Competitive Comments on Service Area 20 Linear Accelerator Applications

submitted by

University of North Carolina Hospitals at Chapel Hills

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), University of North Carolina Hospitals at Chapel Hill (UNC Hospitals) submits the following comments related to competing applications to develop an additional linear accelerator in Service Area 20 to meet a need identified in the 2014 State Medical Facilities Plan (SMFP). UNC Hospitals' comments include "discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards." See N.C. GEN. STAT. § 131E-185(a1)(1)(c). In order to facilitate the Agency's ease in reviewing the comments, UNC Hospitals has organized its discussion by issue, specifically noting the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity relative to each issue, as they relate to the following applications:

- UNC Hospitals Radiation Oncology, Holly Springs Campus (UNC Hospitals), Project ID #J-10318-14
- Duke University Health System d/b/a Duke Raleigh Hospital (Duke Raleigh), Project ID # J-10322-14
- The Prostate Health Center (TPHC), Project ID # J-10320-14

GENERAL COMMENTS

Background Regarding Linear Accelerator Need in Service Area 20

Since 2007, two additional linear accelerators in Service Area 20 have been awarded and one additional unit is currently under review. None of these three linear accelerators were the result of a need determination generated by the standard methodology in the *State Medical Facilities Plan (SMFP)*. The 2007 SMFP included a special need adjustment for one additional linear accelerator in Service Area 20 while linear accelerator utilization in Table 9H suggested a surplus of 1.57 units. The CON for that linear accelerator was awarded to CCNC and was recently approved to be transferred by Duke Raleigh but is still undeveloped. The 2009 SMFP included a need for a statewide demonstration project for a multidisciplinary prostate health center to include a linear accelerator. The Prostate Health Center (TPHC) was awarded a Certificate of Need to develop that linear accelerator in Raleigh while linear accelerator utilization shown in Table 9F suggested a surplus of 1.86 units. The linear accelerator in the current review is the result of a special need adjustment in the 2014 SMFP which shows a linear accelerator surplus of 2.32 units in Table 9G , excluding TPHC's inventory and utilization.

Service Area 20 Linear Accelerator Deficit/(Surplus)

SMFP Year	Linear Accelerator Deficit/(Surplus)
2007	(1.57)
2008	(2.31)
2009	(1.86)
2010	(1.77)
2011	(1.95)
2012	(2.43)
2013	(2.41)
2014	(2.32)

Source: 2007 to 2014 SMFPs.

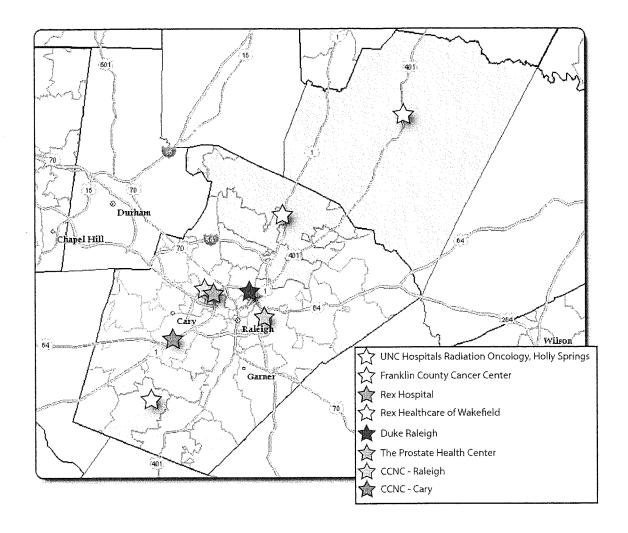
Data from the *SMFP* suggests that the utilization of Service Area 20 providers has not been sufficient to generate the need for additional capacity for at least seven years and yet three additional units have become available to the population. UNC Hospitals believes that the underutilization of existing Service Area 20 providers can in part be attributed to two factors: the lack of geographic access for radiation therapy services within the service area and the outmigration of patients to nearby academic medical centers. <u>UNC Hospitals' proposal is the only project that will address both of these issues; the proposals from Duke Raleigh and TPHC fail to address either.</u> Specifically, UNC Hospitals proposes to develop a new site for linear accelerator care which it expects will increase geographic access to radiation therapy in Wake County and as a

result is likely to increase the utilization of linear accelerators in the county. Additionally, UNC Hospitals proposes to reduce the outmigration of Service Area 20 patients by shifting Service Area 20 patients who currently seek care at UNC Hospitals linear accelerators in Chapel Hill to the proposed UNC Hospitals' site in Holly Springs. By contrast, Duke Raleigh proposes to add capacity at an existing site of linear accelerator care and does not propose to reduce outmigration of patients by shifting patients to that linear accelerator. Similarly, TPHC proposes to add capacity at an existing site of linear accelerator care and does not propose to reduce outmigration of patients.

UNC Hospitals believes this is a vital distinction as its proposal is the only one of the three applications that will increase access to, and utilization of, linear accelerators in Service Area 20 overall, in particular by better distributing linear accelerator equipment throughout the service area. Duke Raleigh and TPHC's applications will merely shift patients from existing sites of care within Wake County. As a result, these latter two proposals will only serve to exacerbate the underutilized linear accelerator resources that exist within the service area. Moreover, TPHC's application proposes to shift patients from several outlying counties such as Sampson and Wayne which will further decrease the utilization of the linear accelerators in those counties (both of which have underutilized linear accelerators). Without a compelling reason demonstrating that patients should leave their home counties and travel many miles for care that involves daily treatments (which TPHC does not provide), its proposal serves to unnecessarily duplicate the resources existing in those counties and available to the residents of those counties.

Expansion of Geographic Access

As provided by the Access Basic Principle in the *SMFP* and exemplified by numerous comparative reviews by the Agency, applicants that propose greater geographic access to services are encouraged and given preference. UNC Hospitals is the only applicant to offer increased geographic access in the current review. As shown in the map below of the existing and proposed Service Area 20 linear accelerators, UNC Hospitals' proposal will add access to linear accelerator services in southern Wake County, whereas Duke Raleigh and TPHC will add capacity to existing sites.



Notably, geographic access is of greater importance in assessing the comparative value of linear accelerator projects, particularly in light of the underutilization of linear accelerator capacity in Wake County. As discussed in UNC Hospitals' application (pages 73-74), its medical director, Dr. Lawrence Marks, co-authored a study that found that increasing local access to radiation therapy services increases utilization. The study, which followed breast cancer patients to examine the effects of expanded access to radiation therapy on treatment choice was published in the *International Journal of Radiation Oncology, Biology and Physics* and concluded:

There was an increased utilization of BCT [breast conserving therapy] at a community hospital following the opening of an on-site radiotherapy facility. As there were no known changes in demographics or surgical staffing during the evaluated period, the effect can be ascribed to the accessibility of the on-site radiation treatment unit and an active presence of radiation oncologists. The five mile distance between the community hospital and the tertiary care facility [prior to opening the radiotherapy unit, breast irradiation for BCT was available at a

major tertiary care center located only five miles from the community hospital] appears to be a larger barrier to BCT than might be expected.

The data provided through this study indicated that a five-mile travel distance affected patients' use of radiation oncology services and suggested that greater distances may create a more significant impact in utilization of these particular services. Please see Exhibit 21 in the UNC Hospitals application for the study documentation and Exhibit 26 in the UNC Hospitals application for Dr. Marks' letter of support which refers to the study. Based on this study, it is likely that the enhanced accessibility through the development of UNC Hospitals' proposed Holly Springs site, combined with the active presence of radiation oncologists, will increase access and could lead to higher utilization for the local population. Since the nearest site is much more than five miles away, it is likely that the utilization of radiation therapy services will increase with the expanded access provided by UNC Hospitals' proposal.

UNC Hospitals is the only applicant that proposes to increase geographic access and thus is the only applicant that will increase the radiation therapy utilization of the Service Area 20 population. Both Duke Raleigh and TPHC propose to shift patients from other providers as demonstrated by the assumed increased market share in both applications. The shift of patients from existing providers proposed by Duke Raleigh and TPHC will not only serve to unnecessarily duplicate existing resources but will fail to expand access to patients who face geographic barriers.

Outmigration of Patients

UNC Hospitals is the only applicant that proposes to develop capacity to increase the number of people in Service Area 20 served by equipment located in Service Area 20. Service Area 20 patients are currently leaving the area for care and UNC Hospitals' proposal is the only one of the three under review that will reduce that outmigration. According to 2014 Hospital License Renewal and Registration and Inventory of Medical Equipment data, 23 percent of Service Area 20 patients leave for linear accelerator care. Of note, the top two locations where these patients seek care are UNC Hospitals and Duke University Hospital, two large academic medical centers in nearby counties.

FFY 2013 Service Area 20 (Wake and Franklin) Linear Accelerator Patients by Site of Care

Facility	Patients	% of Total
Rex Hospital	591	31.0%
CCNC	558	29.3%
Duke Raleigh Hospital	299	15.7%
Franklin County Cancer Center	21	1.1%
Service Area 20 Sites of Care Subtotal	1,469	77.0%
UNC Hospitals	212	11.1%
Duke University Hospital	130	6.8%
Clayton Radiology Oncology	47	2.5%
Maria Parham Medical Center	13	0.7%
Duke Regional Hospital	12	0.6%
Wilson Medical Center	10	0.5%
Smithfield Radiation Oncology	5	0.3%
Vidant Medical Center	2	0.1%
Nash General Hospital	2	0.1%
High Point Regional Health System	1	0.1%
Southeastern Regional Medical Center	1	0.1%
FirstHealth Moore Regional Hospital	1	0.1%
NC Radiation Therapy - Greenville	1	0.1%
NC Radiation Therapy - Goldsboro	1	0.1%
Outmigration Subtotal	438	23.0%
Total	1,907	100.0%

Source: 2014 Hospital License Renewal Application and Registration and Inventory of Medical Equipment.

UNC Hospitals is the only applicant that proposes to reduce the number of Service Area 20 patients that leave the service area for care by shifting patients from the UNC Hospitals location in Chapel Hill to the proposed site in Holly Springs. Please note that while Duke Raleigh's application discusses shifting patients from Duke University Hospital, it proposes that those patients will be shifted to existing equipment at former CCNC sites, not to its proposed additional linear accelerator; thus, this shift will occur irrespective of the approval of its application, and not as a result of the proposed project. UNC Hospitals proposes to shift 44 Wake County patients in the third project year from UNC Hospitals' campus in Orange County to its proposed Holly Springs campus in Wake County (see page 85 of the UNC Hospitals application). These 44 patients will reduce the outmigration of Service Area 20 patients and increase the utilization of Service Area 20 linear accelerators. By contrast, Duke Raleigh and TPHC propose to shift Service Area 20 patients from other providers through market share gains as demonstrated in both applications. The shift of patients proposed by Duke

Raleigh and TPHC from existing providers will not only serve to unnecessarily duplicate existing resources and will fail to result in better utilization of linear capacity.

Reasonableness of Utilization Projections

Because Duke Raleigh and TPHC's applications assume the shift of patients from existing providers and overstate the number of linear accelerator patients in the market, their projection methodologies are exceptionally aggressive and exhibit growth in patient volumes that far exceeds reasonable assumptions. By contrast, UNC Hospitals' application relies on the shift of existing patients within the UNC Health Care System, in particular the referral of patients from Wake, Harnett, and Lee counties who currently seek care at UNC Hospitals in Chapel Hill to Holly Springs. As a result, UNC Hospitals' projection methodology is reasonable and conservative. The tables below calculated the growth rates assumed by each applicant based on a comparison of existing patient volumes, including the cases expected to shift to Wake County locations, and projected patient volumes. As shown, both Duke Raleigh and TPHC project double-digit growth in every year until project year three. By comparison, UNC Hospitals projects 2.2 percent growth annually which is more reasonable, conservative, and supported by actual linear accelerator utilization data, population growth, and its historical experience.

Duke Raleigh Projected Growth of Linear Accelerator Patients

Source/Site	Existing (2014)	Projected (2018)	CAGR*
Duke Raleigh Hospital^	411	526	6.4%
CCNC to Shift [†]	372	718	17.9%
Duke University Hospital to Shift to Duke Raleigh Acquired CCNC Sites**	36	38	1.5%
Total	819	1,282	11.9%

^{*}Compound annual growth rate.

The Prostate Health Center Projected Growth of Linear Accelerator Patients

	Existing (2014)	Projected (2018)	CAGR
Total Patients	205	423	19.9%

Source: Existing from page 113, projected from page 185.

[^]Page 95.

 $^{^{\}dagger}$ CCNC 2014 corrected for 46 percent shift to UNC Health Care System, as described below. Thus, CCNC 2014 = $372 = 689 \times (1 - 46\%)$. See pages 4 and 8 of narrative in Exhibit 19.

