WAKE RADIOLOGY
ONCOLOGY SERVICES, PLLC

RADIATION ONCOLOGY
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8/01/08

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

RE: Petition from Parkway Urology, P.A., D/B/A Cary Urology/P.A.

Dear Ms. Potter,

We understand that Cary Urology has submitted a petition for an adjusted need determination for an additional "specialty" linear accelerator in Service Area 20.

At this time, there is no need for this type of additional linear accelerator in Area 20. A certificate of need is currently available for an additional linear accelerator in Service Area 20 and this certificate of need is the subject of a contested case to which the Petitioner here, Parkway Urology, is a Party. Prior to the addition of that accelerator, the four linear accelerators at Rex Hospital and the single linear accelerator in Cary at our facility have available treatment capacity.

While multidisciplinary care is essential for treatment of all cancers, we are not aware of any evidence that suggests that having all the physicians in the same facility results in improved outcome. Multidisciplinary care has been delivered in separate facilities effectively for many years. There will not be any cost savings by sharing radiographic studies among physicians in the center. Diagnostic radiographic studies are often different than the CT scans done for radiation therapy planning that require specialized positioning to insure precise delivery of radiation. We do not believe that medical oncologists, radiologists and pathologists, who are part of the multidisciplinary treatment of prostate carcinoma, will be part of the proposed facility, so the proposal may not include all disciplines involved in the care of prostate or other genitourinary cancers.

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In regards to the need for a new linear accelerator to provide care to the under-served population within Service Area 20, we feel this need is already met by care that the current providers deliver. At our facility, we treat all patients regardless of their ability to pay.

In summary, we do not feel that an additional "specialty" linear accelerator in Service Area 20 is indicated because of the available treatment capacity of current linear accelerators, the addition of a new linear accelerator based on the 2007 SMFP, the multidisciplinary care that is already provided in the area, and the lack of need for a special center to provide access to an under-served population given care that is already provided by current centers.

Sincerely,

Scott Sailer, MD
Co-Medical Director

Andrew S. Kennedy
Co-Medical Director

TRIANGLE RADIATION ONCOLOGY SERVICES, INC.
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Raleigh, NC 27605

Phone: (919) 784-3018
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DEPARTMENT OF RADIATION ONCOLOGY REX HEALTHCARE

R.D. Ornitz, M.D.
(Pete) L.G. Hoffman, M. D.
C.W. Scarantino, M.D., Ph.D.
Catherine M. Lee, M.D.

August 7, 2008

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

Re: Petition from Parkway Urology, PA., D/B/A Cary Urology, P.A.

Dear Ms. Potter:

I have had an opportunity to review the application and current events relating to the application of Parkway Urology, PA. and Cary Urology P.A. to seek approval for the addition of an IGRT/IMRT linear accelerator in service Area 20 for the specific treatment of prostate cancer. It is to be emphasized that my comments are purely personal and do not represent those of Rex Healthcare and the University of North Carolina.

I have been practicing radiation oncology in Wake County for 29 years. Certainly, as the growth of the county has exponentially increased, there was historically a definite need for additional linear accelerators to meet the service needs of Area 20. At the present time, there are four dedicated radiation oncology programs represented by Wake Radiology in Cary, Cancer Centers of North Carolina in Raleigh, Duke University Medical Center, and Rex Healthcare/University of North Carolina. These facilities currently have seven linear accelerators operating with an eighth unit recently approved for dedication at CCNC.

I have carefully reviewed the communications you have received from Dr. Robert W. Fraser, President of Southeast Radiation Oncology in Charlotte, as well as those of Dr. Roger F. Anderson, representing the position of CARROS. These letters are brilliantly crafted and I will not simply recapitulate the arguments made for rejecting the application from Parkway Urology. It is however important for me to state that in my opinion, a very dangerous and negative precedent would be set if the North Carolina Division of Health Service Regulation approved a linear accelerator for a specific site-specific treatment center. Specifically, there would be no reason if such approval occurred, that other centers might not be developed for the treatment of patients with primary brain tumors, head and neck cancer, gynecologic malignancy, or endothoracic malignancies.

It is important to emphasize that Rex Healthcare/UNC currently has an extremely active and comprehensive program for the treatment of urologic malignancies. It is in fact the most common type of patient we treat. Our program is quite comprehensive relating to the ability to treat patients with the most modern external beam techniques utilizing IGRT. Our interstitial prostate seed program dedicated in 1998 has treated well over 800 patients. Rex Healthcare has a specific clinical navigator to assist patients with sundry logistical issues ranging

from transportation to our clinic for treatment as well as referral to support groups. The Department of Radiation Oncology at Rex Healthcare has never turned a patient away based upon ability to pay.

