CATAWBA VALLEY MEDICAL CENTER

August 4, 2008

DFS Health Planning
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AUG 04 2008

Medical Facilities
Planning Section

Ms. Carol Potter
Medical Facilities Planning Section
701 Barbour Drive
Raleigh, NC 27693

Dear Ms. Potter:

This letter is in opposition to allowing a prostate cancer specific linac center in the Raleigh area.

Wake County already has four linac centers capable of IMRT with one center only two miles from the proposed new center in Cary. It is actually further away from the rural counties of Harnett and Franklin.

It is absurd to have organ specific linac centers as this could undermine the existing allocation formula for linac CONs in North Carolina and also offers a lucrative opportunity of self referral.

For these reasons, again, I oppose a prostate cancer specific linac center in the Raleigh area or anywhere else in the state.

Sincerely,

WRS

Reggie Sigmon, MD

RS/drd

Fax: 919-715-4413

Lawrence B. Marks, M.D.
Professor and Chair
Radiation Oncology
CB#7512 101 Manning Dr.
Chapel Hill, NC 27599-7512

phone: (919) 966-0400
fax: (919) 966-7681
email: marks@med.unc.edu

August 1, 2008

DFS Health Planning
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-- 04 2008
Medical Facilities
Planning Section

Carol J. Potter
Medical Facilities Planning Section
701 Barbour Dr.
Raleigh, NC 27603
Fax: 919-715-4413

Dear Ms. Potter:

I am writing to strongly advise against the linear accelerator dedicated for prostate therapy, as currently being proposed in Cary. There are already many linear accelerators in the area that are well able to provided excellent radiotherapy for patients with prostate cancer. Providing a CON for a machine, focusing on a particular disease type, is not, in my opinion, good public policy.

Excellent multidisciplinary care for patients with prostate cancer is available at many centers in our area. In particular, multidisciplinary tumor boards are commonplace here at UNC, at Duke, as well as many other hospitals in the area.

I believe that the designation of a machine focusing on a particular type (e.g. prostate cancer) may lead to a rapid increase in the number of similar requests for accelerators designated for a variety of other disease types, throughout the state.

As the Chairman of Radiation Oncology at UNC, I can unequivocally state that we will provide care for any patient in need, whether insured or indigent. We will be most happy to care for any patient with prostate cancer that come here to UNC, or at our other facilities at Rex and in Smithfield.

Thank you very much for your consideration.

Sincerely,

Lawrence B. Marks

Lawrence B. Marks

1400 Matthews Township Parkway · Matthews · N.C. 28105
Phone (704) 845-8800 · Fax (704) 845-8809 · www.rocc.net

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AUG 07 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 <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,

CaroMont Cancer Center
Gaston Memorial Hospital

DFS Health Planning
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AUG 07 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:

I am a radiation oncologist in practice in Gastonia, North Carolina. It is my opinion, as a specialist in cancer treatment, 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. The use of radiation therapy requires the use of cutting edge 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.

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

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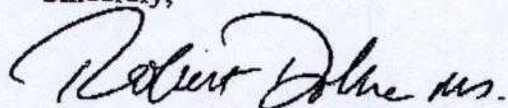


Robert M. Doline, M.D.

04 August 2008

SOUTHEASTERN RADIATION ONCOLOGY

DFS Health Planning
RECEIVED
AUG 07 2008
Medical Facilities
Planning Section

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

Re: Petition from Parkway Urology, PA, d/b/a Cary Urology, PA

Dear Ms. Potter:

North Carolina Certificate of Need legislation was designed to ensure that all of our citizens have access to quality care while avoiding wasteful duplication of certain very costly services such as radiation oncology. Those of us who have applied for CON's in the past have been required to steadfastly adhere to these regulations and clearly demonstrate that our proposals would enhance the care of our patients in a cost-effective manner without detriment to our neighboring programs.

