

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 17, 2016

Findings Date: October 17, 2016

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Project ID #: F-11210-16

Facility: Carolinas Medical Center

FID #: 943070

County: Mecklenburg

Applicant: The Charlotte-Mecklenburg Hospital Authority

Project: Acquire an intraoperative MRI scanner pursuant to Policy TE-2, which will be located in a renovated OR

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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

The applicant, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center (CMC), proposes to acquire an intraoperative magnetic resonance imaging scanner (iMRI) to be located at CMC pursuant to Policy TE-2 of the 2016 State Medical Facilities Plan (SMFP).

Need Determination

The applicant does not propose to increase the number of licensed beds in any category, add any new health services or acquire equipment for which there is a need determination in the 2016 SMFP. Therefore, there are no need determinations in the 2016 SMFP that are applicable to this review.

Policies

There are two policies in the 2016 SMFP which are applicable to this review: Policy TE-2: Intraoperative Magnetic Resonance Scanners and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy TE-2: Intraoperative Magnetic Resonance Scanners states:

“Qualified applicants may apply for an intraoperative Magnetic Resonance Scanner (iMRI) to be used in an operating room suite.

To qualify, the health service facility proposing to acquire the iMRI scanner shall demonstrate in its certificate of need application that it is a licensed acute care hospital which:

- 1. Performed at least 500 inpatient neurosurgical cases during the 12 months immediately preceding the submission of the application; and*
- 2. Has at least two neurosurgeons that perform intracranial surgeries currently on its Active Medical Staff; and*
- 3. Is located in a metropolitan statistical area as defined by the US Census Bureau with at least 350,000 residents.*

The iMRI scanner shall not be used for outpatients and may not be replaced with a conventional MRI scanner.

The performance standards in 10A NCAC 14C .2703 would not be applicable.

Intraoperative procedures and inpatient procedures performed on the iMRI shall be reported separately on the hospital license renewal application.

These scanners shall not be counted in the inventory of fixed MRI scanners; the procedures performed on the iMRI will not be used in calculating the need methodology and will be reported in a separate table in Chapter 9.”

In Section III.2, pages 59-62, the applicant states that CMC meets each of the requirements for being a qualified applicant, specifically,

1. CMC performed 991 inpatient neurosurgical cases from June 2015 to May 2016, the twelve months immediately preceding the submission of this application. (p. 59)
2. CMC has more than two neurosurgeons currently on its Active Medical Staff at CMC that perform intracranial surgeries. (p. 60 and Exhibit 6)
3. CMC is located in the Charlotte-Concord-Gastonia, NC-SC Metropolitan Statistical Area which includes seven counties in North Carolina, including Mecklenburg County, and three counties in South Carolina. The applicant states that the Charlotte-Concord-Gastonia, NC-SC Metropolitan Statistical Area includes 2,454,119 residents, exceeding the 350,000 resident requirement. (p. 61)

On pages 61-62, the applicant further states:

“Policy TE-2 outlines additional requirements to which CMC will comply. These additional requirements are as follows:

- The proposed iMRI scanner will not be used for outpatients and will not be replaced with a conventional MRI scanner.*
- The performance standards in 10A NCAC 14C .2703 do not apply and as such have not been included in this application.*
- CMC will report intraoperative procedures and inpatient procedures performed on the iMRI separately on its hospital license renewal application.*
- Lastly, CMC understands that the proposed iMRI scanner will not be counted in the inventory of fixed MRI scanners and the procedures performed on the iMRI will not be used in calculating the need methodology and will instead be reported in a separate table in Chapter 9 of the SMFP.”*

Exhibit 8 contains a letter from the President of CMC documenting that CMC will comply with the requirements of Policy TE-2.

The applicant adequately demonstrates that CMC is a qualified applicant and that it meets the requirements set forth in the policy and will comply with all policy requirements. Therefore, the application is consistent with Policy TE-2 and conforming with this criterion, subject to Conditions (4) and (5) in Criterion (4).

