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Administrator

DFS Health Planning
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AUG 08 2008
Medical Facilities
Planning Section

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,

Scott P. Lankford, MD

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August 7, 2008

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

DFS Health Planning
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Medical Facilities
Planning Section

Dear Ms. Potter:

As a practicing radiation oncologist in North Carolina, I am deeply concerned with the attempt by Parkway Urology, PA, d/b/a Cary Urology, PA to receive a Certificate of Need for a linear accelerator. This group of Urologists is misleading the board into thinking that a 'prostate specific' radiation department is of value to the community. There is absolutely no evidence that an organ-specific radiation oncology center provides better outcomes than a comprehensive radiation therapy center.

Radiation Oncology is a highly specialized field of medicine that focuses on treatment of cancer patients. In addition, radiation oncologists are a vital part of the multi-disciplinary team caring for oncology patients of all cancer types. Linear accelerators are expensive, complex and potentially dangerous medical devices. They are to be supervised and regulated by radiation oncologists, who are trained in the use, application and safety of these machines as well as state and national regulatory agencies.

Based on state regulations, there are specific criteria to be met in order for a CON to be awarded for such a machine. Currently, the 2008 *SMFP* notes that North Carolina has an excess capacity of linear accelerators. Awarding a CON to this urology group would invalidate the CON process and regulatory status of the state. In addition, it would create a rush of other specialties trying to build extremely expensive radiation centers. With an excess of linear accelerators, the potential for inappropriate use of linear accelerators would be tremendous as clinics strive to cover the multi-million dollar expense of the center and to make it profitable.

Wake County is already served by 7 linear accelerators (with an additional unit approved for operation), capable of the most technologically advanced treatment methods. In addition, Duke University Medical Center and the University of North Carolina-Chapel Hill are within 30 miles of Cary and are nationally recognized radiation centers with NCI designation. Thus, there is absolutely no need for an additional linear accelerator for this

service area and much less for a 'prostate specific' center. Duke University has been ranked as the 6th best urology program in the country, according to the July 25th 2008 US News and World Report. It is evident that the prostate patients in Cary already have ample access to excellent radiation therapy and urologic oncology care.

Radiation Oncology facilities owned by referring physicians, such as Urologists, create an extremely lucrative opportunity for self-referral. In addition, there is a great threat that solid, evidence based medicine would be supplanted by financial based medical care.

I urge the division of health services to deny this CON award to Parkway Urology, P.A. as it will in no way serve the patients of this state in a favorable manner.

Sincerely,

William Bobo

William Bobo, MD

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July 30, 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 Carol:

The Agency response, made in declining an earlier petition from the above, suggested that the petitioner "consider a petition for an adjusted need determination... for a linear accelerator in Service Area 20," which would address the issue of access for "the underserved population in the service area," and also demonstrate the related medical advantages of such a center. I would like to cite the following data to show that Wake County, as well as the entire Research Triangle region, is already well-served by several multidisciplinary cancer centers that are currently providing excellent care for prostate and other cancer patients. Our research has demonstrated that these centers are already providing care to indigent and other "underserved" groups in the area. Not only is there no need for an additional linac center in Service Area 20, an additional linac would adversely affect the current providers. Before summarizing our other objections to this petition, let me review the situation in Service Area 20, as well as the adjacent Research Triangle region.

"North Carolina Cancer Facts & Figures, 2004"[1] (NCCFF, the most recent data), contains a number of charts, tables and graphs developed by the N.C. Central Cancer Registry. The document notes that "Approximately one man in eleven will develop prostate cancer during his lifetime... (and) Prostate cancer is the second leading cause of cancer death among men."[2,3]

Table 9 shows "2004 Prostate Cancer Incidence Rates by County" but I have revised the data to *rank order* North Carolina counties. You will note that for Service Area 20, Wake is 25th out of 100 North Carolina counties, while Harnett is 51st and Franklin is 66th.[4] Walter L. Shepherd, M.A., Program Director of the North Carolina Comprehensive Cancer Program, gave us his *opinion* that northeast North Carolina and the non-metropolitan areas of our state east of I-95 may have patient populations which are now underserved for cancer care services. However, he indicated that his program has little available data at the diagnosis level, which could better pinpoint the possible presence of a maldistribution of such resources.[5]

