REX
UNC HEALTH CARE

State Health Coordinating Council
Medical Facilities Planning Section
NC Division of Health Service Regulation
NC Department of Health and Human Services
Attention: Carol Potter
701 Barbour Drive
Raleigh, NC 27603

Dear Ms. Potter,

Thank you for the opportunity to comment on the petition, which was submitted to the State Health Coordinating Council (SHCC), regarding the need for new radiation oncology services. Our comments below pertain to the petition filed by Cary Urology for a new linear accelerator in Service Area 20.

Rex Healthcare strongly opposes the petition because no need exists for an additional linear accelerator in Service Area 20, as reflected by the SMFP and its methodology. We hope that the following information will be useful to the Council as it considers the petition.

If we can provide any further information on linear accelerator utilization, please contact me at (919)-784-3181. Thank you for your consideration.

Sincerely,

Steve Burriss,
Vice President Ambulatory Care, Rex Healthcare

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COMMENTS BY REX HOSPITAL, INC. OPPOSING CARY UROLOGY'S PETITION FOR SPECIAL NEED FOR RADIATION ONCOLOGY LINEAR ACCELERATOR SERVICE AREA 20 2009 STATE MEDICAL FACILITIES PLAN

Rex Hospital, Inc. ("Rex") files the following comments in response to Cary Urology's petition for a special need for a linear accelerator (or "linac") for Service Area 20 to be included in the 2009 State Medical Facilities Plan. Rex currently operates the Rex Prostate Center of Excellence in Raleigh.

I. Current Service Area 20 Linacs Are Substantially Underutilized

The Proposed 2009 State Medical Facilities Plan ("SMFP") indicates that Service Area 20 currently has seven (7) linear accelerators in operation. The historical utilization by facility is summarized in the Table 1 below.

Table 1:

Total Radiation Oncology Procedures (ESTVs) by Service Area 20 Provider								Ave Ann %
Facility	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005[2]	FY 2006	FY 2007	Incr. 2003 -2007
Rex Healthcare	28,455	28,133	30,130	25,343	20,113	16,184	18,838	-7.5%
Wake Radiology / Oncology	8,542	7,033	6,764	7,503	7,004	5,960	5,597	-3.5%
Duke Raleigh Hospital	1,594	4,585	4,997	5,201	6,969	7,323	6,923	7.7%
Cancer Centers of NC[1]					2,534	8,924	10,062	99.0%
Totals	38,591	39,751	41,891	38,047	36,620	38,391	41,420	-0.2%

Source: SMFP 2003-2009 and from the Registration and Inventory of Medical Equipment, Linear Accelerator Equipment forms for February 2007.

Notes: [1]The Cancer Centers of North Carolina linear accelerator became operational in 2005, consequently, the average annual percent increase is calculated for 2005-2007.

[2]Effective in FY 2007 SMFP, the need determination methodology was modified by eliminating one of the procedures (77427, Weekly Radiation Therapy Management) thereby reducing procedure (ESTV) counts for freestanding oncology centers like WROS and CCNC.

As the utilization statistics demonstrate, total volumes in Service Area 20 were flat between 2003 and 2007. In fact, two of the four providers experienced an average annual decrease in volumes. Rex's annual volumes decreased by an average of 7.5% per year and Wake Radiology / Oncology Services decreased by an average of 3.5% per year.

In addition to the seven (7) linear accelerators included in the Proposed 2009 SMFP, two (2) additional units are in operation in the service area, but unaccounted for in the SMFP. Betsy Johnson Regional Hospital operates a linear accelerator in Harnett County, and Franklin County Cancer Center operates a linear accelerator in Franklin County. The utilization of these units is unknown.

The 2007 SMFP also identified the need for one (1) additional linear accelerator. This unit is not yet operational. Consequently, there are a total of ten (10) operating and approved linear accelerators in Service Area 20.

Table 2 below shows Service Area 20 linear accelerator utilization by unit for 2007 by facility. The total average use by unit in 2007 was 5,917 ESTVs, which is 12.3% below the SMFP's need threshold of 6,750 ESTVs.

