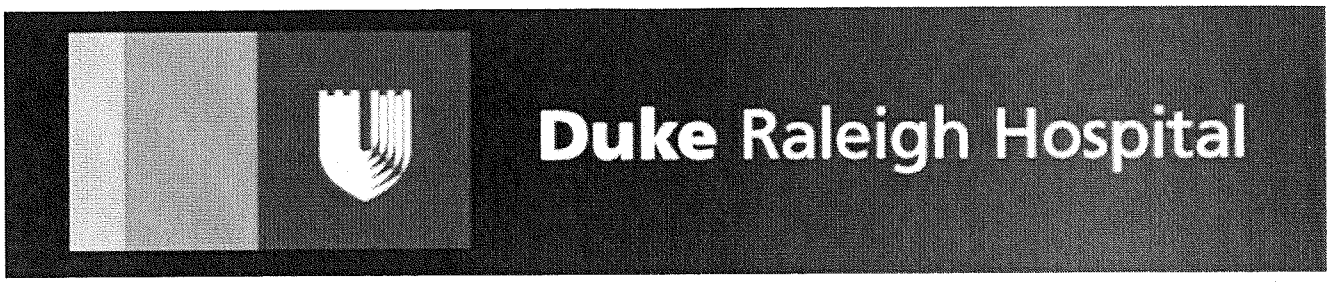
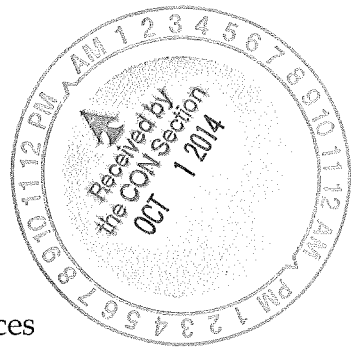




October 1, 2014

Michael J. McKillip, Project Analyst
Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
701 Barbour Drive
Raleigh, North Carolina 27626-0530

RE: Comments on Linear Accelerator CON Applications for Service Area 20

Dear Mr. McKillip:

Enclosed please find comments prepared by Duke Raleigh Hospital (DRAH) regarding the competing CON applications for one new linear accelerator to meet the need identified in the *2014 State Medical Facilities Plan* for Service Area 20. We trust that you will take these comments into consideration during your review of the applications.

If you have any questions about the information presented here, please feel free to contact me at (919) 668-0857. I look forward to seeing you at the public hearing.

Sincerely,

Catharine W. Cummer

Catharine W. Cummer
Regulatory Counsel, Strategic Planning
Duke University Health System

COMMENTS REGARDING COMPETING CERTIFICATE OF NEED APPLICATIONS
LINEAR ACCELERATOR NEED DETERMINATION FOR SERVICE AREA 20

SUBMITTED BY DUKE RALEIGH HOSPITAL
October 1, 2014

Three applicants submitted Certificate of Need (CON) applications in response to the need identified in the *2014 State Medical Facilities Plan (SMFP)* for one additional linear accelerator for Service Area 20 (Wake and Franklin counties). In accordance with N.C.G.S. §131E-185(a.1)(1), this document includes comments relating to the representations made by the other applicants and a discussion about whether the material in those applications complies with the relevant review criteria, plans, and standards. These comments also address the issue of which of the competing proposals represents the most effective alternative for development of an additional linear accelerator for the local service area.

Specifically, the CON Section, in making its decision, should consider several key issues. These include, but are not limited to:

(1) The extent to which the proposed projects represent a cost-effective alternative;
(2) The extent to which the proposed projects will increase access to radiation therapy services for the residents of the service area, especially the elderly and medically underserved groups; and
(3) The extent to which the competing applicants submitted conforming applications.

The remainder of this document addresses each of these issues, in turn.

Comparative Analysis

Cost Effectiveness

A key issue to consider when evaluating the competing applications is the extent to which the proposed projects represent a cost-effective alternative for developing a radiation therapy program. DRAH's proposal represents the most cost effective alternative.

In the current healthcare marketplace, where cost of care is a major concern with payors and the public, average procedure charge is an important measure of consumer value. DRAH, as shown in its application, has the most competitive fees for the proposed project.

Comparison of Charges, Reimbursement and Costs

Third Operating Year	UNC	Parkway Urology	Duke Raleigh Hospital
Per Patient:			
Gross Revenue	$59,861	$53,467	$56,647
Net Revenue	$22,695	$18,833	**$17,449**
Cost	$10,742	$17,791	$13,493

Source: CON applications

Third Operating Year	UNC	Parkway Urology	Duke Raleigh Hospital
Per Treatment:			
Gross Revenue	$3,914	$1,562	$2,116
Net Revenue	$1,484	$550	$652
Cost	$702	$520	**$504**

Source: CON applications

DRAH projects the lowest net revenue per patient of the competing applications. This is an actual, tangible benefit to the residents of Service Area 20 in that DRAH's reimbursement reflects a focus on competitive and reasonable pricing for high quality radiation therapy services for residents of the Service Area.

A comparison of each applicant's average cost per treatment shows DRAH's proposal to be the most effective option for the need determined linear accelerator, with the lowest projected cost per patient treatment.

By contrast, UNC projects the highest charges, net revenues and costs of all the applicants, and is thus is the least cost-effective alternative.

As noted later in these comments, the Parkway Urology financial projections (including calculations of charges, revenues, and costs per patient and per treatment) are not reliable because Parkway's application is not conforming to Criterion 3.

Access

Access to radiation therapy services is another essential comparative factor. DRAH proposes to bring its linear accelerator to market earlier than the two competing applicants.

Projected Linear Accelerator Availability Date

Applicant	Start Date
Duke Raleigh Hospital	**July 1, 2015**
Parkway Urology	January 1, 2016
UNC	July 1, 2016

Source: CON applications

The need determination in the 2014 SMFP is for Linear Accelerator Service Area 20, which includes Wake and Franklin counties. DRAH proposes the most access for Wake and Franklin residents, as shown in the table below.

Projected Service Area 20 Patient Origin

Applicant	Wake County	Franklin County	Combined SA 20 Patient Origin
Duke Raleigh Hospital	70.2%	5.0%	**75.2%**
Parkway Urology	58.2%	3.0%	61.2%
UNC	61.0%	0.0%	61.0%

Source: CON applications, PY2

In addition, DRAH projects to serve the highest number of Service Area 20 patients of any of the applicants, as shown in the following table.

Service Area 20 Patients Served

Applicant	Wake County	Franklin County	Combined SA 20 Patients
Duke Raleigh Hospital	334	24	**358**
Parkway Urology	233	12	245
UNC	124	0	124

Source: CON applications, PY2

The following table illustrates each applicant's projected percentages of procedures to be provided to Medicaid and Medicare recipients in the second year of operation following completion of the project.

Projected Medically Underserved Access

APPLICANT	Projected Percentage of Total Procedures Provided to Medicare Recipients	Projected Percentage of Total Procedures Provided to Medicaid Recipients
Duke Raleigh Hospital	**45.7%**	**4.7%**
Parkway Urology	58.6%	1.6%
UNC	41.5%	12.2%

Source: CON applications

As shown in the previous table, UNC projects the lowest percentage of services to be provided to Medicare recipients, and Parkway Urology projects the lowest percentage of services to be provided to Medicaid recipients.

It is also important to note that, as stated later in these comments, UNC did not actually project a payor mix for the proposed Holly Springs linear accelerator. The payor mix

shown above is representative of the UNC Department of Radiation Oncology, which is located in an entirely different Linear Accelerator Service Area.

Also noted in these comments is the questionable nature of the Parkway Urology payor mix projections. Parkway Urology provides radiation therapy for men with prostate cancer, and is owned by urologists. Parkway's projections for the proposed second linear accelerator at its Prostate Health Center include referral letters from ophthalmologists, nephrologists, cardiologists, obstetrician/gynecologists, and orthopedic surgeons. It is very questionable how Parkway can presume to show a need for a linear accelerator based on this prospective referral pattern. Therefore, Parkway's payor mix assumptions are not reliable.

Demand for Applicant's Existing Services

Given the SMFP need determination for an additional linear accelerator in Service Area 20, a comparison of each applicant's historical utilization and of the capacity of each applicant's existing services is relevant.

The following table shows the ESTV procedures performed in Linear Accelerator Service Area 20 by each applicant from FY2011 through FY2013.

Historical Demand for Service Area 20 Linear Accelerators

Applicant	FY2011	FY2012	FY2013
Duke Raleigh Hospital	7,486	9,807	9,526
Parkway Urology	NA	NA*	7,242
Rex/UNC (4 machines)	18,898	19,401	18,118

*Prostate Health Center opened May 1, 2013.
Source: SMFPs and CON applications.

As shown in the table, utilization of the Rex/UNC linear accelerators decreased 4.1% between FY2011 and FY2013. During this same period, utilization of the DRAH linear accelerator increased 27.3%. Parkway Urology opened recently (May 2013), and its services are limited to men's prostate health.

The following table shows the utilization of the applicants' existing linear accelerators as a percent of the minimum performance standard of 6,750 ESTV's per year per unit in the most recent full reporting year (FY2013) for which data is available for all applicants.

Service Area 20 Linear Accelerators

	LINAC Units	FY2013 ESTVs	Average ESTVs Per Linear Accelerator	Minimum ESTVs per Linear Accelerator	Percent of Minimum Performance Standard
Duke Raleigh Hospital	1	9,526	9,526	6,750	141%
Parkway Urology	1	7,242	7,242	6,750	107%
Rex/UNC	4	18,118	4,530	6,750	67%

Source: Data are from the Proposed 2015 SMFP and the Parkway CON application.

