Comments on Harnett Health Cancer Center

submitted by

Johnston Radiation Oncology

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Johnston Radiation Oncology (JRO) submits the following comments related to an application to develop a linear accelerator in Harnett County. JRO's 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 review of these comments, JRO has organized its discussion by issue, noting some of 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 application:

- **Harnett Health Cancer Center, Project ID # J-11062-15**

Harnett Health's application should not be approved as proposed. JRO has identified the following specific issues, each of which contributes to Harnett Health's non-conformity:

- Failure to Include All the Necessary Applicants
- Failure to Provide Reasonable and Supported Utilization Projections
- Failure to Provide Reasonable Market Share Assumptions
- Failure to Demonstrate Conformity with the CON Rules
- Failure to Demonstrate the Availability of Funds and Financial Feasibility of the Project
- Failure to Demonstrate Reasonable Staffing for the Project
- Failure to Identify the Population to Be Served
- Failure to Demonstrate that Payor Mix Assumptions are Reasonable and Supported

Each of the issues listed above are discussed in turn below. Please note that relative to each issue, JRO has identified the statutory review criteria and specific regulatory criteria and standards creating the non-conformity.

GENERAL COMMENTS

While the proposed project includes the acquisition and development of a linear accelerator in Harnett County, which is subject to a need determination in the *2015 SMFP*, the Agency should take note of the fact that the project includes

multiple service components in addition to the linear accelerator. Although these other components may not be subject to need determinations, some are reviewable, per se, such as the simulator, and others are reviewable as new institutional health services because of the capital cost involved in their development, such as the development of medical oncology services. In addition, while a considerable portion of the capital cost of the project arises from the acquisition of the linear accelerator and associated construction, the majority of the revenue for the project is from the medical oncology portion of the project, not the radiation oncology portion. Given the tenuous financial condition of Harnett Health System ("Harnett Health"), the large capital expenditure proposed in this project that results in increased indebtedness of the applicant, and numerous other issues described in detail below, JRO believes that after careful consideration of the application, the Agency should disapprove Harnett Health's application.

ISSUE-SPECIFIC COMMENTS

Failure to Include All the Necessary Applicants

JRO believes that the information in the application clearly demonstrates that in addition to Harnett Health System, Inc., Cumberland County Hospital System, Inc. should also be an applicant. The evidence regarding this position is as follows:

1. Cumberland County Hospital System, Inc. (d/b/a Cape Fear Valley Health System, "CFVHS") is paying for the project in its entirety (i.e., incurring the obligation for a capital expenditure), without any financial consideration for the use of its capital, and without expecting any repayment to begin until the second year of the project to continue for thirty years. CFVHS is not a bank or vendor, but is itself a healthcare provider. CFVHS is also involved directly in providing services for the project, as described below. Therefore, unlike unrelated, third party transactions such as a bank loan, CFVHS is an existing healthcare provider incurring an obligation to expend capital for the project.

2. The funding documentation relies solely on the financial wherewithal of CFVHS. The application provides no demonstration of the ability of Harnett Health to repay the capital to CFVHS or in any way fund the project outside of the donation from CFVHS. This also supports the fact that CFVHS is incurring the financial obligation for the project.

3. Multiple services will be provided directly by CFVHS but billed by Harnett Health.

With a service as complex and multi-faceted as oncology, JRO understands that providers often contract with other organizations for those services, with patients typically billed by the contracted party, such as physicians and other medical professionals. For other services, such as physical therapy or off-site pharmacy services, providers may have referral relationships (either directly or through the physicians caring for the patients) to enable patients to receive these services. In these forgoing circumstances and others similar to them, the other organizations may be providing a service utilized by patients being served by the applicant, but are not part of the service being offered and billed as part of its proposed new institutional health service. In those cases, the other organizations are certainly not a necessary applicant in the review.

Unlike those circumstances, however, this application proposes to provide services as part of the project that will be billed for by Harnett Health, but that will be provided by CFVHS. An examination of Sections II.1, II.2, II.8, VII and the pro formas of the application make this clear. Specifically, the following services and staff will be provided by CFVHS but are included in the expenses for Harnett Health as shown in the pro formas, and therefore are included in the patient charges from Harnett Health:

a. Physicians (radiation and medical oncologists), employed by CFVHS but included in the professional salaries on the Harnett Health pro forma (and thus billed as part of the service by Harnett Health, as also stated on page 24);
b. Clinical nurse manager (pages 346-347);
c. Service line director (pages 350-351);
d. Physicist (page 36);
e. Social work services (page 18);
f. Certified tumor registrar (page 23);
g. Dietician (page 23);
h. Dosimetrist (pages 23 and 37);
i. Staff recruitment (page 83);
j. Management (without a management agreement for the service, page 22); and,
k. Maintenance service contract (page 38).

The application makes it clear in multiple locations, including page 24, that patients will receive only one bill for all services provided, from Harnett Health, including the oncologists' fees. As noted in the table in Section II.1.(b), several of the providers will be CFVHS staff, but the services rendered by those staff will be billed by Harnett Health. In addition, the application states that CFVHS will

provide management services for the Cancer Center @ Central Harnett, although it does not provide a management agreement for those services, or state the fees or consideration that will be provided in exchange for those services. The hospital management agreement included in Exhibit 2 of the application does not include management of the Cancer Center.