^{**2014} Duke Shift calculated based on 10 percent assumed shift x 2014 volumes shown on page 9 of narrative in Exhibit 19 (36 patients = $10\% \times [17 + 19 + 34 + 23. + 265]$). See page 10 of narrative in Exhibit 19 for 2018 volumes.

UNC Health Care System in Wake County Projected Growth of Linear Accelerator Patients

Source/Site	Existing (2014)	Projected (2019)	CAGR
UNC Hospitals to Shift to Holly Springs Site*	101	111	2.0%
CCNC to Shift (both to Rex and Holly Springs)	278	381	6.5%
Rex Hospital (Existing Patients - Does Not Include Shift from CCNC)	674	684	0.3%
Total	1,053	1,176	2.2%

^{*}UNC Hospitals to Shift to Holly Springs calculated based on pages 83-85. 2014 volume calculated based on 50 percent shift of Holly Springs Service Area patients, 50 percent shift of Harnett County patients, and 25 percent shift of Lee County patients (101 patients = $50\% \times 77 + 50\% \times 78 + 25\% \times 93$).

It is clear from the above comparison that UNC Hospitals proposal includes reasonable utilization projections, whereas the projections provided by Duke Raleigh and TPHC simply are beyond belief.

THE PROSTATE HEALTH CENTER (TPHC)

TPHC's application should not be approved as proposed. In summary, TPHC has submitted an unnecessary application which could result in the addition of two linear accelerators and it has failed to demonstrate the need for its project.

UNC Hospitals has identified the following specific issues, each of which contributes to the application's non-conformity:

- (1) Submission of an Unnecessary Application
- (2) Failure to Demonstrate the Need Based on Prior Application
- (3) Failure to Propose the Most Effective Alternative
- (4) Overstated Market Need
- (5) Unsupported Assumptions for Palliation Patients
- (6) Unsupported Market Share Assumptions
- (7) Failure to Provide Required Services of Demonstration Project
- (8) Failure to Demonstrate the Financial Feasibility of the Project

Submission of an Unnecessary Application

In June 2014, TPHC submitted a CON application requesting an additional linear accelerator to add to its demonstration project for a multidisciplinary prostate health center (Project ID # J-10300-14). In that application and subsequent materials filed in response to comments, TPHC asserted that it could add linear accelerator capacity without regard to need determinations in the *SMFP* because there were no applicable need methodologies or policies. In August 2014, TPHC submitted a CON application (identical in scope and intent) in response to a need determination for an additional linear accelerator in Service Area 20 (Project ID # J-10320-14). Simply put, TPHC cannot have it both ways. It is contradictory for TPHC to argue that it can add capacity without regard to the *SMFP* and that it can add capacity in response to a need determination.

If the SMFP "neither provides nor prohibits a specific mechanism" to add capacity at TPHC as argued (see page 71 of Project ID # J-10300-14), then it cannot also be true that TPHC can add capacity in response to a need determination in Service Area 20. If "the only way to assure that the demonstration model's focus on prostate cancer is not constrained to meet the increasing demand for its services, when our linear accelerator reaches capacity is to apply in the separate Certificate of Need application batch set aside for demonstration projects located in HSA IV, which we have done", then it cannot also be true that TPHC can apply for a need determination in Service Area 20 (see page 6 of Kevin Khoudary's presentation at the public hearing for Project ID # J-10300-14).

If "there is no need determination in the State Medical Facilities Plan applicable to the statewide service area of The Prostate Health Center" as stated in Renee Montgomery's

memo provided as Attachment D to TPHC's Response to Comments for Project ID # J-10300-14, then it cannot also be true that TPHC can respond to a need determination in Service Area 20 with an identical proposal. Ms. Montgomery further argues that "[t]he comment has been made that if The Prostate Health Center needs a second linear accelerator, it could apply for the allocation of a linear accelerator in Service Area 20 (Wake and Franklin Counties) in the 2014 SMFP. This argument ignores the fact that this application is to expand linear accelerator capacity to meet the needs of The Prostate Health Center's demonstration project which has a statewide service area. For that reason, The Prostate Health Center has filed this application for the review to begin July 1, 2014 which includes Category J - the category that includes demonstration projects." Clearly, TPHC has argued that the Service Area 20 need determination is not applicable to the needs of its facility. Therefore, it is entirely inconsistent for TPHC to propose to meet the need for a linear accelerator in Service Area 20 in its current application. Given its statements and actions, it is clear that TPHC's current application (J-10320-14) is an unnecessary application filed in an attempt to coerce its competitors to withdraw their opposition to its prior application (J-10300-14). TPHC intends to use its current application as leverage in any future mediation or litigation in order to pressure its competitors to allow it to add a linear accelerator. The Agency should not permit TPHC to do so and deny both applications.

UNC Hospitals believes that TPHC's prior application (J-10300-14) should be denied as it seeks to add linear accelerator capacity for which there is no need determination, a position that is detailed in the comments filed by Duke University Health System, Rex Hospital, and WakeMed Health & Hospitals. While TPHC argued that "the only way" it could add capacity was through an application submitted for a Category J review, it is perfectly clear that is not true. Only two months later, TPHC submitted an application (J-10320-14) to add capacity in response to the Service Area 20 linear accelerator need determination. This second application to add capacity confirms that TPHC's prior application should be denied.

As discussed in detail above, TPHC's application is filed in contradiction to its prior statements and was filed with the intention to coerce its competitors rather than to meet the need for linear accelerator services. TPHC should be found non-conforming with Criterion 1, 3, and 6.

Failure To Demonstrate the Need Based on Prior Application

TPHC is not precluded from applying for the Service Area 20 need determination; however, its current application should be denied for the reasons detailed throughout these comments. In particular, TPHC's current application proposes to add a linear accelerator and its prior application, currently under review, also proposes to add a linear accelerator.

TPHC states in its application that "[w]hen this Certificate of Need is awarded, [it] will withdraw the application for a second linear accelerator ... filed in June 2014 [J-10300-14]" (page 2). This statement is simply inadequate to determine that TPHC will not develop two additional linear accelerators. If the Agency approves Project ID # J-10330-14 and issues a CON prior to the resolution of the current application, then TPHC will not be able to withdraw its prior application any longer as the application will no longer be under review. If the Agency denies Project ID # J-10300-14 and TPHC appeals the decision, then TPHC will still not be able to withdraw its prior application any longer as it will no longer be under review.

If both applications are approved, TPHC would operate three linear accelerators. Said another way, TPHC's current application is a proposal to add a third linear accelerator to its facility. However, TPHC's entire application assumes that it will only operate two linear accelerators. As such, its utilization projections, financial statements, documentation of financing, staffing projections, construction design, etc. are inadequate to demonstrate the project's conformity with the review criterion. TPHC has failed to demonstrate the need for its three proposed linear accelerators in the current application. As such, TPHC's application should be denied.

TPHC's application if approved could result in three linear accelerators and its application fails to demonstrate the need for that capacity or that it would be financially feasible. TPHC should be found non-conforming with Criterion 3, 4, 5, 6, 7, 12, and 18a.

Failure to Propose the Most Effective Alternative

As noted above, TPHC submitted a CON application in June 2014 to acquire an additional linear accelerator. That application proposed to serve prostate and genitourinary cancer patients only on its linear accelerators. TPHC argued that additional capacity was needed as the demand for its unique services exceeded its capacity. TPHC stated that:

The unmet need that necessitates a second linear accelerator at The Prostate Health Center has several dimensions.

• The importance of <u>a center dedicated to prostate health in North Carolina</u>. The Prostate Health Center is <u>unique</u> in the state in its focus on men's urological health, its combination of outreach and prevention with treatment and research and its close alignment of specialty care providers with primary care.

- The need in the 2014 State Medical Facilities Plan (SMFP) for a Demonstration Project for a Statewide Linear Accelerator, issuance of a certificate of need to Parkway Urology on February 23, 2011, as part of a demonstration project for a model multi-disciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men (page 134) and the importance of capacity in that demonstration to meet the needs of its intended service population.
- Continued increases in <u>prostate cancer and genito-urinary cancer cases</u> in North Carolina.
- Need for <u>capacity</u> of The Prostate Health Center to respond to requests from patients from a wide service area,
- Sustained increases in the factors that contribute to <u>prostate and other</u> <u>genito- urinary cancer</u> including an increasing population and average age of the population.
- The need for <u>capacity</u> to respond to physician referrals.

Emphasis added. See page 70 of Project ID # J-10300-14.

TPHC makes nearly identical statements in its current application, further underscoring its argument that there is a need for additional capacity to treat prostate cancer patients. Simply put, TPHC stated in its prior application that "[t]he number of new prostate cancer and related cases in the state and service area continues to grow . . . without expansion, The Center will not be able to serve all the patients who request its services" (page 90).

Rather than continue its focus on prostate cancer and the needs of the patients it identified in the June 2014 application, TPHC's current application proposes to expand its services to include patients with other cancer types. TPHC is currently designed as a demonstration project for a multidisciplinary and comprehensive approach to <u>prostate care</u> with screening, urologist physician services, brachytherapy, etc. all coordinated or provided at one location. TPHC has argued strongly that it needs additional capacity to meet the needs of prostate cancer patients and that capacity is needed because it provides a unique service dedicated to prostate patients. Based on that argument, TPHC's current application cannot be the most effective alternative. It is illogical for TPHC to propose to expand its capacity and to provide less capacity than it has suggested is needed to prostate cancer patients. TPHC has argued that it is uniquely able to provide care to prostate cancer patients and that it needs an additional linear accelerator to treat them (and them alone). Therefore, it is not more effective to propose to add a linear accelerator and treat other types of cancer so that prostate cancer patients have less access to the capacity they need according to TPHC.

On page 110 of its current application, TPHC addresses its proposed expansion of services and its rejection of the alternative to restrict its services to prostate cancer:

Restrict Services to Prostate Cancer

The Prostate Health Center has developed an innovative and integrative approach to disease specific cancer treatment. It has been well received by physicians and patients. The radiation oncologists and radiation therapists at the Center are experienced in other types of cancer treatment. The existing and proposed equipment is the latest available technology providing highest quality therapeutic benefit. For these reasons, the Center has decided not to limit its services to prostate and GU cancers should it be permitted to acquire a second linear accelerate. For the same cost, the applicant can selectively expand its scope to more of the population in need. Thus, restricted access was rejected.

However, TPHC does not propose to offer similarly comprehensive and multidisciplinary services for other cancer types. Thus, it cannot offer the approach it provides for prostate cancer to patients with other cancers. There is no discussion in the current application of other physician specialties joining TPHC that would create the multidisciplinary approach such as ENT, endocrinology, pulmonology, or breast surgery. There is almost no discussion of screening efforts for additional cancer types which serves as a foundational element for TPHC's prostate outreach efforts. The exception is a letter of support from Raleigh Radiology committing to screening patients that TPHC sends to them, which is not equivalent to the screening efforts conducted for prostate patients currently. Given this discussion, it is clear that the TPHC is not proposing to offer the same comprehensive multidisciplinary approach to other cancers as it has designed for prostate cancer, contrary to its assertions in its application.

If there is a need for an additional linear accelerator, as TPHC has argued, then clearly the most effective alternative for TPHC, which is designed to treat prostate cancer, is to devote all of its capacity to prostate cancer patients. TPHC's current proposal includes breast, ENT, and lung cancer. TPHC is not designed to treat patients with these cancer types. It does not have the same comprehensive and multidisciplinary design for these cancer types as it already proposed or implemented for prostate cancer (please see the discussion below regarding TPHC's failure to provide all of the required services for the demonstration project). Thus, it is clearly not the most effective alternative for TPHC to devote some of its proposed additional capacity to treat non-prostate patients.

TPHC's application does propose the most effective alternative. TPHC should be found non-conforming with Criterion 4.

Overstated Market Need

Throughout its application, TPHC projects cancer cases for its service area and North Carolina. These projections are overstated throughout and bear no resemblance to actual linear accelerator utilization.

Overstated Statewide Need

On page 93, TPHC states "[b]ecause all new cancer cases are as yet unserved, they are by definition unmet need. A standard of 250 patients per linear accelerator and 50 percent of new cancers benefiting from linear accelerator treatment would require 106 linear accelerators to treat the 2013 new cancer cases for all sites (53,200 / 250 / 2). The state has 121 linear accelerators, of which three are low utilization and at least one is not operational. Adding palliative care and retreatments at 15 percent of new cases would bring the total need to 136 linear accelerators for just 2013 ((121-3)*1.15=135.7)" (see page 93). TPHC's statement is that North Carolina currently has 15 fewer linear accelerators than are needed (135.7 need linear accelerators needed – 121 existing linear accelerators = a deficit of 14.7 linear accelerators). However, it is clear from utilization data collected in the 2014 SMFP that this is inaccurate. As shown on Table 9H, North Carolina as a whole has a surplus of 31.95 linear accelerators, based on actual utilization; thus, it is clear that TPHC overestimates the number of linear accelerators needed in the state.

