PETITION

Petition to the State Health Coordinating Council
Regarding Special Need for Radiation Oncology – Linear Accelerator Service Area 20
2009 State Medical Facilities Plan

State Health Coordinating Council
Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

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REQUESTED ADJUSTMENT

This petition requests inclusion of a special need for a multidisciplinary prostate health center in Service Area 20 that will offer a full range of services to treat men with urological and prostate cancer.

The adjusted need would appear on page 146 of Chapter 9 Radiation Oncology Services – Linear Accelerators the subsection, Adjusted Need Determination for a Linear Accelerator and would read as follows:

> *In response to a petitioner's request for an adjustment to the need determination for linear accelerators, there is an adjusted special need determination for one linear accelerator in Service Area 20 to be located in a dedicated prostate health center that is organized to provide multidisciplinary diagnosis, treatment and therapy by practicing urologists, oncologists and others; that has an organized outreach and advisory feedback program designed to address the special needs of African Americans and other high risk groups.*

Table 9J would be adjusted to read as follows:

HSA	Linear Accelerator Service Area	Linear Accelerator Need Determination	Certificate of Need Application Due Date	Certificate of Need Beginning Review Date
IV	20	1*	January 15,2009	February 1, 2009

*To be located in a dedicated Prostate Health Center that is organized to provide multidisciplinary diagnosis, treatment and therapy involving at least 10 urologists practicing in the service area and an organized outreach and feedback program to meet the needs of African Americans and other high risk groups.

- Services to be offered should include the disciplines of urology, oncology and biofeedback therapy, a focused prostate/ urological cancer tumor board, a linear accelerator, chemotherapy, brachytherapy, and post-treatment living skills therapy.
- Staffing should include the involvement of at least 10 urologists practicing in the service area who have treated prostate patients; a licensed pelvic rehabilitation specialist, radiation oncologist, a urologic pharmacologist and a hematologist/oncologist. It should care for approximately 200 prostate cancer cases a year
- Accessibility to high-risk populations should be a key feature of the center. To address the particularly high incidence of prostate cancer among North Carolina African Americans, the center should have an organized African American education/outreach program integrated with existing support groups. As the center develops, other special need groups may be identified.
- The center should have an Advisory Board composed of representatives of Prostate Cancer Advocacy groups, prostate cancer patients and survivors.
- The project should include evaluation by a third party researcher, and should provide the state with a report on outcomes of this disease-specific service and how the model could be extended to other parts of the state.

REASONS FOR THE PROPOSED ADJUSTMENT

Summary

This petition is based upon the need for and importance of a comprehensive multispecialty prostate health center in North Carolina to demonstrate the impact that such a structure can have on patient outcomes. It involves the critical role that a linear accelerator plays in treatment of prostate cancer and unique risks associated with linear accelerator treatment of prostate cancer. It responds to the imbalance in availability of linear accelerators in Service Area 20, and the high level of prostate cancer in North Carolina, particularly among African Americans, and the large number of African Americans at risk in Service Area 20. The following paragraphs explore each of these issues.

Prostate Cancer Incidence

Prostate cancer is extremely prevalent, with one in six men developing prostate cancer during his lifetime.[1] In a recent article in the NC Medical Journal, researchers at UNC reported that based on SEER data, North Carolina men had an age adjusted death rate from prostate cancer of 35.6/100,000. This exceeded the national average by 17.5 percent[2], a statistic that greatly concerns Cary Urology. North Carolina has one of the highest death rates from prostate cancer in the United States. See Attachment B.

Based on the 2007 projections from the North Carolina Cancer Registry, male urologic cancers represent 21.4 percent of all cancers diagnosed and eight percent of all cancer deaths in North Carolina. Prostate cancer accounts for the majority of urologic cancers (15.7 percent of total cancers). The disease itself is extremely prevalent and is second to lung cancer as a cause of death.

North Carolina has the undesirable attribute of having a very high prostate cancer death rate, statistically greater than national average. The rate is higher among African Americans. The disparity has the attention of the Prostate Cancer Research Program supported by the Department of Defense. Information from its Disparity Study shows that, regardless of similar socioeconomic status between the two states, African Americans in North Carolina have the highest prostate cancer death rates and in Louisiana have one of the lowest. The project has also found that few African Americans with prostate cancer participate in prostate cancer support groups. This limits screening and knowledge of the disease process. This phenomenon is presently being studied by a North Carolina-Louisiana study through a $10 million grant from the Department of Defense. See Attachment C.

