August 8, 2008

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

Re: Cary Urology petition for Prostate Center of Excellence

Dear Ms. Potter:

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)

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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