ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: November 21, 2012

PROJECT ANALYST: Bernetta Thorne-Williams
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: P-8834-12 / Carteret County General Hospital Corporation d/b/a Carteret General Hospital / Construct a new Cancer Center and replace existing linear accelerator / Carteret County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Carteret County General Hospital Corporation d/b/a Carteret General Hospital (CGH) proposes to construct a new 33,225 square feet Cancer Center that will consolidate and relocate its existing radiation (Coleman Radiation Oncology Clinic) and medical (Raab Medical Oncology Clinic) oncology departments, and related rehabilitation services on campus. The applicant also proposes to replace its existing linear accelerator. The applicant does not propose to develop beds or services or acquire equipment for which there is a need determination in the 2012 State Medical Facilities Plan (SMFP). However, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 40 of the 2012 SMFP, is applicable to the review of this proposal. Policy GEN-4 states:

"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

In Exhibit 25, the applicant provides its written statement, which states:

"<u>Optimize Energy Performance</u>

1. *Domestic hot water will be provided by gas fire heaters with a 96% thermal efficiency.*
2. *The HVAC system will consist of two 98% efficiency condensing gas boilers and two high efficiency air cooled scroll chillers. The chillers will have a minimum EER of 10.2.*
3. *A primary/secondary piping arrangement that utilizes VFDs will be used for both hydronic systems.*
4. *Air will be distributed by multiple sectional air handlers that incorporate an air side economizer and VFDs for energy savings. Individual spaces will be controlled with VAV boxes and hot water heating coils. The entire system will be controlled with an extension of the Owner's DDC system.*
5. *Lighting in the building will utilize high efficiency T-5 lamps that are controlled with occupancy sensors.*

<u>Protect and Conserve Water</u>

1. *Water saving strategies in the building will include dual flush water closets and pint flush urinals. In addition, metered faucets will be utilized where applicable to further reduce water consumption.*

<u>Enhance Indoor Environment Quality</u>

1. *Outdoor air will be provided to meet the DHSR requirements and the NC Mechanical Code. All air handlers will utilize 30% pre-filters and 90% final filters. A dehumidification sequence will be used to keep the indoor relative humidity below 55%. An electric steam generator in the air handlers will be used to keep the humidity above 30%. A ducted exhaust*

system will be used to exhaust all required areas. The discharge will be greater than 30 feet from the fresh air intake."

The applicant included a written statement describing the project's plan to assure improved energy efficiency sustainability and water conservation. Therefore, the application is consistent with Policy GEN-4 and conforming to this criterion.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

Carteret County General Hospital Corporation d/b/a Carteret General Hospital (CGH) proposes to construct a new single-story, 33,225 square feet Cancer Center that will consolidate its existing radiation (Coleman Radiation Oncology Clinic) and medical (Raab Medical Oncology Clinic) oncology departments, and related rehabilitation services. The applicant has selected three potential sites all of which are owned by the hospital and are on the campus. The applicant also proposes to replace its existing linear accelerator. In Section II.1, page 20, the applicant states the proposed projected includes three distinct service programs, briefly described below:

- *"Radiation oncology including one Varian TrueBeam or equivalent linear accelerator, a relocated CT simulator, treatment planning and oncology medical offices;*
- *Medical Oncology consisting of an estimated 18 treatment bays, medical oncologist office and patient / family consultation, a pharmacy and laboratory;*
- *Rehabilitation services including physical, speech, occupational, massage, yoga, reiki, and art therapies;*
- *Care-coordination and screening; and*
- *Multi-disciplinary parent and family support including conference and media center."*

<u>Population to be Served</u>

In Section III.5(a), page 85, the applicant states:

"CGH defines the primary geographic boundaries of the proposed service area as Carteret, Craven, and Onslow Counties."

The following tables illustrate historical and projected patient origin for radiation and medical oncology services for the first two operating years of the project, as reported by the applicant in Section III.4(b), page 84, and Section III.5(c), pages 86-87.

Radiation Oncology - EBRT						
	Current FY 2011		Projected FFY 2016 and 2017			
County	# of Patients	% of Total	# of Patients Year 1	% of Total	# of Patients Year 2	% of Total
Carteret	171	81.8%	200	82.9%	207	83.1%
Craven	11	5.3%	10	4.1%	10	4.0%
Onslow	26	12.4%	30	12.4%	31	12.4%
Wake	1	0.5%	1	0.5%	1	0.5%
Total	**209**	**100.0%**	**241**	**100.0%**	**249**	**100.0%**

Applicant's Source: 2012 License Renewal Application

Medical Oncology - Chemotherapy						
	Current FY 2011		Projected FFY 2016 and 2017			
County	# of Patients	% of Total	# of Patients Year 1	% of Total	# of Patients Year 2	% of Total
Carteret	302	79.9%	354	80.6%	365	80.7%
Craven	17	4.5%	16	3.6%	16	3.5%
Duplin	1	0.3%	-	-	-	-
Durham	1	0.3%	-	-	-	-
Onslow	52	13.8%	61	13.9%	63	13.9%
Pamlico	2	0.5%	-	-	-	-
Wake	1	0.3%	-	-	-	-
Pennsylvania	1	0.3%	-	-	-	-
Vermont	1	0.3%	-	-	-	-
Other*	-	-	8	1.9%	8	1.9%
Total	**378**	**100.0%**	**439**	**100.0%**	**452**	**100.0%**

Applicant's Source: CGH Internal Data
*Other Includes: Durham, Duplin, Pamlico, Wake, Pennsylvania, and / or Vermont.