Unique Aspects of Prostate / Urological Cancer

The major issue associated with prostate cancer is who to treat and how aggressively. When this organ becomes cancerous, treatment choices involve preserving function in nearby organs. Prostate cancer rarely, if ever, involves a single tumor with well-defined margins; rather, it involves multiple cancerous cells dispersed throughout the organ. Prostate cancer often causes the prostate to enlarge enough to nestle within part of the bladder.

Prostate cancer treatment options include watchful waiting, surgery, hormonal ablation, radiation, chemotherapy, and combinations of these treatments. Age and health status of the patient play a significant role in the choice of treatment; patient preference is also involved. Because patients have the disease for 10 to 20 years, during which time they move around, results from studies are often not statistically significant. Patients in the studies are often lost during critical follow-up periods. This makes the physician's job of advising patients difficult. Overall, anyone who has investigated prostate cancer and searched the literature typically becomes more confused the more they learn.

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[1] Source: DEVCAN Software, Probability of Developing or Dying of Cancer Software, Version 5.2. Statistical Research and Applications Branch, National Cancer Institute, 2005. http://srab.cancer.gov/devcan.

[2] Gaston, Kris, MD; Pruthi, Raj, MD. "Racial Differences in Prostate Cancer." North Carolina Medical Journal 67.2 (2006): 130-134.

The prostate is a soft tissue gland. It shifts around in the body, and is very close to the bladder and the rectum. A complex system of nerves and tiny valves governs flow of fluids through the prostate. The prostate gland is surrounded by a web of nerves and blood vessels that supply the bladder, prostate, penis, urethra, and seminal vesicles. See anatomy in Attachment A. Why is this so important? Disruption of any single tissue in this delicate network can cause major changes in physiologic function. Treating urologic cancers requires highly skilled and finely tuned techniques.

Where surgery is possible, removing the prostate has high potential for putting the prostate cancer in remission. Today, surgery on prostate cancer can preserve the delicate network of nerves, tissues, and connections of other organs that touch the prostate. We have Johns Hopkins' Dr. Patrick Walsh to thank for this nerve sparing radical prostatectomy technique.

Certain patients can have the same results with brachytherapy, a process of surgically implanting short half-life radioactive seeds in the affected gland. This technique requires collaboration between a surgeon and a radiation oncologist. One reviews the anatomy and guides the implant and the other reviews the cancer status and organizes the dosage and choice of seeds. Continuous follow-up by the surgeon while the radioactive seeds destroy the cancer assures preservation of the non-cancerous surrounding tissues.

Many patients benefit from combinations of external beam and brachytherapy, which can involve coordination of oncology services in two different locations.

About half of the people who can benefit from prostate cancer treatment need external beam radiation delivered by a linear accelerator. Linear accelerator treatments vary in dosage (grey) and in the degree to which they can be focused. Traditional external beam therapy involves lower dosages, up to 72 grey, but significant collateral tissue damage is an undesirable side effect. Conformal radiation can increase the dosage (grey). It also increases the collateral damage to healthy tissue. A linear accelerator with IMRT is more focused and permits use of higher dosage radiation (77 grey) that kills prostate and cancer cells by painting a tight, controlled beam of radiation across and through the prostate. In all of these, the external radiation beam must pass through the body to reach the prostate. The painting action of the beam, along with the high dosage is powerful in its ability to destroy the DNA in the cancer cells. However, during this treatment, non-cancerous tissue in the path of the radioactive high energy beam is at risk of injury. The same energy that kills the cancer can, and does, harm other healthy tissue.

During the two- to three-month linear accelerator treatment time, most patients are under the care of a radiation oncologist, whose focus is on the impact of radiation energy on cell death. Patients have little or no contact with the urologist, whose focus is on the anatomy and function of these organs and glands.