The NCCF document also notes: "North Carolinians are truly fortunate to have so many excellent cancer treatment and research facilities within the state."[6] Indeed, within twenty-nine (29) miles[7] of Cary are Duke and UNC, both with National Cancer Institute-Designated Comprehensive Cancer Programs (the other NC program so designated is located at Wake Forest University).[8] In addition, UNC-Rex Hospital, just nine (9) miles away, is a Community Hospital Comprehensive Cancer Program.[9] These accreditations were awarded by the Commission on Cancer of the American College of Surgeons.[10]

Duke University Medical Center (DUMC) tied for the 8th ranking in the recent *U.S. News and World Report's* 2008 listing of best hospitals.[11] In that same issue, the DUMC urology department was ranked 6th best in the country.[12] The DUMC website notes that "With the recruitment of (Urology) Division Chief, Judd W. Moul, M.D., former Director of Defense Center for Prostate Disease Research in 2004, the Division has developed a focused Duke Prostate Center in collaboration with the Duke Cancer Center, the Radiation Oncology Department and Medical Oncology. Initiatives include multidisciplinary care for newly diagnosed prostate cancer, the high-intensity focused ultrasound (HIFU) program for prostate cancer and expanding care at Durham Regional Hospital and Duke Raleigh Hospital."[13]

The UNC Lineberger Comprehensive Cancer Center offers a specialization in urologic oncology and at its website notes "The Urologic Oncology Program brings leading-edge multidisciplinary and compassionate care to our patients. Urology oncology specialists from surgery, medicine, radiation therapy, radiology, pathology, and nursing form a single patient care team and deliver individualized patient care in a coordinated and caring manner." [14] It further notes that it is "The only public comprehensive cancer center in North Carolina, treating patients from all 100 counties in the state... provides a multidisciplinary approach, giving patients the benefit of many specialists in one place (and is) Home of the Carolina Community Network, a program that aims to reduce breast, prostate, and colorectal cancers in adult African-Americans."[15]

One of the many ongoing UNC research studies is projected to "provide a unique and cost-efficient opportunity to evaluate environmental factors that may contribute to racial differences in prostate cancer severity among North Carolina men."[16] Also, an *NCI Cancer Bulletin* noted that the UNC Lineberger Comprehensive Cancer Center "is a Department of Defense Prostate Cancer Center of Excellence...(and) The Center has special research expertise in medically underserved populations and health disparities, as well as an emerging strength in molecular studies of racial differences in breast, colon, and prostate cancers". [17] It is also important to note that construction of the new $200M North Carolina Cancer Hospital on the UNC campus will be completed by mid-2009.[18]

UNC-Rex Hospital Cancer Center is a 2007 recipient of a V Foundation grant in the amount of $500,000, "to create the Rex Prostate Cancer Center of Excellence...The grant will allow Rex to further develop and expand four components of the comprehensive prostate cancer program; Outreach and Education, Community Screenings, Clinical Treatment and Follow up, and Survivorship...The program will not only increase community awareness about prostate cancer it will also give men with inadequate funds the ability to receive a free screening. The goal for the Rex Prostate Center of Excellence is to reduce the mortality rate in men due to prostate cancer."[19]

From the above, it seems clear that while prostate cancer is an ongoing concern, particularly in some other areas of North Carolina, the Research Triangle already has a number of cancer centers with an existing focus on treating this disease in a multidisciplinary setting, effectively challenging the notion that *access* to such services is either inconvenient or unavailable to patients throughout Wake County, including Cary.