As indicated in the previous table, the linear accelerators at Rex/UNC operated at only 67 percent of the minimum performance standard of 6,750 ESTV procedures in the most recent reporting year. Also, the linear accelerator at Parkway Urology operated at 107 percent of the minimum performance standard of 6,750 ESTV procedures in FY2013. In contrast, the linear accelerator at DRAH operated at 141 percent of the minimum performance standard of 6,750 ESTV procedures in the most recent reporting year. Clearly, DRAH has the greatest need for additional LINAC capacity.

Specific Application Review Considerations

#J-10318-14 University of North Carolina Hospitals at Chapel Hill (UNC)

Comments specific to Criterion 1

- Policy GEN-3: Basic Principles of the 2014 SMFP is applicable to review of the UNC CON application. Policy GEN-3 states:

  > *"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."*

  UNC did not adequately demonstrate the population to be served or the need the population has for its proposal and therefore, the applicant's projected revenues and expenses are unsupported and unreliable. Thus, UNC did not demonstrate that the project is a cost effective approach that would maximize healthcare value for resources expended. Please see comments regarding Criteria 3 and 5 for details.

- UNC did not adequately demonstrate the project would maximize healthcare value for resources expended because UNC, via its wholly owned and operated Rex Hospital, has existing linear accelerators that are currently operating well below capacity. Use of one or more of these linear accelerators would be a less costly option. Please see comments regarding Criterion 4.

- UNC did not adequately demonstrate the project will promote equitable access. UNC did not project a payor mix for the proposed Holly Springs linear accelerator, yet projects a Holly Springs linear accelerator service area that differs from the existing UNC Department of Radiation Oncology service area. Also, the UNC payor mix projection in Section VI.15 is not reasonable because it unreasonably assumes the same payor mix for the overall UNC Department of Radiation Oncology, despite proposing to serve a market that will differ from that which the Department currently serves. Please see comments regarding Criterion 13c.

- Consequently, for each of these reasons, UNC does not conform to Criterion 1.

Comments specific to Criterion 3

- UNC attempts to develop a projection methodology for DRAH's radiation therapy services on pages 60-62 of its application. However, UNC cannot and should not project patient volume for another applicant in a competitive CON batch review. With respect to demonstrating conformity with statutory and regulatory review criteria, each applicant is evaluated based on the information provided in their respective applications; not the information provided by a competing applicant. DRAH provided specific methodology and assumptions for projecting radiation therapy utilization on its existing and proposed linear accelerators and, separately, for the equipment which may be acquired from CCNC. The discussion provided by UNC on pages 60-62 is in no way relevant to DRAH's proposal as described in Project I.D. # J-10322-14.[1]

- UNC failed to properly and adequately identify the population to be served. Specifically, in response to III.4.(b), UNC failed to provide historical linear accelerator patient origin for Rex Hospital despite the fact that UNC projects nearly one-third of its patients will be referred from Rex during project year three (i.e. p. 93, 80 Rex patient referrals/275 total patient referrals). UNC is the 100% owner of Rex Healthcare which owns and operates Rex Hospital; therefore, it is relevant to acknowledge and provide historical patient origin for Rex Hospital. Additionally, UNC failed to provide relevant information regarding the impact the proposed Holly Springs service will have on linear accelerator patient origin both at Rex Hospital and UNC. Given, UNC projects to deplete Rex linear accelerator patient utilization by nearly 12% (80 Rex linear accelerator patient referrals in PY3 ÷ 663 FY13 Rex linear accelerator patients = 12.1%), it is relevant to consider the impact the project will have on Rex's linear accelerator utilization and patient origin. UNC failed to provide any discussion relevant to this matter. Consequently, UNC failed to properly and adequately identify the population to be served and the application does not conform to Criterion 3.

---

[1] UNC's discussion of DRAH is also misleading, in that it claims that DRAH will have access to three additional linear accelerators upon acquisition of CCNC's radiation oncology sites, yet UNC and Rex have appealed the determination of good cause for the transfer of the CON for CCNC's third linear accelerator.

- UNC did not demonstrate that its projected linear accelerator utilization is based on reasonable and supported assumptions. First, on page 91 UNC projects that Rex's linear accelerator patients from the Holly Springs Service Area, Harnett County and Lee County will increase during the next five years. UNC projects Rex's linear accelerator patients from the described area to increase based on the respective population growth rates; however, these growth rates are in sharp contrast to the recent linear accelerator patient utilization at Rex. Please refer to the table below.

Rex Hospital – Linear Accelerator Patients by County

	FY2012	FY2013	*Annual Change*
Wake	626	519	*-17.1%*
Harnett	11	11	*0.0%*
Lee	1	2	*Net 1 patient*
Other	133	131	*-1.5%*
Total	771	663	*-14.0%*

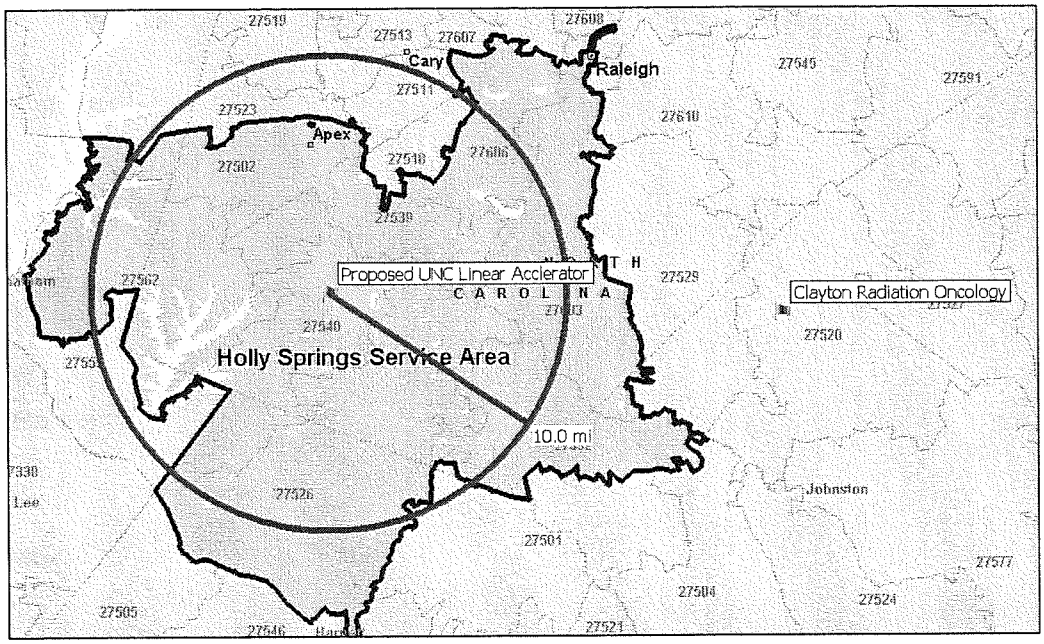
Source: 2013-2014 Hospital license renewal applications

Despite positive population growth in Wake, Harnett and Lee counties, the number of Rex linear accelerator patients has decreased dramatically in recent years. UNC does not adequately demonstrate why it is reasonable to project that Rex's linear accelerator patients will increase for the next five years despite a negative historical growth trend.

Second, it is unreasonable to project that 90 percent of Rex's linear accelerator patients from the Holly Springs service area will be referred to the Holly Springs linear accelerator. For example, on page 81 the applicant states, "*throughout the remainder of the application, utilization from the Holly Springs Service Area is determined based on patient volume from those ZIP codes which are included in the Service Area in their entirety [emphasis added] and the estimated patient volume from Raleigh ZIP codes 27603 and 27606, based on the percent of the population that resides within 10 miles of the proposed site.*" However, most of the zip codes identified in the Holly Springs service area and the map on page 80 extend well beyond the 10-mile radius of the proposed site. For example, zip code 27592 (Willow Springs) extends into Johnston County, a county which already hosts two linear accelerators. In fact, patients residing in the Johnston County portion of zip code 27592 (Willow Springs) are closer to UNC's Clayton Radiation Oncology than to the proposed Holly Springs linear accelerator service. Additionally, substantial portions of zip codes 27526

(Fuquay-Varina) and 27562 (New Hill) extend well beyond a 10-mile radius of the proposed Holly Springs site, as illustrated in the following map.

Map of Holly Springs Service Area w/ 10-mile Radius



UNC failed to demonstrate why it is reasonable to exclude patient volume from zip codes 27603 and 27606 that reside outside the 10-mile radius from the proposed site, but not exclude the patient volume from zip codes 27529, 27526, and 27562 that reside outside the 10-mile radius.

UNC also failed to demonstrate why is it reasonable to assume that 90 percent of Rex patients from the proposed service area will utilize the proposed Holly Springs linear accelerator. The 79 patients (p.91) treated at Rex Healthcare during FY2014 were served by a total of four (4) linear accelerators. This capacity facilitates greater efficiencies with regard to scheduling compared to the single linear accelerator which is proposed to be available in Holly Springs. Given the limited access at the proposed site (i.e. one linear accelerator), it is unreasonable to assume that 90 percent of Rex's patients from the proposed service area can be accommodated and will utilize the proposed service. Finally, UNC states on page 34 of the application that patients will have their initial treatment planning at either UNC Hospitals or Rex Healthcare; thus, it is highly unlikely that 90 percent of Rex's patients from the

proposed service area will choose to have their treatment planning and simulation performed at Rex Hospital and linear accelerator treatment performed at a UNC hospital-based facility in Holly Springs. Therefore, UNC failed to demonstrate its projected utilization is based on reasonable and supported assumptions. Consequently, the application does not conform to Criterion 3.

