	*75%*

Determine the number of treatments and field checks per patient level.

	Treatments	***Field Checks***
New Prostate Cancer EBRT		
IMRT	*40*	*8*
New Prostate Cancer Combo		
IMRT	*25*	*5*
New Prostate Cancer Post-Op EBRT		
IMRT	*33*	*6*
New GU Cancer EBRT		
Complex	*25*	*5*
IMRT	*30*	*6*
Palliative Cancer EBRT (Prostate and GU)		
Simple	*10*	*2*
Intermediate	*10*	*2*
Complex	*10*	*2*

Assumptions:

These estimates are based on the experience of Dr. Leung, radiation oncologist. Verified by his literature standards research.

Step C-4

Apply the levels of treatments from Step C-2 and treatments and field checks per patient determined in Step C-3 to the total number of patients from each county in Step C-1.

Step C-5

Adjust for additional patient whose treatments occur in prior or subsequent years. Apply a factor of 69.5 percent to one month's patients to get number of treatments that will occur in the subsequent year

	2012	***2013***	***2014***
Total Linear Accelerator Patients	*129*	*163*	*225*
Patients per Month	*11*	*14*	*19*
Average Treatments per patient	*43*	*42*	*39*
Factor	*69.5%*	*69.5%*	*69.5%*
Treatments from prior year	*0*	*329*	*399*
Treatments provided in next year	*329*	*399*	*515*
Net Lost	*329*	*70*	*116*

Deduct the resulting treatment adjustment for the entire Center to the new prostate IMRT cases for the county with the largest number of patients, Wake County. The tables on the following pages show the resultant procedures by County for 2012, 2013, and 2014.

Assumption:

For calculation purposes, Wake County, which has the largest number of cases is most likely to have the patients who transition from one year to the next.

Average treatments per patient were calculated by dividing the total number of treatments per year from Step C-4 by the total number of EBRT patients per year in Step C-1. The increase in palliative patients decreases the average treatments per patient in later years.

A factor of 69.5 percent was calculated by assuming an equal number of patients per week in the last month of each year, December, and an equal number of patients per month in each year. Use the average treatments per patient, 41. The following shows the methodology for a month with ten patients spread evenly among five weeks in a month. Assume five treatments per week per patient and an average of 41 total treatments per patient."

On pages 212-213, the applicant describes it methodology and assumptions for projecting simulation procedures as follows:

"The number of other procedures associated with Linear Accelerator service such as physics services, dosimetry services, simulator procedures, weekly management, etc. were estimated for each patient type based Dr. Leung's experience. … The above "Other Procedures" include CT simulator procedures (CPT Codes 77280, 77285, 77290). Total simulator procedures are summarized in the table below.

Total CT Simulator Procedures

2012	***2013***	***2014***
253	*310*	*415*

On pages 215-216, the applicant describes it methodology and assumptions for projecting brachytherapy procedures as follows:

"*Determine the number of brachytherapy patients by county* [as shown in Exhibit 90 of the application]….

Brachytherapy Patients

Number of Patients	***2012***	***2013***	***2014***
Wake	*25*	*30*	*40*
Sampson	*0*	*0*	*0*
Harnett	*1*	*2*	*2*
Franklin	*0*	*0*	*0*
Durham	*0*	*0*	*0*
Lee	*0*	*0*	*0*
Johnston	*0*	*0*	*0*
Duplin	*0*	*0*	*0*
Chatham	*0*	*0*	*0*
Out of Area	*1*	*1*	*2*
Total	***27***	***33***	***44***

Diagnostic Code: lCD 185

Step E-2

Determine the number of procedures per brachytherapy patient.

Assumptions:

Based on his professional experience, Dr. Leung projects each brachytherapy patient will

receive 14 procedures during his course of treatment. These procedures include pre-implant procedures, implant procedures, and post treatment procedures.

Step E-3

Multiply the number of brachytherapy patients in Step 1 by the projected number of procedures per patient in Step 2.

Brachytherapy Procedures

Number of Procedures	***2012***	***2013***	***2014***
Wake	*350*	*420*	*560*
Sampson	*0*	*0*	*0*
Hamett	*14*	*28*	*28*
Franklin	*0*	*0*	*0*
Durham	*0*	*0*	*0*
Lee	*0*	*0*	*0*
Johnston	*0*	*0*	*0*
Duplin	*0*	*0*	*0*
Chatham	*0*	*0*	*0*
Out of Area	*14*	*14*	*28*
Total	***378***	***462***	***616***

On page 217 of the application, identifies the number of patients who will receive chemotherapy in the first three years of operation as follows:

Medical Oncology Patients

	2012	**2013**	**2014**
Medical Oncology	7	8	9

The applicant describes it methodology and assumptions for projecting medical oncology chemotherapy procedures as follows:

"Based on the experience of Dr. Mark L. Graham, II, medical oncologist, each treated prostate and/or GU cancer cases undergoes five chemotherapy sessions, or treatments. …"

Medical Oncology Sessions

	2012	**2013**	**2014**
Chemotherapy Sessions	35	40	45

On pages 218-221 of the application, describes it methodology and assumptions for projecting biofeedback and living skills counseling services as follows:

"Based on the professional experience and expertise of Dr. Khoudary and Jane Talley, RN in treating prostate and GU cancers, it is estimated that 20 percent of all the patients requiring surgery and EBRT will receive biofeedback therapy. … Based on the professional experience of Dr. Khoudary and Jane Talley, RN in treating prostate and GU cancer, it is estimated that each biofeedback patient will require three sessions to complete his treatment.

Based on the professional experience and expertise of Dr. Khoudary, and Jane Talley, RN in treating prostate and GU cancers, it is estimated that 20 percent of all the patients requiring surgery and EBRT will need living skills counseling. … Based on the professional experience of Dr. Khoudary and Jane Talley, RN in treating prostate and GU cancer, it is estimated that each living skills counseling patient will require three sessions to complete their treatment."

In Section IV.1 of the application, the applicant provides the following utilization projections for the proposed linear accelerator in the first three years of operation of the proposed project.

Time Period	Linear Accelerator Patients*	Linear Accelerator Treatments**	Total ESTV Treatments**
Project Year 1: CY2012	129	5,239	4,781
Project Year 2: CY2013	163	6,663	6,109
Project Year 3: CY2014	225	8,755	8,024

*From page 203 of the application.
**From page 180 of the application.

As shown above, the applicant projects to treat 225 patients and perform 8,024 ESTV procedureswith the linear accelerator at the proposed multidisciplinary prostate health center in the third year of operation, which exceeds the utilization threshold of 6,750 ESTV treatments per linear accelerator in the third operating year as required in 10A NCAC 14 .1903(a)(2). The applicant's utilization projections are based on population estimates for the counties in proposed service area, cancer incidence rates from the North Carolina Center for Health Statistics and Central Cancer Registry for 2006, and assumptions regarding projected percentage of new prostate cancer patients (market shares) that will be referred to Cary Urology's proposed prostate health center from each of the counties in the service area. In determining its projected market shares by county, the applicant states it considered several factors, including the percentage of county residents who received radiation oncology services in Wake County in 2007-2008, number of urologists in the county who have expressed an intention to refer patients to Cary Urology's prostate health center, Cary Urology's historical patient origin data, the ease of access in terms of geographic proximity and availability of convenient roads and highways, and the number of existing linear accelerators in the county. Also, the applicant states its estimates of the utilization of linear accelerator services for the treatment of prostate cancer in terms of the percentage of patients eligible for radiation therapy services (50 percent of new prostate cancer patients) and the number of treatments per patient (8,024/225 = 35.7 ESTVs/patient) are based on its experience providing those services. Exhibit 27 of the application contains letters from 25 urologists in the proposed service area expressing support for the proposed project and their intention to refer prostate cancer patients for linear accelerator services at Cary Urology's proposed prostate health center. Therefore, the applicant demonstrated that its projections are based on reasonable assumptions.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need the population to be served has for the proposed project. Consequently, the application is conforming with this criterion.

Carolinas Prostate Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a CMC-University [CPC] propose to acquire one linear accelerator, one computed tomography (CT) simulator, and one brachytherapy unit, and develop a multidisciplinary prostate health center in Charlotte. In Section I.11 of the application, the applicants state Carolinas Prostate Center, LLC is a limited liability company whose members are The Charlotte-Mecklenburg Hospital Authority (CMHA) and Radiation Oncology Centers of the Carolinas, Inc. (ROCC). In Section I.4, the applicants state

> *"The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-University (CMC-University) will own the facility where Carolinas Prostate Center, LLC (CPC) proposes to locate the proposed prostate health center. CMC-University will collect a monthly lease from CPC. CMC-University will construct the proposed 10,875 square feet of space to accommodate the proposed center. CMC-University will not own or operate the proposed radiation therapy equipment."*

In Section I.6 of the application, the applicants state CMHA d/b/a Carolinas HealthCare System (CHS) will provide management services for CPC. On page 29 of the application, the applicants state the multidisciplinary prostate health center will not be licensed as part of the hospital. In Section II.1, pages 22-

23, the applicants describe the project as follows:

> *"CPC proposes to establish a multidisciplinary prostate health center focused on the treatment of prostate cancer, particularly among African American men. The proposed project is in response to the need for one dedicated additional linear that shall be part of a demonstration project for a multidisciplinary prostate health center in the 2009 State Medical Facilities Plan (SMFP). CPC proposes to purchase one linear accelerator, one CT simulator and one brachytherapy unit. … CPC plans to locate the proposed prostate health center in newly constructed space adjoining the CMC-University hospital facility. … CMC-University will design and construct the 10,875 square foot addition specifically to provide the services proposed in this application. CMC-University will lease the space to CPC."*

On pages 23-28 of the application, the applicants identify the program components as radiation therapy, brachytherapy, urology, medical oncology/chemotherapy, biofeedback, and living skills counseling.

Population to Be Served

In Application Section III.5(c), the applicants provide projected patient origin for CPC's proposed multidisciplinary prostate health center in the second year of operation (CY2012), as shown in the table below.

CPC's Prostate Health Center
Patients by County – Year 2

County	Percent of Total
Mecklenburg	82.7%
Cabarrus	10.5%
Union	3.6%
Stanly	1.2%
Rowan	0.7%
Gaston	0.6%
Iredell	0.3%
Lincoln	0.3%
Total	**100.0%**

In Section III.1, page 78, the applicants identify Mecklenburg County as the primary service area, and the remaining counties in HSA III (Cabarrus, Union, Stanly, Rowan, Gaston, Iredell, and Lincoln) as the secondary service area. The applicant adequately identified the population proposed to be served.

NEED ANALYSIS

In Section IV.1(c), pages 116-117 of the application, the applicants provide tables showing the projected utilization of the proposed multidisciplinary prostate health center by program component in the first three years of the project, which are summarized in the following table.

Multidisciplinary Prostate Health Center Utilization Projections by Program Component	Year 1 CY2011	Year 2 CY2012	Year 3 CY2013
Urology Visits	165	253	296
Brachytherapy Treatments	49	76	89
Medical Oncology Chemotherapy Treatments	99	152	177
Therapy Visits*	66	101	118
Linear Accelerator ESTV**	3,950	6,055	7,076

*Combines biofeedback and living skill therapy.

**ESTV = Equivalent simple treatment visit

In Section III.1(b) of the application, the applicants describes their assumptions and methodology for the utilization projections for urology visits, linear accelerator services, medical oncology/chemotherapy, brachytherapy, biofeedback, and living skills counseling services as follows.

"Because the proposed prostate health center is focused exclusively on treating males with prostate cancer, CPC utilized male population data provided by the NC Office of State Budget and Management. The following table provides male population data for CPC's primary and secondary service area.

Carolinas Prostate Center, LLC
Primary and Secondary Service Area
Projected Male Population 2009-2013

	2009	***2010***	***2011***	***2012***	***2013***
Cabarrus	*87,535*	*89,995*	*92,568*	*95,141*	*97,714*
Gaston	*100,484*	*101,269*	*102,024*	*102,779*	*103,535*
Iredell	*78,828*	*80,815*	*82,855*	*84,896*	*86,935*
Lincoln	*37,997*	*38,656*	*39,314*	*39,972*	*40,629*
Mecklenburg	*457,225*	*469,456*	*482,190*	*494,925*	*507,659*
Rowan	*69,430*	*69,976*	*70,548*	*71,119*	*71,690*
Stanly	*29,886*	*30,005*	*30,124*	*30,243*	*30,363*
Union	*101,653*	*105,845*	*110,193*	*114,541*	*118,888*
Service Area Total	***963,038***	***986,017***	***1,009,816***	***1,033,616***	***1,057,413***

Source: NC Office of State Budget and Management, http://demog.state.nc.us/

2) Cancer Incidence Rate

CPC obtained the prostate cancer incidence rates for the counties in its primary and secondary service areas. The following provides the most recent age-adjusted prostate cancer incidence rates for the counties in HSA III.

2006 Prostate Cancer Incidence per 100,000 Population

County	***Prostate Cancer Incidence Rate***
Cabarrus	*207.5*
Gaston	*164.0*
Iredell	*121.5*
Lincoln	*183.3*
Mecklenburg	*156.5*
Rowan	*138.5*
Stanly	*153.2*
Union	*118.7*

Source: North Carolina Central Cancer Registry, 4/2009. Please see Exhibit 16.

According to the North Carolina State Center for Health Statistics, the Mecklenburg County prostate cancer incidence rate increased 2.02 percent from 2005 to 2006 (the most recent data available). Additionally, prostate cancer incidence rates for Cabarrus, Lincoln, Rowan and Stanly counties also increased during the same time period. Please refer to Exhibit 16 for annual prostate cancer incidence rates for the counties in HSA III during 2000 to 2006.

Additionally, the aging African American population in HSA III is projected to increase nearly 30 percent during the next four years. According to the North Carolina Central Cancer Registry,

as the average age of the population increases, the increase of cancer will increase as well. Therefore, prostate cancer incidence rates are likely to continue to increase for these counties in the future. However, to remain conservative, CPC projects no growth in prostate cancer incidence rates for purposes of projecting utilization for the proposed project.

3) Total Projected Prostate Cancer Patients based on Cancer Incidence Rates

Using the North Carolina State Office of Budget and Management county populations (1) and the projected county cancer incidence rates (2), CPC calculated the number of projected prostate cancer patients in the primary and secondary service area.

Total Prostate Cancer Patients based on Cancer Incidence Rates

	2009	***2010***	***2011***	***2012***	***2013***
Cabarrus	*182*	*187*	*192*	*197*	*203*
Gaston	*165*	*166*	*167*	*169*	*170*
Iredell	*46*	*47*	*48*	*49*	*49*
Lincoln	*70*	*71*	*72*	*73*	*74*
Mecklenburg	*716*	*735*	*755*	*775*	*794*
Rowan	*96*	*97*	*98*	*98*	*99*
Stanly	*46*	*46*	*46*	*46*	*47*
Union	*121*	*126*	*131*	*136*	*141*
Service Area Total	***1,440***	***1,474***	***1,509***	***1,543***	***1,578***

Source: Service Area Population x Current 2006 Prostate Cancer Incidence Rate
Totals may not foot due to immaterial rounding.

4) Estimated Radiation Therapy Patients

According to the American College of Radiology (ACR), radiation oncology, together with surgical and medical oncology, is one of the three primary disciplines involved in cancer treatment. Radiation therapy with either curative or palliative intent is used to treat approximately 60% of all cancer patients. ACR further states, 'the ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented.'

Based on the experience of CPC's members treating patients with prostate cancer, approximately 50 percent of prostate cancer patients receive radiation therapy only. Of this 50 percent who receive radiation therapy:

- *85 percent receive external beam radiation therapy (EBRT)*
- *10 percent receive brachytherapy, and*
- *5 percent receive a combination of EBRT and brachytherapy.*

Additionally, based on the experience of CPC's members treating patients with prostate cancer, an additional 10 percent of prostate cancer patients receive a prostatectomy and salvage EBRT treatment.

Projected Radiation Therapy Patients
Health Service Area III

	% of Total Prostate Cancer Cases	***CY2011***	***CY2012***	***CY2013***

Projected Prostate Cancer Patients		*1,509*	*1,543*	*1,578*
Radiation Therapy Patients	*50%*	*754*	*772*	*789*
EBRT	*85%*	*641*	*656*	*671*
Brachytherapy	*10%*	*75*	*77*	*79*
Combination EBRT + Brachytherapy	*5%*	*38*	*39*	*39*
Surgery				
Salvage EBRT	*10%*	*151*	*154*	*158*
Total Prostate EBRT Patients		*830*	*849*	*868*
Total Radiation Therapy Patients		*905*	*926*	*947*

The following table provides the resulting projected number of prostate cancer patients receiving radiation therapy in the primary and secondary service areas.

Projected Radiation Therapy Patients
Health Service Area III

	2011	***2012***	***2013***
Cabarrus	*115*	*118*	*122*
Gaston	*100*	*101*	*102*
Iredell	*29*	*29*	*30*
Lincoln	*43*	*44*	*45*
Mecklenburg	*453*	*465*	*477*
Rowan	*59*	*59*	*60*
Stanly	*28*	*28*	*28*
Union	*78*	*82*	*85*
Service Area Total	***905***	***926***	***947***

Totals may not foot due to immaterial rounding.

5) Projected Patient Market Share

CPC made reasonable market share assumptions for the proposed prostate cancer treatment services. As described previously, CPC's members treated a combined 236 prostate cancer treatment patients during 2008. Thus, through its members, CPC will have a broad base of referring physicians from which to draw.

