



Prostate Health Center
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August 16, 2013

Nadine Pfeiffer, Branch Manager
Planning Section
Division of Facility Services
801 Ruggles Drive
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Petition Filed by Duke University Health System for Linear Accelerator in Service Area 20

Dear Ms. Pfeiffer,

Having reviewed the petition filed by Duke, we wish to provide additional comments regarding reasons why this petition should be denied.

First, as the Duke petition notes, several linear accelerators in Service Area 20 have unrealized potential.

- Certificate of Need awarded to Cancer Centers of North Carolina in 2011 (CCNC).
- Grandfathered linear accelerator in Franklin County.

CCNC has filed Progress Reports, which have been accepted by the Division of Health Service Regulation, indicating that it intends to develop the project and is proceeding with the CON. Until and unless that award is withdrawn, that linear accelerator can proceed at any time and could be operational, conceivably before a CON filed for a linear accelerator need identified in the *2014 State Medical Facilities Plan* would be operational.

The Franklin County linear accelerator, referenced as the “low volume machine,” is operational. It is an older model of linear accelerator and has limited scope. However, new provisions in the Budget Bill, approved July 31, 2013, specifically wording in GS 131E-184(f)(1) would permit replacement of that equipment by Exemption. Hence, that linear accelerator could now potentially convert quickly to state of the art equipment. The owner no longer faces a CON dollar restriction.

Second, the Proposed 2014 State Medical Facilities Plan, Table 9G, does not include in the inventory, the Prostate Health Center, located only five miles from Duke,. Nor does it include its impact on Service Area 20 providers. The oversight is problematic with regard to the *2014 Plan*. The Prostate Cancer Center opened in May 2013. Data used to develop the *2014 Plan* come from 2012 activities. Provider data from 2012 do not recognize the impact of this new equipment, which is located in Service Area 20. However, a CON filed in 2014 and awarded in 2014 or 2015, would very much be affected by and affect the Prostate Health Center. Approximately 40 to 50 percent of linear accelerator treatments involve prostate cancer

cases. Our statewide service area does and will include patients from Service Area 20, one of the most populous areas in the state.

Third, the petition's argument that CCNC gained access to a second linear accelerator with acquisition of the Wake Radiology equipment and placed development of its third linear accelerator on a slow path, is an admission by Duke that other providers see reason to pause before bringing new capacity on line. If the Division of Health Service Regulation finds it important to withdraw or suspend development of the CCNC 2011 award, such action should occur before need for another linear accelerator in Service Area 20 is identified.

Fourth, the *2014 Plan* subdivided Service Area 20. Harnett County, formerly in Service Area 20, is now its own service area. This will reasonably permit Harnett County to develop local capacity. Patients who came to providers in Wake County in 2012 will now have a local option that is not recognized in the 2012 data. Those patients and their use patterns will affect potential volumes in all linear accelerators that will be operational as a result of the *2014 Plan*. They potentially represent 6750 fewer ESTV's in Service Area 20. Because the methodology is based on use patterns, and not on population, their pattern changes could increase the surplus in Service Area 20 from 2.32 to 3.32 in 2014.

Fifth, Duke's petition admits that linear accelerators at Rex, also in Service Area 20, are operating below 6,750 ESTV's. It ignores the linear accelerators approved/ acquired by Duke under academic exemptions in adjacent Service Area 16 (Durham) which also shows surplus capacity (2.21 surplus).

Finally, the Duke petition indicates that replacement of its equipment should be on its planning horizon. The same Budget Bill (GS 131-184(f)(1) permits Duke to acquire a replacement that will have much higher efficiency, without a CON. The Duke petition considers only one alternative; and its discussion of the Basic Principles makes no attempt to demonstrate the cost effectiveness or value of its petition.

Together, these matters demonstrate too many variables, any one of which could seriously affect the use of linear accelerators at Duke Raleigh or elsewhere in Service Area 20. Approval of this petition could increase the operating cost at any or all of the existing facilities, by adding excess capacity to the service area. The impact could reduce access to services and increase costs at existing providers. There is no evidence that it would reduce consumer cost. The Prostate Health Center and CCNC operate the only Service Area 20 centers classified as freestanding, thus lower payment rates, by the payors.

We know yours is a difficult job and we appreciate the time and thoughtful attention you give to this important issue.

Sincerely,

Kevin Khoudary, MD, FACS

John Leung, MD, Board Certified Radiation Oncologist

Michael Garofalo, MD, Radiation Oncologist

The Prostate Health Center