In addition to regionally and nationally accredited programs, these facilities are also committed to the provision of indigent care. The DUMC website notes "Today Duke remains the primary provider of indigent patient care in the state of North Carolina..."[20] Recently, UNC Vice Chancellor and Dean William L. Roper presented to the UNC Faculty Council about the work of the UNC Health Care System and the School of Medicine. He noted that "UNC Hospitals delivers more uncompensated care than any hospital in North Carolina...on par with major hospitals in Atlanta and Chicago."[21] He further noted "our hospitals admit 800 patients each day, one-third of whom are indigent and received $500,000 per day in uncompensated care."[22] In 2007 UNC-Rex Hospital provided $66M in uncompensated care; it also offers a "Prostate Cancer

Assistance Fund (which) helps pay for screenings for uninsured or underserved men, as well as follow-up treatment assistance once diagnosed.[23] Clearly, financial need is not a bar to accessing the services of these Cary area cancer programs.

Service Area 20 and the Research Triangle are already well-served by a plethora of linac centers, providing excellent multidisciplinary care to local prostate patients, both affluent and indigent. An additional linac center in Service Area 20 would only steal patients from the current providers, making it harder for them to accomplish their mission of treating ALL the cancer patients in the region. Because IMRT treatment for prostate cancer is so well-reimbursed, the financial impact on the surrounding centers would be magnified.

Cary already has a linac center equipped with IMRT/IGRT at Wake Radiology and Oncology, located only 2 miles south of the proposed center at Cary Urology. The current center is therefore closer to the rural patients of Service Area 20 living in Harnett and Franklin counties than the proposed new center. Cary is one of the most affluent communities in North Carolina, and a second linac center there is poorly situated to provide access to "underserved" populations. The Rex Prostate Cancer of Excellence, at the nearby UNC Rex Hospital in Raleigh, already has as one of its missions to provide care to patients with "inadequate funds."

Specialty-specific or organ-specific linac centers have not been demonstrated to provide better medical outcomes than well-equipped comprehensive linac facilities, nor is there any reason to expect that they would. The principles for treating a localized cancer adjacent to critical normal organs with radiation are essentially the same for all sites. There is no reason to expect that a for-profit linac center owned by the referring urologists and dedicated to prostate cancer treatment would provide any better outcomes than a similarly-equipped comprehensive university hospital, community hospital, or free-standing linac facility, so long as the radiation was delivered with image-guidance (IGRT) and intensity modulation (IMRT).

The planners in the CON section have developed a time-tested methodology for determining linac need, that has to date prevented wasteful duplication of high cost linac capacity. The needs formula is periodically reviewed and revised to reflect changing treatment patterns and new technologies. An additional linac in Cary is precisely the kind of duplication of service that the CON statutes were designed to prevent. Approval of an extra organ-specific linac for Service Area 20 would not only result in overcapacity there, it would also set a terrible precedent, assuring that similar "demonstration projects" for other specialty-specific linacs would be forthcoming from other surgical and medical groups. I predict that the common denominator for all such projects, as in the present case, will be ownership of the linac by the referring physician group, with the potential for that group to financially profit from the linac treatments. I feel strongly that if the petition for a urology-sponsored linac facility is approved, the MFPS will be setting a precedent that we all will regret.

Thank you for letting me comment on this issue.

Sincerely,

Robert W. Fraser, M.D., F.A.C.R.

PS – I would like to thank our administrator, Paul Williams, for his excellent help in researching this topic.

Bibliography

[1] *North Carolina Cancer Facts & Figures, 2004*, (NCCFF), a joint publication of the North Carolina Division of Public Health and the American Cancer Society, Southeast Division
[2] NCCFF 29.
[3] NCCFF 29.
[4] NCCFF 23.
[5] Phone conversation with Walter Shepherd on 7/23/2008 (919-707-5330).
[6] NCCFF 52.
[7] Mapquest, www.mapquest.com, indicates the distances from Cary Urology to the following are: UNC-Rex Hospital, 9.26 miles, Duke University Medical Center, 27.22 miles, and UNC Hospitals, 28.50 miles.
[8] NCCFF 55.
[9] NCCFF 55.
[10] NCCFF 54.
[11] U.S. News & World Report, July 25, 2008, (USNWR) http://health.usnews.com/sections/health/best-hospitals.
[12] USNWR, http://health.usnews.com/sections/health/best-hospitals.
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[14] UNC Lineberger Comprehensive Cancer Center website, http://cancer.med.unc.edu/patient/programs/urologic.asp.
[15] www.unclineberger.org.
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[18] http://www.nccancerhospital.org/news/2007/topoff/.
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[23] www.rexhealth.com/_documents/FoundationAnnReport07.jpg.pdf.