Table 2:

Fiscal Year 2007 Service Area 20 Linear Accelerator Utilization				
Facility	Total ESTVs	ESTVs/ Unit	ESTV Need Threshold	% Over (Under) Threshold
Rex Healthcare	18,838	4,710	6,750	-30.2%
Wake Radialolgy / Oncology	5,597	5,597	6,750	-17.1%
Duke Raleigh Hospital	6,923	6,923	6,750	2.6%
Cancer Centers of NC	10,062	10,062	6,750	49.1%
Totals	41,420	5,917	6,750	-12.3%

Source: 2009 Draft SMFP.

It is significant to note that two (2) of the four (4) facilities operated at levels significantly below the need threshold in 2007. Rex's average ESTVs per unit was 4,710, or approximately 30.2% below the need threshold. Wake Radiology / Oncology Services' average ESTVs per unit was 5,597 in 2007, or about 17.1% below the need threshold.

In summary, there are currently ten (10) linear accelerators either operational or approved in Service Area 20. The historical data indicates that total oncology procedures have remained flat over the last five years, while the Area 20 linac inventory has increased from 6 to 10. Thus, many of the Area 20 linacs are underutilized. In light of these facts, it is quite unreasonable to petition for a special need for one (1) additional linear accelerator in this service area.

II. Dedicated Equipment to Disease Specific Population

The Proposed 2009 SMFP, page 144 states the following:

> *Presently, existing radiation oncology programs are reasonably convenient to the population of the state. The high cost of establishing new programs and the possibilities for achieving further equipment and staff economies of scale are critical considerations in evaluating the need for new radiation oncology treatment center programs.*

Contrary to this policy, the petitioner's requested need adjustment is extremely specific (page 1 of petition):

> *. . . 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.*

The petitioner further recommends that Table 9J specifically be modified with a footnote that reads as follows:

> **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* (emphasis added).

The extreme specificity of the special need adjustment request will, by design, create inefficiency, or a *dis*economy of scale, related to the cost and use of the linear accelerator. Further, the establishment of a minimum threshold of ten (10) urologists involved, or **50%** of the total number of specialists currently practicing in the service area, creates unreasonable inflexibility in the execution of the plan.

It is also significant to note that this special need determination, if approved, will likely open the door to many disease specific center requests. This will lead to a further erosion in the cost-efficient use of linear accelerators in North Carolina. See Part III below, entitled Petition Proposes Change in Need Methodology.

III. Petition Proposes Change in Need Methodology

The petitioner is essentially asking for a change in need methodology for linear accelerators. Consequently, the request was inappropriately submitted as a "special need petition." The idea of creating a disease specific center does not constitute a special need that is unique to Service Area 20. This proposed change in need methodology should be addressed early in the SMFP development process, when changes in need methodology are considered.

As the petitioner states as part of the Q&A on page 15 of the petition:

> ***Q:*** *This project represents a state precedent – what will prevent others from asking for a disease specific center?*
>
> ***A:*** *In an urban setting, where scarce specialty providers become separated from one another and have little time for essential collaboration, more disease specific centers are a good idea... The state's task will be to monitor distribution, to consider convenient location, a care delivery structure that supports collaborative care protocol development, to set the criteria for such centers and to assure sufficient organized volume to support a single disease focused program."*

This point of view represents a radical departure from the current need methodology employed by the SHCC and the Medical Facilities Planning Section. Approving this proposed "special need adjustment" would have serious, negative, unintended ramifications on the delivery and cost of linear accelerator services in North Carolina.

IV. Lack of Outcome Data/ Impact on Care

On page 6 of the petition, the petitioner states that *"multidisciplinary approaches generally improve clinical outcomes and involve diminished morbidity."* However, the petitioner provides no statistical support for this assertion. Further, a multidisciplinary approach can be achieved without investing in dedicated, high cost, in-house equipment. For instance, Cary already has a linear accelerator equipped with IMRT / IGRT at Wake Radiology / Oncology Services, located only two miles south of the proposed center at Cary Urology. This existing center has available capacity to serve additional patients, as the historical utilization statistics above demonstrate.

