

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 25, 2013

PROJECT ANALYST: Gloria C. Hale
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: F-10101-13 /Union Memorial Regional Medical Center, Inc. d/b/a Carolinas Medical Center-Union and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-Union /Replace existing Varian 2100CD linear accelerator located at the Edwards Cancer Center /Union 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.

CA

Union Memorial Regional Medical Center, Inc. d/b/a Carolinas Medical Center-Union is expected to merge into The Charlotte-Mecklenburg Hospital Authority on or about April 1, 2013. At that time, Union Memorial Regional Medical Center, Inc. d/b/a Carolinas Medical Center-Union will no longer be a legal entity. Union Memorial Regional Medical Center, Inc. d/b/a Carolinas Medical Center-Union (CMC-Union) currently owns and operates one linear accelerator, a Varian 2100CD, located at the Edwards Cancer Center in the Outpatient Treatment Pavilion on the campus of CMC-Union, which was acquired pursuant to the certificate of need issued for Project I.D. #F-6133-99. The applicants propose to replace the existing Varian 2100CD with a Varian High Energy Clinac iX linear accelerator. The Varian High Energy Clinac iX linear accelerator package includes Varian's volumetric modulated arc radiation delivery hardware and Varian's volumetric modulated arc treatment planning software. In addition, CMC-Union will purchase an Octavius II Phantom, a dosimetric tool used for mandatory quality assurance checks. Lastly, the linear accelerator suite control/work area will be renovated to address inefficiencies with current layout and to

improve functionality. The applicants do not propose to develop beds, add new health services or acquire medical equipment for which there is a need determination in the 2013 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2013 SMFP that are applicable to this review.

However, Policy GEN-4 is applicable to this review.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities 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 for 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, pages 50-51, the applicants state that they will work with CHS’ Facility Management Group, consisting of experienced and highly trained architects and engineers, to develop the proposed project, ensuring that energy efficient systems are in place. Specifically, the applicants state that their team will do the following,

- *“Meet or exceed the requirements of the North Carolina Building Code in effect when construction drawings are submitted for review to the DHSR Construction Section.*
- *Refer to United States Green Building Council (USGBC) LEED guidelines and GGHC to identify opportunities to improve the efficiency and performance.*
- *Design for maximum efficiency and life cycle benefits within the chilled water system.*
- *Replace existing lights with energy efficient lights.”*

The applicants further state that the proposed project “*will be designed in full compliance with applicable local, state, and federal requirements for energy efficiency and consumption.*”

The applicants adequately describe the project’s plan to assure improved energy efficiency; however, the applicants do not describe the project’s plan to assure improved water conservation.

Therefore, the application is conforming to this criterion subject to the following condition:

Prior to issuance of the certificate of need, Union Memorial Regional Medical Center, Inc. and The Charlotte-Mecklenburg Hospital Authority shall provide to the Certificate of Need Section a written statement describing the project’s plan to assure improved water conservation.

- (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 applicants are Union Memorial Regional Medical Center, Inc. d/b/a CMC-Union and The Charlotte-Mecklenburg Hospital Authority d/b/a CMC-Union. Union Memorial Regional Medical Center, Inc. owns CMC-Union in Monroe (Union County) which is the only licensed, acute care hospital in the county. In addition, Union Memorial Regional Medical Center, Inc. owns CMC-Waxhaw in Waxhaw (Union County) which is an emergency care facility and outpatient center.

The Charlotte-Mecklenburg Hospital Authority (CMHA) is the ultimate parent of CMC-Union. The applicants provide a listing of the health care facilities and services owned, managed, or leased by CMHA in North Carolina and other states in Exhibit 4.

CMC-Union operates one linear accelerator at Edwards Cancer Center located in the Outpatient Treatment Pavilion on the CMC-Union campus. This linear accelerator was acquired pursuant to the certificate of need issued for Project I.D. #F-6133-99. CMC-Waxhaw, also in Union County, does not have a linear accelerator. CMHA owns and operates seven health care facilities in the state that have linear accelerators, as listed below:

Facility	Location	Number of Linear Accelerators	County
Carolinas Medical Center	Charlotte	3	Mecklenburg
Carolinas Medical Center-Union	Monroe	1	Union
Carolinas Medical Center-Northeast	Concord	3	Cabarrus
Cleveland Regional Medical Center	Shelby	1	Cleveland
Valdese General Hospital	Valdese	2	Burke
University Radiation Therapy Center	Charlotte	1	Mecklenburg
Pineville Radiation Therapy Center	Pineville	1	Mecklenburg

