

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 21, 2012
PROJECT ANALYST: Bernetta Thorne-Williams
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: G-10032-12/ Alamance Regional Medical Center, Inc/ Replace one of two existing linear accelerators /Alamance 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

The applicant, Alamance Regional Medical Center, Inc (ARMC), whose parent company is ARMC Health Care, is a licensed 238 acute care beds hospital (which consists of 182 general acute care beds, 44 psychiatric beds and 12 substance abuse beds). ARMC was conditionally approved in Project I.D. # G-8828-12 to expand and renovate its existing emergency and surgery departments, upgrade the central energy plant, and relocate the existing Cancer Center and rehabilitation services. In this application, the applicant proposes to replace one of two linear accelerators owned and operated by ARMC.

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 Section III.2, page 34, the applicant states:

"Because the project includes only minor upfits to the existing linear accelerator vault to accommodate the new equipment, the ability to improve energy efficiencies and conservation of resources rests in the efficiencies present in its existing facility. However, as with all of ARMC's services, engineering management constantly seeks ways to improve and conserve energy and more efficiently utilize hospital resources. ... Furthermore, the proposed replacement equipment was designed to use less energy than its predecessors, in particular the equipment that will be replaced. In that way, this project will improve the energy efficiencies associated with radiation oncology services at ARMC."

In Section XI.7, page 87, the applicant states:

"In May 2012, ARMC submitted an application to expand and renovate several hospital departments including the construction of a new Cancer Center (Project ID # G-8828-12). The May application, ... proposed to relocate all campus cancer services to the new building with the exception of the two linear accelerators, which will remain in the existing vaults but will be immediately adjacent to the new space. ...

As an existing facility, the Cancer Center's HVAC and utilities are in place. However, with the development of the new Cancer Center, ARMC and its maintenance team will maximize the efficiencies already in place by connecting with the new systems that will operate in the new building. ... ARMC will continue to analyze the existing services to determine ways to improve efficiencies, including water conservation and utilities management."

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

The applicant, Alamance Regional Medical Center, Inc (ARMC), whose parent company is ARMC Health Care, is a licensed 238 acute care beds hospital (which consists of 182 general acute care beds, 44 psychiatric beds and 12 substance abuse beds). ARMC was conditionally approved in Project I.D. # G-8828-12 to expand and renovate its existing emergency and surgery departments, upgrade the central energy plant, and relocate the existing Cancer Center and rehabilitation services. In this application, the applicant proposes to replace one of two linear accelerators owned and operated by ARMC. The Varian Clinac 2100C linear accelerator was purchased in 1995 and is located in the Cancer Center.

In Section II.1, page 15, the applicant describes the proposed projected. The applicant states:

“The May application, ... proposed to relocate all campus cancer services to the new building with the exception of the two linear accelerators, which will remain in the existing vaults but will be immediately adjacent to the new space. ...

ARMC proposes to replace its ... older of its two linear accelerators, with a Varian TruBeam linear accelerator package, including software and hardware upgrades to existing support equipment. Because the vault is more than 17 years old, ARMC will refurbish the vault area prior to installation of the new equipment.

Population to be Served

In Section III.5(a), page 37, the applicant states:

“ARMC’s primary service area is Alamance County. ... In FY 2011, 87 percent of ARMC’s facility-wide patient origin and 85 percent of its linear acceleratory patient origin was attributed to Alamance County.”

The following table illustrates historical and projected patient origin for radiation oncology services for the first two operating years of the project, as reported by the applicant in Section III.4(b), page 36, and Section III.5(c), page 38.

Linear Accelerator Services					
	Current FY 2011	Projected FFY 2014 and 2015			
<i>County</i>	<i>% of Total</i>	<i># of Patients Year 1</i>	<i>% of Total</i>	<i># of Patients Year 2</i>	<i>% of Total</i>
<i>Alamance</i>	<i>84.4%</i>	<i>10,596</i>	<i>84.4%</i>	<i>10,960</i>	<i>84.4%</i>
<i>Other*</i>	<i>15.6%</i>	<i>1,959</i>	<i>15.6%</i>	<i>2,026</i>	<i>15.6%</i>
Total	100.0%	12,555	100.0%	12,986	100.0%

*Other includes Caswell, Chatham, Guilford, Mecklenburg, Orange, Person, Randolph, Rockingham, and Surry Counties in North Carolina, and other states.