On page 7, the petitioner states that *"Treating urologic cancers requires highly skilled and finely tuned techniques."* In fact, treating **any** cancer with a linear accelerator requires "highly skilled and finely tuned techniques" and prostate cancer is not unique. Damage to surrounding tissue as a result of linear accelerator treatments is **always** a concern and consideration, regardless of the type of cancer being treated. Again, the petitioner does not provide any data to support the improved efficiency, cost, or outcomes related to the housing of dedicated, high cost equipment at a disease-specific center. On the contrary, patients who have complications or require chemotherapy, surgery, or whose cancer has spread to other organs, a comprehensive cancer center would be the more effective treatment setting.

V. Failure to Establish Need in Service Area 20

The petitioner fails to establish a need for the proposed service in Service Area 20. According to the Proposed 2009 SMFP, in determining whether an additional linear accelerator is needed in a service area, two of the following three criteria must be met:

1. The linear accelerators in existing radiation oncology centers should be performing greater than 6,750 procedures (ESTVs) per accelerator per year.

2. The population that lives in the radiation oncology service area is sufficiently great to support the addition of another accelerator (population per accelerator greater than 120,000).

3. The patient origin data shows that over 45 percent of the patients come from outside of the service area.

Service Area 20 does not meet any of the above criteria. A discussion of the failure to meet the first criterion is included in Part I above. To reiterate, the average Area 20 ESTVs per linac in 2007 was 5,917, well below the SMFP's 6750-ESTV threshold for establishing need

Service Area 20 also does not meet the second criterion. Table 3 below summarizes an analysis of the population per unit when the two linear accelerators that are not currently included in the Service Area 20 inventory are considered (Harnett and Franklin Counties):

Table 3:

Adjusted Population Per Linear Accelerator in Service Area 20	
2008 Civilian Population	1,033,705
SMFP Linacs	8
SMFP Population/Linac	129,213
Total Actual Linacs	10
Adjusted Actual Population/Linac	103,371
Source: 2009 Draft SMFP, licenure applications and published literature on Franklin Cancer Center.	

When the two additional units are factored into the calculation, the population per linear accelerator becomes 103,371. This population per linear accelerator is well below the threshold of 120,000 population per unit.

The Proposed 2009 SMFP indicates that 16.32% of the patients treated in Service Area 20 reside outside of Service Area 20. Consequently, Service Area 20 does not meet the third criterion since fewer than 45% of its patients reside outside of the service area.

In order to establish a case for a particular need for a linear accelerator in Service Area 20, one of the arguments that the petitioner offers (on page 8) is as follows:

> *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.*

There are several errors in this logic. First, this unreasonably assumes that the new linear accelerator would capture 100% of the prostate cancer cases. There will always be a significant portion of the population that will be treated at comprehensive cancer centers either by referral or by choice. As discussed previously, patients who have complications or require chemotherapy, surgery, or whose cancer has spread to other organs will be more effectively treated at a comprehensive cancer center.

Second, the current inventory of linear accelerators is already underutilized. As the petitioner states on page 3, "*Based on the 2007 projections from the North Carolina Cancer Registry, male urologic cancers represent 21.4 percent of all cancers diagnosed . . . .*" If all of these patients were to be treated at the new center, the utilization of the existing linear accelerators would further erode. While the petitioner stresses that these are new patients, the average treatment cycle for a prostate patient is 2 to 3 months. When the 2 to 3 month treatment cycle is complete, the capacity becomes available to treat new patients. Consequently, the ongoing diagnosis of new patients is essential to the utilization of existing equipment over time.

Another argument offered by the petitioner is as follows:

> *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 location 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.*

This argument actually serves to **discourage** the addition of another treatment facility in the area. Adding another center in Service Area 20 will further fragment the delivery of services. While the petitioner envisions the clustering of services in one location, the reality would be to merely add another option to the current complex network of services.

In summary, Service Area 20 does not meet the standard criteria as set forth in the Proposed 2009 SMFP to establish a need for a new linear accelerator. Further, the petitioner does not establish a case for a special need in Service Area 20.