In addition, CMHA is a partial owner of three linear accelerators in South Carolina, as listed in the following table:

Facility	Location	Number of Linear Accelerators	County
Rock Hill Radiation Therapy	Rock Hill	2	York, SC
Lancaster Radiation Therapy Center	Lancaster	1	Lancaster, SC

The service area for linear accelerators that includes Union County, Service Area 7, consists of both Union County and Mecklenburg County. A listing of the facilities and the number of linear accelerators at each facility in Service Area 7 is provided in the following table:

Facility	Location	Number of Linear Accelerators	County
Carolinas Medical Center	Charlotte	3	Mecklenburg
Carolinas Medical Center-Union	Monroe	1	Union
University Radiation Therapy Center	Charlotte	1	Mecklenburg
Pineville Radiation Therapy Center	Pineville	1	Mecklenburg
Matthews Radiation Oncology	Matthews	1	Mecklenburg
Presbyterian Hospital	Charlotte	4	Mecklenburg

The applicants propose to replace the existing Varian 2100CD linear accelerator at the Edwards Cancer Center on the campus of CMC-Union with a Varian High Energy Clinac iX linear accelerator in the existing vault. The existing Varian 2100CD linear accelerator became operational in 2002. CMC-Union performed 7,438 procedures (ESTVs) on its linear accelerator from October 1, 2010 – September 30, 2011, as indicated in the 2013 SMFP. Although the proposed project does not need to meet the 6,750 procedures (ESTVs) minimum threshold to determine whether the linear accelerator is needed, the existing linear accelerator does exceed this minimum.

Population to be Served

In Sections III.4(a) and (b), page 53, the applicants provide patient origin by county for CY 2012 for both the entire facility and for radiation therapy services provided at CMC-Union, as illustrated below:

CMC-Union CY 2012

County	Percent of Patients for Entire Facility	Percent of Patients for Radiation Therapy Services
Union	68.3%	70.4%
Anson	11.1%	19.7%
Chesterfield, SC	9.4%	7.0%
Mecklenburg	3.4%	2.8%
Other*	7.8%	n/a
Total	100.0%	100.0% [99.9%]

* Other includes counties identified on page 53 and “other states”.

In Section III.5(c), page 55, the applicants project that the patient origin for radiation therapy services in Project Year 1 (CY 2015) and Project Year 2 (CY 2016) will be consistent with CMC-Union's historical patient origin.

The applicants provide a map of CMC-Union's service area for radiation therapy services in Section III.5(b), page 54. The highlighted counties on the map include: Union and Anson Counties in North Carolina and Chesterfield County in South Carolina. These counties account for 97.1 percent of CMC-Union's total radiation therapy patient origin.

The applicants adequately identify the population to be served.

Demonstration of Need

In Section III.1(a), page 34, the applicants summarize the factors contributing to the need to replace CMC-Union's existing linear accelerator as follows:

- Age of the existing equipment;
- Advances in linear accelerator technology; and
- Demographics

Age of the Existing Linear Accelerator

In Section III.1(a), pages 35-36, the applicants discuss the inadequacies of the existing Varian 2100CD which became operational at CMC-Union in 2002. Due to its age, it does not have the advanced capabilities available in newer models which, in turn, impact on the level of care "*needed by a modern radiation oncology program.*" It cannot be upgraded to provide volumetric modulated arc therapy (RapidArc) or on-board imaging (OBI) image guided radiotherapy (IGRT) and maintaining it has been more costly and has resulted in much downtime. As a result of downtime, up to 21 percent of patients have had radiation treatments after 5pm, resulting in a hardship for elderly patients in particular.

Advances in Linear Accelerator Technology

In Section III.1(a), pages 36-38, the applicants discuss the benefits of replacing the existing linear accelerator with more advanced technology available from a newer model. Technological advances have improved radiation planning and delivery which results in greater precision in targeting tumors, the ability to escalate radiation dose in a shorter period of time, and to minimize exposure to healthy organs. The applicants describe the capabilities of the newer technology on page 37 as follows:

"The proposed replacement equipment will provide volumetric modulated arc therapy (or RapidArc, a form of IMRT) and OBI IGRT, which the existing equipment does not offer and cannot be upgraded to provide. With newer linear accelerators, including the replacement Varian High Energy Clinac iX linear accelerator proposed in this application, the treatments are directed by computer-controlled collimators that pinpoint the exact site to be radiated, minimizing collateral exposure and optimizing the delivery to the targeted site. Moreover, physicians and

technicians no longer have to enter the vault as often to make changes to patient position as IGRT technology allows for micro adjustments from outside the vault.”