In Section II.1, pages 119-120, the applicant states how the residents of the service area will have access to the proposed services, including those residents that are low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups. The applicant states:

"CGH records show that in 2012 YTD, 8.2 percent of CGH patients were African American, 0.2 percent were Hispanic; 9.0 percent were non-white. …

CGH will continue to make its services available to all persons in need of medical care, including the low income, underserved, medically indigent, uninsured, and the underinsured.

…

CGH will continue to provide services to all patients regardless of race or ethnicity … gender … of a person's handicap. …

…"

The applicant adequately identified the population it proposes to serve.

Need for the Proposed Project

The applicant states the need to consolidate its oncology services and replace the existing linear accelerator at CGH is based on the following factors:

- Expand and consolidate oncology services;
- The increasing demand for medical oncology services at CGH;
- Improved capability and continuous operation of the linear accelerator;
- Continuity of cancer care;
- Sustained growth and aging of the service area population; and
- Increasing prevalence and incidence of cancer in the service area.

Expand and consolidate oncology services

In Section III.1(a), pages 54-56, the applicant states:

"Moving CGH cancer services from their dispersed and cramped locations in the hospital to a dedicated outpatient facility is needed to improve patient care.

…

In an outpatient setting, specifically dedicated to one type of service, patients and their caregiver supporters have the advantage of convenient parking, easy entrance and exit from the facility and less stressed setting. …

…

Meeting the health reform goals of patients' engagement in their own health improvement and collaboration among providers serving the same patient will require:

- *Access to a variety of services dedicated specifically to patients and family members who are dealing with the financial, spiritual, genetic, and psychosocial issues unique to cancer;*

- *Space that permits those who choose to have interaction between patients undergoing similar treatments;*
- *Well configured space for staff and physicians to encourage work efficiency, privacy and noise control, which is not available in the cramped quarters that house CGH cancer services;*
- *A consolidated point of access for non-cancer care physicians to cancer specialists (such as radiation oncologists, adult medical oncologist, and pathologist); and*
- *Close proximity to the hospital should inpatient care be required in an urgent manner.*

The current facilities are cramped, separate from one another and provide limited support space for collaborative care."

The increasing demand for medical oncology services at CGH

In Section II.1(a), pages 56-57, the applicant states:

"CGH has seen its medical oncology utilization increase rapidly in recent years. Historical data show that from 2008 to 2011, CGH medical oncology cases increased by nearly 30 percent. This increasing demand results in an increasing need for the supply of medical oncology services at CGH. Current space is no longer adequate to absorb patient care requirements. Medical oncology space accessible to patients occupies less than 5,000 square feet. The number of treatment stations was increased from seven to 11 in 2012, by moving provider offices away from the chemotherapy spaces, but the stations have no patient privacy and the wait list for treatment is still three weeks from the date of request.

2008 to 2011 CGH Medical Oncology Utilization

	2008	***2009***	***2010***	***2011***
Cases	*292*	*331*	*346*	*378*
Percent Increase		*13.4%*	*4.5%*	*9.2%*
CAGR				*8.99%*

Source: CGH Internal Data"

Improved capability and continuous operation of the linear accelerator

In Section III.1(a), page 57, the applicant states:

"CGH proposes to replace its Varian Clinac iX linear accelerator with a new Varian TruBeam linear accelerator or equivalent that will have 3D CRT, IGRT and SBRT capability.

CGH's Varian Clinac iX linear accelerator is functional, but is over two years old. By the time the proposed Cancer Center will be operational, the Clinac iX linear accelerator will be over five years old. On average, because this technology is

changing rapidly, as the manufacturers learn better ways to improve outcomes, meeting community standard of care means that linear accelerators need to be replaced every seven years. … Logistically, it does not make sense to relocate a five-year old linear acceleratory that would have to be replaced in two years or less.

More importantly, relocating the existing Clinac iX linear accelerator would require that it be shut down for nearly a month. Radiation oncology patients receive treatment multiple times per week, so this would create an unacceptable situation for patients receiving radiation therapy treatment at CGH. CGH's existing linear accelerator is the only linear accelerator in Carteret County. The closet other providers are Carolina East Medical Center in New Bern and Onslow Radiation Oncology in Jacksonville. Carolina East Medical Center is located more than 35 miles from CGH and approximately 45 minutes travel time. Onslow Radiation Oncology is located nearly 40 miles from CGH and approximately 45 minutes travel time. …"

In Section II.1, pages 21-22, the applicant explains some of the benefits to having a replacement linear accelerator. The applicant states:

"The Varian TrueBeam system is a highly-accurate, high dose rate linear accelerator system capable of a broad range of therapies including 3D CRT, IMRT, IGRT and SBRT. The system offers multiple does rate options and full 360 degree range of treatment delivery angles, dual independent jaw collimator system, supporting dynamic jaw tracking and dynamic collimator rotation. Clinical benefits include the highest dose rate for shorter sessions, high-speed real time network control, ability to target very small lesions, rapid on-board imaging, sub-millimetric positioning accuracy, laser guard protection sensor to alert the operator of proximity to the patient, and a cone-beam computed tomography (CT) for patient set ups with ultra-precise CT scans. More specifically, the technology will enable the linear accelerator operator to administer ultra-precise doses of radiation while sparing maximum amount of normal tissues."