However, the above table showed patient treatments, not patients. In supplemental information provided by the applicant, the applicant states that linear accelerator services in its Cancer Center had a 6.9% CAGR from calendar year 2009-2011. To project future patient volume growth the applicant used half of its historical growth, 3.4% to project the number of patients to be served on its existing and proposed linear accelerators for FFY 2014 and FFY 2015, as illustrated in the table below.

	Current FY 2011	FY 2012	Projected FFY 2014	Projected FFY 2015
	# of Patients			
Total	425	389	416	430

Source: Applicant's supplemental information

In Section VI.13 and VI.15(a), pages 62-63, the applicant states the historical payor mix for Medicaid patients receiving linear accelerator services was 9.0% and the payor mix for Medicare and Medicare Managed Care was 60.9%. The applicant does not expect any changes to its current payor mix as a result of the proposed project.

In Section VI, pages 52-55, 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. On page 52, the applicant states:

“AMRC [sic] is not only easily accessible by these underserved groups, but by the remainder of the population as well. Hospital policies and procedures do not discriminate with regard to patient care, access on the basis of race, ethnicity, sex, age, religion, income, residence or any other factor which might restrict access to services. ...”

In Section III.5(d), page 38, the applicant states:

“ARMC does not expect any changes in its patient origin as a result of the proposed project.”

The applicant adequately identified the population it proposes to serve.

Need for the Proposed Project

The applicant states the need to replace the existing linear accelerator is based on the following factors:

- Age of existing linear accelerator; and
- Advanced technology;

In Section III.6(a), page 38, the applicant states, *“ARMC is the only radiation oncology provider in Linear Accelerator Service Area 15 as designated by the 2012 SMFP.”*

Age of existing linear accelerator

In Section III.1, page 28, the applicant states:

“The primary need presented in this project is to replace existing radiation therapy equipment that is more than 17 years old and well past its seven-year useful life as measured by the American Hospital Association’s equipment lifetimes standards. The existing Varian Clinac 2100C linear accelerator ... became operational in 1995. While it was state-of-the-art at the time it was installed, it has now become less reliable than is optimal for patient care Furthermore, when the equipment requires a service team for repairs, the cost is approximately \$350 per hour for repairs. ... [P]atient treatments must be delayed, which is very inconvenient, particularly for patients that are as ill as many of the radiation therapy patients.”

In Section III.1, pages 29-30, the applicant states:

“Another critical need for replacement of the equipment is the fact that Varian is phasing out the platform for the 2100C because it is three generations past its prime. In fact, in January 2012, ARMC had to install a software update to even keep the 2100C in operation. Without a new linear accelerator, ARMC would be limited to one operational linear accelerator when the 2100C platform is no longer available.”

Advanced technology

In Section II.1(a), pages 18-19, the applicant states:

“ARMC proposes to purchase a Varian TruBeam linear accelerator package that includes software and hardware upgrades for all existing support equipment in the radiation oncology department. The project also includes replacement laptops for the physicians

with software for the new equipment, electronic medical records software and Eclipse Treatment Planning System. The department software includes upgrades for scheduling, pharmacy, charges, faxing, electronic prescriptions, Cancer Registry software, and research protocol tracking software. ...

The TruBeam technology was developed only 18 months ago by Varian. ... [W]hich will allow ARMC to be on the leading edge of technology.

The TruBeam radiotherapy and radiosurgery system is optimized to destroy cancer and has been built with intelligent engineering, innovative features and intuitive operation. ... [P]rovides a unique capability that allows clinicians to tailor patient's treatments for their particular type of cancer. Operating radiation therapy equipment that has such a pinpoint accuracy (within ½ millimeter in all directions) means that patients can be treated with higher radiation per dose and with shorter visit times per treatment. Imaging and treatment processes have been automated and streamlined for improved performance. ... The system seamlessly integrates breathing patterns effect on critical organs during the actual treatment allowing the physician to treat to higher does. ...

The TruBeam was designed as a versatile platform system that can be used for all forms of advanced external-beam radiotherapy including image-guided radiotherapy and radiosurgery (IGRT and IGRS), intensity-modulated radiotherapy (IMRT), stereotactic body radiotherapy (SBRT) and RapidArc radiotherapy. ...

...”