Based on this information, it is clear that in addition to Harnett Health, CFVHS is incurring an obligation for the capital expenditure for the new institutional health service, as well as offering many of the non-contracted services to be provided at Central Harnett Hospital and billed to patients by Harnett Health. Therefore, CFHVS should also be an applicant for the proposed project.

For these reasons, the application should not be approved.

Failure to Provide Reasonable and Supported Utilization Projections

The application fails to demonstrate the need for the proposed project, including multiple service components: linear accelerator, medical oncology and CT simulator. Each of these issues is discussed below.

Failure to Demonstrate the Need for the Linear Accelerator

In its application, Harnett Health projects the number of patients it proposes to serve on the proposed linear accelerator as well as the number of medical oncology services it will serve. These projections are not supported by the historical utilization of linear accelerator services in the applicant's proposed service area.

On page 49, Harnett Health projects that, in total, Harnett County will have 360 cancer patients be radiated in CY 2016 as shown in table below excerpted from the application.

Total Expected Harnett County
Radiation Therapy Patients

Age Group	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021
Total Projected Harnett County Cancer Patients	636	653	670	688	707	726
Projected Cases Radiated = 50%	318	326	335	344	353	363
Projected Cases Radiated 2x = 13.2%	42	43	44	45	47	48
Projected Total Harnett County Cases Radiated	360	369	379	389	400	411
Convert Volumes to FFY						
				FFY 2019	FFY 2020	FFY 2021
Projected Total Harnett County Patients Radiated				387	397	408

Source: Exhibit 10, Table 1

Source: page 49 of Harnett Health application.

As shown in table below, excerpted from Exhibit 10 of the Harnett Health application, linear accelerator providers in North Carolina provided services to a total of 246 Harnett County patients in FY 2014.

Table 4. Harnett County Linac Utilization and Market Share

County	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014
FirstHealth-Moore	24	31	32	33	49
Cape Fear Valley	63	54	60	39	45
UNC Hospitals	33	32	37	44	43
Smithfield Radiation	18	26	24	33	24
Johnston Radiation	6	12	7	13	21
Duke	7	16	9	23	17
Rex	22	15	11	11	17
Cancer Centers of NC	21	47	38	34	16
Duke Raleigh	11	7	75	9	11
All Other	21	6	4	2	3
Total	226	246	297	241	246
Total w/o Duke Raleigh	215	239	222	232	235
Annual Growth		11.2%	-7.1%	4.5%	1.3%

Source: Annual LRAs
Note Duke Raleigh volume in FFY 2012 inaccurate

As such, Harnett Health's projections indicate that the number of Harnett County patients receiving linear accelerator services will grow 46 percent between 2014 and 2016 (46 percent = 360 patients in 2016 ÷ 246 patients in 2014 – 1). Harnett Health provides no information to support this significant increase in the number of linear accelerator patients in Harnett County. In fact, data from the North Carolina Central Cancer Registry shown on pages 46-47 of the application indicate that there were only two more new cancer cases in 2015 than

in 2014. No two year period provided in the North Carolina Central Cancer Registry data supports a 46 percent increase over two years as projected by Harnett Health.

In the 2006 Onslow County Linear Accelerator Review, the Agency found Onslow Radiation Oncology non-conforming with Criterion 3 based on a determination that *"the North Carolina State Center for Health Statistics reports an annual increase from 2004-2005 of only 1.1% in new cancer cases in Onslow County. In comparison, the applicant projects a five year overall increases in cases of 18.3% ...between 2005 and 2010, which is about 3.6% per year... Thus, the applicant's projections of new cancer cases in Onslow County are unreasonably high in comparison to statistical data provided by the North Carolina State Center for Health Statistics"* (page 17). The Onslow County review was a similar circumstance: the development of the first linear accelerator in a newly-developed service area. Nonetheless, the Agency did not accept the applicant's growth rate for the reasons stated above, and should similarly deny Harnett Health based on the discrepancy between the historical data and projected growth of linear accelerator patients in Harnett Health' projections.

On page 51 of its application, Harnett Health projects the number of patients that its proposed linear accelerator will serve by county of origin, as shown below.

Cancer Center @ Central Harnett
Projected Harnett County Patient Volume
Federal Fiscal Years

Calendar Year	FFY 2019	FFY 2020	FFY 2021
Projected Total Harnett County Cases Radiated	387	397	408
Market Share of Projected Total Cases Radiated to New Linear Accelerator	40%	50%	60%
Harnett County Cases to New Linear Accelerator	155	199	245

Source: Exhibit 10, Table 1

Harnett Health projects to serve 245 Harnett County linear accelerator patients by the third year of operation, which is only one fewer patient than the total number of Harnett County linear accelerator patients (as shown above, 246 patients in 2014). Thus, in the third year of operation, Harnett Health projects that it will serve nearly 100 percent of Harnett County linear accelerator patients. Harnett Health states in its application that it projects to serve only 60 percent of Harnett County linear accelerator patients based upon data from other North Carolina linear accelerator providers. Therefore, the projected utilization of the Harnett Health linear accelerator is not based on reasonable and supported assumptions.