See Exhibit 6 for a copy of the vendor quote and other descriptive materials for the proposed replacement linear accelerator.

Continuity of cancer care

In Section III.1(a), pages 58-60, the applicant states:

"Carteret is a large rural county divided by bodies of water into two distinct areas: Morehead to Cape Carteret and Down East. Travel time between the most distant points takes almost two hours. CGH is located in the center, in Morehead City, and is the only hospital in the county.

CGH is also the only provider of radiation therapy and medical oncology services in Carteret County. …

…

Radiation Oncology – External Beam Radiation Therapy (EBRT)
EBRT is one of the most effective modalities utilized today to destroy rapidly dividing cancer cells. …According to the National Cancer Institute, radiation therapy is used to treat approximately 60 percent of all cancer patients.

…

Radiation therapy may be used in early stage cancers to cure or control the disease. … In certain types of cancer it may be used along with surgery and/ or chemotherapy.

Medical Oncology – Chemotherapy
Chemotherapy is also one of the most effective treatments used to destroy cancer cells and put the disease into remission. …
…

Therapeutic support services
Increasing evidence shows that cancer therapy from radiation and medical oncology is more effective when complemented by therapies that address the stress, fatigue and physiologic side effects of these treatments. …" (Emphasis in original).

In Section II.1(a), page 31, the applicant states:

"Cancer rehabilitation helps a person with cancer obtain the best physical, social, psychological, and work-related functioning during and after cancer treatment. …"

In Section II.1(a), pages 32-38, the applicant provides a description of each of the rehabilitative services that are provided, as follows:

"<u>Physical Therapy</u>

Physical therapy aims to improve quality of life and independence … by improving your ability to be active and comfortable. Physical therapists evaluate movement potential and help establish agreed upon goals to reduce pain, improve mobility, and restore physical functions/performance. Depending on your condition, you may focus on flexibility, strength, endurance, coordination and/or balance.

…

<u>Occupational Therapy</u>

…

Common side effects of cancer or its treatment include fatigue, pain, weakness, cognitive difficulties, anxiety or depression, and changes in self-esteem or self-image. Occupational therapy practitioners address these effects through intervention aimed at restoring function … developing home exercise programs to improve strength and mobility; modifying activities … or modifying environments … .

Occupational therapy intervention methods can remediate, compensate, or adapt a patient's ability to assist … in achieving a maximum level of independence and quality of life. …

…

Speech Therapy

Some cancers or cancer treatments may make it more difficult to communicate with people. …

A speech and language therapist can help you find the best ways to communicate … . Difficulties with swallowing can be caused by cancer or its treatments. … [S]*peech and language therapists … offer practical help with … particular swallowing difficulties.*

Massage Therapy

[M]*assage can decrease stress, anxiety, depression, and pain, and fatigue. Increase alertness. …*

Massage is also used to relieve pain and stiffness, increase mobility, rehabilitate injured muscles, and reduce the pain of headaches and backaces.

Yoga Therapy

Some … offer their patients yoga as a therapy in an effort to provide a more integrative approach to care. …

Yoga is a form of nonaerobic [sic] *exercise that involves a program of precise postures, breathing exercises, and meditation. …*

[P]*atients who did yoga saw improvements in social and emotional well-being …*

Reiki Therapy

Reiki Therapy is a Japanese energy-based therapy that promotes healing and overall wellness. …

Reiki Therapy involves using the body's energy fields to heal and maintain wellness. …

Some cancer patients claim that Reiki Therapy has helped with pain management, relaxation, and side effects of treatment like nausea and stomach upset.

Reiki Therapy is a complementary therapy, used to ease the emotional and physical side effects of treatment.