- UNC failed to demonstrate why is it reasonable to assume that 50 percent of UNC radiation therapy patients from the Holly Springs service area and Harnett County will utilize the proposed Holly Springs linear accelerator. The 249 patients (p.83) treated at UNC Hospitals during FY2014 were served by a total of five (5) linear accelerators, two of which are configured for stereotactic radiosurgery and one that is a CyberKnife. These linear accelerator systems provide highly specialized radiation therapy services and are greatly different compared to the proposed Holly Springs linear accelerator. Indeed, on page 95 UNC states, "UNC *Hospitals performs several treatment types beyond Simple, Intermediate and Complex and IMRT.*"

  The proposed Holly Springs linear accelerator will not be a CyberKnife, nor will it have stereotactic capabilities. However, UNC failed to identify how many of the 249 linear accelerator patients from the Holly Springs Service area and Harnett County received stereotactic and/or CyberKnife treatments during FY2014. Without this pertinent information, the methodology assumptions and resulting UNC patient projections are not supported. This is further demonstrated by the fact that these patients already have access to four linear accelerators at two locations within the UNC System in Wake County operated by Rex Hospital with significant available capacity, yet have received their radiation oncology services instead in Chapel Hill.

  Additionally, UNC states on page 34 of the application that patients will have their initial treatment planning at either UNC Hospitals or Rex Healthcare; thus, it is highly unlikely that 50 percent of UNC's patients from the proposed service area will choose to have their treatment planning and simulation performed at UNC and linear accelerator treatments performed at a separate facility in Holly Springs.

  Finally, UNC Hospitals in Chapel Hill hosts considerably greater linear accelerator capacity (i.e. five linear accelerators) compared to the single linear accelerator which is proposed to be available in Holly Springs. Given the limited access at the proposed site (i.e. one linear accelerator), it is unreasonable to assume that 50 percent of UNC's patients from the proposed service area will utilize the proposed Holly Springs service. Therefore, UNC failed to demonstrate its projected

utilization is based on reasonable and supported assumptions. Consequently, the application does not conform to Criterion 3.

- The proposed new linear accelerator is not necessary to accommodate the potential linear accelerator referral volume from the six CCNC medical oncologists who will purportedly join the UNC Health Care System. Specifically, UNC owns 100% of Rex Healthcare which owns 100% of Rex Hospital; thereby, the four existing underutilized linear accelerators are unequivocally part of the UNC Health Care System. During FY2013, the four linear accelerators at Rex Hospital treated a total 663 linear accelerator patients, or an average of 166 patient per machine (663 patients ÷ 4 machines = 166 patients per machine). For sake of argument, even with the addition of the six CCNC medical oncologists' FY13 patient volume (p. 86: 302 patients), the four existing Rex linear accelerators would continue to be underutilized [Rex FY13 663 linear accelerator patients + six CCNC medical oncologists FY13 302 linear accelerator referrals = 965 linear accelerator patients ÷ 4 machines = 241 patients per machine]. Similarly, Rex's utilization in FY13 was 18,118 ESTVs; assuming a capacity of 6750 ESTVs per machine, Rex has capacity for 27,000 ESTVs, or an additional 8,882 ESTVs. To the extent that "UNC Health Care System is adding the volume equivalent of one linear accelerator" by the hiring of these physicians, Rex has excess capacity more than equivalent of one linear accelerator to accommodate this projected volume increase.

  Of further note, according to the data on page 86 of UNC's application, the linear accelerator patient referral volume for the six CCNC medical oncologists assumedly joining UNC Health Care System has experienced a decrease for three consecutive years; however, UNC projects patient referrals for these physicians to increase during the next five years. Therefore, given the available linear accelerator capacity within the UNC Health Care System in Wake County (i.e. Rex Hospital), the need for the proposed additional UNC linear accelerator in Holly Springs is not justified. Consequently the application does not conform to Criterion 3.

Comments specific to Criterion 4

UNC failed to demonstrate that its proposal represents the least costly or most effective alternative. Specifically,

- UNC repeatedly states throughout its application that its proposal to develop a new linear accelerator in Holly Springs will allow UNC to "repatriate Wake County patients". However, there are currently no barriers restricting repatriation of Wake County patients to a UNC Health Care System linear accelerator service in Wake County. Specifically, as previously discussed, Rex Hospital, which is a UNC-owned facility, operates four (4) underutilized linear accelerators. In fact, UNC repeatedly references the current average volume of Wake County's linear accelerators as being underutilized (example p.62), the primary source of which is Rex Hospital. During FY2013 (the most recent data publically available), the four Rex LINACs operated at 18,118 ESTVs. This represents an average of 4,530 (18,118/4) ESTVs per linear accelerator, which is 33% below the State's threshold for capacity of a linear accelerator. On page 567 of its application, UNC states that during FY2013 Rex treated 636 patients on its four linear accelerators. This represents an average of 159 patients per linear accelerator, which is 36% below the State's threshold for capacity of a linear accelerator. Therefore, UNC is currently able to "repatriate Wake County patients" simply by using Rex Hospital's underutilized linear accelerators. In fact, the application proposes that these patients would receive a significant portion of treatment planning and ancillary services from Rex Healthcare even with if this project were approved (see, e.g., pp. 34, 36, and 51-53).

  UNC attempts to obfuscate its ownership of Rex Hospital when in fact, UNC owns 100% of Rex Hospital. Specifically, UNC is the sole corporate member of Rex Healthcare. Rex Healthcare is a holding company and sole member of Rex Hospital. Thus, UNC is the ultimate owner of Rex Hospital. Furthermore, the amended and restated articles of incorporation of Rex Hospital, Inc. (see Attachment 1) Article III (xiii) state the purpose for which the corporation is organized are:

  > *"To make donations, transfer assets and provide other forms of aid and assistance to, for the benefit of, or in connection with the University of North Carolina Health Care System"*

  Therefore, Rex Hospital currently has the capacity to accommodate the repatriation of Wake County patients from UNC, and is obligated by its articles of incorporation to assist with such patient care needs.

  On page 102 of its application, UNC dismissed the alternative to relocate a Rex linear accelerator to Holly Springs based on the 2012 CON approval to replace the

Rex linear accelerator located in Wakefield stating, "*the CON Section determined in 2012 that Rex Healthcare has demonstrated the need for four linear accelerators.*" However, that CON decision was based on the need to replace a linear accelerator, not to add inventory to a UNC-owned facility in Wake County. Furthermore, the average utilization per linear accelerator at Rex Hospital has declined 6.6% since 2012, as shown in the following table.

Average ESTVs per Linear Accelerator
FY2012-FY2013

Provider	FY2012	FY2013	Change
Rex Hospital	4,850	4,530	-6.6%

Source: 2014 SMFP, Proposed 2015 SMFP

Given the available linear accelerator capacity at Rex Hospital, continued decreasing utilization of radiation therapy services at Rex Hospital, and obligation of Rex Hospital to assist UNC, the UNC application failed to adequately demonstrate that it could not reasonably transfer one of the linear accelerator assets from its owned facility (i.e. Rex Hospital) and develop it in Holly Springs for the purposes of its proposed project. Doing so would certainly have been a less costly and more effective alternative.

- UNC did not adequately demonstrate that its projected utilization was based on reasonable, credible and supported assumptions. See Criterion (3). An application that cannot be approved cannot be an effective alternative.

Comments specific to Criterion 5

- UNC did not adequately demonstrate the population to be served or the need the population has for its proposal. Therefore, UNC did not reasonably demonstrate the immediate and long-term financial feasibility of its Holly Springs linear accelerator proposal, because its plan is not based upon reasonable projections of the costs of and charges for providing health services. See Criterion 3 for additional discussion.

- UNC did not project any payor mix for the proposed Holly Springs linear accelerator, and did not reasonably project an overall payor mix for the Department of Radiation Oncology. See Criterion 13c for more details. Therefore, UNC did not use reasonable assumptions to project the charges and costs to demonstrate financial feasibility; its application does not conform to Criterion 5.

Comments specific to Criterion 6

UNC did not adequately demonstrate that its proposal would not result in the unnecessary duplication of radiation therapy services in Service Area 20. Specifically,

- UNC did not adequately demonstrate in its application that the linear accelerator it proposes to develop in Wake County is needed. See discussion regarding population and projected utilization in Criterion 3.

- UNC repeatedly references the current average volume of Wake County's linear accelerators as being underutilized (example p. 62); however, UNC fails to disclose that the culprit for this is actually its own facility in Wake County, i.e. Rex Hospital. Based on FY2013 utilization, the existing linear accelerators at DRAH and CCNC were each operating well above minimum performance standards. It was the radiation therapy utilization at Rex Hospital that brought the average linear accelerator utilization down to 4,766 ESTVs per accelerator.

  UNC states on page 102 of its application and page 564 of Exhibit 24 that "*the CON Section determined in 2012 that Rex Healthcare had demonstrated the need for four linear accelerators.*" UNC is referring to the Agency Findings for CON Project I.D. # J-10063-12 in which Rex Healthcare of Wakefield proposed to replace a linear accelerator. However, UNC is misinterpreting and misstating the CON Agency's decision. Specifically, page 14 of the Agency Findings provide the Agency's determination of conformity to Criterion 3 which state, *In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need to replace the existing linear accelerator and adequately demonstrates all residents of the area will have access to the proposed services. Therefore, the application is conforming to this criterion.*" In its review of Criterion 3, the Agency provides no discussion or analysis of Rex's three linear accelerators located in the hospital facility. The Agency's analysis of Criterion 3 was only with respect to whether Rex Healthcare of Wakefield demonstrated the need to replace the single linear accelerator at that

location. Therefore, the decision rendered in CON Project I.D. # J-10063-12 is isolated specifically to replacement equipment and should not be misrepresented as acknowledgement for the need for anything beyond the scope described therein. Furthermore, the findings for CON Project I.D. # J-10063-12 cannot be used to support the unreasonable projections described in Exhibit 24 of the UNC application, especially in light of declining patient utilization for the four Rex linear accelerators, as shown in the following table.