CPC projects market share individually for each of the counties in its proposed service area. Logically, CPC projects the greatest market share in Mecklenburg County, the location of the proposed prostate health center and the host to the largest African American male population in the service area. CPC projects that it will achieve 20% market share in Mecklenburg County during the first year of the proposed project. To clarify, this is not 20% of all prostate cancer patients. Rather, CPC projects a market share of 20% for prostate cancer patients who will receive radiation therapy (which equates to approximately 12% market share for all prostate cancer patients (91/755)). CPC projects its patient volume to continue to ramp up during the second year of the project and projects 30% market share during CY2012. Again, CPC projects 30% market share in Mecklenburg County during the second project year for prostate cancer patients receiving radiation therapy (which equates to approximately 18% market share for all prostate cancer patients). During the third project year (CY2013), CPC conservatively projects its market share to increase to 33% of radiation therapy prostate cancer patients.

CPC projects comparatively lower market shares for the counties in its secondary service area. This is logical and reasonable because patients from counties in the secondary service area may travel longer distances to receive care at the proposed prostate health center. However, CPC projects that some prostate cancer patients will travel from adjacent counties to receive care at the proposed facility. Patients currently travel from adjacent counties to receive care at CMHA and ROCC facilities in Mecklenburg County, thus it is reasonable to project that patients will

continue to do so upon completion of the proposed project. Additionally, CPC will offer the state's first multidisciplinary prostate health center, thus patients may desire to travel further distances to receive coordinated care not currently available locally. CPC projects its market share for counties in the secondary service area will increase as more patients from its primary service area utilize the proposed services. Similar to a ripple effect, the growing market share in Mecklenburg County will have a gradually spreading positive effect on CPC's market share for counties in its secondary service area.

CPC further supports its market share assumptions based on the following factors:

- *CPC will offer the state's first multidisciplinary prostate health center.*
- *CPC will coordinate with existing outreach initiatives to educate African American men about prostate cancer and treatment options.*
- *CPC's services will be accessible by all patients, regardless of their ability to pay.*
- *CPC will conduct clinics, specifically targeted toward African American males, to screen patients at risk for prostate cancer.*
- *CPC's members have long-standing positive relationships with local referring physicians. Please refer to Exhibit 20 for letters of support from local physicians which indicate their intent to refer patients to the proposed prostate health center.*

The following table provides CPC's projected market share for the proposed project.

Carolinas Prostate Center, LLC
Projected Market Share
CY2011-CY2013

County	***PY1***	***PY2***	***PY3***
	CY2011	***CY2012***	***CY2013***
Cabarrus	*10.0%*	*15.0%*	*20.0%*
Gaston	*1.0%*	*1.0%*	*1.0%*
Iredell	*2.0%*	*2.0%*	*3.0%*
Lincoln	*1.0%*	*1.0%*	*1.0%*
Mecklenburg	*20.0%*	*30.0%*	*33.0%*
Rowan	*1.0%*	*2.0%*	*3.0%*
Stanly	*5.0%*	*7.5%*	*10.0%*
Union	*5.0%*	*7.5%*	*10.0%*

Note - projected market shares are for prostate cancer patients receiving radiation therapy.

6) Projected Radiation Therapy Patients

CPC multiplied the projected radiation therapy patients calculated in #4 by the projected patient market share in #5 to derive the projected number of radiation therapy patients for the first three years of the proposed project.

Carolinas Prostate Center, LLC
<u>Unduplicated</u> Radiation Therapy Patients
CY2011-CY2013

County	***PY1***	***PY2***	***PY3***
	CY2011	***CY2012***	***CY2013***
Cabarrus	*12*	*18*	*24*
Gaston	*1*	*1*	*1*
Iredell	*I*	*I*	*I*
Lincoln	*0*	*0*	*0*
Mecklenburg	*91*	*139*	*157*
Rowan	*1*	*1*	*2*
Stanly	*1*	*2*	*3*

Union	*4*	*6*	*8*
Service Area Total	***110***	***169***	***197***

Source: Projected Radiation Therapy Patients x Patient Market Share Totals may not foot due to immaterial rounding.

As described previously, of the prostate cancer patients who receive radiation therapy:

- *85 percent receive EBRT*
- *10 percent receive brachytherapy, and*
- *5 percent receive a combination of EBRT and brachytherapy.*

As described previously, approximately 10 percent of prostate cancer patients receive a prostatectomy and salvage EBRT treatment.

Thus the following number of patients will receive EBRT and brachytherapy at the proposed prostate health center.

7) Projected Radiation Therapy Treatments and ESTVs

Prostate cancer patients receive, on average, more external beam radiation treatments than is typical for most cancers. CPC examined the historical prostate patient and procedure utilization for ROCC's dedicated outpatient linear accelerators.

Radiation Oncology Centers of the Carolinas
Historical Prostate Cancer Linear Accelerator Utilization
CY2007-CY2008

	CY2007	***CY2008***
Prostate LINAC Patients	*108*	*118*
Prostate LINAC Procedures	*4,749*	*4,973*
Procedures per Patient	***43.97***	***42.14***
Prostate LINAC ESTVs	*4,387*	*4,709*
ESTVS per Patient	***40.62***	***39.90***

Source: Radiation Oncology Centers of the Carolinas

Based on outpatient CY2008 utilization, prostate cancer patients received an average of approximately 42.14 treatments and 39.90 ESTVs. This is also consistent with CHS' experience providing prostate cancer radiation therapy services. For purposes of projecting utilization for the proposed project, CPC projects each prostate cancer EBRT patient will receive 42.14 treatments and 39.90 ESTVs.

Based on its members' historical experience providing brachytherapy services, CPC projects prostate cancer patients will receive an average of approximately three (3) treatments.

CPC anticipates that its projected procedure mix for radiation therapy patients will remain consistent with its members historical experience providing radiation therapy services. CPC projects the following patient treatments on the proposed linear accelerator.

Carolinas Prostate Center, LLC
Projected Linear Accelerator Utilization
CY2011-CY2013

	PY1	***PY2***	***PY3***
	CY2011	***CY2012***	***CY2013***
EBRT Patients	*99*	*152*	*177*
EBRT Procedures	*4,172*	*6,395*	*7,474*

ESTVs	*3,950*	*6,055*	*7,076*

Carolinas Prostate Center, LLC
Projected Brachytherapy Utilization
CY2011-CY2013

	PY1	***PY2***	***PY3***
	CY2011	***CY2012***	***CY2013***
Brachytherapy Patients	*16*	*25*	*30*
Brachytherapy Procedures	*49*	*76*	*89*

8) Other Prostate Health Center Services

As described previously, CPC will also offer urology, medical oncology, chemotherapy, biofeedback therapy, and living skills counseling and therapy services. The following assumptions were utilized to project utilization for each of these services.

A urological physician is typically present only in the surgical option of treatment for prostate cancer patients. Urologists specializing in male sexual health can be adjunct providers in a multidisciplinary prostate health center for patients with prostate cancer. Although a patient's primary focus at the proposed prostate health center will be obtaining treatment for prostate cancer, some patients will have questions and concerns about sexual function after prostate therapies. Relevant urology services will be available to patients at the proposed prostate cancer center via Urology Specialists of the Carolinas. Based on the collective experience of its members treating patients with prostate cancer, CPC projects 30 percent of its projected radiation therapy patients will seek urology services related to sexual function after prostate therapies. These patients may seek up to five to seven physician visits. To remain conservative, CPC project each patient will receive five physician visits.

Patients who have undergone prostate surgery may also receive subsequent radiation therapy. Additional radiation therapy within three to six months of surgery can prevent reoccurrence of cancer in many men. This radiation therapy care will be coordinated at the proposed prostate health center. Surgical care for these patients will be coordinated with each patient's Urologist which may include Urology Specialists of the Carolinas. These patients would coordinate follow up urologic care with their Urologist. … CPC projects the following patients and visits for urology services.

Carolinas Prostate Center, LLC
Radiation Therapy Patients Utilizing Urology Services
CY2011-CY2013

	CY2011	***CY2012***	***CY2013***
Patients	*33*	*51*	*59*
Visits	*165*	*253*	*296*

With regard to chemotherapy, biofeedback, and living skills counseling services, on page 100, the applicants state

"Medical Oncology, i.e. chemotherapy services will be provided to the proposed multidisciplinary prostate health center by Carolinas Hematology/Oncology Associates. When chemotherapy is needed in addition to primary treatment of surgery or radiation, this part of the treatment is managed by a medical oncologist. … Chemotherapy generally is not a standard treatment for prostate cancer. Since most tumors are slow-growing and occur in older men, the side effects from chemotherapy usually outweigh any benefit that treatment may provide. Prostate cancer chemotherapy is almost always a salvage therapy for advanced prostate cancer. … Based on the experience of CPC's members treating patients with prostate cancer, CPC

projects 5 percent of its patients will receive chemotherapy. … CPC estimates patients will receive chemotherapy treatments for an average of three cycles (each cycle lasting approximately 21 days). During each cycle patients will receive an average of six chemotherapy treatments for a total projected 18 chemotherapy treatments per prostate cancer patient (3 cycles x 6 chemotherapy treatments).

Carolinas Prostate Center, LLC
Radiation Therapy Patients Receiving Chemotherapy Services
CY2011-CY2013

	CY2011	***CY2012***	***CY2013***
Patients	*5*	*8*	*10*
Visits	*99*	*152*	*177*

As described previously, biofeedback therapy and living skills counseling and therapy services will be provided by CMC-University's Outpatient Rehab Services. CMC-provides therapy services for urologic disorders such as pelvic pain and urinary incontinence. Treatments for various disorders include exercises for muscle control/strengthening/spasms, biofeedback, manual massage, education for exercises to conduct at home and ADL therapy. … Based on its members' collective experience treating patients with prostate cancer, CPC projects 5% of its radiation therapy patients will receive outpatient therapy services (including biofeedback and living skills therapy). Each patient will have an average of 12 visits.

Carolinas Prostate Center, LLC
Radiation Therapy Patients Receiving Outpatient Therapy Services
CY2011-CY2013

	CY2011	***CY2012***	***CY2013***
Patients	*5*	*8*	*10*
Visits	*66*	*101*	*118*

As shown above, the applicants project to treat 177 patients and perform 7,076 ESTV treatments with the linear accelerator at the proposed multidisciplinary prostate health center in the third year of operation, which exceeds the utilization threshold of 6,750 ESTV treatments per linear accelerator in the third operating year as required in 10A NCAC 14 .1903(a)(2). The applicant's utilization projections are based on population estimates for the eight counties in proposed service area, cancer incidence rates from the North Carolina Central Cancer Registry, and assumptions regarding projected percentage of new prostate cancer patients (market shares) that will be referred to CPC's proposed prostate health center from each of the counties in the service area. The applicants state the projected market shares by county are supported by several factors, including the historical experience of CPC's members in the treatment of prostate cancer patients from the service area, their existing relationships with local referring physicians, and the proposed CPC facility's position as "*the states first multidisciplinary prostate health center.*" Also, the applicant states its estimates of the utilization of linear accelerator services for the treatment of prostate cancer in terms of the percentage of patients eligible for radiation therapy services (50 percent of new prostate cancer patients) and the number of treatments per patient (39.90 ESTVs/patient) are based on its experience providing those services. Exhibit 21 of the application contains letters from 36 physicians in the proposed service area, including radiation oncologists, medical oncologists, internal medicine and family medicine physicians, expressing support for the proposed project and their intention to refer prostate cancer patients CPC's proposed prostate health center for linear accelerator services. Therefore, the applicant demonstrated that their projections are based on reasonable assumptions.

In summary, the applicants adequately identified the population to be served and adequately demonstrated the need the population to be served has for the proposed project. Consequently, the application is conforming with this criterion.

Wake-Prostate Center of Excellence, LLC and Cancer Centers of North Carolina, P.C. [WPCOE]

propose to acquire one linear accelerator, one computed tomography (CT) simulator, and one brachytherapy unit, and develop a multidisciplinary prostate health center to be located in a new 16,073 square foot outpatient facility at 23 Sunnybrook Road in Raleigh. In Section I.11 of the application, the applicants state

> *"The proposed Wake-Prostate Center of Excellence (WPCOE) will be a join venture between AOR Management Company of Virginia, LLC (AOR), a wholly owned subsidiary of US Oncology, and WakeMed. AOR will have a 90% interest in WPCOE and WakeMed will have a 10% interest. Cancer Centers of North Carolina, PC (CCNC) will be the operator for the entity and will direct provision of radiation therapy and brachytherapy services. The medical equipment and assets will be held by WPCOE."*

In Section I.6 of the application, the applicants state, *"WPCOE will hold the assets and provide management services, and Cancer Centers of North Carolina, P.C. will be the operator and provide clinical services."* In Section III.1, page 72, the applicants describe the project as follows:

> *"Wake-Prostate Center of Excellence, LLC (WPCOE) is a joint venture between US Oncology and WakeMed. It proposes to develop a comprehensive prostate cancer center in a freestanding medical office building on the campus of WakeMed Hospital in Raleigh, Wake County. WPCOE will offer standard cancer treatment services such as medical oncology, chemotherapy, and radiation oncology but will also offer access to urology services and support services such as biofeedback therapy, dietary/nutritional counseling, social work services, and cancer rehabilitation focused on the unique needs of prostate patients, including African Americans in the service area. Ancillary services such as routine lab work, pathology, CT simulation, medical physics, and dosimetry support will also be provided."*

On pages 23-24 of the application, the applicants identify the program components as radiation therapy, brachytherapy, urology, medical oncology, chemotherapy, biofeedback, and living skills counseling.

Population to Be Served

In Application Section III.5(c), the applicants provide projected patient origin for linear accelerator and brachytherapy services at WPCOE's proposed multidisciplinary prostate health center in the second year of operation (4/2012-3/2013), as shown in the table below.

WPCOE Linear Accelerator Patients by County – Year 2

County	Total Patients	Percent of Total
Primary Service Area		
Wake	81	56.3%
Harnett	10	6.9%
Franklin	9	6.3%
Secondary Service Area		
Johnston	6	4.2%
Nash	6	4.2%
Granville	4	2.8%
Sampson	2	1.4%
Other*	26	18.1%
Total	**144**	**100.0%**

*The applicant lists the counties included in the *"Other"* category on page 103 of the application.

WPCOE Brachytherapy Patients by County – Year 2

County	Total Patients	Percent of Total
Primary Service Area		

Wake	8	57.1%
Harnett	1	7.1%
Franklin	1	7.1%
Secondary Service Area		
Johnston	1	7.1%
Nash	1	7.1%
Sampson	1	7.1%
Nash	1	7.1%
Granville	1	7.1%
Total	**14**	**100.0%**

In Section III.5(b), page 102, the applicants state projected patient origin for brachytherapy and linear accelerator patients is based on WakeMed's and CCNC's historical patient origin and the geographic travel patterns of the proposed service area. The applicant adequately identified the population proposed to be served.

NEED ANALYSIS

In Section III.1(b), page 83 of the application, the applicants provide a table showing the projected utilization of the proposed multidisciplinary prostate health center for linear accelerator services and brachytherapy services in the first three years of the project, which are summarized in the following table.

Multidisciplinary Prostate Health Center Utilization Projections by Program Component	**Year 1 2011**	**Year 2 2012**	**Year 3 2013**
Brachytherapy Patients	12	14	18
Linear Accelerator ESTV*	4,860	5,760	7,200

*ESTV = Equivalent simple treatment visit

In Section III.1(b) of the application, the applicants describes their assumptions and methodology for the utilization projections for linear accelerator services brachytherapy services as follows.

> *"As shown in Exhibit 3* [on page 80 of the application], *the members and operators of WPCOE already treat a significant number of prostate cancer patients requiring external beam radiation treatment (EBRT) in the proposed service area. WPCOE estimates that its members and operators serve nearly 27 percent of prostate cancer patients in the primary service area, with higher market shares in Wake and Franklin Counties. In the secondary service area, WPCOE's members and operators have a 14.1 percent market share and treat significant numbers of prostate cancer patients in Johnston, Sampson and Granville Counties. WakeMed and CCNC have a combined 22.9 percent market share in the service area overall. … Note that WakeMed does not currently offer radiation therapy services but provided other treatment (including surgical and diagnostic services) to 103 prostate cancer patients in 2008. For purposes of this analysis, WPCOE has assumed that 60 percent of these patients would be eligible for EBRT, based on American College of Radiology Practice Guidelines….*
>
> *Exhibit 4* [on page 83 of the application] *presents a summary of WPCOE's utilization projections for the first three years following implementation of the demonstration prostate center. The projected number of 2008 prostate cancer patients in the service area was obtained from the North Carolina Central Cancer Registry. WPCOE then projected the total number of prostate cancer patients in the interim years and the first three years of operation based on growth in the male population aged 45 and older in the service area. It is therefore expected that the number of prostate cancer patients will grow from 787 in 2008 to 881 by 2011 (Year 1) and 942 by 2013*

(Year 3). Applying the ACR estimate that 60 percent of these patients will be eligible for radiation therapy yields a potential EBRT volume of 529 service area prostate patients in Year 1 and 565 prostate patients by Year 3.