In addition, the applicants state, on page 38, that the proposed replacement equipment will decrease the entire treatment time, from 20-30 minutes to 10 minutes. In addition, the applicants state that the precise delivery of radiation will improve recovery time and reduce side effects and complications.

Demographics

In Section III.1(a), pages 38-40, the applicants state that Union County’s population is expected to increase, in particular those over 65 years of age, which will in turn increase utilization of healthcare services. The applicants state,

“Union County is the eighth fastest growing county in North Carolina based on numerical growth and the tenth fastest...based on percentage growth. ...the population of Union County is expected to grow 17.6 percent between 2010 and 2020.

By 2020, 13.2 percent of the total population in Union County will be over the age of 65 (more than 31,000 people). ...Union County will have the thirteenth largest number of residents over the age of 65 in 2020.”

The applicants provide a table in Section III.1(a), page 42, showing projected population growth in Union County, as illustrated below:

	2012	2017	2012-2017 CAGR
Union County	209,170	226,430	1.6%

In addition, the applicants cite The Journal of Clinical Oncology which states that adults ages 65 and above needing radiation therapy will increase by 38 percent between 2010 and 2020. Therefore, the proposed replacement linear accelerator with its new radiation therapy technology will benefit the higher utilization expected from this age group.

The applicants adequately demonstrate the need to replace the existing Varian 2100 CD linear accelerator with a Varian High Energy Clinac iX linear accelerator at CMC-Union.

Projected Utilization

In Section IV.1(c), page 59, the applicants project linear accelerator utilization at CMC-Union for the first three fiscal years after completion of the project, as illustrated in the table below:

	Project Year 1	Project Year 2	Project Year 3
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	FY 2015 1/01/15 –12/31/15	FY 2016 1/01/16 –12/31/16	FY 2017 1/01/17 – 12/31/17
# of Units	1	1	1
# of Treatments	7,344	7,431	7,519
# of ESTVs	7,821	7,914	8,007

The applicants provide the assumptions and methodology used to project linear accelerator utilization in Section III.1(b), pages 41-47, summarized as follows:

The historical radiation therapy treatments (2D/3D and IMRT) grew 1.2 percent annually from CY 2009 to CY 2012 as illustrated in the following table from page 41:

CMC-Union Historical Radiation Therapy Utilization

	CY2009	CY2010	CY2011	CY2012	CY2009 to CY2012 CAGR
# of Patients	420	449	430	470	3.8%
2D/3D* & IMRT** Treatments	6,843	7,290	6,496	7,089	1.2%
AFCRs^	801	952	878	921	4.8%
ESTVs^^	7,244	7,766	6,935	7,550	1.4%

***2D/3D or conformal radiotherapy includes simple, intermediate, and complex treatments*

***Intensity Modulated Radiation Treatment*

^Additional Field Check Radiographs

^^Equivalent Simple Treatment Visits calculated using weights from the 2013 SMFP, 1.0 for 2D/3D & IMRT treatments and 0.5 for AFCRs

Source: CMC-Union internal data”

The applicants state in Section III.1(b), page 43, that radiation therapy treatments are conservatively expected to grow 1.2 percent annually, in keeping with the historical growth from CY 2009 to CY 2012 for treatments. The applicants chose to use the 1.2 percent CAGR to project utilization rather than the 1.6 percent projected population growth from 2012 to 2017 for Union County.

The applicants make an adjustment in the projected number of radiation therapy treatments for CY 2014 to account for downtime in order to accommodate the removal of the old linear accelerator and the installation and commissioning for the replacement linear accelerator. A downtime period of two months is anticipated during which time patients will receive radiation therapy treatments at one of CMHA’s other existing linear accelerators in the area. The applicants state that the closest unit is in Lancaster, South Carolina. In addition, the applicants expect there will be a ramp up period during the three months immediately following the start date since it is likely that some patients may choose to continue their treatment at the alternative treatment site. The applicants state on page 43, “As new patients are diagnosed and scheduled for treatment, the volume at CMC-Union is expected to return to its historical pre-replacement growth trend.”