While JRO understands that Harnett Health is projecting utilization for a new service (radiation oncology), it also believes that it is prudent to compare the outcome of the methodology with available utilization statistics to determine if the projections are reasonable. Based on the discussion above, clearly they are not. JRO believes that the sources of the overstatement of utilization likely originate in the assumptions in Exhibit 10, Table 1, shown above and on page 49 of the application. In particular, Harnett Health based its assumption of retreatments, 13.2 percent, on the experience of CFVHS. However, the types of cancer being treated at CFVHS are certainly likely to be different than those that comprise the Harnett County cancer cases; thus, a different experience with regard to second course of treatments can be expected and may be part of the cause of the wide gap between actual historical utilization and the projected utilization in the application. Harnett Health also referred to the NCI/ASTRO guidelines in Exhibit 14 as supporting its assumption that 50 percent of its patients would be treated on a linear accelerator. However, the language in the exhibit refers to all forms of radiation therapy, not solely external beam treatments (such as are provided by a linear accelerator), and continues on page 426 to discuss the use of brachytherapy as a treatment. Brachytherapy is also radiation therapy, but does not use a linear accelerator. The application does not indicate if or how this fact was considered in the assumptions. For these reasons, as well as other possible factors, known or unknown, the results of the application's utilization projections for patients needing linear accelerator treatments are overstated and unreasonable.

Notwithstanding the unreasonableness of the projections standing alone, JRO believes the Agency should deny Harnett Health on the basis of consistency with its previous decision to deny an application based on unreasonable projections for linear accelerator patients in Harnett County. The Agency denied a proposal to relocate an existing linear accelerator after a review of patient projections in comparison to historical linear accelerator data revealed similar large differences. In its findings for the 2011 Wake County Acute Care Beds review, the Agency denied Rex Hospital's proposal to relocate a linear accelerator to Holly Springs based upon a finding that the "projected utilization of the linear accelerator at Rex Holly Springs is not based on reasonable and supported assumptions" (page 90). As shown below, the Agency found that:

> *the existing linear accelerator providers in the counties surrounding Harnett County provided services to a total of 228 Harnett County residents in FY2010. In the first year of operation (FY2015), the applicant projects it will serve 112 Harnett County patients with its proposed linear accelerator in Holly Springs, which is equivalent to almost half (49.1 percent) of total number of patients served by the providers in surrounding counties in FY2010. Also, the applicant's projections of total*

Harnett County patients to be served at the proposed Holly Springs facility in the first year of operation (112 patients in FY2015) is nearly twice the number served at the most frequently used provider by Harnett residents, Cape Fear Valley Medical Center (63 patients in FY2010), and 60 percent higher that (sic) the total number of Harnett County patients served by all of the existing Wake County providers combined (71 patients in FY2010). Therefore, the projected utilization of the linear accelerator at Rex Holly Springs is not based on reasonable and supported assumptions. The applicant did not adequately demonstrate the need to relocate one of its four existing linear accelerators to the new hospital in Holly Springs.

See page 90 of Findings for 2011 Wake County Acute Care Beds

The Agency determined that Rex Holly Springs' projected utilization was unreasonable as it was equivalent to almost half of the total patients served historically in Harnett County. Similarly, the Agency should find that Harnett Health's projected utilization, which is equivalent to 100 percent of the total patients historically served in Harnett County, is also unsupported and unreasonable. JRO believes the Agency should deny Harnett Health on the basis of these issues as well.

Failure to Demonstrate the Need for Medical Oncology

The application proposes to develop 10 treatment recliners and eight patient exam rooms for medical oncology purposes, as noted on page 18 of the application. The application fails to demonstrate the need for these spaces. In Section III.1, the application projects the number of chemotherapy patients, based on the number of radiation patients. However, the application never explains the basis for the number of spaces needed for chemotherapy patients, either for the chemotherapy treatments or for patient examination. While the exact dimensions or total square footage of the space to be used for medical oncology is not broken out in the application, the line drawings in Exhibit 13 show that it is a considerable portion of the proposed new construction. Based on the project cost per square foot of $485.44 shown on page 99 (for space other than the linear accelerator), the cost to develop this space is in the millions of dollars. Without any discussion of the rationale driving the need for the proposed number of treatment spaces, as a foundational issue, the application fails to document the need to develop the proposed space, including the number of exam rooms and treatment stations proposed.

Moreover, Harnett Health's utilization projections for the number of hematology/oncology patients at its facility are tied directly upon its projected number of linear accelerator patients. Thus, if the Agency finds the radiation

oncology projections to be unreasonable (as JRO believes it should), then the medical oncology projections are also unreasonable.

As stated on pages 53-54 of its application, "[b]ased upon historical utilization data at CFV Cancer Center 60% of total hematology/oncology patients receive radiation therapy treatments in addition to other therapies. The following table projects future Hematology/Oncology patients at the Cancer Center @ Central Harnett.

Cancer Center @ Central Harnett Projected New Hematology/Oncology Patients

	FFY 2019	FFY 2020	FFY 2021
New Patients Hematology/ Oncology	303	390	490

Source: Exhibit 10, Table 3

The following table shows the calculations that result in the projected number of hematology/oncology patients and shows the direct relationship between Harnett Health's linear accelerator patient projections and its hematology/oncology patient projections. As noted above, Harnett Health assumes that 60 percent of hematology/oncology patients receive linear accelerator treatment. Thus, the ratio of linear accelerator to hematology/oncology patients is 1 to 1.67 (1.67 = 1 ÷ 60 percent).