VI. Not Most Effective Alternative

The petitioner did not select the most effective alternative. On page 11, the petitioner discusses the option of working with existing radiation therapy providers. The petitioner argues:

> "*Already in short supply, the 20 urologists in Service Area 20 do not have the time to continuously observe individual patients among the eight (8) treatment centers.*"

However, the petitioner does not discuss the opportunity for the urologists to network or joint venture with an existing service area provider, such as the Rex Prostate Cancer Center of Excellence or Wake Radiation Oncology (fewer than two miles away).

Coordination with an existing provider would serve to consolidate resources, offer a broader complement of services, improve equipment utilization and lower costs.

VII. Proposed Service Will Result in Unnecessary Duplication of Services

Since the current equipment is underutilized (see Part I), it can be safely assumed that no 'pent up' demand is present due to lack of access to services. Thus, adding equipment should not generally result in an overall increase in number of treatments in the service area. Consequently, the addition of another linear accelerator in Service Area 20 will only serve to dilute the utilization of the current equipment. Table 4 below summarizes the impact of adding an 11th linear accelerator to Service Area 20.

Table 4:

Criteria	2009 SMFP	Additional Unit
Number of Units[1]	10	11
Adjusted Actual Pop/Linac	103,371	93,973
ESTVs/Unit[2]	5,917	4,602

Notes:
[1]Includes units operating in Harnett and Franklin counties.
[2]Based on 2007 reported procedures for 7 inventoried linear accelerators.

Adding another linear accelerator to Service Area 20 would result in an average utilization of 4,602 ESTVs per linac, based on 2007 reported procedures. This is **31.8% below** the per unit threshold of 6,750, which is required to establish need for a new linear accelerator (1 - 4,602 / 6,750).

It is also important to note that several area providers offer prostate cancer services. Rex Cancer Center is a 2007 recipient of the Jimmy V Foundation grant in the amount of $500,000 to create the Rex Prostate Center of Excellence. The grant will enable the Center to expand four components of their comprehensive prostate center program:

- Outreach and education
- Community screenings
- Clinical treatment and follow up
- Survivorship.

The goal of Rex's program is to reduce the mortality rate in men due to prostate cancer. It is significant to note that these specific strategies aimed at early intervention are the appropriate and proven avenues to influence outcomes/mortality rates. Conversely, the petitioner's proposal to provide additional linear accelerator services in a service area where the service is readily accessible and equipment is already underutilized is unlikely to have an impact on mortality rates.

Also, the Duke Raleigh Cancer Center offers a multidisciplinary approach to prostate center treatment. The treatment team consists of a urologist, radiation oncologist,

and , if necessary, a medical oncologist. The physicians coordinate care by meeting with the patient in sequence and then conferring collaboratively to determine the optimal care plan for the patient.

VIII. Conclusion

Rex opposes Cary Urology's petition for a special adjustment to need for a Linear Accelerator for Service Area 20. The current linacs in Service Area 20 are already substantially underutilized and the addition of another accelerator would exacerbate this problem. Further, Cary Urology did not prove its case for a specific need for a dedicated linear accelerator at a disease-specific center in Service Area 20. Also, the petitioner is, in essence, proposing a change in the Statewide SMFP need determination methodology, not allowed at this stage in the process. Finally, other similar disease-specific programs are already offered in Service Area 20, such as the Rex Prostate Cancer Center of Excellence and Duke Raleigh Cancer Center's multidisciplinary approach to prostate cancer treatment.

August 7, 2008

Memorandum

To: Christopher Ullrich, MD
Chairman, Technology and Equipment Committee
State Health Cooordinating Council

From: Suzanne H. Freeman, President, Carolinas Medical Center
William J. Fulkerson, MD, CEO, Duke University Hospital
Donny C. Lambeth, Interim President, North Carolina Baptist Hospital
Steve Lawler, President, Pitt County Memorial Hospital
Gary L. Park, President, UNC Hospitals

Subject: Petition Submitted by Cary Urology

This memorandum forwards the comments of the state's academic medical center teaching hospitals on the petition submitted by Cary Urology. Our comments have been reviewed by and reflect the opinions of the physician leadership, especially the chairmen and chiefs of urology, radiation oncology, medical oncology, and radiology at each of our institutions.