Policy GEN-4 states:

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

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

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as

described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$5 million. In Section VIII.2, page 103, the applicant states the proposed capital expenditure is \$13,146,665. In Section III.2, pages 62-64 and Section XI.7, pages 117-118, the applicant provides written statements which describe its plan to assure improved energy efficiency and water conservation as part of the project. Therefore, the application is consistent with Policy GEN-4 and conforming to this criterion, subject to Condition (6) in Criterion (4).

Conclusion

In summary, the application is consistent with Policy TE-2 and Policy GEN-4. Consequently, the application is conforming to this criterion, subject to Conditions (4), (5), and (6) in Criterion (4).

- (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 acquire an iMRI scanner to be located at CMC pursuant to Policy TE-2 of the 2016 SMFP. The iMRI will be developed in a renovated OR adjacent to an iMRI inpatient diagnostic room on the fifth floor of the medical center, as shown in the line drawings in Exhibit 3. In Section III.1, page 41, the applicant states:

“In addition, when not in use for intraoperative scans, the iMRI will provide additional inpatient diagnostic MRI capacity needed for inpatients at CMC.”

The applicant is a licensed North Carolina acute care hospital and provides documentation of meeting each requirement to be a qualified applicant. The discussion regarding Policy TE-2, its requirements and CMC’s qualifications found in Criterion (1) is incorporated herein by reference. Therefore CMC is a qualified applicant to apply for an iMRI.

Population to be Served

On page 154, the 2016 SMFP defines the service area for fixed MRI scanners as *“a single county, except where there is no licensed acute care hospital located within the county.”* Policy TE-2 does not specifically address service area. Thus, the service area for the proposed fixed iMRI scanner consists of Mecklenburg County. Providers may serve residents of counties not included in their service area.

In Section III.4, page 66, the applicant states that CMC does not currently operate an iMRI; therefore, it has no historical data for that service component. As stated in the application, the proposed iMRI scanner will be used for intraoperative and inpatient procedures; therefore, the applicant provides the current (CY2015) patient origin for acute care services at CMC, as summarized in the table below.

**CMC Acute Care Services
Patient Origin CY2015**

County	% of Total Patients
Mecklenburg	56.5%
Gaston	5.8%
Union	5.5%
York, SC	5.1%
Cleveland	3.1%
Lincoln	2.4%
Lancaster, SC	2.4%
Cabarrus	2.4%
Iredell	1.9%
Other*	14.7%
Total	100.0%

Totals may not sum due to rounding

*Includes 79 NC counties and other states

In Section III.5, page 69, the applicant provides the projected patient origin for CMC's proposed iMRI scanner services for the first two operating years, CY2018 and CY2019, as summarized in the table below.

County	Operating Year 1 CY2018		Operating Year 2 CY2019	
	# iMRI Procedures	% of Total Procedures	# iMRI Procedures	% of Total Procedures
Mecklenburg	300	47.3%	295	47.1%
Gaston	45	7.2%	45	7.2%
York, SC	45	7.1%	45	7.1%
Union	41	6.4%	40	6.4%
Cleveland	22	3.5%	22	3.5%
Cabarrus	21	3.3%	21	3.3%
Lancaster, SC	19	3.0%	19	3.0%
Lincoln	15	2.3%	15	2.3%
Iredell	15	2.3%	15	2.3%
Other*	111	17.6%	110	17.6%
Total	634	100.0%	626	100.0%

Totals may not sum due to rounding

*Includes 89 NC cities and counties and other states

In Section III.5(d), page 70, the applicant provides its assumptions for projecting patient origin, stating:

“CMC assumed that the patient origin for its projected intraoperative scans would be equivalent to its CY 2015 patient origin for neurosurgical cases. Similarly, CMC assumed that patient origin for its projected inpatient diagnostic scans to be performed by the iMRI would be equivalent to its CY 2015 patient origin for inpatient MRI scans. Thus, the projected patient origin for the proposed iMRI scanner is a weighted average of CMC’s historical patient origin for neurosurgical cases and inpatient diagnostic MRI scans.”

The applicant adequately identifies the population to be served.

Analysis of Need

In Section III.1(a) and (b) of the application, the applicant discusses the factors which it states support the need for the proposed project. On page 41, the applicant states that the overall need for the proposed project is based on the following factors:

- The clinical benefits of iMRI technology (p. 42-45);
- The need to expand access to iMRI services (p. 45-46);
- The dynamic population growth in Mecklenburg County (p. 46-48); and
- The need for inpatient MRI capacity at CMC (p. 48).