At the risk of being politically incorrect or offensive, I must state that it is my opinion that the application of Parkway Urology is flagrantly flawed and simply offers arguments for approval that are quite transparent relating to its justification. Only recently earlier this week, it was reported by the National Institute of Health, that they do not recommend screening for prostate cancer in patients over age 75 due to the fact that there has been no substantive body of data suggesting that early detection improves long-term outcome. There is no reason to expect that yet another redundant and unnecessary site-specific prostate cancer treatment center would impact upon either access to medical care or improvement in outcome. It must be stated that the only justification for this application rests with the very high reimbursement currently available for patients undergoing IGRT treatment for prostate cancer. One would speculate as to whether this application would have ever been submitted if the financial bottom line were coequal to what profit margin may be made on reimbursements for such procedures as TURPs. It is my best judgement that the entire justification for this type of application must rest with financial remuneration as opposed to any legitimate argument that it would improve patient care or outcome.

In summary, I believe that the application for another linear accelerator for the treatment of prostate cancer (Mens Health Center) is a flagrantly spurious proposal that is unnecessary based upon the existing and/or approved linear accelerators for Service Area 20 with the fact being that at this time there is under utilization of existing equipment in Wake County. I believe that approval of this application would set a very negative and dangerous precedent for the future, and at the risk of being somewhat overly direct, cast significant doubt upon the credibility of your office in carrying out your major charge to limit unnecessary expensive medical technology and avoid redundant and unnecessary medical services which increase the cost of healthcare. I am hopeful that you will do the right thing in terms of seeing this application for what it is, and make the appropriate judgement.

Sincerely,

Robert D. Ornitz, M.D

Robert D. Ornitz, MD/INTER
Department of Radiation Oncology
Rex Healthcare

RDO:ady; DD: 08/07/2008 8:40 A; DT: 08/07/2008 10:05 A; 000794503/#2002576

copy: Leroy G. Hoffman, MD/IOMAIL
Catherine M. Lee, MD/IOMAIL
Charles W. Scarantino, M.D./INTER
Robert W. Fraser, III, M.D.; 200 Queens Road, Suite 400; Charlotte, NC 28204
David M. Brizel, M.D.; DUMC; Department of Radiation Oncology; Durham, NC 27710

2 Original

Dr. Thomas L. Walden, Jr., MD
Gibson Cancer Center
1200 Pine Run Drive
Lumberton, North Carolina 28358

August 7, 2008

Ms. Carol Potter
Medical Facilities Planning Section
701 Barbour Drive
Raleigh, North Carolina 27603

Re: Cary Urology' Application for a Prostate Cancer-Specific Linear Accelerator in Service Area 20

Dear Ms. Potter,

I am writing to express my reservations regarding a proposed application for a certificate of need for a prostate-specific linear accelerator in Service Area 20 including Wake, Harnett, and Franklin Counties. I am a practicing radiation oncologist in the Lumberton and Fayetteville area through Southeastern Radiation Oncology. I have been informed that a petition is to be filed with the State Health Coordinating Council requesting a change in the formulas/criteria for allocating certificates of need for linear accelerators, to allow for a specific disease – prostate cancer. I am perplexed that this would be considered in light of the ready access to radiation therapy for all cancers already available in the Raleigh area and meeting the current county population requirements. Patients in this region have access to multidisciplinary cancer centers in Raleigh and availability to the outstanding academic centers of Duke and the University of North Carolina as well as locally in Raleigh through their affiliate health systems. Further, it is my understanding that this proposed center would be located in Cary, only two miles from a current radiation oncology center. This affluent community is already well provided with medical access.

One of the drawbacks to treatment options for prostate cancer is not the need for a specialized "center", but rather that patients with prostate cancer receive adequate informed view points on their treatment options. To address this issue, some states have passed laws making it mandatory that patients with particular cancers be seen by all the specialists in that area of a cancer for evaluation to become fully aware of their treatment options, prior to receiving definitive treatment.