Harnett Health Hematology/Oncology Patient Projections

	FFY 2019	*FFY 2020*	*FFY 2021*
Projected Linear Accelerator Patients	182	234	288
Ratio to Hematology/Oncology Patients	1.67	1.67	1.67
Projected Hematology/Oncology Patients	303	390	480

While the application presents medical oncology as almost an adjunct to the linear accelerator service, JRO believes the Agency should not overlook the need to thoroughly analyze the medical oncology service. Not only does the service comprise a significant portion of the capital cost, as discussed above, but the medical oncology portion of the project represents over 70 percent of the total net revenue for the project; thus, as it relates to the impact of the assumptions on the project, the medical oncology portion is incredibly significant. Yet no independent assumptions are provided in the application, and none of the support letters reference the medical oncology portion of the application.

In addition, the application states that medical oncology services are currently being provided at Betsy Johnson Hospital in Dunn. Since the projected number of chemotherapy patients is based on the number of radiation patients, and since radiation will only be provided in Lillington, while chemotherapy is proposed

for both locations, it is reasonable to assume that some of the chemotherapy patients will be treated in Dunn, not at the proposed expansion at Central Harnett Hospital. Page 12 of the application states that 130 oncology patients were treated at Dunn in the past year; while it is possible that some of those patients who also need radiation may come to Lillington for care, it is likely that some of those medical oncology patients, especially those who do not need radiation, will remain in Dunn for care. Thus, the methodology used by the applicant to determine the number of medical oncology patients fails to account for the patients treated in Dunn and overstates the number of patients in need of care in Lillington.

The application also fails to demonstrate the need for this space based solely on the projected number of chemotherapy patients. The need for treatment space is not defined directly by the number of chemotherapy patients, given the wide variation in the numbers of treatments per patient and the length and number of courses or cycles of treatment, which are usually based on the type of cancer being treated, its stage, and whether the chemotherapy is the sole treatment or is adjunct to radiation or surgery. In addition, a chemotherapy patient may take the drug orally, through an injection or intravenously. The first two methods can sometimes be administered at home by the patient or a family member; the last method is generally provided at the hospital or other clinical setting. However, the application fails to distinguish among the various types of treatments being provided by the projected number of patients, or to use any methodology whatsoever to project a number of patient treatments to be provided in the treatment recliners or examination rooms. Such projections are essential at understanding the need for the medical oncology portion of the project, as they can help justify the proposed number of treatment areas, by determining the capacity of each area, and thereby calculating the need a certain number of rooms or treatment areas. In this application, Harnett Health provides no capacity definition for its medical oncology space.

This type of methodology has been used in multiple CON applications for medical oncology services. For example, a 2004 application by NorthEast Medical Center (PID # F-7136-04) to expand its number of chemotherapy bays projected chemotherapy volume (treatments) and defined capacity as 555 treatments per station per year. In a 2010 application (PID # J-8470-10), Rex Hospital proposed adding infusion therapy chairs and projected capacity to be 468 treatments per chair per year. Both of these applications were approved. In a recently-filed application (PID # F-11105-15), Levine Cancer Institute-Concord projected to expand its infusion therapy space, citing a capacity of 425 patient treatments per chair per year. While the methodologies in these applications do not represent the entire universe of methodologies that can be used to demonstrate need for medical oncology space, the complete lack of any methodology, capacity

definition or other connection between the projected number of patients and the proposed number of spaces to treat those patients in the Harnett Health application, compared to extensive explanations of the need for a particular number of treatment areas in these other applications provides clear evidence of the insufficiency of the Harnett Health application to demonstrate need for the proposed medical oncology space.

Failure to Demonstrate the Need for a CT scanner

The application proposes to develop a CT/simulator for the project, apparently through the acquisition of a CT scanner to provide, at least in part, simulations. Included in the capital cost for the project is more than $609,000 for a "Philips Brilliance Big Bore CT Simulation package" (Exhibit 3), and the line drawings in Exhibit 13, page 408 show that the applicant intends to build a room to house the CT simulator in the proposed new construction. However, other information in the application contradicts the proposal to acquire a CT scanner to serve as a simulator. Page 348 includes a letter from Mr. Mike Jones, the Administrator of the Central Harnett Hospital, which clearly indicates that the intent is to upgrade an existing CT scanner at Central Harnett Hospital with software to make it capable of serving as a simulator. The letter also makes it clear that the CT scanner will provide both diagnostic scans and simulations, as it states, "[t]his CT will provide **services for hospital patients and simulator services** for the Cancer Center @ Central Harnett" (emphasis added). Given these contradictions, it is unclear whether the applicant proposes to acquire a new CT scanner or upgrade an existing CT scanner with simulation software, and whether the applicant intends to utilize either the proposed or existing CT scanner for diagnostic procedures as well as simulations. If the proposed CT scanner will be used for procedures other than simulations, as the letter from Mr. Jones indicates, then the CON rules for CT scanners apply, the application failed to provide reasonable and necessary responses, and should be found non-conforming with those rules. If the applicant does not intend to upgrade an existing CT scanner, as stated in Mr. Jones' letter, but to acquire a new CT scanner for this purpose, then the applicant failed to demonstrate why this is the most effective alternative, given Mr. Jones' statement that clearly indicates the potential to use existing equipment for the simulations. In addition, the selected alternative (Site B, per pages 60 and 571 of the application) was chosen, in part due to the "great relationship with imaging (CT & MRI)" available at that location in the rear of the hospital. This statement also seems to imply that the existing CT scanner is in close proximity to and available for patients in the cancer center. Thus, the application is unclear regarding its plan to develop a simulator and fails to demonstrate the need for the capital expenditure proposed for the CT scanner to be used for simulation, including the construction costs necessary to develop the simulator room shown in Exhibit 13.