Now these concepts are being challenged in Service Area 20, and to some extent in our own Service Area 18, by a group of urologists who contend that they are the only ones who can ensure access to quality cost-effective care for their patients with prostate cancer. These proposals, I believe, are nothing more than a not-so-thinly-veiled effort to control and manipulate the prostate cancer "market" for their own financial gain.

For some time now, urologists have been particularly fond of brachytherapy since they have a reimbursable role in that modality. However, my group was recently approached by a urologist who, like the urologists in Service area 20, was interested in acquiring a linear accelerator for the purpose of creating a "prostate cancer center of excellence". When we questioned him about the services that would be offered at his center, specifically in regards to brachytherapy, he clearly indicated that he and his associates would forego implant in favor of more profitable intensity modulated radiation therapy (IMRT). In our own Service Area 18, a radiation oncologist whose sole practice for several years has been prostate brachytherapy has submitted a CON application to acquire a linear accelerator. The emphasis in his proposal is clearly on external beam irradiation and he indicates that brachytherapy might "potentially" be offered at some point in the future.

Please also note the national trend in androgen deprivation therapy for metastatic prostate cancer. For years the preference of most urologists was LH-RH analogs, e.g. leuprolide or goserelin. However, falling reimbursement for office administration of LH-RH analogs has resulted in a shift back toward orchiectomy, a fully reimbursable surgical procedure.

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

AUG-07-2008 13:05 SOUTHEASTERN RAD ONC 910 609 6398 P.002

The Triangle Area of North Carolina is internationally recognized for excellence in medicine. Duke, Duke Raleigh Hospital, UNC, UNC-Rex Hospital and Wake Radiology and Oncology already provide optimal multidisciplinary care for prostate cancer patients and offer a clear choice of modalities including traditional surgery, robotic surgery, brachytherapy, IMRT/IGRT, etc., without regard to financial incentives. In addition, all of these institutions have exemplary well-documented records for providing indigent care.

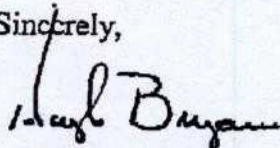
The current State Medical Facilities Plan shows no need for an additional linear accelerator in Service Area 20. Since allocations in the plan are based on the utilization of existing services and capacity, those of us who have followed the rules must assume that the time-tested formula used by the CON Section shows that every patient with every diagnosis is being well cared for. Therefore, what justification can there be for allocating another linear accelerator for an organ-specific center for prostate cancer? Why not breast, tonsil, cervix, rectum, lung, etc., etc.?

We treat a number of patients from Harnett County with prostate cancer at our two facilities in Cumberland County. We currently offer brachytherapy and IMRT/IGRT and Cyberknife radiosurgery will be available in the fall of next year. If the urologists in Service Area 20 feel that capacity is a problem, we are always able and willing to treat more of their patients without regard for reimbursement.

Multidisciplinary centers are good for oncology patients. They ensure the availability of ancillary and support services and they facilitate exchange of ideas, innovative thinking and self-scrutiny so that in the end our patient get the best of care without regard to other incentives that should have no place in medicine.

We urge you to deny the petition from Parkway Urology, PA, d/b/a Cary Urology, PA.

Sincerely,



J. Hugh Bryan, MD
Medical Director
Radiation Oncology
Cape Fear Health System

DukeMedicine

Duke University Medical Center

Thursday, August 07, 2008

Carol G. Potter
NC Division of Health Service Regulation
Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, NC 27699-2714
VIA FACSIMILE (919) 715-4413

DFS Health Planning
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AUG 07 2008
Medical Facilities
Planning Section

Ref: Petition from Cary Urology, P.A.

Dear Ms. Potter:

I am writing regarding the request of a CON by the Cary Urology Group to develop a "Prostate Cancer Center of Excellence" and to acquire a linear accelerator to be housed in this facility. Apparently this Center would have no professional or operational connection with the existing medical centers that provide multidisciplinary care for a variety of diseases, including cancer of the prostate.