On page 83 of the application, the applicants provide at table (Exhibit 4) showing its utilization projection, which is summarized below:

	Historical 2008	**Interim 2009**	**Interim 2010**	**PY1 2011**	**PY2 2012**	**PY3 2013**
Prostate Cancer Patients	787	820	851	881	911	942
Number Treatable w/ Radiation Therapy	472	492	511	529	547	565
Expected Market Share				18.2%	21.6%	26.2%
Service Area Patients Treated by WPCOE				96	118	148
In migration				21	26	32
Total Patients Treated by WPCOE				117	144	180
Average Treatments per Patient		40	40	40	40	40
Total Treatments (ESTVs)				4,680	5,760	7,200
Expected Brachytherapy Patients (10%)				12	14	18

On page 81 of the application, the applicants state

"WPCOE assumed that it would capture an 18.2 percent market share of these patients in Year 1 of the demonstration project, increasing to 26.2 percent market share by Year 3. … This estimate is conservative since WPCOE's members and operators already treat an estimated 22.9 percent of prostate cancer patients requiring EBRT in the service area. WPCOE expects that its market share will increase based on the comprehensive services it provides, its outreach to minority communities, and the growing recognition that WPCOE will receive as its services become well known to referring physicians. WPCOE expects that 82 percent of its patients will reside in either its primary or secondary service area. An additional 18 percent of patients are expected to be the result of in-migration from other counties. The proposed prostate center is thus expected to treat 117 EBRT-eligible patients in Year 1 and 180 EBRT eligible patients by Year 3.

Currently, the most effective treatment protocols for prostate cancer require a higher than average number of radiation therapy treatments. These treatments are primarily complex radiation therapy treatments and IMRT, which delivers a higher and more effective radiation dose over a longer course of treatment. WPCOE has therefore assumed that patients would require 40 EBRT sessions, which results in 4,680 treatments in Year 1, increasing to 7,200 treatments by Year 3. This treatment volume in Year 3 exceeds the SMFP-mandated threshold of 6,750 treatments by Year 3.

Finally, WPCOE estimates that approximately 10 percent of its patients will require Brachytherapy, a form of radiotherapy in which radioactive seeds are placed inside the prostate. A projected 12 Brachytherapy patients will receive treatment in Year 1 increasing to 18 Brachytherapy patients in Year 3."

As shown above, based on the table shown on page 83 of the application, the applicants project to treat 180 patients and perform 7,200 ESTV treatments with the linear accelerator at the proposed multidisciplinary prostate health center in the third year of operation. However, the applicants' projections are based on an assumption that is not supported by the documentation provided the applicants. Specifically, in the table shown on page 83 of the application, the applicants assume that fully 60 percent of cancer patients will receive external beam radiation therapy (EBRT), and that another approximately two percent of prostate cancer patients will receive brachytherapy. However, based on the American College of Radiology (ACR)

guidelines provided by the applicants in Exhibit 35 of the application, the ACR estimates that only 60 percent of patients will be appropriate candidates for radiation therapy, which is identified as either EBRT or brachytherapy. The ACR guidelines provided by the applicants in Exhibit 35 state

> *"Radiation therapy with either curative or palliative intent is used to treat up to 60% of all cancer patients. Radiation therapy uses ionizing radiation, delivered with either external beam therapy or radioisotopes, to destroy or inhibit the reproductive ability of neoplastic cells."*

Therefore, based on the applicants' statements, as well as the documentation provided by ACR, the applicants should have deducted, rather than added, the number of patients they projected will receive brachytherapy from patients identified as appropriate candidates for radiation therapy services. The following table shows the revised projections:

	PY1 2011	**PY2 2012**	**PY3 2013**
Prostate Cancer Patients	881	911	942
Number Treatable w/ Radiation Therapy	529	547	565
Expected Market Share	18.2%	21.6%	26.2%
Service Area Patients Treated by WPCOE	96	118	148
In migration	21	26	32
Total Patients Treated by WPCOE	117	144	180
Deduct Brachytherapy Patients	*-12*	*-14*	*-18*
Patients Treatable with EBRT	**105**	**130**	**162**
Average Treatments per Patient	40	40	40
Total Treatments (ESTVs)	**4,200**	**5,200**	**6,480**

As shown above, based on the applicants' statements and the estimates in the ACR guidelines regarding the percentage of cancer patients to be treated with radiation therapy services, the revised projections result in an estimate of 162 patients and 6,480 ESTV treatments for the linear accelerator at the proposed multidisciplinary prostate health center in the third year of operation, which is below the utilization threshold of 250 patients or 6,750 ESTV treatments per linear accelerator in the third operating year as required in 10A NCAC 14 .1903(a)(2). Therefore, the applicant did not demonstrate that its projections are based on reasonable assumptions. Consequently, it is not reasonable to project the applicant will reach the utilization threshold of 250 patients or 6,750 ESTV treatments in the third operating year as required in 10A NCAC 14 .1903(a)(2).

In summary, the applicant did not adequately demonstrate the need the population to be served has for the proposed linear accelerator. Consequently, the application is not conforming with 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.

C
Cary Urology

NA
UNCH-CH
CPC
WPCOE

Cary Urology proposes to relocate brachytherapy services from its existing office in Cary to the proposed

facility in Raleigh. In Section III.7 of the application, the applicant states

> *"The distance between the two facilities is about 15 to 17 miles, which can be travelled in about 20 minutes. … Cary Urology's urologic surgery practice will remain at its existing location. Upon completion of The Prostate Health Center, the brachytherapy services will be relocated to the Center. Relocating the brachytherapy will have a positive impact on access for all service area urology patients. … Incremental costs of providing brachytherapy at the new location will be negligible, and will not affect patient charges for services. Commitment to serve Medicare, Medicaid and charity care patients will not be affected by the proposed location. … The proposed sites are reasonably close to urology practices that propose to refer patients; patients will have access to comprehensive external beam treatment and rehabilitative care of male urologic cancers in one convenient, familiar location. Medically underserved male urologic patients in all area urology practices will thus have improved access to a system of continuously improving evidence-based, disease specific care. Access via Interstate Routes 40, 440, and 540 to the proposed site are excellent. Access via State Route 64 is also excellent."*

The applicant adequately demonstrated that the needs of the population presently served will be met adequately by the proposed relocation of brachytherapy services from its existing office in Cary to the proposed facility in Raleigh.

(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.

C
UNCH-CH
Cary Urology
CPC

NC
WPCOE

UNCH-CH - In Section III.3 of the application, the applicant describes the alternatives it considered. The application is conforming with all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a), and 10A NCAC 14C .1900 for discussion. Therefore, the applicant adequately demonstrated that its proposal is its most effective alternative and is conforming with this criterion.

Cary Urology - In Section III.3 of the application, the applicant describes the alternatives it considered. The application is conforming with all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a), and 10A NCAC 14C .1900 for discussion. Therefore, the applicant adequately demonstrated that its proposal is its most effective alternative and is conforming with this criterion.

CPC - In Section III.3 of the application, the applicants describe the alternatives they considered. The application is conforming with all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a), and 10A NCAC 14C .1900 for discussion. Therefore, the applicants adequately demonstrated that their proposal is their most effective alternative and is conforming with this criterion.

WPCOE - In Section III.3 of the application, the applicants describe the alternatives they considered. However, the application is not conforming with all other applicable statutory and regulatory review criteria. See Criterion (1), (3), (5), (6), (18a), and 10A NCAC 14C .1900 for discussion of the statutory and regulatory review criteria. Therefore, the applicants did not adequately demonstrate that the proposal is an effective alternative. Consequently, the application is not 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
UNCH-CH
Cary Urology
CPC

NC
WPCOE

UNCH-CH - In Section VIII.1, the applicant projects its capital cost for the project to be $4,685,851, which includes $4,039,341 for the linear accelerator. In Section VIII.3, the applicant states the project will be financed with accumulated reserves. In Section IX.1, the applicant projects no start-up expenses or initial operating expenses. In Exhibit II-23 of the application, the applicant provides a letter from the Chief Financial Officer of UNC Health Care System which states, "*This letter is to confirm the availability of funding in excess of $4,685,851 specifically for use for the capital costs associated with the development of the above referenced* [linear accelerator] *project.*"

Exhibit II-24 of the application contains the financial statements for University of North Carolina Hospitals, Chapel Hill for the year ended June 30, 2007, and shows that UNC Hospitals had $214 million in cash and cash equivalents. The applicant adequately demonstrated the availability of funds for the projected capital costs described in the application.

The applicant projects its revenue will exceed expenses in each of the first three years of operation following completion of the proposed project. The costs and revenues are based on reasonable assumptions including projected utilization. See the pro forma financial statements in the application and Criterion (3) for utilization assumptions. The applicant adequately demonstrated that the immediate and long-term financial feasibility of the proposal is based upon reasonable projections of costs and charges, and is conforming with this criterion.

Cary Urology - In Section VIII.1, the applicant projects its capital cost for the project to be $9,771,773, which includes $1,225,481 for site costs, $3,218,703 for construction costs, $4,164,860 for equipment costs, and $1,162,729 for other miscellaneous costs. In Section VIII.3, the applicant states the project will be financed with conventional loans. In Section IX.1, the applicant projects $276,995 in start-up expenses and $729,105 in initial operating expenses, for total working capital required of $1,006,100. In Section IX.2, the applicant proposes to finance total working capital with a commercial loan. In Exhibit 73 of the application, the applicant provides a letter from North State Bank which states:

> *"We are familiar with Cary Urology, its physicians and their medical operations. We understand that Cary Urology is applying for a Certificate of Need to acquire a linear accelerator and develop external beam radiation therapy services at its newly proposed center, The Prostate Health Center. Cary Urology expects the capital costs to be less than $10 million. It is also our understanding that start-up costs and initial operating expenses are expected to be less than $1.5 million. … We welcome the opportunity to assist Cary Urology with this endeavor by potentially providing the financing for the capital costs and working capital for the project. … Please accept this letter as an indication of our willingness to assist with this project."*

Therefore, the applicant adequately demonstrated the availability of funds for the projected capital and working capital costs described in the application.

The applicant projects its revenue will exceed expenses in the second third years of operation following completion of the proposed project. The costs and revenues are based on reasonable assumptions including projected utilization. See the pro forma financial statements in the application and Criterion (3) for utilization assumptions. The applicant adequately demonstrated that the immediate and long-term financial feasibility of the proposal is based upon reasonable projections of costs and charges, and is conforming with this criterion.

CPC - In Section VIII.1, the applicants, Carolinas Prostate Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a CMC-University, project their capital cost for the project to be $9,190,454. The applicants state Carolinas Prostate Center, LLC will incur $5,660,454 in capital costs, including $900,000 for construction costs, $3,618,454 for equipment costs, and $1,142,000 in miscellaneous other costs. The applicants state The Charlotte-Mecklenburg Hospital Authority d/b/a CMC-University (CMC-University) will incur $3,530,000 in capital costs, including $250,000 for site costs, $2,850,000 for construction costs, and $430,000 for miscellaneous costs. In Section VIII.3, the applicants state CMC-University will finance its capital costs with $3,530,000 in accumulated reserves. The applicants state Carolinas Prostate Center, LLC will finance its capital costs with a $2,830,227 conventional loan and a fund transfer of $2,830,227 from Carolinas HealthCare System. In Section IX.1, the applicants project they will incur $80,000 in start-up expenses and $120,000 in initial operating expenses, for total working capital required of $200,000. In Section IX.2, the applicants propose to finance total working capital with a commercial loan for $100,000 and a fund transfer from Carolinas HealthCare System in the amount of $100,000. In Exhibit 12 of the application, the applicants provide an April 9, 2009 letter from the Chief Financial Officer of Carolinas HealthCare System which states

> *"As the EVP-Chief Financial Officer for Carolinas HealthCare System (CHS), I have authority to obligate funds from accumulated reserves of CHS for projects undertaken by CHS facilities. Carolinas HealthCare System is the not-for-profit parent company for CMC-University. I am familiar with the CON application regarding Carolinas Prostate Center, LLC (CPC) to develop a prostate health center on the campus of CMC-University in Charlotte. As part of the project, CMC-University will construct an addition to its hospital facility, which it will then lease to CPC for the prostate health center. I can and will commit CHS's reserves to cover the CMC-University capital costs associated with this project. The anticipated CMC-University portion of the project is approximately $3.6 million."*

Also in Exhibit 12 of the application, the applicants provide an April 9, 2009 letter from the Chief Financial Officer of Carolinas HealthCare System which states

> *"As the EVP-Chief Financial Officer for Carolinas HealthCare System (CHS), I have authority to obligate funds from accumulated reserves of CHS for projects undertaken by CHS facilities. Carolinas HealthCare System is a 50% member of Carolinas Prostate Center, LLC (CPC). I am familiar with the CON application regarding Carolinas Prostate Center, LLC (CPC) to develop a prostate health center on the campus of CMC-University in Charlotte. I can and will commit CHS's reserves to cover 50% of the CPC capital costs associated with this project, including the project capital cost and working capital. The anticipated CPC portion of the project cost (both capital and working capital) is up to approximately $3 million. Upon approval of the CPC CON project, CHS will transfer the necessary funds to CPC. CHS does not expect, and CPC will have no obligation, to return these funds to CHS."*

Also in Exhibit 12 of the application, the applicants provide a letter from First Citizen's Bank which states

> *"First-Citizens Bank & Trust Company ("First Citizens Bank") has been contacted by Carolinas Prostate Center, LLC (the "Applicant") in regard to its application with your department for a Certificate of Need and proposal to under a capital expenditure that will result in the offering of a new institutional health service as defined by Article 9 of Chapter 131E or the North Carolina General Statutes. … In this regard, the Applicant has requested that First*

Citizens Bank consider providing financing for the Project on the following general terms:

Loan Amount:	*$3,000,000*
Loan Purpose:	*Finance the cost of leasehold improvements, purchase radiation equipment capital costs, start-up working capital and operating expenses*
Term:	*Ten (10) years*
Rate:	*LIBOR plus 1.50%*

First Citizens Bank has conducted a preliminary review of the financial condition of the Applicant, which has consisted almost exclusively of a review of one of the Applicant's members, Radiation Oncology Centers of the Carolinas, Inc, and, based upon this review, we are willing to consider providing financing for the Project."

Exhibit 13 of the application contains the financial statements for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System for the year ended December 31, 2007, and shows that CHS had $195 million in cash and cash equivalents. The applicants adequately demonstrated the availability of funds for the projected capital costs described in the application.

The applicants project their revenue will exceed expenses in the second and third years of operation following completion of the proposed project. The costs and revenues are based on reasonable assumptions including projected utilization. See the pro forma financial statements in the application and Criterion (3) for utilization assumptions. The applicants adequately demonstrated that the immediate and long-term financial feasibility of the proposal is based upon reasonable projections of costs and charges, and are conforming with this criterion.

WPCOE - In Section VIII.1, the applicants, Wake-Prostate Center of Excellence, LLC and Cancer Centers of North Carolina, P.C., project their capital cost for the project to be $9,461,456, including $343,400 for site costs, $3,693,145 for construction costs, $3,518,261 for equipment costs, and $1,906,650 in miscellaneous other costs. The applicants state WakeMed Health and Hospitals will incur $683,784 in capital costs and AOR Management Company of Virginia, LLC will incur $6,154,053 in capital costs. Also, in Section VIII.3, the applicants state that $2,623,620 in capital costs will be incurred by the *"Developer through Lease,"* including $803,650 for *"tenant upfit allowance,"* and $1,819,970 for the *"land, shell, and core."* In Section IX.1, the applicants project they will incur $319,501 in start-up expenses and $280,000 in initial operating expenses, for total working capital required of $599,501. In Section IX.2, the applicants propose to finance total working capital with an *"Equity Contribution from JV* [joint venture] *members."* In Exhibit 47 of the application, the applicants provide an April 15, 2009 letter from the Chief Financial Officer of WakeMed Health and Hospitals which states

"This letter confirms that WakeMed, as a member of Wake-Prostate Center of Excellence, LLC (WPCOE), will make available funds for the proposed Multidisciplinary Prostate Health Demonstration project to support the capital expenditure required for the acquire of the proposed linear accelerator and development of the proposed center. The cost for the development for the proposed WPCOE is $9,461,456. Projected start-up costs for the proposed WPCOE are $599,501. Of the capital costs, $2,623,620 are covered by lease from a developer for a net cost to the members of $6,837,836. … WakeMed as a 10 percentmember of WPCOE will contribute $683,784 to the capital costs and $59,951 to the start-up costs for the proposed center. These funds will come from unrestricted reserves of WakeMed."

Also in Exhibit 47 of the application, the applicants provide an April 15, 2009 letter signed by Senior Vice President-Southeast Region for US Oncology, Inc. and the Manager for AOR Management Company of Virginia, LLC which states

"We are writing this letter to document the intentions of US Oncology, Inc. and AOR Management of Virginia, LLC ("AOR"), with regard to the referenced certificate of need

project. AOR is member/owner along with WakeMed, of a new limited liability company, Wake-Prostate Center of Excellence, LLC ("WPCOE"). … AOR also provides management and capital services to Cancer Centers of North Carolina, P.C. ("CCNC") pursuant to an existing management services agreement (the "Existing Management Services Agreement").

This letter confirms that upon issuance of a certificate of need for the above referenced project, US Oncology, Inc. will provide funds to AOR, and AOR in turn, pursuant to the Existing Management Services Agreement and as member/owner of Wake-Prostate Center of Excellence, LLC (WPCOE), will make those funds available for the proposed Multidisciplinary Prostate Health Demonstration project to fund the capital expenditure required for the acquisition of the proposed linear accelerator and other capital costs associated with the development of the proposed center, as well as start up costs.