Benefits of Prostate Health Center

1. Prostate Health Center Vision

This proposal involves a center where patients with urologic and prostate cancer can expect individual, custom-tailored therapy, organized to meet their unique situations. To avoid bias in recommended patient treatments, it involves practicing urologists and oncologists as owners. It involves outreach and screening of patients at risk, as well as evaluation and feedback on the impact of clinical and outreach initiatives. Cary Urology is the official proponent for this petition. However, the proposed model involves participation of several urology practices and oncology practices.

Organizing such a prostate health center is not easy. It requires a multidisciplinary team of specialists whose skills complement each other. It involves breakthrough organization, rearranging silos of clinical specialties into a patient-centered structure that facilitates feedback and permits the team to make tissue-sparing decisions. Reducing the impact of urologic cancers on the lives of patients involves complex treatment plans that consider how the whole body functions, how the whole body will respond to the treatment, as well as how the treatment will reduce the cancer. It requires specialists in the fields of anatomy, radiation, pharmacology, and chemotherapy.

The proposed Prostate Health Center provides counseling and care management; a full range of radiation oncology treatment including brachytherapy, external beam radiotherapy, and a combination of the two; and surgical and radiation together with biofeedback training, incontinence management, and sexual rehabilitation, its own tumor board, pharmaceuticals and psychological counseling. By statute, North Carolina requires a Certificate of Need for the linear accelerator.

The center makes a difference in individual care because of the way service is delivered. It makes a difference in health status because of the way it connects to the community. Hence, it has a strong, organized outreach component consisting of screening, support groups and advocacy.

The income from the Prostate Health Center's linear accelerator covers its own costs and provides the extra resources needed to cover treatment of all urological/ prostate cancer patients, regardless of their ability to pay. It also subsidizes the outreach and evaluation efforts and the tumor board.

2. Multidisciplinary Approach to Prostate/ Urological Cancer

Unfortunately, North Carolina's linear accelerator radiation oncology centers are designed such that a radiation oncologist must divide his/her time planning treatments for patients with lung, breast, kidney, cervix, stomach, prostate and other cancer types. In an urban area with multiple centers, the radiation oncologist will have limited contact with the prostate cancer patient's urologist. A single urologist can have patients being treated by five or six different centers at any given time. This dispersion of effort limits the ability for a radiation oncologist and a urologist to consult on the status of their patients during the two- to three-month radiation treatment period. If chemotherapy is also part of the treatment, the dispersion of care can reach even further. In

practice, the patient and urologist make a decision about the treatment option and if it involves radiation and/or chemotherapy, the patient is referred to those specialists to return only upon completion of the course of treatment.

These treatment silos result in preventable damage to nearby organs. The concept of a multidisciplinary approach to the treatment of prostate cancer is not new. The resolution, well developed at cancer centers outside North Carolina, is a multidisciplinary prostate health center. The MD Anderson Cancer Center, in Houston, Texas has a well-developed program. So do Dana Farber Cancer Institute in Boston, Massachusetts; Kirkland Prostate Center at the University of Alabama at Birmingham; The Center for Prostate Cancer at University of Minnesota Medical Center in Minneapolis, Minnesota; UC Davis Cancer Center/Prostate Cancer Clinic in Sacramento, California.

North Carolina does not have a true multidisciplinary prostate health center. No North Carolina provider focuses exclusively on the very complex issues associated with total treatment of prostate and urologic cancer. Yet, the numbers justify a focused approach. Approximately half of prostate cancers are treated with radiation therapy; 80 percent of which involves use of a linear accelerator. Prostate cancer treatment represents approximately 20 percent of all radiation treatments performed.

Changing the orientation of prostate/urological cancer treatment from medical-specialty to disease-specific orientation is the only practical way to address the many physiologic challenges that occur during prostate cancer treatment and management of prostate/urological health. Combining screening, diagnosis, treatment, and lifestyle management in a comprehensive, coordinated health care program involving oncologists, urologists, pharmacologists, pathologists and therapy specialists would require a linear accelerator.