In Section III.1, pages 28-29 the applicant states:

“During the past 15 years, radiation therapy has experienced huge leaps in technology development. For example, the 2100C provides the radiation close in rectangular blocks. Any part of the body that falls within that specific block will be radiated however, rarely the patient requires radiation of the entire rectangular area One method used to avoid radiating areas of the body not involved in the cancer is to create blocks of alloy material designed and formed to cover parts of the body near the targeted site, which must be protected from the radiation. Each patient has his or her own set of blocks created specifically for the treatment sessions. During the simulation process, molds are made of the patient's legs, upper body, arms (whichever part is to be treated and needs to remain immobile and protected), which will allow the patient to be positioned in the same place for each treatment assuring that the exact area is radiated. With newer linear accelerators, including the 21 EX Silhouette, the newer of the two linear accelerators operated by ARMC, as well as the TruBeam proposed in this application, the treatments are directed by computer-controlled collimators that pinpoint the exact site to be radiated, minimizing collateral exposure. Furthermore, the 2100C treatments can only provide radiation from three or four angles as opposed to the newer equipment which has an infinite number of possible angles from which to radiate the site. The 2100C is more labor intensive as well in that between each change of site, the radiation technician must enter the vault, reposition the very heavy blocks, leave the vault and perform the

treatment. For a patient that must be treated from several angles, the time required per treatment can be quite lengthy, particularly compared to the newer equipment that performs all the scans from any angle without interruption to the process to reset the blocks as blocks are not required. Moreover, the TruBeam has the capability to allow the physician and the technicians to make micro adjustments from outside the vault, whereas, the 2100C uses X-ray technology that requires the technician to enter the vault to make any changes to the equipment.”

Projected Utilization

In Section III.1(b), page 30, the applicant provides its historical volume and Compound Annual Growth Rate (CAGR) for its linear accelerator services, as illustrated in the table below.

Year	Procedures
2009	9,935
2010	9,632
2011	11,346
CAGR	6.9%

Source: ARMC internal data; calendar year total

In Section III.1(b), pages 30-31, the applicant states its projected linear accelerator volume is based on the following assumptions:

1. *“Using the base volume of 2011 procedures, linear accelerator procedures are conservatively projected to grow at only one-half of the historical CAGR, 3.4 per year, through the third project year. ARMC believes this assumption is reasonable because it bases growth on the actual historical experience of the existing linear accelerators. Moreover, ARMC performed 1,006 total procedures on its linear accelerators in 2008, which equates to a compound annual growth rate of 4.3 percent from 2008 to 2011 ...*
2. *ARMC then assumed that the average mix of its linear accelerator procedures by type in the last three full years will remain constant through the project years. This assumption is reasonable because it results in a distribution of projected total annual procedures that mimics past experience.*
3. *For ARMC’s projection of ESTV’s, it assumed that the base volume, excluding Additional Field Check Radiographs (AFCR) and Total Body Radiation (TBR), would include simple, intermediate, complex and IMRT procedures, all of which have an ESTV weighting of 1.0. The AFCR and TBR procedures have weighting factors of 0.5 and 2.5, respectively, per the 2012 State Medical Facilities Plan (SMFP)”*

See Exhibit 9 of the application for ARMC’s historical and projected procedures based on ESTV’s type. In Section III.1(b), page 32, the applicant summarizes the results of its assumptions and methodology, as illustrated in the tables below.

<i>Year</i>	<i>Procedures</i>	<i>ESTV's</i>
2012	11,735	11,578
2013	12,138	11,976
2014 (PY1)	12,555	12,387
2015 (PY2)	12,986	12,812
2016 (PY3)	13,432	13,252

“The projected ESTV procedures per linear accelerator are shown in the following table each of the project years:

<i>Projected ESTV's per Linac</i>	
2014(PY1)	6,193
2015(PY2)	6,406
2016 (PY3)	6,626

Based on the calculations shown above, ARMC projects that each linear accelerator will perform an average of 6,626 ESTV's by the third project year. ...”

In Section IV.1, page 42, the applicant provides the historical and projected utilization for AMRC radiation services, as illustrated in the tables below.

Historical and Projected Radiation Oncology Utilization

	Prior Full FY 2010 1/1/10- 12/31/10	Last Full FY 2011 1/1/11- 12/31/11	Interim Full FY 2012 1/1/12- 12/31/12	Interim Full FY 2013 1/1/13- 12/31/13	First Full FY 2014 1/1/14- 12/31/14	Second Full FY 2015 1/1/15- 12/31/15	Third Full FY 2016 1/1/16- 12/31/16
# of units	2	2	2	2	2	2	2
# of ESTV Treatments	9,474	11,184	11,578	11,976	12,387	12,812	13,252

As illustrated in the table above, the applicant projects to perform 12,387 Equivalent Simple Treatment Visit (ESTV) procedures in FY 1, 12,812 procedures in FY 2, and 13,252 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). ARMC is the only radiation oncology provider in linear accelerator services in Alamance County.