As a result of these issues, the application is non-conforming with Criteria 3, 4, 5, 6 and 12 and should be denied.

Failure to Provide Reasonable Market Share Assumptions

Harnett Health will be a new provider of radiation therapy services. In projecting its utilization, Harnett Health states that it "assumes a 60% market share" of Harnett County linear accelerator patients (page 50). As supporting information, Harnett Health provides home-county market share data from other community radiation therapy providers as shown below.

Community Hospital Linear Accelerator Market Share of Home County

Community Hospital	Linear Accelerator Market Share of Home County
Hugh Chatham	19.4%
FH Moore	80.1%
Watauga	86.8%
Scotland Memorial	56.8%
Nash	57.7%
CMC Cleveland	60.5%
CMC Union	40.3%
SERMC	55.3%
Vidant Beaufort	56.6%
Morehead Memorial	61.1%
Lenoir Memorial	61.8%
Wilson	83.8%
Stanly	59.0%
Randolph	89.9%
Alamance	64.0%
Rowan	63.3%
Lexington	10.5%
Harnett	
Avg Mkt Share	56.6%
Avg Mkt Share w/o 2Hi 2Low	65.9%

Source: 2015 LRAs; Exhibit 10, Table 3

See page 50.

Harnett Health's analysis of this data notes that "[o]*f the community hospitals in the above list two facilities are similar to Harnett Health in that they are located in counties like Harnett County which is located between two growing metropolitan areas: Alamance Regional Medical Center and Randolph Medical Center [sic]. Market share of the home*

county for these two providers was 64.0% and 89.9% respectively. Based upon these two comparisons, for the purposes of its projected utilization Harnett Health assumes a 60% market share."

However, there are significant differences among Harnett Health, Alamance Regional Medical Center ("ARMC") and Randolph Hospital ("RH"), particularly with regard to oncology services. ARMC has operated a comprehensive cancer center for many years, with multiple sites of medical oncology care and two linear accelerators. RH operates a younger program; however, it has worked closely with the provider that cared for most of its radiation oncology patients prior to developing its own service, Cone Health, to ensure that patients are treated in Randolph County. As noted in the Harnett Health application, there is no one dominant provider of radiation oncology services for Harnett County patients, so even though the applicant may work with Cape Fear Valley in the same way, it will not have as positive an impact on Harnett Health's utilization, given that Harnett County's radiation oncology patients are split among so many other providers.

In addition, the Agency has previously found that it is unreasonable for new providers to assume that their market share will be comparable with other existing providers in the state. In its findings for the 2012 Health Service Are IV Inpatient Rehabilitation Beds Review, the Agency found Johnston Health (one of the owners of JRO) non-conforming with Criterion 3 and stated that "[i]*t is not reasonable for Johnston to assume that its initial market share for rehabilitation services, as a small start-up provider of these services, would be comparable with other existing rehabilitation programs in the state. Moreover, inpatient rehabilitation service areas are not county-based, but rather based on regions and* 'strategically located' *facilities*" (page 83). JRO believes the Agency should deny Harnett Health on the basis of this issue as the Agency denied the Johnston Health proposal on a similar basis.

As a result, the application should not be approved, and is non-conforming with Criteria 3, 4, and 5 as well as the performance standards in the CON Rules.

Failure to Demonstrate Conformity with the CON Rules

Section II.8 of the application presents the responses to the rules for radiation therapy equipment. On page 29, in response to 10A NCAC 14C .1902(b)(1), which requires a list of all radiation therapy equipment and documentation of each item's capabilities and capacities, the application refers to Exhibit 3. The list in Exhibit 3, page 149, contains four items, including the linear accelerator, the simulator, treatment planning software and "physics and simulator equipment." Exhibit 3 also includes vendor quotes and specifications for items 1 through 3.

No information is provided, however, for the "physics and simulator equipment." Thus, the application fails to provide documentation of the capabilities and capacities of the "physics and simulator equipment." This missing information is of particular interest, given the existence of another line item for the CT simulator (item #2), which would appear to obviate the need for additional simulator equipment as proposed in item #4. If the application proposes more than one simulator, then it is also non-conforming with 10A NCAC 14C .1902(b)(5). In any case, the application is non-conforming with the rule at .1902(b)(1).

In response to 10A NCAC 14C .1902(b)(2), which requires documentation of the fair market value and purchase price of the equipment, the application refers again to Exhibit 3, which contains the vendor quotes for items # 1, 2 and 3, discussed above. The exhibit fails to provide a quote or other basis for the fair market value of the proposed "physics and simulator equipment" in Item #4. As such, the application is non-conforming with this rule.

