Technology & Equipment Committee
Linear Accelerator Petition-1
Regarding the Proposed 2009 SMFP
For the Final 2009 SMFP

Agency Analysis:

Petitioner:

Parkway Urology, PA, d/b/a Cary Urology PA (Cary Urology)
Cary, Wake County, North Carolina

Request

This petition requests inclusion of a special need determination in the 2009 State Medical Facilities Plan (SMFP) for a multidisciplinary prostate health center in Service Area 20 that would offer a full range of services to treat men with urological and prostate cancer with a particular focus on services provided to minority populations. Currently, the 2009 Proposed SMFP indicates that there is no need for an additional linear accelerator in Service Area 20.

Background Information

In the Proposed NC 2009 SMFP, there are 67 hospitals and freestanding oncology treatment centers statewide in North Carolina with 113 linear accelerators that are operational, have a certificate of need in hand, or for which there is a prior year need determination.

Governor Easley approved the 2007 State Medical Facilities Plan to include a need for one additional linear accelerator in Service Area 20, to be awarded to an existing provider of radiation oncology services in Service Area 20 which meets applicable policies in the State Medical Facilities Plan, and applicable criteria in the Certificate of Need Law and Administrative Rules. Five competing applications were submitted in 2007 to address this need, one of which was filed by the petitioner. Raleigh Hematology Oncology Associates, PC was approved and the four other applications were disapproved. The decision was appealed by Wake Radiology, Parkway Urology and Rex Hospital, and litigation is pending.

At its Spring 2008 meeting, the State Health Coordinating Council (SHCC) denied a similar petition from the same petitioner for a change to the methodology for linear accelerators. The SHCC suggested that the petitioner consider a petition for an adjusted need determination in the Proposed 2009 SMFP for a linear accelerator in Service Area 20, addressing the issue of access to some of the underserved population in the service area.

Analysis/Implications

The petitioner reports that prostate cancer is extremely prevalent, with one in six men developing prostate cancer during his lifetime. In a recent NC Medical Journal article, researchers at UNC, using data from Surveillance Epidemiology and End Results (SEER), reported that North Carolina men had an age-adjusted death rate from prostate cancer of 35.6/100,000. This exceeded the national average by 17.5 percent. North Carolina has one of the highest death rates from prostate cancer in the United States. Based on the 2007 projections from the North Carolina Cancer Registry, male urologic cancers represent 21.4 percent of all cancers diagnosed and eight percent of all cancer deaths in North Carolina. Prostate cancer accounts for the majority of urologic cancers (15.7 percent of total cancers). The disease itself is prevalent, second only to lung cancer as a cause of death.

The petitioner continues by stating that prostate cancer death rate is higher among African Americans. The disparity has the attention of the Prostate Cancer Research Program supported by the Department of Defense. Information from its Disparity Study shows that, regardless of similar socioeconomic status between the two states, African Americans in North Carolina have the highest prostate cancer death rates and in Louisiana have one of the lowest. The project has also found that few African Americans with prostate cancer participate in prostate cancer support groups. This limits screening and knowledge of the disease process. This phenomenon is presently being studied by a North Carolina-Louisiana study through a $10 million grant from the Department of Defense.

A linear accelerator is critical to the treatment of prostate cancer. Approximately half of prostate cancers involve radiation therapy; 80 percent of which involves use of a linear accelerator. Prostate cancer treatment represents approximately 20 percent of all radiation treatments (ESTVs) performed. The petitioner states that the technology is important because urologic cancers are located in areas of the body that involve intricate networks of organs, blood vessels, nerves and muscles. Disruption of any single tissue can cause major changes in physiologic function.

Reducing the impact of urologic cancers on the lives of patients involves complex treatment plans that consider how the whole body functions, how the whole body will respond to the treatment, as well as how the treatment will reduce the cancer. It requires specialists in the fields of anatomy, physiology, radiation, pharmacy and chemotherapy.

According to the petitioner, changing the orientation of prostate/urological cancer treatment from medical-specialty to disease-specific orientation is the only practical way to address the many physiologic challenges that occur during prostate cancer treatment and management of prostate/urological health. A comprehensive prostate health center requires a multidisciplinary team of specialists whose skills complement each other. It involves breakthrough organization, rearranging silos of clinical specialties into a patient-centered structure that facilitates feedback and permits the team to make tissue-sparing decisions. Reducing the impact of urologic cancers on the lives of patients involves complex treatment plans that consider how the whole body functions, how the whole body will respond to the treatment, as well as how the treatment will

reduce the cancer. It requires specialists in the fields of anatomy, radiation, pharmacology, and chemotherapy.

The petitioner continues by saying that multidisciplinary approaches generally improve clinical outcomes and diminish morbidity. Common features include: the collaboration of multiple disciplines including urology, radiation oncology, hematology oncology, and a host of supportive professionals, a common medical record, and a tumor board that focuses on contemporaneous review of cases. With the concentrated effort, the community of physicians and providers develop a deeper understanding of risk profiles of patients, impact of changes in treatment regimen on both elimination of the cancerous tissue and preservation of vital functions in nearby organs. Ready communication across the multidisciplinary approaches including incontinence nursing, behavioral therapy, and biofeedback, erectile dysfunction therapy, radiation injury/wound nurses, and pharmacology working together make a significant care difference. A single medical record diminishes redundancy of both laboratory radiography and paperwork.

