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January 3, 2011

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

RE: Public 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-8611-10**

Dear Mr. Yakaboski 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. 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.

### Overview

We believe the Agency should find the above-referenced application non-conforming with specific criteria in the Certificate of Need statute. Specifically, the application is non-conforming with Statutory Criteria GS-131E-183(a) (1) (3), (4), (5), (6) and (8) on its own merits. It is also non-conforming with GS-131E-183(b).

### Criterion (1) Policies

The application from UNC Hospitals asks to qualify a seventh linear accelerator under the very restrictive parameters of *2010 State Medical Facilities Plan (SMFP) Policy AC-3: EXEMPTION FROM PLAN PROVISIONS FOR CERTAIN ACADEMIC MEDICAL CENTER TEACHING HOSPITAL PROJECTS.*

The project does not meet the tests for the exemptions requested in this application. A project submitted under this exemption for a hospital designated prior to January 1, 1990:

“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.”<sup>1</sup>

The application does not mention four such institutions that are within 20 miles of the proposed location of the equipment.

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).

All miles above are from Google Maps. Because Policy AC-3 is silent on rounding rules, standard rounding rules apply and each mileage rounds 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 that the proposed teaching or research cannot be achieved effectively at any of these locations. If anything, the application suggests that students would do better in smaller training groups, where they would get close experience with patients.
- The only training adaptation proposed in this application is a larger control station with multiple viewing screens. While this may provide a convenience and comfort factor for students, it hardly merits the \$9 million proposed expenditure.
- The application describes the need for training facilities for physicists and dosimetrists. Most of the dosimetry work occurs, not at the viewing station, but in the work room and on the RTP systems (application page 38). Here, dosimetrists and physicists review patient data, calculate tumor size and dosage. The application proposes no changes to the workroom or the RTP systems, which it indicates are in short supply. Without these adjustments, which are not included in the capital cost, by the application’s own admissions, UNC Hospitals does not have capacity to absorb the proposed increase in students.

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<sup>1</sup> 2010 State Medical Facilities Plan, p. 24.

### Criterion 3 Need

The application forecasts that demand for services will almost double in five years. However, the forecasts are incomplete and not supported by reasonable assumptions.

For example, on page 46, the application counts “Procedure” codes without identifying what procedure codes are referenced. Asterisks in Section III are not footnoted and the forecasts of patients follow no logical pattern. In fact, procedures per patient calculate to 52 in FY 2009 and 48.1 in forecast FY 2015. The ratio of procedures per patient is almost two times the average number of linear accelerator procedures per patient reported on state license renewal forms.<sup>2</sup> This suggests either over utilization or that UNC is counting procedures not directly related to linear accelerator treatments.

The application makes no attempt to tie number of procedures to number of students, or to demonstrate quantitatively why the increased students cannot be trained on the existing or replacement equipment.

Moreover, although UNC Hospitals elected not to include its Mobetron linear accelerator (Exhibit 2 in the application) in its count of linear accelerators, the application gives no indication that Mobetron patients or procedures were subtracted from procedure counts presented in Sections III and IV. The application contains no spreadsheets or supporting documentation for the procedure information.

In a further distortion of data, the application’s forecasts of patient need for services rely for justification on the compound annual growth rate (CAGR) of three annual procedure counts, one of which is estimated. UNC Hospitals uses the three-point CAGR in order to make its utilization forecasts of 8 to 11 percent annual increases in procedures appear conservative.

The narrative overlooks the fact that UNC Hospitals forecasts that it will do 25,569 more linear accelerator procedures per year five fiscal years after 2010. The sole justification for this enormous growth is the following statement.

“These projected growth rates are reasonable based on the calculated CAGR, and are conservative in nature especially when considering the aging population, cancer incidence rates, and continual advances being made in radiation therapy technology.”  
(*application, page 67.*)

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<sup>2</sup> UNC Hospitals reported 27.8 on the 2008 Hospital License Renewal Forms. The state average for hospitals was 24.95 in 2008.