In response to 10A NCAC 14C .1902(b)(7), the application provides a projected number of patients for Harnett County, but does not break out any of the other counties it proposes to serve (either under the rule or in Exhibit 10), which is a total of 15 percent of patients. Therefore, the application fails to provide a number of patients by county for this 15 percent and is non-conforming with this rule.

In response to 10A NCAC 14C .1903(a)(2), the application provides the projected number of patients for the first three project years. However, as discussed above, the projections are not reasonable, and the application fails to demonstrate that the proposed linear accelerator will be utilized at the required minimum threshold.

As a result of these errors, the application should be found non-conforming with 10A NCAC 14C .1902(b)(1), .1902(b)(2), .1902(b)(5), .1902(b)(7) and .1903(a)(2), and should be disapproved.

Failure to Demonstrate the Availability of Funds and Financial Feasibility of the Project

The application contains multiple issues related to funding for and the financial feasibility of the proposed project. Each of these issues is discussed below.

Understated and Unreliable Capital Costs

In Section VIII, page 88, the application states the capital costs for the project will be $11,999,000, including site costs, construction, equipment and other costs. According to line 13 of the capital cost table on page 88 and the total of the equipment list in Exhibit 3, page 149, the fixed equipment cost will be $5,139,322. The linear accelerator is $4,019,527 of that cost, based on the information in Exhibit 3. Based on these figures, the total capital cost except for the linear accelerator can be calculated to be $7,979,473 ($11,999,000 - $4,019,527 = $7,979,473). According to page 59 of the application, the cost for "Site B," was "estimated at $10,270,000 excluding the cost of the linear accelerator" (emphasis added). The application states on page 60 that Site B was chosen as the most effective alternative. Adding the cost stated on page 59 with the linear accelerator cost results in a total capital cost of $14,289,527. Thus, the application understates the capital costs for the proposed project.

The architect's letter, provided on page 410 in Exhibit 13, states that the construction costs, including site work and professional fees, will be $5,399,500. However, the capital costs on page 88 include $713,000 for site costs, $4,809,500 for construction and $400,000 for A&E fees, for a total of $5,922,500. Thus, the basis for the application's projected capital costs is unclear and unreliable, as it differs from the costs estimated by the architect.

The capital costs on page 88 also include $600,000 in costs for movable equipment and furniture, and $224,178 for "other" costs. No explanation of the basis for the "other" costs is provided, nor does the application indicate what those costs represent. Section VIII.2 requests an itemized list of medical equipment over $10,000, to which the applicant refers to Exhibit 3 for an "itemized list of furniture and equipment for patient rooms...." However, Exhibit 3 lists only the fixed equipment and provides no basis for the cost for the $600,000 for furniture and equipment.

Thus, the capital costs in the application are not reliable and are understated.

Insufficient Documentation of Funding

In Section VIII, page 89 of the application states that the funding for the project will come from a no-interest loan from the accumulated reserves of CFVHS to Harnett Health. Section VIII.4 requests letters from the lender documenting certain items, to which Harnett Health pointed to a letter from the CFVHS CFO in Exhibit 30. While the letter does include some of the information requested in Section VIII.4, it is missing some information, notably 4(e), which requests "verification that the lender has examined the financial position of the borrower and found it to be adequate to support the proposal." Not only does Ms. Williams' letter not include this information, but given the precarious financial

situation at Harnett Health, it is uncertain if not unlikely that Ms. Williams could make such a statement.

On page 90, the application states that the proposed loan will be amortized over 30 years, with payback beginning in 2020. However, neither the funding letter from the CFVHS CFO nor the letter from the CEO of Harnett Health state that the payback will not begin until 2020, which is part of the second and third project years. This is also a requirement of Section VIII.5, which requests verification that the lender has agreed to the amortization schedule provided. The lack of documentation for this statement is particularly important, given the unusual nature of the terms of the loan, including the provision for no interest. Further, while the application does include a letter of support for the project from the CFVHS Board, there is nothing to indicate that the CFVHS Board supports the loaning of more than $12 million (for which it has fiduciary responsibility) to Harnett Health with no interest consideration, much less an agreement that the payback will not begin until well after the project's completion.

Sections VIII.9 and 10 of the application discuss the availability of funds for the project, and while the application provides audited financial statements for both Harnett Health and CFVHS, it fails to demonstrate that the funds are available. In particular, the application fails to list any of the ongoing and recently completed projects at CFVHS, which include many millions of dollars of capital costs. Thus, while the audited financials for CFVHS show the availability of funds as of FY 2014, the application fails to discuss the impact of other CON projects on these funds, as required. While the application states in Section VIII.10(b) that the "impact of funding these projects is considered in the pro forma income statement, cash flow and balance sheets provided as part of this project," this statement is incorrect. The pro forma financials do not include any statements for CFVHS; thus, the impact on that organization is not provided. In addition, the application contains no cash flow statement at all. The impact of this project is also not shown on the income statement for Harnett Health. Finally, the balance sheet for Harnett Health fails to accurately reflect the impact of this transaction, as discussed in the following section.