Art Therapy

Art therapy is used to help people manage physical and emotional problems by using creative activities to express emotions. …

Art therapy is based on the idea that the creative act can be healing. …

…"

Sustained growth and aging of the service area population

In Section III.1(a), pages 60-62, the applicant states:

"Population estimates from the [sic] *Claritas … project that between 2012 and 2018 Carteret, Craven, and Onslow County's population will increase by more than 22,000 residents, or approximately 6.4 percent.*

…

Service Area Population

County	***2012***	***2013***	***2014***	***2015***	***2016***	***2017***	***2018***	***% Increase 2012-2018***	***CAGR 2012-2018***
Carteret	*65,980*	*66,448*	*66,921*	*67,396*	*67,875*	*68,357*	*68,843*	*4.34%*	*0.71%*
Craven	*100,792*	*101,450*	*102,111*	*102,778*	*103,448*	*104,123*	*104,802*	*3.98%*	*0.65%*
Onslow	*181,061*	*183,538*	*186,048*	*188,593*	*191,173*	*193,788*	*196,439*	*8.49%*	*1.37%*
Total	***347,833***	***351,436***	***355,080***	***358,767***	***362,496***	***366,255***	***370,053***	***6.39%***	***1.04%***

Source: Claritas 2011

Residents of Carteret, Craven, and Onslow Counties are also aging. The table below shows Claritas projections for the population age 65 and older. Between 2011 and 2016, Carteret, Craven, and Onslow County's population age 65 and older will increase by more than 6,300 residents, or approximately 14.8 percent.

Projected 2011 and 2016 Population Age 65 and Older

County	***2011***	***2016***	***% Increase 2011-2016***	***CAGR 2011-2016***

Carteret	*12,733*	*14,775*	*16.04%*	*3.02%*
Craven	*16,525*	*18,573*	*13.39%*	*2.36%*
Onslow	*13,529*	*15,769*	*16.56%*	*3.11%*
Total	***42,787***	***49,117***	***14.79%***	***2.80%***

Source: Claritas 2011

Additionally, the Carteret County median age is not only higher than the State; it is also advancing faster than the State.

…

The risk of developing cancer increases with age. … More than 60 percent of cancers in the United States occur in people age 65 and older."

Increasing prevalence and incidence of cancer in the service area

In Section III.1(a), pages 63-65, the applicant states:

"Cancer is the second most common cause of death in the United States, exceeded only by heart disease. …

The Central Cancer Registry (CCR) of the North Carolina Center State Health Statistics (NCCSHS) projects there will be 55,444 new cancer cases in North Carolina in 2012. The CCR also projects that of these … 706 new cancer cases will occur in Carteret, Craven, and Onslow Counties, respectively. … For 2011, CCR projected 527, 544, and 627 cases for Carteret, Craven, and Onslow Counties respectively.

Reflecting the increased age and other factors the new cancer case incidence rate in Carteret and Onslow Counties have increased by approximately 5.0 and 3.9 percent over the last three years.

CCR forecasts data on three-year historical trends. … CGH only recently filed all of its 2010 cancer cases reports to the CCR. Therefore, new cancer case projections by the CCR for the service area, particularly Carteret County, are likely artificially low. At this writing the NC Cancer Center had not adjusted its forecasts. …

Carteret County New Cancer Case Incidence

	2009	***2010***	***2011***
New Cancer Cases	*471*	*448*	*527*
Population	*64,586*	*65,048*	*65,514*

New Cancer Rate / 1,000	*7.29*	*6.89*	*8.04*
Percent Change	*16.04%*	*-5.56%*	*16.80%*
CAGR			***5.03%***

Source: CCR, NCCSHS for cases and Claritas for population

Onslow County New Cancer Case Incidence

	2009	***2010***	***2011***
New Cancer Cases	*565*	*556*	*627*
Population	*173,765*	*176,175*	*178,618*
New Cancer Rate / 1,000	*3.25*	*3.16*	*3.51*
Percent Change	*13.50%*	*-2.94%*	*11.23%*
CAGR			***3.90%***

Source: CCR, NCCSHS for cases and Claritas for population

The National Center for Health Statistics recently released a SEER report [sic] *noted, 'During the most recent five years for which there are data (2004-2008), overall cancer incidence rates declined slightly in men (by 0.6 percent per year) and were stable in women … During the same time period, new cancer incidence rates in Craven County decreased approximately 1.7 percent per year. However, as noted in Exhibit 24 they went up in 2012. SEER data are age adjusted and based on an assumption of a constant age mix. In Carteret County in particular, and North Carolina in general, the median age is increasing.*

Craven County New Cancer Case Incidence

	2009	***2010***	***2011***
New Cancer Cases	*556*	*512*	*544*
Population	*98,837*	*99,486*	*100,139*
New Cancer Rate / 1,000	*5.63*	*5.15*	*5.43*
Percent Change	*8.31%*	*-8.51%*	*5.56%*
CAGR			***-1.73%***

Source: CCR, NCCSHS for cases and Claritas for population

The increased population noted earlier will reduce the rates, but new out by increasing the total cases. Increased new cancer incidence will require more treatment capacity."

See Exhibit 23 for Central Cancer Registry (CCR) data used by the applicant.

In Section III.1(b), pages 65-75, the applicant describes its assumptions and the 12-step methodology it used to project the number of cancer cases in the proposed service area. Projected increases are based on growth in the service area population and an increase in cancer incidence rates in Carteret, Craven and Onslow counties. The applicant adequately demonstrates projected cancer cases are based on reasonable, credible and supported assumptions.

<u>Projected Utilization</u>

In Section IV.1, pages 92-95, the applicant provides the historical and projected utilization for CGH's radiation and medical oncology services prior to completion of the project, as illustrated in the tables below.