The applicant demonstrates on the pages as listed above, the clinical benefits of iMRI technology, the need to expand access to iMRI services, the projected population growth in Mecklenburg County, and CMC’s need for additional inpatient 3 Tesla strength MRI capacity.

Projected Utilization

The applicant describes the assumptions and methodology used to project utilization in Section III.1(b), pages 49-57, stating on page 49 that CMC intends to use the proposed iMRI for intraoperative MRI scans and, when otherwise idle, for inpatient diagnostic MRI scans. The applicant further states that the utilization of the proposed iMRI is projected separately for intraoperative scans and inpatient diagnostic scans.

Intraoperative Scans

On page 52, the applicant provides the projected intraoperative MRI cases for CY2018 through CY2020, as shown below.

CMC Neurosurgery Cases Using iMRI

	CY2018	CY2019	CY2020
Intracranial Tumor Surgery	282	288	295
Percent iMRI Utilization	41%	41%	41%
iMRI Intracranial Tumor Surgery	116	118	121
Pediatric Neurosurgery	126	129	132
Percent iMRI Utilization	5%	5%	5%
iMRI Pediatric Neurosurgery	6	6	7
Total iMRI Utilization	122	125	128

Assumptions:

- Neurosurgical cases at CMC will grow 2.3% annually through 2021. CMC assumes this is conservative in comparison to its most recent annual growth of 6.5% from CY2015 to CY2016. The following table from page 50 of the application projects CMC neurosurgery cases through CY2020.

	CY2016	CY2017	CY2018	CY2019	CY2020	CAGR
Intracranial Tumor Surgery	1,001	1,024	1,048	1,072	1,097	2.3%

- The number of neurosurgery patients by procedure type was estimated, based on CMC's experience, and presented on page 50. The excerpt below shows the total number of projected cases for the two procedure types of neurosurgery cases for which CMC is projecting to use the iMRI technology.

	% of Total Neuro Cases	CY2018	CY2019	CY2020
Intracranial Tumor Surgery	26.90%	282	288	295
Pediatric Neurosurgery	12.00%	126	129	132

- Percent of CMC intracranial tumor surgeries assumed to benefit from iMRI is 41%. Percent of CMC pediatric neurosurgeries assumed to benefit from iMRI is 5%.

	% of Cases that will Benefit from iMRI	CY2018	CY2019	CY2020
Intracranial Tumor Surgery	41.0%	116	118	121
Pediatric Neurosurgery	5.0%	6	6	7
Total iMRI Utilization		122	125	128

The table above shows CMC expects to perform 122, 125, and 128 intraoperative MRI scans in the first, second, and third operating years, respectively.

Inpatient Diagnostic Scans

On pages 52-53, the applicant states:

“The proposed iMRI is designed for intraoperative cases, but can perform traditional inpatients diagnostic scans as well. As discussed in Section III.1(a), CMC’s MRI scanners are highly utilized. Similarly, MRI utilization is growing for high acuity, clinically complex inpatients, some of whom would benefit from the 3 Tesla magnet strength provided by the iMRI. As such, CMC expects that the proposed iMRI will offer additional capacity for its inpatients to receive 3 Tesla strength diagnostic MRI scans with reduced turnaround times.”

On page 54, the applicant provides the number of projected inpatient diagnostic scans on the iMRI, as shown in the table below, based on the assumptions that follow the table.

	CY2018	CY2019	CY2020
Days per Year for Inpatient Diagnostic Cases	128	125	122
Scans per Day	4	4	4
Inpatient Diagnostic Scans	513	501	490

Totals may not sum due to rounding

Assumptions:

- Given that the neurosurgical cases that will utilize the iMRI have lengthy case times, no inpatient diagnostic cases will be performed on days when the iMRI is used intraoperatively.
- Scheduled inpatient diagnostic cases will occur weekdays, Monday through Friday, excluding holidays.
- Only one neurosurgery case requiring iMRI will be performed per day such that the 122 cases in CY2018 will be performed on 122 different days, the 125 cases in CY2019 will be performed on 125 different days, and the 128 cases in CY2020 will be performed on 128 different days, thus the following table shows the number of days available for inpatient diagnostic cases.