I have reviewed the petition prepared by the Urology Group and submitted to your office for consideration. In this petition the proponents claim that prostate cancer patients are not being cared adequately in this area and that the facility that they propose would provide multidisciplinary care for prostate cancer patients. They also claim, rightly so, that cancer of the prostate has higher incidence among African American men with a disproportionate representation of individuals with lower socioeconomic status. These individuals experience more difficulty accessing our health care system. The Cary Urology Group makes many assertions to justify their petition including the claim that they would extend care to individuals that are not able to cover the expenses for their care either through insurance or their own resources.

I have been in practice in this area since 1971 when I joined the faculty of what was then North Carolina Memorial Hospital in Chapel Hill. In 1983 I came to work at Duke where I have been since. I have also been very involved with the practice of radiation oncology in the community hospitals which are affiliated with the academic centers where I have practiced. For many years I was in charge of the Radiation Oncology Department at the First Health-Moore Regional Hospital in Pinehurst, NC. In my years of practice I have had the opportunity to care for many patients with cancer of the prostate.

BOX DUMC 3085
DEL Radiation Oncology
Durham, NC 27710

TEL 919.660.2100
FAX 919.668.7345

dukemedicine.org

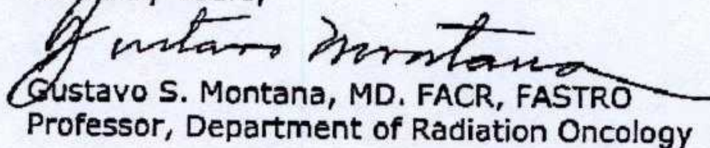
While the assertion that the Urology Group makes regarding the incidence and disproportionate number of African American males with cancer of the prostate is true, I find no basis for most, if not all, the other assertions that they make to justify their petition.

Patients with cancer of the prostate in this area are well cared for and have access to multidisciplinary centers of their choosing. The institution that I know best, Duke University Medical Center, has a very capable and very well organized multidisciplinary team offering the full range of treatment, irrespective of the nature and extent of the condition a patient may have. This is also very true of the University of North Carolina Hospital in Chapel Hill. Moreover, both, Duke and UNC, have affiliated facilities (e.g. Raleigh Community Hospital, Rex Hospital, Durham Regional Hospital, etc) in the triangle that provide the full range of treatment to patients with cancer of the prostate. These institutions also offer multidisciplinary care that extends well beyond the immediate needs of their cancer of the prostate. It should be noted that many of these patients have associated medical problems for which they can receive care in these medical centers as well as continued care by their own primary care physicians and other specialists. Patients with cancer of the prostate can also develop metastatic disease, spread of their tumor to other sites, during their life history and requiring other types of care. This is readily available in medical centers and facilities that offer comprehensive care.

I find it disheartening if not totally inappropriate to attempt to justify this development on the basis that better care will be provided to patients with cancer of the prostate. The complexity of the treatment with radiation therapy nowadays requires a large group of people with different types of background and expertise. I cannot see how this could be provided in the facility proposed. Were this to be accepted for cancer of the prostate there would be other groups that would make similar requests. Approval of this request would be the first step in the fragmentation of care of patients with cancer and this would have serious detrimental effects on all patients with cancer in our area.

I strongly urge you to examine the justification for this petition very carefully. I hope that you deny this request as it has no promise of improving the care of patients with cancer of the prostate as the petitioners claim.

Sincerely Yours,



Gustavo S. Montana, MD. FACR, FASTRO
Professor, Department of Radiation Oncology

GM:bw

CATAWBA VALLEY MEDICAL CENTER

August 4, 2008

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Medical Facilities
Planning Section

Ms. Carol Potter
Medical Facilities Planning Section
701 Barbour Drive
Raleigh, NC 27693

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For these reasons, again, I oppose a prostate cancer specific linac center in the Raleigh area or anywhere else in the state.