Multidisciplinary approaches generally improve clinical outcomes and involve diminished morbidity. Common features include: the collaboration of multiple disciplines including urology, radiation oncology, hematology oncology, and a host of supportive professionals, a common medical record, a tumor board that focuses on contemporaneous review of cases. With the concentrated effort, the community of physicians and providers develop a deeper understanding of risk profiles of patients, impact of changes in treatment regimen on both elimination of the cancerous tissue and preservation of vital functions in nearby organs. Ready communication across the multidisciplinary approaches including incontinence nursing, behavioral therapy, and biofeedback, erectile dysfunction therapy, radiation injury/wound nurses, and pharmacology working together make a significant care difference. A single medical record diminishes redundancy of both laboratory radiography and paperwork. When medical care was primarily an inpatient service, this type of coordination occurred in the hospital. Technology has shifted care to the outpatient setting where services are dispersed to multiple locations. Today, we need new systems to accommodate the shift.

Radiation therapy involving IMRT on equipment that has on-board imagers produces valuable information for patient management. Today, that information is used only to position the patient for the treatment. In a focused center that has a single medical record, these images can be shared among disciplines, reduce the number of imaging studies done mid-treatment and have a significant impact on the total cost of care management. Because the urologists will be in the center, radiologists and urologists together will have the advantage of viewing real-time images while the patient is available to discuss how his body is reacting to treatment.

Cary Urology's two years of experience with brachytherapy confirms the patient outcome value of cooperation across medical disciplines. We now involve a urologic pathologist and have a urologist and radiation oncologist in our office cooperating on care regimens for our patients. Potential complications are, thus, carefully considered and advanced by both sets of clinical skills. Cary Urology staff also includes a registered nurse who has specialized training in bladder and sphincter rehabilitation post treatment. This multidisciplinary approach within the confines of the same office has dramatically improved the Cary Urology's efficiency, efficacy, and the patient satisfaction.

A model is working at MD Anderson Prostate Cancer Center. See Attachment E.

3. Development of Evidence-Based Protocols

Health care delivery is now sharply focused on repeatable best practices. Concentrating prostate cancer care in one location will provide more opportunities to organize, refine, and challenge assumptions about treatment approaches. A focused prostate health center will provide a continuous learning organization, which is one of the key recommendations of the NIH classic report, *Crossing the Quality Chasm.* The fifth platform of the document, Evidence-based Decision Making, is taking shape. To be effective, it requires continuous information on the same processes applied to people who have similar problems.

4. Value to North Carolina Cancer Registry

North Carolina has an excellent Central Cancer Registry. The Central Cancer Registry (CCR) collects, processes, and analyzes data on all cancer cases diagnosed among North Carolina residents. All health care providers are required by law to report cases to the CCR, but the primary data source is the hospitals of the state. The CCR supplements hospital data with reports from physicians who diagnose cases that are not seen in a hospital. Death certificates and pathology laboratory reports are used to help identify cases that are missed in the routine reporting. Duplicate reports are consolidated in the data editing process. This is primarily a cancer surveillance activity, monitoring the incidence of cancer among the various populations of the state. Finding and refining data for cases treated outside the hospital presents a challenge. With a dedicated prostate center, outpatient data quality should improve substantially.

5. Evaluation

We will soon initiate a database to record and measure at least three definable types of radiation injury to our prostate patients: radiation prostatitis, radiation cystitis and admissions to the hospital for hematouria or other surgical corrections. In just two of the involved practices, we will have a sizeable database by the time of the application. Within a year of operation, we should begin to see a measurable change in patient outcomes.

Shaw University's Daniel Howard, PhD, and the Institute for Health, Social and Community Research have expressed willingness to assist with the outreach and outcomes evaluation. See Attachment F for information.

Particular Need / Opportunity in Service Area 20

North Carolina has high prostate cancer rates, and rates are particularly high among African Americans. Service Area 20, which includes Wake, Harnett and Franklin Counties, is uniquely suited for a prostate health center with a linear accelerator.

- It is the only North Carolina Linear Accelerator Service Area in which the ratio of residents to linear accelerator exceeds 120,000. Page 152, the *Proposed 2009 State Medical Facilities Plan* shows a ratio of 129,000. Thus it meets one of the criteria in the Methodology on page 145 for showing need for an additional linear accelerator.
- Service Area 20 is approximately 22 percent African American, according to the State Demographer. One in five males in Service Area 20 is at high risk.
- Using SEER data, the State Center for Health Statistics estimates that Service Area 20 had approximately 500 new prostate cancer cases in 2007. With half of them candidates for linear accelerator treatment, the area has enough prostate cancer patients in its boundaries to satisfy the standard of 250 patients for a linear accelerator. In fact, fewer than 180 patients can make a program viable.
- The population of this area is also growing faster than the state average.

