

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 29, 2013
PROJECT ANALYST: Gregory F. Yakaboski
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: F-10058-12 / The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center / Replace MRI Scanner / Mecklenburg 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.

NA

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center (“CMC”) proposes to replace its Philips Intera 1.5T fixed magnetic resonance imaging (“MRI”) scanner at CMC and install a Siemens Magnetom Aera 1.5T replacement MRI scanner. The applicant does not propose to increase the number of licensed beds in any category, add services, or acquire equipment for which there is a need determination in the 2012 State Medical Facilities Plan (SMFP).

There is one policy in the 2012 SMFP applicable to the review of the application:

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES

“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."

CMC provides a written statement regarding Policy GEN-4, in Section III.2, pages 53-55 and Section XI.7, pages 113-115, describing the project's plan to assure improved energy efficiency and water conservation, as follows:

"CHS is committed to energy efficiency and sustainability that balances the need for healthcare services and environmental sustainability in the communities it serves. The project's plan to assure improved energy and water conservation in accordance with Policy GEN-4 requirements is discussed below.

... Design for maximum efficiency and life cycle benefits within each impacted mechanical system: heating, cooling, water and sewer.

... CMC will work with experienced architects and engineers to develop this proposed project to ensure energy efficient systems are an inherent part of the proposed project... The design team for the proposed project has Energy Star, Leadership in Energy and Environmental Design (LEED) and Hospitals for a Healthy Environment Green Guide for Healthcare (GGHC) experience.

... CMC utilizes and enforces engineering standards that mandate use of state-of-the-art components and systems. The proposed project will be designed in full compliance with applicable local, state, and federal requirements for energy efficiency and consumption."

The applicant adequately described the project's plan to assure improved energy efficiency and water conservation. Thus, the application is conforming to Policy GEN-4. Therefore, the application is 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

CMC proposes to replace an existing MRI scanner at CMC and install the replacement MRI scanner in the existing MRI department. CMC currently operates a total of five fixed MRI scanners. One of these is a dedicated pediatric MRI scanner located in the Levine Children's Hospital at CMC.

Population to be Served

In Section III.4, page 59, the applicant provides the current patient origin for MRI services provided at CMC during Federal Fiscal Year (FFY) 2011, as shown in the following table.

County	% of Total Patients
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Mecklenburg	55.9%
Union	7.2%
York, SC	6.9%
Gaston	5.8%
Cleveland	2.8%
Cabarrus	2.6%
Lancaster, SC	2.0%
Lincoln	2.0%
Iredell	1.3%
Stanly	1.2%
Catawba	1.1%
Other*	11.2%
TOTAL	100.0%

Note: For purposes of patient origin projections, CMC assumes one patient equals one unweighted MRI scan.

*Other includes Abbeville, Aiken, Alamance, Alexander, Anderson, Anson, Ashe, Avery, Bamberg, Barnwell, Beaufort, Berkeley, Bladen, Brunswick, Buncombe, Burke, Caldwell, Caswell, Charleston, Cherokee (NC & SC), Chester, Chesterfield, Columbus, Cumberland, Dare, Darlington, Davidson, Davie, Dorchester, Durham, Edgecombe, Fairfield, Florence, Forsyth, Franklin, Georgetown, Graham, Granville, Greenville, Greenwood, Guilford, Halifax, Harnett, Haywood, Henderson, Hoke, Horry, Jackson, Kershaw, Lee (NC & SC), Lenoir, Lexington, Macon, Madison, Marlboro, McDowell, Montgomery, Moore, New Hanover, Newberry, Onslow, Orangeburg, Pasquotank, Pickens, Polk, Randolph, Richland, Richmond, Robeson, Rockingham, Rowan, Rutherford, Sampson, Scotland, Spartanburg, Stanly, Sumter, Surry, Transylvania, Union (SC), Wake, Washington, Watauga, Wayne, Wilkes, Williamsburg, Wilson and Yadkin counties, as well as other states.

In Section III.5, page 62, the applicant provides the projected patient origin for MRI services to be provided at CMC during the first two project years, as shown in the table below.