When medical care was primarily an inpatient service, this type of coordination occurred in the hospital. Technology has shifted care to the outpatient setting where services are dispersed to multiple locations. The petitioner argues that new systems and models are needed to accommodate the shift.

The petitioner explains that the concept of a multidisciplinary approach to the treatment of prostate cancer is not new, yet no such centers exist in NC. The MD Anderson Cancer Center, in Houston, Texas has a well-developed program, as do the Dana Farber Cancer Institute in Boston, Massachusetts; Kirkland Prostate Center at the University of Alabama at Birmingham; The Center for Prostate Cancer at University of Minnesota Medical Center in Minneapolis, Minnesota; and the UC Davis Cancer Center/Prostate Cancer Clinic in Sacramento, California.

According to the NC Division of Public Health State Center for Health Statistics, both the incidence of prostate cancer and mortality due to prostate cancer are significantly higher for minority men in North Carolina. In comparison, the health disparity is not as evident in the incidence of and mortality due to female breast cancer.

The petitioner states that Service Area 20 is approximately 22 percent African American, according to the State Demographer. One in five males in Service Area 20 is at high risk. Using SEER data, the State Center for Health Statistics estimates that Service Area 20 had approximately 500 new prostate cancer cases in 2007. With half of them candidates for linear accelerator treatment, the area has enough prostate cancer patients in its boundaries to satisfy the standard of 250 patients for a linear accelerator.

The petitioner states that a comprehensive, multidisciplinary prostate health center should be developed, where patients with urologic and prostate cancer can expect individual, custom-tailored therapy, organized to meet their unique situations. The Prostate Health Center should provide counseling and care management; a full range of radiation oncology treatment including brachytherapy, external beam radiotherapy, and a combination of the two; and surgical and

radiation together with biofeedback training, incontinence management, and sexual rehabilitation, its own tumor board, pharmaceuticals and psychological counseling. The Center should also provide outreach and screening of patients at risk, as well as evaluation and feedback on the impact of clinical and outreach initiatives.

The petitioner states that, at present, Service Area 20 has more than 20 urologists and eight radiation centers. In the three counties, chemotherapy is delivered in hospitals, radiation centers and in hematology/oncology offices. All of these providers have different medical record systems. Their service locations are scattered over a 1.5-hour travel radius. This presents more than 160 different possible medical records for prostate cancer patients. The petitioner states that there is no practical way to have effective tumor boards and multidisciplinary approaches to this disease entity with such a structure, because the sheer number of treatment locations works against any effective coordination among physician specialists treating the same patient. The petition includes support from churches, prostate cancer support groups, and African American prostate support groups. These groups play an essential role in maximizing exposure and education among people at risk.

"Equitable access to timely, clinically appropriate and high quality health care for all the people of North Carolina..." (2009 NC Proposed SMFP, page 4) is a basic principle adopted by the NC State Health Coordinating Council. A Prostate Health Center should embody the basic principle of access to care by medically underserved populations, and strive to remedy some of the health disparity for minority men in NC.

Agency Recommendation

Although the petitioner presents a compelling argument for location of a linear accelerator in Service Area 20 for development of a prostate health center, the Agency concludes that providers in other areas of the state should also have the opportunity to apply for a certificate of need for a linear accelerator to develop such a center. Therefore, the Agency recommends denial of the petition, and inclusion in the final 2009 SMFP of a statewide need determination for one dedicated linear accelerator that shall be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men.

The Linear Accelerator Demonstration Project shall include the following components:

- Development of a multidisciplinary prostate health center to provide urology services, medical oncology services, biofeedback therapy, chemotherapy, brachytherapy and living skills counseling and therapy in the same building.
- Location of prostate health center in close proximity to minority communities.
- A medical director who shall be either a urologist certified by the American Board of Urology, a medical oncologist certified by the American Board of Internal Medicine, or a radiation oncologist certified by the American Board of Radiology.
- Commitment to sponsor regular case conferences and tumor boards.
- Written policies that prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay.

- Written strategies that include specific activities designed to assure the services will be accessible by indigent patients without regard to their ability to pay.
- Written description of patient selection criteria, including referral arrangements for high-risk patients.
- An organized African American Prostate Cancer Education/Outreach Program that partners with and complements existing initiatives such as the NC Minority Prostate Cancer Awareness Action Team.
- An Advisory Board composed of representatives of prostate cancer advocacy groups, prostate cancer patients and survivors that meets regularly and provides feedback about effective practices or changes that need to be made.
- Commitment to prepare an annual report at the end of each of first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that shall include:
  - The total number of patients treated;
  - The number of African-Americans treated;
  - The number of other minorities treated; and
  - The number of insured, underinsured and uninsured patients served by type of payment category.
- Documentation of arrangements made with a third party researcher (preferably a historically black university) to evaluate the efficacy of the model during the fourth operating year of the Center and develop recommendations whether or not the model should be replicated in other parts of the State. The report and recommendations of the researcher shall be provided to the Medical Facilities Planning Section and the Certificate of Need Section in the first quarter of the fifth operating year of the project.