Average ESTVs per Linear Accelerator, FY2012-FY2013

Provider	FY2012	FY2013	Change
Rex Hospital	4,850	4,530	-6.6%

Source: 2014 SMFP, Proposed 2015 SMFP

Given the available linear accelerator capacity at Rex Hospital and continued decreasing utilization of radiation therapy services at Rex Hospital, the UNC application failed to adequately demonstrate that the proposed project would not result in unnecessary duplication of existing services.

- UNC failed to adequately demonstrate that the four linear accelerators owned by Rex Hospital would be utilized at or above minimum performance standards because its methodology is based on assumptions that are unreasonable and not supported. Specifically, Exhibit 24 provides the projection methodology for Rex's four linear accelerators. In this methodology, UNC projects linear accelerator patient referrals from the six CCNC medical oncologists (who purportedly will join UNC Health Care System) to increase 6.5% annually for the next five years. This is in stark contrast to the recent number of declining patient referrals for these six medical oncologists, as shown in the following table.

UNC HCS CCNS Medical Oncologists
Historical Linear Accelerator Referrals

	Linear Accelerator Referrals	Change
FY12	325	--
FY13	302	-7.1%
FY14*	278	-7.9%

*FY14 data is based on 11 months annualized
Source: CON Project I.D. J-10318-14, Exhibit 24, page 568

The number of linear accelerator patient referrals from the six medical oncologists has decreased consistently since FY12; however, UNC utilized a 6.5% compound annual growth rate that is entirely inconsistent with relevant, recent utilization. This is likely because a 6.5% compound annual growth rate is necessary for UNC to project to achieve the minimum performance standard of 250 patients per linear accelerator. In addition, the application specifically projects a significant redirection of patients from Rex to the UNC Holly Springs site, further exacerbating Rex's underutilization.

Of particular import is the fact that UNC is inconsistent with its growth rate projections for the six CCNC medical oncologists. Specifically, on page 86 of its application, UNC acknowledges "*their referral volume has decreased slightly since its peak in FY2012*". Subsequently, on pages 88-89 of its application, UNC applied population-based growth rates to the six CCNC medical oncologists' patient referrals. UNC failed to acknowledge this assumption in its methodology described in Exhibit 24. Thus, because UNC utilized aggressive growth rates to project CCNC medical oncologist patient referrals, which were also inconsistent with growth rates used previously in the application, the Rex linear accelerator patient projections were not based on reasonable and supported assumptions. Consequently, UNC failed to adequately demonstrate the proposed Holly Springs linear accelerator would not result in unnecessary duplication of existing services.

Comments specific to Criterion 13c

- UNC didn't reasonably project how the elderly and medically underserved groups will be served by its proposed project. First, UNC provides no projection of the payor mix for the proposed Holly Springs linear accelerator, and also provided no historical data regarding the UNC radiation oncology patient payor mix for the Holly Springs service area. It is interesting to note that in Section VI.14 of a 2011 CON application (CON Project I.D. # J-8669-11) for a Rex Holly Springs hospital, UNC did project a new payor mix for a proposed linear accelerator. This is exactly the same geographic location as the proposed UNC Holly Springs linear accelerator, for which UNC now chooses to not provide a payor mix projection. The Agency cannot be expected to find an applicant conforming to Criterion 13c

when the applicant does not specify the extent to which the elderly and medically underserved patients will be served by the proposed new linear accelerator.

- Second, as shown in Sections VI.13 and VI.15, UNC assumes the projected payor mix for the UNC Hospitals Department of Radiation Oncology to be unchanged from its current payor mix. This is unreasonable because UNC defines a different service area for the proposed Holly Springs linear accelerator, which is in a different linear accelerator service area than UNC Hospitals. Holly Springs and Wake County are in Service Area 20, while Chapel Hill and Orange County are in Service Area 14. UNC provides no justification for the unreasonable assumption that its departmental radiation oncology payor mix will be exactly the same as the current payor mix.

  As described on page 107 of its application, during FY2014 UNC received 4.3% of its radiation oncology patients from Harnett County. Also on this page, UNC states that 17.8% of its patients were from Wake County. By contrast, on page 110, UNC projects that 28% of its Holly Springs linear accelerator patients will originate from Harnett County, and that 61% of its patients will be from Wake County. These represent a significantly different projected patient origin than the current patient origin. A problem for UNC is that the demographics of these counties differ significantly from the North Carolina average (North Carolina being the service area for UNC Hospitals, including radiation oncology). In particular, Wake County and Harnett County are both much younger than the North Carolina average. According to the most recent figures from United States Census Bureau, in 2013 14.3% of North Carolinians were below 65 years of age. Yet in Wake County, only 9.7% of citizens are age 65+, and in Harnett County only 10.9% of citizens are elderly (65+). Further, UNC's target primary service area of Wake County is more affluent than the North Carolina average. Again, according to Census Bureau data, in 2013 the median household income in North Carolina is $46,450, with 16.8% of the population living below poverty level. Yet for the same time period, in Wake County the median household income is $65,826 (42% higher than the state average) and 10.9% (35% lower than the North Carolina average) of the Wake County population lives below the poverty level. With such a different demographic representation of UNC's targeted service area, it is completely unreasonable to project no change in the payor mix.

  Comparing UNC and Rex's payor mix and patient origin for their existing services as reported on their respective 2014 hospital license renewal applications is informative on this point. For example, UNC, which derived 16.7% of its

ambulatory surgery patients from Wake and Harnett County, reported 21.9% of ambulatory surgery cases as Medicaid. Rex, by contrast, derived 73.3% of ambulatory surgery patients from Wake and Harnett Counties, and had a much lower Medicaid percentage (only 5.6%) for that service.

On page 144, UNC actually acknowledges that its payor mix for the patients to be served in Holly Springs will differ from the mix it projected using the UNC historical mix, even though it does not include any projection of what the anticipated Holly Springs payor mix might be. UNC then makes a mathematically illogical statement that "the impact of the incremental volume is not expected to change the overall payor mix for UNC Hospital's radiation oncology service". This is an entirely unreasonable claim. A projected payor mix cannot be the same as an historical payor mix if incremental volume associated with a new unique service area is included in the calculations.

For these reasons, UNC is non-conforming to Criterion 13c.

- As previously stated in these comments, approximately one-third of projected patient referrals to the proposed linear accelerator project will be from Rex Healthcare. Given that the historical Medicaid and charity care payor mix of Rex has been low, it would appear that one reason for the deficient and unreasonable payor mix assumptions is an attempt by UNC to use a Medicaid and charity care payor mix that the CON Section would find more favorable. However, it is important to note that while UNC Hospitals has a mandate to care for all North Carolina citizens regardless of their ability to pay, as shown in Attachment 2, UNC Hospitals is one of only two hospitals in North Carolina that receive special considerations with regard to caring for Medicaid patients. Specifically, the North Carolina General Assembly authorized supplemental payments for UNC Hospitals and its physicians who care for Medicaid patients. The inequity of this special treatment has been questioned by many in North Carolina.

Comments specific to Criterion 18a

- UNC did not reasonably demonstrate how any enhanced competition will have a positive impact upon the cost effectiveness and access to the services proposed. In

fact, the UNC application is the least cost-effective option of all the applicants. Specifically, as shown in the tables below, UNC projects the highest charges, reimbursement and cost of any applicant. UNC proposes the highest charges and revenues per patient, and also projects the highest charges, revenues and costs per treatment.

Comparison of UNC Charges, Reimbursement and Costs

Third Operating Year	UNC	Parkway Urology	Duke Raleigh Hospital
Per Patient:			
Gross Revenue	**$59,861**	$53,467	$56,647
Net Revenue	**$22,695**	$18,833	$17,449
Cost	**$10,742**	$17,791	$13,493

Source: CON applications

Third Operating Year	UNC	Parkway Urology	Duke Raleigh Hospital
Per Treatment:			
Gross Revenue	**$3,914**	$1,562	$2,116
Net Revenue	**$1,484**	$550	$652
Cost	**$702**	$520	$504

Source: CON applications

- As previously discussed in these comments, UNC did not reasonably project how the elderly and medically underserved groups will be served by its proposed project. UNC did not project a payor mix for the proposed Holly Springs linear accelerator, yet projects a Holly Springs linear accelerator service area that differs from the UNC radiation oncology service area. Also, the UNC payor mix projection is not reasonable because it unreasonably assumes the same payor mix for the overall UNC Department of Radiation Oncology, despite proposing to serve a market that will differ from that which the Department currently serves. Please refer to the narrative in Criterion 13c for details.

10A NCAC 14C .1903(a)(1) Performance Standard

- The UNC application does not conform to 10A NCAC 14C .1903(a)(1) because the applicant has existing linear accelerators in the radiation therapy service area that do not meet the minimum performance standard of 6,750 ESTVs per machine or 250 patients per machine. The applicant, University of North Carolina Hospitals at Chapel Hill (UNC), owns 100 % of Rex Hospital. Rex Hospital operates four linear accelerators that performed 18,118 ESTVs (average 4,530 ESTVs per machine) on 663 patients (average 166 patients per machine). Therefore, the applicant does not conform to this rule.

10A NCAC 14C .1903(a)(2) Performance Standard

- The UNC application does not conform to 10A NCAC 14C .1903(a)(2) because the Holly Springs linear accelerator patient projections are not based on reasonable and supported assumptions. Please see discussion regarding Criterion 3.

10A NCAC 14C .1903(a)(3) Performance Standard

- The UNC application does not conform to 10A NCAC 14C .1903(a)(3) because the Rex Hospital linear accelerator patient projections are not based on reasonable and supported assumptions. Please see discussion regarding Criterion 6.