In summary, the applicant adequately demonstrated the need to replace its existing linear accelerator. Furthermore, the applicant adequately demonstrates the need for the proposal for all of the following reasons:

- 1) The age of the existing Varian Clinac 2100C linear accelerator;
- 2) The projected difficulty in continuing to have the existing linear accelerator serviced;

- 3) Historical and projected linear accelerator volume as the only Acute Care facility in Alamance; and
- 4) ARMC is the only radiation oncology provider in linear accelerator service area 15.

The applicant adequately identified the population to be served and demonstrated the need the population has for each component of 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

- (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 35-36, the applicant describes the two alternatives considered which include the following:

- 1) Maintain Status Quo – the applicant decided to do nothing would not address the issue that Varian is phasing out the platform for the existing linear accelerator as it is three years past its prime. Additionally, this alternative would not address the technology advancements that have occurred in the past 17 years in the field of linear accelerators.
- 2) Replacement of the existing 2100C linear accelerator with a TruBeam linear accelerator.

The applicant concluded that option number 2, replacement of the existing linear accelerator was its most effective and least costly alternative because it involves the replacement of a 17 year old linear accelerator for which Varian is no longer making a platform for and the replacement of the existing linear accelerator would also allow for the use of new technology to provide higher, more accurate radiation treatment for cancer patients.

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 application is conforming to all other applicable statutory and regulatory review criteria. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **Alamance Regional Medical Center, Inc. shall materially comply with all representations made in its certificate of need application.**
 2. **Alamance Regional Medical Center, Inc. shall acquire no more than one linear accelerator to replace the existing linear accelerator for a total of no more than two linear accelerators upon project completion.**
 3. **Alamance Regional Medical Center shall dispose of the existing Varian 2100C linear accelerator by removing it from North Carolina; and the Varian 2100C linear accelerator shall not be re-deployed into service in North Carolina without first obtaining a certificate of need.**
 4. **Alamance Regional Medical Center, Inc. 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, Alamance Regional Medical Center, Inc. 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 71-72, the applicant states the capital cost for the project will be \$4,225,986 including \$300,000 for construction contract, \$3,838,618 for fixed equipment purchase/lease, \$72,368 for movable equipment purchase/lease, and \$15,000 for architect/engineering fees. In Section VIII.3, page 73, the applicant states that the project will be funded by the accumulated reserves of its parent company, ARMC Health Care. Exhibit 16 contains a September 17, 2012 letter from the Chief Financial Officer for Alamance Regional Medical Center, which states:

“As the Chief Financial Officer for ARMC I am responsible for the financial operations of the hospital. As such, I am very familiar with the organization's financial position.

ARMC will fund the capital costs of the project, estimated to be \$4,225,986, with hospital reserves. As shown ... audited financials included with the application, ARMC has sufficient cash and assets limited as to use in reserves required for the capital costs of the proposed project.

...”

Exhibit 17 of the application contains the consolidated financial statements for ARMC Health Care and Affiliates for the years ending December 31, 2010 and December 31, 2011. As of December 31, 2011, ARMC Health Care and Affiliates had \$37,568,565 in cash and cash equivalents, unrestricted net assets of \$160,495,294 and \$161,184,886 in 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 for the entire hospital and its linear accelerator services. The applicant projects that linear accelerator services for its Cancer Center revenues will exceed operating expenses in each of the first three full fiscal years, as illustrated in the table below.

