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July 30, 2008

RECEIVED

By Kelli Fisk at 3:57 pm, Aug 01, 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) miles⁷ 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.

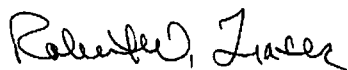
Cary already has a linac center equipped with IMRT/IGRT at Wake Radiology and Oncology, located only 2 miles south of the proposed center at Cary Urology. The current center is therefore closer to the rural patients of Service Area 20 living in Harnett and Franklin counties than the proposed new center. 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>.
- ¹³ Duke University Medical Center website, <http://urolog.surgery.duke.edu/>.
- ¹⁴ UNC Lineberger Comprehensive Cancer Center website, <http://cancer.med.unc.edu/patient/programs/urologic.asp>.
- ¹⁵ www.unclineberger.org.
- ¹⁶ <http://cehs.sph.unc.edu/projects/pro2007.html>.
- ¹⁷ National Cancer Institute *NCI Cancer Bulletin*, June 20, 2006, V. 3, N. 25, www.cancer.gov.
- ¹⁸ <http://www.nccancerhospital.org/news/2007/topoff/>.
- ¹⁹ <http://www.golfclassic.org/Grants.html#2007>.
- ²⁰ http://pediatrics.duke.edu/modules/dept_peds_cmmtty/index.php?
- ²¹ <http://www.unc.edu/faculty/faccoun/minutes/2007-08/M07FC09.shtml>.
- ²² <http://www.unc.edu/faculty/faccoun/minutes/2007-08/M07FC09.shtml>.
- ²³ [www.rexhealth.com/ documents/FoundationAnnReport07.jpg.pdf](http://www.rexhealth.com/documents/FoundationAnnReport07.jpg.pdf).