The applicants explain the methodology used to account for both downtime and ramp up time expected in Section III.1(b), page 44. To accommodate for the downtime period, the applicants first projected that CMC-Union would provide 7,258 radiation therapy treatments in CY 2014, or approximately 605 treatments per month. Second, the applicants subtracted two months worth of treatments (605 treatments per month x 2 months = 1,120 treatments) from the projected total of 7,258 to account for the downtime period, resulting in 6,048 treatments. Third, the applicants assumed that the ramp up period would be three months in duration and would have one-third less the number of treatments than expected [(605 treatments x 3 months = 1,815)/3 = 605] in CY 2014. Therefore, accounting for downtime, 6,048 treatments would be expected minus 605 treatments for ramp up which would then be equal to 5,443 radiation therapy treatments in CY 2014. The following table illustrates CMC-Union’s adjusted CY 2014 radiation therapy utilization by quarter:

**CMC-Union
 Adjusted CY 2014 Radiation Therapy Utilization**

	Q1 CY2014 (1/1/14 - 3/31/14)	Q2 CY2014 (4/01/14 – 6/30/14)	Q3 CY 2014 (7/01/14 – 9/30/14)	Q4 CY2014 (10/01/14 – 12/31/14)	CY2014 Total
# of Treatments	1,814	1,814	1,814	1,814	7,258
Adjustment	-1,210	-605	0	0	-1,815
# of Adjusted Treatments	604	1,209	1,814	1,814	5,443

In Section III.1(b), page 45, the applicants state that although the number of treatments per patient varies based on whether 2D/3D or IMRT treatments are received, they do not expect CMC-Union’s mix of patients receiving these types of treatments to vary from its current experience. They also assume that projected patients would have the same number of treatments, on average, as patients did in CY 2012. Therefore, the applicants project the number of future treatments per patient based on its recent historical experience. The following table provides the historical and projected number of patients through the third project year:

**CMC-Union
 Historical and Projected Radiation Therapy Patients**

	CY2011	CY2012	Interim CY2013	Interim CY2014	Projected CY2015	Projected CY2016	Projected CY2017
# of Treatments	6,496	7,089	7,173	5,443	7,344	7,431	7,519
Treatments per Patient	15.1	15.1	15.1	15.1	15.1	15.1	15.1
# of Patients	430	470	476	361	487	493	498

Next, the applicants accounted for field check radiographs since they receive ESTV weighting. Additional Field Check Radiographs (AFCRs) were projected by assuming that patients would have 2.0 AFCRs, on average, based on CMC-Union’s CY 2012 experience. ESTVs were then projected using weight factors from the 2013 SMFP (2D/3D and IMRT treatments = 1.0 and AFCRs = 0.5). In Section III.(b), page 47, ESTV projections are provided from actual experience in CY 2012 through the third project year, CY 2017, as illustrated below:

**CMC-Union
 Projected Radiation Therapy Utilization**

	Actual CY 2012	Interim CY 2013	Interim CY 2014	Projected CY 2015	Projected CY 2016	Projected CY 2017	CAGR
# of Patients	470	476	361	487	493	498	1.2%
# of Treatments	7,089	7,173	5,443	7,344	7,431	7,519	1.2%
AFCRs	921	932	707	954	965	977	1.2%
ESTVs	7,550	7,639	5,796	7,821	7,914	8,007	1.2%

As illustrated in the table above, the applicants project that 7,821 ESTV procedures will be performed in Project Year 1, (CY 2015), 7,914 in Project Year 2, (CY 2016), and 8,007 in Project Year 3 (CY 2017). The applicants propose to replace CMC-Union’s linear accelerator, not to acquire an additional, new linear accelerator. Therefore, the applicants are not required to demonstrate that the replacement linear accelerator will perform at least 6,750 procedures (ESTVs) per year, as required by 10A NCAC 14C .1903(a).

The applicants adequately demonstrate projected utilization is based on reasonable, credible, and supported assumptions.

In summary, the applicants adequately identify the population to be served and demonstrate the need to replace the existing linear accelerator. 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 51-52, the applicants discuss the alternatives considered prior to the submission of this application, which include:

- 1) Maintaining the Status Quo – The applicants indicate that maintaining the status quo is not an effective alternative because it would not be in the best interest of CMC-Union’s patients and would not provide current standards in radiation therapy technology. The current linear accelerator does not have the capability of providing advances in technology and therefore, cannot provide clinically proven best practice.
- 2) Replace Existing Equipment for Under \$2,000,000 – The applicants state that purchasing replacement equipment that is less costly would provide a lower level of service. The scope of services that could be provided and the needs of CMC-Union’s patients would not be met by less costly equipment and would force patients to choose between traveling much further for state-of-the-art services or settling for less than optimal services closer to home. Therefore, this alternative was not chosen.
- 3) The applicants state that purchasing a Varian High Energy Clinac iX linear accelerator would meet all the needs of its patients, physicians, staff and community. Further, it would allow them to treat patients more effectively and efficiently. Therefore, the applicants have chosen to pursue this alternative.