We believe that the petition should be disapproved. In reaching that conclusion, we were guided by the following considerations:

1) The Petition argues that the state's comprehensive cancer centers are incapable of providing the focused, integrated, multidisciplinary care prostate cancer patients need and deserve. That is simply not true. All five of our hospitals have prostate centers that integrate urologists, radiation oncologists, medical oncologists, radiologists, and essential support services in teams providing patient-centric care for prostate cancer patients. The team approach has also been implemented at other comprehensive cancer centers like the Duke Raleigh Cancer Center in Service Area 20. A brochure from Duke Raleigh Hospital describes the patient's experience this way:

Upon referral, newly diagnosed prostate cancer patients are brought to the multi-disciplinary clinic after being contacted by the coordinator to explain the multi-disciplinary process and are made aware of the expectations. The coordinator reviews records with the medical and radiation oncologist to determine what staging studies are necessary prior to the patient's clinic appointment. The patient is then contacted and scheduled for the appropriate studies deemed necessary to prescribing a plan of care, and the studies are performed prior to the clinic date.

On the day of an actual prostate clinic appointment, the patient is seen by a Duke urologist, radiation oncologist, and medical oncologist, (if necessary) in the radiation department of the cancer center. The physicians see the patient sequentially and confer collaboratively to decide upon the very best plan of care for the patient. The physicians then reconvene with the patient, (who has been given a "break time" while the physicians are in conference), to deliver the recommended treatment plan and all of the best possible options. After the patient has been given the recommendations by the physicians, the coordinator then reviews and summarizes the plan of care with the patient and family, also providing all educational materials necessary to support the recommendation for care. Contact information for all physicians and the coordinator are given to the patient, along with any needed follow-up appointments for care. A phone call is made by the coordinator to all patients one week after the clinic appointment and patients are encouraged to phone the coordinator with any questions or concerns.

The Petition claims that "North Carolina does not have a true multidisciplinary prostate health center." As the prostate clinics and centers at our hospitals demonstrate, that claim is false.

2) The Petition argues that "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 continuing learning organization.... " In theory and in practice, academic medical center teaching hospitals are continuous learning organizations, staffed by physician-scientists providing comprehensive cancer services, including chemotherapy and surgery as well as radiation oncology, and participating in clinical trials comparing the benefits of new and alternative treatment approaches. They now perform, and they are far better positioned to perform, research on the benefits and costs of treatment than the center that the petitioner proposes.

3) The Petitioner provides no evidence to support the proposition that the care to be provided at the prostate center that the Petitioner proposes would be better, more effective, or more efficient than the care now provided at the comprehensive cancer centers in and near Service Area 20. Indeed, for many patients treatment at a comprehensive cancer center would be better, more effective, and more efficient than treatment at the facility the Petitioner wants to establish. This is especially true for patients who require hormone therapy, chemotherapy and/or surgery, patients who have treatment-related complications, patients who have concurrent medical conditions (e.g., heart disease), and patients whose cancer that has spread to other organs.

4) The Petition claims that "Prostate cancer is extremely prevalent" in North Carolina, implying that the incidence rate is higher than the national average. In fact, the most recent CDC data (for the years 2002-2004) show that 32 states had a higher incidence rate than North Carolina, and the incidence rate for the nation as a whole (155.4 per 100,000) was higher than the rate for North Carolina (150.4).

5) What is higher in North Carolina is the death rate from prostate cancer. For the same period, the CDC reports a death rate in North Carolina of 29.1 and a death rate of 25.4 for the nation as a whole..

Research and experience both suggest that the reason for the higher death rate in North Carolina is deferral of treatment. For many patients who defer, whatever the reason, the radiation therapy that the Petitioner proposes to provide is not a viable alternative. Those patients will have

to be referred to a comprehensive cancer center for treatment. Moreover, as the Petitioner's prostate health center would rely largely on referrals from community urologists rather than screening or other early identification measures, it is clear that operation of the center would have little if any impact on incidence rates or deferral rates.

6) The Petitioner stresses the need to improve prostate cancer care for African-American men. However, the Petitioner's Certificate of Need application for a Prostate Health Center submitted in August 2007 included a 17-page description of the need for the facility that made no mention of the special needs of African-American men. Indeed, the term "African-American" was not mentioned, and the needs of the underserved were not discussed. And the distribution of procedures projected for self-pay/charity/ indigent patients (2.2%) and Medicaid patients (2.0%) suggests that their needs would not be specifically addressed.

