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CON Section

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June 1, 2010

Mr. Michael McKillip, Project Analyst
Mr. Craig Smith, Chief
Certificate of Need Section
NC Division of Health Service Regulation
701 Barbour Drive
Raleigh, North Carolina 27626

RE: Request for Public Hearing and Comments on the Certificate of Need application filed by UNC Hospitals to acquire a Linear Accelerator under the Academic Exemption, AC-3 / Orange County
Project ID # **J-8500-10**

Dear Mr. McKillip and Mr. Smith:

On behalf of Parkway Urology, PA, d/b/a Cary Urology, PA, thank you for the opportunity to comment on the above-referenced application for a Certificate of Need. This letter is also a formal request that the Agency conduct a Public Hearing on this application in accordance with GS 131E-185(a)(2). Cary Urology is an affected party. Cary Urology applied for and was approved by the Agency to develop a linear accelerator in a dedicated prostate health center that proposes to serve patients from the same service area claimed by this applicant and proposes to conduct research and teaching in association with its linear accelerator.

The application from UNC Hospitals asks to qualify a sixth linear accelerator for the hospital under the very restrictive parameters of 2010 State Medical Facilities Plan Policy AC-3: EXEMPTION FROM PLAN PROVISIONS FOR CERTAIN ACADEMIC MEDICAL CENTER TEACHING HOSPITAL PROJECTS. According to Policy AC-3, a project submitted under this exemption:

> "shall also demonstrate that the Academic Medical Center's teaching or research cannot be achieved effectively at any non-Academic Medical Center Teaching Hospital provider which currently offers the service for which the exemption is requested and which is within 20 miles of the Academic Medical Center Teaching Hospital." [Policy AC-3, page 24, 2010 SMFP]

Four such institutions have linear accelerators within 20 miles of the proposed location of the equipment. The application does not specifically address any of them.

1. Wake Radiology Oncology Services (18.7 miles),
2. Rex Hospital Blue Ridge Road (20.2 miles),
3. Raleigh Hematology Oncology Associates Cancer Center (20.4 miles), and
4. Durham Regional Medical Center (12.4 miles), where Durham Regional Hospital has a linear accelerator.

All miles above are from Google Maps. Because Policy AC-3 is silent on rounding rules, standard rounding rules apply. All of these mileages round mathematically to 20 or less.

Some of the existing linear accelerators within the 20-mile radius have tomographic and IGRT capabilities, both of which the application proposes as new teaching opportunities. The application provides no documentation to show that the proposed teaching or research cannot be achieved effectively at any of these locations. In fact, the only reason given for not using other locations for training is the reported reluctance of other unnamed host institutions to cover the salary of the resident trainee.

In fact, the application very clearly indicates that UNC Hospitals is not proposing to restrict the proposed linear accelerator to research or teaching. On page 13, the application notes that the proposed equipment is intended for "... meeting our patients needs." The application is similarly clear on page 25.

Special Rules apply to Linear Accelerator CON applications. In addressing these, the application ignores the Declaratory Ruling, a copy of which is included on its page 121, in which the Agency rules that the Mobetron is a linear accelerator. The application routinely notes that UNC Hospitals has four, rather than five linear accelerators.

On page 24, the application avoids directly responding to Special Rule 10 NCAC 14C.1903(2), which requires that 250 patients be treated on each of the applicant's existing linear accelerators. Instead, the application provides a quarterly average summary of patients treated. Linear accelerator treatments extend over many weeks and the same patient can be treated in two different quarters. On page 31, the application reports only four of its existing five linear accelerators in the count of patients per linear accelerator. With five linear accelerators, the number of patients in the last reported fiscal year (2009) is 239.47. The application does not address the ESTV alternative standard. On application page 63, for the hospital's FY 2009, the application reports that patients per linear accelerator was 220 (1104/5) and for its FY 2010, the number forecast is 239 (1197/5).

The application also fails to consider the impact of the proposed equipment on UNC's own ancillary and support services. Though noting that UNC Hospitals has only two simulators (page 10), the application fails to consider the impact of a sixth linear accelerator on capacity of the simulators or to mention Radiation Physics as a support service on page 14, or the extent to which current simulators can support the proposed equipment. In fact, the application indicates that Medical Physics and Dosimetry training is a reason for the proposed equipment, and that workstations are at a premium, but does not propose additional workstation capacity. Registered nurse staffing is similarly thin, with only 5.7 RN's to cover six linear accelerators, in two different locations, 11 scheduled hours a day, five days a week and two additional days on demand.

Finally, though the applicant proposes to use reserves to finance the project, the Agency should consider the drain on state taxes needed to build and support UNC Hospitals' cancer program. Taxpayers obligated $180 million in debt to build the Cancer Center and costs and obligations have exceeded that (164+28.6+12.3+35.1= 240). Moreover, UNC Hospitals requires $42 million a year in state operating subsidy (Exhibit 25). This is of concern for multiple reasons beyond the state's budget shortfall. Capital costs in Section VIII appear understated. The discounted value of movable equipment is less than the FMV and the Capital Costs include no funds to finish construction of the vault that the application claims is unfinished.

In reviewing this project, we ask the Agency to consider principles and statutory criteria. In the Findings of Fact for the Certificate of Need Statute (GS §131E-175), the General Assembly of North Carolina identified several guiding principles aimed at strengthening the health care delivery system in North Carolina and ensuring that its population has broad based access to services. Findings of Fact (2), (3) and (6) bear special consideration in this review:

(2) That the increasing cost of health care services offered through health service facilities threatens the health and welfare of the citizens of this State in that citizens need assurance of economical and readily available health care.

(3) That, if left to the market place to allocate health service facilities and health care services, geographical maldistribution of these facilities and services would occur and, further, less than equal access to all population groups, especially those that have traditionally been medically underserved, would result.

The application proposes that more than 75 percent of patients served will come from outside its Linear Accelerator Service Area 14 (page 58).

(6) That excess capacity of health service facilities places an enormous economic burden on the public who pay for the construction and operation of these facilities as patients, health insurance subscribers, health plan contributors, and taxpayers.

These Findings of Fact tie closely to two Basic Principles governing the 2010 State Medical Facilities Plan ("SMFP"):

(2) Access Basic Principle. Equitable access to timely, clinically appropriate and high quality health care for all the people of North Carolina is a foundation principle for the formulation and application of the North Carolina State Medical Facilities Plan.

(3) Value Basic Principle. The SHCC defines health care value as maximum health care benefits per dollar expended. …Cost per unit of service is an appropriate metric when comparing providers of like services for like populations.

The referenced CON application requires certificate of need approval by its definition as "new institutional health services," per GS §131E-178 (a):

> No person shall offer or develop a new institutional health service without first obtaining a certificate of need from the Department.

As such, the application must be reviewed by the CON Section with the same scrutiny in regard to each CON Review Criteria as any other certificate of need application. This application fails to conform to or is in conflict with statutory review criteria, the General Assembly's Findings of Fact, and the Plan's principles. To summarize:

- The application fails to demonstrate that the population to be served has a need for the proposed services, hence, fails the test of Criterion 3.
- The application fails to demonstrate all of the required tests for Policy AC-3 are met.

Thank you for your time and attention. Our comments are intended to highlight problems, not to provide a comprehensive analysis of the application. We understand the difficulties presented in these types of reviews and appreciate your attention to details. Should you have any questions, please do not hesitate to call me.

Sincerely,

Kevin Khoudary, MD / pp

Kevin Khoudary, M.D.