We understand that the total capital cost for the development of the proposed WPCOE is $6,837,836.19, to be incurred by WPCOE; and that projected start up costs and working capital total of $599,501. AOR holds 90 percent of the membership interests of WPCOE, and as a 90 percent owner, and upon issuance of the certificate of need, AOR will contribute at least $6,154,053.00 to the capital costs and at least $539,551 to the start up costs and working capital for the proposed center. AOR will provide this funding pursuant to its role as a member of WPCOE and pursuant to the Existing Management Services Agreement with CCNC, which will oversee the clinical operations of WPCOE. … These funds will come from the unrestricted reserves of US Oncology."

Exhibit 48 of the application contains the financial statements for WakeMed for the year ended September 30, 2008, and shows that WakeMed had $31 million in cash and cash equivalents. Exhibit 49 of the application contains the financial statements for US Oncology, Inc. for the year ended December 31, 2008, and shows that US Oncology, Inc. had $104 million in cash and cash equivalents. The applicants adequately demonstrated the availability of funds for the projected capital costs described in the application.

The applicants project their revenue will exceed expenses in each of the first three years of operation following completion of the proposed project. However, the applicants' projections of the number of radiation therapy treatments to be performed in each of the first three operating years are unsupported and unreliable. Consequently, cost and revenues which are based on the number of treatments to be performed are also unsupported and unreliable. See Criterion (3) for discussion of projections.

As a result, the applicants failed to demonstrate that the financial feasibility of the proposed project is based on reasonable projections of costs and revenues. Therefore, the application is not 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.

C
UNCH-CH
Cary Urology
CPC

NC
WPCOE

UNCH-CH - The 2009 SMFP identifies a statewide need for one dedicated linear accelerator that shall be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer. The applicant proposes to acquire a dedicated linear accelerator that will be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of

prostate cancer at the North Carolina Cancer Hospital in Chapel Hill. The applicant proposes to acquire no more than one linear accelerator. See Criterion (3) for discussion. The applicant adequately demonstrated that the proposal would not result in unnecessary duplication of existing or approved linear accelerator services, and is conforming with this criterion.

Cary Urology - The 2009 SMFP identifies a statewide need for one dedicated linear accelerator that shall be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer. The applicant proposes to acquire a dedicated linear accelerator that will be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer at a new facility in Raleigh. The applicant proposes to acquire no more than one linear accelerator. See Criterion (3) for discussion. The applicant adequately demonstrated that the proposal would not result in unnecessary duplication of existing or approved linear accelerator services, and is conforming with this criterion.

CPC - The 2009 SMFP identifies a statewide need for one dedicated linear accelerator that shall be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer. The applicants propose to acquire a dedicated linear accelerator that will be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer at CMC-University Medical Center in Charlotte. The applicants propose to acquire no more than one linear accelerator. See Criterion (3) for discussion. The applicants adequately demonstrated that the proposal would not result in unnecessary duplication of existing or approved linear accelerator services, and are conforming with this criterion.

WPCOE - The 2009 SMFP identifies a statewide need for one dedicated linear accelerator that shall be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer. The applicants propose to acquire a dedicated linear accelerator that will be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer at a new facility in Raleigh. The applicants propose to acquire no more than one linear accelerator. However, WPCOE did not adequately demonstrate the need the population they project to serve has for the proposed services. See Criterion (3) for discussion. Therefore, the applicants did not adequately demonstrate that the proposed project would not result in the unnecessary duplication of existing or approved linear accelerator services and is not conforming with this criterion.

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

C
All Applicants

UNCH-CH – In Section VII.1 of the application, the applicant provides tables showing its current staffing dedicated to prostate cancer services, which includes 3.6 FTE positions, and its projected staffing for the prostate center in second full year following completion of the proposed project, which includes 9.2 FTE positions. In Section VII.3, the applicant describes its experience the manner in which it will recruit the personnel required to staff the proposed project. In Section VII.8, the applicant identifies Paul Godley, M.D. as the medical director for the proposed prostate center. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services and is conforming with this criterion.

Cary Urology – In Section VII.1 of the application, the applicant provides a table showing its projected staffing for the prostate center in second full year following completion of the proposed project, which includes 16.54 FTE positions. In Section VII.3, the applicant describes its experience and the manner in which it will recruit the personnel required to staff the proposed project. In Section VII.8, the applicant identifies Kevin Khoudary, M.D. as the medical director for the proposed prostate center. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to

provide the proposed services and is conforming with this criterion.

CPC – In Section VII.1 of the application, the applicants provide a table showing its projected staffing for the prostate center in second full year following completion of the proposed project, which includes 9.5 FTE positions. In Section VII.3, the applicants describe their experience and the manner in which they will recruit the personnel required to staff the proposed project. In Section VII.8, the applicants identify Timothy Gajewski, M.D. and Roberto Ferraro, M.D. as the co-medical directors for the proposed prostate center. The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services and are conforming with this criterion.

WPCOE – In Section VII.1 of the application, the applicants provide a table showing its projected staffing for the prostate center in second full year following completion of the proposed project, which includes 10.75 FTE positions. In Section VII.3, the applicants describe their experience and the manner in which they will recruit the personnel required to staff the proposed project. In Section VII.8, the applicants identify John Reilly, M.D., William Berry, M.D., and Karl Pete, M.D. as the medical directors for the proposed prostate center. The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services and are conforming with 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
All Applicants

UNCH-CH – In Section II.2 of the application, the applicant states all of the necessary ancillary and support services for the proposed prostate health center are currently provided at the North Carolina Cancer Hospital. In Section V.2(b) of the application, the applicant provides a list of hospitals with which it has transfer agreements. In Exhibit II-16 of the application, the applicant provides 16 letters from physicians supporting the proposed project. The applicant adequately demonstrates that the proposed project will be coordinated with the existing health care system. Therefore, the application is conforming with this criterion.

Cary Urology – In Section II.2 of the application, the applicant describes the ancillary and support services to be provided. In Section V.2(b) of the application, the applicant states a hospital transfer agreement with WakeMed will be arranged. Exhibit 10 contains a letter from WakeMed stating their intention to develop a transfer agreement with Cary Urology. In Exhibits 27, 63, 86, and 96 of the application, the applicant provides 167 letters from physicians supporting the proposed project. The applicant adequately demonstrates that the proposed project will be coordinated with the existing health care system. Therefore, the application is conforming with this criterion.

CPC – In Section II.2 of the application, the applicants state all of the necessary ancillary and support services for the proposed prostate health center are currently provided at CMC-University or will be provided through the management agreement between CPC and CMHA. In Section V.2(b) of the application, the applicants state that patients in need to transfer to an inpatient facility will be transferred to CMC-University. In Exhibit 21 of the application, the applicants provide 36 letters from physicians supporting the proposed project. The applicants adequately demonstrate that the proposed project will be coordinated with the existing health care system. Therefore, the application is conforming with this criterion.

WPCOE – In Section II.2 of the application, the applicants state all of the necessary ancillary and support services for the proposed prostate health center will be provided directly by WPCOE or through arrangements with CCNC, WakeMed, or WakeMed Faculty Practices. In Section V.2(b) of the application, the applicants state a hospital transfer agreement with WakeMed will be arranged. Exhibit 18 contains a letter from WakeMed stating their intention to develop a transfer agreement with WPCOE. In Exhibits 38 and 39 of the application, the applicants provide 33 letters from physicians supporting the proposed project.

The applicants adequately demonstrate 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

NA

(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
Cary Urology
CPC
WPCOE

NA
UNCH-CH

Cary Urology - The applicant proposes to construct a 12,315 square foot outpatient facility to be located on Waverly Drive in Raleigh to accommodate the prostate health center. Exhibit 13 of the application contains the architect’s certified cost estimate of $467,125 for site development and $3,065,431 for construction costs, which is consistent with the applicant’s projected site and construction costs contained in Section VIII.1 of the application. In Section XI.7 of the application, the applicant states that applicable energy savings features will be incorporated into the construction plans. The applicant adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction costs will not unduly increase costs and charges for health services. See Criterion (5) for

discussion of costs and charges. The application is conforming with this criterion.

CPC - The applicants propose to construct a 10,375 square foot addition to the CMC-University facility in Charlotte to accommodate the prostate health center. Exhibit 15 of the application contains the architect's certified cost estimate of $250,000 for site development and $3,750,000 for construction costs, which is consistent with the applicants' projected site and construction costs contained in Section VIII.1 of the application. In Section XI.7 of the application, the applicants state that applicable energy savings features will be incorporated into the construction plans. The applicants adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction costs will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. The application is conforming with this criterion.

WPCOE - The applicants proposes to upfit 16,073 square feet of leased space in a medical office building to be developed at 23 Sunnybrook Road in Raleigh to accommodate the prostate health center. Exhibit 53 of the application contains the architect's certified cost estimate of $4,663,267 for construction costs and $4,798,189 for *"soft costs"* for a total capital project cost of $9,461,456, which is consistent with the applicants' projected costs contained in Section VIII.1 of the application. In Section XI.7 of the application, the applicants state that applicable energy savings features will be incorporated into the construction plans. The applicants adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction costs will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. The application is conforming with 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
All Applicants

UNCH-CH - In Section VI.2 of the application, the applicant states that it does not discriminate on the basis of income, race, ethnicity, sex, handicap, age, or any other factor which might restrict access to services. In Section VI.12 of the application, the applicant provides the following table showing the utilization of the UNC Hospital's entire facility by payer category for FY2008.

Payer Category	Patient Days/Procedures as % of Total Utilization
Self Pay/Indigent/Charity	5.6%
Medicare/Medicare Managed Care	30.7%
Medicaid	29.1%
Commercial Insurance	1.4%
Managed Care	27.4%
Other (TRICARE, State)	5.8%
Total	**100.0%**

In Section VI.13 of the application, the applicant provides the following table showing the utilization of the UNC Hospital's radiation oncology services by payer category for FY2008.

Payer Category	Patient Days/Procedures as % of Total Utilization
Self Pay/Indigent/Charity	5.8%
Medicare/Medicare Managed Care	39.3%
Medicaid	14.4%
Commercial Insurance/Managed Care	34.1%
Other (TRICARE, State)	6.4%
Total	**100.0%**

Also in Section VI.13 of the application, UNCH-CH provides projections by service component for prostate cancer patients from FY2008, and those service component payer category percentages are significantly different from the payer category percentages for UNCH-CH's entire facility as a whole. For example, the percentage of services for prostate cancer patients provided to Medicare recipients ranged from 52.8 percent to 78.7 percent, and the percentage of services for prostate cancer patients provided to Medicaid recipients ranged from zero to 3.0 percent, depending on the particular program component [See pages 248-250 of the application]. The applicant demonstrates that medically underserved populations currently have access to the applicant's existing services and is conforming to this criterion.

Cary Urology - In Section VI.2 of the application, the applicant states that it does not discriminate on the basis of income, race, ethnicity, sex, handicap, age, or any other factor which might restrict access to services. In Section VI.12 of the application, the applicant provides the following table showing the utilization of Cary Urology's services by payer category for 2008.

Payer Category	Patient Days/Procedures as % of Total Utilization
Self Pay	0.8%
Medicare	22.7%
Medicaid	1.8%
Commercial Insurance/Managed Care	16.7%
Blue Cross/Other	58.0%
Total	**100.0%**

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

CPC - In Section VI.12 of the application, the applicants state CPC is not an existing facility. However, Radiation Oncology Centers of the Carolinas, Inc. (ROCC), which is a member of CPC, currently provides radiation oncology services. Based on data reported by ROCC in the *Registration and Inventory of Medical Equipment, Linear Accelerator Equipment-January 2009* the ROCC radiation oncology facilities provided 45.3% of its services to Medicare recipients and 3.3% of its services to Medicaid recipients in FY2008. Also, CMC-University is an operating division of CMHA, which is a member of CPC. Based on data reported by CMC-University in the *2009 Renewal Application for Hospital*, the hospital provided 22.5% of its outpatient services to Medicare recipients and 5.5% of its outpatient services to Medicaid recipients in FY2008. The applicants demonstrate that medically underserved populations currently have access to the applicants' existing services and are conforming to this criterion.

WPCOE - In Section VI.12 of the application, the applicants state WPCOE is not an existing facility. However, Cancer Centers of North Carolina, PC. (CCNC), which is a member of WPCOE,

currently provides radiation oncology services. Based on data reported by CCNC in the *Registration and Inventory of Medical Equipment, Linear Accelerator Equipment-January 2009* the CCNC radiation oncology facility provided 38.4% of its services to Medicare recipients and 8.4% of its services to Medicaid recipients in FY2008. Also, WakeMed is a member of WPCOE. Based on data reported by WakeMed in the *2009 Renewal Application for Hospital*, the hospital provided 19.2% of its outpatient services to Medicare recipients and 18.9% of its outpatient services to Medicaid recipients in FY2008. The applicants demonstrate that medically underserved populations currently have access to the applicants' existing services and are 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
All Applicants

UNCH-CH - In Section VI.10 of the application, the applicant states that no civil rights access complaints have been filed against UNC Hospitals in the last five years.

Cary Urology - In Section VI.10 of the application, the applicants state that no civil rights access complaints have been filed against BRSC in the last five years.

CPC - In Section VI.10 of the application, the applicants states that no civil rights access complaints have been filed against the members of CPC in the last five years.

WPCOE - In Section VI.10 of the application, the applicants state that no civil rights access complaints have been filed against the members of WPCOE in the last five years.

(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
All Applicants

UNCH-CH - In Section VI.14 of the application, the applicant projects the following payer mix for the entire UNC Hospitals' facility in the second operating year.

Payer Category	Patient Days/Procedures as % of Total Utilization
Self Pay/Indigent/Charity	5.6%
Medicare/Medicare Managed Care	30.7%
Medicaid	29.1%
Commercial Insurance	1.4%
Managed Care	27.4%
Other (TRICARE, State)	5.8%
Total	**100.0%**

In Section VI.14(b) of the application, the applicant states the payer mix projections are based on its most recent historical (FY2008) experience. Also, in Section VI.15(a), the applicant projects the following payer mix for the program components for prostate cancer patients in the second operating

year.

Prostate Cancer Patients-Chemotherapy Payer Category	Patient Days/Procedures as % of Total Utilization
Self Pay/Indigent/Charity	3.3%
Medicare/Medicare Managed Care	78.7%
Medicaid	1.6%
Commercial Insurance/Managed Care	13.1%
Other (TRICARE, State)	3.3%
Total	**100.0%**

Prostate Cancer Patients-Medical Oncology Payer Category	Patient Days/Procedures as % of Total Utilization
Self Pay/Indigent/Charity	5.5%
Medicare/Medicare Managed Care	76.0%
Medicaid	1.2%
Commercial Insurance/Managed Care	9.5%
Other (TRICARE, State)	7.8%
Total	**100.0%**

Prostate Cancer Patients-Radiation Oncology Payer Category	Patient Days/Procedures as % of Total Utilization
Self Pay/Indigent/Charity	4.3%
Medicare/Medicare Managed Care	59.1%
Medicaid	3.0%
Commercial Insurance/Managed Care	21.1%
Other (TRICARE, State)	12.5%
Total	**100.0%**

Prostate Cancer Patients-Urology Payer Category	Patient Days/Procedures as % of Total Utilization
Self Pay/Indigent/Charity	4.8%
Medicare/Medicare Managed Care	52.8%
Medicaid	1.5%
Commercial Insurance/Managed Care	28.3%
Other (TRICARE, State)	12.6%
Total	**100.0%**

Prostate Cancer Patients-Brachytherapy Payer Category	Patient Days/Procedures as % of Total Utilization
Self Pay/Indigent/Charity	20.0%
Medicare/Medicare Managed Care	60.0%

Medicaid	0.0%
Commercial Insurance/Managed Care	0.0%
Other (TRICARE, State)	20.0%
Total	**100.0%**

Prostate Cancer Patients-Biofeedback Payer Category	**Patient Days/Procedures as % of Total Utilization**
Self Pay/Indigent/Charity	3.8%
Medicare/Medicare Managed Care	56.9%
Medicaid	1.5%
Commercial Insurance/Managed Care	26.4%
Other (TRICARE, State)	11.4%
Total	**100.0%**

Prostate Cancer Patients-Living Skills Payer Category	**Patient Days/Procedures as % of Total Utilization**
Self Pay/Indigent/Charity	3.8%
Medicare/Medicare Managed Care	56.9%
Medicaid	1.5%
Commercial Insurance/Managed Care	26.4%
Other (TRICARE, State)	11.4%
Total	**100.0%**

In Section VI.15(b) of the application, the applicant states the payer mix projections by program component are based on its most recent historical (FY2008) experience. The applicant demonstrated that medically underserved populations will have adequate access to the proposed services and is conforming with this criterion.

Cary Urology - In Section VI.14 of the application, the applicant projects the following payer mix for Cary Urology's services in the second operating year.

Payer Category	**Patient Days/Procedures as % of Total Utilization**
Self Pay	0.8%
Medicare	61.2%
Medicaid	6.8%
Commercial Insurance/Managed Care	24.4%
Blue Cross/Other	6.8%
Total	**100.0%**

In Section VI.14(b) of the application, the applicant states, "*Because Cary Urology's Brachytherapy cancer patients are approximately the same age as patients who will be treated at The Prostate Health Center, it is assumed that The Prostate Health Center's payor mix will equal that of Cary Urology's historical Brachytherapy payor mix.*" The applicant demonstrated that medically underserved populations will have adequate access to the proposed services and is conforming with this criterion.