The August 4 Petition paints a different picture and incorporates letters of support from African-American churches and advocacy groups. But the Petition makes no specific commitments, either in behalf of the proposed center or in behalf of the urologists referring patients.

7) The Petition argues that still another LINAC is needed in Service Area 20, over and above the one included in the 2007 State Medical Facilities Plan, which is not yet in operation. To make that claim, the Petition revises the methodology used in the Plan to determine supply and need. The Petition compares Service Area population/LINAC rates across Service Areas and concludes that Service Area 20 is underserved. But Service Area population is used in the Plan methodology as a threshold, and not to determine the supply or need. The appropriate measure of supply and need is the one employed in the Plan: Service Area ESTVs/Service Area LINACs. .

The use of that measure is demonstrated on page 152 of the Proposed 2009 Plan. Table 9F shows that the 8 existing and approved LINACs in Service Area 20 provided an average of 5,178 ESTVs during FY2007. That average is below the average for the state's Service Areas (5,425) and well below the point (an average of 6,750 ESTVs) at which the state would begin to find need for an additional LINAC.

8) If an additional LINAC were found necessary in Service Area 20, or any other Service Area, awarding the Certificate of Need to a comprehensive cancer center would

- Benefit all cancer patients, rather than those with a single disease
- Reduce the risk of underutilization resulting from subspecialization
- Protect against the possibility that advances in treatment for cancer at any one tumor site would result in reduced utilization of the machine or inappropriate utilization.

9) There is good reason to question the projected utilization and financial feasibility of a LINAC located at the prostate center that the Petitioner proposes. The Petitioner's Certificate of Need application demonstrated feasibility by including form letters signed by 15 urologists practicing in Service Area 20. Except for the opening sentence, which gave the physician's name, practice location, and years in practice, the letters were identical, and each closed with this sentence: "If the Prostate Health Center application is approved, I expect to direct 2 to 3 patients per month to the Prostate Health Center for prostate external beam radiation treatment." On the basis of those letters, the application projected receiving 360 to 480 referrals the first year - and achieving a market share of 38% the first year, 44% the second year, and 49% the third year - even though one letter was signed by a physician who anticipated beginning practice five months after the application was submitted and others who were in their first years of practice. None of the letters gave the numbers of patients the physicians were then referring for external beam

treatment for prostate cancer, the sites to which they were referred, or any account of their experience with existing sites, so it is worth noting that in FY2007 very few Wake County patients received LINAC procedures outside Wake County. Given the proximity of the cancer centers at Duke University Hospital and UNC Hospitals, that pattern suggests that community urologists and their patients were largely satisfied with the alternatives now available in Service Area 20.

SUMMARY

According to the 2008 State Medical Facilities Plan, petitions for adjustments to need determinations are expected to show that "unique or special attributes of a particular geographic area or institution give rise to resource requirements that differ from those provided by application of the standard planning procedures and policies..." Like most of the other counties of North Carolina, the counties forming Service Area 20 have incidence rates and mortality rates for prostate cancer that are higher than any of us would like, but they are by no means unique or special, and there is no reason to think that their resource requirements are different from those provided by application of the standard planning procedures and policies.

Moreover, the Petition fails to provide a convincing "Statement of the adverse effects on the population of the affected area that are likely to ensue if the adjustment is not made". As noted above, there is no reason to think that incidence or mortality rates will be reduced by approval of the adjustment the Petitioner seeks, and the Petition is therefore unable to show adverse effects from disapproval of the petition. In fact, if there are adverse effects on the population, they are likely to result from the fragmentation of care that would result from the operation of a prostate center providing only some of the services that prostate cancer patients may require.

Finally, the Petition is unable to provide "Evidence that health service development permitted by the proposed adjustment would not result in unnecessary duplication of health resources in the area." In fact, the data provided in the Proposed 2009 Plan cited above suggest that development of the prostate center in Service Area 20 would lead to unnecessary duplication of health resources in the area.