County	Year 1: Projected # Patients	Year 1: % of Total	Year 2: Projected # Patients	Year 2: % of Total
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		Patients		Patients
Mecklenburg	9,425	55.9%	9,592	55.9%
Union	1,212	7.2%	1,233	7.2%
York, SC	1,156	6.9%	1,176	6.9%
Gaston	980	5.8%	997	5.8%
Cleveland	476	2.8%	485	2.8%
Cabarrus	444	2.6%	452	2.6%
Lancaster, SC	341	2.0%	347	2.0%
Lincoln	333	2.0%	339	2.0%
Iredell	212	1.3%	216	1.3%
Stanly	198	1.2%	202	1.2%
Catawba	187	1.1%	190	1.1%
Other*	1,890	11.2%	1,923	11.2%
TOTAL	16,854	100.0%	17,152	100%

Note: For purposes of patient origin projections, CMC assumes one patient equals one unweighted MRI scan.

*Other includes Abbeville, Aiken, Alamance, Alexander, Anderson, Anson, Ashe, Avery, Bamberg, Barnwell, Beaufort, Berkeley, Bladen, Brunswick, Buncombe, Burke, Caldwell, Caswell, Charleston, Cherokee (NC & SC), Chester, Chesterfield, Columbus, Cumberland, Dare, Darlington, Davidson, Davie, Dorchester, Durham, Edgecombe, Fairfield, Florence, Forsyth, Franklin, Georgetown, Graham, Granville, Greenville, Greenwood, Guilford, Halifax, Harnett, Haywood, Henderson, Hoke, Horry, Jackson, Kershaw, Lee (NC & SC), Lenoir, Lexington, Macon, Madison, Marlboro, McDowell, Montgomery, Moore, New Hanover, Newberry, Onslow, Orangeburg, Pasquotank, Pickens, Polk, Randolph, Richland, Richmond, Robeson, Rockingham, Rowan, Rutherford, Sampson, Scotland, Spartanburg, Stanly, Sumter, Surry, Transylvania, Union (SC), Wake, Washington, Watauga, Wayne, Wilkes, Williamsburg, Wilson and Yadkin counties, as well as other states.

On page 60, the applicant states the following regarding projected patient origin:

“CMC projects that Mecklenburg County will remain its primary service area and Union, Gaston, Cleveland, Cabarrus, Lincoln, Iredell, Stanly, and Catawba counties in North Carolina and York and Lancaster counties in South Carolina will be secondary service areas. Over 55 percent of CMC’s MRI patients originate from Mecklenburg County. Patients from the medical center’s secondary service area represent approximately 33 percent of MRI patients. In total, CMC’s primary and secondary service area represent nearly 88 percent of MRI patients.”

In Section III.5(d), page 63, the applicant states: *“CHS does not anticipate any change in patient origin during the first two federal fiscal years as listed in the projected patient origin.”*

The applicant provides current and projected patient origin for MRI services, including the assumptions used to project patient origin. The applicant adequately identifies the population to be served.

Need for the Proposed Replacement MRI Scanner

CMC proposes to replace its Philips Intera 1.5T fixed MRI scanner with a new Siemens Magnetom Aera 1.5T MRI replacement scanner.

The applicant discusses the need to replace the existing MRI scanner in Section III.1, pages 35-47. On page 35, the applicant states:

“The unmet need that necessitates the proposed project is primarily qualitative in nature, involving the need of patients and physicians for updated equipment, which directly impacts the ability of the radiology department to provide the best possible care in the most efficient manner.”

The applicant states that age, quality and capabilities of the existing Philips Intera 1.5T fixed MRI scanner all contribute to the need to replace it.

1) Age of the Existing MRI Scanner

The applicant states the existing MRI scanner is approximately 11 years old, outdated and well past its useful life as measured by the American Hospital Association’s equipment lifetimes standards. See Exhibit 15 and pages 36-37 of the application.

2) Available Software Upgrades for Existing MRI Scanner

The applicant states there is only one more software update available. See page 37 of the application.

3) Bariatric and Claustrophobic Patients

The applicant states the proposed MRI scanner, a Siemens Magnetom Aera 1.5T, will enhance CMC’s MRI imaging capabilities. The proposed replacement MRI scanner features a wide bore design and a heavy duty table both of which will aid in scanning bariatric and claustrophobic patients. See page 40 of the application.

4) Imaging Capabilities and Quality of Images

The applicant states the proposed replacement MRI scanner would provide greater overall image detail and specifically enhance cardiac imaging capabilities. See pages 40-45 of the application.

