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MOORE REGIONAL HOSPITAL

August 6, 2008

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

DFS Health Planning
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AUG 07 2008
Medical Facilities
Planning Section

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

Dear Ms. Potter,

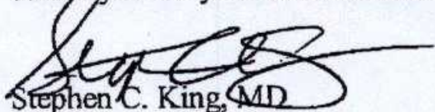
We are writing to express our strong opposition to the petition from Parkway Urology, P.A. for the inclusion of a "special need for a multidisciplinary prostate health center in Service Area 20" including the need for an additional IMRT/IGRT capable linac in this Service Area. We believe that the proposed change in methodology for assigning linear accelerator need is both unnecessary for appropriate patient care, and has the potential to completely undermine the foundation of the CON system by misallocating these expensive resources and encouraging unnecessarily expensive care.

Wake county is already served appropriately by four Linacs with IMRT/IGRT capability, including one in Cary just a short distance from the petitioner's practice. These existing facilities already engage in multidisciplinary prostate cancer care, which does not require that all of the involved specialties/treatments be housed under one roof.

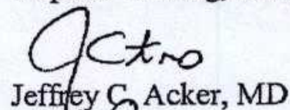
Furthermore, the existing facilities in Wake County, as well as other regional facilities at Duke, UNC, and at our facilities in Pinehurst, care for indigent patients regularly and without limitation. The premise that there is an "underserved" population of patients that could be served by the addition of a prostate specific linear accelerator in Cary is fallacious and disingenuous.

Finally, awarding a linac CON to a urology group creates a perverse incentive for self referral and can potentially result in overutilization or inappropriate utilization of expensive radiation therapy services.

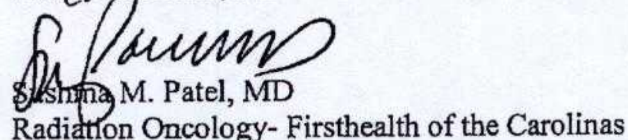
Thank you for your consideration of these issues.



Stephen C. King, MD



Jeffrey C. Acker, MD



Sushma M. Patel, MD
Radiation Oncology- Firsthealth of the Carolinas

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Medical Facilities
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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:

I am writing in response to the petition by the Parkway Urology, P.A. d/b/a Cary Urology to change the methodology in allocating linear accelerator CON's to one designed specifically for prostate cancer-specific linac center. I am a practicing Radiation Oncologist in the Department of Radiation Oncology at the Rex Cancer Center.

I do not agree with the petitioner that a need exists for a linear accelerator as a special need for a comprehensive multispecialty prostate health center, since many aspects of a multidisciplinary center exists at the Rex Cancer and lacks only an official name at this time. The multidisciplinary team includes Radiation and Medical Oncologists, Urologists, nurse navigators for only prostate patients as well as cancer support specialists including but not limited to a psyco-social worker and nutritionists. In addition there is a highly regarded outreach program with an advisory board consisting of urologists, physicians, and community leaders of the underserved population as well as private community physicians. The outreach educational and screening programs have been in existence in the African American population for eleven years and have been very successful. I personally have participated in this screening program in the last several years. The commitment from the V Foundation was in part predicated on the existence and success of the entire program that has been in existence at Rex. To say that these programs do not exist or are not successful does at best reflect a lack of knowledge, understanding and capriciousness on the part of the petitioner.

I will state at this point that the only logical reason for the petitioners need for a linear accelerator is a means to increase revenue. The argument provided by the petitioner is an attempt to hide this fact. There was no more or less a need for these services ten years ago when IMRT was not available. However, the current state of reimbursement for IMRT has awakened the entrepreneurs within the urology

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community to a new source of revenue especially in states without a CON law.

At this point I would like to present some arguments for the proposed adjustment provided by the petitioner which in truth are specious and should be addressed (beginning on page 5 of the petition).