Linear accelerators are expensive, and the American Board of Radiology certified Radiation Oncologists who treat cancer patients are well trained in the treatment of all cancers, including prostate. Because of the potential treatment options of these machines, it would not only be a disservice to allocate its use solely for a specific cancer (when adequate and multidisciplinary facilities are clearly available to Area 20), but could open up a "rush" for other specialists/ cancer sites to petition for similar exemptions. A private specialty facility would also not be able to provide extensive coverage for indigent patients and would most likely be supported by self-referral by the urology group. Advances in the treatment of prostate cancer by radiation oncologist have come through radiation oncology, radiation physicists, and the supporting industries.

I do not see the benefit to Area 20, or the state at-large from an organ-specific certificate of need. I do see erosion of the benefit to the state health care system if the certificate of need process is further compromised, inhibiting existing facilities from maintaining state-of-the-art equipment to help all cancer patients. I strongly request the state not to permit certificates of need for linear accelerators to treat specific organ systems.

Sincerely,

Dr. Thomas L. Walden, Jr., MD
Radiation Oncologist

Carolinas Medical Center-Union
Edwards Cancer Center

August 7, 2008

Dear Ms. Potter,

I understand that Dr. Kevin Khoudary and the Cary Urology group have filed a petition for a CON to start a radiation oncology facility dedicated specifically to the treatment of prostate cancer in Wake County, NC. As the Medical Director of the Radiation Oncology Department at CMC-Union, in Monroe (Union County), NC, I would like to express my strong opposition to this proposal.

Prostate cancer patients in Wake County are currently well-served by four radiation treatment centers. These centers are capable of providing modern radiotherapy, using IMRT and IGRT, for prostate cancer patients. In addition, the nearby university centers of UNC and Duke University provide excellent multidisciplinary care for prostate cancers in the region.

I do not believe that it is wise for the state, or for any agency, to approve CONs for centers that are specifically dedicated to the treatment of any one type of cancer. This would open the door to other specialty groups that might propose a center for the treatment of breast cancer, or for lung cancer, or gynecologic cancer, etc. There is no reason to believe that state of the art radiation care cannot be provided by competent, well-trained radiation specialists in the centers currently in operation in the region.

Finally, and ***most important***, a radiation facility owned by Urologists, and specifically dedicated to the treatment of prostate cancer, raises very serious concerns about the potential for self-referral abuse and over-utilization. These abuses are much more likely to occur when the treatment facility is owned by physicians who are making the referrals to that facility, and when the referring physicians are benefiting substantially from those referrals.

P.O. Box 5003 • Monroe, NC 28111 • 704-225-2826

Carolinas Medical Center-Union
Edwards Cancer Center

Thank you very much for your consideration. Please feel free to contact me if you have any questions, or if I might provide any further information.

Sincerely,

Thomas G. Trautmann

Thomas G. Trautmann, M.D.

Medical Director, Radiation Oncology Department

CMC-Union Hospital

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North Carolina Hospital Association

August 8, 2008

MEMORANDUM

TO: Ms. Carol Potter, Planner
Medical Facilities Planning Section

FROM: Mike Vicario, Vice President of Regulatory Affairs
919-677-4233 <mvicario@ncha.org>

SUBJECT: Cary Urology Petition for Prostate Health Center

In April of this year NCHA commented on a petition submitted by Cary Urology to establish an IMRT/IGRT - capable linear accelerator (LINAC) to treat patients in a prostate health cancer. In that letter we expressed concerns that the petition was proposing a *disease-based methodology* in addition to the existing *utilization based* methodology for linear accelerators, which would result in duplication of health resources in the area. The petition for an adjustment to the need determination through the establishment of a "dedicated prostate health center" submitted by Cary Urology on August 1 also duplicates existing health resources in the area, services which are currently provided by at least two cancer treatment centers in Wake and adjacent counties. We recommend that this petition be disapproved.

Because radiation oncology patients normally receive a course of multiple linear accelerator treatments over several days, they generally seek treatment sites close to their homes. This petition cites State Center for Health statistics data showing 490 new prostate cancer cases in 2007 for the area, and assumes that 245 will be enough patients for a viable center. However this assumes that the center will serve 100% of the new cases in the area, a questionable claim when residents in the area are very near the NCI designated comprehensive cancer treatment centers at Duke and UNC and the comprehensive community cancer treatment center at Rex Health System.