	CY2018	CY2019	CY2020
Weekdays per year excluding Holidays	250	250	250
Days per Year for Intraoperative Cases	122	125	128
Days per Year for Inpatient Diagnostic Cases	128	125	122

- The iMRI will perform four inpatient diagnostic scans per day, on days when the scanner is not used intraoperatively, based on the demand for 3 Tesla strength scans and reduced turnaround times by CMC’s growing clinically complex inpatient population.

Summary

Based on the projected number of intraoperative and inpatient diagnostic scans projected above, the table on page 54 and shown below provides the total number of scans projected to be performed annually on the iMRI.

	CY2018	CY2019	CY2020
Intraoperative Scans	122	125	128
Inpatient Diagnostic Scans	513	501	490
Total Scans	634	626	617

Totals may not sum due to rounding

Projected utilization is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to acquire one intraoperative MRI scanner.

Access

In Section VI.2, page 83, the applicant states CMC provides services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment. In Section VI.15, page 91, the applicant projects that 39.3% of iMRI patients to be served will be Medicare beneficiaries and 16.0% will be Medicaid recipients. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will likely have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the project and adequately demonstrates the extent to which all residents, including underserved groups, will likely have access to the proposed services. 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.

CA

In Section III.3, pages 64-65, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintain the Status Quo - the applicant states that this option would not be in the best interest of its patients. The applicant further states that as an academic medical center, CMC serves as a regional referral center for high acuity, specialty services, and as the safety-net provider in the region; thus, has an obligation to its patients. Therefore this alternative was rejected.
- Replace an Existing MRI Scanner with an iMRI – the applicant states that this option is unreasonable as CMC would add iMRI capacity at the expense of traditional MRI capacity. Therefore this alternative was rejected.
- File a CON to Develop an iMRI in Response to a Need Determination in the SMFP– the applicant states this is unreasonable given that the need determination in the 2016 SMFP was in response to the utilization of traditional MRI patients and thus, the development of an iMRI would meet only a small portion of that need. Also, given the specialization and longer case times, iMRI scanners are not likely to be as highly utilized as traditional MRI scanners and thus would be unlikely to meet the MRI performance standards. As a result, this alternative was rejected.
- Develop the Project as Proposed – the applicant states that the most effective alternative was to develop the iMRI pursuant to policy TE-2 in the 2016 SMFP. The applicant further states that the development of the project will enhance CMC's ability to perform high quality scans during surgical procedures and allow for the provision of additional diagnostic inpatient MRI capacity needed at CMC.

After considering the alternatives, the applicant chose the proposed alternative as the most effective alternative to meet the identified need.

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

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to 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 acquire no more than one intraoperative magnetic resonance imaging scanner to be located in an existing operating room at Carolinas Medical Center.**
 - 3. 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 which would otherwise require a certificate of need.**
 - 4. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall not use the intraoperative magnetic resonance imaging scanner for outpatients and shall not replace it with a conventional MRI scanner.**
 - 5. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall report intraoperative procedures and inpatient procedures performed on the intraoperative magnetic resonance imaging scanner separately on the hospital license renewal application.**
 - 6. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall 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 representations in the written statement as described in paragraph one of Policy GEN-4.**
 - 7. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing 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

CMC proposes to acquire an intraoperative MRI scanner to be used in a renovated operating suite at CMC pursuant to Policy TE-2 of the 2016 SMFP.

Capital and Working Capital Costs

In Section VIII.2, pages 100 – 103, the applicant states the total capital cost is projected to be as follows:

ITEM	COST
Construction, including contingency	\$4,381,197
Fixed Equipment	\$6,824,849
Movable Equipment	\$1,276,619
Other (Consultant Fees/Other)	\$664,000
Total Capital Costs	\$13,146,665

In Section IX.1, page 107, the applicant states there will be no start-up expenses and no initial operating expenses associated with the project.