	Project Yr 1 1/1/14-12/31/14	Project Yr 2 1/1/15-12/31/15	Project Yr 3 1/1/16-12/31/16
Gross Patient Revenue	\$9,476,881	\$10,096,264	\$10,756,128
Deductions from Gross Patient Revenue	\$4,781,258	\$5,093,748	\$5,426,662
Net Patient Revenue	\$4,695,623	\$5,002,516	\$5,329,466
Total Expenses	\$3,183,695	\$3,510,778	\$3,609,860
Net Income	\$1,511,928	\$1,491,738	\$1,719,606

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

Alamance Regional Medical Center, Inc. in Burlington is the only hospital in Alamance County. ARMC provides currently operates two linear accelerators. In this application, ARMC proposes to replace the older of the two linear accelerators, the Varian Clinac 2100C. Both linear accelerators currently operate and are projected to operate at the performance standards for radiation therapy equipment. The applicant adequately demonstrates the need for the replacement linear accelerator based on reasonable, credible and supported projected utilization (which is based on historical utilization as the only hospital in Alamance County and as a Community Cancer Center recognized by the American College of Surgeons). See Criterion (3) for additional discussion of the respective services and the recent and projected utilization for linear accelerator services which is incorporated hereby as if fully set forth

herein. This analysis demonstrates the reasonableness of the proposed project. Thus, the applicant adequately demonstrates the need to replace one of its two existing linear accelerators at Alamance Regional Medical Center, Inc will not result in the unnecessary duplication of 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.3(a) and (b), page 65, the applicant states:

“The proposed project does not involve any new services. No new positions will result from the proposed project.”

In Section VII.1(a) and (b), pages 64-65, the applicant provides the existing and the projected staff for ARMC’s linear accelerator services, as illustrated in the table below.

Position	Existing FTE Positions	Proposed FTE Positions
Radiation Therapist	4.5	5.0
Medical Dosimetrist	2.0	2.0
Simulation Therapist	1.0	1.0
Physician’s Nurse		1.0
Acute LPN	1.0	1.0
Lead Radiation Therapist	1.0	1.0
Total	9.5	11.0

In Section V.3(c), page 47, the applicant states Dr. Glenn S. Chrystal will continue to serve as the Medical Director for Radiation Oncology services at ARMC. The applicant further states on page 47, that Dr. Janak K. Choksi will continue to serve as the Medical Director for Medical Oncology serves. See Exhibit 12, copies of the curriculum vitae for both medical directors.

The applicant adequately demonstrated the availability of adequate health manpower and management personnel for the provision of the proposed service. 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 services and the necessary ancillary and support services are currently available. In Section II.2(a), page 22, the applicant states:

“Because radiation therapy is an existing service at ARMC, no additional ancillary and support services will be required. As the project proposes to replace an existing linear accelerator rather than acquire additional equipment, no additional support will be required.”

See Exhibit VI, for a letter dated September 17, 2012, from the President of Alamance Regional Medical Center documenting that ARMC has sufficient ancillary and support services.

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.

NA

- (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 61-62, 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 1/1/11-12/31/11		
As a % of Total Utilization		
	Entire Hospital	Linear Accelerator Services
Self Pay/Indigent/Charity	9.9%	1.0%
Medicare/Medicare Managed Care	56.9%	60.9%
Medicaid	11.4%	9.0%
Managed Care/Commercial	16.6%	26.9%
Other*	5.2%	2.2%
Total	100.0%	100.0%

*Others includes workers comp and other government payors

In Section VI.2, pages 52-54, the applicant states:

“Hospital policies and procedures do not discriminate with regard to patient care, access on the basis of race, ethnicity, sex, age, religion, income, residence or any other factor which might restrict access to services. In addition to fair and equitable policies and procedures, ARMC has undertaken many community-minded initiatives to make its services more accessible to all residents ion the service area.

ARMC is fully committed to the health and well-being of the residents of Alamance County. To foster benefits for the community Some of these programs and services that are sponsored and / or supported by ARMC include:

Alamance Cares: ... a non-profit agency focused on stopping the spread of HIV / AIDS ...

Alamance Eldercare: ... a non-profit agency with a staff of ... social workers to help seniors (60 or older) and caregivers identify and find the help they need. ...

Alamance Medication Assistance Program (AlaMAP): ... provides medication access, ... education, and ... management to persons who have limited financial resources and no prescription insurance coverage. ...

Charles Drew Clinic: ... is a part of the Piedmont Health Services. Healthcare services are provided on a sliding fee scale ...

Healthy Alamance: ... is a partnership between Alamance Regional Medical Center, Alamance County Health Department, Alamance-Caswell-Rockingham Local Management Entity (LME) and Alamance Department of Social Services. ... [D]esigned to help improve access to and increase awareness of preventive health services ... eliminate health disparities among the disadvantaged. ...

Open Door Clinic: ... services residents of Alamance County between the ages of 18 and 64 who do not have any form of health insurance ...