CPC - In Section VI.14 of the application, the applicants project the following payer mix for CPC's services in the second operating year.

Payer Category	Patient Days/Procedures as % of Total Utilization
Self Pay/Indigent/Charity	4.0%
Medicare	69.0%
Medicaid	4.0%
Managed Care	9.0%
Blue Cross	14.0%
Total	**100.0%**

In Section VI.14(b) of the application, the applicants state, *"CPC based the oncology treatment payor mix based on the current outpatient mix for CHS* [Carolinas HealthCare System] *facilities in Mecklenburg County."* The applicant demonstrated that medically underserved populations will have adequate access to the proposed services and is conforming with this criterion.

WPCOE - In Section VI.14 of the application, the applicants project the following payer mix for WPCOE's services in the second operating year.

Payer Category	Patient Days/Procedures as % of Total Utilization
Self Pay/Indigent/Charity	5.14%
Medicare/Medicare Managed Care	47.23%
Medicaid	9.86%
Commercial Insurance	15.30%
Managed Care	22.47%
Total	**100.0%**

In Section VI.14(b) of the application, the applicant states, *"Charges are based on the 2009 Fee Schedule at CCNC. Percentage allocation for each payor is based on the types of patients expected to be seen at WPCOE."* The applicant demonstrated that medically underserved populations will have adequate access to the proposed services and is conforming with 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
All Applicants

All Applicants - In Section VI.9 of the application, all applicants state that patients will have access to the services offered by a range of means, including physician referral.

(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

All Applicants

UNCH-CH - In Section V.1 of the application, the applicant states UNCH-CH is an academic teaching hospital with many health professional training programs and affiliations. The applicant is conforming with this criterion.

Cary Urology. In Section V.1 of the application, the applicant states it *"will offer The Prostate Health Center as a training site to students in appropriate fields of study."* Exhibit 68 contains copies of letters from Cary Urology to several area healthcare professional training programs expressing the applicant's willingness to serve as a training site. Therefore, the applicant is conforming with this criterion.

CPC - In Section V.1 of the application, the applicants state that, "*as a facility managed by CMHA, CPC will have a positive and close working relationship with health care training programs."* Exhibit 10 of the application contains a copy of a letter from Cabarrus College of Health Sciences regarding a clinical training agreement with the applicants. The applicant is conforming with this criterion.

WPCOE - In Section V.1 of the application, the applicants state WakeMed has extensive relationships with many health professional training programs, and that WakeMed's health professional training programs will have access to the applicants' proposed prostate health center. Exhibit 37 of the application contains a list of these arrangements. The application is conforming with 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
UNCH-CH
Cary Urology
CPC

NC
WPCOE

UNCH-CH. The applicant adequately demonstrated that its proposed project would have a positive impact upon the cost effectiveness, quality, and access to the proposed services. See Criteria (3), (5), (7), (8), and (13). Therefore, the application is conforming to this criterion.

Cary Urology. The applicant adequately demonstrated that its proposed project would have a positive impact upon the cost effectiveness, quality, and access to the proposed services. See Criteria (3), (5), (7), (8), (12), (13), and (20). Therefore, the application is conforming to this criterion.

CPC. The applicants adequately demonstrated that their proposed project would have a positive impact upon the cost effectiveness, quality, and access to the proposed services. See Criteria (3), (5), (7), (8), (12), and (13). Therefore, the application is conforming to this criterion.

WPCOE. The applicants did not demonstrate that the proposed services will have a positive impact on the

cost effectiveness of the proposed services. See Criteria (1), (3), and (5).

(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
CPC

NA
Cary Urology
WPCOE

UNCH-CH is accredited by the Joint Commission on Accreditation of Health Care Organizations and certified for Medicare and Medicaid participation. 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. Therefore, the application is conforming with this criterion.

Cary Urology. The applicant's existing facility is not licensed or certified by the Division of Health Services Regulation.

CMC-University is accredited by the Joint Commission on Accreditation of Health Care Organizations and certified for Medicare and Medicaid participation. 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. Therefore, the application is conforming with this criterion.

WPCOE. The proposed WPCOE facility is a new facility and CCNC's existing facility is not licensed or certified by the Division of Health Services Regulation.

(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
UNCH-CH
Cary Urology
CPC

NC
WPCOE

UNCH-CH. The proposal submitted by UNCH-CH is conforming with all applicable Criteria and

Standards for Radiation Therapy Equipment required by 10A NCAC 14C .1900, as indicated below.

Cary Urology. The proposal submitted by Cary Urology is conforming with all applicable Criteria and Standards for Radiation Therapy Equipment required by 10A NCAC 14C .1900, as indicated below.

CPC. The proposal submitted by CPC is conforming with all applicable Criteria and Standards for Radiation Therapy Equipment required by 10A NCAC 14C .1900, as indicated below.

WPCOE. The proposal submitted by WPCOE is not conforming with all applicable Criteria and Standards for Radiation Therapy Equipment required by 10A NCAC 14C .1900, as indicated below.

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- **All Applicants.** The applicants used the correct application form.

(b) An applicant proposing to acquire radiation therapy equipment shall also provide the following additional 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 describes the radiation therapy equipment to be acquired and provides documentation of the capabilities of the proposed linear accelerator in Section II.8, page 52, and Exhibit I-15 of the application. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** The applicant describes the radiation therapy equipment to be acquired and provides documentation of the capabilities of the proposed linear accelerator, CT simulator, and brachytherapy unit in Exhibits 7 and 8 of the application. In Section IV.2, page 224 of the application, the applicant defines the capacity of the brachytherapy unit as 260 patients per year. Therefore, the application is conforming to this rule.

-C- **CPC.** The applicants describe the radiation therapy equipment to be acquired and provide documentation of the capabilities of the proposed linear accelerator, CT simulator, and brachytherapy unit in Exhibit 4 of the application. In Section IV.2, page 118 of the application, the applicants defines the capacity of the brachytherapy unit as 624 procedures per year. Therefore, the application is conforming to this rule.

-C- **WPCOE.** The applicants describe the radiation therapy equipment to be acquired and provide documentation of the capabilities of the proposed linear accelerator, CT simulator, and brachytherapy unit in Exhibits 21, 43, and 44 of the application. In Section IV.2, page 110 of the application, the applicants define the capacity of the brachytherapy unit as 250 patients per year. Therefore, the application is conforming to this rule.

(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.** In Exhibit I-15, the applicant provided the purchase price quotation for the linear accelerator and related equipment. The applicant states the purchase price is equivalent to the fair market value. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** In Exhibits 7 and 8, the applicant provided the purchase price quotations for the linear accelerator and related equipment. The applicant states the purchase price is equivalent to the fair market value. Therefore, the application is conforming to this rule.

-C- **CPC.** In Exhibit 4, the applicants provide the purchase price quotation for the linear accelerator and related equipment. The applicants state the purchase price is equivalent to the fair market value. Therefore, the application is conforming to this rule.

-C- **WPCOE.** In Exhibits 21, 43, and 44 of the application, the applicants provide the purchase price

quotation for the linear accelerator and related equipment. Therefore, the application is conforming to this rule.

(3) the projected number of patient treatments by county and by simple, intermediate and complex 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, pages 53-64 of the application, the applicant provides the projected number of patient treatments by county and by simple, intermediate and complex treatments to be performed on both its four existing and one proposed linear accelerator for each of the first three years of operation following the completion of the project. The follow table summarizes the applicant's projections by county and year of operation:

Linear Accelerator Treatments* Utilization Projections by County	**Year 1**	**Year 2**	**Year 3**
Wake	1,828	1,915	2,005
Orange	1,739	1,821	1,907
Durham	780	817	855
Alamance	627	656	687
Chatham	627	656	687
Lee	550	576	603
Cumberland	396	415	435
Johnston	345	362	379
Other**	4,360	4,566	4,782
Totals	**11,252**	**11,784**	**12,340**

*See application pages 57-64 for projections of treatments by treatment type (i.e., simple, intermediate, and complex) by county for each of the first three years of operation.
*See application pages 58-64 for a complete listing of the counties included in *"Other"* category.

In Section III.1 of the application, the applicant documents the assumptions by which utilization is projected. See Criterion (3) for discussion of reasonableness of the assumptions. Therefore, the application is conforming to this rule.

-C- Cary Urology. In Section IV.1, pages 209-211 of the application, the applicant provides the projected number of patient treatments by county and by simple, intermediate and complex treatments to be performed on its proposed linear accelerator for each of the first three years of operation following the completion of the project. The follow table summarizes the applicant's projections by county and year of operation:

Linear Accelerator Treatments* Utilization Projections by County	**Year 1**	**Year 2**	**Year 3**
Wake	4,257	5,613	7,586
Harnett	271	283	297
Franklin	116	120	125
Lee	115	119	124
Johnston	62	59	62
Duplin	48	48	48
Durham	48	48	48
Sampson	48	48	48
Chatham	45	47	49
Other	229	279	368
Totals	**5,239**	**6,664**	**8,755**

*See application pages 209-211 for projections of treatments by treatment type (i.e., simple, intermediate, and complex) by county for each of the first three years of operation.

In Section III.1 and Section IV.1 of the application, the applicant documents the assumptions by which utilization is projected. See Criterion (3) for discussion of reasonableness of the assumptions. Therefore, the application is conforming to this rule.

-C- **CPC.** In Section II.8, page 38 of the application, the applicants provide the projected number of patient treatments by county and by simple, intermediate and complex treatments to be performed on its proposed linear accelerator for each of the first three years of operation following the completion of the project. The follow table summarizes the applicants' projections by county and year of operation:

Linear Accelerator Treatments* Utilization Projections by County	**Year 1**	**Year 2**	**Year 3**
Mecklenburg	3,435	5,288	5,967
Cabarrus	437	674	923
Union	149	232	321
Stanly	53	79	106
Gaston	38	38	39
Iredell	22	22	34
Rowan	22	45	68
Lincoln	16	17	17
Totals	**4,172**	**6,395**	**7,474**

*On page 38 of the application, the applicants project to perform only complex treatments, and do not project to perform any simple or intermediate treatments, in the first three years of operation.

In Section III.1 of the application, the applicants document the assumptions by which utilization is projected. See Criterion (3) for discussion of reasonableness of the assumptions. Therefore, the application is conforming to this rule.

-C- **WPCOE.** In Section II.8, pages 55-56 of the application, the applicants provide the projected number of patient treatments by county and by simple, intermediate and complex treatments to be performed on its proposed linear accelerator for each of the first three years of operation following the completion of the project. The following table summarizes the applicants' projections by county and year of operation:

Linear Accelerator Treatments* Utilization Projections by County	**Year 1**	**Year 2**	**Year 3**
Wake	3,120	3,880	4,680
Harnett	320	400	520
Franklin	320	360	440
Johnston	240	240	280
Nash	200	240	320
Granville	160	160	200
Sampson	80	80	120
Other**	240	400	640
Totals	**4,680**	**5,760**	**7,200**

*On pages 55-56 of the application, the applicants do not project to perform any simple or intermediate treatments in the first three years of operation.

**The applicants state the *"Other"* category includes Lee, Wayne, Wilson, Orange, Northampton, Moore, Durham, Chatham, and Duplin counties, and out of state.

In Section III.1 of the application, the applicants document the assumptions by which utilization is projected. See Criterion (3) for discussion of reasonableness of the assumptions. Therefore, the application is conforming to this rule.

(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 64, the applicant states the proposed radiation therapy equipment will be operational from 7:00 a.m. to 6:00 p.m., Monday through Friday. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** In Section II.8, page 80, the applicant states the proposed radiation therapy equipment will be operational from 8:00 a.m. to 5:00 p.m., Monday through Friday. Therefore, the application is conforming to this rule.

-C- **CPC.** In Section II.8, page 39, the applicants state the proposed radiation therapy equipment will be operational from 7:00 a.m. to 5:00 p.m., Monday through Friday. Therefore, the application is conforming to this rule.

-C- **WPCOE.** In Section II.8, page 56, and Exhibit 22 of the application, the applicants state the proposed radiation therapy equipment will be operational at least 7 hours per day, 5 days per week. Therefore, the application is conforming to this rule.

(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 65, the applicant states that it currently operates four linear accelerators and two simulators, and does not propose to acquire a simulator as part of this project. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** In Section II.8, page 80, the applicant states the proposed prostate health center will have one new linear accelerator and one new simulator. Therefore, the application is conforming to this rule.

-C- **CPC.** In Section II.8, page 39, the applicants state the proposed prostate health center will have one new linear accelerator and one new simulator. Therefore, the application is conforming to this rule.

-C- **WPCOE.** In Section II.8, page 57, the applicants state the proposed prostate health center will have one new linear accelerator and one new simulator. Therefore, the application is conforming to this rule.

(6) documentation that the services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies; and

-C- **UNCH-CH.** In Section II.8, page 65, the applicant states the facility will meet all the requirements of the federal, state and local regulatory bodies. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** In Section II.8, page 80, the applicant states the facility will meet all the requirements of the federal, state and local regulatory bodies. Therefore, the application is conforming to this rule.

-C- **CPC.** In Section II.8, page 40, the applicants state the facility will meet all the requirements of the federal, state and local regulatory bodies. Therefore, the application is conforming to this rule.

-C- **WPCOE.** In Section II.8, page 57, the applicants state the facility will meet all the requirements of the federal, state and local regulatory bodies. Therefore, the application is conforming to this rule.

(7) the projected number of patients that will be treated by county in each of the first three years of operation following completion of the proposed project.

-C- **UNCH-CH.** In Section II.8, pages 65-68, the applicant provides a table showing the projected number of patients that will be treated by county in each of the first three years of operation following completion of the proposed project. See Criterion (3) for discussion of reasonableness of projections. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** In Section IV.1, page 203, the applicant provides a table showing the projected number of patients that will be treated by county in each of the first three years of operation following completion of the proposed project. See Criterion (3) for discussion of reasonableness of projections. Therefore, the application is conforming to this rule.

-C- **CPC.** In Section II.8, pages 40-41, the applicants provide tables showing the projected number of patients that will be treated by county in each of the first three years of operation following completion

of the proposed project. See Criterion (3) for discussion of reasonableness of projections. Therefore, the application is conforming to this rule.

-C- **WPCOE.** In Section II.8, page 57, the applicants provide a table showing the projected number of patients that will be treated by county in each of the first three years of operation following completion of the proposed project. See Criterion (3) for discussion of reasonableness of projections. Therefore, the application is conforming to this rule.

(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 additional 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;

-C- **UNCH-CH.** The applicant provides a description of all services to be provided by the proposed multidisciplinary prostate health center, including a description of each of the services listed in this rule, in Sections II.1 and III.1 of the application. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** The applicant provides a description of all services to be provided by the proposed multidisciplinary prostate health center, including a description of each of the services listed in this rule, in Sections II.1 and III.1 of the application. Therefore, the application is conforming to this rule.

-C- **CPC.** The applicants provide a description of all services to be provided by the proposed multidisciplinary prostate health center, including a description of each of the services listed in this rule, in Sections II.1 and III.1 of the application. Therefore, the application is conforming to this rule.

-C- **WPCOE.** The applicants provide a description of all services to be provided by the proposed multidisciplinary prostate health center, including a description of each of the services listed in this rule, in Sections II.1 and III.1 of the application. Therefore, the application is conforming to this rule.

(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;

-C- **UNCH-CH.** The applicant provides 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, the N.C. Cancer Hospital, in Sections II.1 and II.8, page 69 of the application. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** The applicant provides 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 in Section II.8, page 81 of the application. Therefore, the application is conforming to this rule.

-C- **CPC.** The applicants provide 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 in Section II.8, page 44 of the application. Therefore, the application is conforming to this rule.

-C- **WPCOE.** The applicants provide 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 in Section II.8, page 58 of the application. Therefore, the application is conforming to this rule.

(3) description of any services that will be provided by other facilities or in different buildings;

-NA- **UNCH-CH.** The applicant does not identify any services that will be provided by other facilities or in a different building.

-C- **Cary Urology.** In Section II.8, page 82, the applicant identifies the services that will be provided by other facilities or in a different building, including laboratory, pathology, and physical therapy services, which will be provided through arrangement with WakeMed. Therefore, the application is conforming to this rule.

-NA- **CPC.** The applicants do not identify any services that will be provided by other facilities or in a different building.

-C- **WPCOE.** In Section II.8, page 58, the applicants identify the services that will be provided by other facilities or in a different building, including diagnostic imaging, which will be provided through arrangement with WakeMed.. Therefore, the application is conforming to this rule.

(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,

-C- **UNCH-CH.** The applicant provides the demographics of the population in the county in which the proposed multidisciplinary prostate health center will be located, Orange County, in Section II.8, pages 70-71 of the application. The applicant reports 13.1% of the population in the county is African American. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** The applicant provides the demographics of the population in the county in which the proposed multidisciplinary prostate health center will be located, Wake County, in Section II.8, pages 83-84 of the application. The applicant reports 20.38% of the population in the county is African American. Therefore, the application is conforming to this rule.

-C- **CPC.** The applicants provide the demographics of the population in the county in which the proposed multidisciplinary prostate health center will be located, Mecklenburg County, in Section II.8, pages 45-46 of the application. The applicants report 29.9% of the population in the county is African American. Therefore, the application is conforming to this rule.

-C- **WPCOE.** The applicants provide the demographics of the population in the county in which the proposed multidisciplinary prostate health center will be located, Wake County, in Section II.8, pages 59-60 of the application. The applicants report 20.5% of the population in the county is African American. Therefore, the application is conforming to this rule.