Sincerely,

John del Charco MD

Fax: 919-715-4413

ONCOLOGY SERVICES, PLLC

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AUG 08 2008
Medical Facilities
Planning Section

RADIATION ONCOLOGY
Andrew S. Kennedy, M.D.
Scott L. Sailer, M.D.
William A. Dezarn, Ph.D., DABR

DIAGNOSTIC RADIOLOGY
Robert A. Cerwin, M.D.
Robert E. Schaaf, M.D.
Richard J. Max, M.D.
Bryan M. Peters, M.D.
Charles V. Pope, M.D.
Alan B. Fein, M.D.
David Ling, M.D.
Claire M. Poyet, M.D.
William T. Djang, M.D.
Holly J. Burge, M.D.
John Sierra, M.D.
Michael L. Ross, M.D.
Andrew C. Wu, M.D.
William G. Way, M.D.
Dennis M. O'Donnell, M.D.
Karen A. Coates, M.D.
David F. Merten, M.D.
Emily K. Folz, M.D.
J. Mark Spargo, M.D.
Susan L. Kennedy, M.D.
Joseph W. Melamed, M.D.
G. Glenn Coates, M.D.
Elizabeth A. Rush, M.D.
John Matzko, M.D.
Kerry E. Weinrich, M.D.
Randy D. Cork, M.D.
Carroll C. Overton, M.D.
William J. Vanarthos, M.D.
Lyndon K. Jordan, III, M.D.
Joseph B. Cornett, M.D.
Philip C. Pretter, M.D.
M. Rans Douglas, M.D.
Margaret R. Douglas, M.D.
Imre Gaal, Jr., M.D.
Randy D. Secrist, M.D.
Thomas L. Presson, Jr., M.D.
Philip R. Saba, M.D.
Stephen R. Mills, M.D.
R. David Mintz, M.D.
Cynthia I. Caskey, M.D.
Michael D. Kwong, M.D.
Melissa C. Lipton, M.D.
Louis F. Posilico, M.D.
Duncan P. Rougier-Chapman, M.D.
Paul A. Haugan, M.D.
Carmelo Cullotto, M.D.

ADMINISTRATOR
W. H. Johnson

BUSINESS MANAGER
B. V. Hill

August 6, 2008

Carol G. Potter
Medical Facilities Planning Section
701 Barbour Drive
Raleigh, NC 27603

Dear Ms. Potter:

My name is Dr. Robert Schaaf. I am the President of Wake Radiology Oncology Services in Cary North Carolina. I write this letter in opposition to an adjusted need determination in Service Area 20 requesting one additional linear accelerator for dedicated prostate treatments.

Wake Radiology Oncology Services, PLLC has provided full service radiation therapy services in the Cary Community for years, including IMRT for prostate cancer patients since 1998. Wake Radiology approached local hospitals in 1997 to co-develop our cancer center in Cary; there were no takers at that time. IMRT was very new and unfamiliar – so we built the facility ourselves after obtaining a Certificate of Need. To this day we solely own and operate our facility. Advanced radiation therapy services are available at Duke University in Durham, Duke Raleigh Hospital, UNC Chapel Hill, Rex Hospital and US Oncology. There are eight, not seven, operating linacs currently servicing Area 20 with IMRT available at all sites except Franklin Regional Cancer Treatment Center in Louisburg.

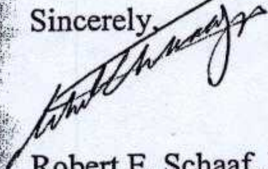
Wake Radiology Oncology Services approached Cary Urology in 2001-2003 to create a multi -disciplinary prostate brachytherapy center based at WakeMed Cary Hospital. The project failed to materialize for lack of support by Cary Urology. Cary Urology went on to establish their own office-based program to the exclusion of those of us attempting community hospital based approaches at WakeMed Cary and Rex hospitals. How is it that a multidisciplinary prostate brachytherapy program under the roof of Cary Urology is developed, but considered unacceptable when proposed at WakeMed Cary or Rex hospitals by local radiation oncologists in Raleigh and Cary? There is no evidence that multidisciplinary care is better practiced under one roof. One could make a strong argument that it may in fact be compromised in the hands of self referring physicians. I refer you to the attached op-ed piece that

300 Ashville Avenue, Suite 110, Cary, NC 27511 • (919) 854-4588 • Fax (919) 854-9950
www.wakeradiology.com

appeared on the editorial page of the July 30, 2008 News and Observer written by Dr. Peter Bach of Memorial Sloan-Kettering Cancer Center in New York. Medicare is currently studying the ancillary service rules enjoyed by self referring physicians and will likely curtail the practice in the near term.