Senior Advantage: ... is a unique program that offers seniors a package of health-related services such as a quarterly newsletter, health screenings, educational seminars, insurance assistance, discounts and coupons. ...”

See Exhibit 14 for a copy of ARMC’s Admission, Charity and Bad Debt Policies.

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 Alamance 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)
Alamance	16%	6.1%	21.0%
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.

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 Alamance Regional Medical Center. 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 61, the applicant states:

“ARMC has no obligations to provide uncompensated care, community service or access to care by the medically underserved, minorities or handicapped persons during the last three years. However, in order to maintain ARMC’s § 501 (c)(3) tax exempt status, it is necessary to fulfill a general obligation to provide access to health care services for all patients needing care regardless of their ability to pay.

...

This includes charity care for patients who are unable to pay. In fact, ARMC spends over \$100,000 every day providing charity care to patients in need.

...

Finally, ARMC is in full compliance with Title III of the Americans with Disabilities Act, the Civil Rights Act, and all other federally mandated regulations concerning minorities and handicapped persons.”

In Section VI.10(a), page 60, the applicant states:

“No civil rights equal access complaints have been filed against ARMC facilities 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

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In Section VI.14(a) and Section VI.15(a), pages 62-63, the applicant provides the projected payor mix for the second full fiscal year (2015) of operations for the proposal, as illustrated in the table below.

Entire Hospital and Oncology Services		
Payor Mix		
FFY 1/1/15-12/31/15		
As a % of Total Utilization		
	Entire Hospital	Linear Accelerator Services
Self Pay/Indigent/Charity	9.9%	1.0%
Medicare/Medicare Managed Care	56.9%	60.9%
Medicaid	11.4%	9.0%
Managed Care/Commercial	16.6%	26.9%
Other*	5.2%	2.2%
Total	100.0%	100.0%

*Others includes workers comp and other government payors

In Section VI.15(b), page 63, the applicant states:

“ARMC does not expect any changes in its current payor mix as a result of the proposed project.”

The applicant demonstrated that medically underserved populations will have adequate access to the proposed service components. 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.

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In Section VI.9(a), page 59, the applicant states:

“ARMC has provided oncology services to Alamance County for many years and receives referrals to its facility from physicians and other healthcare facilities in the region through established relationships. Patients can access these services by making a new consult appointment with a physician. Persons will have access to radiation oncology services at ARMC through referrals from physicians on the medical staff. ... ”

The applicant demonstrated the 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.

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In Section V.1(a) and (c), pages 44-46, the applicant provides documentation that ARMC will continue to accommodate the clinical needs of area health professional training programs. The table below includes some of the clinical training programs that currently utilize ARMC.

School	Clinical Program
Alamance Community College	Nursing
Duke University – Graduate Program	Physical Therapy
Elon University – Graduate Program	Physical Therapy
Guilford Tech Comm College – Associate Degree	Allied Health
Rockingham Comm College – Associate Degree	Allied Health
North Carolina A&T University	Nursing
University of NC at Chapel Hill	Physical Therapy Occupational Therapy Radiologic Science Pharmacy Nursing

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.

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The applicant currently provides the only radiation oncology services available in Alamance County. In Section V.7, pages 49-50, the applicant discusses how the proposed replacement of its existing Varian Clinac 2100C linear accelerator will foster competition by promoting cost effectiveness, quality, and access to services in the proposed service area.

Further, in Section V.7, pages 49-50, the applicant provides a narrative which explains why ARMC believes the replacement of the existing linear accelerator is critical to its mission to provide quality care to patients residing in Alamance 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 services.

The applicant adequately demonstrates that its proposal would enhance competition by promoting cost effectiveness, quality and access to the proposed service components based on 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 Forms 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.

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ARMC 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, a complaint survey was conducted on February 23-24, 2012, for which sanctions or penalties related to quality of care were imposed by the State resulting in the identification of an Immediate Jeopardy (IJ). The IJ resulted from an incidence that occurred beginning on February 16, 2012 in which the hospital failed to, *“Provide organized nursing services and systems in place to ensure a safe setting and safe care for the protection of psychiatric patients, staff and visitors.”* A plan of correction for the hospital was put in place on February 24, 2012. The incident did not occur within the Cancer Center. The expansion and renovation of the previously approved ARMC application, Project I.D. # G-8828-12, once developed, should facilitate the hospital’s compliance with its corrective action plan. 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