This sweeping assumption makes no reference to: what population is aging, what cancer will be treated by the proposed equipment or to specific cancer incidence rates. The Agency has not accepted unsupported forecasts from other CON applicants for other services. The statute does not exempt an academic medical center from Criterion 3 (GS 131E-183(a)(3)). Nor does the statute exempt the academic medical center from Criterion 5, which requires financial forecasts to be based on "...reasonable projections of costs of and charges for...."

The following are examples of applications for equipment CON's that the Agency denied for failure to justify need.

Project ID	Applicant	Competitive
J-7932-07	Wake Radiology Oncology Services	Yes
J-8336-09	Wake Prostate Center of Excellence, LLC	Yes
H-8063-08	FirstHealth of the Carolinas	No
P-7752-06	Crystal Coast Radiation Oncology	Yes
P-7769-06	Onslow Radiation Oncology, LLC	Yes
F-7524-06	Pineville Radiation Therapy Center, LLC	Yes
F-7518-06	Presbyterian Hospital	Yes
H-7510-06	Radiation Oncology Centers of the Carolinas	Yes
M-8133-08	Cumberland County Hospital System	Yes
N-8143-08	The Radiation Medical Center, LLC	Yes
N-7872-07	Scotland Memorial Hospital, Inc.	No

Charting the data points illustrates the amount of synthetic stretch involved in UNC Hospital's use of CAGR to justify its future forecast.

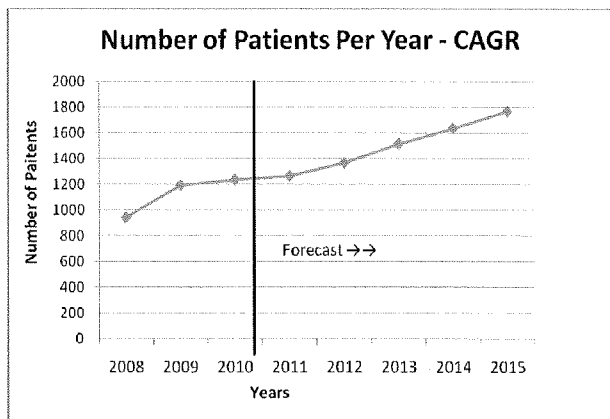


Figure 1. Forecast using CAGR approach in the UNC Hospitals Application

When the three base points are tested by a trendline, using the MS Excel charting function, the historical curve follows a second order polynomial with a perfect  $R^2$  of 1. In trending, the  $R^2$  measures the difference between expected and actual using the formula described by the line. When the value is 1.0, the line predicts the values; the lower the value, the less true is the fit. The trend used by UNC is closer to a linear trend, which has an  $R^2$  of 0.85.

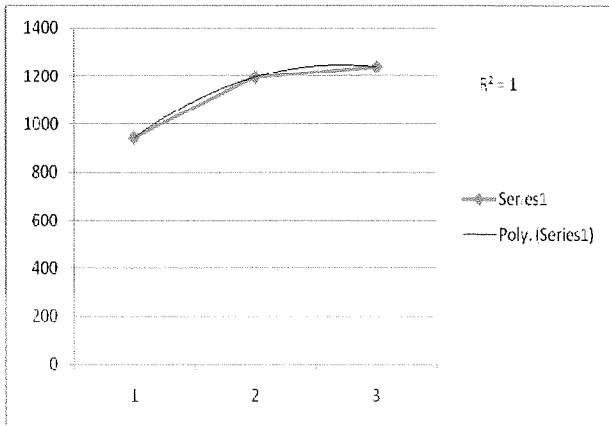


Figure 2. Trendline analysis using second degree polynomial.

Forecast forward, the polynomial equation for Figure 2 shows the linear accelerators with no utilization after 3.5 years. The point of this analysis is that, lacking a detailed explanation of its assumptions, UNC Hospital has not provided reasonable forecasts of need or utilization.