(B) the percentage of the population in the county that is male,

-C- **UNCH-CH.** The applicant reports 47.7% of the population in Orange County is male. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** The applicant reports 49.74% of the population in Wake County is male. Therefore, the application is conforming to this rule.

-C- **CPC.** The applicants report 49.3% of the population in Mecklenburg County is male. Therefore, the application is conforming to this rule.

-C- **WPCOE.** The applicants report 49.6% of the population in Wake County is male. Therefore, the application is conforming to this rule.

(C) the percentage of the population in the county that is African American male,

-C- **UNCH-CH.** The applicant reports 5.9% of the population in Orange County is African American male. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** The applicant reports 9.52% of the population in Wake County is African American male. Therefore, the application is conforming to this rule.

-C- **CPC.** The applicants report 13.9% of the population in Mecklenburg County is African American male. Therefore, the application is conforming to this rule.

-C- **WPCOE.** The applicants report 9.6% of the population in Wake County is African American male.

Therefore, the application is conforming to this rule.

(D) the incidence of prostate cancer for the African American male population in the county, and

-C- **UNCH-CH.** The applicant reports the incidence of prostate cancer in the African American male population in Orange County is 226.8 per 100,000. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** The applicant reports the incidence of prostate cancer in the African American male population in Wake County is 239.0 per 100,000. Therefore, the application is conforming to this rule.

-C- **CPC.** The applicants report the incidence of prostate cancer in the African American male population in Mecklenburg County is 209.8 per 100,000. Therefore, the application is conforming to this rule.

-C- **WPCOE.** The applicants report the incidence of prostate cancer in the African American male population in Wake County is 238.0 per 100,000. Therefore, the application is conforming to this rule.

(E) the mortality rate from prostate cancer for the African American male population in the county;

-C- **UNCH-CH.** The applicant reports the mortality rate from prostate cancer for the African American male population in Orange County is 83.4 per 100,000. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** The applicant reports the mortality rate from prostate cancer for the African American male population in Wake County is 69.7 per 100,000. Therefore, the application is conforming to this rule.

-C- **CPC.** The applicants report the mortality rate from prostate cancer for the African American male population in Mecklenburg County is 61.2 per 100,000. Therefore, the application is conforming to this rule.

-C- **WPCOE.** The applicants report the mortality rate from prostate cancer for the African American male population in Wake County is 73.4 per 100,000. Therefore, the application is conforming to this rule.

(5) documentation that the proposed center is located within walking distance of an established bus route and within five miles of a minority community;

-C- **UNCH-CH.** The applicant provides documentation that the proposed center is located within walking distance of an established bus route and within five miles of a minority community in Section II.8, page 71, and Section III.1(a), pages 135-139 of the application. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** The applicant provides documentation that the proposed center is located within walking distance of an established bus route and within five miles of a minority community in Section II.8, page 85, and Exhibits 5 and 6 of the application. Therefore, the application is conforming to this rule.

-C- **CPC.** The applicants provide documentation that the proposed center is located within walking distance of an established bus route and within five miles of a minority community in Section II.8, pages 47-49 of the application. Therefore, the application is conforming to this rule.

-C- **WPCOE.** The applicants provide documentation that the proposed center is located within walking distance of an established bus route and within five miles of a minority community in Section II.8, page 60, and Section III.1(a), pages 96-99 of the application. Therefore, the application is conforming to this rule.

(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;

-C- **UNCH-CH.** The applicant provides 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 in Section II.8, pages 72-73 of the application. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** The applicant provides 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 in Section II.8, page 85, and Exhibit 51 of the application. Therefore, the application is conforming to this rule.

-C- **CPC.** The applicants provide 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 in Section II.8, page 50, and Exhibit 7 of the application. Therefore, the application is conforming to this rule.

-C- **WPCOE.** The applicants provide 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 in Section II.8, page 60, and Exhibit 24 of the application. Therefore, the application is conforming to this rule.

(7) documentation that the center will establish its own prostate/urological cancer tumor board for review of cases;

-C- **UNCH-CH.** The applicant provides documentation that the center will establish its own prostate/urological cancer tumor board for review of cases in Section II.8, page 73 of the application. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** The applicant provides documentation that the center will establish its own prostate/urological cancer tumor board for review of cases in Section II.8, page 85, and Exhibit 51 of the application. Therefore, the application is conforming to this rule.

-C- **CPC.** The applicants provide documentation that the center will establish its own prostate/urological cancer tumor board for review of cases in Section II.8, pages 50-51 of the application. Therefore, the application is conforming to this rule.

-C- **WPCOE.** The applicants provide documentation that the center will establish its own prostate/urological cancer tumor board for review of cases in Section II.8, page 60, and Exhibits 25 and 26 of the application. Therefore, the application is conforming to this rule.

(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;

-C- **UNCH-CH.** Exhibit I-17 of the application contains a copy of the applicant’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. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** Exhibit 52 of the application contains a copy of the applicant’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. Therefore, the application is conforming to this rule.

-C- **CPC.** Exhibit 11 of the application contains a copy of the applicants’ 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. Therefore, the application is conforming to this rule.

-C- **WPCOE.** Exhibit 33 of the application contains a copy of the applicants’ 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. Therefore, the application is conforming to this rule.

(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;

-C- **UNCH-CH.** Section II.8, page 74, Section III.1(a) and Exhibit I-17 of the application contain written strategies and activities the center will follow to assure its services will be accessible by patients without regard to their ability to pay. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** Section II.8, pages 86-87, Section II.1, and Exhibits 52 and 53 of the application contain written strategies and activities the center will follow to assure its services will be accessible by patients without regard to their ability to pay. Therefore, the application is conforming to this rule.

-C- **CPC.** Section II.8, page 51, and Exhibit 11 of the application contain written strategies and activities the center will follow to assure its services will be accessible by patients without regard to their ability to pay. Therefore, the application is conforming to this rule.

-C- **WPCOE.** Section II.8, page 61, and Exhibit 33 of the application contain written strategies and activities the center will follow to assure its services will be accessible by patients without regard to their ability to pay. Therefore, the application is conforming to this rule.

(10) description of the center's outreach activities and the manner in which they complement existing outreach initiatives;

-C- **UNCH-CH.** In Section II.8, page 74, Section III.1(a), and Exhibit I-20 of the application, the applicant provides a description of the center's outreach activities and the manner in which they complement existing outreach initiatives. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** In Section II.8, pages 87-88, and Section II.1 of the application, the applicant provides a description of the center's outreach activities and the manner in which they complement existing outreach initiatives. Therefore, the application is conforming to this rule.

-C- **CPC.** In Section II.8, pages 51-53 of the application, the applicants provide a description of the center's outreach activities and the manner in which they complement existing outreach initiatives. Therefore, the application is conforming to this rule.

-C- **WPCOE.** In Section II.8, page 61 of the application, the applicants provide a description of the center's outreach activities and the manner in which they complement existing outreach initiatives. Therefore, the application is conforming to this rule.

(11) documentation of number and type of clinics to be conducted to screen patients at risk for prostate cancer;

-C- **UNCH-CH.** In Section II.8, pages 74-75, the applicant provides documentation of number and type of clinics to be conducted to screen patients at risk for prostate cancer. On page 74, the applicant states, *"UNC Hospitals entire extended primary care network (which encompasses all primary care clinics, including satellite and affiliate clinics) perform prostate cancer screenings of appropriate men according to the American Cancer Society guidelines."* Therefore, the application is conforming to this rule.

-C- **Cary Urology.** In Section II.8, pages 88-89, the applicant provides documentation of number and type of clinics to be conducted to screen patients at risk for prostate cancer. Therefore, the application is conforming to this rule.

-C- **CPC.** In Section II.8, page 53, the applicants provide documentation of number and type of clinics to be conducted to screen patients at risk for prostate cancer. Therefore, the application is conforming to this rule.

-C- **WPCOE.** In Section II.8, pages 62, the applicants provide documentation of number and type of clinics to be conducted to screen patients at risk for prostate cancer. On page 62, the applicants state, *"WPCOE plans to offer at least one clinic per quarter to screen patients at risk for prostate cancer."* Therefore, the application is conforming to this rule.

(12) written description of patient selection criteria, including referral arrangements for high-risk patients;

-C- **UNCH-CH.** In Section II.8, pages 75-76 of the application, the applicant provides a written description of patient selection criteria, including referral arrangements for high-risk patients. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** In Section II.8, page 90 of the application, the applicant provides a written description of patient selection criteria, including referral arrangements for high-risk patients. Therefore, the application is conforming to this rule.

-C- **CPC.** In Section II.8, page 54 of the application, the applicants provide a written description of patient selection criteria, including referral arrangements for high-risk patients. Therefore, the application is conforming to this rule.

-C- **WPCOE.** In Section II.8, page 62 of the application, the applicants provide a written description of patient selection criteria. Exhibit 18 of the application contains a letter from WakeMed documenting referral arrangements for comprehensive emergency services to WPCOE's patients. Therefore, the application is conforming to this rule.

(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 patientsserved by type of payment category;

-C- **UNCH-CH.** In Section II.8, page 76, the applicant provides a commitment to prepare an annual report to include the information in (A) through (D) above at the end of each of the first three operating years. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** In Section II.8, page 91, the applicant provides a commitment to prepare an annual report to include the information in (A) through (D) above at the end of each of the first three operating years. Therefore, the application is conforming to this rule.

-C- **CPC.** In Section II.8, page 54, the applicants provide a commitment to prepare an annual report to include the information in (A) through (D) above at the end of each of the first three operating years. Therefore, the application is conforming to this rule.

-C- **WPCOE.** In Section II.8, page 62 of the application, the applicants provide a commitment to prepare an annual report to include the information in (A) through (D) above at the end of each of the first three operating years. Therefore, the application is conforming to this rule.

(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

-C- **UNCH-CH.** In Section II.8, page 77, and Exhibits I-19 and I-21, the applicant provides documentation of its arrangements with Shaw University as required in this rule. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** In Section II.8, pages 92-93, and Exhibits 19 and 58, the applicant provides documentation of its arrangements with Shaw University as required in this rule. Therefore, the application is conforming to this rule.

-C- **CPC.** In Section II.8, pages 54-55, and Exhibit 3 of the application, the applicants provide documentation of its arrangements with John C. Smith University as required in this rule. Therefore, the application is conforming to this rule.

-C- **WPCOE.** In Section II.8, pages 62-63, and Exhibit 29 of the application, the applicants provide documentation of its arrangements with St. Augustine's College as required in this rule. Therefore, the application is conforming to this rule.

(15) if the third party researcher is not a historically black university, document the reasons for using a different researcher for the project.

-NA- **UNCH-CH.** In Section II.8, page 77, the applicant states Shaw University is a historically black university.

-NA- **Cary Urology.** In Section II.8, page 93, the applicant states Shaw University is a historically black

university.

-NA- **CPC.** In Section II.8, page 55, the applicants state John C. Smith University is a historically black university.

-NA- **WPCOE.** In Section II.8, page 63, the applicants state St. Augustine's College is a historically black university.

10A NCAC 14C .1903 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a linear accelerator shall demonstrate that each of the following standards will be met:

(1) an applicant's existing linear accelerators located in the proposed radiation therapy service area performed at least 6,750 ESTV treatments per machine or served at least 250 patients per machine in the twelve months prior to the date the application was submitted;

-C- **UNCH-CH.** In Section II.8, page 78 of the application, the applicant states its four existing linear accelerators served 1,020 patients in the twelve months ended January 31, 2009, which is equivalent to 255 patients per machine [1,020/4 = 255]. Therefore, the application is conforming to this rule.

-NA- **Cary Urology.** The applicant does not own a linear accelerator.

-C- **CPC.** In Section II.8, page 56, the applicants states that Carolinas Prostate Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a CMC-University do not own a linear accelerator. However, The Charlotte-Mecklenburg Hospital Authority (CMHA) d/b/a Carolinas HealthCare System (CHS) is the parent company for CMC-University. In Section II.8, page 56 of the application, the applicant states that CHS' seven existing linear accelerators served 2,386 patients in the twelve months ended February 28, 2009, which is equivalent to 341 patients per machine [2,386/7 = 341]. On page 56 of the application, the applicants state, "*PRTC* [Pineville Radiation Therapy Center, LLC] *is a wholly owned subsidiary of CMHA, thus, CPC provides the following historical utilization information for information purposes only. PRTC recently began operating a linear accelerator in late January 2009. Based on year-to-date utilization, PRTC projects an annualized 276 patients on its linear accelerator."* Also, on pages 56-57 of the application, the applicants state, "*ROCC* [Radiation Oncology Centers of the Carolinas, Inc.] *is a member of CPC, thus, CPC provides the following historical utilization information for information purposes only. ROCC currently owns three linear accelerators. During April 1, 2008 to March 31, 2009, these three linear accelerators treated 991 patients, or 330 patients per linear accelerator (991/3)."* Therefore, the application is conforming to this rule.

-C- **WPCOE.** In Section II.8, page 63 of the application, the applicants, Wake-Prostate Center of Excellence, LLC and Cancer Centers of North Carolina, P.C. (CCNC), state WPCOE does not own a linear accelerator. However, CCNC currently owns one linear accelerator. The applicants state that CCNC's one existing linear accelerator performed 10,321 ESTVs in the twelve months ended September 30, 2008. Therefore, the application is conforming to this rule.

(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 79 of the application, the applicant demonstrates the proposed new linear accelerator is reasonably projected to serve 254 patients during the third year of operation of the new equipment. See Criterion (3) for discussion of reasonableness of the projections. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** In Section IV.1 of the application, the applicant demonstrates the proposed new linear accelerator is reasonably projected to perform 8,024 ESTV treatments during the third year of operation of the new equipment. See Criterion (3) for discussion of reasonableness of the projections. Therefore, the application is conforming to this rule.

-C- **CPC.** In Section II.8, page 57 of the application, the applicants demonstrate the proposed new linear accelerator is reasonably projected to perform 7,076 ESTV treatments during the third year of operation of the new equipment. See Criterion (3) for discussion of reasonableness of the projections. Therefore, the application is conforming to this rule.

-NC- **WPCOE.** In Section II.8, pages 63-64 of the application, the applicants project the proposed new linear accelerator will perform 7,200 ESTV treatments during the third year of operation of the new equipment. However, the applicants did not demonstrate that their projections are reasonable and therefore did not adequately demonstrate that either standard required in this rule would be met. See Criterion (3) for discussion of reasonableness of the projections. Therefore, the application is not conforming to this rule.

(3) an applicant's existing linear accelerators located in the proposed radiation therapy service area are projected to be utilized at an annual rate of 6,750 ESTV treatments or 250 patients per machine during the third year of operation of the new equipment.

-C- **UNCH-CH.** In Section II.8, page 79 of the application, the applicant demonstrates the four existing linear accelerators and the new proposed linear accelerator are reasonably projected to treat 1,270 patients, or 254 patients per machine [1,270/5 = 254], during the third year of operation of the new equipment. See Criterion (3) for discussion of reasonableness of the projections. Therefore, the application is conforming to this rule.

-NA- **Cary Urology.** The applicant does not own a linear accelerator.

-C- **CPC.** In Section II.8, page 57, the applicants states that Carolinas Prostate Center, LLC does not own a linear accelerator. In Section II.8, page 58 of the application, the applicants state that CHS' seven existing linear accelerators are projected to serve 3,347 patients, or 478 patients per machine, in third year of operation of the new equipment. On page 59 of the application, the applicants state that PRTC's one existing linear accelerator is projected to serve 336 patients in third year of operation of the new equipment. On page 61 of the application, the applicants state that ROCC's three existing linear accelerators are projected to perform 31,872 ESTV treatments, or 10,624 ESTV treatments per machine, in third year of operation of the new equipment. Therefore, the application is conforming to this rule.

-NC- **WPCOE.** In Section II.8, page 66 of the application, the applicants state, *"As discussed above, CCNC performed 10,321 ESTVs on its one existing linear accelerator in the year ending September 30, 2008."* However, the applicants did not adequately demonstrate that their projections are reasonable and therefore did not adequately demonstrate the standard would be met. See Criterion (3) for discussion of reasonableness of the projections. Therefore, the application is not conforming to this rule.

(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- **All Applicants.** None of the applicants propose to acquire a linear accelerator to be used exclusively for clinical research and teaching.

(c) An applicant proposing to acquire radiation therapy equipment other than a linear accelerator shall provide the following information:

(1) the number of patients that are projected to receive treatment from the proposed radiation therapy equipment, classified by type of equipment, diagnosis, treatment procedure, and county of residence; and

-NA- **UNCH-CH.** In Section II.8, page 80, the applicant states that it is not proposing to acquire radiation equipment other than the linear accelerator.

-C- **Cary Urology.** In Section IV.1, page 216, the applicant provides the number of prostate cancer patients that are projected to receive treatment from the proposed brachytherapy equipment by county of residence. Therefore, the application is conforming to this rule.

-C- **CPC.** In Section II.8, pages 62-63, the applicants provide the number of prostate cancer patients that are projected to receive treatment from the proposed brachytherapy equipment by county of residence. Therefore, the application is conforming to this rule.

-C- **WPCOE.** In Section II.8, page 67, the applicants provide the number of prostate cancer patients that are projected to receive treatment from the proposed brachytherapy equipment by county of residence. Therefore, the application is conforming to this rule.

(2) the maximum number and type of procedures that the proposed equipment is capable of performing.