County	Estimated 2007 Prostate Cancer Cases
Wake	390
Harnett	65
Franklin	35
Total	490

http://www.schs.state.nc.us/SCHS/CCR/proj07co.pdf

At present, Service Area 20 has more than 20 urologists and eight radiation centers. In the three counties, chemotherapy is delivered in hospitals, radiation centers and in hematology/oncology offices. All of these providers have different medical record systems. Their service locations are scattered over a 1.5-hour travel radius. This presents more than 160 different possible medical records for prostate cancer patients. There is no practical way to have effective tumor boards and multidisciplinary approaches to this disease entity with such a structure. The sheer number of treatment locations works against any effective coordination among physician specialists treating the same patient.

The support of the vast majority of urologists in Service Area 20, along with radiation oncologists and medical oncologists provides a strong clinical infrastructure. Social support through churches and support groups will extend the outreach and feedback to clarify the value of treatment in the social network.

We have enthusiastic support from churches, prostate cancer support groups, and African American prostate support groups. No patient with cancer has ever been turned away from Cary Urology for lack of payment and the same polices will apply to this organization. For the proposed prostate health center, churches and support groups throughout the service area have pledged support and participation in continuous outreach. These groups play an essential role in maximizing exposure and education among people at risk.

Thus, Service Area 20 is an ideal location in which to demonstrate the effectiveness of multidisciplinary prostate health care.

ADVERSE EFFECTS ON THE POPULATION IF THE ADJUSTMENT IS NOT MADE

Service Area 20

Generally, the Radiation Oncology-Linear Accelerator Methodology has successfully provided statewide access to linear accelerators. However, access remains uneven. Urban centers like Areas 10 and 12 (Guilford and Forsyth) have 69,000 and 80,000 persons per operational linear accelerator, almost twice as much access as Area 20. According to the Proposed 2009 State Medical Facilities Plan, the Service Area 20 ratio is 129,000. Service Area 20 will continue to have the lowest access in the state.

Prostate Care

Focus of the equipment is a second problem. Application of the State's Methodology has produced centers that treat all types of cancers. In fact, the reviews favor the multispecialty centers, focusing on quantities of people served and unit cost per person served. Prostate cancer care is focused and involves more treatments per patient. Without a designated focus in the Plan, this densely populated area may never realize the benefits of a focused center.

It took multiple CON applications for replacement equipment for the state to approve stereotactic radiation therapy. Stereotactic radiation is far more expensive and benefits only a small proportion of cancer patients. By contrast, prostate cancer patients account for approximately 20 percent of radiation therapy patients and none of the approved equipment is dedicated to treatment of prostate or male urologic cancers.

Nationally, there is a shortage of urologists that was caused by closure of training programs a decade ago. Efficiently using the time of these specialists is an important feature of access to care. Access is one of the key reasons for late treatment of prostate cancer among high risk groups. Late stage

intervention has less probability of five-year survival, hence the likelihood that an area where one in five persons is African American will sustain above average death rates. North Carolina death rates from prostate cancer stay above the national norm. North Carolina ranks second nationally in prostate cancer in African-American men.

In Service Area 20, where cancer care is so disperse, prostate cancer patients whose optimal choice involves external beam radiotherapy may stay disconnected from their urologists during three crucial months. When treatment is complete, the patients will still return to the urologists, for aftercare of the effects of radiation treatment and of life without a prostate. Side effects of the harm to blood vessels will continue to show up months after the radiation treatment. Radiation damage to these tissues is not reversible; the body does not repair itself quickly enough. The community will lose the chance to reduce/eliminate the complications by involving the specialty that is trained to recognize small anatomical differences in the radiation treatment process.

Without a prostate health center as described here, patients getting combination therapies (surgery + external beam (linear accelerator) + brachytherapy) will continue to scuttle around, getting care at multiple locations. Medical records will remain fractionated in multiple non-compatible formats. Imaging studies will be repeated and pharmaceutical regimens will be at risk of coordination failures.