Historical and Projected Radiation Oncology Utilization EBRT Procedures10/1/09-10/1/14

EBRT Treatment Delivery Category	**FY 2010** 10/1/09-9/30/10	**FY 2011** 10/1/10-9/30/11	**FY 2012** 10/1/11-9/30/12	**FY 2013** 10/1/12-9/30/13	**FY 2014** 10/1/13-9/30/14	**FY 2015** 10/1/14-9/30/15
Simple Treatment Delivery	41	18	18	19	20	20
Intermediate Treatment Delivery	163	1	1	1	1	1
Complex Treatment Delivery	2,101	2,852	2,907	3,003	3,099	3,195
IMRT Treatment Delivery	1,895	1,462	1,490	1,539	1,589	1,638
Additional Filed Checks	238	190	194	200	206	213
ESTVs (Equivalent Simple Treatment Visit)	119	95	97	100	103	106
EBRT Cases	204	209	213	220	227	234
Total	**4,438**	**4,523**	**4,610**	**4,762**	**4,914**	**5,067**
Total with ESTVs	**4,319**	**4,428**	**4,513**	**4,662**	**4,811**	**4,960**

Historical and Projected Medical Oncology – CGH Chemotherapy Cases

	FY 2010 10/1/09-9/30/10	**FY 2011** 10/1/10-9/30/11	**FY 2012** 10/1/11-9/30/12	**FY 2013** 10/1/12-9/30/13	**FY 2014** 10/1/13-9/30/14	**FY 2015** 10/1/14-9/30/15
Chemotherapy Cases	346	378	387	399	413	426

In Section IV.1(c) pages 95-96, the applicant provides the projected utilization for the first three full fiscal years after project completion for CGH's radiation and medical oncology services, as illustrated in the table below.

EBRT Procedures FY 2016 – FY 2018

EBRT Treatment Delivery Category	**Project Yr 1 FFY** 10/1/15-9/30/16	**Project Yr 2 FFY** 10/1/16-9/30/17	**Project Yr 3 FFY** 10/1/17-9/30/18

Simple Treatment Delivery	21	21	22
Intermediate Treatment Delivery	1	1	1
Complex Treatment Delivery	3,291	3,400	3,496
IMRT Treatment Delivery	1,687	1,743	1,792
Additional Filed Checks ESTVs (Equivalent Simple Treatment Visit)	219 110	227 113	233 116
EBRT Cases	241	249	256
Total	**5,219**	**5,393**	**5,545**
Total with ESTVs	**5,109**	**5,280**	**5,429**

As illustrated in the table above, the applicant projects to perform 5,109 Equivalent Simple Treatment Visit (ESTV) procedures in FY 1, 5,280 procedures in FY 2, and 5,429 in FY 3. The applicant proposes to replace its existing linear accelerator, not to acquire a new linear accelerator. Therefore, the applicant is not required to demonstrate that the existing linear accelerator will perform at least 6,750 procedures (ESTVs) per year, as required by 10A NCAC 14C .1903(a). The existing linear accelerator is the only one in Carteret County. The nearest linear accelerators are in Craven and Onslow Counties and are almost one hour's travel time from Morehead City. Travel time would be even longer from parts of Carteret County.

Projected Medical Oncology
CGH Chemotherapy Cases FY 2016 – FY 2018

	Project Yr 1 FFY 10/1/15-9/30/16	**Project Yr 2 FFY** 10/1/16-9/30/17	**Project Yr 3 FFY** 10/1/17-9/30/18
Chemotherapy Cases	439	452	467

The applicant does not propose to increase the number of chemotherapy treatment bays [18], as part of this project.

In Section III.1(b), pages 65-75, the applicant describes its assumptions and the 12-step methodology it used to project utilization at CGH. Projected increases are based on growth in the service area population and an increase in cancer incidence rates in Carteret, Craven and Onslow counties. The applicant adequately demonstrates projected utilization is based on reasonable, credible and supported assumptions.

The applicant adequately demonstrated the need to relocate and consolidate its existing cancer services and to replace its existing linear accelerator to accommodate projected growth and increasing age of the population to be served.

In summary, the applicant adequately identified the population to be served and demonstrated the need the population has for the project. Therefore, the application is conforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The relocated oncology services would continue to be located on the same campus. Therefore, this criterion is not applicable to this review.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C

In Section III.3, pages 78-81, the applicant describes several alternatives considered which include the following:

1) Status Quo – the applicant decided doing nothing would not address the issue of lack of space within the hospital for existing services and would mean services would continue to be provided in scattered locations which is not the most effective alternative from the hospital's perspective or the patients.

2) Relocate the Existing Linear Accelerator – the applicant concluded that this option would require shutting down its existing linear accelerator for nearly a month, thus creating an unacceptable situation for patients who receive radiation treatment multiple times per week.

3) Different Vendor – The applicant rejected this idea because Varian offered competitive pricing, trade-in and other compatibility and training features.

4) Smaller Facility – The applicant considered a new building with 10,000 or fewer square feet, however, the applicant concluded that this was not an effective alternative.
5) Joint Venture – The applicant concluded a joint venture would add complexity and cause the program to lose its non-profit status.