For all these reasons, we believe that the Committee should disapprove the Petition.

LNRO
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August 7, 2008

Ms. Carol G. Potter
NC Division of Health Service Regulation
Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, NC 27699-2714

RE: Petition from Parkway Urology, P.A., d/b/a Cary Urology, P.A.

Dear Ms. Potter:

As a radiation oncologist specializing in the provision of cancer treatment, I feel that the preferential "carving out" of a single diseased organ by regulatory decision would be detrimental to the current multidisciplinary approach to cancer care now being practiced in North Carolina, which requires a critical mass of high technology and expert support staff in addition to the radiation oncologist, in order to provide appropriate and efficient treatment for not only prostate cancer, but a wide variety of both common and uncommon cancers.

If a more common cancer such as prostate were to receive designation for a 'special' treatment center through a revision to the carefully crafted methodology outlined in the *State Medical Facilities Plan (SMFP)*, our multidisciplinary and comprehensive community-wide approach to cancer care for other organs such as breast, brain, lung, and colorectal would be fragmented among multiple referring specialties, leading to potentially negative outcomes for our patients, some of whom are being treated for cancer at more than one site.

Organ-specific 'special' treatment centers could lead to a statewide proliferation of linear accelerators, as advocates for various disease sites argue that their own special disease of interest should receive equal consideration through the establishment of additional 'special' treatment centers - even though the 2008 *SMFP* (Table 9H) notes that North Carolina has an *excess* capacity of linear accelerators; ignoring the existing *SMFP* methodology would only exacerbate the current excess capacity. It is important to note that there is no evidence that organ-specific radiation oncology centers provide better medical outcomes than comprehensive community or academic centers, so no medical advantage is to be gained from such an approach.

Wake County itself is already served by no less than four (4) radiation oncology centers, capable of IMRT/IGRT therapy for prostate cancer, which bracket the proposed Cary center. In fact, just two miles from the petitioner, there already exists a radiation oncology center in Cary, which was among the first in North Carolina to offer IMRT services. In addition, linear accelerators are located in the two other Service Area 20 counties, Franklin and Harnett, while renowned multidisciplinary academic cancer centers at Duke University Medical Center (DUMC) and UNC-Chapel Hill are both within 30 miles of Cary. Finally, it should be noted that the July 25, 2008 "US News and World Report" ranked the DUMC urology program as the 6th best in the country.

The economic viability of existing cancer centers, which in many cases offer millions of dollars in uncompensated care to indigent and underinsured patients, could be jeopardized if care were to be offered under the single disease concept. Advertising campaigns purporting to offer a 'new improved' form of treatment would be at best disingenuous, sapping patients and resources from existing cancer treatment centers. In fact, patients in the Research Triangle region are already well-served by several multidisciplinary cancer centers which provide excellent care for prostate and other cancer patients. Clearly, there is ample evidence that abundant resources already exist for the treatment of prostate cancer patients in the Research Triangle area, so the issue of access is well addressed.

The Cary area is one of the most affluent in the country. In its report "Top 50 MSAs by Total Personal Income, 2006", the U.S. Department of Commerce Bureau of Economic Analysis ranked Raleigh-Cary as the 50th richest Metropolitan Statistical Area (MSA). Similarly, for "Metro Areas by Median Household Income, 2007", Freddie Mac ranked Raleigh-Cary as the 42nd richest MSA. Though the North Carolina Comprehensive Cancer Program has little available data indicating underserved areas at the diagnosis level, e.g. prostate cancer, it seems reasonable that some of the North Carolina non-metropolitan, rural or poorer counties would be more deserving of and experience a greater benefit from additional excess linear accelerator capacity as has been proposed.

Radiation oncology facilities owned by referring physicians create a lucrative opportunity for self-referral, which has received special attention from the Centers for Medicare and Medicaid Services (CMS). In fact, CMS is reviewing whether to continue the current in office "ancillary service" exception enjoyed by such facilities; if this exception should be eliminated, the proposed prostate cancer center would then be illegal.

Thank you for allowing me to submit comments on this very important set of issues.

Sincerely,

Arthur W. Chaney, III, M.D.