5) Growing Population

On page 45, the applicant states the *“need to replace its existing outdated equipment is also supported by population growth and aging which drives increased utilization of healthcare services. Mecklenburg County and its surrounding communities are among the fastest growing regions in the country.”*

6) Aging Population

On page 46, the applicant states “By 2020, 11.8 percent of the total population in Mecklenburg County will be over the age of 65 (more than 129,000 people). Based on NC OSBM projections, Exhibit 18, of the counties in North Carolina, Mecklenburg County will have the second largest number of residents over the age of 65 in 2020. Further, within this decade, Mecklenburg County’s 65+ population is projected to grow by 57.8 percent. These data are significant because, typically, older residents utilize healthcare services at a higher rate than those who are younger.¹”

Projected Utilization

In Section III.1(b), pages 48-49 the applicant provides historical utilization for its MRI scanners, as shown in the table below.

CMC Historical Utilization MRI Scanners				
	CY 2009	CY 2010	CY 2011	CY 2012*
# of Procedures	14,624	15,095	16,060	16,458
# of Weighted Procedures	19,402	20,146	21,628	22,424

*Annualized based on six months of actual data from 1/1/12 through 6/3012.

In Section IV.1, page 68, the applicant provides projected utilization for its MRI scanners through the first three years of operation after completion of the proposed project.

CMC Projected Utilization MRI Scanners			
	1st Full FY FY 14	2nd Full FY FY 15	3rd Full FY FY 16
# of Units*	4	4	4
# of Procedures	16,927	17,227	17,531
# of Weighted Procedures	22,796	23,199	23,610

*CMC currently operates a total of five fixed MRI scanners. One of the five MRI scanners is a dedicated pediatric MRI scanner located in the Levine Children’s Hospital at CMC. Given that the dedicated pediatric MRI scanner is not counted in the inventory of MRI scanners in the 2012 SMFP, the table above does not include the procedures performed on the dedicated pediatric MRI scanner.

In Section IV.1, page 68, the applicant states:

¹ Federal Interagency Forum on Aging Related Statistics, Older Americans 2012: Key Indicators of Well-Being, available at http://www.agingstats.gov/Main_Site/Data/2012_Documents/Health_Care.aspx (noting that older Americans use more healthcare per capita than any other age group). See Exhibit 19, page 2, of the application.

“As defined in the 2012 State Medical Facilities Plan, the annual maximum capacity of a single fixed MRI scanner is 6,864 procedures based on operation of the scanner for 66 hours per week and 52 hours per year with an average procedure time of 30 minutes per MRI procedure.”

In Section III.1, page 48, the applicant provides the assumptions and methodology used to project MRI utilization through the third year of the proposed project, which are shown in the tables that follow.

The following table illustrates MRI procedures performed in calendar years 2009-2012.

	CY 2009	CY 2010	CY 2011	CY 2012*
Inpatient w/ Contrast or Sedation	2,699	2,783	3,098	3,452
Inpatient w/o Contrast or Sedation	2,113	2,152	2,360	2,460
Outpatient w/ Contrast or Sedation	4,435	4,910	5,364	5,550
Outpatient w/o Contrast or Sedation	5,377	5,250	5,238	4,996
Total Unweighted Procedures	14,624	15,095	16,060	16,458

*Annualized based on six months of actual data from 1/1/12 through 6/30/12

The MRI procedures shown in the table above were converted to weighted procedures using the conversion factors found in the 2012 SMFP and the Criteria and Standards for Magnetic Imaging Scanners, promulgated in 10A NCAC 14C .2700.

	Weighted Conversion Factor
Inpatient w/ Contrast or Sedation	1.8
Inpatient w/o Contrast or Sedation	1.4
Outpatient w/ Contrast or Sedation	1.4
Outpatient w/o Contrast or Sedation	1.0

The results are shown in the table below:

	CY 2009	CY 2010	CY 2011	CY 2012*
Inpatient w/ Contrast or Sedation	4,858	5,009	5,576	6,214
Inpatient w/o Contrast or Sedation	2,958	3,013	3,304	3,444
Outpatient w/ Contrast or Sedation	6,209	6,874	7,510	7,770
Outpatient w/o Contrast or Sedation	5,377	5,250	5,238	4,996
Total Weighted Procedures	19,402	20,146	21,628	22,424

*Annualized based on six months of actual data from 1/1/12 through 6/30/12.