The applicant concluded that developing the project as proposed was its most effective and least costly alternative because it results in the *"best patient care."*

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative to meet the need to consolidate outpatient cancer services and replace the existing linear accelerator. The application is conforming to this criterion and approved subject to the following conditions.

1. **Carteret County General Hospital Corporation d/b/a Carteret General Hospital shall materially comply with all representations made in its certificate of need application.**

2. **Carteret County General Hospital Corporation d/b/a Carteret General Hospital shall acquire no more than one linear accelerator to replace the existing linear accelerator for a total of no more than one linear accelerator upon project completion.**

3. **Carteret County General Hospital Corporation d/b/a Carteret General Hospital shall use the existing linear accelerator for a Trade-in-Allowance, subsequently, the vendor shall not return the Varian Clinac iX linear accelerator to service in North Carolina without first obtaining a certificate of need.**

4. **Carteret County General Hospital Corporation d/b/a Carteret General Hospital shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and which would otherwise require a certificate of need.**

5. **Prior to issuance of the certificate of need, Carteret County General Hospital Corporation d/b/a Carteret General Hospital shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing to the Certificate of Need Section.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, pages 144-145, the applicant states that the total capital cost of the project will be $19,858,383, including $1,436,840 for site costs, $6,983,758 for construction costs, $8,883,429 for equipment purchase/lease, $830,625 furniture, $100,000 for landscaping, $523,932 architect/engineering fees, $10,000 for legal fees, $50,000 for CON preparation fees, and $1,039,799 for other (contingency). In Section IX, page 152, the applicant projects there will be no start-up expenses or initial operating expenses associated with the proposed project. In Section VIII.3, page 147, the applicant states that the project will be funded by means of Carteret County General

Hospital Corporation's accumulated reserves. Exhibit 29 contains a June 6, 2012 letter signed by the Chief Financial Officer for Carteret General Hospital, which states:

> *"This letter is to confirm that the capital cost and working capital requirements of Carteret General Hospital's Cancer Center project will be financed with accumulated reserves. As Chief Financial Officer, I have the authority to obligate up to $22,000,000 of Carteret General Hospital Corporation's accumulated reserves for the capital cost and working capital requirements of the Cancer Center Project. … The amount of $22,000,000 is more than sufficient to cover the capital costs and working capital requirements of the project and these funds are not committed to any other use."*

Exhibit 34 of the application contains the audited financial statements for Carteret County General Corporation (CCGC) and Affiliates for the years ending September 30, 2011 and September 30, 2010. As of September 30, 2011, CCGC had $47,244,525 in cash and cash equivalents, unrestricted net assets of $62,545,949 and $102,709,879 in total net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

The applicant provided pro forma financial statements for the first three years of the project, for the entire hospital and the proposed Cancer Center. The applicant projects that Cancer Center revenues will exceed operating expenses in each of the first three full fiscal years, as illustrated in the table below.

Cancer Center

	Project Yr 1 10/1/15-9/30/16	Project Yr 2 10/1/16-9/30/17	Project Yr 3 10/1/17-9/30/18
Gross Patient Revenue	$74,161,695	$79,488,920	$85,236,617
Deductions from Gross Patient Revenue	$49,583,071	$54,038,126	$58,865,831
Net Patient Revenue	$24,578,624	$25,450,794	$26,370,785
Total Expenses	$20,783,904	$21,967,294	$23,260,222
Net Income	$3,798,554	$3,487,465	$3,114,649

The applicant also projects a positive net income for the entire hospital in each of the first three full fiscal years of the project. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions regarding cost and charges. See Criterion (3) for discussion of utilization projections which is incorporated hereby as if fully set forth herein. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and charges, and therefore, the application is conforming to this criterion.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

Carteret General Hospital in Morehead City is the only hospital in Carteret County. CGH currently provides radiation and medical oncology services to the residents of Carteret and surrounding counties and is the only provider of these services located in Carteret County. In this application, CGH proposes to expand and consolidated its existing oncology services (radiation and medical) and related support services, to a freestanding cancer center on the hospital campus. The applicant adequately demonstrates the need for its proposal. See Criterion (3) for the discussion regarding the need to relocate and consolidate oncology services which is incorporated hereby as if fully set forth herein.

The applicant adequately demonstrates the relocation and expansion of the existing oncology services currently provided at CGH will not result in the unnecessary duplication of existing or approved oncology services. Consequently, the application is conforming to this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.1(a), pages 130-136, the applicant provides the current and proposed staffing for its cancer center for the second full fiscal year, as illustrated in the table below.