Information that could alter treatment approaches on the individual patient or across multiple patients will not be shared among the physicians who are treating them; patients may have images done by both the radiation oncologist and the urologist, which is not cost effective. Tumor boards will continue with a generalized focus on multiple types of cancers and local knowledge about prostate cancer will develop slowly.

Without specific ties to local advocacy groups, local treatment centers will have less impact on the information that is communicated to persons at high risk of prostate cancer and the physician community. Advocacy groups lack the resources to do this independently.

Male Health

Over its 20 years, Cary Urology has pioneered achievements in men's health including cutting edge services such as da Vinci prostatectomies, in-office prostate brachytherapy, and incontinence therapy, erectile dysfunction management, and counseling.

Notwithstanding multiple advances during the 21st century, male longevity continues to lag in comparison to the female counterpart and the divide is growing. In the 1900s, the average life expectancy was similar for males and females. Today, women are expected to live five to six years longer. Men's health issues are varied and complex and bridge physical and mental well being. Even with these achievements to protect against the current high death rate for male urologic cancers, more are needed. Without a focused center, advances will come more slowly.

ALTERNATIVES CONSIDERED AND REJECTED

Status Quo

Status quo fails to address the issues around prostate cancer treatment in North Carolina and specifically in Service Area 20. If it worked, the disparities would not exist and outcomes would be better.

Cary Urology is a multidisciplinary prostate health center within the limits of state statutes. Cary Urology offers four urologists, a radiation oncologist who provides brachytherapy in collaboration with the urologists, and a licensed pelvic rehabilitation specialist nurse and urologic pharmacologist. It successfully treats approximately 25 percent of its prostate cancer patients in its offices with excellent results. However, it is unable to directly treat the remaining majority, because state law requires a Certificate of Need to obtain a linear accelerator and none is available. Other urologists in Service Area 20 offer office consultation and surgical services. Attracting a hematologist oncologist to work specifically with prostate cancer patients requires a critical mass of patients. Organizing a critical mass requires a linear accelerator that can be shared among practicing physicians.

Work with Existing Radiation Therapy Providers

Sheer limitation of time prevents urologists from visiting every linear accelerator in Raleigh once a week, let alone once every day, to observe patient progress. Already in short supply, the 20 practicing urologists in Service Area 20 do not have the time to continuously observe individual patients among the eight (8) radiation treatment centers. For the medical records alone, this involves 160 different possible combinations of data formats. This is impossible to handle in a well-supplied discipline. It is unfathomable in a shortage specialty. Nationwide, almost half (47.21 percent) of practicing urologists are over 55. The supply of urologists is approximately 5 to 10 percent less than needed today and, at current trends, the shortfall will grow to approximately 20 percent in the next 15 to 20 years.

There is also no practical way to have effective tumor boards that focus on prostate cancer at eight separate locations involving the same urologists.

The urology workforce by the numbers

Number of active urologists (2006)	9,864
Number of people per urologist (2006)	30,200
Estimated percentage of urologists who are women	3.94% (389)
Estimated percentage of urologists age 55 years and older	47.21% (4,657)
Estimated percentage of urologists with foreign medical degrees	16.29% (1,607)
Estimated percentage increase in urologists, 1995 to 2004	7.73%

Source: Adapted from *Physician specialty data: a chart book*. Center for Workforce Studies, Association of American Medical Colleges. August 2006

Support and Sustain Existing Outreach Networks

The advocacy groups have an extensive network of prostate screening and awareness activities. These are important and are tied back to urologists in the service area. However, the screening effort is not directed back to a central treatment program. Hence, it becomes diluted; patients are individually separated and segregated, and the screening alone does not improve patient outcomes.

Wait for Need in a Future State Medical Facilities Plan

As noted earlier, the structure of the SMFP and review criteria favor linear accelerators in centers that treat all types of cancer and focus on optimizing the linear accelerator equipment. We filed a CON application for a focused center in 2007. That application was found fully conforming, but was denied because another center would reach more people faster. That center was an existing general radiation oncology center that had an organized base of patients. Moreover, while that approval is in litigation, and with the current formula requiring existing or approved CON's to be performing at 6,750 ESTV's each, it may take years to show additional need in Service Area 20.