As shown in the table above, CMC’s four fixed MRI scanners (excluding the dedicated pediatric MRI scanner) performed an average of 5,606 weighted MRI procedures per scanner in CY 2012 (annualized) which exceeds the minimum performance standard found in 10A NCAC 14C .2703(b)(1) (3,328 weighted MRI procedures per scanner.) It must be noted that that rule is not applicable to this review. The comparison is made to the minimum performance standard to illustrate that CMC’s four existing fixed MRI scanners (excluding the dedicated pediatric MRI scanner) are well utilized, which supports the applicant’s assertion that a replacement is needed even without any anticipated growth in volume.

In Section III.1, pages 49-50, the applicant states:

“While its annualized 2012 unweighted and weighted MRI procedure volume represents a 2.5 percent and 3.7 percent increase over 2011 volumes, respectively, and despite the fact that CMC expects an overall increase in MRI utilization to result from the replacement of its outdated equipment, the medical center has chosen to very conservatively project future MRI utilization based on population growth. More than 55 percent of CMC’s MRI patients originate from Mecklenburg County. According to the NC Office of State Budget and Management population statistics, Exhibit 17, the population of Mecklenburg County is projected to grow by a compound annual growth rate (CAGR) of 1.8 percent from 2010 to 2020.

To be as conservative, CMC applied an annual growth rate of 1.8 percent to its total 2011 unweighted MRI scans through CY2016, the third calendar year of the proposed project. Note that this methodology results in a lower projection of MRI procedures in 2012 than the annualized data provided above suggests is actually likely to be realized. CMC then distributed the total projected unweighted MRI scans by type based on the actual mix experienced in 2011, the last full year of data available.”

The following table illustrates projected unweighted MRI procedures through CY 2016.

	CY 2012	CY 2013	CY 2014	CY 2015	CY 2016
Inpatient w/ Contrast or Sedation	3,153	3,209	3,265	3,323	3,382
Inpatient w/o Contrast or Sedation	2,402	2,444	2,487	2,531	2,576
Outpatient w/ Contrast or Sedation	5,459	5,555	5,654	5,754	5,855
Outpatient w/o Contrast or Sedation	5,331	5,425	5,521	5,619	5,718
Total Unweighted Procedures	16,344	16,633	16,927	17,227	17,531

The following table illustrates projected weighted MRI procedures through CY 2016.

	CY 2012	CY 2013	CY 2014	CY 2015	CY 2016
Inpatient w/ Contrast or Sedation	5,675	5,775	5,878	5,982	6,087
Inpatient w/o Contrast or Sedation	3,362	3,422	3,482	3,544	3,607
Outpatient w/ Contrast or Sedation	7,642	7,778	7,915	8,055	8,198
Outpatient w/o Contrast or Sedation	5,331	5,425	5,521	5,619	5,718
Total Weighted Procedures	22,011	22,400	22,796	23,199	23,610

The applicant projects the replacement MRI scanner will begin operating on October 1, 2013. Projected utilization shown in the tables above are for calendar years. The applicant converted the calendar year projections to Federal Fiscal Year (FFY) for each of the three Project Years “by adding one-fourth of the previous calendar year’s volume and three-fourths of the next calendar year’s volume (e.g. $CY2013 \times .25 + CY2014 \times .75 = FFY 2014$).” The following table illustrates projected unweighted MRI procedures during the first three Project Years.

	PY 1: FFY 2014	PY 2: FFY 2015	PY 3: FFY 2016
Inpatient w/ Contrast or Sedation	3,251	3,309	3,367
Inpatient w/o Contrast or Sedation	2,477	2,520	2,565
Outpatient w/ Contrast or Sedation	5,629	5,729	5,830
Outpatient w/o Contrast or Sedation	5,497	5,594	5,693
Total Unweighted Procedures	16,854	17,152	17,455

The following table illustrates projected weighted MRI procedures during the first three Project Years.

	PY 1: FFY 2014	PY 2: FFY 2015	PY 3:FFY 2016
Inpatient w/ Contrast or Sedation	5,852	5,956	6,061
Inpatient w/o Contrast or Sedation	3,467	3,529	3,591
Outpatient w/ Contrast or Sedation	7,881	8,020	8,162
Outpatient w/o Contrast or Sedation	5,497	5,594	5,693
Total Weighted Procedures	22,697	23,098	23,507

In Project Year 3 (FFY 2016), CMC projects to perform 5,877 weighted MRI procedures per scanner ($23,507/4 = 5,877$). There is no need for additional MRI scanners in the applicant’s MRI Service Area (Mecklenburg County); however, this application is for a replacement MRI scanner. Projected utilization is based on reasonable, credible and supported assumptions regarding historical utilization and projected population growth. Therefore, the applicant adequately demonstrates the need to replace the MRI scanner.