Availability of Funds

In Section VIII.3, page 103, the applicant states the capital cost of the project will be funded with Carolinas HealthCare System (CHS) accumulated reserves. In Exhibit 23, the applicant provides a July 15, 2016 letter from the Chief Financial Officer of CHS, documenting the availability of sufficient funds for the capital cost of the proposed project. Exhibit 24 contains The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System 2015 Financial Statements which indicate, on page 552, that as of December 31, 2015, CHS had \$173,937,000 in cash, cash equivalents and short-term investments; \$1,134,555 in total current assets; and a total net position (total assets less total liabilities) of \$3,889,878. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

In the pro forma financial statements (Forms C, D, and E), the applicant provides financial information for CMC's proposed iMRI service, as summarized below.

CMC iMRI Services

Intraoperative MRI	Project Year 1	Project Year 2	Project Year 3
Projected # of Intraoperative Scans	122	125	128
Projected # of Inpatient Diagnostic Scans	513	501	490
Total Projected # of iMRI Scans	634	626	617
Projected Average Charge(Gross Patient Revenue / Projected # of Scans)	\$ 3,361	\$ 3,461	\$ 3,565
Gross Patient Revenue	\$ 2,131,927	\$ 2,166,408	\$ 2,200,331
Deductions from Gross Patient Revenue	\$ 1,706,256	\$ 1,765,816	\$ 1,820,622
Net Patient Revenue	\$ 425,671	\$ 400,592	\$ 379,709
Total Expenses	\$ 1,603,828	\$ 2,002,520	\$ 2,011,482
Net Income (Loss)	\$ (1,178,157)	\$ (1,601,928)	\$ (1,631,773)

Totals may not sum due to rounding

As the table above shows, operating expenses exceed revenues for the proposed iMRI service in each of the first three years of operation.

However, the proforma financials for the entire facility (Form B) shows that revenues far exceed expenses in each of the first three years project years, with net income of \$311,156,000, \$290,909,000, and \$284,372,000, respectively.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. 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 proposes to acquire an intraoperative MRI scanner to be located at CMC pursuant to Policy TE-2 of the 2016 SMFP.

On page 154, the 2016 SMFP defines the service area for fixed MRI scanners as “a single county, except where there is no licensed acute care hospital located within the county.” Policy

TE-2 does not specifically address service area; thus, the service area for CMC’s proposed fixed iMRI consists of Mecklenburg County. Providers may serve residents of counties not included in their service area.

There are no existing iMRI scanners in Mecklenburg County. The following table identifies the provider, number, and average utilization of each of the fixed MRI scanners in Mecklenburg County, summarized from Table 9P of the 2016 SMFP.

Provider	Fixed MRI Scanners	Total Weighted MRI Scans	Average Procedures
Carolinas Medical Center	5	30,045	6,009
Carolinas Medical Center-Pineville	1	10,601	10,601
Carolinas Medical Center-University	1	6,276	6,276
Novant Health Huntersville Medical Center	1	7,173	7,173
Novant Health Imaging Museum	1	2,699	2,699
Novant Health Matthews Medical Center	2	6,850	3,425
Novant Health Presbyterian Medical Center	3	13,206	4,402
Carolinas Imaging Services-Ballantyne	1	2,946	2,946
Carolinas Imaging Services-Southpark	1	2,878	2,878
Novant Health Imaging Ballantyne	1	1,942	1,942
Novant Health Imaging Southpark	1	3,463	3,463
OrthoCarolina Spine Center	1	9,079	9,079
Total Mecklenburg County Fixed MRIs	19	97,158	5,114

As the table above shows, the seven Carolinas Medical Center fixed MRI scanners are operating above the utilization threshold of 4,805 procedures. The CHS-owned and operated freestanding fixed MRI scanners located at Carolinas Imaging Services, Ballantyne and Southpark, serving outpatients, are not operating at capacity. However, county-wide, the average number of MRI procedures per fixed MRI scanner in Mecklenburg County is above the threshold.