Furthermore, the application is conforming or conditionally conforming to all other statutory review criteria. Therefore, the application is approvable. An application that cannot be approved is not an effective alternative.

In summary, the applicants adequately demonstrate that their proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Union Memorial Regional Medical Center, Inc. d/b/a Carolinas Medical Center-Union and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-Union shall materially comply with all representations made in the certificate of need application.**
 - 2. Union Memorial Regional Medical Center, Inc. d/b/a Carolinas Medical Center-Union and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-Union shall acquire no more than one linear accelerator to replace the existing Varian 2100CD linear accelerator for a total of no more than two linear accelerators upon completion of this project and Project I.D. #F-7525-06 involving the relocation of one linear accelerator from Carolinas Medical Center to Carolinas Medical Center-Union.**
 - 3. Union Memorial Regional Medical Center, Inc. d/b/a Carolinas Medical Center-Union and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-Union shall dispose of the Varian 2100CD linear accelerator by removing it from North Carolina.**
 - 4. Union Memorial Regional Medical Center, Inc. d/b/a Carolinas Medical Center-Union and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-Union 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 that would otherwise require a certificate of need.**
 - 5. Union Memorial Regional Medical Center, Inc. d/b/a Carolinas Medical Center-Union and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-Union shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (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, page 92, the applicants project the total capital cost will be \$3,017,025, which includes \$252,000 for construction, \$2,482,995 for fixed equipment, \$122,630 for movable equipment, \$3,500 for furniture, and \$130,500 for consultant fees for architect and engineering services. A contingency fee is also included for \$25,400.

In Section IX.1, page 97, the applicants indicate there will be no start-up or initial operating expenses for the project. In Section VIII.3, page 93, the applicants indicate that the total capital costs will be funded with the accumulated reserves of CMHA. Exhibit 29 contains a

letter from the Executive Vice-President and Chief Financial Officer of Carolinas HealthCare System (CMHA d/b/a CHS) documenting the availability and use of these funds for the proposed project. The letter states,

“Carolinas HealthCare System will commit the total of \$3,017,025 to develop the proposed project. ...Carolinas HealthCare System will fund the capital cost from existing accumulated cash reserves. The expenditure will not impact any other capital projects currently underway or planned for at this time.”

In addition, the applicants include a letter, in Exhibit 29, from the Chief Financial Officer of Union Memorial Regional Medical Center, Inc. d/b/a CMC-Union, documenting CMC-Union’s commitment to using the funds from CHS for the proposed project.

Exhibit 30 contains the audited financial statements for CMHA d/b/a CHS for the years ending 2010 and 2011. According to the condensed combined balance sheets as of December 31, 2011, CMHA had \$53,073,000 in cash and cash equivalents, \$5,595,420,000 in total assets and deferred outflows and \$2,911,029,000 in total net assets (total assets less total liabilities). The applicants adequately demonstrate the availability of sufficient funds for the capital needs of the project.

The applicants project a positive net income for CMC-Union’s Radiation Therapy Service in each of the first three operating years of the project as shown in the table below:

CMC-Union Radiation Therapy Service	Project Year 1 1/01/15 - 12/31/15	Project Year 2 1/01/16 - 12/31/16	Project Year 3 1/01/17 - 12/31/17
Projected # of Treatments	7,344	7,431	7,519
Projected Average Charge* (Gross Patient Revenue/Projected # of Treatments)	\$1,255	\$1,293	\$1,332
Gross Patient Revenue	\$9,219,436	\$9,608,473	\$10,013,927
Deductions from Gross Patient Revenue	\$6,723,280	\$7,006,986	\$7,302,663
Net Operating Revenue	\$2,496,156	\$2,601,488	\$2,711,264
Total Expenses	\$2,346,250	\$2,452,855	\$2,517,976
Net Income	\$149,906	\$148,633	\$193,288

* Rounded to the nearest whole dollar by the Project Analyst.