1. Prostate Care: The majority of reports in the literature is either sponsored by the National Cancer Institute or from highly reputable institutions, and is usually peer reviewed prior to being published in leading journals. Studies which have little follow-up or admit that the majority of patients were lost do not get published. Moreover, the confusion in the literature is based more on the past prejudices that have existed between the urology and radiation communities which hindered good randomized studies. The current results on the control of low risk prostate cancer comparing radiation therapy and surgery appear to be comparable at least at the 10 year mark. Will the petitioner give the choice to the patient or encourage the choice which results in more revenue? At the present time we are asked to present the pros and cons of radiation therapy for each individual, should this be eliminated from the options for the patient.

2. Unique Aspects of Prostate/Urological Cancer: The stated use of the linear accelerator with IMRT to achieve high dose (Gray or Gy not **grey** as stated in the petition) is correct. However, IMRT is also used to minimize side effects, which it has done as has been reported in the literature, but not stated by the petitioner. In all the years of practice I never had the need for an on site urologist to address the side effects of radiation, the patient is usually seen by the radiation oncologist, who is trained to treat the radiation side effects unless there is a severe reaction where surgery is needed.

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3. Multidisciplinary Approach to Prostate: Radiation oncology centers are designed to treat all patients with cancer. There have been no reports in the literature which show or even mention the possibility of an advantage of having a center which treats only one disease. The remainder of the arguments regarding the lack of a true multidisciplinary prostate health center in North Carolina while pointing to other centers fails to recognize the fact that none of the centers have linacs dedicated to prostate but have physicians dedicated to the treatment of prostate cancer. The arguments are sophomoric in perception and delivery while presenting information relative to the petitioners point. The Radiation Oncologists at the Rex Cancer Center have over 5 years of experience with brachytherapy and several years with IMRT. Analysis of our results with brachytherapy showed our control rate for low and intermediate risk prostate cancer are comparable to those reported by many of the centers noted by the petitioner. We have accomplished this with the help of urologists in a collaborative multidisciplinary manner, by discussing cases with the individual urologists as well as at multidisciplinary conferences.
4. Finally, it is important to address the argument on the underserved. The service and outreach programs established at Rex have gone unmentioned by the petitioner. The volunteer service at screening sessions, the outreach programs mentioned above which address the underserved have also gone unmentioned. The petitioner fails to give details of the programs which will replace these and fails to mention where the center will be. If it is Cary how will patients from underserved areas get to the center, which is not at this time on available public transport lines.

5. Many questions need to be asked regarding every aspect of this petition. I am hopeful that the members of the Medical Facilities Planning Section will give the public the opportunity to address this question in order to make a rational decision.

In summary, I have chosen to address only some of the more capricious points made by the petitioner. The petition, in general, fails to provide a cogent argument for a special center for the treatment of prostate cancer. There was not a full disclosure of all the facts but just the facts which satisfied his case. It is incumbent on the medical facilities planning section to investigate the points of the petition and

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evaluate it on the merit of the arguments. The petition is about revenue and approval of the petition will only strengthen the argument for the elimination of the CON law. If the petitioner is granted favor, the it the only conclusion the medical community can make is to eliminate the CON law in order to provide for a level playing field for all specialties to purchase whatever is necessary to provide for a multidisciplinary approach for all cancer.

Sincerely,
Robert Amety, M.D for
Charles Scarantino, M.D

Charles W. Scarantino
UNC/Rex Radiation Oncology
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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 <u>no</u> 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.