Financial Statement Errors

The application proposes a loan of $12,135,000 to Harnett Health for the capital and operating needs of the project. As a zero-interest loan, it is correct that no interest cost would be shown on the income statement. However, the principal amount should be reflected on the balance sheet for Harnett Health and it is increasing both its liabilities (debt) and its assets. Page 104 of the application presents the balance sheet for Harnett Health, and shows an entry of $11.9

million in FY 2018 under "Construction in Progress." There is no apparent entry related to the balance of the loan amount. In the first project year, FY 2019, the $11.9 million appears to shift to the line items for "Buildings" and "Fixed and Moveable Equipment." However, there is no increase in liabilities that reflects the loan from CFVHS. Specifically, long term debt decreases over this time period, and the line item "Due to Cape Fear Valley" exists well before the project, appears unrelated to this loan and does not change to reflect the addition of this loan. The assumptions for Form A on page 113 refer to "Chart II" for other liabilities; however, this chart does not appear to be included in the application. Thus, it is unclear if and how Harnett Health will actually carry the liability of this loan on its balance sheet, and its balance sheet is unreliable. As noted above, this is particularly concerning given the current financial condition of Harnett Health.

The income statements also fail to include all the expenses associated with the project. Specifically, the assumptions on page 114 regarding expenses for insurance, building and ground maintenance state that they are "not broken out to departments but in system cost." Without the allocation of overhead costs, the application provides no funding for the provision of necessary ancillary and support services, including those previously mentioned as well as housekeeping, laundry and linens, dietary, other building and equipment depreciation, general and administrative costs, and others. While Harnett Health may not allocate overhead costs such as these to the department for internal purposes, the Agency has previously determined that applicants must include overhead allocation to revenue generating departments to show the true cost of providing that service. In Agency Findings for Project ID # F-6380-01, the Agency found the application non-conforming with Criterion 5, even though it was conforming with Criterion 3, on the basis of failing to include the necessary overhead expenses in the departmental pro formas. Those findings state, in part:

> *"It is not reasonable to assume there will be zero costs for all of the line items listed above, particularly Administrative/Other Personnel, Plant Operation/Maintenance and Other Supplies. For example, the applicant states in Section VII.6, page 72, that existing administrative and support personnel will continue to provide support to the shared fixed cardiac catheterization lab. Therefore, some portion of their salaries, personnel taxes and benefits should be allocated to the shared fixed cardiac catheterization lab. The applicant did not include these costs in either the "General and Administrative" or "Other Overhead/Rent" line items because no costs were projected for those line items. Further, Exhibit 12 contains a copy of a service agreement with Siemens which includes the Multistar. However, no costs were projected for equipment maintenance. In addition, regarding building depreciation, the applicant states "*not

tied to dept." *However, the applicant does not adequately explain why it did not allocate building depreciation costs to the proposed shared fixed cardiac catheterization lab."*

Harnett Health's statement that the overhead costs are "not broken out to department" demonstrates the similarities with the assumptions in the above-referenced application, which led to its non-conformity with Criterion 5.

The income statement is also missing expenses for CFVHS' management fees. Section X, page 95 of the application indicates that management fees are deferred until the third year of the agreement, which would occur during FY 2017. An examination of the expenses on the Harnett Health income statement indicates no increase of an amount sufficient to cover the management fees during that year (except for salaries, benefits and medical supplies, none of which would be appropriate categories). The assumptions for the income statements also fail to note the inclusion of management fees in the expense projections. These missing costs are of particular importance given that the pro formas project net losses to continue through the first year in which the hospital-wide management fees would commence, adding to the loss that is already projected, which would also further negatively impact Harnett Health's balance sheet. The service specific income statements also fail to include any allocation of an appropriate portion of the CFVHS management fees. The application also states on page 67 that the Cancer Center @ Central Harnett will be managed by CFVHS. This service is not included in the management agreement in Exhibit 2, which states on page 147, "Services not specifically described in this Exhibit B are not included as part of the Management Services Fee...and shall be paid separately as an Additional Services Fee...." Thus, the service specific pro formas (and, by default the Harnett Health pro forma) fail to include the expense associated with CFVHS' management of the proposed Cancer Center.

The income statement also understates the appropriate costs for depreciating the equipment, particularly the proposed linear accelerator. The application states on page 87 that the depreciation schedule is based on the AHA's guidelines, which is appropriate; however, the AHA guidelines for depreciating a linear accelerator are seven years, not the 10 assumed in the application. Therefore, the application understates its depreciation expense and overstates its net income.

As a result of these issues, the application is non-conforming with Criterion 5 and should not be approved.

Failure to Demonstrate Reasonable Staffing for the Project

As noted above, the medical oncology portion represents a significant part of the revenue for the project, more than 70 percent. Based on the discussion in the staffing portion of the application, Section VII, it appears that the staffing is for the radiation oncology portion of the project only. Specifically, the statement above the staffing table refers to the staffing for the "Radiation Oncology Team" discussed in Exhibit 13 [sic, 14], which is a document produced by the American Society for Radiation Oncology (ASTRO). Thus, it appears that the staffing is based solely on the needs of the radiation oncology part of the project and do not include staffing for the medical oncology service. While the medical oncology pro forma does include costs for staffing, the source of those costs is unclear, as is what staff, if any, from the staffing table in Section VII are for the medical oncology service.

Thus, the applicant has failed to demonstrate that it will provide sufficient and reasonable staffing for the project, and is non-conforming with Criterion 7.