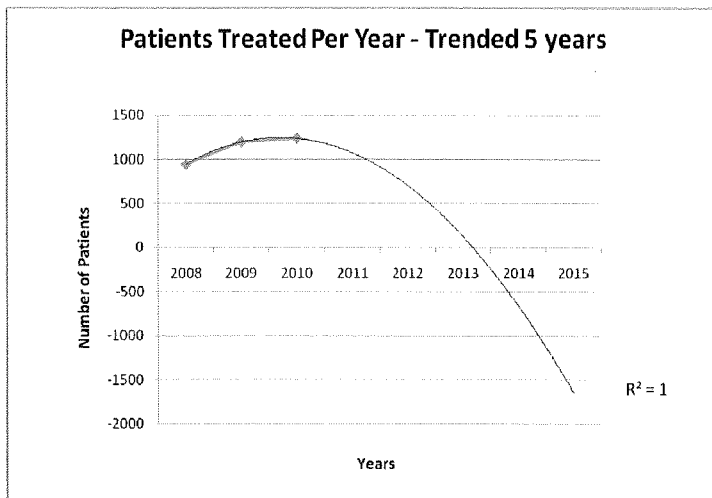


Figure 3. Trendline from Figure 2 extended five years forward.

The application contains significant discussion about the importance of training on newer technology, but makes no attempt to quantify why the same training could not occur by replacing some of the existing older technology at UNC Hospitals. None of the training argument involves a quantitative relationship between trainees and number of linear accelerators.

In fact, in projecting utilization, the application ignores the fact that the proposed linear accelerator would be located in two-county Service Area 14, consisting of Chatham and Orange counties. Service area 14 has only 197,084 people in 2010 according to the Office of State Budget and Management. The *2010 State Medical Facilities Plan* methodology for calculating linear accelerator need sets a benchmark of 120,000 people per linear accelerator. Using that, the service area should have fewer than two linear accelerators. It has five, has an approved and appealed CON for a sixth, all owned by the applicant and at the same address; and UNC Hospitals is now requesting a seventh on the same campus.

The patient origin presented on pages 29 and 30 show Orange, Chatham, Wake and Durham Counties represent the plurality of users of this equipment, representing 44 percent of the total. The application contains no explanation of how or why UNC Hospitals would attract 43 percent more patients from these counties between 2010 and 2015  $((1760-1237) / 1237 = 43\%)$ .

#### Criterion (4) Alternatives

It seems incongruous that an applicant given to such excess would need supplemental funding from the people of North Carolina to support its operations. In FY 2010, according to the Applicant's own financial statements, taxpayers provided \$41 million to subsidize operations directly. The application anticipates drawing \$9 million from the hospital's reserves to acquire and renovate space for this proposed expenditure. Those reserves were effectively provided by taxpayers, because operating funds saved as reserves are the direct result of operating subsidies. In addition, the State borrowed \$180 million to build the cancer center.<sup>3</sup> Costs of that debt are not reflected in the CON application's capital cost, because space was built in anticipation of this equipment. However, alternative use of that space should be considered in evaluating this application.

At a time when the Governor is forced to cut jobs and programs in other departments, it is highly unreasonable for the State's premier medical school to engage in excessive spending for an unnecessary program. The new capital cost per oncology resident (4) will exceed \$2 million. That capital cost does not include the cost of the building. The cost to staff and operate the equipment may not be offset by the expected revenue gains, because utilization forecasts are overstated.

The application fails to consider these alternatives.

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<sup>3</sup> Exhibit 23, p. 442.

### Criterion (5) Financial Feasibility

With forecasts of utilization unsupported, the financial forecasts are not reasonable.

We note that the forecasts in the Proforma Income and Expense statement for the linear accelerator are not consistent with the number of patients referenced in Section IV. Compare pages 114 and 66. Thus, the application is internally inconsistent, and the data cannot be considered reliable or reasonable.

### Criterion 8 – Ancillary Support

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 seventh linear accelerator on capacity of the simulators or to mention Radiation Physics as a support service on page 16, 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 propose additional workstation capacity only for the observation area. The project includes no improvements to the physics planning area.

### Summary

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), (4) 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.
- (4) That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services.

- (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 project 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 exemption 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.