August 7, 2008

Memorandum

To: Christopher Ullrich, MD
Chairman, Technology and Equipment Committee
State Health Cooordinating Council

From: Suzanne H. Freeman, President, Carolinas Medical Center
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Subject: Petition Submitted by Cary Urology

This memorandum forwards the comments of the state's academic medical center teaching hospitals on the petition submitted by Cary Urology. Our comments have been reviewed by and reflect the opinions of the physician leadership, especially the chairmen and chiefs of urology, radiation oncology, medical oncology, and radiology at each of our institutions.

We believe that the petition should be disapproved. In reaching that conclusion, we were guided by the following considerations:

1) The Petition argues that the state's comprehensive cancer centers are incapable of providing the focused, integrated, multidisciplinary care prostate cancer patients need and deserve. That is simply not true. All five of our hospitals have prostate centers that integrate urologists, radiation oncologists, medical oncologists, radiologists, and essential support services in teams providing patient-centric care for prostate cancer patients. The team approach has also been implemented at other comprehensive cancer centers like the Duke Raleigh Cancer Center in Service Area 20. A brochure from Duke Raleigh Hospital describes the patient's experience this way:

Upon referral, newly diagnosed prostate cancer patients are brought to the multi-disciplinary clinic after being contacted by the coordinator to explain the multi-disciplinary process and are made aware of the expectations. The coordinator reviews records with the medical and radiation oncologist to determine what staging studies are necessary prior to the patient's clinic appointment. The patient is then contacted and scheduled for the appropriate studies deemed necessary to prescribing a plan of care, and the studies are performed prior to the clinic date.

On the day of an actual prostate clinic appointment, the patient is seen by a Duke urologist, radiation oncologist, and medical oncologist, (if necessary) in the radiation department of the cancer center. The physicians see the patient sequentially and confer collaboratively to decide upon the very best plan of care for the patient. The physicians then reconvene with the patient, (who has been given a "break time" while the physicians are in conference), to deliver the recommended treatment plan and all of the best possible options. After the patient has been given the recommendations by the physicians, the coordinator then reviews and summarizes the plan of care with the patient and family, also providing all educational materials necessary to support the recommendation for care. Contact information for all physicians and the coordinator are given to the patient, along with any needed follow-up appointments for care. A phone call is made by the coordinator to all patients one week after the clinic appointment and patients are encouraged to phone the coordinator with any questions or concerns.

The Petition claims that "North Carolina does not have a true multidisciplinary prostate health center." As the prostate clinics and centers at our hospitals demonstrate, that claim is false.

2) The Petition argues that "Concentrating prostate cancer care in one location will provide more opportunities to organize, refine, and challenge assumptions about treatment approaches. A focused prostate health center will provide a continuing learning organization…." In theory and in practice, academic medical center teaching hospitals are continuous learning organizations, staffed by physician-scientists providing comprehensive cancer services, including chemotherapy and surgery as well as radiation oncology, and participating in clinical trials comparing the benefits of new and alternative treatment approaches. They now perform, and they are far better positioned to perform, research on the benefits and costs of treatment than the center that the petitioner proposes.

3) The Petitioner provides no evidence to support the proposition that the care to be provided at the prostate center that the Petitioner proposes would be better, more effective, or more efficient than the care now provided at the comprehensive cancer centers in and near Service Area 20. Indeed, for many patients treatment at a comprehensive cancer center would be better, more effective, and more efficient than treatment at the facility the Petitioner wants to establish. This is especially true for patients who require hormone therapy, chemotherapy and/or surgery, patients who have treatment-related complications, patients who have concurrent medical conditions (e.g., heart disease), and patients whose cancer that has spread to other organs.

4) The Petition claims that "Prostate cancer is extremely prevalent" in North Carolina, implying that the incidence rate is higher than the national average. In fact, the most recent CDC data (for the years 2002-2004) show that 32 states had a higher incidence rate than North Carolina, and the incidence rate for the nation as a whole (155.4 per 100,000) was higher than the rate for North Carolina (150.4).

5) What is higher in North Carolina is the death rate from prostate cancer. For the same period, the CDC reports a death rate in North Carolina of 29.1 and a death rate of 25.4 for the nation as a whole..

Research and experience both suggest that the reason for the higher death rate in North Carolina is deferral of treatment. For many patients who defer, whatever the reason, the radiation therapy that the Petitioner proposes to provide is not a viable alternative. Those patients will have

to be referred to a comprehensive cancer center for treatment. Moreover, as the Petitioner's prostate health center would rely largely on referrals from community urologists rather than screening or other early identification measures, it is clear that operation of the center would have little if any impact on incidence rates or deferral rates.