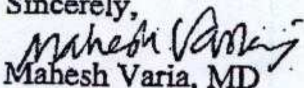
The economic viability of existing cancer centers, which in many cases offer millions of dollars in uncompensated care to indigent and underinsured patients, could be jeopardized if care were to be offered under the single disease concept. Advertising campaigns purporting to offer a 'new improved' form 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,



Mahesh Varia, MD
Department of Radiation Oncology
UNC School of Medicine

SOUTHEASTERN
RADIATION
ONCOLOGY

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Medical Facilities
Planning Section

To: Carol G. Potter
Medical Facilities Planning Section
701 Barbour Drive
Raleigh N.C. 27603
FAX (919) 715-4413

Re: Cary Urology's application for a prostate cancer-specific linear accelerator in Service Area 20

Dear Ms. Potter,

August 4, 2008

I am writing a letter to express my concern about the possibility of a prostate-specific linear accelerator (linac) in the Raleigh area. I am a radiation oncologist practicing in Fayetteville, NC with Southeastern Radiation Oncology, and I am affiliated with the Cape Fear Valley Health System. It is my understanding that a group of urologists has filed a petition with the State Health Coordinating Council (SHCC) asking for a change in methodology in allocating linear accelerator certificates of need (CON's). There are several reasons outlined in the petition claiming to support this need for an additional linear accelerator, including access to care, specifically for indigent or underserved populations, as well as the purported need for "better multidisciplinary management" of prostate cancer. I would like to submit that these reasons are without any merit, and could in fact lead to inferior outcomes and health care for the patients of this region.

According to the Prostate Cancer Coalition of North Carolina (www.pccnc.org), across the United States 218,890 men were projected to be diagnosed with prostate cancer in 2007, of whom 33,370 will die of their disease, for a 15.2 % nationwide mortality rate. In the State of North Carolina, there were 6420 men projected to be diagnosed with prostate cancer in 2007, of whom 835 will die, giving a mortality rate of 13.0%. These statistics strongly suggest that the men of North Carolina are currently receiving treatment for their prostate cancer that is actually better than the nationwide average, refuting the idea that prostate cancer patients as a whole are underserved in this state.

Multidisciplinary care is indeed a vital component of cancer care. At our comprehensive Cancer Center, weekly Tumor Board meetings are held, and all treating specialties are invited. Moreover, ancillary services such as social workers, dieticians, support groups, financial assistance are all available to patients at no charge, something that a stand alone prostate specific center would be unable to provide. Academic multidisciplinary consultations are also available at Duke and UNC, should the patient wish a second opinion.

J. Hugh Bryan, M.D.
P.O. Box 41208 · Fayetteville, NC 28309 · 910/609-6690 · 800/682-3367 · FAX 910/609-6313
Cape Fear Valley Medical Center

Nearby rural areas such as Harnett County and Sampson County are already served well by linear accelerators in Cary (Wake Radiology and Oncology) and at Health Pavilion North (part of Cape Fear Valley Health System), which bracket these areas, as well as Sampson Regional Cancer Center in Clinton. The proposed location of the new linear accelerator is in fact two miles north of the currently existing linac in Cary. It is disingenuous to suggest that patients in these rural counties would be served BETTER by locating an additional linear accelerator in Cary, FURTHER away from these areas.

Patients who are indigent are never turned away from our facilities at Cape Fear Valley Health System. We have a significant proportion of patients who are Medicaid or uninsured, and they receive intensity modulated radiotherapy (IMRT) and image guided radiation (IGRT) at our facilities. There are other major centers such as Duke and University of North Carolina at Chapel Hill, well within reach for most patients in the counties in question, who also provide radiotherapy for this population. The proposed linac would in fact be located in Cary, a very affluent community, with an excellent payor mix, further casting doubt on the purported reason of reaching underserved populations as described in the petition.

The Raleigh/Cary area is already well served by multiple linear accelerators, one of which is only two miles from the proposed new facility. Sophisticated radiotherapy such as IMRT and IGRT are very labor and resource intensive endeavors. By sapping the resources from the currently existing facilities, this proposed linac would do exactly what the CON laws were fundamentally designed to prevent – the needless duplication of services, resulting in decreased resources for all facilities, which in turn would make it more difficult to invest in newer and better treatment in the future. This could actually lead to less desirable outcomes for cancer patients overall, and prostate cancer patients specifically.