The applicants also project a positive net income for the entire facility in each of the first three operating years of the project as illustrated in the table below:

CMC-Union Entire Facility	Project Year 1 1/01/15 - 12/31/15	Project Year 2 1/01/16 - 12/31/16	Project Year 3 1/01/17 - 12/31/17
Gross Patient Revenue	\$601,415	\$634,393	\$664,117
Deductions from Gross Patient Revenue	\$391,574	\$413,046	\$432,398
Net Patient Revenue	\$209,841	\$221,348	\$231,718
Total Revenue	\$214,060	\$225,609	\$236,022
Total Expenses	\$204,045	\$213,038	\$221,383
Operating Income	\$10,016	\$12,570	\$14,639
Non-Operating Revenue	\$3,943	\$5,138	\$6,797
Net Income	\$13,959	\$17,708	\$21,436

The assumptions used by the applicants in preparation of the pro forma financial statements, including projected utilization, are reasonable and supported. See the Pro Forma Section for the pro formas and the applicants' assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. The applicants adequately demonstrate 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

CMC-Union currently owns and operates one linear accelerator at its Edwards Cancer Center located on campus. The applicants propose to replace the existing Varian 2100CD linear accelerator with a new Varian High Energy Clinac iX linear accelerator. The applicants are not proposing to add beds, equipment or new services in Union County. CMC-Union is the only acute care medical facility in the county that owns and operates a linear accelerator.

CMC-Union's co-applicant, CMHA d/b/a CMC-Union, will be merging with Union Memorial Regional Medical Center d/b/a CMC-Union during the review period for this application. CMHA currently owns and operates 12 linear accelerators in North Carolina in the following counties: Mecklenburg, Cabarrus, Cleveland, Union, and Burke. In addition, CMHA is a partial owner of three linear accelerators located in Rock Hill, South Carolina and Lancaster, South Carolina. However, the service area for linear accelerators that is applicable to the proposed project, Service Area 7, as defined in the 2013 SMFP, consists of Mecklenburg, Union, and Anson counties only. There are six healthcare facilities in Service Area 7 with a total of 11 linear accelerators. From October 1, 2010 – September 30, 2011, two of the six healthcare facilities did not meet the 2013 SMFP minimum threshold of 6,750 procedures (ESTVs) per linear accelerator, while four healthcare facilities exceeded it, illustrated as follows:

Facility Name	County	Number of Linear	Average	% of
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		Accelerators	Number of Procedures per Unit	Capacity*
Presbyterian Hospital	Mecklenburg	4	3,155	47%
Matthews Radiation Oncology	Mecklenburg	1	10,723	159%
University Radiation Oncology	Mecklenburg	1	7,118	106%
Carolinas Medical Center-Union	Union	1	7,438	110%
Carolinas Medical Center	Mecklenburg	3	6,537	97%
Pineville Radiation Therapy Center	Mecklenburg	1	9,128	135%

* The project analyst calculated the percent of capacity by dividing the average number of procedures per unit by the 6,750 ESTVs threshold defined on page 140 of the 2013 SMFP. Percentages are rounded to the nearest whole percentage point.

CMC-Union performed 7,438 procedures (ESTVs) on its linear accelerator from October 1, 2010 – September 30, 2011, as indicated in the 2013 SMFP. Although the proposed project does not need to meet the 6,750 procedures (ESTVs) minimum threshold to determine whether the linear accelerator is needed, the existing linear accelerator does exceed this minimum.

As shown in the table above, CMC-Union’s one existing linear accelerator operated at 110 percent of capacity. Presbyterian Hospital is the only healthcare facility whose linear accelerators, on average, are operating well below capacity according to the table above. However, it is unlikely that CMC-Union’s radiation therapy patients would travel to Presbyterian Hospital for treatments since in CY 2012, over 90 percent of CMC-Union’s radiation therapy patients came from Union County and Anson County combined. Moreover, the applicants state in Section III.6(b), *“Without the effective replacement of CMC-Union’s equipment, existing providers would have difficulty accommodating CMC-Union’s volume and continued growth in demand for radiation therapy services.”*

The applicants adequately demonstrate that the proposed project would not result in the unnecessary duplication of existing or approved linear accelerators in Service Area 7. Therefore, 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, page 83, the applicants provide the current and projected staffing for CMC-Union’s Radiation Therapy Services during the second operating year (FY 2016), as shown in the following table:

CMC-Union’s Current and Projected Staffing

	Current Staff CY 2012	Projected Staff Project Year 2 CY 2016
Position	Total # of Full Time Equivalent (FTE) Positions	Total # of Full Time Equivalent (FTE) Positions
Director	1.00	1.00
Radiation Therapist	5.00	5.00
Registered Nurse	1.00	1.50
Office Staff	2.00	2.00
Physicist*		
Dosimetrist*		
TOTAL	9.00	9.50

*Contracted employee

In Section VII.5(b), page 85, the applicants state that CMC-Union plans “to add 0.5 RN FTE to address the projected incremental volume increase.” The applicants state CMC-Union uses several approaches for recruitment, including print and online media outlets, social networking sites, search engines, and e-postcards. In addition, the facility participates in job fairs, school career fairs, and offers co-workers referral bonuses. Moreover, there are three schools of nursing within the CMHA system from which to recruit nurses. The applicants state that there is minimal difficulty recruiting nursing staff.