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August 1, 2008

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Planning Section

Ms. Carol G. Potter
North Carolina Division of Health Service Regulation
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FAX #: 919-715-4413

Dear Carol:

This letter is in regards to a petition from Parkway Urology, P.A., doing business as Cary Urology, P.A. This letter is intended to oppose the petition for an adjusted need determination for a linear accelerator in service area 20. It is clear that Wake County is well served by four cancer centers with linear accelerators capable of delivering both IMRT and IGRT for prostate cancer. As such, this is not an underserved area or diagnosis. Furthermore, Cary does have a facility two miles away from the proposed urology linear accelerator center. This proposed certificate of need would provide a linear accelerator in an area with two nearby academic institutions, namely UNC and Duke which offer the highest quality care for prostate cancer incorporating a variety of treatments including radiation oncology, surgery and medical oncology. As such, the certificate of need application does not warrant consideration under any rationale that it would serve an "underserved population".

In addition to its fundamental weaknesses as a needs determination, this application is related to the development of an organ-specific linear accelerator center. Unfortunately, national trends related to this form of business venture seem to indicate that patients are typically referred for treatment using the linear accelerator for financial reasons rather than clinical indications.

If a certificate of need is awarded to produce an organ-specific linear accelerator center in service area 20, unfortunately, this will prohibit future CON applications for linear accelerators for multidisciplinary care in this service area. As such, in an effort to improve urology care, the state may ultimately sacrifice care for lung cancer, breast cancer, head and neck cancer and brain

tumors. The methodology that the state of North Carolina has used to award certificates of need is designed to avoid duplication of services and provide the greatest access to all citizens to linear accelerator therapy options. In effect, the proposed CON for a urology linear accelerator may open greater access to prostate cancer patients and limit future access to linear accelerator treatments for all other types of malignancies.

Thank you for considering my comment on this issue.

Sincerely,

Matthew Manning, M.D., President
Greensboro Radiation Oncologists, P.A.
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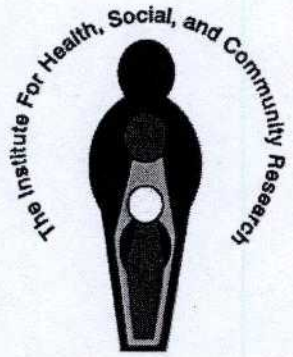

August 4, 2008

Ms. Carol G. Potter, Planner
Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Ms. Potter,

This letter signifies my strong and enthusiastic support of Cary Urology's petition for an adjusted need determination for Radiation Oncology Services – Linear Accelerators. Specifically, I endorse the petition filed by Cary Urology to change the methodology to include the need for a Linear Accelerator in Service Area 20. The basis of this firm support comes from my involvement and expertise in prostate cancer research, education, and outreach in the African American community for the past several years.

As you are probably well aware, prostate cancer is the leading cancer among men, and the second leading cause of cancer mortality among men in the United States. In 2008, an estimated 186,320 men will be diagnosed with prostate cancer, and about 28,660 men are expected to die. Incidence among African American men appears to be about 60 percent higher than the rate for white men and mortality is about 2.4 times higher than for white men. In addition, there is some evidence that prostate cancer may develop at earlier ages in African American men than in the general male population. African American men also have a higher likelihood of having more advanced stage at the time of diagnosis. ***Even more troubling is that some North Carolina counties have the highest incidence of and death from prostate cancer in the world, irrespective of race.***

Briefly, I am a Professor of Health Policy, and the Director of the Institute for Health, Social, and Community Research at Shaw University. My research interests include the examination of epidemiologic patterns of health outcomes that disproportionately affect African Americans; minority health and racial health disparities; health services; and, health policy. I have numerous scientific, peer-reviewed manuscripts in prominent journals and I have actively participated as a Principal Investigator, Co-Principal Investigator, and Co-Investigator on grant research funded by the National Institutes of Health (NIH): National Center on Minority Health and Health Disparities (NCMHD), National Center for Research Resources (NCRR), National Institute on Drug Abuse (NIDA), and, National Institute on Aging (NIA); the United States Department of Health and Human Services (DHHS): Centers for Medicare and Medicaid

The Institute for Health, Social, and Community Research at Shaw University
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Services (CMS), and, AHRQ; and, the United States Department of Defense (DoD), which pertain to health services, minority health, and racial health disparities research. I have received grant awards that have totaled over $20 million dollars.