6) The Petitioner stresses the need to improve prostate cancer care for African-American men. However, the Petitioner's Certificate of Need application for a Prostate Health Center submitted in August 2007 included a 17-page description of the need for the facility that made no mention of the special needs of African-American men. Indeed, the term "African-American" was not mentioned, and the needs of the underserved were not discussed. And the distribution of procedures projected for self-pay/charity/ indigent patients (2.2%) and Medicaid patients (2.0%) suggests that their needs would not be specifically addressed.

The August 4 Petition paints a different picture and incorporates letters of support from African-American churches and advocacy groups. But the Petition makes no specific commitments, either in behalf of the proposed center or in behalf of the urologists referring patients.

7) The Petition argues that still another LINAC is needed in Service Area 20, over and above the one included in the 2007 State Medical Facilities Plan, which is not yet in operation. To make that claim, the Petition revises the methodology used in the Plan to determine supply and need. The Petition compares Service Area population/LINAC rates across Service Areas and concludes that Service Area 20 is underserved. But Service Area population is used in the Plan methodology as a threshold, and not to determine the supply or need. The appropriate measure of supply and need is the one employed in the Plan: Service Area ESTVs/Service Area LINACs. .

The use of that measure is demonstrated on page 152 of the Proposed 2009 Plan. Table 9F shows that the 8 existing and approved LINACs in Service Area 20 provided an average of 5,178 ESTVs during FY2007. That average is below the average for the state's Service Areas (5,425) and well below the point (an average of 6,750 ESTVs) at which the state would begin to find need for an additional LINAC.

8) If an additional LINAC were found necessary in Service Area 20, or any other Service Area, awarding the Certificate of Need to a comprehensive cancer center would

- Benefit all cancer patients, rather than those with a single disease
- Reduce the risk of underutilization resulting from subspecialization
- Protect against the possibility that advances in treatment for cancer at any one tumor site would result in reduced utilization of the machine or inappropriate utilization.

9) There is good reason to question the projected utilization and financial feasibility of a LINAC located at the prostate center that the Petitioner proposes. The Petitioner's Certificate of Need application demonstrated feasibility by including form letters signed by 15 urologists practicing in Service Area 20. Except for the opening sentence, which gave the physician's name, practice location, and years in practice, the letters were identical, and each closed with this sentence: "If the Prostate Health Center application is approved, I expect to direct 2 to 3 patients per month to the Prostate Health Center for prostate external beam radiation treatment." On the basis of those letters, the application projected receiving 360 to 480 referrals the first year - and achieving a market share of 38% the first year, 44% the second year, and 49% the third year - even though one letter was signed by a physician who anticipated beginning practice five months after the application was submitted and others who were in their first years of practice. None of the letters gave the numbers of patients the physicians were then referring for external beam

treatment for prostate cancer, the sites to which they were referred, or any account of their experience with existing sites, so it is worth noting that in FY2007 very few Wake County patients received LINAC procedures outside Wake County. Given the proximity of the cancer centers at Duke University Hospital and UNC Hospitals, that pattern suggests that community urologists and their patients were largely satisfied with the alternatives now available in Service Area 20.

SUMMARY

According to the 2008 State Medical Facilities Plan, petitions for adjustments to need determinations are expected to show that "unique or special attributes of a particular geographic area or institution give rise to resource requirements that differ from those provided by application of the standard planning procedures and policies..." Like most of the other counties of North Carolina, the counties forming Service Area 20 have incidence rates and mortality rates for prostate cancer that are higher than any of us would like, but they are by no means unique or special, and there is no reason to think that their resource requirements are different from those provided by application of the standard planning procedures and policies.

Moreover, the Petition fails to provide a convincing "Statement of the adverse effects on the population of the affected area that are likely to ensue if the adjustment is not made". As noted above, there is no reason to think that incidence or mortality rates will be reduced by approval of the adjustment the Petitioner seeks, and the Petition is therefore unable to show adverse effects from disapproval of the petition. In fact, if there are adverse effects on the population, they are likely to result from the fragmentation of care that would result from the operation of a prostate center providing only some of the services that prostate cancer patients may require.

Finally, the Petition is unable to provide "Evidence that health service development permitted by the proposed adjustment would not result in unnecessary duplication of health resources in the area." In fact, the data provided in the Proposed 2009 Plan cited above suggest that development of the prostate center in Service Area 20 would lead to unnecessary duplication of health resources in the area.

For all these reasons, we believe that the Committee should disapprove the Petition.