In summary we believe there is no compelling reason to adjust the need determination at the behest of Cary Urology. Cary Urology is, of course, free to avail themselves of the existing CON process and, in fact, have done so in their most recently denied application. Cary Urology is currently challenging that denied application. There is no rational basis for an organ based linac dedicated to prostate, or lung, or brain, or gastric, or colon, or GYN cancers. Service Area 20 needs are well met by some of the best facilities in the southeast. We respectfully recommend you deny this request.

Sincerely,



Robert E. Schaaf, MD
President

Attachment

The scan scam? How fee-for-service fails patients

BY PETER B. BACH

NEW YORK

The longstanding push-pull between Medicare and Congress has erupted again. Congress, overriding a presidential veto, recently canceled Medicare's scheduled 10.6 percent cut in payment rates for doctors and instead raised the rates 1.1 percent. But this action fails to address the problem with the Medicare payment system, which is not the amounts doctors are paid but the way their payments are calculated.

Medicare pays doctors for specific services. If a patient has a checkup that includes an X-ray, a urine analysis and a physical, Medicare pays the doctor three separate fees.

Each fee is meant to reimburse the doctor for the time and skill he or she devotes to the patient. But it is also supposed to pay for overhead, and this is where the problem begins. To Medicare, a doctor's overhead (or "practice expense") includes such items as rent, staff salaries and the cost of high-tech medical equipment. When the agency pays a fee to a doctor who has performed a CT scan, it is meant to cover some of the cost of buying or leasing the scanner itself. Services using more expensive equipment generate higher fees.

Any first-year business school student can see the profit opportunity here. The cost of a CT scanner is fixed, but a doctor earns fees each time it is used. This means that a scanner becomes highly profitable as soon as it's paid for.

In contrast, the doctor-patient visit, which involves no expensive equipment, offers no significant profit opportunity. So the best way for a doctor to make money in his practice is not to spend time with patients but to use equipment as much as possible. That means moving the maximum number of patients through the practice and spending the minimum amount of time with each one.

From 2000 to 2005, the number of Medicare patients seen by doctors increased by 8.5 percent, while the number of services each one received was up 14 percent, according to the Government Accountability Office.

•••

IT'S NOT ONLY MEDICARE THAT PAYS DOCTORS ON A FEE-FOR-SERVICE BASIS; most private insurers do also. This is part of the reason that spending on physician services nationwide has risen every year since 2000 by about $25 billion. This year the tab will exceed $500 billion.

Doctors who do their own CT scanning and other imaging order roughly two to eight times as many imaging tests as those who do not have their own equipment, a 2002 study by researchers at the University of North Carolina found. Altogether, doctors are ordering roughly $40 billion worth of unnecessary imaging each year — which adds up to nearly 2 percent of the total Americans pay for health care.

No wonder the Government Accountability Office last month urged Medicare to find a way to constrain doctors' use of imaging tests.

Over the years, Congress and Medicare have made various attempts to stamp out some of the most egregious excesses in Medicare payments. Sometimes they have succeeded. In 2004 and 2005, when Congress lowered the fees associated with anti-testosterone drugs used to treat prostate cancer, urologists and other doctors prescribed them less.

Around the same time, though, urologists started buying multimillion-dollar radiation therapy machines for treating prostate cancer. Reimbursement for radiation treatment remains very generous.

Clearly, scattershot strategies aimed at individual fees are unlikely to reduce health care costs. More fundamental changes are needed in the way doctors are paid.