#J-10320-14 Parkway Urology, PA

Comments specific to Criterion 1

- Policy GEN-3: Basic Principles of the 2014 SMFP is applicable to review of the Parkway CON application. Policy GEN-3 states:

  "A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

  Parkway did not adequately demonstrate the population to be served or the need the population has for its proposal and therefore, the applicant's projected revenues and expenses are unsupported and unreliable. Thus, Parkway did not demonstrate that the project is a cost effective approach that would maximize healthcare value for resources expended. Please see comments regarding Criteria 3 and 5 for details.

- Parkway did not adequately demonstrate the project would maximize healthcare value for resources expended because Parkway's application contradicts its own CON application just filed two months prior, in which Parkway advocates for addition of a second linear accelerator to expand its prostate health center. Parkway itself does not consider this proposal to be the most effective option. Please see comments regarding Criterion 4.

- Parkway did not adequately demonstrate the project will promote equitable access. Parkway did not reasonably demonstrate how the elderly and medically underserved groups will be served. Please see comments regarding Criterion 13c.

- Consequently, for each of these reasons, Parkway does not conform to Criterion 1.

Comments specific to Criterion 3

- Parkway's methodology for projecting radiation therapy procedures is based on unrealistic assumptions resulting in overstated utilization projections. Specifically, it is unreasonable to project that a "Prostate Health Center" can achieve substantial service area market share in the areas of breast, lung, colorectal, ENT, and gynecological cancer. Page 185 of the application indicates that Parkway projects 22% of its cancer patients will be non-prostate patients. These projections are based on unreasonable assumptions.

  From a common sense perspective, it is highly unlikely that a female patient will seek radiation therapy services from a provider that currently focuses exclusively on prostate cancer. Despite referral estimates from three OB/GYN physicians, patient choice will almost certainly lead the anticipated female patients to an existing radiation therapy provider that has proven experience caring for female cancers. Case in point, Parkway failed to provide any letters from female patients stating their desire to receive breast or gynecological cancer treatment at the Prostate Health Center. Additionally, Parkway points out on page 141 of its application that 57% of early stage breast cancer patients and 49% of late stage breast cancer patients receive some form of surgery (i.e. breast conserving surgery or mastectomy) as part of their cancer treatment. The breast cancer patients who will undergo surgery as part of their treatment will have their care coordinated by a multi-disciplinary team of medical oncologists, oncologic surgeons, and radiation oncologists; however Parkway does not offer surgical services. Parkway provided no information or documentation to describe how it will coordinate surgical services for breast cancer patients. For these reasons, the Parkway market share projections for breast cancer and gynecological cancer patients are not reasonable and unsupported, and the application does not conform to Criterion 3.

  Parkway states on pages 150-151 of its application that 16% of early stage lung cancer patients and 6% of late stage lung cancer patients receive surgery as part of their cancer treatment. The lung cancer patients who will undergo surgery as part of their treatment will have their care coordinated by a multi-disciplinary team of medical oncologists, oncologic surgeons, and radiation oncologists; however Parkway does not offer surgical services. Parkway projects to attain 5% market share for lung cancer cases in Wake County during the initial three years of the proposed project. Parkway provided no information or documentation to describe how it will coordinate surgical services for lung cancer patients. For these reasons,

the Parkway market share projections for lung cancer patients are not reasonable and unsupported, and the application does not conform to Criterion 3.

Parkway states on page 160 of its application that 11% of stage I & II colon cancer patients, 64% of stage III colon cancer patients, and 41% of stage IV colon cancer patients receive surgery as part of their cancer treatment. The colon cancer patients who will undergo surgery as part of their treatment will have their care coordinated by a multi-disciplinary team of medical oncologists, oncologic surgeons, and radiation oncologists; however Parkway does not offer surgical services. Parkway projects to attain 5% market share for colon cancer cases in Wake County during the initial three years of the proposed project. Parkway provided no information or documentation to describe how it will coordinate surgical services for colon cancer patients. For these reasons, the Parkway market share projections for colon cancer patients are not reasonable and unsupported, and the application does not conform to Criterion 3.

- A review of the letters in Exhibit 10 shows physicians who anticipate they will refer up to 2,580 cases per year to the Prostate Health Center. However, it is not apparent in these letters where the patients are being served now and thus, whether it is reasonable to expect this number of referrals to be redirected to the Prostate Health Center. For example, according to page 99 of Parkway's application, approximately 7,306 cancer cases (of the types to be served by the Parkway project) are estimated in the defined service area counties. Given that the number of estimated cancer referrals equates to approximately 35%(2,580 ÷ 7,306) of total cancer cased in the Parkway service area, the accuracy and reliability of these physician estimates is questionable at best. In other words, it is highly unlikely that the 63 physicians in Exhibit 10 are responsible for 35% of all prostate, breast, lung, colorectal, ENT, and genito-urinary cancer referrals in Wake, Harnett, Johnston, Sampson, Franklin, Lee, Duplin, Wayne, and Durham counties. Consequently, the applicant did not adequately demonstrate the reasonableness of the estimated 2,580 referrals to the Prostate Health Center per year and thus failed to substantiate the reasonableness of the applicant's projected market shares.

- Parkway projects the highest ratio of ESTVs per patient of the competing applications. Please refer to the following table.

Comparison of ESTVs per Patient, Project Year 3

	Duke Raleigh Hospital	Parkway Urology	UNC at Holly Springs
Yr. 3 Patients	526	423	275
Yr. 3 ESTVs	12,116	14,431	6,934
ESTVs/Patient	23.0	**34.1**	25.2

Source: #J-10318-14, #J-10320-14, and J-10322-14

Parkway's ratio of ESTVs per patient is over 48% higher compared to DRAH and over 35% higher compared to UNC. Parkway provides no explanation for why its ratio of ESTVs per patient is such an outlier compared to other radiation therapy providers. It is likely that this high ratio of ESTVs per patient is necessary for Parkway to reach the minimum performance standard for two linear accelerators. For example, if the DRAH ratio of 23.0 ESTVs per patient is applied to Parkway's Year Three patient projections then the resulting ESTVs would equal only 9,729 ESTVs which would not meet the minimum performance standards defined in 10A NCAC 14C .1903(a)(2) [23.0 ESTVs x 423 Parkway patients = 9,729 ESTVs ÷ 2 linear accelerators = 4,865 ESTVs per linear accelerator]. For sake of argument, Parkway may claim that their historical ESTVs per patient are comparatively higher because prostate cancer requires more treatments per patient. However, this assumption would invalidate a presumption that this high ratio would continue in the future because Parkway is proposing to no longer exclusively focus on prostate cancer care. Specifically, Parkway projects that 22% of patients will be non-prostate cancer cases. Absent any supported explanation for the unreasonably high ratio of ESTVs per patient, the Parkway application did not demonstrate that its projected utilization is based on reasonable and supported assumptions. Consequently, the application does not conform to Criterion 3.

Comments specific to Criterion 4

- Parkway did not demonstrate that the least costly or most effective alternative has been proposed. In June 2014, Parkway submitted a CON application to add a second linear accelerator, focused on prostate and urological cancer, to its Prostate Health Center. By so doing, Parkway is contending that its June proposal to expand the Prostate Health Center demonstration project by adding a second linear accelerator is the most effective alternative. This is an inherent contradiction of Parkway's August 2014 CON application, which instead proposes to add a second linear accelerator at the Prostate Health Center and change the focus of the center. Parkway itself apparently cannot judge which is the most effective alternative, and thus demonstrates that neither CON application represents the most effective alternative. Therefore, Parkway's application does not conform to Criterion 4.

  Parkway's proposal to convert its prostate health center to a full service radiation oncology treatment center is not the most effective option for an additional key reason. Parkway's Prostate Health Center is a demonstration project, specifically designated by the State Health Coordinating Council and included in the Governor's 2009 State Medical Facilities Plan, to *"focus on the treatment of prostate cancer, particularly in African American men"*[2]. This demonstration project was approved in response to a 2008 petition, submitted by Parkway Urology itself, which claimed that a multidisciplinary center, with urologists and oncologists, is needed *"to focus exclusively on the very complex issues associated with total treatment of prostate and urological cancer"*[3]. Parkway's 2008 petition also states:

  > *"Focus of the equipment is a problem. Application of the State's Methodology has produced centers that treat all types of cancers. In fact, the reviews favor the multidisciplinary centers, focusing on quantities of people served and unit cost per person served. Prostate cancer care is focused and involves more treatments per patient."*[4]

  With this CON application, Parkway is now proposing to switch its Prostate Health Center to a traditional multispecialty radiation oncology treatment center. In fact, on page 27 of its CON application Parkway even states it could change the name of the Prostate Health Center to reflect this proposed change in focus. This is certainly not consistent with the 2008 Parkway special need petition and the need that

---

[2] 2009 State Medical Facilities Plan, page 121.
[3] 2008 Parkway Urology Special Need Prostate Health Center Petition, p. 6.
[4] Ibid. p.9.