Failure to Identify the Population to Be Served

On page 61 of its application, Harnett Health provides its response to Section III.5.(c) as follows:

(c) Project patient origin (by percentage) by county of residence for the proposed project for the first two years of operation following completion of the project. (See example format below)

Cancer Center @ Harnett Health
Proposed Patient Origin

County	Percent of Linear Accelerator Pt Origin
Harnett	85.0%
Other Counties	15.0%
Total	100.00%

Source: Exhibit 10, Table 6

As shown above, Harnett Health only provides its projected patient origin for linear accelerator patients. Harnett Health fails to provide the projected patient origin for its simulator service or its hematology/oncology services, both of which are new institutional health services being developed as part of this project. Even if one assumes that the simulator patient origin mirrors that of the

linear accelerator patients, the application fails to provide such assumptions. In addition, although the utilization of medical oncology patients is based on the linear accelerator patient methodology, no information is provided in the application regarding the origin of the medical oncology patients, nor is it reasonable to assume that the patient origins would be the same. As discussed in the application, Harnett Health already treats hematology/oncology patients in Dunn. If the service at Dunn will continue (and nothing in the application indicates that it will not), patient origin for the service in Lillington would likely be impacted by the presence of another site of service in the county, which is unlike the proposed radiation oncology service.

As stated on page 12, Harnett Health currently provides hematology/oncology services through its relationship with CFVHS. The failure to provide historical patient origin for this service is inconsistent with its statements on page 12 of the application, excerpted below:

> *In August of 2014, the CFV Cancer Center @ Harnett (CFVCCH) was established. Oncologists from Cape Fear Valley Hematology and Oncology began providing chemotherapy services at that time. Since August 2014 the CFV hematology/oncology physicians in Dunn have seen 366 patients of which, 130 patients, or 35.5%, are oncology patients. The Cancer Center @ Harnett (CCH) operates fulltime with two MD's available on Mondays and Tuesdays and one 1 MD available Wednesday-Friday. The hours at CCH are 8-4:30 PM.*
>
> See page 12.

However, in response to Section III.4.(b), Harnett Health provides no information about the historical patient origin for this service as shown in the response below:

> (b) For each service component included in the proposed project, provide the current patient origin (by percentage) by county of residence for the service component.
>
> Not applicable. Harnett Health does not currently provide comprehensive cancer services.

As CFVHS, its physicians, and Harnett Health currently serve medical oncology patients in Harnett, historical patient origin data is available. Given its failure to provide either the historical or projected patient origin for the hematology/oncology services, Harnett Health has not identified the population to be served by the proposed project.

As a result, the application should not be approved, and is non-conforming with Criterion 3 and the CON Rules.

Failure to Demonstrate that Payor Mix Assumptions are Reasonable and Supported

In response to Section VI.15, Harnett Health projects that its payor mix for radiation therapy and chemotherapy will be equivalent to the historical payor mix for cancer patients served by CFVHS. Harnett Health provides no explanation for why the projected payor mix for a cancer center in Harnett County will be identical to the historical payor mix for cancer patients in Cumberland County. In response to Section VI.13, Harnett Health states that it does not currently provide radiation therapy or medical oncology services. This is inconsistent with the statements on page 12 of the application, excerpted above which demonstrate that CFVHS, its physicians, and Harnett Health currently serve medical oncology patients in Harnett. Given this existing service, historical payor mix data is available, but Harnett Health does not provide it and instead has based its financial assumptions on the experience of a facility in Cumberland County.

Further examination of the historical payor mix for Harnett Health and CFVHS indicates that the patient populations at each provider are very different. As shown below, Harnett Health's payor mix for inpatient services and outpatient surgery has higher percentages of Medicare and lower percentages of Commercial/Managed Care.

Inpatient Payor Mix Comparison
Harnett Health and Cape Fear Valley Health System

	Harnett Health Inpatient (First 6 months of 2015 per pg 78)	*Harnett Health Inpatient (2015 HLRA)*	*Cape Fear Valley Health System (2015 HLRA)*
Self Pay/Indigent/Charity	6.7%	6.9%	5.1%
Medicare	62.8%	52.9%	50.2%
Medicaid	20.3%	23.8%	25.5%
Comm. Ins./Mgd. Care	8.2%	7.5%	14.4%
Other	2.0%	8.9%	4.8%
Total	100.0%	100.0%	100.0%

Outpatient Surgery Payor Mix Comparison
Harnett Health and Cape Fear Valley Health System

	Harnett Health Inpatient (2015 HLRA)	*Cape Fear Valley Health System (2015 HLRA)*
Self Pay/Indigent/Charity	2.5%	4.7%
Medicare	48.4%	29.8%
Medicaid	18.0%	19.8%
Comm. Ins./Mgd. Care	26.5%	37.2%
Other	4.6%	8.4%
Total	100.0%	100.0%

The differences among payor mixes are particularly substantial for outpatient surgery, which, like radiation therapy and hematology/oncology, is a scheduled outpatient service. Given these differences, and the lack of any demonstration by Harnett Health of the reasonableness of using CFVHS' historical cancer payor experience, it is clear that the projected payor is not based on reasonable and supported assumptions. As the payor mix is not reasonable, Harnett Health's financial projections are not reasonable.

As a result, the application should not be approved, and is non-conforming with Criteria 5 and 13.