•••

FOR THEIR TIME, DOCTORS SHOULD BE GIVEN A STIPEND for each of their patients. It should be larger for patients with complicated medical conditions and smaller for those who are healthy, and it should not be influenced by the number of services or tests a doctor orders.

For overhead, doctors should be paid an amount that covers the typical cost of tests and treatments needed to address a patient's condition. This strategy — known as "case rate" or "prospective" payment — is standard in hospitals. The hospital receives a payment for dealing with a patient's underlying condition rather than individual payments for each test and treatment. This approach offers no incentive to run unneeded tests, and it has been credited with substantially slowing the growth in Medicare payments to hospitals.

Without changes to the way Medicare pays doctors, the fights in Congress over raising or lowering payment rates will continue. And doctors will still have no financial incentive to do what is most important: spend more time with their patients.

THE NEW YORK TIMES

Peter B. Bach, a doctor at Memorial Sloan-Kettering Cancer Center, was a senior adviser to the administrator of the Centers for Medicare and Medicaid Services from 2005 to 2006.

Raleigh N and O
7/30/08

DUKE UNIVERSITY MEDICAL CENTER

Christopher G. Willett, M.D.
L.R. Prosnitz Professor and Chairman
Department of Radiation Oncology

August 8, 2008

DFS Health Planning
RECEIVED

AUG 08 2008

Medical Facilities
Planning Section

Ms. Kelli Fisk
NC Division of Health Service Regulations
Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, NC 27699

FAX: (919) 715-4413

Re: Cary Urology petition for Prostate Center of Excellence

Dear Ms. Fisk:

We would like to register our strong opposition to the proposal from Cary Urology for a dedicated prostate cancer linear accelerator. We wish to speak to issues of quality of care raised by the petition. It contains a number of inaccuracies and distortions:

1) Petitioner alleges (page 2) that there is a strong need for a comprehensive multi-specialty prostate center and that none exists in the state. To the contrary, for a number of years Duke University Medical Center has cared for its prostate cancer patients in a multidisciplinary fashion, with twice weekly clinics and consultation on an almost daily basis between urologists, radiation oncologists, and medical oncologists. These clinics are conducted in the Morris Building of the Duke Comprehensive Cancer Center, where all the Hospital's linear accelerators are located. Urology offices are in Duke Hospital South, immediately adjacent to the Morris Building. Additionally, at centers such as Duke, radiation oncologists subspecialize, so that, in fact, there are two full-time radiation oncologists who devote themselves principally to urologic cancer. There is also urologic subspecialization of our physics and dosimetry teams.

2) At Duke Hospital Raleigh there are full-time Duke Hospital faculty members in radiation oncology, urology, and medical oncology. They are all located in close physical proximity to one another. The multidisciplinary approach to the management of prostate cancer is standard at this institution as well. Additionally, the full resources of Duke University are available for cases of unusual complexity or difficulty.

3) The multidisciplinary approach is extremely useful in arriving at patient management decisions and affording the patient different viewpoints on therapeutic alternatives. The petitioners have distorted the nature of the multidisciplinary process, however, by stating that the continuous on site presence of a urologist at the accelerator facility will result in a reduced frequency of complications. For example, "continuous follow-up by the surgeon while the radioactive seeds destroy the cancer assures preservation of the noncancerous surrounding tissues." (page 4)

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Follow-up does not prevent complications of treatment. Complications of radiation are minimized or prevented by the skillful application and administration of radiation by the entire radiation oncology team. Follow-up simply recognizes the complications once they occur. Additionally, the radiation oncologist is a trained oncologic specialist, not one whose "focus is on the impact of radiation energy on cell death." (page 4) He or she is fully qualified to recognize and in most instances deal with side effects of therapy as they arise while the patient is in treatment.