Parkway then claimed exist. This is inconsistent with the need determination in the 2009 SMFP, which was specifically for a prostate health center demonstration project, designed to continue for five years. Parkway's Prostate Health Center is only in its second year of operation. Finally, this is not consistent with Parkway's own pledge, as stated in its 2009 CON application:

> *"A project for a linear accelerator that will be involved in the treatment of multiple site cancers, other than urological cancers, cannot truly be 'focused on the treatment of prostate cancer'. The proposed linear accelerator will be used exclusively for the treatment of prostate and urologic cancers. The Prostate Health Center physicians and Staff will be focused on the treatment of prostate cancer. The Prostate Health Center Tumor Board will focus on prostate cancer. The Center proposes an organized African American prostate cancer education/outreach program to partner with and complement the NC Minority Prostate Cancer Awareness Action Team initiatives."*[5]

By its own argument, therefore, Parkway's current proposal to treat a wide variety of cancers would undercut the value of its demonstration project by diluting its focus. Moreover, if Parkway is approved for a second linear accelerator at the Prostate Health Center in order to broaden its scope of service, it will be breaking its own commitment to abide by the conditions of approval of its 2009 CON application, specifically Condition #1:

> *"Parkway Urology, PA, d/b/a Cary Urology, PA shall materially comply with all representations made in the certificate of need application."*[6]

Therefore, Parkway's proposal does not represent the most effective alternative in terms of continuing the demonstration project for a model prostate health center focused on the treatment of prostate cancer, and thus, Parkway's application does not conform to Criterion 4.

---

[5] Parkway 2009 CON application, p.146.
[6] 2009 Linear Accelerator Demonstration Project Agency Findings, p.114.

- Parkway's proposal is not the least cost alternative or most effective alternative because urologist ownership of linear accelerators leads to costly higher referrals for IMRT. In July 2013, the United States Government Accountability Office published a striking study concluding that physicians who could self-refer prostate cancer patients for radiation oncology - that is, urologists and other physicians who owned linear accelerators to which they could refer their prostate cancer patients - were significantly more likely to refer patients for IMRT and less likely to refer them to other, less costly treatments than non-self-referring physicians:

> *Among all providers who referred a Medicare beneficiary diagnosed with prostate cancer in 2009, those that self-referred were 53 percent more likely to refer their patients for IMRT and less likely to refer them for other treatments, especially a radical prostatectomy or brachytherapy. Compared to IMRT, those treatments are less costly and often considered equally appropriate but have different risks and side effects. Factors such as age, geographic location, and patient health did not explain the large differences between self-referring and non-self-referring providers. These analyses suggest that financial incentives for self-referring providers – specifically those in limited specialty groups – were likely a major factor driving the increase in the percentage of prostate cancer patients referred for IMRT.*[7]

This finding was supported by another study published last year in the New England Journal of Medicine:

> *[T]his study shows that men treated by self-referring urologists, as compared with men treated by non–self-referring urologists, are much more likely to undergo IMRT, a treatment with a high reimbursement rate, rather than less expensive options, despite evidence that all treatments yield similar outcomes. The findings raise concerns regarding the appropriate use of IMRT, especially among older Medicare beneficiaries, for whom the risks of undergoing intensive irradiation probably exceed the benefits. Recent evidence suggests that the IMRT self-referral arrangement is becoming more common; by the end of 2011, approximately 19% of urology practices had incorporated IMRT services into their practice. Permitting urologists to self-refer for IMRT may contribute to increased use of this expensive therapy.*[8]

---

[7] GAO 13-525, Medicare: Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny (July 2013)

[8] Jean M. Mitchell, "Urologists' Use of Intensity-Modulated Radiation Therapy for Prostate Cancer," New England Journal of Medicine, 2013; 369:1629-1637 (October 24, 2013). See also Justin E. Bekelman et al., "Effect of Practice Integration between Urologists and Radiation Oncologists on Prostate Cancer

Citing the GAO Report, the American Society for Radiation Oncology (ASTRO) has concluded that "[c]ontrary to the claims of limited specialty [urology] groups, GAO's report confirms that these practices are not truly integrated health care centers, but that they are moneymaking schemes intended to increase volume and achieve high profits."[9] Therefore, compelling evidence supports a conclusion that there is no need for additional urologist-owned linear accelerators as proposed by the Prostate Health Center.

Moreover, as part of the American Board of Internal Medicine's Choosing Wisely initiative, created to promote conversations across multiple medical specialties between patients and physicians to help patients choose care that is supported by evidence and truly necessary, ASTRO has also published a recommendation that all physicians discuss active surveillance without therapy as an option before initiating management of low-risk prostate cancer. Perhaps reflecting this recommendation to consider active surveillance in lieu of therapy for some prostate patients, the 2013 GAO report showed that overall Medicare utilization for prostate-cancer related IMRT (including services provided in hospital outpatient departments and non-self-referring physician offices) began to decrease slightly starting in 2007. GAO Report, Appendix II. The exception was "switchers" who developed the ability to self-refer patients for IMRT; these switchers became 46.6% more likely to refer patients for IMRT after the switch, and 52.2% less likely to refer patients for brachytherapy. GAO Report, p 40.

Treatment Patterns, The Journal of Urology, 2013: DOI: 10.1016/j.juro.2013.01.103 (prostate cancer patients of urologists who own linear accelerators are more likely to receive radiation treatment in lieu of surgery than patients treated by urologists without an ownership stake in the equipment).

[9] August 1, 2003 ASTRO Press Release.

The Prostate Health Center appears to have followed this trend of "switchers" referring significantly more patients for linear accelerator treatments after acquisition of a linear accelerator, despite the national trend of overall flat or declining radiation oncology utilization for prostate patients. In its 2009 application, Cary Urology stated that in its experience, approximately 50% of new prostate cancers are appropriately treated with radiation therapy. (See 2009 application for Project ID J-8331-09, pp. 114 and 193). Including post-surgery EBRT patients, Cary Urology projected a total of 125 patients would receive EBRT either alone or combination with brachytherapy and/or surgery in the first year of service (including prostate, GU, and palliative care patients), or approximately 46% of all patients. See 2009 application, pp. 200 and 202. 9% of all patients were projected to get brachytherapy in the first year of the project. The remainder were projected to have surgery, medical oncology, or a "watchful waiting" approach.

The Prostate Health Center's June 2014 application for Project ID J-10300-14 documents a striking shift in that referral pattern. After the acquisition of a physician-owned linear accelerator to which to refer patients, the Center now reports that 205 patients, or more than 70% of the total, received radiation oncology treatments on its linear accelerator (with an additional 3.5% electing radiation therapy elsewhere). Application, J-10300-14, p. 125. Fewer than 4% of all patients (9 out of 285) received brachytherapy (which as the GAO Report points out is a much cheaper alternative), a significant decrease from the prior treatment rate. The Prostate Health Center offered no explanation for this radical increase in linear accelerator utilization rates for its patients, and the corresponding decrease in brachytherapy, surgery, and watchful waiting. Therefore, any future projections based on the Prostate Health Center's current utilization of its linear accelerator are unreasonable.

Comments specific to Criterion 5

- Parkway did not adequately demonstrate the population to be served or the need the population has for its proposal. Therefore, Parkway did not reasonably demonstrate the immediate and long-term financial feasibility of its LINAC proposal, because its plan is not based upon reasonable projections of the costs of and charges for providing health services. See Criterion 3 for additional discussion.

- Parkway did not reasonably project the extent to which it would serve medically underserved groups with the proposed LINAC. See Criterion 13c for more details. Therefore, Parkway's application does not conform to Criterion 5.

Comments specific to Criterion 6

- Parkway did not adequately demonstrate that projected utilization is reasonable, credible or supported. Therefore, Parkway did not adequately demonstrate in its application that the linear accelerator it proposes to develop in Wake County is needed in addition to the existing linear accelerators in Service Area 20. Please refer to Criterion 3 for additional discussion. Consequently, the application is not conforming to this criterion.

Comments specific to Criterion 13c

- Parkway did not reasonably project how the elderly and medically underserved groups will be served by its proposed project. Parkway's actual payor mix does not approximate the projected payor mix from its 2009 CON application. In particular, the Prostate Health Center documents a surprisingly low percentage of its patients to be served by Medicaid, as shown in the table below.

Parkway Payor Mix Comparison

	2009 Application	Actual/2014 Application
Self-Pay	0.8%	4.3%
Medicare	61.2%	57.7%
Medicaid	**6.8%**	**0.4%**
Commercial/Managed Care	24.4%	11.4%
Other (BCBS/Other)	6.8%	22.2%
TOTAL	100%	100%

Source: CON applications

The Prostate Center's Medicaid population in particular is significantly lower than projected, an unexpected result for a demonstration project to reach out to an underserved population. In fact, its Medicaid population now constitutes a smaller percentage of its radiation oncology patients than the percentages both of its entire practice and specifically of brachytherapy services were at the time of its application in 2009 (1.8% and 6.8% respectively).[10] The Parkway application therefore does not conform to Criterion 13(c) regarding access for underserved patients.

- On page 228, Parkway's historical payor mix table VI.2 totals to only 96%, and therefore is an unreliable basis from which to assess the projected Parkway payor mix.

- As shown in Sections VI.13 and VI.15, Parkway assumes the projected Medicaid payor mix (1.6%) will be four times higher than its current Medicaid payor mix (0.4%). Parkway provides no justification for this unreasonable projection that its Medicaid payor mix, though the lowest of all the applicants, will be 4X its current Medicaid payor mix.

  For all these reasons, Parkway is non-conforming to Criterion 13c.

Comments specific to Criterion 14

- Parkway did not adequately demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area. Parkway's Prostate Health Center opened in May 2013, yet Parkway still does not have any agreement with an area health professional training program.

Comments specific to Criterion 18a

- Parkway did not reasonably demonstrate how any enhanced competition will have a positive impact upon the cost effectiveness of the services proposed. In fact, the Parkway application is not the most cost-effective option of the applicants. Specifically, as shown in the table on the following page, Parkway projects the highest cost per patient of any applicant.

[10] 2009 Application, p. 246.