Overstated Service Area Need

Overstatements and unsupported assumptions are found throughout TPHC's 60-step methodology. TPHC's application proposes to expand its services beyond prostate cancer to six types of cancer in total. It is important to note that TPHC does not project to serve all cancer types. For example, TPHC does not propose to serve brain cancer. The six cancer types that TPHC projects to serve are:

- 1. prostate
- 2. breast
- 3. lung
- 4. colorectal
- 5. ENT and;
- 6. genitourinary (GU).

In its methodology, TPHC projects the number of number of cases by cancer site requiring external beam therapy projected for 2014, as summarized in the table below.

	Prostate	Breast	Lung	Colorectal	ENT	GU	Total for Six Cancer Types
Wake	649	476	265	86	114	62	1,652
Harnett	90	60	37	11	15	8	222
Johnston	134	92	55	17	23	12	333
Sampson	57	38	24	8	11	5	142
Franklin	57	36	. 23	7	11.	5	138
Lee	51	34	21	7	9	4	127
Duplin	56	35	23	7	11	5	136
Wayne	104	70	44	14	17	10	259
Durham	190	144	81	26	34	19	493
Total	1,388	985	573	183	244	130	3,503

Source: Prostate on page 134; breast on page 144; lung on page 152; colorectal on page 168; ENT based on page 172 totals x assumed 35 percent treated by external beam therapy; GU based on page 177 totals x assumed 10 percent treated by external beam therapy.

As TPHC is only projecting the number of linear accelerator patients for six types of cancer, its volumes should be less than the total number of linear accelerator patients (all types of cancer). However, when TPHC's projections are compared to the actual total number of patients that received linear accelerator treatment in these counties (all cancer types), it appears that TPHC's projections are overstated. The table below compares TPHC's projected volumes for its six cancer types to the total number of patients that received linear accelerator treatment from data included on the 2014 Hospital License Renewal Applications and Registration and Inventory of Medical Equipment forms.

	TPHC Total for Six Cancer Types	Total Linear Accelerator Patients (All Cancer Types)	TPHC Total for Six Cancer Types as Percent of Total
Wake	1,652	1,737	95%
Harnett	222	241	92%
Johnston	333	402	. 83%
Sampson	142	194	73%
Franklin	138	170	81%
Lee	127	203	62%
Duplin	136	181	75%
Wayne	259	308	84%
Durham	493	598	83%
Total	3,503	4,034	87%

Source: TPHC projections summarized in table above. Total linear accelerator patients (all cancer types) from 2014 Hospital License Renewal Applications and Registration and Inventory of Medical Equipment forms.

Based on this comparison, TPHC's application projects that its six cancer types will be 95 percent of radiation therapy patients in Wake County and 87 percent of all patients in the service area. This projection is unreasonable. Data from the North Carolina Central Cancer Registry (NCCCR) for 2014 summarized in the table below (see Exhibit 52 of TPHC's application) indicates that these six cancer types represent only 75 percent of new cancer cases, well below TPHC's 87 percent projection.

Site	New Cancer Cases	Percent of Total
Prostate	8,399	14.7%
Breast	9,610	16.8%
Lung	8,624	15.0%
Colorectal	4,746	8.3%
ENT	3,919	6.8%
GU	7,599	13.3%
Subtotal for TPHC's Six Cancer Types	42,897	74.9%
Other Cancer Types	14,409	25.1%
Total	57,306	100.0%

Source: Exhibit 52 TPHC application.

Given that TPHC's projections suggest that these six cancer types will be 95 percent of radiation therapy patients in Wake County and 87 percent of all patients in the service area and NCCCR data indicates that these cancer types comprise only 75 percent of

cases, it appears that TPHC's projected linear accelerator patients are overstated. Furthermore, data from UNC Hospitals and Rex Healthcare linear accelerator services indicates that these cancer types represent <u>only 71 percent</u> of their linear accelerator patients, compared to the 87 percent of cases projected by TPHC.

Site	UNC Hospitals and Rex Healthcare Linear Accelerator Patients by Type
Head and Neck	10.3%
Lung and Trachea	18.5%
Breast	22.3%
Gastrointestinal	7.0%
Genitourinary & Prostate	13.2%
Subtotal for TPHC's Cancer Types	71.3%
Other Cancer Types	28.7%
Total	100.0%

Thus, based on actual utilization of existing linear accelerators treating patients in the service area, TPHC's projections are overstated.

TPHC's overstatement of market volumes results in an overstatement of its facility projections. Specifically, TPHC applies market share assumptions to its overstated market volumes in order to calculate its facility volumes. The 2014 NCCCR data summarized above indicates that TPHC's volumes are overstated by 16 percent (16.0 percent = 87 percent ÷ 75 percent -1). In order to eliminate the overstatement, TPHC's volumes should be reduced by an estimated 13.8 percent (13.8 percent = 75 percent ÷ 87 percent - 1). Note, UNC Hospitals conservatively has utilized the NCCCR data to calculate the overstatement, rather than the UNC/Rex data which suggests a greater overstatement. If TPHC's volumes are reduced by 13.8 percent, the proposed linear accelerator will not be appropriately utilized according to the planning threshold of 6,750 ESTVs per unit as shown below.

CORRECTED TPHC Linear Accelerator Utilization

	Project Year Three	ESTVs per Linac
Original TPHC ESTVs	14,431	7,216
Percent Reduction to Account for Overstatement (13.8 percent)	-1,990	
Corrected TPHC ESTVs	12,441	6,221

Given that TPHC's application fails to demonstrate that the proposed linear accelerator will be effectively utilized it has failed to demonstrate the need for the project.

TPHC's application fails to demonstrate the need for one additional linear accelerator. TPHC should be found non-conforming with Criterion 3, 4, 5, and 6.

Unsupported Assumptions for Palliation Patients

Another factor that contributes to TPHC's overstated need projections is its unsupported addition of palliation cases. On page 181, TPHC provides estimates for the percentage of <u>additional patients</u> that it assumes will require palliation.

Step 45

Determine percentage of cases requiring palliation

Table IV.76 Percentage of additional Patients from Each Cancer Type Requiring Palliation

Туре	2014	2015	2016	2017	2018
Prostate	1% ·	1%	3%	6%	10%
Breast	0%	0%	5%	10%	15%
Lung	0%	0%	3%	6%	10%
Colorectal	0%	0%	10%	15%	20%
ENT	0%	0%	5%	10%	15%
Genital/Urinary	1%	1%	3%	6%	10%

Source: Dr. Leung

The estimated percentages for additional palliation range from 1 to 20 percent, change over time, and have absolutely no supporting basis. TPHC provides no information as to the origin of these percentages or to demonstrate the reasonableness of these assumptions. As such, TPHC's projections are not based on reasonable and supported assumptions.

TPHC's application fails to demonstrate the need for one additional linear accelerator. TPHC should be found non-conforming with Criterion 3, 4, 5, and 6.

Unsupported Market Share Assumptions

Throughout its utilization methodology, TPHC provides market share assumptions for six different types of cancer across nine counties. The only quantitative justification that TPHC provides for these market share assumptions is the letters of support received by physicians and included in Exhibit 10 of TPHC's application. The reliance on these letters as a basis for market share assumptions is problematic for several reasons.

TPHC's proposes to treat patients from all nine of its service area counties within all six cancer types. <u>However</u>, the letters of support fail to include a single letter from any physician in five of the nine counties proposed to be served (see chart below).

	Various*	GI/ Endocrine	Uro.	Gen. Surgery	Pulm.	ENT	Ob/ Gym	Int. Med.	Family Med.	Total
Wake	11	6	10	6	1	4	3	6	10	57
Harnett	0	0	0	0	0	0	0	1	0	1
Johnston	1	0	1	0	0	0	0	1	1	4
Sampson	0	1	0	0	0	0	0	0	1	2
Franklin	0	0	0	0	0	0	0	0	0	0
Lee	0	0	0	0	0	0	0	0	0	0
Duplin	0	0	0	0	0	0	0	0	0	0
Wayne	0	0	0	0	0	0	0	0	0	0
Durham	0	0	0	0	0	0	0	0	0	0
Other^	0	0	0	0	0	0	0	1	0	1
Total	12	7	11	6	1	4	3	9	12	65
# of Counties in Service Area	2	2	2	1	1	1	1	3	3	4

Source: Exhibit 10 of TPHC application.

Although TPHC projects to serve 54 patients from Franklin, Lee, Duplin, Wayne, and Durham counties in its second project year (see page 114), it does not have a single letter from a physician in these counties. Additionally, TPHC lacks sufficient support from referring physicians for the six cancer types it proposes. For example, TPHC has one letter of support from a pulmonologist, who practices in Wake County, despite proposing to treat more than lung cancer patients with radiation therapy from all nine counties proposed. As the summary chart above demonstrates, in four of the specialty

^{*}Various includes cardiology, sports medicine, plastic surgery, orthopedics, eye, nephrology, pathology, and physical medicine and rehab.

[^]Other includes Moore County which is outside TPHC's service area.

groupings (general surgery, pulmonary, ENT, and Ob/Gyn), TPHC only has support from Wake County. Three specialty grouping (various, GI/Endocrine, and urology) only have support from Wake and one other county. The maximum number of counties that show supporting physicians in any one specialty grouping is three.

Moreover, one of the clearest deficits is the absence of supporting letters from additional medical oncologists. For many types of cancer, when cancer is diagnosed, if not before, patients are under the care of a medical oncologist, who coordinates the care with a team of physicians, which may include surgeons, radiation oncologists, and others. The lack of support from medical oncologists in particular indicates that TPHC does not have sufficient support from physicians who are in a position to refer patients for radiation for the new sites proposed to be treated by TPHC. Dr. Mark Graham, the sole medical oncologist discussed in the application, currently works with TPHC in some capacity, but does not practice there as noted in the letter in Exhibit 16 of TPHC's application.

As the text of the letters indicates, the supporting physicians are indicating support for TPHC's historic services, specifically the treatment of prostate cancer in men, particularly African-American men. The letters do not indicate support for TPHC's proposed project which seeks to treat breast, lung, ENT, and other cancers well beyond its initial scope. These physician letters indicate support and referrals for prostate cancers, not all of the types of cancers that TPHC proposes to treat.

Even assuming that the letters of support indicate that these physicians are committing to referring patients for cancer types beyond prostate, the referral numbers in the letters do not support TPHC's patient volumes. As TPHC notes throughout its projection methodology not all patients with cancer are appropriate for linear accelerator treatment. For example, TPHC's methodology indicates that 573 or 40 percent of the 1,417 total lung cancer cases in the service area in 2014 require radiation (pages 147 to 152). TPHC's supporting pulmonologist indicates he will refer three patients monthly to TPHC. If all of those referrals have lung cancer, and 40 percent require radiation, then TPHC could expect to treat 15 patients annually for lung cancer. However, TPHC's projected radiation cases by cancer type show as many as 22 cases annually, suggesting that TPHC has overstated lung cases by as much as 51 percent.

Table IV.75 Projected Parkway Urology Radiation Cases by Cancer Type

Туре	2014	2015	2016	2017	2018
Prostate	206	235	266	298	302
Breast	0	0	24	25	26
Lung	0	0	21	21	22
Colorectal	0	0	8	8	8
ENT	0	0	12	13	13
Genital/Urinary	9	10	10	10	10
Total	216	244	342	376	382

On pages 135-136 of its application, TPHC describes the market share assumptions it employs in its utilization methodology for prostate cancer. TPHC provides little justification for its projected near doubling of its share of prostate cancer in Wake County stating only "[d]o not increase market in 2014 for any county except Wake County, increase that by 0.5 percent in 2014 . . . [i]ncrease Wake County by increments of 3 percent a year for 2015 through 2017" (page 135). It is unclear how many of the supporting physicians are already referring their prostate cancer patients to TPHC and thus would not represent incremental market share gains. For example, Dr. Kizer's letter indicates he will refer two patients monthly to the "new" Prostate Health Center, but he is a current member of the medical staff as noted on page 15 of the application. The significance of the letters from other members of Associated Urologists of North Carolina (which comprise 10 of the 11 supporting urologists) are also unclear as that practice is described on page 21 and 22 of the application as currently actively involved in TPHC as well as a physician practice at which Dr. Kevin Khoudary, TPHC's President and Owner, practices medicine part-time. Finally, there are multiple radiation therapy providers in Wake County which provide significant competition for patients. As such, TPHC's assumed gain in market share is unsupported.