In Section II, page 25, the applicant states it plans to temporarily use an existing mobile MRI scanner while the existing fixed MRI is removed, the space renovated and the new MRI scanner is installed. The applicant states:

“CMC intends to temporarily use an existing vendor-owned mobile unit while the existing fixed unit is removed from CMC and the permanent fixed replacement is obtained and installed. During this time, the mobile MRI unit will be temporarily placed on-site at CMC for imaging CMC’s of outpatient and inpatient MRI studies. Patients will be escorted to and from the mobile MRI unit by a member of the CMC MRI staff. Patients will be observed at all times while on the mobile MRI unit. Once CMC’s permanent fixed replacement magnet is installed, the temporary equipment would of course be returned to the vendor and at no time would CMC operate more than five fixed MRI scanners. Given that the permanent replacement MRI is expected to be operational in approximately four months, CMC does not expect the temporary mobile MRI to be on-site for more than that time (the exact dates of which are unknown pending issuance of the CON).”

In summary, the applicant adequately identified the population to be served and demonstrated the need to replace the MRI scanner at CMC. Consequently, the application is conforming with 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.

CA

In Section III.3, pages 55-57, the applicant described several alternatives considered prior to submitting this application:

- 1) Maintain the Status Quo. The applicant rejected this alternative because it would not be in the best interest of the medical center's patients, as the existing MRI scanner no longer meets the expected standards for MRI technology.
- 2) Replace and Update Components of the Existing System. The applicant rejected this alternative because it would only delay the need to replace the scanner.
- 3) Replace the Existing MRI Scanner with a 1.5T in current location. The applicant determined that this was the most effective alternative because the new scanner will be state-of-the-art and will enable the medical center to treat patients more effectively and efficiently.

The applicant adequately demonstrated that the proposal is its least costly or most effective alternative to meet the need to replace the scanner. The application is conforming to all applicable statutory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative. Therefore, the application is conforming with this criterion and approved subject to the following conditions.

- 1. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall materially comply with all representations made in the certificate of need application.**
- 2. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center 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.**

3. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center 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, pages 98-99, the applicant projects the capital cost for the proposed project will be \$3,605,250, as shown in the table below:

Construction Contract	\$1,580,000
Miscellaneous Project Costs	
Fixed Equipment	\$1,498,534
Movable Equipment	\$6,750
Furniture	\$7,500
Architect & Engineering	\$188,000
Legal Fees	\$38,000
Other (commissioning fees)	\$25,000
Other (Contingency)	\$261,466
Total Capital Cost of Project	\$3,605,250

In Section VIII.3, page 99, the applicant states the capital cost will be financed with the accumulated reserves of The Charlotte-Mecklenburg Hospital Authority. In Section IX.1, page 104, the applicant states that there will not be any start-up or initial operating expenses associated with the project. In Exhibit 28, the applicant provides a letter from the Executive Vice-President and Chief Financial Officer for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System, which states

“As the Chief Financial Officer for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System, I am responsible for the financial operations of Carolinas Medical Center. As such, I am very familiar with the organization’s financial position. The total capital expenditure for this project is estimated to be \$3,605,250. There are no start-up costs related to this project.”

Carolinas HealthCare System will fund the capital cost from existing accumulated reserves. This expenditure will not impact any other capital projects currently underway or planned for at this time. For verification of the availability of these funds and our ability to finance these projects internally, please refer to the line items ‘Cash and cash equivalents’ and ‘Other assets: designated as funded depreciation,’ in the audited financial statements included with this Certificate of Need application.”

Exhibit 29 contains audited financial statements for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System for the year ended December 31, 2011. The line item “Cash and cash equivalents,” shows \$53,073,000 as of December 31, 2011. The line item “Other assets: designated as funded depreciation,” shows \$1,922,872,000 as of December 31, 2011. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

The applicant provided pro forma financial statements in the Pro Forma Section (immediately following Section XII) for the first three operating years of the project following completion. The applicant projects that revenues will exceed operating costs in each of the first three years of operation for MRI services. The revenue projections provided on Form C, are as follows:

MRI Services

	1st Full FY 2014	2nd Full FY 2015	3rd Full FY 2016
# of Procedures	16,927	17,227	17,531
Projected Average Gross Charge per Procedure	\$3,434.70	\$3,537.62	\$3,643.89
Gross Revenue	\$58,139,191	\$60,942,515	\$63,881,010
Projected Average Net Revenue (Reimbursement) per Procedure	\$1,250.52	\$1,287.99	\$1,326.69
Net Revenue	\$21,167,686	\$22,188,338	\$23,258,204

Source: Proforma Section, pages 119-126.