-NA- **UNCH-CH.** In Section II.8, page 80, the applicant states that it is not proposing to acquire radiation equipment other than the linear accelerator.

-C- **Cary Urology.** In Section IV.1, page 224, the applicant states the maximum number of procedures the proposed brachytherapy equipment is capable of performing is 260 per year, assuming each procedure requires 90 minutes and the equipment is leased and available to the applicant 52 days per year (1 day per week), 8 hours per day. Therefore, the application is conforming to this rule.

-C- **CPC.** In Section IV.1, page 118, the applicants state the maximum number of procedures the proposed brachytherapy equipment is capable of performing is 624 per year, assuming each procedure requires 20 minutes and the equipment is available 4 hours per week, 52 weeks per year. Therefore, the application is conforming to this rule.

-C- **WPCOE.** In Section II.8, page 67, the applicants state the maximum number of procedures the proposed brachytherapy equipment is capable of performing is 250 per year, assuming one procedure per day, 250 operating days per year. Therefore, the application is conforming to this rule.

(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 II.8 and III.1 of the application, the applicant documents the assumptions and methodology by which utilization is projected. See Criterion (3) for discussion of reasonableness of the assumptions. Therefore, the application conforms to this rule.

-C- **Cary Urology.** In Section II.8 and IV.1, the applicant documents the assumptions and methodology by which utilization is projected. See Criterion (3) for discussion of reasonableness of the assumptions. Therefore, the application conforms to this rule.

-C- **CPC.** In Section II.8 and III.1 of the application, the applicants document the assumptions and methodology by which utilization is projected. See Criterion (3) for discussion of reasonableness of the assumptions. Therefore, the application conforms to this rule.

-C- **WPCOE.** In Section II.8 and III.1 of the application, the applicants document the assumptions and methodology by which utilization is projected. See Criterion (3) for discussion of reasonableness of the assumptions. Therefore, the application conforms to this rule.

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.** The applicant provides documentation of an organized program of continuing education for radiation therapy staff in Section II.8, pages 82-84, and Exhibit I-15 of the application. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** The applicant provides documentation of an organized program of continuing education for radiation therapy staff in Section II.8, page 96, and Exhibit 59 of the application. Therefore, the application is conforming to this rule.

-C- **CPC.** The applicants provide documentation of an organized program of continuing education for radiation therapy staff in Section II.8, page 64, and Exhibit 9 of the application. Therefore, the application is conforming to this rule.

-C- **WPCOE.** The applicants provide documentation of an organized program of continuing education for radiation therapy staff in Section II.8, page 67, and Exhibit 31 of the application. Therefore, the application is conforming to this rule.

(2) a program for the collection of utilization data relative to the applicant's provision of radiation therapy

services;

-C- **UNCH-CH.** The applicant provides documentation of a program for the collection of utilization data relative to the applicant's provision of radiation therapy services in Section II.8, page 84. Therefore, the application is conforming to this rule.

-C- **Cary Urology.** The applicant provides documentation of a program for the collection of utilization data relative to the applicant's provision of radiation therapy services in Section II.8, page 96. Therefore, the application is conforming to this rule.

-C- **CPC.** The applicants provide documentation of a program for the collection of utilization data relative to the applicants' provision of radiation therapy services in Section II.8, page 64. Therefore, the application is conforming to this rule.

-C- **WPCOE.** The applicants provide documentation of a program for the collection of utilization data relative to the applicants' provision of radiation therapy services in Section II.8, page 68. Therefore, the application is conforming to this rule.

(3) medical laboratory services;

-C- **UNCH-CH.** In Section II.8, page 84, the applicant states that medical laboratory services are available to patients at the N.C. Cancer Hospital. The application is conforming to this rule.

-C- **Cary Urology.** In Section II.8, page 96, the applicant states that medical laboratory services will be available to patients through LabCorp and WakeMed. Exhibits 10 and 24 contain letters from WakeMed and LabCorp, respectively. The application is conforming to this rule.

-C- **CPC.** In Section II.8, page 64, the applicants states that medical laboratory services are available to patients at CMC-University. The application is conforming to this rule.

-C- **WPCOE.** In Section II.8, page 68, the applicants state that medical laboratory services will be available to patients through WakeMed. Exhibit 11 contains a letter from WakeMed. The application is conforming to this rule.

(4) pathology services; and

-C- **UNCH-CH.** In Section II.8, page 85, the applicant states that pathology services are available to patients at the N.C. Cancer Hospital. The application is conforming to this rule.

-C- **Cary Urology.** In Section II.8, page 97, the applicant states that pathology services will be available to patients through LabCorp and WakeMed. Exhibits 10 and 24 contain letters from WakeMed and LabCorp, respectively. The application is conforming to this rule.

-C- **CPC.** In Section II.8, pages 64-65, the applicants states that pathology services are available to patients at CMC-University. The application is conforming to this rule.

-C- **WPCOE.** In Section II.8, page 68, the applicants state that medical laboratory services will be available to patients through WakeMed. Exhibit 11 contains a letter from WakeMed. The application is conforming to this rule.

(5) pharmaceutical support services.

-C- **UNCH-CH.** In Section II.8, page 85, the applicant states that pharmaceutical support services are available to patients at the N.C. Cancer Hospital. The application is conforming to this rule.

-C- **Cary Urology.** In Section II.8, page 97, the applicant states that pharmaceutical support services will be available to patients through local pharmacies and WakeMed. Exhibit 10 contains a letter from WakeMed. The application is conforming to this rule.

-C- **CPC.** In Section II.8, page 65, the applicants states that pharmaceutical support services are available to patients at CMC-University. The application is conforming to this rule.

-C- **WPCOE.** In Section II.8, page 68, the applicants state that pharmaceutical support services will be available to patients through WakeMed. Exhibit 11 contains a letter from WakeMed. The application is conforming to this rule.

(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

-C- **UNCH-CH.** In Section II.8, page 86, and Section III.1.(a), the applicant provides a written description of the center's plans and strategies to establish an African American Prostate Cancer Education/Outreach Program that will partner with and complement existing support groups. The application is conforming to this rule.

-C- **Cary Urology.** In Section II.1.(a), pages 55-57 of the application, the applicant provides a written description of the center's plans and strategies to establish an African American Prostate Cancer Education/Outreach Program that will partner with and complement existing support groups. The application is conforming to this rule.

-C- **CPC.** In Section II.8, pages 65-66, and Section III.1.(a), the applicants provide a written description of the center's plans and strategies to establish an African American Prostate Cancer Education/Outreach Program that will partner with and complement existing support groups. The application is conforming to this rule.

-C- **WPCOE.** In Section II.8, page 68, and Section II.1.(a), the applicants provide a written description of the center's plans and strategies to establish an African American Prostate Cancer Education/Outreach Program that will partner with and complement existing support groups. The application is conforming to this rule.

(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.

-C- **UNCH-CH.** In Section II.8, pages 86-87, and Section III.1.(a), the applicant provides a written description of the center's plans and strategies to establish 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. The application is conforming to this rule.

-C- **Cary Urology.** In Section II.1.(a), page 54 of the application, the applicant provides a written description of the center's plans and strategies to establish 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. The application is conforming to this rule.

-C- **CPC.** In Section II.8, pages 66-67, and Section III.1.(a), the applicants provide a written description of the center's plans and strategies to establish 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. The application is conforming to this rule.

-C- **WPCOE.** In Section II.8, page 69, the applicants provide a written description of the center's plans and strategies to establish 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. The application is conforming to this rule.

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, page 87, the applicant states the UNC Hospitals radiation therapy service currently employs six radiation oncologists. Exhibits 1-7 and 23 of the application contain the curricula vitae for the physicians.

-C- **Cary Urology.** In Section II.8, page 97, the applicant identifies Drs. John Leung and Connie Nguyen as the radiation oncologists for the project. Exhibit 29 contains letters from the physicians expressing their intention to serve as medical director and provide medical coverage for the proposed service. Exhibit 2 of the application contains the curricula vitae for the physicians.

-C- **CPC.** In Section II.8, page 67, the applicants identify Southeast Radiation Oncology Group, P.A. (SERO) as the radiation oncologists for the project. Exhibit 7 contains a letter from SERO expressing their intention to provide medical coverage for the proposed service.

-C- **WPCOE.** In Section II.8, page 69, the applicants identify Cancer Centers of North Carolina, P.C. (CCNC) as the radiation oncologists for the project. Exhibit 13 contains a letter from CCNC expressing their intention to provide medical coverage for the proposed service. Exhibits 10 and 14 of the application contains the curricula vitae for the physicians.

(2) Radiation Physicist;

-C- **UNCH-CH.** In Section II.8, page 87, the applicant states the UNC Hospitals radiation therapy service currently employs six medical physicists.

-C- **Cary Urology.** In Section II.8, page 97, the applicant states a radiation physicist will be provided through a contract with Physics and Computer Planning, Inc. Exhibit 23 contains a letter from Physics and Computer Planning, Inc. offering these services to the applicant.

-C- **CPC.** In Section II.8, page 67, the applicants state a radiation physicist will be provided through a contract with Physics and Computer Planning, Inc. Exhibit 7 contains a letter from Physics and Computer Planning, Inc. offering these services to the applicants.

-C- **WPCOE.** In Section II.8, page 69, the applicants identify Cancer Centers of North Carolina, P.C. (CCNC) as the provider of a radiation physicist for the project. The applicants state CCNC currently employs one full-time radiation physicist.

(3) Dosimetrist or Physics Assistant;

-C- **UNCH-CH.** In Section II.8, page 88, the applicant states the UNC Hospitals radiation therapy service currently employs three clinical dosimetrists.

-C- **Cary Urology.** In Section II.8, page 98, the applicant states dosimetrist services will be provided through a contract with Physics and Computer Planning, Inc. Exhibit 23 contains a letter from Physics and Computer Planning, Inc. offering these services to the applicant.

-C- **CPC.** In Section II.8, page 67, the applicants state dosimetrist services will be provided through a contract with Physics and Computer Planning, Inc. Exhibit 7 contains a letter from Physics and Computer Planning, Inc. offering these services to the applicants.

-C- **WPCOE.** In Section II.8, page 69, the applicants identify Cancer Centers of North Carolina, P.C. (CCNC) as the provider of a dosimetrist for the project. The applicants state CCNC employs one full-time dosimetrist.

(4) Radiation Therapist;

-C- **UNCH-CH.** In Section II.8, page 88, the applicant states the UNC Hospitals radiation therapy service currently employs twelve radiation therapists.

-C- **Cary Urology.** In Section IV.1, page 253, the applicant states it will employ 3.39 FTE radiation therapists by the second full year of operation of the proposed project.

-C- **CPC.** In Section II.8, page 67, the applicants state they will employ 4.0 FTE radiation therapists to staff the proposed project.

-C- **WPCOE.** In Section II.8, page 70, the applicants state they will employ 3.0 FTE radiation therapists to staff the proposed project.

(5) Radiation-Oncology Administrator;

-C- **UNCH-CH.** In Section II.8, page 88, the applicant states, "*The Department of Radiation Oncology at UNC Hospitals is staffed by 0.25 FTE Radiation-Oncology Administrator.*"

-C- **Cary Urology.** In Section VII.1, page 255, the applicant states it will staff the center with 1.0 FTE administrator.

-C- **CPC.** In Section VII.1, page 136, the applicant states it will staff the center with 1.0 FTE administrator ("*manager*").

-C- **WPCOE.** In Section II.8, page 70, the applicants state administrative direction will be provided to the center through a management services agreement between WPCOE and CCNC.

(6) Registered Nurse or LPN;

-C- **UNCH-CH.** In Section II.8, page 88, the applicant states the UNC Hospitals radiation therapy service currently employs 5.7 FTE registered nurses.

-C- **Cary Urology.** In Section IV.1, page 253, the applicant states it will employ 1.13 FTE registered nurses by the second full year of operation of the proposed project.

-C- **CPC.** In Section II.8, page 68, the applicants state they will employ 1.0 FTE registered nurses to staff the proposed project.

-C- **WPCOE.** In Section II.8, page 70, the applicants state they will employ 1.0 FTE registered nurses to staff the proposed project.

(7) Physical Therapist;

-C- **UNCH-CH.** In Section II.8, page 88, the applicant states the UNC Hospitals currently provides physical therapy services which will be available upon request.

-C- **Cary Urology.** In Section II.8, page 98, the applicant states that physical therapy services will be available to patients through WakeMed. Exhibit 10 contains a letter from WakeMed.

-C- **CPC.** In Section II.8, page 68, the applicants state CMC-University currently provides physical therapy services which will be available upon request.

-C- **WPCOE.** Exhibit 11 of the application contains a letter from WakeMed that states physical therapy services will be available to WPCOE patients through WakeMed.

(8) Dietician;

-C- **UNCH-CH.** In Section II.8, page 89, the applicant states, "*The hospital has a dedicated outpatient oncology dietician who will be available to prostate patients as needed.*"

-C- **Cary Urology.** In Section II.8, page 99, the applicant states, "*WakeMed Raleigh and independent dietician have agreed to work in cooperation with The Prostate Health Center to provide dietician services on referral.*" Exhibit 10 contains a letter from WakeMed.

-C- **CPC.** In Section II.8, page 68, the applicants state CMC-University currently provides dietician services which will be available upon request.

-C- **WPCOE.** In Section II.8, page 70, the applicants state that dietician services will be available to patients through WakeMed. Exhibit 11 contains a letter from WakeMed.

(9) Pharmacist;

-C- **UNCH-CH.** In Section II.8, page 89, the applicant states the UNC Hospitals currently employs pharmacists who will be available upon request.

-C- **Cary Urology.** In Section II.8, page 99, the applicant states patients will have access to pharmacist services through their local pharmacy or the patient's individual insurance plan pharmacy, and through WakeMed. Exhibit 10 contains a letter from WakeMed.

-C- **CPC.** In Section II.8, page 68, the applicants state CMC-University currently employs pharmacists who will be available upon request.

-C- **WPCOE.** In Section II.8, page 70, the applicants state that pharmacist services will be available to patients through WakeMed. Exhibit 11 contains a letter from WakeMed.

(10) Social Worker; and

-C- **UNCH-CH.** In Section II.8, page 89, the applicant states the UNC Hospitals currently employs social workers who will be available upon request.

-C- **Cary Urology.** In Section VII.1, page 253, the applicant states it will employ 1.0 FTE social worker to staff the center.

-C- **CPC.** In Section II.8, page 68, the applicants state CMC-University currently employs social workers who will be available upon request.

-C- **WPCOE.** Exhibit 11 of the application contains a letter from WakeMed that states social worker services will be available to WPCOE patients through WakeMed.

(11) Maintenance Engineer.

-C- **UNCH-CH.** In Section II.8, page 89, the applicant states the UNC Hospitals currently employs maintenance engineers who will be available to the center.

-C- **Cary Urology.** In Section II.8, page 99, the applicant states maintenance services will be provided through maintenance contracts with the equipment vendors.

-C- **CPC.** In Section II.8, page 69, the applicants state CMC-University currently employs maintenance engineers who will be available to the center.

-C- **WPCOE.** In Section II.8, page 70, the applicants state maintenance services will be provided through maintenance contracts with the equipment vendors.

(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

-C- **UNCH-CH.** In Section II.8, page 89, the applicant identifies the medical director as Dr. Paul Godley, a medical oncologist certified by the American Board of Internal Medicine. Exhibit I-24 contains a letter from Dr. Godley expressing his intention to serve as medical director for the center. Exhibit I-22 contains Dr. Godley's curriculum vitae.

-C- **Cary Urology.** In Section V.2, page 228, the applicant identifies the medical director as Dr. Kevin Khoudary, a urologist certified by the American Board of Urology. Exhibit 28 contains a letter from Dr. Khoudary expressing his intention to serve as medical director for the center. Exhibit 2 contains Dr. Khoudary's curriculum vitae.

-C- **CPC.** In Section II.8, page 69, the applicants identify the co-medical directors as Drs. Timothy Gajewski and Roberto Ferraro, who are both urologists certified by the American Board of Urology. Exhibit 5 contains letters from Drs. Gajewski and Ferraro expressing their intention to serve as co-medical directors for the center. Exhibit 5 contains curriculum vitae for both physicians.

-C- **WPCOE.** In Section II.8, page 70, the applicants identify the co-medical directors as Dr. Karl Pete, a urologist certified by the American Board of Urology, Dr. William Berry, a medical oncologist certified by the American Board of Internal Medicine, and Dr. John Reilly, a radiation oncologist certified by the American Board of Radiology. Exhibit 7, 9, and 13 of the application contain letters from Drs. Pete, Berry, and Reilly expressing their intention to serve as co-medical directors for the center. Exhibits 8 and 10 contain curriculum vitae for both physicians.

(2) a multidisciplinary team consisting of medical oncologists, radiation oncologists, urologists, urologic pharmacologists, pathologists and therapy specialists.

-C- **UNCH-CH.** In Section II.8, page 90, and Section III.1(a) of the application, the applicant provides documentation that the center will have a multidisciplinary team consisting of medical oncologists, radiation oncologists, urologists, urologic pharmacologists, pathologists and therapy specialists.

-C- **Cary Urology.** In Section II.1(a) of the application, the applicant provides documentation that the center will have a multidisciplinary team consisting of medical oncologists, radiation oncologists, urologists, urologic pharmacologists, pathologists and therapy specialists.