Dr. Peter Back of Memorial Sloan-Kettering Cancer Center was a senior adviser to the administrator of the Centers for Medicare and Medicaid Services from 2005 to 2006. In a July 30 letter to the editor in the Raleigh News & Observer, Dr. Back suggests that physicians' acquisition of radiation therapy machines for treating prostate cancer may be driven by generous reimbursement for these treatments when other treatment modalities have suffered

cutbacks. This petition proposes that LINAC revenues could provide the resources needed to cover treatment of other patients and services. However the financial viability of the center is dependent upon attracting all of the LINAC treatable prostate disease cases in service area 20, unlikely for even a large specialty clinic.

The petitioner has not demonstrated that this approach represents an improvement over existing cancer treatment programs. The approach is also duplicative of the existing methodology as it results in "double counting" of projected prostate cases that are used to project need. For these reasons, NCHA recommends that the Council disapprove this petition and encourage the petitioner to work with existing linear accelerator providers.

Thank you for the opportunity to comment on this petition, and please feel free to contact me if you have questions.

MOUNTAIN RADIATION ONCOLOGY

Eric F. Kuehn, M.D.
Kellie S. Condra, M.D.
Sesalie L. Smathers, M.D.
Matthew C. Hull, M.D.
Marilyn L. Haas, Ph.D., ANP-C

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90 Asheland Avenue
P.O. Box 1430
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807 N. Justice Street
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07 August 2008

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

Re: Petition from Parkway Urology, P.A., D/B/A Cary Urology, P.A.

Dear Ms. Potter,

I have recently become aware of a petition from the above group of urologists to have a proposed prostate cancer center designated as a "special treatment center" in an effort to obtain a CON for a linear accelerator. As a practicing radiation oncologist in Asheville, I would like to voice my opposition to this attempt. In non-CON states, similar "prostate centers" have been built and are generally owned by urologists. A widely held opinion is that these centers, through self-referral, are intended for the economic benefit of the physician owners without any real goal of patient benefit. The Federal Government apparently shares this perception, and these centers have received significant attention from CMF. Consideration is apparently being given to eliminating the current in-office "ancillary service" exception that they currently enjoy. If CMF moves forward with this, these prostate centers would not longer be legal.

In addition to this issue, designating a prostate center as a "special treatment center" would also open the possibility of creating other special treatment centers for other disease subsites such as breast cancer and colorectal cancer. My fear is that these centers would "carve out" the better reimbursed cancer treatments and would lead to, not only a proliferation of linear accelerators in the state, but to a decreased economic viability of the existing accelerators which would be left with the lower reimbursing treatments. In this way, these "special treatment centers" would actually hurt overall cancer care in our state. In my mind, these are precisely the type developments that our existing CON laws are designed to prevent.

On a final note, good, multidisciplinary cancer care already exists in the vast majority of the existing cancer centers and clearly doesn't require that the referring physicians and cancer treatment equipment be housed in the same facility. It simply requires that there is good communication among the various disciplines that care for each of the patients.

Thank you for your consideration of this matter.

Sincerely,

Eric F. Kuehn, M.D.
Mountain Radiation Oncology

EFK/mcb

Subject: [Fwd: Cary Urology]
From: "Carol G. Potter" <Carol.Potter@ncmail.net>
Date: Fri, 08 Aug 2008 13:56:30 -0400
To: Kelli Fisk <Kelli.Fisk@ncmail.net>

-------- Original Message --------
Subject: Cary Urology
Date: Fri, 08 Aug 2008 13:53:19 -0400
From:julian_rosenman@med.unc.edu
To: Carol.Potter@ncmail.net

August 8, 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:

Money and Medicine are uncomfortable bedfellows; even more so when the disease is cancer. It is the job of the state to be sure that "better patient care" is not just an empty justification for "more profitable business."

Running and maintaining high standards of care in radiation therapy is a difficult business. Difficult and often without incentive because most clinicians who are not radiation oncologists cannot judge how well the radiation is being done. Thus poor work is not always penalized by a loss of referral base. Most radiation departments work with academic centers and spend a great deal of time and effort to be sure that the quality of treatment is good, that is they self-police within the radiation oncology community. Departments who do this already exist in Raleigh and Cary.

I have no confidence that a new radiation oncology department put into place by urologists, that was not part of the radiation oncology community, and who has not requested help from the academic centers would offer patients better radiation care than the ones already existing. Indeed, based on the above discussion, it may well be that such a department would do poorer work, relying on self-referral from the urologists to maintain their operation.

For these reasons I believe the state should not permit an unneeded, possibly inferior radiation treatment center, whose major purpose cannot be justified in terms of improved patient care, but rather in terms of increased revenue.

Julian Rosenman, MD
University of North Carolina