The applicant also provided pro forma financial statements in the Pro Forma Section (immediately following Section XII) for the first three Project Years for Carolina HealthCare System. The applicant projects that revenues will exceed expenses in each of the first three years Project Years. The revenue projections provided on Form B, are as follows:

Carolina HealthCare System

	1st Full FY 2014	2nd Full FY 2015	3rd Full FY 2016
Total Revenue	\$1,483,735,000	\$1,578,661,000	\$1,670,883,000
Total Expenses	\$1,282,630,000	\$1,348,046,000	\$1,415,705,000
Net Revenue	\$201,105,000	\$230,615,000	\$255,178,000

See the pro formas, pages 122-126, for the pro forma assumptions. Projected costs and revenues are based on reasonable assumptions, including projected utilization. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and charges and the application is conforming with 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.

The applicant proposes to replace its existing, outdated Philips Intera 1.5T fixed magnetic MRI scanner with a new Siemens Magnetom Aera 1.5T MRI scanner and to renovate existing space to accommodate the replacement equipment. The project will not result in the addition of an MRI scanner to the inventory of fixed MRI scanners in Mecklenburg County. The applicant adequately demonstrated the need to replace the outdated equipment. See Criterion (3) for discussion regarding the need to replace the existing scanner and historical and projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the applicant adequately demonstrated that the proposal would not result in the unnecessary duplication of existing or approved MRI scanners in Mecklenburg County. Consequently, the application is conforming with 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, pages 90-91, the applicant provides current and projected staffing for MRI services. The applicant also states that no new positions will result from this project.

Position	Current Staffing CY 2012		Proposed Staffing CY 2015	
	Total # of FTE Positions	Average Annual Salary per FTE Position	Total # of FTE Positions	Average Annual Salary per FTE Position
Technologists	14.6	\$65,922	14.6	\$74,153
Clerical	1.0	\$26,145	1.0	\$29,410
Supervisor	1.0	\$83,138	1.0	\$93,519
Total	16.6		16.6	

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed MRI services. Therefore, the application is conforming with 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

CMC is an existing acute care hospital and provides ancillary and support services for its inpatient and outpatient services. In Section II.2, page 26, the applicant states:

“As an existing academic medical center teaching hospital, CMC currently has all ancillary and support services in place necessary to support hospital operations. These existing ancillary and support services will also support the replacement equipment proposed in this application. CMC’s existing ancillary and support services, including pre-admission testing, laboratory, radiology, pharmacy, dietary,

housekeeping, couriers, maintenance, and administration, among others, are available to support the proposed replacement equipment. Please see Exhibit 6 for a letter from Spencer Lilly, Acting Divisional President and Chief Operating Officer of CHS Central Division, verifying the availability of ancillary and support services for this project.”

In Section V, pages 70-75, and Exhibits 22, 23 and 33 the applicant documents that MRI services are coordinated with the existing health care system. Exhibit 33 contains letters of support for the proposed project,

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

C

In Section VI.13, page 88, the applicant provides the payor mix for MRI services provided during CY 2011.

CMC-MRI Services Calendar Year 2011 Current Procedures as Percent of Total Procedures	
Self-Pay/Indigent/Charity/Other*	11.9%
Medicare / Medicare Managed Care	33.1%
Medicaid	11.8%
Commercial / Managed Care	43.1%
Total	100.0%

*Other includes workers comp and other government payors.

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 Mecklenburg, Union, Gaston, Cleveland, Cabarrus, Lincoln, Iredell, Stanly, Catawba counties and statewide.

County	June 2010 Total # of Medicaid Eligibles as % of Total Population *	June 2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	CY 2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Mecklenburg	15.0%	5.1%	20.1%

Union	11.0%	3.4%	18.0%
Gaston	20.0%	8.6%	19.0%
Cleveland	23.0%	10.6%	18.6%
Cabarrus	14.0%	4.9%	18.5%
Lincoln	15.0%	6.2%	19.0%
Iredell	14.0%	5.5%	18.3%
Stanly	17.0%	7.6%	18.3%
Catawba	17.0%	6.2%	19.1%
Statewide	17.0%	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 is not as likely to use CMC's MRI services as the population over the age of 21.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 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.