4) State of the art external beam radiation therapy for prostate cancer generally involves the use of intensity modulated radiotherapy (IMRT). It also involves the use of complex immobilization devices, as well as image guided therapy to account for patient and prostate movement. These technically complex activities are best performed by the radiation oncologist and a team of physicists, dosimetrists, and radiation therapists with a broad experience in the technology of radiotherapy not limited to one disease. It has also been repeatedly observed that outcomes for cancer therapy correlate well with the size of the center, both in terms of cure of the cancer and minimization of side effects. Thus, centers with multiple linear accelerators, as well as multiple radiation oncologists, physicists, dosimetrists, etc are likely to have better outcomes than single accelerator centers. It is, in fact, quite likely that the proposed Cary Urology Prostate Center rather than increasing the quality of prostate cancer care will reduce it.

5) On page 6, the petition alleges that information obtained from onboard imaging utilized during the IMRT process "may be shared among disciplines reducing the number of imaging studies done mid treatment and have a significant impact on the total cost of care management." In fact, these studies are not diagnostic studies and are performed solely to assure the accuracy of radiation beam positioning. There is no particular role for prostate imaging studies to assess progress during the course of radiation therapy. The statement "radiologists and urologists together will have the advantages of viewing real time images while the patient is available to discuss how his body is reacting to treatment" is medically without foundation. These images tell nothing about how the patient is reacting to treatment.

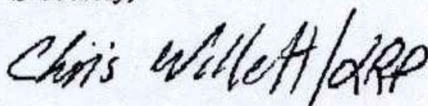
6) The petition further alleges "the community will lose the chance to reduce/eliminate the complications (of radiation) by involving a specialty that is trained to recognize small anatomical differences in the radiation treatment process." (page 10) Again, recognition of complications is very different from preventing them. The prevention of radiation complications is the responsibility of the radiation oncology team and is best achieved by very careful planning and execution of the technical aspects of treatment. The notion that this is better achieved in a single accelerator radiation oncology practice as opposed to a large center with multiple professionals involved in the patient's care is simply fallacious. The notion (page 11) that urologists should visit every linear accelerator where prostate cancer patients are being treated at a minimum of once weekly, perhaps daily, to "observe patient progress" is similarly demeaning of the radiation oncologist's skills in managing this disease and would contribute little, since urologists have no training in the technical aspects of radiotherapy.

7) Financial aspects: the petitioners indicate that part of the revenues from linear accelerator treatments will be used to finance the care of indigent patients. Duke University presently, of course, accepts all patients without regard to ability to pay. Cary Urology indicates that it also does so at present. No data are presented to indicate that Cary Urology anticipates treating a greater number or proportion of indigent patients than they presently do. Accordingly, it would appear that the linear accelerator revenues will simply contribute to the current margins of Cary Urology.

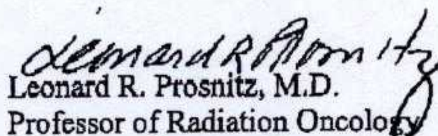
For all of the above reasons we would ask that this petition be rejected. It will do nothing to improve the care of the prostate cancer patients and indeed is likely to make it worse. It further sets a bad precedent in North Carolina for the establishment of specific disease-related linear accelerators not managed by the specialty specifically trained in their use, i.e. radiation oncologists. Radiation oncology is best practiced in a setting specifically devoted to that specialty where broad oncologic, radio-biologic, and physical principles can be applied, in addition to knowledge of the specific disease site, by the radiation oncology team.

The Cary Urology proposal is retrogressive. We respectively urge you to reject this petition in order to serve the best interests of North Carolina patients. Thank you for your consideration.

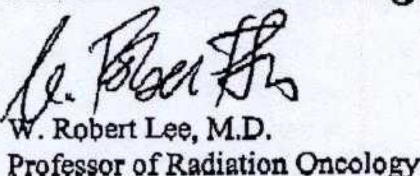
Sincerely,



Christopher G. Willett, M.D.
L. R. Prosnitz Professor and Chairman



Leonard R. Prosnitz, M.D.
Professor of Radiation Oncology



W. Robert Lee, M.D.
Professor of Radiation Oncology

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