Comparison of Parkway Charges, Reimbursement and Costs

3rd Operating Yr	UNC	Parkway Urology	Duke Raleigh Hospital
Per Patient:			
Gross Revenue	$59,861	$53,467	$56,647
Net Revenue	$22,695	$18,833	$17,449
Cost	$10,742	**$17,791**	$13,493

Source: CON applications

- Parkway did not reasonably demonstrate how any enhanced competition will have a positive impact upon the access to the services proposed. Specifically, as shown in the table below, Parkway projects the lowest Medicaid access of any applicant.

Comparison of Parkway Projected Payor Mix

Second Operating Year	UNC	Parkway Urology	Duke Raleigh Hospital
Self-Pay	7.2%	5.2%	1.2%
Medicare	41.5%	58.6%	45.7%
Medicaid	12.2%	**1.6%**	4.7%
Commercial/Managed Care	32.5%	8.4%	46.3%
Blue Cross	0.0%	26.2%	0.0%
Other	6.6%	0.0%	2.2%

Source: CON applications

In addition, Parkway projects by far the lowest charity care and bad debt of all the applicants. Please see the following tables.

Comparison of Parkway Projected Charity Care

Second Operating Year	UNC	Parkway Urology	Duke Raleigh Hospital
% of Gross Revenue	9.1%	**4.0%**	8.4%
$ Amount	$3,828,703	**$856,349**	$2,125,877

Source: CON applications

Comparison of Parkway Projected Bad Debt

Second Operating Year	UNC	Parkway Urology	Duke Raleigh Hospital
% of Gross Revenue	11.8%	**0.1%**	1.9%
$ Amount	$4,958,299	**$21,409**	$470,703

Source: CON applications

It is noteworthy that even though the Parkway charity care and bad debt projections pale against the other applicants, they far exceed Parkway's actual charity care and bad debt record. During the 15-month period from May 1, 2013 through July 31, 2014 Parkway's charity care was only $165,815, or 1.3% of gross revenues, and Parkway's total bad debt was only $889, or 0.1% of gross revenues. The credibility of Parkways' charity care and bad debt projections is debatable. At any rate, Parkway is clearly the least effective alternative with regard to access for the medically underserved.

- In recruitment and retention of direct-care personnel, salaries are a significant competitive factor, which influences quality of care. The competing applicants provided the following information in Section VII. DRAH compared the proposed salaries for these key direct-care staff as shown in the table below.

Direct Care Staff Salaries, Year 2

	Duke Raleigh Hospital	Parkway	UNC
RN	$81,737	**$71,991**	$83,159
Radiation Therapist	$87,208	**$71,917**	$88,062

Source: CON Applications, Section VII

Parkway projects by far the lowest salary for both nurses and radiation therapists. Therefore, Parkway is the least effective alternative with regard to direct care staff salaries.

10A NCAC 14C .1903(a)(2) Performance Standard

- The Parkway application does not conform to 10A NCAC 14C .1903(a)(2) because the utilization projections are not based on reasonable and supported assumptions. Please see discussion regarding Criterion 3.

CONCLUSION

In summary, the approved applicant should demonstrate a plan and ability to meet at least the following key objectives:

(1) The extent to which the competing applicants submitted conforming applications;

(2) The extent to which the proposed projects represent a cost-effective alternative; and

(3) The extent to which the proposed projects will increase access to radiation therapy services for the residents of the service area, especially the elderly and medically underserved groups.

DRAH is well positioned to meet the radiation therapy needs of Service Area 20. DRAH is the most experienced provider of radiation therapy services in Wake County, and as such, possesses the expertise necessary to continue to provide the expanded services as proposed in our application. Additionally, the DRAH proposal provides the greatest access to care to residents of the Service Area, and is targeted to serving underserved residents. As described throughout this document, the competing applications do not satisfy all of the CON review criteria. We believe our application demonstrates that DRAH is the most effective alternative that satisfies all CON Review criteria, and comprehensively meets the needs of the entire Service Area as well.

Attachment 1: Rex Hospital, Inc. Restated Articles of Incorporation

20 104 9036

State of North Carolina
Department of the Secretary of State

SOSID: 0184751
Date Filed: 4/13/2000 1:43 PM
Elaine F. Marshall
North Carolina Secretary of State

ARTICLES OF RESTATEMENT FOR NONPROFIT CORPORATION

Pursuant to §55A-10-06 of the General Statutes of North Carolina, the undersigned corporation hereby submits the following for the purpose of restating its Articles of Incorporation.

1. The name of the corporation is: Rex Hospital, Inc.

2. The text of the Restated Articles of Incorporation is attached.

3. (*Check a, b, c, and/or d, as applicable.*)

   a. _____ These Restated Articles of Incorporation were adopted by the board of directors and do not contain an amendment.

   b. _____ These Restated Articles of Incorporation were adopted by the board of directors and contain an amendment not requiring member approval. (*Set forth a brief explanation of why member approval was not required for such amendment.*)_____
   _____

   c. ___X___ These Restated Articles of Incorporation contain an amendment requiring member approval, and member approval was obtained as required by Chapter 55A of the North Carolina General Statutes.

   d. _____ These Restated Articles of Incorporation contain an amendment requiring approval by a person whose approval is required pursuant to N.C.G.S. §55A-10-30, and such approval was obtained.

4. These articles will be effective upon filing, unless a delayed date and/or time is specified:_____

This the 13th day of April , 2000

Rex Hospital, Inc.
Name of Corporation

James B. Hyler Jr.
Signature

James B. Hyler, Jr., Chairman
Type or Print Name and Title

Notes:
1. Filing fee is $10, unless the Restated Articles of Incorporation include an amendment, in which case the filing fee is $25. This document and one exact or conformed copy of these articles must be filed with the Secretary of State.

(Revised January 2000) *(Form N-03)*
CORPORATIONS DIVISION P.O. BOX 29622 RALEIGH, NC 27626-0622

AMENDED AND RESTATED

ARTICLES OF INCORPORATION

OF

REX HOSPITAL, INC.

ARTICLE I

The name of the corporation is REX HOSPITAL, INC.

ARTICLE II

The period of duration of the corporation shall be perpetual.

ARTICLE III

The purposes for which the corporation is organized are:

(i) To promote and advance charitable, educational and scientific purposes by supporting and operating for the benefit of and to carry out the purposes of the University of North Carolina Health Care System.

(ii) To own, lease, establish, maintain and operate hospitals, clinics, and other related facilities to provide for the care and treatment of persons suffering from illnesses, injuries or disabilities which require hospital care, all of which shall be open to the general public, free of discrimination based upon race, creed, color, sex or national origin.

(iii) To supply modern equipment and facilities to aid in the diagnosis and treatment of disease, and to furnish to the staff of physicians and surgeons who practice in its hospitals an

opportunity to offer to their patients, quickly and economically, the sum of their combined skill and experience.

(iv) To furnish to the said staff of physicians and surgeons the use of such physical equipment for the practice of their profession as will enable them with minimum hardship to give their best efforts without compensation to those unable to pay for their services, as well as to facilitate them in their service to patients who are able to pay.

(v) To furnish the equipment and organization for the instruction and training of doctors, nurses, and technicians in order to carry forward in the future the plan herein set out for the alleviation of disease, and to grant diplomas or certificates in connection with such instruction or training.

(vi) To carry on any educational activities related to the care of the sick and disabled and the promotion of health and preventive medicine, which in the opinion of the Board of Directors may be justified by the facilities, personnel, funds, or other resources that are, or can be made available.

(vii) To aid, as far as practicable, in the instruction and promotion of research and scientific investigation in all branches of medicine and surgery.

(viii) To participate, so far as circumstances may warrant, in any activity designed and carried on to promote the general health of the community.

(ix) To appoint a medical staff composed of such physicians and surgeons as may be recommended by the medical staff, who, in the judgment of the Board of Directors, are properly qualified to conduct the professional work of the hospital, and including trained and experienced

technicians, and to promulgate suitable rules governing the conduct of all physicians, surgeons, and technicians who are permitted to practice in said hospital.

(x) To use the revenues of the corporation and the profits, if any, for the purpose of affording hospital care to those unable to pay for the same, promoting betterment of public health, to maintain its hospitals and equipment in good repair and modern condition, and in general to use, invest, and hold all revenues and the profits, if any, for the purposes for which this corporation is organized.

(xi) To assume and pay any just debts of the hospital which may have been incurred prior to its incorporation.

(xii) To solicit, accept and acquire by gift, devise, bequests or otherwise donations, money and property of every kind, nature and description, from any person, firm or corporation, including any municipality, county, state or the United States of America, and to hold, manage, administer, use and invest such money and property and to apply the principal or interest as may be directed by the donor, or as the Board of Directors or member of the corporation may determine in the absence of such direction.

(xiii) To make donations, transfer assets and provide other forms of aid and assistance to, for the benefit of, or in connection with the University of North Carolina Health Care System and its charitable, tax-exempt affiliates, and otherwise to promote, by guarantee, loan or otherwise, the interests of the University of North Carolina Health Care System and its charitable, tax-exempt affiliates.

(xiv) In furtherance of the foregoing, and otherwise, to engage in any and all activities ordinarily carried on by a nonprofit corporation.

ARTICLE IV

The corporation shall have a sole member. The sole member of the corporation shall be Rex Healthcare, Inc., which is a North Carolina nonprofit corporation exempt from Federal Income Tax under Section 501(c)(3) of the Internal Revenue Code of 1986.

ARTICLE V

No part of the net earnings of the corporation shall inure to the benefit of or be distributable to its member, directors, officers, or other private persons, except that the corporation shall be authorized and empowered to pay reasonable compensation for services rendered and to make payments and distributions in furtherance of the purposes set forth in Article III above. No substantial part of the activities of the corporation shall be the carrying on of propaganda, or otherwise attempting to influence legislation, and the corporation shall not participate in, or otherwise intervene in (including the publishing or distribution of statements) any political campaign on behalf of any candidate for public office. Notwithstanding any other provisions of these articles, the corporation shall not carry on any other activities not permitted to be carried on (a) by a corporation exempt from Federal Income Tax under Section 501(c)(3) of the Internal Revenue Code of 1986 (or the corresponding provision of any future United States Internal Revenue Law) or (b) by a corporation, contributions to which are deductible under Section 170(c)(2) of the Internal Revenue Code of 1986 (or the corresponding provision of any future United States Internal Revenue Law).