Department	**Existing FTE Positions**	**Proposed FTE Positions**
Medical Oncology		
Medical Oncologists	1.00	2.00
Nurse Practitioner	1.00	1.00
RN's	7.40	9.40
RN Nurse Navigator	0.50	1.00
Research Coordinator	0.50	1.00
Medical Records/Coding	1.00	1.00
Social Workers	0.50	0.50
Dieticians	0.20	0.40

Pharmacists	1.00	1.00
Pharmacy Technicians	1.00	2.00
Lab/ Technicians	1.00	1.00
Phlebotomist	1.00	1.00
Administrator	1.00	1.00
Radiation Oncology		
Therapist	3.00	3.00
Aides	0.50	1.00
Administrator	1.00	1.00
Administration		
Clerical	1.00	1.00
Tumor Registrar*	1.00	-
Scheduling	2.00	3.00
Courier	2.00	2.00
Total	**27.60**	**33.30**

As illustrated in the table above, the applicant proposes to increase the number of FTE positions from 27.6 to 33.3. In Section VII.3(a), page 138, the applicant states:

> *"No new types of positions will result from the proposed project. CGH currently employs staff in each of the proposed positions. New therapies will be provided by contractors."*

In Section VII.8(a), page 141, the applicant states that Dr. Jeffrey Vinton, MD, will continue to serve as the Chief of Staff/Medical Director for CGH. See Exhibit 40 for letters dated April 1, 2012 from Dr. James Loynes and Dr. John Powell, expressing their willingness to continue to serve as the Medical Director for medical oncology and radiation oncology services, respectively.

The applicant adequately demonstrated the availability of adequate health manpower and management personnel for the provision of the proposed services. Therefore, the application is conforming to this criterion.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant is an existing hospital and provider of oncology and rehabilitative services and the necessary ancillary and support services are currently available. In Section II.2(a), page 43, the applicant provides a summary of the availability of the necessary ancillary and support services.

See Exhibit 8, for a letter dated March 14, 2012, from the President of Carolina Therapy Services, Inc., documenting that CGH currently offers physical, occupational

and speech therapy services. Exhibit 8 also contains a letter from a certified oncology massage therapist documenting that CGH will continue to provide massage therapy. See Exhibit 9, for a letter dated April 1, 2012, from the Chief Executive Officer of CGH documenting that CGH offers the necessary ancillary and support services. Exhibit 46 contains physician letters of support.

The applicant adequately demonstrated the availability of the necessary ancillary and support services and that the proposed services would be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section II.1, page 20, the applicant states that CGH has chosen three potential sites for the proposed single-story project. All sites are currently owned by the hospital and are located on or adjacent to the main hospital campus.

In Section XI.2(a), page 158, the applicant states that the primary site consists of 2.70 acres and is located at 201 Penny Lane. In Section XI.3, page 160, the applicant states that the secondary site under consideration consists of 1.23 acres and is located at 3601 Bridges Street. In Section XI.3, page 162, the applicant provides information on the tertiary site under consideration which consists of 14.9 acres and is located at 3500 Arendell Street. All of the sites being considered are located in Morehead City and would be part of the hospital campus. The applicant further states in Section XI, that the secondary and tertiary sites are, *"available in the event that CGH finds unexpected problems with the primary site."*

See Exhibit 3 for a site map indicating the location of each of the proposed. In Section XI.4, page 164, the applicant provides the existing and proposed square footage for the proposed cancer center, as illustrated in the table below:

Cancer Center	**Estimated Square Feet**	**Construction Cost Per Sq. Ft**	**Total Cost Per Sq. Ft**
Medical Oncology	9,487		
Radiation Oncology	8,007		
Administration	5,783		
Support Space	1,993		
Circulation	7,955		
Total	**33,225**	**$253.44**	**$597.69**

Exhibit 33 contains a February 1, 2012 letter from the President of Skinner, Lamm & Highsmith Architects, which states:

> *"I have reviewed the scope of work and estimated construction costs for Carteret General Hospital's proposed Cancer Center project. The proposed project will be designed and built in compliance with all applicable federal, state and local ordinances and requirements for licensed acute care hospitals. …*
>
> *I certify that I am a Licensed Architect in the State of North Carolina. I also certify that to the best of my knowledge, the above construction related costs of the proposed project are complete and correct and are based on several recent projects, of similar program and design, we have completed in North Carolina."*

Exhibit 25 contains the applicant's energy efficiency and sustainability plan and water conservation plan. See Criterion (1) for additional discussion regarding energy conservation which is incorporated hereby as if set forth fully herein.

The applicant adequately demonstrates that the cost, design, and means of construction represent the most reasonable alternative for the proposed hospital expansion and

renovation project. See Criterion (5) for discussion of costs and charges which is incorporated hereby by reference as if fully set forth herein. Therefore, the application is conforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.12 and VI.13, pages 126-127, the applicant provides the payor mix during Calendar Year 2011 for the entire hospital and oncology services, as illustrated in the table below:

Entire Hospital and Oncology Services

Payor Mix FFY 10/1/10 - 9/30/11 As a % of Total Gross Revenue			
	Entire Hospital	Radiation Oncology	Medical Oncology
Self Pay	7.6%	1.7%	0.9%
Medicare	50.6%	60.7%	60.4%
Medicaid	10.0%	8.5%	9.0%
Commercial	24.4%	25.2%	25.6%
Tricare	7.5%	3.9%	4.1%
Total	**100.0%**	**100.0%**	**100.0%**

In Section VI.2, page 119, the applicant states:

"CGH has a patient responsibility policy that asks patients to inform staff about their cultural, psychosocial, spiritual and personal values, beliefs and

preferences. CGH policy is to honor these to the extent medically and physically possible. … "

See Exhibit 42 for a copy of CGH's Patient's Rights Policy.