Notwithstanding the issues related to the letters of support, TPHC's market share assumptions are unreasonable given the increased shift of patients from distant counties where linear accelerators exist such as Sampson, Johnston, Durham, and Wayne counties. None of these counties have linear accelerators that are fully utilized. It is unreasonable for TPHC to project that patients from these counties will seek care at a center that offers equivalent services to its home county providers in terms of a broad range of cancer services, as TPHC will no longer have a special focus on prostate cancer, for linear accelerator treatment which can require daily treatment for multiple weeks. Patients are simply not going to be willing repeatedly travel significant distances for care that could be received in their own communities.

Finally, as discussed above, TPHC's proposal to broaden its services outside of prostate cancer care will eliminate the very factor that TPHC believes has led to its success, namely its specialization towards care for prostate cancer patients. TPHC, through its name, its leadership (specifically Drs. Kevin Khoudary and Henry Unger, both urologists), and its design as a demonstration project for the treatment of prostate cancer, is currently and will in the future be associated for patients and referring physicians as a specialized provider of prostate cancer treatment. Please see the excerpt below from TPHC's application page 12 showing its front entrance with "The Prostate Health Center" signage:

Figure I.1 - Front Entrance View of The Prostate Health Center 117 Sunnybrook Road, Raleigh, NC 27610



UNC Hospitals believes that the proposed addition of other cancer types will both diminish TPHC's stature as a center for prostate cancer while at the same time, its historic specialization in prostate cancer alone will diminish its ability to attract patients with other cancer types. Patients and referring physicians are not likely to see a facility with a "Prostate Health Center" sign on its entrance as a provider for breast or lung cancer, for example.

Most importantly, TPHC's proposal lacks a defining feature of its demonstration project: a multidisciplinary and comprehensive approach for other types of cancer care. TPHC's original proposal offered a multidisciplinary and comprehensive approach to prostate care with screening, urologist physician services, brachytherapy, etc. all coordinated or provided at one location. By contrast, TPHC does not propose to offer similarly comprehensive and multidisciplinary services for other cancer types. There is

no discussion of other physician specialties such as ENT, endocrinology, pulmonology, or breast surgery joining THPC. There is almost no discussion of screening efforts for additional cancer types which serves as a foundational element for TPHC's prostate outreach efforts. The exception is a letter of support from Raleigh Radiology committing to screening patients that TPHC sends to them, which is not equivalent to the screening efforts conducted for prostate patients currently. Given this discussion, it is clear that the TPHC is not proposing to offer the same comprehensive multidisciplinary approach to other cancers as it has designed for prostate cancer, contrary to its assertions in its application. Given this issue, UNC Hospitals believes that it is unreasonable for TPHC to propose to treat other cancer types beyond prostate and GU cancer. As shown in the table below, excerpted from page 189, TPHC's prostate and GU cancer patients alone only account for 12,458 ESTVs or 6,229 ESTVs per linear accelerator.

Cancer Type	ESTVs	ESTVs per Linac
Prostate	12,165	6,083
Genital/Urinary	293	147
Total	12,458	6,229

Thus, TPHC has failed to provide adequate support for its assumed utilization and has failed to demonstrate the need for its project.

TPHC's application fails to demonstrate the need for the project. TPHC should be found non-conforming with Criterion 3, 4, 5, and 6.

Failure to Provide Required Services of Demonstration Project

While the proposed project does not involve the development of a demonstration project, TPHC exists as a demonstration project per the 2009 SMFP. As such, it must continue to meet the requirements of the demonstration in order to maintain material compliance with its existing CON. Based on information contained in the application, it is apparent that TPHC is not providing the necessary components of its demonstration project, as explained below.

The conditions of the statewide need determination for the Linear Accelerator Demonstration Project as outlined in the 2009 SMFP state that the project shall include the "development of a multidisciplinary prostate health center to provide

- urology services,
- medical oncology services,
- biofeedback therapy,
- chemotherapy,

- brachytherapy, and
- living skills counseling and therapy in the same building."

In its 2009 application, TPHC extensively described its plan to provide all of the components listed above. However, its current application does not demonstrate that it is providing all of the aforementioned services, as required. If, in fact, these services are not currently being provided, in order for the applicant to provide them and come into compliance with its CON requirements, it would incur associated expenses which are not being accounted for on the pro formas; this would negatively impact TPHC's net income. The analysis below describes these issues in detail.

TPHC's pro forma financial statements from its 2009 application included rent revenue for several components of multidisciplinary prostate health center components. The Form B financial statements from the 2009 application demonstrate total rent revenue (other revenue) of \$500,921 in the third project year (2014). This amount was derived from the following five service components:

- Linac and Simulator \$162,636
- Brachytherapy Services \$0
- Therapy \$162,636
- Medical Oncology \$13,012
- Urological Screening and Diagnosis \$162,636

However, TPHC's Form B financial statement in the 2014 application that is the subject of this review reflects only \$24,701 in other revenue (rent revenue) in Interim Full Year 2014 inflated by three percent in future years. The total in Interim Full Year 2014 (\$24,701) only covers the medical oncology revenue projected in the 2009 application. The Form B financial statement in the 2014 application records \$63,847 in other revenue in Partial Year 2013 (or \$109,452 annualized) while the 2009 application projected \$480,709 in other revenue for full year 2013. While there may be some expected differences between projected and actual financials, clearly TPHC's other rent revenue is virtually non-existent, indicating that the required components of the multidisciplinary prostate health center are not being provided.

Furthermore, based on discrepancies between the descriptions of the providers of the service components in the Service Component Staffing table (pages 36-39), the staffing tables in Section VII, and Form C in the pro forma financial statements in the current 2014 application, TPHC does not adequately demonstrate that all of the required services as outlined in the original certificate of need are being provided, or will be provided. Specifically, while biofeedback and living skills counseling services are indicated on the Service Component Staffing table, expenses for these services do not appear to be accounted for on Form C.

On page 37 of its application, TPHC states that biofeedback therapy will be provided by Ruth Boone, RN with a reference to a letter in Exhibit 14. Exhibit 14 contains a letter from Ruth Boone indicating her interest in providing biofeedback services to TPHC and potential full-time employment in the future, suggesting that Ms. Boone provides services to TPHC under contract. However, no such contract hours are included in Table VII.1.(b), pages 235-236, nor is there any projection of a full-time position for Ms. Boone in Table VII.1.(b). Furthermore, there does not appear to be any expenses included in Form C for this contracted service.

On page 37 of its application, TPHC states that living skills counseling will be provided by Kim Jones, MA with a reference to a letter in Exhibit 15. Exhibit 15 contains a letter from Kim Jones, MA indicating her interest in providing living skills counseling to TPHC at a contracted rate of \$30 per hour for an estimated 10 hours per week, which would equate to an annual contract expense of \$15,600. However, no such contract hours are included in Table VII.1.(b) nor is there a contracted expense for this service in Form C.

The purpose of the demonstration project as outlined in the 2009 SMFP and TPHC's 2009 certificate of need is to provide a multidisciplinary prostate health center that provides all six service components (urology services, medical oncology services, biofeedback therapy, chemotherapy, brachytherapy, and living skills counseling and therapy) in the same building. Since there is no evidence that biofeedback therapy or living skills counseling are being provided at this time, or that they will be in the future, it appears that TPHC is not operating in compliance with its approved 2009 CON.

Similarly, while not a factor in considering whether or not TPHC is operating as a multidisciplinary center per its 2009 application, it does not adequately demonstrate the provision of all projected ancillary and support services. Specifically, on page 39 of its application, TPHC states that nutritional counseling will be provided by WakeMed and/or Zeina Hamra, RD. Table VII.1.(b) projects a total of 520 contract hours for a Dietician at an hourly contract rate of \$65.56 for the second year of the project, which equates to a total contract expense of \$34,091 for the year. This expense does not appear on Form C.

Given its failure to provide the required multidisciplinary services, TPHC does not demonstrate the need for the proposed project. Moreover, TPHC has omitted several contract service expenses from its projected pro formas rendering its financial projections unreasonable and suggesting a lack of available support services.

As a result, the application should not be approved, and is non-conforming with Criterion 1, 3, 5, 7 and 8.

Failure to Demonstrate the Financial Feasibility of the Project

The application contains multiple errors in the sections relating to financials, including payor mix, staffing and the pro formas. The errors include inconsistencies and incorrect calculations; as a result, the financial feasibility of the project has not been demonstrated.

Balance Sheet Errors

The balance sheet fails to include all of the facility's liabilities. Specifically, according to a Complaint (14 CVS 3884) filed in Superior Court by the general contractor who constructed TPHC, the applicant owes an additional \$607,222 from the cost of the project's building and materials that has not been paid. Further, the Plaintiff in that case has also requested a lien on the facility (14 CVS 525), given the unpaid balance that it states it is owed. While it appears from the most recent court documents in that case that the lien may have been discharged, it is clear that the applicant has not yet finished paying for the construction of its facility, the ability of the applicant to pay these funds is doubtful. From the balance sheet on page 191, it is clear that the applicant has not accounted for this amount, as the current liabilities are far less than \$600,000. The balance sheet also shows that there is insufficient cash to pay this amount, and given the projected net losses, the applicant has failed to demonstrate its ability to pay this amount. Moreover, neither the balance sheet nor income statement includes the transfer of more than \$212,000; thus, the actual balance sheet and income statement should reflect this increase in expenses and change in assets, liabilities and/or fund balance. The applicant also failed to demonstrate the ability to fund this amount through additional loans. .Please see Attachment 1 for the copy of the documents filed in Superior Court that demonstrate these issues.

Staffing and Ancillary/Support Service Inconsistencies

As noted above, TPHC's application shows inconsistencies between stated service offerings, Table VII.1.(b), and Form C for biofeedback therapy, living skills counseling, and nutrition counseling that result in the omission of expenses that would be required for the provision of these services. As such, TPHC's expenses are understated and its net income rendering its pro forma financial statements unreasonable and unreliable.

Payor Mix Errors

In its application, TPHC provides its current and projected payor mix for its linear accelerator patients.

	Current Payor Mix	Projected Payor Mix
Charity Care	3.0%	4.0%
Self-Pay	1.25%	1.22%
Medicare	57.67%	58.62%
Medicaid	0.44%	1.56%
Commercial Insurance/Managed Care	11.42%	8.41%
Other (BCBS/Other)	22.22%	26.15%
Total	96.0%	100.0%

As shown in the table below, TPHC's current payor mix only totals 96 percent, and thus is an inaccurate representation of its patient mix.

Assuming that TPHC's current payor mix is representative of some of its existing patients, the application assumes that TPHC's Medicare payor mix will increase. TPHC fails to provide an adequate rationale for this projected increase. TPHC's application states only that "[p]ayor mix is based on current data from The Prostate Health Center, adjusted for the change in cancer types" (page 229). There is no quantitative or qualitative data provided that would enable the Agency to determine the reasonableness of TPHC's payor mix assumptions. However, the Agency does have the data provided by UNC Hospitals and Duke Raleigh, two existing providers in Wake County, which indicate that TPHC's assumptions are unreasonable.

As noted in the table below, TPHC's Medicare payor mix is projected to be much higher than UNC Hospitals and Duke Raleigh.

Applicant	Projected Percentage of Total Procedures Provided to Medicare Recipients
UNC Hospitals	41.50%
Duke Raleigh	45.80%
TPHC	58.62%

If TPHC's payor mix is adjusted for its proposed expansion of the types of cancer types it will serve, it is reasonable to assume that TPHC's payor mix would change to more closely resemble UNC Hospitals and Duke Raleigh, both of which serve a broad range of cancer types.

As such, TPHC has provided inaccurate data for its current payor mix and failed to demonstrate the reasonableness of its proposed payor mix.

As a result of these issues, the application is non-conforming with Criterion 5 and should not be approved. With respect to the issues involving staffing, the applicant has failed to demonstrate that it will provide sufficient staffing and support services for the project, and is non-conforming with Criteria 7 and 8. With respect to the issues involving payor mix, the application should also be found non-conforming with Criterion 13(a) and 13(c).

DUKE RALEIGH HOSPITAL (DUKE RALEIGH)

Duke Raleigh's application should not be approved as proposed. UNC Hospitals has identified the following specific issues, each of which contributes to the application's non-conformity:

- (1) Failure to Demonstrate Need
- (2) Overstated Need
- (3) Failure to Account for the Dissolution of CCNC
- (4) Duplication of Existing Resources and Failure to Demonstrate Reasonableness of Market Share Assumptions

Failure to Demonstrate Need

Duke Raleigh's application fails to demonstrate the need for its proposal which would result in the addition of a linear accelerator for a total of five linear accelerators. While Duke Raleigh's states that it proposes to "acquire a second linear accelerator" (page 3), it also notes that:

Duke University Health System, Cancer Centers of North Carolina ("CCNC"), and US Oncology, Inc. have been in negotiations and have reached an agreement in principle regarding a proposed transaction for the acquisition and continued operation of existing oncology centers in Wake County that are currently owned and operated by CCNC and AOR, a wholly owned subsidiary of US Oncology. Specifically, the parties are negotiating the potential acquisition of the Macon Pond and Cary Oncology Centers currently operated by CCNC (including the linear accelerators associated with the Centers). Duke has submitted correspondence to the CON Section regarding this proposed transaction.