In Section V.3(c), page 65, the applicants identify the Chief of the Medical Staff at CMC-Union in addition to the Medical Director of the Radiology Oncology service.

The applicants adequately demonstrate the availability of sufficient health manpower to continue providing radiation therapy 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.

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In Section II.2(b), page 26, the applicants state that all ancillary and support services are currently in place and that no additional services will be required. The applicants include a letter from the President of CMC-Union in Exhibit 8 that documents the availability of these services for the radiation oncology service. The letter states,

“As the project proposes to replace CMC-Union’s existing linear accelerator rather than acquire additional equipment, no additional support will be required. The existing ancillary and support staff will be sufficient to support the equipment replacement proposed in this application. These services are currently available and will continue to be made available following completion of the proposed project.”

In Section V.4(a), page 66, the applicants state that CMC-Union, as a long-time acute care provider and the only medical center in the county, has established relationships with many healthcare practitioners in the county, in addition to the Department of Social Services and the Health Department. The applicants state in Sections V.2(a), (b) and (c), page 64, that CMC-Union has existing transfer agreements with area healthcare facilities, including Carolinas Medical Center, Presbyterian Hospital, and Anson Community Hospital. Letters of support from physicians that refer to the radiation oncology service are included in Exhibit 34. The information provided in these sections and exhibits is reasonable and credible and supports a finding of conformity with 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;

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The following table illustrates the payor mix for the last fiscal year (1/01/12 – 12/31/12) for the entire CMC-Union facility and for its Radiation Therapy Service, as reported by the applicants in Sections VI.12 and 13, page 80:

Payor Category	Entire CMC-Union Facility Patient Days as Percent of Total Utilization	CMC-Union Radiation Therapy Services Treatments as Percent of Total Utilization
Self Pay/ Indigent/ Charity	7.3%	4.5%
Medicare/ Medicare Managed Care	46.0%	47.8%
Medicaid	24.4%	10.3%
Managed Care / Commercial Insurance	21.2%	37.1%
Other *	1.1%	0.3%
Total	100.0%	100.0%

*"Includes Worker's Comp and Other Government"

In Section VI.2, page 71, the applicants state that services at CMC-Union are provided to "all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay and will continue to do so following completion of the proposed project." In addition, Exhibit 26 contains a copy of CHS' System-wide Hospital Admission, Credit and Collection Policy, which includes CHS' Non-Discrimination Policy. The Non-Discrimination Policy states that no one will be denied services based on race, color, religion, national origin, sex, age, disability or source of payment.

In Section VI.3, page 72, the applicants state that \$51.6 million, or 10.4% of gross revenue, was provided in charity care and bad debt by CMC-Union in CY 2012. In addition, on page 73, the applicants state, "CHS is committed to providing financial assistance to every person in need of medically necessary treatment even if that person is uninsured, ineligible for other government programs, or unable to pay based on their individual financial situation."

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, as shown in the following table for Union County and Statewide:

	Total # of Medicaid Eligibles as % of Total Population June 2010*	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010*	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center) *
Union County	11%	3.42%	18.0%
Statewide	17%	6.71%	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 in State Fiscal Year 2010 was 48.6% for those age 20 and younger and 31.6% 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 applicants demonstrate that medically underserved populations currently have adequate access to linear accelerator services provided at CMC-Union. 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;

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In Section VI.11, page 79, the applicants state “*CMC-Union does not have any obligations to provide uncompensated care. However,...the medical center provides...a considerable amount of bad debt and charity care and in CY 2012 provided more than \$51.6 million in bad debt and charity care.*” Moreover, the applicants state in Section VI.4(a), page 72, that all persons will continue to have access to services regardless of their ability to pay. In addition, in Section VI.10(a), page 79, the applicants state that there have been no civil rights equal access complaints filed against any affiliated entity of CHS in the last 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 Sections VI.14 – VI.15, pages 81-82, the applicants project the payor mix for the second operating year, (FY 2016), as shown in the following table:

Payor Category	Entire CMC-Union Facility Patient Days as Percent of Total Utilization, 1/01/16 – 12/31/16	CMC-Union Radiation Therapy Services Treatments as Percent of Total Utilization, 1/01/16 – 12/31/16
Self Pay/ Indigent/ Charity	7.3%	4.5%
Medicare/ Medicare Managed Care	46.0%	47.8%
Medicaid	24.4%	10.3%
Managed Care / Commercial Insurance	21.2%	37.1%
Other *	1.1%	0.3%
Total	100.0%	100.0%

* “Includes Worker’s Comp and Other Government”

The applicants state they based the projected payor mix shown above on actual payor mix for CY 2012 using the assumption that these current ratios will remain essentially unchanged. The applicants acknowledge that there may be payor mix shifts due to the implementation of the Affordable Care Act, however they state there is uncertainty at this time as to how much shift will occur.

The applicants demonstrate that medically underserved populations will continue to have adequate access to linear accelerator services at CMC-Union. Therefore, the application is conforming to 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 Sections VI.9(a) and (b), pages 77-78, the applicants describe the means by which a person will have access to the project's services. Access to CMC-Union's services is accomplished through referrals from physicians and healthcare facilities in the region through established relationships. Physicians treating patients with cancer-related illnesses have admitting privileges at CMC-Union and the applicants state that these established referral relationships are not expected to change. Exhibit 34 includes letters from many of these physicians indicating their willingness to continue to refer patients to the radiation therapy services offered at CMC-Union. In addition, in Section VI.6, page 75, the applicants state that patients can access services through emergency services where an appropriate on-call specialist physician is required to see them to determine if a medical condition exists that needs to be treated. The applicants further state on page 75, "*Patients who are required to be admitted to the hospital and who do not have a primary care physician will be cared for by a hospitalist who is contracted and subsidized by the medical center.*" Moreover, patients can access primary care services at CMC-Union's Franklin Street Ambulatory Clinic.

The information provided is reasonable and credible and supports a finding of conformity 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, pages 61-63, the applicants document that CMC-Union accommodates the clinical needs of health professional training programs in the service area. CMC-Union offers inpatient clinical training and comprehensive outpatient training opportunities in the county and has extensive relationships with several colleges' health professional training programs. These colleges and their training programs are listed in a table provided on page 61. The applicants state that clinical training for these programs will be continued and that CMC-Union's programs and departments are available for other clinical training programs interested in establishing clinical rotations for its students. 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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CMHA operates seven health care facilities in the state for a total of 10 linear accelerators. One of those facilities is CMC-Union which has only one linear accelerator and is the only provider in the county with a linear accelerator. The applicants propose to replace CMC-Union's existing Varian 2100CD linear accelerator in its existing vault with a new Varian High Energy Clinac iX linear accelerator. The applicants are not proposing to add beds, equipment or new services in Union County.

In Section V.7, pages 67-69, the applicants discuss the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality, and access. The applicants state that competition will be enhanced by the purchase of a replacement linear accelerator with leading-edge, state-of-the-art technology which will, in turn, result in improvement in the delivery of radiation oncology services in Union County. The applicants state on page 69,

“...CMC-Union believes the proposed project will promote safety and quality in the delivery of healthcare services while promoting equitable access and maximizing healthcare value for resources expended for the residents of Union and surrounding counties.”

See also Sections II, III, V, VI, and VII. The information provided by the applicants in each of these sections is reasonable, credible, and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost effectiveness, quality, and access to linear accelerator services in Union County.

This determination is based on a review of the information in the sections of the application referenced above and the following analysis:

- The applicants adequately demonstrate the need to replace the existing linear accelerator at CMC-Union with a Varian High Energy Clinac iX linear accelerator;
- The applicants adequately demonstrate that the proposal is a cost-effective alternative to meet the need;

- The applicants will continue to provide quality services;
- The applicants will continue to provide adequate access to medically underserved populations; and
- The proposal will have a positive impact on competition by providing residents with increased access to quality services.

Therefore, the application 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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CMC-Union is a licensed, acute care hospital and is accredited by The Joint Commission. CMC-Union has been designated as a Comprehensive Community Cancer Center by the American College of Surgeons. According to the records in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents have 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

The applicants propose to replace an existing linear accelerator, not acquire an additional linear accelerator. Therefore the Criteria and Standards for Radiation Therapy Equipment, promulgated in 10A NCAC 14C.1900, are not applicable to this review.