The applicant adequately demonstrates the need CMC has for the proposed iMRI. The applicant demonstrates that its projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved fixed MRI scanner services in Mecklenburg County. 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 93, the applicant states that CMC does not currently operate an iMRI. The applicant also states that it projects to employ a total of 3.0 FTE positions (2.0 FTE OR Clinical Nurses and 1.0 FTE MRI technologist) to staff the proposed iMRI scanner in the second year of the project. The applicant states that no new positions will result from the project. In Section VII, pages 95-96, the applicant describes its experience with and the process for recruiting and retaining staff. In Section V.3, pages 78-79, the applicant identifies John Camp, MD as Chief of the Medical Staff at CMC, Domagoj Coric, MD as Medical Director and Chief of Neurosurgery at CMC, and Jonathan Clemente, MD as Medical Director of Radiology at CMC. Exhibit 28 of the application contains copies of letters from area physicians expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section II.2, pages 30-31, the applicant describes the manner in which it will provide the necessary ancillary and support services. Exhibit 8 contains a letter from CMC's President documenting the availability of the necessary ancillary and support services. Exhibit 28 contains letters of support from physicians expressing support and referral services for the project. The applicant discusses coordination with the existing health care system in Section V, pages 77-80. The applicant adequately demonstrates that the necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;

- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to renovate an existing CMC operating suite to house the iMRI scanner. Exhibit 22 contains a letter from an architect that estimates construction costs that are consistent with the project capital cost projections provided by the applicant in Section VIII.2, page 102 of the application. The applicant provides line drawings in Exhibit 3 showing the area to be renovated. In Section XI.7, pages 117-118, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.12, page 90, the applicant reports the following payor mix for CMC for CY2015:

Patient Days as a Percent of Total Utilization

PAYOR CATEGORY	PERCENT
Medicare/Medicare Managed Care	33.8%
Medicaid	21.6%
Managed Care/Commercial Insurance	34.5%
Self-Pay/Other*	10.0%
Total	100.0%

*Other includes workers' compensation and unspecified payors
 Totals may not sum due to rounding

As the table above shows, in CY2015, 33.8% and 21.6% of CMC's patients were Medicare and Medicaid recipients, respectively. In Section VI.2, page 83, the applicant states:

"CMC provides services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment."

Exhibit 18 contains copies of CMC's patients' rights and non-discrimination policies.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Mecklenburg	10%	52%	49%	15%	6%	19%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table_2014_Estimate_as_of_December_22_2015.

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant's 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, women or handicapped persons utilizing health services.

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, pages 89-90, the applicant states:

“CMC has had no obligations to provide uncompensated care, community service, or access to care by medically underserved, minorities, or handicapped persons during the last three years. However, as stated earlier, CHS facilities, including CMC, provide and will continue to provide services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment. Additionally, in the last full fiscal year (CY 2015), CMC provided more than \$399 million, or 7.4 percent of gross revenue, in charity care and bad debt.”

In Section VI.10, page 89, the applicant states that no civil rights complaints have been filed against any affiliated entity of CHS in the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section VI.14 and VI.15, pages 90-91, the applicant projects CMC facility-wide and CMC iMRI payor mix during the second year of operation following project completion, which is shown in the following table.

**Projected Payors by Percent of Total
CY2019**

PAYOR	CMC FACILITY- WIDE PATIENT DAYS	CMC iMRI PATIENTS
Medicare/Medicare Managed Care	33.8%	39.3%
Medicaid	21.6%	16.0%
Managed Care/Commercial Insurance	34.5%	32.1%
Self-Pay/Other*	10.0%	12.6%
TOTAL	100.0%	100.0%

*Other includes workers' compensation and unspecified payors

As shown above, the applicant projects that over 55% of all CMC patient days and CMC iMRI patients are expected to be recipients of Medicare and/or Medicaid.

The applicant demonstrates that medically underserved populations will continue to have adequate access to services offered at CMC. 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 Section VI.9, page 88, the applicant describes the range of means by which a person will have access to CMC's iMRI services. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, 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, pages 75-76, the applicant states that it already has established relationships with area health professional training programs, including 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 applicant states that CMC also has a contractual agreement with the University of North Carolina at Chapel Hill to manage the Charlotte Area Health Education Center (AHEC), which coordinates various educational programs and produces continuing medical education programming for employees of CHS and other healthcare providers. The information provided in the application is reasonable and supports a finding of conformity to 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

CMC proposes to acquire an intraoperative MRI scanner to be located at CMC pursuant to Policy TE-2 of the 2016 SMFP.