In addition, a certificate of need was issued effective February 4, 2011 to CCNC and AOR to acquire a second linear accelerator with stereotactic radiation surgery capabilities ("Trilogy Linac") to be located at the Macon Pond Center (Project I.D. No J-7941-07). The Trilogy Linac project has not been fully developed. Duke has also requested and received a determination from the CON Section that good cause would exist to transfer the Trilogy Linac CON from CCNC and AOR to DUHS if the proposed acquisition is accomplished.

The parties continue to engage in due diligence regarding this proposed transaction and at the time of filing of this application, no binding agreement has been signed.

See pages 7-8.

As the Agency is aware, the acquisition of these three linear accelerators by Duke Raleigh has been approved the CON Section in correspondence dated August 8, 2014 (and included as Exhibit 15 in UNC Hospitals' application). It is simply unreasonable for Duke Raleigh's application to assume that it will only operate two linear accelerators when there is clear evidence and correspondence indicating that it will add three linear accelerators, one of which is approved but undeveloped. Given that its application argues that Duke Raleigh has a need for one additional linear accelerator, and that it has already acquired three linear accelerators, it is clear that the Duke Raleigh's need has been met. For example, Duke Raleigh states on pages 10-11 of its application that "[a]s a result of the increase in demand at DRAH, a strategic plan was developed by the Duke Cancer Institute (DCI) and DRAH leadership to expand Radiation Oncology services at the Duke Raleigh Cancer Center . . . [t]he second phase of the plan (this project) is to acquire a new linear accelerator and place it in the vacated vault, increasing DRAH's inventory to a total of two linear accelerators . . . [t]herefore, in response to the growing number of patient in need of cancer care in Wake County and surrounding communities, DRAH seeks to acquire a second linear accelerator" (emphasis added). Duke Raleigh's acquisition of three linear accelerators prior to the filing of the current application brings its inventory of linear accelerators to four units, or two more than its strategic plan indicates.

Duke Raleigh's application fails to demonstrate the need for the project. Duke Raleigh should be found non-conforming with Criterion 3, 4, 5, and 6.

Overstated Need

Duke Raleigh's application projects the need for its proposed project as well as Service Area 20 need, more broadly, by applying North Carolina Central Cancer Registry use rates to projected population totals and the assumption that 57.2 percent will receive radiation therapy on a linear accelerator. As Duke Raleigh states on page 66, "based on the previously described methodology, during 2014 it is estimated that approximately 2,930 cancer patients in Service Area 20 . . . may seek radiation therapy via linear accelerator. Based on the minimum patient performance standard of 250 patients per linear accelerator, this equates to a need for 12 linear accelerators in Service Area 20 . . . Therefore, the need for an additional linear accelerator in Service Area 20 is warranted." However, a cursory review of the data indicates that Duke Raleigh's market data projections are overstated by 54 percent. According to the actual linear accelerator utilization submitted on Hospital License Renewal Applications and Registration and Inventory of Medical Equipment forms, only 1,907 Service Area 20 patients received care on a linear accelerator in 2013. Duke Raleigh's estimates are 154 percent of actual linear accelerator volumes and are overstated by 1,023 patients, the equivalent of four linear accelerators.

The table below compares Duke Raleigh's 2014 estimates, which include counties beyond Service Area 20, to actual volumes. As shown, in total, Duke Raleigh has overstated linear accelerator volumes by 1,181 cases.

Comparison of Duke Raleigh Estimated and Actual Linear Accelerator Patients

County	Duke Raleigh Estimated	Actual	Difference	Percent Overstated/ (Understated)
Franklin	183	170	13	8%
Harnett	337	241	96	40%
Johnston	515	402	113	28%
Nash	250	301	-51	(14%)
Wake	2,747	1,737	1,010	58%
Total	4,032	2,851	1,181	42%
Service Area 20	2,930	1,907	1,023	54%

Source: Duke Raleigh Application pages 66 and 90; 2014 Hospital License Renewal Application and Registration and Inventory of Medical Equipment.

Clearly, this overstatement of volumes shows that Duke Raleigh's utilization methodology is not based on reasonable and supported assumptions. As discussed below, the appropriate utilization of Duke Raleigh's linear accelerators is entirely dependent upon increases in market share. Duke Raleigh's assumed increases in market share are applied to these overstated market volumes and thus, regardless of whether its market share percentage assumptions are reasonable or unreasonable, the resulting calculated cases are overstated. Thus, Duke Raleigh's future utilization is also overstated. When utilization methodology for the two linear accelerators to be operated at Duke Raleigh Hospital is revised to exclude the overstatement in market volumes, the projected number of linear accelerator patients is 354, or 177 patients per linear accelerator, which is below the standard for appropriate utilization of 250 patients per machine. Thus, Duke Raleigh fails to demonstrate the need for the proposed additional linear accelerator.

Duke Raleigh Hospital Only (2 Machines) Projected Linac Patients Revised to Exclude Overstatement of Market Volumes

	2018 Projected Linac Patients (pg 90)	Overstatement of Market Volumes	2018 Projected Cancer Patients Revised to Exclude Overstatement	Projected Market Share	Duke Raleigh Hospital Linac Patients
Franklin Co.	192	108%	178	13.4%	24
Harnett Co.	361	140%	258.	3.5%	9
Johnston Co.	545	128%	426	5.1%	22
Nash Co.	246	86%	288	4.0%	12
Wake Co.	2,972	158%	1,879	12.5%	234
		In-Migration (15.1%)			53
Total					354
		Patients/Linac			177

Similarly, when the utilization methodology for the five total linear accelerators to be operated by Duke Raleigh is revised to exclude overstatement in market volumes, the projected number of linear accelerator patients is 863, or 173 per machine. Thus, Duke Raleigh fails to demonstrate the need for all of its linear accelerators.

Duke Raleigh Total Projected Linac Patients CORRECTED and No Market Share Increase

	2018 Projected Linac Patients (pg 90)	Overstatement of Market Volumes	2018 Projected Cancer Patients Revised to Exclude Overstatement	Projected Market Share	Duke Raleigh Total Linac Patients
Franklin Co.	192	108%	178	25.4%	45
Harnett Co.	361	140%	258	11.5%	30
Johnston Co.	545	128%	426	11.3%	48
Nash Co.	246	86%	288	5.1%	15
Wake Co.	2,972	158%	1,879	31.5%	591
		In-Migration (11.6%)		To appropriate the second	96
Total Prior to Duke Univ. Hospital Shift					825
Duke Univ. Hospital Shift					38
Total					863
Patients/Linac					173

Of note, in a prior CON application (Project ID # J-8669-11), Rex Hospital proposed relocating one of its existing linear accelerators to Holly Springs. The Agency found the proposed relocation of the linear accelerator to be non-conforming with Criterion 3 and noted that <u>projected volumes were not reasonable in comparison to actual volumes</u>. The

Agency's analysis in that case included a similar analysis of the applicant's projected linear accelerator volumes for the market in comparison to the actual number of linear accelerator patients by county. The Agency should use the same approach in evaluating Duke Raleigh's overstated market volumes and find it non-conforming with Criterion 3. Of note, UNC Hospitals' current application to develop a linear accelerator in Holly Springs has a different methodology and approach to that one found non-conforming by the Agency in the Rex Hospital Holly Springs application. Specifically, UNC Hospitals' utilization is based on the number of existing patients in the service area that are currently treated by UNC Hospitals, Rex Hospital, and medical oncologists that are joining the UNC Health Care System. Please see Section III.1.b of UNC Hospitals' application. UNC Hospitals' methodology is not based on a projection of the number of total linear accelerator patients in the market and a market share assumption, unlike Duke Raleigh's application.

It should be clear that Duke Raleigh's basis for stating that there is "a need for 12 linear accelerators in Service Area 20" (page 66) is false. As such, Duke Raleigh's application fails to demonstrate the need for the project and fails to demonstrate that the proposed project will not result in unnecessary duplication.

Duke Raleigh's application fails to demonstrate the need for the project. Duke Raleigh should be found non-conforming with Criterion 3, 4, 5, and 6.

Failure to Account for Dissolution of CCNC

In its application, Duke Raleigh provides a utilization methodology in Exhibit 19 for five linear accelerators. This methodology fails to account for the loss of linear accelerator patient volume that will result from the dissolution of that practice. Duke Raleigh states on page 5 of Exhibit 19 that:

Regardless of whether the CCNC asset transaction is concluded, six of the CCNC medical oncologists will be joining the Duke Cancer Institute in Wake County this fall. Duke is also aware that some of the current CCNC medical oncologists will be joining UNC Healthcare and/or retiring. Therefore, to project FY2015 patient market share, DRAH assumes a 20% decrease in FY2014 patient volume at CCNC to reflect this change. Assuming the CCNC transaction is concluded, Duke Cancer Institute physicians are anticipated to refer patients to the existing operational CCNC linear accelerators. Given the pent up demand for DUHS radiation therapy services in Wake County, the CCNC equipment will provide additional capacity for Duke Cancer Institute physicians. Additionally, other non-Duke or CCNC referring providers in the market and local patients are familiar with the existing CCNC locations in Raleigh and Cary and may prefer to use radiation therapy services at these convenient locations. For these reasons, DRAH determined a 20% decrease in patient volume at CCNC during FY2015 was reasonable and conservative.

Duke Raleigh's assumption that its market share will decrease by 20 percent is totally unreasonable and unsupported. Duke Raleigh provides absolutely no quantitative basis for the assumed 20 percent reduction. The likely reason that Duke Raleigh does not provide a quantitative basis is because the actual reduction that will result from the CCNC medical oncologists joining the UNC Health Care System far exceeds 20 percent. As noted in UNC Hospitals' application, six medical oncologists will join the UNC Health Care System, the same number of physicians as are expected to join the Duke Cancer Institute, and these physicians are expected to shift 46 percent of patient volume from CCNC to UNC Health Care System linear accelerators (see page 61 of the UNC Hospitals application). In an attempt to deceive the Agency and falsely demonstrate that its newly acquired linear accelerators would be appropriately utilized, Duke Raleigh assumed that a 20 percent decrease in patient volume (which has no basis whatsoever) rather than the 46 percent reduction which is based on actual physician referral data.

When Duke Raleigh's methodology is corrected to utilize the actual expected reduction in patient volume due to the CCNC medical oncologists joining the UNC Health Care System, it is clear that Duke Raleigh's five linear accelerators (which includes the three existing, one approved but not yet developed and one proposed) will not be appropriately utilized and fail to the meet the performance standards for linear accelerators. Please see Attachment 2 for the detailed data tables for Duke Raleigh's corrected methodology. In summary, when Duke Raleigh's methodology is corrected to utilize the actual number of linear accelerator cases that will shift to the UNC Health Care System, its five linear accelerators are only projected to treat 1,095 patients in the third project year, or 219 per machine.

Duke Raleigh Total Projected Linac Patients CORRECTED

	FY2016	FY2017	FY2018
Franklin Co.	39	41	44
Harnett Co.	33	34	35
Johnston Co.	41	48	57
Nash Co.	14	14	14
Wake Co.	657	728	817
In-Migration	104	115	129
Total	888	980	1,095
Patients/Linac	178	196	219

As demonstrated, when actual data is used for assumptions, Duke Raleigh's linear accelerator utilization fails to meet the performance standard for linear accelerators required under 10 NCAC 14C .1903 (3).

Duke Raleigh's application fails to demonstrate the need for the project. Duke Raleigh should be found non-conforming with Criterion 3, 4, 5, and 6.

<u>Duplication of Existing Resources and Failure to Demonstrate Reasonableness of Market Share Assumptions</u>

On pages 91-94 of its application and pages 4-7 of the narrative accompanying the methodology in Exhibit 19, Duke Raleigh describes the basis for its assumption that it will increase market share for linear accelerator patients. Duke Raleigh's arguments contain numerous unsupported statements and fail to provide a quantitative basis that is consistent with specific percentage increases in market share. Furthermore, Duke Raleigh's projected volume and its ability to effectively utilize the proposed additional linear accelerator and its five total linear accelerators is entirely dependent on the market share increases.