In Section VI.2-4, pages 80-82, the applicant states:

“CMC provides services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay.”

... Patients lacking coverage receive financial counseling to determine eligibility for Public Assistance or Charity Care. Patients who do not qualify for either of these programs will be offered an installment plan. Patients will receive the appropriate medical screening examination and any necessary stabilizing treatment for emergency medical conditions, regardless of ability to pay.”

In Section VI.6, page 83, the applicant states:

“CMC’s services are and will remain accessible to Medicare and Medicaid recipients, the uninsured, and the underinsured.”

The applicant demonstrates that medically underserved populations have adequate access to CMC’s existing MRI services and the application is conforming with 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 87, the applicant states:

“CMC has had no obligations to provide uncompensated care during the last three years. As stated earlier, the medical center provides, without obligation, a considerable amount of bad debt and charity care and in CY 2010 provided approximately \$268 million in bad debt and charity care.

See Exhibit 24 for a copy of the applicant’s admission policies. Regarding the applicant’s obligation not to discriminate in the provision of care on the basis of race, age, etc., in Section VI.2, page 80, the applicant states:

“CMC provides services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay.”

In Section VI.10, page 86, the applicant states that no complaints have been filed against any affiliated entity regarding civil rights equal access in the last five years. The application is conforming with this criterion.

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

C

In Section VI.15, page 89, the applicant provides the projected payor mix for MRI Services in CY 2015, as illustrated in the table below:

CMC-MRI Services

Calendar Year 2015	
Projected MRI Procedures as % of Total Procedures	
Self-Pay / Indigent/Charity/Other*	11.9%
Medicare / Medicare Managed Care	33.1%
Medicaid	11.8%
Managed Care / Commercial Insurance	43.1%
Total	100.0%

*Other includes workers comp and other government payors.

In Section VI.15, page 89, the applicant states that acquisition of the proposed replacement MRI scanner is not expected to impact the facility's payor mix for MRI services.

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

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

C

In Section VI.9, pages 85-86, the applicant describes the range of means by which a person will access MRI services. The application is conforming to this criterion.

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

C

In Section V.1(a-c), pages 70-72, the applicant provides documentation that CMC will continue to accommodate the clinical needs of area health professional training programs. On pages 70-71, the applicant provides a list of institutions with which it has these arrangements. The list of institutions includes: Cabarrus College of Health Sciences; Carolinas College of Health Sciences; Central Piedmont Community College, Queens University of Charlotte, University of North Carolina at Charlotte, Gardner-Webb University, Presbyterian School of Nursing and Mercy School of 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.

C

The applicant proposes to replace an existing MRI scanner in the same location and renovate the space. The project will not increase the inventory of fixed MRI scanners in Mecklenburg County.

In Section V.7, pages 75-78, the applicant describes in detail how the proposed project will foster competition in the proposed service area by promoting the cost effectiveness, quality, and access to services, as follows:

“The proposed project is indicative of CMC’s commitment to containing healthcare costs and maximizing healthcare benefit per dollar expended. CMC believes the proposed project provides greater healthcare value than attempting to update or replace components of its existing Philips Intera 1.5T MRI scanner nearing the end of its useful life. ...

The proposed project will serve to improve the quality of care for MRI services in the service area. At present, CMC provides exceptional MRI services. However, the existing equipment CMC is proposing to replace is reaching the end of its useful life and has begun to hamper efficiencies. As stated throughout the application, the proposed project will allow CMC to provide state-of-the-art care. ...

The proposed project seeks to address this principle [equitable access] and will improve access to state-of-the-art MRI services in the service area. By enhancing access to state-of-the-art MRI services, the proposed project will naturally enhance competition in Mecklenburg County and surrounding areas.”

The information provided by the applicant is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include a positive impact on cost-effectiveness, quality and access to the MRI services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to replace the existing MRI scanner and that it is a cost-effective alternative;
- The applicant will continue to provide quality services; and
- The applicant will continue to provide adequate access to medically underserved populations.

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.

C

CMC is certified by CMS for Medicare and Medicaid participation, and licensed by the NC Department of Health and Human Services. According to files in the Acute and Home Care Licensure and Certification Section in the Division of Health Service Regulation, no incidents have occurred at CMC within the eighteen months immediately preceding the date of the 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