On page 154, the 2016 SMFP defines the service area for fixed MRI scanners as “a single county, except where there is no licensed acute care hospital located within the county.” Policy TE-2 does not specifically address service area; thus, the service area for the proposed fixed iMRI scanner consists of Mecklenburg County. Providers may serve residents of counties not included in their service area.

There are no existing iMRI scanners in Mecklenburg County. The following table identifies the provider, number, and average utilization of each of the fixed MRI scanners in Mecklenburg County, summarized from Table 9P of the 2016 SMFP.

Provider	Fixed MRI Scanners	Total Weighted MRI Scans	Average Procedures
Carolinas Medical Center	5	30,045	6,009
Carolinas Medical Center-Pineville	1	10,601	10,601
Carolinas Medical Center-University	1	6,276	6,276
Novant Health Huntersville Medical Center	1	7,173	7,173
Novant Health Imaging Museum	1	2,699	2,699
Novant Health Matthews Medical Center	2	6,850	3,425
Novant Health Presbyterian Medical Center	3	13,206	4,402
Carolinas Imaging Services-Ballantyne	1	2,946	2,946
Carolinas Imaging Services-Southpark	1	2,878	2,878
Novant Health Imaging Ballantyne	1	1,942	1,942
Novant Health Imaging Southpark	1	3,463	3,463
OrthoCarolina Spine Center	1	9,079	9,079
Total Mecklenburg County Fixed MRIs	19	97,158	5,114

As the table above shows, the seven Carolinas Medical Center fixed MRI scanners are operating above the utilization threshold of 4,805 procedures. The CHS-owned and operated freestanding, fixed MRI scanners located at Carolinas Imaging Services, Ballantyne and Southpark and serving outpatients, are not operating at capacity. However, county-wide, the average number of MRI procedures per fixed MRI scanner in Mecklenburg County is above the threshold.

The applicant does not propose to increase the number of licensed operating rooms in any category, add services, or acquire equipment for which there is a need determination methodology in the 2016 SMFP.

In Section V.7, pages 81-82, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services, stating:

- The development of iMRI services at CMC will reduce repeat surgeries and readmissions, which will reduce unnecessary healthcare expenditures;

- Studies show iMRI allows for improved accuracy of resections, resulting in higher quality and safer care; and
- The proposed iMRI will give residents of the western portion of the state, particularly Mecklenburg County, a more convenient site of care, considering the only other iMRI in North Carolina is located at Duke University Hospital in Durham County.

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

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.

C

Exhibit 3 contains a list of Carolinas HealthCare System owned and/or managed healthcare facilities in North Carolina. In Section I.12, pages 11-13, the applicant lists the fixed and mobile MRIs that it currently owns and operates in North Carolina. In Section II.7, pages 36-37, the applicant states that neither CMC nor any affiliated facility has had its licenses revoked or had its Medicare or Medicaid provider agreements revoked. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, an incident occurred at four of the 20 CHS owned or managed facilities within the eighteen months immediately preceding submission of the application through the date of this decision related to quality of care. As of the date of this decision, three of the facilities were back in compliance and the other one has paperwork pending to be back in compliance after having corrected the issue. After reviewing and considering information provided by the applicants and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at CMC and Carolinas HealthCare System facilities, the applicants provided sufficient

evidence that quality care has been provided in the past. 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

This application is in response to Policy TE-2: Intraoperative Magnetic Resonance Scanners found on page 25 of the 2016 SMFP. The policy states, in part, *“The performance standards in 10A NCAC 14C .2703 would not be applicable.”*

The applicant is a licensed North Carolina acute care hospital which performed at least 500 inpatient neurosurgical cases during the 12 months immediately preceding the submission of the application, has at least two neurosurgeons that perform intracranial surgeries currently on its Active Medical Staff, and is located in a metropolitan statistical area as defined by the US Census Bureau with at least 350,000 residents. Therefore it is a qualified applicant to apply for an iMRI. The Performance Standards found in 10A NCAC 14C .2703 are not applicable to this review.