On page 91 of its application, Duke Raleigh states "[u]pon implementation of the proposed additional linear accelerator, DRAH will achieve market share growth in the primary and secondary service areas. Duke has significant market share growth for several years until further growth became effectively impossible in light of capacity and equipment constraints. With the easing of capacity constraints and the ability to meet pent-up demand, during the first three years, DRAH projects the following annual increase in linear accelerator patient market share." However, Duke Raleigh provides no data to suggest that it has achieved significant market share growth for several years. In fact, Duke Raleigh provides only one year (2014) of market share estimates. As noted above, Duke Raleigh's estimates of the number of linear accelerator patients are significantly overstated, thus its market share estimates are also overstated. Moreover, the historical data that Duke Raleigh does

provide indicates that 1) its volume has declined since its peak in 2012 and 2) that its capacity constraints have been erased. As shown in the table below, excerpted from page 59 of its application, Duke Raleigh's treatment volume peaking in 2012 and declined significantly in 2013 and only slightly increased in 2014.

Duke Raleigh Hospital Historical Linear Accelerator Utilization

Fiscal Year	External Beam / IMRT Treatments*	DRAH Average # of Treatments / Day
2005	6,231	24.6
2006	6,581	26.1
2007	6,101	23.9
2008	6,225	24.6
2009	6,288	24.9
2010	6,594	26.2
2011	6,518	25.8
2012	8,505	33.8
2013	7,908	32.0
2014	7,937	31.7

^{*} In order to calculate average number of treatments per day, treatment volumes exclude the multiplier for IMRT, complex treatments, and additional field check radiographs that are included in the SMFP ESTV table

Source: DRAH internal data

Moreover, Duke Raleigh was able to achieve the utilization in 2012 with one linear accelerator. Thus, the 2013 and 2014 declines were not related to capacity constraints. It has now acquired two additional existing linear accelerators and one undeveloped linear accelerator. These three additional linear accelerators will surely eliminate any capacity constraints and allow Duke Raleigh to address the "pent-demand" it supposes.

More broadly, Duke Raleigh assumes market share gains that will shift volume from other providers in a market where there is a surplus in linear accelerators. Said another way, Duke Raleigh's assumed market share gains will unnecessarily duplicate existing linear accelerators in Wake County. Duke Raleigh's basis for stating that there is "a need for 12 linear accelerators in Service Area 20" (page 66) is false. Duke Raleigh is also well aware that the standard methodology in the SMFP does not indicate a need for additional capacity in Service Area 20 as Duke Raleigh submitted the special need adjustment petition that resulted in the linear accelerator need determination in the 2014 SMFP. Duke Raleigh's petition argued that its lack of capacity resulted in longer hours, delayed appointments, and maintenance issues. However, it did not indicate that

patients were seeking care at other providers due to these issues. This type of evidence would support the assumption that additional capacity would result in increased market share, as assumed in its current application.

Additionally, Duke Raleigh's application argues that the addition of physicians to the Duke Cancer Institute supports its increased market share (see page 93). However, the application does not include letters of support from Dr. Amit Mehta or Dr. Monica Jones. Given the absence of these letters, it is not clear whether these physicians will provide the support for the project anticipated by Duke Raleigh.

Given these factors, UNC Hospitals' believes that Duke Raleigh's assumptions for increased market share are unreasonable. As shown in the analysis in Attachment 3 and summarized below, when the utilization methodology for the two linear accelerators proposed to be located at Duke Raleigh Hospital is revised to exclude any gains in market share, the projected number of linear accelerator patients is 434, or 217 patients per linear accelerator, which is below the standard for appropriate utilization of 250 patients per machine. Thus, Duke Raleigh fails to demonstrate the need for the proposed additional linear accelerator.

Duke Raleigh Hospital Only (2 Machines) Projected Linac Patients No Market Share Increase

	2.10.21222200.0		
	FY2016	FY2017	FY2018
Franklin Co.	22	22	23
Harnett Co.	12	12	13
Johnston Co.	19	20	20
Nash Co.	10	10	10
Wake Co.	292	297	303
In-Migration	63	64	65
Total	419	426	434
Patients/Linac	209	213	217

Similarly, the analysis in Attachment 4 shows the utilization methodology for the five total linear accelerators to be operated by Duke Raleigh when revised to exclude any gains in market share <u>and</u> when corrected with the actual expected reduction in patient volume due to the CCNC medical oncologists joining the UNC Health Care System. As shown, the projected number of linear accelerator patients to be treated on all five machines is 867, or 173 per machine. Thus, Duke Raleigh fails to demonstrate the need for all of its linear accelerators.

Duke Raleigh Total Projected Linac Patients CORRECTED and No Market Share Increase

	FY2016	FY2017	FY2018
Franklin Co.	38	38	39
Harnett Co.	33	34	35
Johnston Co.	39	40	41
Nash Co.	14	14	14
Wake Co.	614	626	639
In-Migration	97	99	101
Total	835	851	867
Patients/Linac	167	170	173

Given this analysis, it is clear that Duke Raleigh proposes to unnecessarily duplicate existing resources and fails to provide a reasonable basis for its proposed market share assumptions.

Duke Raleigh's application fails to demonstrate the need for the project and fails to demonstrate it will not result in unnecessary duplication of existing resources. Duke Raleigh should be found non-conforming with Criterion 3, 4, 5, and 6.

GENERAL COMPARATIVE COMMENTS

The Duke Raleigh, Prostate Health Center, and UNC Hospitals applications each propose to acquire one linear accelerator in response to the 2014 SMFP need determination for Linear Accelerator Service Area 20. UNC Hospitals acknowledges that each review is different and therefore, that the comparative review factors employed by the Project Analyst in any given review may be different depending upon the relevant factors at issue. Given the nature of the review, the Analyst must decide which comparative factors are most appropriate in assessing the applications.

In order to determine the most effective alternative to meet the identified need for one additional linear accelerator in Service Area 20, UNC Hospitals reviewed and compared the following factors in each application:

- Geographic Distribution
- Access by Underserved Groups
- Ancillary and Support Services
- Physician Support
- Gross and Net Revenue per ESTV Procedure
- Operating Expenses per ESTV Procedure
- Demonstration of Need/Unnecessary Duplication

UNC Hospitals believes that the factors presented above and discussed in turn below should be used by the Analyst in reviewing the competing applications. The factors are appropriate and/or have been used in previous competitive linear accelerator review findings.¹

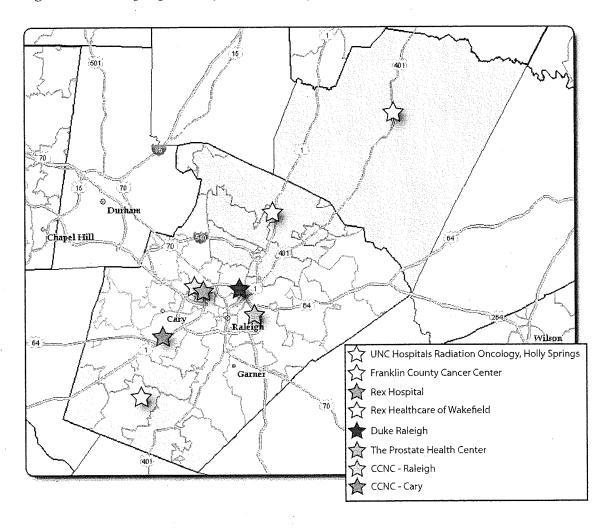
Geographic Distribution

Linear Accelerator Service Area 20 is composed of Franklin and Wake Counties. The following table identifies the location of the existing linear accelerators in Linear Accelerator Service Area 20.

Please note that in developing comparative review factors, UNC looked to a number of competitive linear accelerator reviews for guidance, such as: the 2009 Statewide Prostate Demonstration Project review, the 2008 HSA V linear accelerator review, the 2007 Wake County linear accelerator review, the 2006 Onslow County linear accelerator review, the 2006 Davidson County linear accelerator review, the 2006 Area 7 linear accelerator review, and the 2005 Area 17 linear accelerator review. Where appropriate, UNC included relevant comparative factors used in those reviews. See, e.g., the 2008 HSA V Linear Accelerator Review (using the following comparative factors: geographic distribution, access by underserved groups, ancillary and support services, staffing, revenues, operating costs, and demonstration of need; the 2007 Wake County Linear Accelerator Review (using the following comparative factors: geographic distribution, access by underserved groups, projected gross and net revenue per ESTV procedure, projected operating expenses per ESTV procedure, and demonstration of need).

<i>Facility</i>	Units	County	City/Town
Franklin County Cancer Center	1	Franklin	Louisburg
Cancer Centers of North Carolina (owned by Duke Raleigh)	3	Wake	Cary/Raleigh
Duke Raleigh Hospital	1	Wake	Raleigh
Rex Hospital	4	Wake	Wakefield/Raleigh
TPHC	1	Wake	Raleigh
Totals	10		

The map below indicates the location of UNC Hospitals' proposed facility and the existing sites of care proposed by Duke Raleigh and TPHC.



As indicated in the table and map above, one existing linear accelerator is located in Franklin County and nine linear accelerators are located in Wake County. In this review, both Duke Raleigh and The Prostate Health Center propose to develop an additional linear accelerator in Raleigh at existing sites of care while UNC Hospitals proposes to develop the additional linear accelerator at a new site in Holly Springs.

Therefore, UNC Hospitals is only the applicant that proposes to expand geographic access to care and is therefore the most effective alternative with respect to geographic distribution. As discussed above, geographic access is of greater importance in assessing the comparative value of linear accelerator projects, particularly in light of the underutilization of linear accelerator capacity in Wake County, as expanded geographic access is correlated with increased utilization of linear accelerator services for the local population.

Access by Underserved Groups

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, based on the information provided by the applicants in Section VI.15 of the applications.

Applicant	Projected Percentage of Total Procedures Provided to Medicare Recipients	Projected Percentage of Total Procedures Provided to Medicaid Recipients	Projected Percentage of Total Procedures Provided to Medicare/Medicaid Recipients
UNC Hospitals	41.5%	12.2%	53.7%
Duke Raleigh	45.8%	4.3%	50.1%
TPHC	58.6%	1.6%	60.2%

As shown in the table above, TPHC projects the highest percentage of services to be provided to Medicare and Medicaid recipients combined and Duke Raleigh projects the lowest percentage of services to be provided to Medicare and Medicaid recipients combined. UNC Hospitals projects a significantly higher percentage of service to Medicaid recipients than do either of the other applicants. However, as noted in the application-specific comments above, TPHC projects to serve only six types of cancer; by contrast, UNC Hospitals and Duke Raleigh project to serve all types. As such, a meaningful comparison between the applicants cannot be made as the difference in proposed services will impact the payor mix of each facility. Moreover, TPHC's projected payor mix is based on an incorrect historical calculation, as described above, and the basis for its calculation of projected payor mix is unknown, significantly different from that of existing providers of multi-site radiation oncology services, and is therefore unreasonable.

As shown in the table below, UNC Hospitals projects the highest percentage of services to be provided to self-pay/indigent/charity care patients.

Applicant	Projected Percentage of Total Procedures Provided to Self- Pay/Indigent/Charity Patients
UNC Hospitals	7.2%
Duke Raleigh	4.9%
TPHC	5.2%

Therefore, based on its projected service to Medicaid recipients and self-pay/indigent/charity care patients, UNC is the most effective alternative with regard to provision of projections of medically underserved groups. As noted above, TPHC's provides inaccurate data for its current payor mix and fails to demonstrate the reasonableness of its projected payor mix, and thus is non-confirming with Criterion 13. Further, the applications submitted by both Duke Raleigh and TPHC are non-conforming with both Criteria 3 and 5 as they are based on unreasonable and unsubstantiated volume and financial projections.

Ancillary and Support Services

As previously noted, TPHC has not adequately demonstrated that it is providing, or will provide necessary biofeedback therapy, living skills counseling, or nutritional counseling services, and as such represents an ineffective alternative with regard to ancillary and support services. UNC Hospitals and Duke Raleigh each represent effective alternatives.

Physician Support

The following table illustrates each applicant's level of physician support based on letters of support provided in the application submissions.

Applicant	Physician Support Letters
UNC Hospitals	130
Duke Raleigh	17
TPHC	65

As shown in the table, UNC Hospitals is the most effective with respect to physician support and has two times as much support as TPHC, the next most effective applicant. UNC Hospitals believes the level of support included in the Duke Raleigh and TPHC applicants is insufficient to support their utilization projects. As noted above, Duke Raleigh's application does not includes letters of support from two physicians which are included as part of its basis for its market share growth. Similarly, as noted above, TPHC's application fails to include letters of support from physicians in five of the nine counties it proposes to serve and fails to include adequate support for its additional proposed services. More broadly, the letters of support do not clearly indicate that referring

physicians will refer patients beyond those affected by prostate cancer. Based on these factors, UNC Hospitals is the only applicant that provides adequate physician support and the most effective applicant with respect to this factor.