The American Society for Therapeutic Radiology and Oncology (ASTRO) has recently approached the Centers for Medicare and Medicaid Services (CMS) with concerns about the potential problems with self-referral. Currently exempt from Stark regulations as an "in-office ancillary service", radiotherapy facilities owned by referring physicians have proliferated in some states. This type of potentially inappropriate financial relationship has called into question the rendering of fair and unbiased opinions that physicians are supposed to give their patients. In fact, allegations of overuse of IMRT abound in areas that have seen the implementation of these urology owned radiotherapy facilities, with the use of other treatment options for prostate cancer patients such as radical prostatectomy, radioactive seed implantation and watchful waiting falling drastically.

I hope that the above points can be taken into consideration when the petition in question is evaluated. Please contact me anytime at (910) 609-3840 if I can be of further assistance.

Yours truly,

Istvan Pataki, MD
Southeastern Radiation Oncology
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WAKE FOREST

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Planning Section

July 30, 2008

Ms. Carol G. Potter
NC Division of Health Service Regulation
Medical Facilities Planning Section
701 Barbour Drive
Raleigh, NC 27603

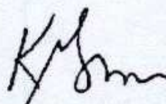
Dear Ms. Potter:

I am writing to express my deep concern regarding a proposal for a linear accelerator to be installed in a urology outpatient facility in Wake County. Currently, radiation treatments are delivered as part of the multidisciplinary care of cancer patients by radiation oncologists. The proposed linac facility is within 2 miles of a current facility that is already providing care. In addition, Wake county is already well-served by 4 linac centers capable of IMRT/IGRT therapy for prostate cancer, which bracket the proposed center at Cary Urology. In addition, there are 2 academic centers of excellence (UNC and Duke) which are located nearby in the Research Triangle area. All of these facilities accept indigent patients.

Adding an extra linear accelerator in a Service Area where the present State formula documents that no need exists will sap patients and resources from existing linear accelerator facilities. Organ-specific linear accelerator centers do not provide better outcomes than comprehensive community or academic centers and could lead to a statewide proliferation of linear accelerators (undermining the existing allocation formula for linac CON's in North Carolina). In addition, linac facilities owned by referring physicians create a lucrative opportunity for self-referral. Medicare is currently reviewing whether the current "ancillary service" exemption enjoyed by such facilities should be eliminated.

Cancer care of patients needs to remain in the care of physicians who are able to manage all sites of disease in a comprehensive fashion. I believe it is a dangerous precedent to allow a facility that will only be caring for urologic cancer.

Sincerely,



Kathryn Greven, M.D.
Professor
Department of Radiation Oncology

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Planning Section

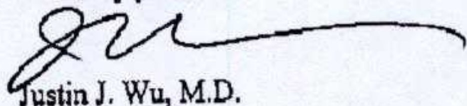
August 8, 2008

Dear Ms. Potter,

I would like to add my voice to the chorus of dissent over the Cary Urology petition for a 'prostate cancer center of excellence'. I am currently a partner with Piedmont Radiation Oncologists in Greensboro, but will be joining the Rex-UNC rad onc division soon. My main objection to their proposal is their business model, in which they will have ownership of the linear accelerator, and thus garner the very lucrative technical fees associated with prostate IMRT. This type of model, in my opinion, is not designed with the well-being of patients in mind, but rather the pocketbooks of the urologists. How this gets past the Stark anti-self-referral regulations is bewildering to me. Also, there is certainly no lack of world-class radiation treatment facilities in the area (Rex, Wake Radiology, UNC, Duke) that already provide cutting-edge treatment to ANY patient with prostate cancer, regardless of their ability to pay, and the area already has more than enough linear accelerators. Thus, I would respectfully ask you to please deny Cary Urology's petition for an "adjusted needs determination" to allow an exception to the CON rules, which would allow for a dedicated prostate linac in Service Area 20.

Thank you so much for your consideration.

Sincerely yours,



Justin J. Wu, M.D.