-C- **CPC.** In Section II.8, page 69, and Section III.1(a), and Exhibit 7 of the application, the applicants provide documentation that the center will have a multidisciplinary team consisting of medical oncologists, radiation oncologists, urologists, urologic pharmacologists, pathologists and therapy specialists.

-C- **WPCOE.** In Section II.8, page 71, and Section II.1(a) of the application, the applicants provide documentation that the center will have a multidisciplinary team consisting of medical oncologists, radiation oncologists, urologists, urologic pharmacologists, pathologists and therapy specialists.

COMPARATIVE ANALYSIS

Pursuant to N.C.G.S. 131E-183(a)(1), no more than one new linear accelerator may be approved in this review for one dedicated linear accelerator that shall be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men. Because the four applications for the Linear Accelerator Demonstration Project collectively propose four new linear accelerators, all four 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 to determine which proposal is a comparatively more effective alternative. For the reasons set forth below and in the rest of the findings, the application submitted by Cary Urology (Project I.D. #J-8331-09) is approved and the applications submitted by UNCH-CH, CPC, and WPCOE are disapproved.

Geographic Access to the Linear Accelerator Demonstration Project

With regard to geographic access to the Linear Accelerator Demonstration Project, the *2009 State Medical Facilities Plan* states

> *"In response to a petition, there is included in this North Carolina 2009 State Medical Facilities Plan a statewide need determination for one dedicated linear accelerator that shall be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men. … The Linear Accelerator Demonstration Project shall include the following components: …Location of the prostate health center in close proximity to minority communities."*

The following table identifies the locations of the four proposed Linear Accelerator Demonstration Projects in this review.

Facility	County	City/Town
UNCH-CH	Orange	Chapel Hill
Cary Urology	Wake	Raleigh
CPC	Mecklenburg	Charlotte
WPCOE	Wake	Raleigh

As indicated in the table above, two of the applicants, Cary Urology and WPCOE, propose to locate the Linear Accelerator Demonstration Project in new facilities in Raleigh (Wake County). UNCH-CH proposes to locate the Linear Accelerator Demonstration Project at the North Carolina Cancer Hospital in Chapel Hill (Orange County). CPC proposes to locate the Linear Accelerator Demonstration Project in an addition to the CMC-University

facility in Charlotte (Mecklenburg County).

African American Male Populations in Service Area

In 10A NCAC 14C .1902 (c)(4), the applicants are asked to provide *the "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;

The following table shows the responses provided by each of the four applicants in this review:

	UNCH-CH	**Cary Urology**	**CPC**	**WPCOE**
County	**Orange**	**Wake**	**Mecklenburg**	**Wake**
2008 Total County Population Estimate (OSMB)	**129,319**	**864,582**	**877,173**	**864,582**
Responses to 10A NCAC 14C .1902 (c)(4)				
(A) Percent African American	13.10%	20.38%	29.90%	20.50%
(B) Percent Male	47.70%	49.74%	49.30%	49.60%
(C) Percent African American (AA) Male	5.90%	9.52%	13.90%	9.60%
(D) Prostate cancer incidence in AA males/100,000	226.8	239.0	209.8	238.0
(E) Mortality rate for AA males/100,000	83.4	69.7	61.2	73.4

Note: Except for the county population estimates, which are from the Office of State Management and Budget website, all data in the table are from estimates reported by the applicants in Section II.8 of applications for the most recent year provided.
Source: UNCH-CH: Pages 70-71 of the application. Cary Urology: Pages 83-84 of the application. CPC: Pages 45-46 of the application. WPCOE: Pages 59-60 of the application.

The following tables show a comparison of the applicants' reported statistics for each proposed service area county and the North Carolina state averages based on data reported by the North Carolina Central Cancer Registry [*North Carolina Prostate Cancer Incidence, 2001-2005, by Race and County*] :

Facility	**County**	**African American Percent**
CPC	Mecklenburg	29.90%
Cary Urology/WPCOE	Wake	20.50%
UNCH-CH	Orange	13.10%

Facility	**County**	**African American Male Percent**
CPC	Mecklenburg	13.9%
Cary Urology/WPCOE	Wake	9.6%
UNCH-CH	Orange	5.9%

Facility	**County**	**Prostate Cancer Incidence in African American Males**
North Carolina Statewide Average		**248.2**
Cary Urology/WPCOE	Wake	238.0
UNCH-CH	Orange	226.8

CPC	Mecklenburg	209.8

Facility	County	Prostate Cancer Mortality in African American Males
UNCH-CH	Orange	83.4
Cary Urology/WPCOE	Wake	73.4
North Carolina Statewide Average		**67.3**
CPC	Mecklenburg	61.2

As shown in the tables above, of the locations proposed by the applicants in this review, Wake County has the highest reported prostate cancer incidence rate among African American males, and Mecklenburg County has the lowest reported prostate cancer incidence rate among African American males. All of the proposed counties reported prostate cancer incidence among African American males that were below the North Carolina statewide average. Also, Orange County has the highest reported prostate cancer mortality rate among African American males, and Mecklenburg County has the lowest reported prostate cancer mortality rate among African American males, and both Orange County and Wake County reported prostate cancer mortality rates among African American males that were significantly above the North Carolina statewide average. Therefore, with regard to geographic access to the proposed services by communities with the highest reported prostate cancer incidence rate among African American males, the applications submitted by Cary Urology and WPCOE are the most effective alternatives, and the application submitted by CPC is the least effective alternative. Also, with regard to geographic access to the proposed services by communities with the highest reported prostate cancer mortality rate among African American males, the application submitted by UNCH-CH is the most effective alternative, and the application submitted by CPC is the least effective alternative.

Proximity to Minority Communities

In 10A NCAC 14C .1902 (c)(5), the applicants are asked to provide "*documentation that the proposed center is located within walking distance of an established bus route and within five miles of a minority community.*"

In Section III.1, pages 135-136 of the application, UNCH-CH states, "*UNC Hospitals examined minority communities by looking at the percentage the minority community comprised of the total population and comparing that percentage to the average for North Carolina. … As illustrated by the map* [on page 137 of the application], *there are multiple African American communities located within five miles of the proposed center. … As illustrated in the map* [on page 139 of the application] *there are multiple non-white minority communities located within five miles of the proposed center.*"

In Section II.8, page 85 of the application, Cary Urology states, "*The majority of the historically African American southeast Raleigh neighborhoods are well within the five mile radius from both proposed sites 1* [primary] *and 2* [secondary]." In Exhibit 5 of the application, Cary Urology provides a table showing that the primary site is located in Raleigh ZIP Code 27610, and that African American males represent 62 percent of the male residents in that Raleigh ZIP Code area.

In Section II.8, pages 47-48 of the application, CPC states, "*The proposed multidisciplinary prostate health center will be located on the CMC-University campus. … Additionally, as described in Section III.1, the proposed multidisciplinary prostate health center will be located in the University City area of Mecklenburg which has a higher percentage of African Americans compared to other areas of the county. The following map* [on page 49 of the application] *indicates a five-mile radius around CPC's proposed facility which demonstrates it will be located within five miles of minority communities.*"

In Section III.1, page 96 of the application, WPCOE states, "*WPCOE is proposing to locate the prostate center in ZIP*

Code 27610. This ZIP Code, as shown in Exhibits 11 and 12, is nearly 80 percent African American. WakeMed and the proposed WPCOE are located in close proximity to this area densely populated by African Americans. WPCOE will be highly accessible geographically to this community."

As indicated above, all of the applicants propose to develop the Linear Accelerator Demonstration Project in close proximity to minority communities. However, there are differences in the size of the African American male populations in the counties in which the applicants proposed to develop the project. Specifically, Orange County has a significantly smaller total population and significantly lower percentage of African American males than Wake and Mecklenburg counties. Therefore, the application submitted by UNCH-CH is determined to be less effective with regard to improving geographic access to the proposed services than the applications submitted by Cary Urology, CPC, and WPCOE.

Demonstration of Need

UNCH-CH, Cary Urology, and CPC adequately demonstrated that the number of linear accelerator treatments they projected to perform is reasonable and adequately demonstrated the need the population it proposes to serve has for the proposed linear accelerator. WPCOE 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)(2) and (3) for discussion.

Financial Feasibility

UNCH-CH, Cary Urology, and CPC adequately demonstrated that the financial feasibility of the proposed project is based upon reasonable projections of costs and revenues. See Criterion (5) for discussion. WPCOE failed to adequately demonstrate that the financial feasibility of the proposed project is based upon reasonable projections of costs and revenues. See Criterion (5) for discussion.

Access by Underserved Groups

The following table illustrates each applicant's projected percentages of procedures to be provided to Medicaid and Medicare recipients for the entire facility in the second full fiscal year of operation following completion of the project, based on the information provided by the applicants in Section VI.14 of the applications.

APPLICANT	Projected Percentage of Total Procedures Provided to Medicare Recipients	Projected Percentage of Total Procedures Provided to Medicaid Recipients
UNCH-CH	30.70%	29.10%
Cary Urology	61.20%	6.80%
CPC	69.00%	4.00%
WPCOE	47.23%	9.86%

As shown in the table above, CPC 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 CPC projects the lowest percentage of services to be provided to Medicaid recipients. The projections for Cary Urology, CPC, and WPCOE are limited to the prostate health center program components in the Linear Accelerator Demonstration Project, including urology, medical and radiation oncology, biofeedback, and living skills counseling. However, the projections provided by UNCH-CH in response to the question in Section VI.14 of the application include all of the hospital's services, and did not include separate projections for the prostate health center as a separate entity which would be comparable to the projections in the other three applications. However, in Section VI.15 of the application, UNCH-CH provides projections by service component for the proposed Linear Accelerator Demonstration Project, and those service component projections are significantly different from the projections for UNCH-CH's entire facility. For example, UNCH-CH projects the percentage of prostate health center services for prostate cancer patients that will be provided to Medicare recipients will range from 56.9 percent to 78.7 percent, and the percentage of

prostate health center services for prostate cancer patients that will be provided to Medicaid recipients will range from zero to 3.0 percent, depending on the particular program component [See pages 251-254 of the application]. Therefore, the projections for UNCH-CH shown in the table above, which are based on UNCH-CH's entire facility, do not accurately reflect UNCH-CH's projections of the patients to be served at the proposed prostate health center because they significantly understate the percentage of prostate health center services to be provided to Medicare recipients, and significantly overstate the percentage of services to be provided to Medicaid recipients.

Projected Average Gross Revenue and Net Revenue Per ESTV Procedure

The following table shows the projected gross revenue and net revenue per ESTV procedure in the third year of operation for each of the applicants. Revenues are from the applicant's pro forma financial statements for the linear accelerator program component (Form C, Statement of Revenues and Expenses). For UNCH-CH and WPCOE, ESTV projections are from Form C, for Cary Urology, ESTV projections are from Section IV.1, page 180 of the application, and for CPC, ESTV projections are from Section III.1, page 98 of the application.

Third Operating Year	**UNCH-CH**	**Cary Urology**	**CPC**	**WPCOE**
Gross Revenue	$10,274,999	$8,040,728	$27,380,009	$18,514,467
Net Revenue	$3,672,138	$5,208,496	$6,693,721	$5,968,847
ESTV	5,156	8,024	7,076	7,200
Per ESTV:				
Gross Revenue	$1,993	$1,002	$3,869	$2,571
Net Revenue	$712	$649	$946	$829

- **UNCH-CH** projects the second lowest net revenue per ESTV.
- **Cary Urology** projects the lowest gross revenue and lowest net revenue per ESTV of the four applications in this review.
- **CPC** projects the highest gross revenue per ESTV and the highest net revenue per ESTV of the four applications in this review.
- **WPCOE** projects the second highest gross revenue per ESTV and the second highest net revenue per ESTV of the four applications in this review. However, the gross and net revenue for WPCOE are based on projections of the number of linear accelerator treatments to be performed that are unsupported and unreliable. See Criterion (3) for discussion. Therefore, the projections of gross and net revenue per ESTV treatment for WPCOE, which are based on the number of treatments to be performed, are not reliable.

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. Operating expenses are from the applicant's pro forma financial statements for the linear accelerator program component (Form C, Statement of Revenues and Expenses). For UNCH-CH and WPCOE, ESTV projections are from Form C, for Cary Urology, ESTV projections are from Section IV.1, page 180 of the application, and for CPC, ESTV projections are from Section III.1, page 98 of the application.

Third Operating Year	**UNCH-CH**	**Cary Urology**	**CPC**	**WPCOE**
Expenses	$2,827,057	$3,069,410	$4,644,015	$3,646,774
ESTV	5,156	8,024	7,076	7,200
Expenses Per ESTV	$548	$383	$656	$506

- **UNCH-CH** projects the second highest operating expenses per ESTV of the four applications in this review.
- **Cary Urology** projects the lowest operating expenses per ESTV of the four applications in this review.
- **CPC** projects the highest operating expenses per ESTV of the four applications in this review.
- **WPCOE** projects the second lowest operating expenses per ESTV of the four applications in this review. However, the operating expenses for WPCOE are based on projections of the number of linear accelerator treatments to be performed that are unsupported and unreliable. See Criterion (3) for discussion. Therefore, the projections of operating expenses per ESTV treatment for WPCOE, which are based on the number of treatments to be performed, are not reliable.

Summary

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

Cary Urology

- Proposes to develop the Linear Accelerator Demonstration Project in Wake County, which has the highest reported prostate cancer incidence rate among African American males of all of the counties proposed by the applicants in the review.
- Proposes to serve the second highest percentage of Medicare recipients of all the applicants.
- Projects the lowest gross revenue and lowest net revenue per ESTV of the four applications in this review.
- Projects the lowest operating expenses per ESTV of the four applications in this review.

The following is a summary of the reasons the proposals submitted by UNCH-CH, CPC, and WPCOE are determined to be less effective alternatives in this review than the approved applicant.

UNCH-CH

- Proposes to develop the Linear Accelerator Demonstration Project in Orange County, which is has the lowest percentage of African American males and the smallest population of African American males of all of the counties proposed by the applicants in the review.
- Proposes to serve the lowest percentage of Medicare recipients of the four applicants in this review.
- Projects the second highest operating expenses per ESTV of the four applications in this review.

CPC

- Proposes to develop the Linear Accelerator Demonstration Project in Mecklenburg County, which has the lowest reported prostate cancer incidence rate among African American males, and the lowest reported prostate cancer mortality rate among African American males, of all of the counties proposed by the applicants in the review.
- Proposes to serve the lowest percentage of Medicaid recipients of all the applicants.
- Projects the highest gross revenue per ESTV and the highest net revenue per ESTV of the four applications in this review.
- Projects the highest operating expenses per ESTV of the four applications in this review

WPCOE

- Applicants did not adequately demonstrate the need the population to be served has for the proposed project. See Criterion (3) for discussion
- Applicants did not adequately demonstrate the long-term financial feasibility of the proposal is based upon reasonable assumptions regarding revenues and operating costs. See Criterion (5) for discussion.
- Applicant did not demonstrate that its proposed linear accelerator will be utilized at an annual rate of at least 250

patients or 6,750 ESTV treatments during the third year of operation, as required in 10A NCAC 14C .1903(a)(2).

- Applicant did not demonstrate that its existing linear accelerators in the proposed service area will be utilized at an annual rate of at least 250 patients or 6,750 ESTV treatments during the third year of operation, as required in 10A NCAC 14C .1903(a)(3).
- Proposes to serve the second lowest percentage of Medicare recipients of all the applicants.
- Projects the second highest gross revenue per ESTV and the second highest net revenue per ESTV of the four applications in this review.

CONCLUSION

The Certificate of Need Section determined that the application submitted by Cary Urology, Project I.D. #J-8331-09, is the most effective alternative proposed in this review for the additional linear accelerator for the Linear Accelerator Demonstration Project and is approved. The approval of the proposals submitted by UNCH-CH, CPC, or WPCOE would result in linear accelerators in excess of the need determination for the statewide Linear Accelerator Demonstration Project. Consequently, the proposals submitted by the other applicants are denied.

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

1. **Parkway Urology, PA, d/b/a Cary Urology, PA shall materially comply with all representations made in the certificate of need application.**

2. **Parkway Urology, PA, d/b/a Cary Urology, PA shall acquire no more than one linear accelerator, one computed tomography (CT) simulator, one digital ultrasound unit, and one brachytherapy unit as part of this project.**

3. **Parkway Urology, PA, d/b/a Cary 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, d/b/a Cary Urology, PA shall develop an organized African American Prostate Cancer Education/Outreach Program that partners with and complements existing initiatives, such as the NC Minority Prostate Cancer Awareness Action Team.**

5. **Parkway Urology, PA, d/b/a Cary Urology, PA shall develop an Advisory Board composed of representatives of prostate cancer advocacy groups, prostate cancer patients and survivors that meets regularly and provides feedback about effective practices or changes that need to be made.**

6. **Parkway Urology, PA, d/b/a Cary Urology, PA shall 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:**
   - **The total number of patients treated;**
   - **The number of African-Americans treated;**
   - **The number of other minorities treated; and**
   - **The number of insured, underinsured and uninsured patients served by type of payment category.**

7. **Parkway Urology, PA, d/b/a Cary Urology, PA shall make arrangements with a third party researcher (preferable a historically black university) to evaluate the efficacy of the mode during the fourth operating year of the Center and develop recommendations whether or not the model should be replicated in other parts of the State. The report and recommendations of the researcher shall be provided to the Medical Facilities Planning Section and the Certificate of Need Section in the first quarter of the fifth operating year**

of the project

8. **Parkway Urology, PA, d/b/a Cary 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.**