Gross and Net Revenue per ESTV Procedure

The following table shows the projected gross revenue and net revenue per ESTV procedure in the third year of operation for each of the applicants. Revenues are from Form C in each applicant's pro forma financial statements, and the ESTV projections are from Section IV.2 of the applications.

Third Operating Year	UNC Hospitals	Duke Raleigh	TPHC
Gross Revenue	\$121,817,070	\$29,796,584	\$22,616,458
Net Revenue	\$46,185,128	\$9,178,166	\$7,966,467
ESTV Treatments	33,990	14,084^	14,431
Per ESTV:			
Gross Revenue	\$3,584	\$2,116	\$1,567
Net Revenue	\$1,359	\$652	\$552

[^]Includes ESTVs & dosimetry treatments

While TPHC and Duke Raleigh's applications project lower gross and net revenue per ESTV than UNC Hospitals, this comparison among the three applicants is inappropriate. UNC Hospitals' financial statements are provided for its Department of Radiation Oncology in total including the proposed linear accelerator as well as UNC Hospitals' linear accelerator services on its main campus. UNC Hospitals provides many specialized procedures such as Cyberknife-based radiosurgery, pediatric cases under anesthesia, and body and limb irradiation, which have significantly higher costs and charges than other linear accelerator procedures. For example, charges for stereotactic radiosurgery are more than \$20,000 per procedure, much higher than the approximate \$2,000 charge for an external beam procedure. Neither Duke Raleigh nor TPHC provides these Cyberknife or other special procedures. As such, the financial results for the three applicants are not comparable.

Additionally, it should be noted that the comparison of hospital and freestanding rates provided by TPHC on page 120 of its application is inappropriate. TPHC compares freestanding global rates to hospital APC and professional fees combined. UNC Hospitals' patient charges, as provided in its application, do not include physician fees. In addition, reimbursement for certain procedures, particularly IMRT, have historically been higher for freestanding facilities than for hospital-based facilities, contrary to the statements by TPHC.

Nonetheless, it should be noted that the applications submitted by both Duke Raleigh and TPHC are non-conforming with both Criteria 3 and 5 as they are based on unreasonable and unsubstantiated volume and financial projections.

Projected Average Operating Expenses Per ESTV Procedure

The following table shows the projected operating expenses per ESTV procedure in the third year of operation for each of the applicants. Operating expenses are from Form C in each applicant's pro forma financial statements, and the ESTV projections are from Section IV.2 of the applications.

Third Operating Year	UNC Hospitals	Duke Raleigh	TPHC
Expenses	\$21,859,380	\$7,097,317	\$7,525,750
ESTV Treatments	33,990	14,084^	14,431
Expenses Per ESTV	\$643	\$504	\$521

[^]Includes ESTVs & dosimetry treatments

As discussed above, a financial comparison among the three applicants is inappropriate as UNC Hospitals is the only one of the three that provides services such as Cyberknife and special procedures which have significantly higher costs and charges.

Furthermore, the applications submitted by both Duke Raleigh and The Prostate Health Center are non-conforming with both Criteria 3 and 5 as they are based on unreasonable and unsubstantiated volume and financial projections.

Demonstration of Need/Unnecessary Duplication

As discussed in the general comments above, UNC Hospitals' application provides the most reasonable projections in regards to demonstration of need. As noted in the application-specific comments, TPHC overstates market volumes for linear accelerator services by 16 percent or more and Duke Raleigh overstates market volumes by 54 percent. Additionally, as noted in application-specific comments, both TPHC and Duke Raleigh assume a shift of patients from existing providers in the form of increased market share assumptions.

As both Duke Raleigh and TPHC's applications assume overstated market volume and a shift of patients from existing providers, their projection methodologies are exceptionally aggressive and exhibit growth in patient volumes that far exceeds reasonable assumptions. By contrast, UNC Hospitals' application relies on the shift of existing patients within the UNC Health Care System, in particular the referral of patients from Wake, Harnett, and Lee counties who currently seek care at UNC Hospitals in Chapel Hill to Holly Springs. As a result, UNC Hospitals' projection methodology is reasonable and conservative. Both Duke Raleigh and TPHC project

double-digit growth in every year until project year three. By comparison, UNC Hospitals projects 2.2 percent growth annually which is more reasonable, conservative, and supported by actual linear accelerator utilization data, population growth, and its historical experience.

Furthermore, as discussed in the general comments above, UNC Hospitals' application proposes the most effective alternative with respect to unnecessary duplication of existing resources. UNC Hospitals' is the only applicant that proposes to increase geographic access and the only applicant that proposes to reduce Service Area 20 outmigration by shifting patients who are currently leaving the area for care. By contrast, Duke Raleigh and TPHC propose to expand the capacity at existing sites of care and both propose to shift patients from other providers as demonstrated by the increased market share assumptions in their applications. Duke Raleigh and TPHC will unnecessarily duplicate existing resources and not expand access to patients who face geographic barriers.

To the degree that the Agency believes that TPHC and Duke Raleigh's overstated market volumes are reasonable, UNC Hospitals believes it is the most effective proposal to take advantage of that growth, given that it is the only proposal that will increase geographic access.

Finally, as discussed in the comments related to each applicant above, Duke Raleigh and TPHC are non-conforming with Criteria 3 and 6 as they did not adequately demonstrate need or that their respective projects would not result in unnecessary duplication of services.

Summary of Comparative Review

As discussed above, UNC Hospitals is the most effective alternative with respect to geographic distribution, access by Medicaid patients, access by self-pay patients, physician support, and demonstration of need/unnecessary duplication. UNC Hospitals and Duke Raleigh each represent effective alternatives with respect to ancillary and support services while TPHC does not. Each of the three applicants have met the minimum requirements for staffing, and therefore are all effective alternatives with regard to staffing. The three applications cannot be compared with respect to gross revenue per ESTV, net revenue per ESTV, or operating expense per ESTV based on the difference in the types of services provided. Based on the comparative review, it is clear that UNC Hospitals proposes the most effective alternative to develop an additional linear accelerator in Service Area 20 and should be approved. Duke Raleigh and TPHC's applications should be denied.

Attachment 1

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STATE OF NORTH CAROLINA			THE GENERAL COURT OF JUSTICE SUPERIOR COURT DIVISION
WAKE COUNTY	ZIII JUL - 7		FILE NO. 13 CVS 8700
ECK SUPPLY CO.,	Land Con Ti)	· ·
Plaintiff,	And the second second], 0.3.0	C. ·
v.)	
T.A. LOVING COMPANY, UROLOGY, P.A. d/b/a CARY P.A., and ALLEN R. WOOD & INC.	UROLOGY,)	
Defendants	,)	
T.A. LOVING COMPANY,	AND THE RESIDENCE OF THE PARTY)	
Third-Party	Plaintiff,)	
v.)	
ALLEN R. WOOD & COMPANY	r, INC.,.)	
Third-Party	Defendant.)	

NOTICE OF CASH DEPOSIT TO DISCHARGE LIENS PURSUANT TO N.C. GEN. STAT. §\$44A-16 and 44A-20

Now comes Parkway Urology, P.A. ("Parkway"), pursuant to N.C. Gen. Stat. §§44A-16 and 44A-20 and gives notice of deposit of cash (\$212,829.17) to discharge liens:

- 1. Parkway owns the real property located at 117 Sunnybrook Road, Raleigh, North Carolina (the "Property").
- 2. Before August 17, 2012, Parkway entered into a general construction contract (the "General Contract") with T.A. Loving Co. ("Loving") whereby Loving agreed to serve as general contractor for the construction of a new building (the "Project") on the Property.

- 3. Eck served a Claim of Lien on Real Property by Second Tier Subcontractor/Supplier dated June 25, 2013 ("Real Property Lien") and a Notice of Claim of Lien on Funds by Second Tier Subcontractor/Supplier dated June 24, 2013 ("Funds Lien"). Parkway received the Real Property Lien and Funds Lien in June, 2013.
- 4. Eck Supply Co. ("Eck") filed a Complaint against Parkway and other Defendants to enforce the Real Property Lien and the Funds Lien.
- 5. In Section 3.19.1 of the General Contract, Loving promised to "comply with the requirements of a contractor under N.C. Gen. Stat. §44A-23(b)(1), including but not limited to the filing and posting of a Notice of Contract." In its Responses to Eck's Requests for Admission in this action, Loving admitted that it failed to file or to post a Notice of Contract within the time required by N.C. Gen. Stat. §44A-23(b)(1).
- 6. In Section 3.19.1 of its General Contract with Parkway, Loving promised to, "within ten (10) days of receipt of notice of the lien, claim of lien or encumbrance, cause the same to be discharged of record at no cost to the Owner [Parkway]." Loving has failed to cause Eck's Real Property Lien and Funds Lien to be discharged of record.
- 7. Section 3.19.1 of the General Contract expressly allows Parkway to "withhold from the next progress payment or any other sum payable to the Contractor [Loving] an amount sufficient to discharge such lien, claim of lien or encumbrance," and to "apply amounts so withheld to discharging such lien, claim of lien or encumbrance." This Section is consistent with Parkway's withholding obligations under N.C. Gen. Stat. § 44A-20.
- 8. Because Loving failed to discharge Eck's Real Property Lien and Funds Lien of record, Parkway now wishes to exercise its right to discharge Eck's Real Property Lien and Funds Lien and to reserve all rights, including but not limited to all rights of indemnity, against Loving.

- 9. Parkway admits that it owes Loving at least \$193,993.23, plus interest at the legal rate since April 9, 2013, for the labor and materials that Loving furnished to improve the Project. Parkway has withheld these funds pursuant to Section 3.19.1 of the General Contract and N.C. Gen. Stat. § 44A-20. Parkway's admission that it owes this amount shall not waive or diminish Parkway's defenses against claims brought by Loving in T.A. Loving Co. v. Parkway Urology, P.A., Wake County case no. 14 CVS 3884.
- 10. In order to discharge Eck's Real Property Lien and Funds Lien pursuant to N.C. Gen. Stat. §§44A-16 and 44A-20, Parkway has deposited with the Wake County Clerk of Superior Court the sum of \$212,829.17 (the "Cash Deposit").
- 11. The Cash Deposit discharges Eck's Real Property Lien and Funds Lien pursuant to N. C. Gen. Stat. §§44A-16 and 44A-20.
- 12. Parkway disclaims and relinquishes all rights in or claims to the Cash Deposit. Parkway acknowledges and agrees that the Court will distribute the entire Cash Deposit to Eck or to Loving (not to Parkway), as the Court in this lawsuit determines their respective interests. Any portion of the Cash Deposit not paid to Eck shall be paid to Loving, as ordered by the Court.
- 13. The Cash Deposit consists of amounts Parkway owes to Loving under the General Contract, which amounts provide the statutory basis for Eck's Funds Lien and Real Property Lien. Therefore, the entire Cash Deposit is a credit against amounts Parkway owes Loving for labor and materials furnished to improve the Project and the Property.
- 14. Parkway demands that Eck immediately dismiss its claims against Parkway as the sole basis for any claim against Parkway was to enforce its Funds Lien or Real Property Lien.

[Signatures appear on the following page.]

Respectfully submitted, this the 26 day of June, 2014.

PINNA, JOHNSTON & BURWELL, P.A.

GRAEBE HANNA & SULLIVAN, PLLC

Roderick W. O'Donoghue, Jr., NCSB #9390 2601 Oberlin Road, Suite 100

Raleigh, North Carolina 27608

Telephone:

(919) 755-1317;

Fax:

(919) 782-0452

Email:

rodonoghue@pjb-law.com

Counsel for Defendant Parkway Urology, P.A.

Christopher T. Graebe, MCSB #17416

4350 Lassiter at North Hills Ave., Ste. 375

Raleigh, North Carolina 27609 Telephone: (919) 863-9092;

Fax:

(919) 863-9095

Email:

cgraebe@ghslawfirm.com

Counsel for Defendant Parkway Urology, P.A.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that he has this day served a copy of the foregoing NOTICE OF CASH DEPOSIT by United States mail, postage prepaid, addressed as follows:

Eric H. Biesecker Nexsen Pruet, PLLC P.O. Box 3463 Greensboro, North Carolina 27402

Henry C. Smith Warren, Kerr, Walston, Taylor & Smith, LLP P.O. Box 1616 Goldsboro, North Carolina 27533-1616

John D. Burns Williams Mullen 301 Fayetteville Street, Suite 1700 Raleigh, North Carolina 27601

E. Scott Tart Narron, O'Hale & Whittington, P.A. P.O. Box 457 Benson, North Carolina 27504

This the day of June, 2014.