With respect to the Institute for Health, Social, and Community Research at Shaw University, its mission is to become a national leader in the multidisciplinary empirical investigation of diverse issues that affect the health and well-being of minorities, particularly African Americans, and their families, and the communities in which they live. To this end, the IHSCR has been involved in a number of prostate cancer-related research projects with leading institutions across the nation. This research, funded by the United States Department of Defense Congressionally Directed Medical Research Program in conjunction with institutions such as Johns Hopkins Bloomberg School of Public Health, School of Medicine, and the Sidney Kimmel Comprehensive Cancer Center as well as the University of North Carolina at Chapel Hill School of Public Health, School of Medicine, and Lineberger Comprehensive Cancer Center, has established infrastructure support for Shaw University investigators to conduct prostate cancer research by providing training and mentorship through collaborative linkages with senior researchers at these institutions. The prostate cancer research has specifically focused in the fields of health services (outcomes) research and epidemiology and have resulted in several publications in peer-reviewed, scientific journals.

I am thrilled about the project by Cary Urology and I am pleased to support their petition for a linear accelerator in Service Area 20. I, along with others, am willing and happy to work towards the outcome research on this project. Resources such as the Institute of Health, Social, and Community Research at Shaw University and its Centers of Survey Research and Biostatistics and Data Management will be one of the many providers and supporters of this project. Please feel free to contact me regarding any questions that you may have.

Sincerely,

Daniel L. Howard, Ph.D.

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August 4, 2008

Ms. Carol G. Potter
North Carolina Division of Health Service Regulation
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Dear Ms. Potter:

Allow me to weigh in on the petition from Parkway Urology, P.A. doing business as Cary Urology, P.A. This letter is sent to oppose the petition for an adjusted need determination for a linear accelerator in service area 20. My comments are brief.

First of all, the population is not underserved. Secondly, multidisciplinary care already exists within the community. Most importantly, the motivation appears to be purely financial. In actual fact, in non-CON states there are companies with a similar model who are now advising much less surgery since it is not as profitable as IMRT for prostate cancer.

I find it hard to justify approval for another linear accelerator for service area 20.

Sincerely,

Robert J. Murray, M.D.
Medical Director
Moses Cone Regional Cancer Center
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July 31, 2008

Ms. Carol G. Potter
NC Division of health Service Regulation
Medical Facilities Planning Section
701 Barbour Drive
Raleigh, NC 27403

Dear Ms. Potter:

We in the Department of Radiation Oncology of Wake Forest University Health Sciences are writing to express our opposition to a CON proposal allowing a linear accelerator to be installed in a urology outpatient facility in Wake County.

Currently, Wake County is well-served by 4 linac centers capable of IMRT/IGRT therapy for prostate cancer. The proposed facility is within 2 miles of the existing Wake Radiation and Oncology center and in close proximity to the Research Triangle that has two academic departments at UNC and Duke. All centers mentioned accept indigent patients. Thus, there is no additional need for the proposed center at Cary Urology.

Because we utilize a multi-disciplinary model at Wake Forest, we strongly feel that cancer patients need to remain in the care of the physicians who manage their overall disease in a comprehensive manner. This situation with the urologists and other specialties becomes further complicated if the physician self refers patients to the physician owned linac facility. The ancillary service referral exemption is under discussion with Medicare at this time.

If we may be of further service, please feel free to contact us.

Sincerely,

A. William Blackstock, MD
Professor and Chairman -Elect

R. Scott Krewson, CPA, MBA
Business Administrator