ARTICLE VI

Upon the dissolution of the corporation, the corporation shall, after paying or making provision for the payment of all of the liabilities of the corporation, dispose of all of the assets of the corporation to the University of North Carolina Health Care System in accordance with the provisions of Article 14 of Chapter 55A of the General Statutes of North Carolina, exclusively for the purposes of the corporation, or, if the University of North Carolina Health Care System is not then exempt from federal income tax under Section 501(c)(3) of the Internal Revenue Code of 1986 (or the corresponding provision of any future United States Internal Revenue Law), then to such other organization or organizations organized and operated for substantially the same purposes as this corporation or exclusively for charitable, educational, religious or scientific purposes as shall at the time qualify as an exempt organization or organizations under Section 501(c)(3) of the Internal Revenue Code of 1986 (or the corresponding provision of any future United States Internal Revenue Law), as the member and Board of Trustees shall determine.

ARTICLE VII

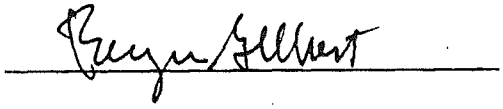
The number, manner of election or appointment and removal, the qualifications and the term of directors shall be as set forth in the bylaws of the corporation. Such provisions shall not be in conflict with the provisions and requirements of Chapter 55A of the General Statutes of North Carolina.

ARTICLE VIII

All corporate powers shall be exercised by or under the authority of, and the affairs of the corporation managed under the direction of, the Board of Directors of the corporation except such powers as are expressly reserved to the University of North Carolina Health Care System by law or by these articles of incorporation or the bylaws of the corporation.

ARTICLE IX

The street and mailing address of the registered office of the corporation in North Carolina is 101 Manning Drive, Chapel Hill, Orange County, North Carolina, 27514, and the name of the registered agent at such address is Benjamin Gilbert. The agent's written consent to appointment appears below:



Benjamin Gilbert

ARTICLE X

The street and mailing address of the principal office of the corporation in North Carolina shall be 4420 Lake Boone Trail, Raleigh, Wake County, North Carolina, 27607.

ARTICLE XI

The approval of the University of North Carolina Health Care System, pursuant to North Carolina General Statutes Section 55A-10-30, shall be required for the merger of the corporation, for the sale of assets other than in the regular course of activities of the corporation and for the dissolution of the corporation.

Attachment 2: Supplemental Payments to Eligible Medical Professional Providers

Center, which was previously known as Pitt County Memorial Hospital, and their base rates shall not be included in the calculation of the statewide median rate.

SUPPLEMENTAL PAYMENTS TO ELIGIBLE MEDICAL PROFESSIONAL PROVIDERS

SECTION 12H.13.(a) Effective July 1, 2014, supplemental payments that increase reimbursement to the average commercial rate for certain eligible medical providers described in the Medicaid State Plan, Attachment 4.19-B, Section 5, Pages 2 and 3, shall be modified as follows:

(1) The number of eligible medical professional providers shall be limited as follows:
   a. 418 with the East Carolina University (ECU) Brody School of Medicine.
   b. 1,176 with the University of North Carolina at Chapel Hill (UNC) Faculty Physicians.
   c. 14 with the UNC Hospitals Pediatric Clinic.
   d. 75 with UNC Physicians Network.
   e. 18 with Chatham Hospital.

(2) Supplemental payments shall not be made for services provided in Wake County.

The Department of Health and Human Services shall not make any other modifications to the portion of the Medicaid State Plan referenced in this section, except as provided herein.

SECTION 12H.13.(b) Beginning on December 31, 2014, and annually thereafter, UNC and ECU shall submit an annual report based on their preceding fiscal year to the Joint Legislative Oversight Committee on Health and Human Services containing all of the following information for each individual provider for whom this supplemental payment is received:

(1) For each service provided by the provider and for which the supplemental payment is received, the location where the service was provided, including county, municipality, and zip code.

(2) The percentage of the provider's total time spent serving Medicaid recipients annually that is for services provided at locations other than the ECU Brody School of Medicine, the Firetower Medical Office, or the UNC School of Medicine.

(3) The amount of Medicaid reimbursement for each service for which a supplemental payment was made for services provided by the provider.

(4) On an annual basis, the percentage of the provider's time spent engaging in the following:
   a. Clinical patient care.
   b. Teaching.
   c. Research.
   d. Other activities.

SECTION 12H.13.(c) Any State plan amendments required to implement this section shall not be subject to the 90-day prior submission requirement of G.S. 108A-54.1A(e).

COST SETTLE NORTH CAROLINA UNIVERSITY HOSPITALS AT SAME RATE AS OTHER HOSPITALS

SECTION 12H.13A. Effective July 1, 2014, the settlement for outpatient Medicaid services performed by UNC Hospitals and Vidant Medical Center, which was previously known as Pitt County Memorial Hospital, shall be done at seventy percent (70%) of costs.

REPEAL SHARED SAVINGS PROGRAM; MAINTAIN CERTAIN RATE REDUCTIONS

SECTION 12H.14.(a) All subsections of Section 12H.18 of S.L. 2013-360, except for subsection (b), are repealed.

SECTION 12H.14.(b) Section 12H.18(b) of S.L. 2013-360 reads as rewritten:

"**SECTION 12H.18.(b)** During the 2013-2015 fiscal biennium, the Department of Health and Human Services shall ~~withhold~~ reduce by three percent (3%) ~~of~~ the payments for the

MEDICAL ASSISTANCE
State: NORTH CAROLINA
PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICES

(c) Supplemental Payments

(1) Supplemental payments will be made to Eligible Medical Professional Providers. These supplemental payments will equal the difference between the Medicaid payments otherwise made under this state plan and the Average Commercial Rate Payment. These supplemental payments will, for the same dates of service, be reduced by any other supplemental payments for professional services found elsewhere in the state plan.

(2) Eligible Medical Professional Providers must meet all of the following requirements. An Eligible Medical Professional Providers must be:

(i) Physicians paid under this Section 5, and other professionals paid under Section 6a-d or Section 17 of this Attachment; and

(ii) Licensed in the State of North Carolina and eligible to enroll in the North Carolina Medicaid program as a service provider; and

(iii) Employed by, contracted to provide a substantial amount of teaching services, or locum tenens of the state-operated school of medicine (SOM) at East Carolina University or the University of North Carolina at Chapel Hill, or employed or locum tenens within the University of North Carolina Health Care System. A professional "contracted to provide a substantial amount of teaching services" is a professional where all or substantially all of the clinical services provided to patients by that contracted professional involves supervision and/or teaching of medical students, residents, or fellows.

Except for professional providers in a Hospital-Based Group Practice, Eligible Medical Professional Providers shall exclude any professional provider that is a member of a group practice acquired or assimilated by the UNC HCS after July 1, 2010. A Hospital-Based Group Practice includes professional providers with the following hospital-based specialties: anesthesiology, radiology, pathology, neonatology, emergency medicine, hospitalists, radiation-oncology, and intensivists.

For a group practice that does not consist of professional providers employed by the SOM, is not a Hospital-Based Group Practice, and was included within the UNC HCS on or before July 1, 2010, the number of Eligible Medical Professional Providers in the group practice may not increase beyond the number of Eligible Medical Professional Providers in the group practice as of July 1, 2010.

(3) Supplemental payments will be made quarterly and will not be made prior to the delivery of services.

(4) The Quarterly Average Commercial Rate to be paid will be determined in accordance with the following calculation.

(i) Compute Average Commercial Fee Schedule: Compute the average commercial allowed amount per procedure code for the top five payers with payment rates. The top five commercial third party payers will be determined by total billed charges. If there are any differences in payment on a per billing code basis for services rendered by different types of medical professionals, the Department will calculate separate Average Commercial Fee Schedules to reflect these differences. The data used to develop the Average Commercial Fee Schedule(s) will be based upon payments from the most recently completed state fiscal year. The Average Commercial Fee Schedules will be computed at least once per fiscal year.

(ii) Calculate the Quarterly Average Commercial Payment Ceiling: For each quarter of the current fiscal year, multiply the Average Commercial Fee Schedule amount, as determined in Paragraph (c)(4)(i) above, by the number of times each procedure code was rendered and paid in the quarter to the Eligible Medical Professional Providers on behalf of Medicaid beneficiaries as reported by the MMIS. If applicable, a separate payment ceiling will be set when payment for the same service differs according to the type of professional rendering the service. The sum of the product for all procedure codes will determine the Quarterly Average Commercial Payment Ceiling.

(5) Supplemental Payments to be paid will be determined in accordance with the following calculation:

(i) Determine the Quarterly Supplemental Payment Ceiling at the Average Commercial Rate using the following formula:

(Quarterly Average Commercial Payment per CPT Code) as calculated x (Medicaid Volume per CPT Code) = Quarterly Supplemental Payment Ceiling at the Average Commercial Rate calculated as outlined in section (4) paragraph (i).

(ii) Supplemental Payments will equal the Quarterly Supplemental Payment Ceiling at the Average Commercial Rate less the total Medicaid payments made for the quarter to Eligible Medical Professional Providers for the procedure codes included in the calculation of the Average Commercial Fee Schedule in paragraph (4)(i) above, as reported from the MMIS. Medicaid volume and payments shall include all available payments and adjustments.