Roderick W. O'Donoghue

WAKE COUNTY CLERK OF SUPERIOR COURT N. LORRIN FREEMAN CIVIL RECEIPTING

File Number 13 CVS 8700

PayeeUVOIOGY Cary UVOIOGY	(Divorce)
(Atty Pd, Address, Ins Co, Case Caption – Upset Bid) TO BE FLAGGED "Y"	GVDC:\$150:00 \$
CVSC Superior \$ 200.00 []	(Outlof State Atty/Fees))
CVDC District \$150.00 [] Small Claims Appeal	Out of State Barvice #24626 N\$ LIMITED DRIVING PRIVLEGE #24335 \$
M#s #21435 \$ CONF OF JUDGMENT #21400 \$	
PPLMINT PROC #21400 \$	Business Court 4 211122 \$1,000 44.
TRIAL DE NOVO #24310 \$ (Appeal Arbitration) MOTIONS #21450 \$	BOND FORHEITURE #22800 \$200 (Before) Judgment)
ALIAS & PLURIES #21455 \$	REGISTRATIONS #27400\$ BONDS SREQITY A #26270\$ PE A TILLER A PROBLEM A PROBL
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ARBITRATION FEE M# #24311 \$	(Surplusitunds) Ernest Money Etca)
<u>IA</u> WRITS #21430 \$ (Executions/Possession)	GONDEMNIATIONS #2613018 URSEI(BID) #26700 \$
<u>IA</u> TRANSCRIPT #21440 \$	Posted By
EFFECTIVE: 7/1/11	•

Attachment 2

CORRECTED Duke Raleigh LINAC Patient Projection Methodology (5 machines)

In Exhibit 19 of its application, Duke Raleigh provides a patient projection methodology for all five linear accelerators in the form of printed tables (see the 2nd and 3rd pages of Exhibit 19). As noted in UNC Hospitals' comments, Duke Raleigh's application overstates the number of projected cancer cases for linear accelerator services in the market, however, for the purposes of this specific discussion, UNC Hospitals has utilized Duke Raleigh's original assumptions regarding market volume, Step 5 of its original methodology.

Step 5: Projected Cancer Patients to Receive External Beam Radiation Therapy

2015 185 343 522 249 2803		,		
Co. 181 183 185 O. 331 337 343 Co. 507 515 522 250 250 249		2016	2017	2018
o. 331 337 343 Co. 507 515 522 250 250 249 260 2747 2803		187	190	192
Co. 507 515 522 250 250 249 2600 2747 2.803		349	355	361
250 250 249 249 250 249 250 249 250 250 250 250 250 250 250 250 250 250		530	538	545
2 690 2 747 2 803		248	247	246
2,000	2,747 2,803	2,859	2,915	2,972

			X CLX
Step 6: DRAH LINAC Patients	NAC Patients		Duk
	FY2013	FY2014	
Franklin Co.	24	22	Fran
Harnett Co.	6	12	Han
Johnston Co.	29	19	John
Nash Co.	15	10	Nas
Wake Co.	274	286	Wal

Duke Raleigh CORRECTED	Duke Raleigh CORRECTED		46%
	2013	2014	2015
Franklin Co.	22	25	14
Harnett Co.	34	35	19
Johnston Co.	29	30	16
Nash Co.	5	3	2
Wake Co.	536	535	289

Combined DRAH + Former CCNC LINAC Patients to	Shift to Duke Raleigh CORRECTED	
Combin	Shift to	

)		
	FY2013	FY2014	FY2015
Franklin Co.	46	47	36
Harnett Co.	43	47	31
Johnston Co.	58	49	35
Nash Co.	20	13	12
Wake Co.	810	821	575

Step 7: DRAH Market Share

ŕ			Proje	Projected Market Share CORRECTED	hare CORREC	TED	Annual M	Annual Market Share Growth 16-18	owth 16-18
	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	Year 1	Year 2	Year 3
Franklin Co.	25.4%	25.6%	19.1%	19.6%	20.6%	22.1%	0.50%	1.00%	1.50%
Harnett Co.	13.0%	13.9%	%0.6	%0.6	%0.6	%0.6	0.00%	%00'0	0.00%
Tohnston Co.	11.4%	9.5%	%2'9	7.2%	8.2%	9.7%	0.50%	1.00%	1.50%
Nash Co.	8.0%	5.2%	4.7%	4.7%	4.7%	4.7%	0.00%	%00.0	0.00%
Wake Co.	30.1%	29.9%	20.5%	22.0%	24.0%	26.5%	1.50%	2.00%	2.50%
The second of									

Step 8: Projected DRAH LINAC Patients CORRECTED

		Interim Year	PY1	PY2	PY3
	FY2014	FY2015	FY2016	FY2017	FY2018
Franklin Co.	47	36	37	39	42
Harnett Co.	47	31	31	32	33
Johnston Co.	49	35	38	44	53
Nash Co.	13	12	12	12	12
Wake Co.	821	575	629	200	788
In-Migration	124	95	104	115	129
Total	1,100	784	851	942	1,056
In-Migration %	11.3%	12.2%	12.2%	12.2%	12.2%

Steps 9 & 10: Duke University Hospital LINAC Patient Shift to DRAH Linacs

January Commander of the Control of	Character and	Jac-	
	FY2016	FY2017	FY2018
Franklin Co.	2	2	2
Harnett Co.	2	2	2
Johnston Co.	3	7	7
Nash Co.	2	2	2
Wake Co.	28	28	29
Total	37	38	38

Franklin Co. 47 36 39 Harnett Co. 47 31 33 Johnston Co. 49 35 41 Nash Co. 13 12 14 Wake Co. 821 575 657 In-Migration 124 95 104 Total 1,101 784 888 Patiented inc. 267 761 178	FY2015 FY2016 FY2017	7 FY2018
ton Co. 47 31 ton Co. 49 35 Co. 13 12 Co. 821 575 gration 124 95 total 1,101 784		44
ton Co. 49 35 Co. 13 12 Co. 821 575 gration 124 95 tedfine 367 261	1 33 34	35
Co. 13 12 Co. 821 575 gration 124 95 1,101 784		22
Gration 821 575 gration 124 95 14101 784 14101 784		14
gration 124 95 1,101 784		817
1,101 784 267 367 261		129
196 298		1,095
107	51 178 196	219

Attachment 3

CORRECTED Duke Raleigh LINAC Patient Projection Methodology (2 machines)

In Section IV and Exhibit 19 of its application, Duke Raleigh provides a patient projection methodology for the two linear accelerators proposed to be operated at Duke Raleigh Hospital. As noted in UNC Hospitals' comments, Duke Raleigh's application overstates the number of projected cancer cases for linear accelerator services in the market, however, for the purposes of this specific discussion, UNC Hospitals has utilized Duke Raleigh's original assumptions regarding market volume.

Step 5: Projected Cancer Patients to Receive External Beam Radiation Therapy

f J						
	2013	2014	2015	2016	2017	2018
Franklin Co.	181	183	185	187	190	192
Harnett Co.	331	337	343	349	355	361
Johnston Co.	507	515	522	530	538	545
Nash Co.	250	250	249	248	247	246
Wake Co.	2,690	2,747	2,803	2,859	2,915	2,972

Step 6: DRAH LINAC Patients	NAC Patients	
	FY2013	FY2014
Franklin Co.	24	22
Harnett Co.	6	12
Johnston Co.	29	19
Nash Co.	15	10
Wake Co.	274	286

Duke Raleigh	Duke Raleigh CORRECTED		20%
	2013	2014	2015
Franklin Co.	22	25	20
Harnett Co.	34	35	28
Johnston Co.	29	30	24
Nash Co.	5	3	2
Wake Co.	536	535	428

RECTED	FY2014
Shift to Duke Raleigh CORRECTED	FY2013
Shift to Dul	

		FY2013	FY2014	FY2015
····	Franklin Co.	46	47	42
	Harnett Co.	43	47	40
1:3	Johnston Co.	58	49	43
	Nash Co.	20	13	12
	Wake Co.	810	821	714
•				

Step 7: DRAH Market Share

			-	No Market M	No Market Share Increases		Annual Ma	Annual Market Share Growin 10-10	01-01 mag
	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	Year 1	Year 2	Year 3
Franklin Co.		12.0%	11.9%	11.9%	11.9%	11.9%	0.00%	0.00%	0.00%
Harnett Co.		3.6%	3.5%	3.5%	3.5%	3.5%	0.00%	0.00%	0.00%
Johnston Co.		3.7%	3.6%	3.6%	3.6%	3.6%	0.00%	0.00%	0.00%
Nash Co.		4.0%	4.0%	4.0%	4.0%	4.0%	0.00%	0.00%	0.00%
Wake Co.		10.4%	10.2%	10.2%	10.2%	10.2%	%00.0	0.00%	0.00%

Step 8: Projected DRAH LINAC Patients CORRECTED

		Interim Year	PY1	PY2	PY3
	FY2014	FY2015	FY2016	FY2017	FY2018
Franklin Co.	22	22	22	22	23
Hamett Co.	12	12	12	12	13
Johnston Co.	19	19	19	20	20
Nash Co.	10	10	10	10	10
Wake Co.	286	286	292	297	303
In-Migration	62	62	63	64	92
Total	411	411	419	426	434
Patients/Linac	411	411	209	213	217
In-Migration %	15.1%	15.1%	15.1%	15.1%	15.1%

Attachment 4

CORRECTED Duke Raleigh LINAC Patient Projection Methodology (5 machines)

In Exhibit 19 of its application, Duke Raleigh provides a patient projection methodology for all five linear accelerators in the form of printed tables (see the 2nd and 3rd pages of Exhibit 19). As noted in UNC Hospitals' comments, Duke Raleigh's application overstates the number of projected cancer cases for linear accelerator services in the market, however, for the purposes of this specific discussion, UNC Hospitals has utilized Duke Raleigh's original assumptions regarding market volume, Step 5 of its original methodology.

Step 5: Projected Cancer Patients to Receive External Beam Radiation Therapy

	2013	2014	2015	2016	2017	2018
Franklin Co.	.181	183	185	187	190	192
Harnett Co.	331	337	343	349	355	361
Johnston Co.	507	515	522	530	538	545
Nash Co.	250	250	249	248	247	246
Wake Co.	2,690	2,747	2,803	2,859	2,915	2,972

	34	Harnett Co.	12	6	Harnett Co.
	22	Franklin Co.	22	24	Franklin Co.
	2013		 FY2014	FY2013	
	Duke Raleigh CORRECTED	Duke Raleigh		NAC Patients	Step 6: DRAH LINAC Patients
gen	Former CCNC LINAC Patient	Former CCNC			

46% 2015

ts to Shift to

2014

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535

536 59

286 19 10

53 15

ohnston Co.

Nash Co. Wake Co.

Franklin Co. Harnett Co.

Johnston Co. Nash Co. Wake Co.

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	FY2013	FY2014	FY2015
Franklin Co.	46	47	36
Hamett Co.	43	47	31
Johnston Co.	58	49	35
Nash Co.	20	13	12
428 Wake Co.	810	821	575
139			

Step 7: DRAH Market Share

				No Market SF	No Market Share Increases		Annual Ma	Annual Market Share Growth 16-18	owth 16-18
	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	Year 1	Year 2	Year 3
Franklin Co.	25.4%	25.6%	19.1%	19.1%	19.1%	19.1%			
Harnett Co.	13.0%	13.9%	%0.6	%0.6	%0.6	%0.6			
Johnston Co.	11.4%	9.5%	6.7%	6.7%	%2.9	%2'9			
Nash Co.	8.0%	5.2%	4.7%	4.7%	4.7%	4.7%			
Wake Co.	30.1%	29.9%	20.5%	20.5%	20.5%	20.5%			

Step 8: Projected DRAH LINAC Patients CORRECTED

		Interim Year	PYI	r r z	rrs
	FY2014	FY2015	FY2016	FY2017	FY2018
Franklin Co.	47	36	36	36	- 37
Harnett Co.	47	31	31	32	33
Johnston Co.	49	35	36	36	37
Nash Co.	13	12	12	12	12
Wake Co.	821	575	586	598	610
In-Migration	124	95	26	66	101
Total	1,100	784	862	813	828
In-Migration %	11.3%	12.2%	12.2%	12.2%	12.2%

Steps 9 & 10: Duke University Hospital LINAC Patient Shift to DRAH Linacs

	,	-	
	FY2016	FY2017	FY2018
Franklin Co.	2	2	2
Harnett Co.	2	2	2
Johnston Co.	3	7	4
Nash Co.	2	2	2
Wake Co.	28	.78	29
Total	37	38	38

Step 11: Total Projected LINAC Patients CORRECTED

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	FY2014	FY2015	FY2016	FY2017	FY2018
Franklin Co.	47	36	38	38	39
Harnett Co.	47	31	33	34	35
Johnston Co.	49	35	39	40	41
Nash Co.	13	12	14	14	14
Wake Co.	821	575	614	626	629
In-Migration	124	95	- 26	66	101
Total	1,101	784	835	851	298
Patients/Linac	367	261	167	170	173