Let Existing Providers Mature and Address Issue – Eventually

Effectively, this is the status quo option. It has failed. The Rex Prostate Cancer Center of Excellence funded by Jimmy Valvano Foundation to the Rex Hospital Foundation received $500,000 over three years. The funding involves education and data collection. This center does not have a multidisciplinary care team of urologists and radiation oncologists. Outreach and Education, Community Screenings, Clinical Treatment and Follow up, and Survivorship are mentioned on the website, but there is no program description. The website describes a Support Group – second Thursday of each month. Free screening once a year. No urologists are involved in program.

Duke Prostate Research involves long waits, and lacks consistency. Service is not continuous or daily, is currently available only on Tuesday and Friday. Urologist and radiation oncologist are in the same building, but not an integrated team that practices together every day. Patients wait hours for consults among the specialists.

UNC-CH offers a support group on the first Wednesday of each month.

These efforts acknowledge the problem, but are making only minor inroads on changes in care delivery. They are not reaching the community physicians who care for large numbers of patients.

EVIDENCE THAT DEVELOPMENT OF PROPOSED SERVICE WOULD NOT RESULT IN UNNECESSARY DUPLICATION OF HEALTH RESOURCES IN THE AREA

This project would not involve duplication.

- There is no existing comparable service in North Carolina.
- High rates of prostate cancer persist in the face of the number of available linear accelerators in Service Area 20.
- Even with the recent approved 2007 linear accelerator, there are more than 120,000 people per linear accelerator in Service Area 20, the only such high ratio in the state.
- Wake County alone is projected to have +200 cases of prostate cancer among non-white population and almost 400 recorded new cases overall in 2007, according to the NC Center for Health Statistics.
- Support Groups agree. Please see many letters of support from grassroots groups that are attached to this petition. (Attachment D)

CONCLUSION

This proposal involves a unique approach to a disease focus that affects more than 250,000 North Carolinians. Organized as proposed, the center would organize the energy and attention of all staff around that disease at all times. Appropriately executed, it should improve treatment for persons with prostate cancer, and promote an understanding of factors that facilitate the disease and help prevent prostate cancer. Its outreach arm should find patients earlier, when tissue preservation is easier.

This is the right time and Service Area 20 is the right place for a multidisciplinary center focused on a disease that affects one in six men. With 490 annual new prostate cancer cases, the service area has sufficient need and a large high risk population to justify a center. It has both urban and rural communities in which to test outreach approaches. It has willing community urologists.

Prostate cancer is a debilitating disease, whose treatment is typically intense and extends over long periods of time – months and even years. It involves the resources and energy of whole families. Studies have repeatedly shown that patients defer treatment when access to care is an issue. Quality studies also demonstrate over and over again the cost savings associated with doing things correctly the first time. A person who gets radiation burns from prostate cancer treatment cannot reverse that outcome. He will seek other treatments to address the side effects: wound therapy, surgery, biofeedback and counseling for sexual and urinary dysfunction, etc.

Men receiving treatment for urologic cancers can suffer from numerous side effects, including urinary, bowel and erectile dysfunction, loss of fertility, testosterone loss, and nerve damage. Ten percent to 25 percent of men with prostate cancer have bladder control problems two years after surgery or radiation therapy, according to research compiled by the Prostate Cancer Foundation. Impotence is even more common; up to 80 percent of men report problems after surgery or radiation. Some men's symptoms get better in time; most patients are never the same.

The management and treatment of these side effects can be more easily managed by a team that offers diagnosis, treatment, follow-up care and counseling at one location. The entire medical staff will have input into the treatment options and will have access to records regarding each patient's history when addressing individual responses to treatment. This will provide each patient convenient access to more individualized and comprehensive treatment from one staff with the optimum opportunity to confer on options.

We can measure the impact and test the outcomes statistically.

A linear accelerator is a key component and cannot be added unless one is made available in the 2009 State Medical Facilities Plan (SMFP). If the SMFP includes a linear accelerator and does not specify prostate health as the intended focus of that equipment, the area will have a low likelihood of getting a multidisciplinary prostate health care center.

Attachments:
A – Prostate Gland Anatomy
B – North Carolina versus National Prostate Cancer Rates
C – Department of Defense Prostate Cancer Research Program
D – Support Letters
E – MD Anderson Prostate Cancer Center Process
F – Outcomes Research