Further in Section VI.2, page 119, the applicant states:

"CGH does not deny needed medical care to any person based [sic] *race, creed, religion, handicap, economic status, social status, or ability to pay. … "*

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Carteret County and statewide.

	Total # of Medicaid Eligibles as % of Total Population	**Total # of Medicaid Eligibles Age 21 and older as % of Total Population**	**% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)**
Carteret	14%	6.6%	19.5%
Statewide	17%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group would not typically utilize the health services proposed in this application.
Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 45.9% for those age 20 and younger and 30.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the

number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrated that medically underserved populations currently have adequate access to the services offered at Carteret General Hospital. Therefore, the application is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 126, the applicant states:

"CGH has no obligation under any applicable Federal regulation to provide uncompensated care. However, CGH provided $21,120,732 in charity care and bad debt during FY 2011. As a responsible member of the community, CGH will continue to provide uncompensated care."

In Section VI.10(a), page 125, the applicant states:

"No civil rights equal access complaints have been filed against CGH in the past five years."

The application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.14(a) and Section VI.15(a), pages 128-129, the applicant provides the projected payor mix for the second full fiscal year (2016) of operations for the proposal, as illustrated in the table below.

Entire Hospital and Oncology Services

Payor Mix FFY 10/1/16 - 9/30/17 As a % of Total Gross Revenue			
	Entire Hospital	Radiation Oncology	Medical Oncology

Self Pay	7.6%	1.7%	0.9%
Medicare	50.6%	60.7%	60.4%
Medicaid	10.0%	8.5%	9.0%
Commercial	24.4%	25.2%	25.6%
Tricare	7.5%	3.9%	4.1%
Total	**100.0%**	**100.0%**	**100.0%**

In Section VI.15(b), page 129, the applicant states:

"CGH reasonably assumes that its payor mix for Radiation Oncology and Medical Oncology will not change from its historical pay mix … ."

The applicant demonstrated that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming with this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9(a), page 124, the applicant states:

"Patients may be referred by a physician or other healthcare provider, or may be admitted after presenting at the emergency department. Typically, a patient's specialty care, surgeon, radiation oncologist, or medical oncologist refers patients for cancer treatment. Any licensed physician may refer patients. CGH has contract emergency and hospitalist staff who provide coverage for persons who arrive at the emergency room without private physician. These CGH physicians can refer patients to the Cancer Center.

…

Patients may self-refer for some of the screening services and some of the complimentary therapeutic services, like yoga."

The applicant adequately demonstrated it offers a range of means by which patients will have access to the proposed services. Therefore, the application is conforming with this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1(a) page 109, the applicant provides documentation that CGH will continue to accommodate the clinical needs of area health professional training programs. The list below illustrates the clinical training programs that currently utilize CGH:

- Carteret Community College
- Coastal Community College
- Pitt Community College
- East Carolina University

See Exhibit 26 for copies of CGH's training agreements.

Additionally, in Section V.1(a) page 109, the applicant states:

"CGH has recently agreed to affiliate with UNC Lineberger Cancer Center for treatment of complex cancer patients and for education and training. …"

The information provided is reasonable and credible and supports a finding of conformity with this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant currently provides the only oncology services available in Carteret County. In Section V.7, pages 115-117, the applicant discusses how the proposed relocation and consolidation of existing oncology services will foster competition by promoting cost effectiveness, quality, and access to services in the proposed service area.

Furthermore, the applicant provides a narrative which explains why CGH believes the relocation and consolidation of its existing oncology services Cancer Center is critical to CGH's mission to provide quality care to patients residing in Carteret County. See also Sections II, III, VI and VII of the application for additional discussion by the applicant about the impact of its proposal on cost effectiveness, quality and access to oncology and rehabilitative services.

The applicant adequately demonstrates that its proposal would enhance competition by promoting cost effectiveness, quality and access to the proposed services based on the information in the application and the following analysis:

1) Projected utilization of the Cancer Center is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding historical and projected utilization which is incorporated hereby as if fully set forth herein. The applicant adequately demonstrates the financial feasibility of the proposal is based upon reasonable projections of costs and charges. See the Pro Formas and Criterion (5) for discussion regarding financial feasibility which is incorporated hereby as if fully set forth herein. Therefore, the applicant adequately demonstrates the cost effectiveness of its proposal.
2) The applicant projects to provide adequate access to medically underserved groups, including self pay / charity care patients, Medicare beneficiaries and Medicaid recipients. See Section VI of the application and Criterion (13c) for discussion regarding projected access by these groups which is incorporated hereby as if fully set forth herein.
3) The applicant adequately documents that it will provide quality care. See Sections II and VII of the application.

Therefore, the applicant adequately demonstrates that its proposal is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

CGH is accredited by the Joint Commission and certified for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, no incidents occurred within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center

teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA