

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: November 6, 2014

PROJECT ANALYST: Celia C. Inman

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: G-10355-14 / MRI of Asheboro, LLC d/b/a MRI of Asheboro / Develop a diagnostic center which is a change of scope for Project ID #G-8342-09 (acquire a 2nd MRI scanner) / Randolph

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

Randolph Hospital Inc. applied for and received certificate of need (CON) approval to acquire its second MRI scanner with Project I.D. #G-8342-09. The 2009 State Medical Facilities Plan (SMFP) included a need determination for one unit of MRI equipment in Randolph County. Randolph Hospital was the sole applicant and was awarded a CON in September 2009 to develop its second MRI in the existing MRI suite at Randolph Hospital. Randolph Hospital states that changes in the economy, market conditions and MRI utilization impeded the development of the project as proposed.

MRI of Asheboro, LLC, a wholly-owned subsidiary of Randolph Hospital, Inc. submits this current application, Project I.D. #G-10355-14, to request approval for a change in scope from the previously approved application. Randolph Hospital proposes to develop the MRI equipment in a freestanding Independent Diagnostic Testing Facility (IDTF), MRI of Asheboro. MRI of Asheboro will be located in separate, leased space in Asheboro, within a half of a mile from Randolph Hospital. IDTF is a term used by the Centers for Medicare & Medicaid Services (CMS). Under the CON law, what the applicant is proposing is a non-hospital based diagnostic center.

The applicant does not propose adding any new health services or acquiring any equipment for which there is a need determination in the 2014 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2014 SMFP that are applicable to this review. Furthermore, there are no policies in the 2014 SMFP that are applicable to this review. Consequently, this criterion is not applicable to this review.

- (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

Effective September 26, 2009, Randolph Hospital was issued a CON for Project I.D. #G-8342-09 to acquire and develop its second MRI scanner in the existing Randolph Hospital MRI suite.

This CON application is for a change in scope of the original application. In Section II.1, page 10, the applicant states:

“In the prior application, Randolph projected MRI volume based on reasonable and expected growth trends at that time. However, economic pressures coupled with the impact of the Affordable Care Act led to decreased utilization of more expensive services as patients became more price sensitive. These factors impeded the materialization of MRI volumes projected in the previous application. When utilization levels projected in its application were not realized, Randolph Hospital delayed implementation of the CON and communicated progress on the project to the CON Section through progress reports, meetings, and telephone calls.”

Randolph Hospital now believes that the previously approved project, even if developed as originally proposed, cannot be developed within the previously approved capital cost amount. On page 11, the applicant states that MRI technology has advanced since 2009, with *“one notable difference being the use of larger magnets in today’s state-of-the-art scanners.”* The applicant states that Randolph Hospital’s existing MRI suite is not large enough to effectively accommodate today’s state-of-the-art scanner and it does not provide a patient restroom, which is now required for compliance with radiology zone requirements. Thus, the existing MRI suite at Randolph Hospital would now have to be renovated to accommodate the second MRI at a cost that the applicant believes would exceed the previously approved capital cost. Moreover, the applicant states that even after renovations, the two MRI scanners would not be conveniently positioned to share control room space. Therefore, given these factors, Randolph Hospital *“believes that the development of the project as originally proposed would not be ideal for staff efficiency, patient convenience, or cost effectiveness.”*

The applicant further explains that surrounding markets have experienced a shift from hospital-based outpatient MRI services to non-hospital based MRI services, increasing competitive pressure on Randolph Hospital to provide freestanding, outpatient MRI services in Randolph County. The applicant states on page 11:

“Since there are currently no freestanding MRI facilities in Randolph County, patients seeking such services must travel to Guilford County, Forsyth County, or further for care.

Moreover, Randolph Hospital, like other healthcare providers, is always considering opportunities to provide better value to its patients. As part of this ongoing process, Randolph Hospital has evaluated its ability to deliver lower cost, high quality services to its patients in convenient locations. The development of the freestanding, outpatient MRI unit as proposed in this change in scope application offers an opportunity to do just that. After additional market and business planning, Randolph Hospital believes a revised plan to develop the MRI equipment at a new freestanding site is the best alternative.”

In Section II.3, pages 16-17, the applicant discusses the three main differences between the scope of the previously approved application, Project I.D. #G-8342-09, and the scope of this proposed project: location of the MRI equipment, type of MRI equipment, and licensure / organizational structure.

The previously approved application proposed locating the MRI on the campus of Randolph Hospital as a new addition to the MRI suite. Randolph Hospital now proposes to develop its MRI project at an existing medical office building located less than one half of a mile from Randolph Hospital, with the MRI being housed within a PDC Cassette with Caring MR Suite, a pre-engineered hospital-grade building designed specifically as an MRI suite.

The previously approved project proposed to acquire a Siemens 1.5 Tesla Magnetom Espree scanner. Because of innovative technological advances since 2009, the current project proposes to acquire a GE Optima 1.5 Tesla with GEM Suite scanner system, a system which the applicant states *“provides high quality magnetic resonance imaging with additional patient friendly features.”*

The previously approved MRI scanner was to be licensed under the Randolph Hospital license. Randolph Hospital now proposes to develop its MRI project as a freestanding diagnostic center, under the ownership and control of MRI of Asheboro, LLC, a newly formed LLC which is wholly owned by Randolph Hospital, Inc. At the time of the submission of the application, the legal formation of the LLC was not complete. During the expedited review of this project, Randolph Hospital received confirmation of MRI of Asheboro, LLC’s legal formation.

In addition to the aforementioned changes, the proposed project will result in a change in total capital costs from the previously approved application: \$26,391, an increase of only one percent ($\$26,391 / \$2,505,618$). On page 17, the applicant states:

“However, as noted above, Randolph Hospital now believes that its project could not be developed, even as originally proposed, within the previously approved capital cost amount. Thus the proposed project actually represents a more cost effective alternative for developing the MRI unit.”

The project, as proposed in this change of scope application, will result in one additional operational MRI scanner in the service area, consistent with the previously approved application.

In several references throughout the application, the applicant states, *“the appropriateness of listing Randolph Hospital as the applicant in lieu of establishing the LLC entity prior to submission of the application was confirmed”* by the Project Analyst. This is a misinterpretation of a communication between the Project Analyst and a Randolph Hospital representative. In late August, prior to the submission of the application, the representative explained the hospital’s inability to complete the formation of the LLC in the short time period prior to the September submission of the application. The Project Analyst suggested that the application could be filed prior to the completion of the paperwork associated with the formation of the LLC with an explanation in the CON application that Randolph Hospital was in the process of forming the LLC to own and operate the MRI facility. During the expedited review of this application, Randolph Hospital confirmed its intention for MRI of Asheboro, LLC to be the applicant and the entity to which this certificate will be issued, if approved. Randolph Hospital’s wholly owned subsidiary, MRI of Asheboro, LLC, will be the owner and operator of the free-standing diagnostic center, MRI of Asheboro, and therefore is the applicant.

Population to be Served

In Section II.4, page 18 of the application, the applicant states:

“Upon becoming operational, the proposed facility will provide all projected Randolph Hospital outpatient MRI procedures, a 100 percent shift from Randolph Hospital to MRI of Asheboro.”

On page 28, the applicant states the projected population to be served is based on historical Randolph Hospital MRI data from FY 2011 through FY 2013. The applicant states that 89.7% of the projected MRI of Asheboro patients will originate from Randolph County, with 10.3% originating from outside of Randolph County.

The applicant adequately identifies the population proposed to be served by the second MRI scanner developed as MRI of Asheboro.

Need Analysis

Randolph Hospital demonstrated the need for the acquisition of its second MRI scanner in the previously approved CON, Project ID# G-8342-09. In Section II, pages 21-22, the applicant demonstrates that the theoretical and statistical need for that second MRI scanner still exists at Randolph Hospital. On page 23, the applicant states:

“...Randolph County has a need for one additional MRI scanner as the historical adjusted procedures each year are well above the 55 percent capacity threshold of 3,775 procedures for a service area with one scanner. Thus, Randolph County has a need for two MRI scanners.”

However, Randolph Hospital states that after careful evaluation, it realized it could no longer cost effectively develop the MRI project in the hospital MRI suite as originally proposed. In addition, the approved 2009 proposed equipment is no longer the optimum choice of equipment for Randolph Hospital’s MRI service. Moreover, the applicant states that patients are opting for the more cost-effective alternative of using freestanding MRI centers when seeking outpatient MRI services.

In Section II.4, pages 18-29, the applicant discusses the need for the change in scope of the previously approved project; specifically, the need for freestanding MRI services in Randolph County. Upon becoming operational, MRI of Asheboro will provide all projected Randolph Hospital outpatient MRI procedures. The proposed project does not include the acquisition of an MRI scanner. Randolph Hospital was previously approved to acquire and develop a second MRI scanner; the proposed project merely seeks approval to develop the MRI scanner in a non-hospital based setting by a wholly-owned LLC. The applicant provides the following to illustrate the need for freestanding MRI services in Randolph County:

- Randolph County does not have any freestanding MRI facilities.
- Randolph County residents seeking an MRI at a freestanding facility must travel to Guilford County, Forsyth County, or further for care.
- The development of the MRI as part of a freestanding facility will result in lower out-of-pocket expenses for patients:
 - Insurance companies tier out-of-pocket requirements depending on the type of facility where patients receive care.
 - Insurance companies categorize hospital-based services in a higher out-of-pocket tier, regardless of whether the service is classified as inpatient or outpatient care; thus patient’s out-of-pocket expenses are greater.
 - Freestanding facilities are categorized in a lower tier, thus reduced out-of-pocket expenses are passed along to the patient.
- The freestanding MRI facility will offer patients a new convenient location for MRI services, expanding access both geographically and financially.
- The development of a freestanding MRI facility has the potential to foster competitive pricing practices.

On page 21, the applicant states:

“The proposed project described in this application maintains the intent of the original awarded project: to meet the need for MRI services for residents of Randolph County through the delivery of convenient, high-quality care. In fact, Randolph Hospital believes the project as proposed in this application is an improvement to its previously approved application as the current proposal allows for the delivery of care in a lower cost, more convenient setting with more advanced MRI equipment.”

The applicant adequately demonstrates the need to develop the previously approved MRI scanner as a non-hospital based service, rather than as a hospital-based service.

Projected Utilization

In Section II.4, on pages 24-29 of the application, the applicant discusses the projected utilization for MRI of Asheboro. The Project Analyst presents the applicant’s discussion below, outlined in steps.

Step 1 – Historical Randolph County Residents MRI Patients

On page 24, the applicant states:

“In order to project utilization of MRI of Asheboro, Randolph Hospital analyzed historical Randolph County market trends, the mix of outpatient and inpatient Randolph County patients, and the ratio of MRI procedures to patients.”

The applicant states the use of hospital license renewal applications (HLRA) and the Division of Health Service Regulation (DHSR) Planning Branch’s inventory of MRI equipment patient origin tables submitted for 2011 through 2013 utilization to determine Randolph County residents’ use of MRI services. Exhibit 8 contains detail calculations. The applicant states the following assumptions for distributing total MRI patients by inpatient and outpatient MRI services:

- all MRI procedures occurring in a freestanding facility are outpatient procedures, and
- any hospital serving Randolph County patients will have a distribution of inpatient and outpatient procedure equal to Randolph Hospital.

Thus, on page 25, based on the assumptions above, the applicant provides tables demonstrating the estimated number of Randolph County residents receiving inpatient and outpatient MRI services in the last three years, including the compound annual growth rates (CAGR) from 2011 through 2013. The following table summarizes the data provided by the applicant.

Randolph County Historical MRI Patients by Setting

FY	Outpatient Freestanding	Outpatient Hospital-based	Total Outpatient Patients	Inpatient	Total Patients
2011	2,376	4,510	6,886	1,068	7,954
2012	2,658	4,219	6,877	1,070	7,947
2013	2,598	4,572	7,170	1,098	8,268
CAGR	4.6%	0.7%	2.0%	1.4%	2.0%

Sources: 2012-2014 HLRA MRI Patient Origin Tables, 2012-2014 Inventory of Medical Equipment MRI Patient Origin Tables

Step 2 – Projected Randolph County Outpatient MRI Patients

The applicant uses FY 2013 as a base year and assumes Randolph County outpatient MRI utilization continues to grow at the historical rate of 2.0% to project outpatient Randolph County MRI Patients through FY 2018, as follows:

Randolph County Projected Outpatient MRI Patients

Fiscal Year	Outpatient Patients
2013	7,170
2014	7,317
2015	7,466
2016	7,618
2017	7,774
2018	7,932
CAGR	2.0%

Step 3 –Randolph Hospital’s Projected Market Share of Randolph County Outpatient MRI Patients

On page 26, the applicant states:

“Historically, Randolph Hospital has held 42.3 percent market share of the county’s outpatient MRI market as summarized in the table below. Randolph Hospital believes its outpatient market share has decreased as a result of increased competition from IDTFs in surrounding counties.”

Randolph Hospital provides the following table showing historical hospital market share of Randolph County outpatient MRI patients.

**Randolph County Projected
 Outpatient MRI Patients**

FY	Outpatient Patients
2011	43.1%
2012	43.2%
2013	40.7%
Average	42.3%

The applicant states the source for the above data is Randolph Hospital internal data, the 2012-2014 HLRA MRI Patient Origin Tables, the 2012-2014 Inventory of Medical Equipment MRI Patient Origin Tables, and Randolph Hospital estimates.

Assuming that Randolph Hospital continues to hold its average historical outpatient market share, the following number of Randolph County outpatient MRI patients are projected to be served by Randolph Hospital.

**Randolph Hospital Projected
 Randolph County Outpatient
 MRI Patients**

FY	Outpatient Patients
2014	3,097
2015	3,160
2016	3,225
2017	3,290
2018	3,358

Totals may not foot due to rounding.

Step 4 – Project Randolph Hospital’s Randolph County MRI Outpatient Procedures

On page 27, the applicant states:

“In order to determine the number of procedures associated with the projected Randolph County outpatient MRI patients, Randolph Hospital analyzed its historical ratio of procedures to patients. The following table demonstrates the calculation of this ratio.

Randolph Hospital Historical Ratio of Procedures to Patients

<i>FY</i>	<i>Total MRI Procedures</i>	<i>Total MRI Patients</i>	<i>Ratio of MRI Procedures to Patients</i>
<i>2011</i>	<i>4,132</i>	<i>3,760</i>	<i>1.10</i>
<i>2012</i>	<i>4,172</i>	<i>3,294</i>	<i>1.27</i>
<i>2013</i>	<i>3,994</i>	<i>3,624</i>	<i>1.10</i>

Source: 2012-2014 HLRAs.”

The applicant states it determined that the 2013 ratio of 1.10 MRI procedures per patient was the most accurate and conservative assumption with which to calculate projected MRI procedures. The following table demonstrates projected outpatient procedures based on 1.10 MRI procedures per patient.

**Randolph Hospital Projected
 Randolph County MRI Outpatient Procedures**

FY	Outpatient Patients	Ratio of Procedures to Patients	Outpatient Procedures
2014	3,097	1.10	3,413
2015	3,160	1.10	3,483
2016	3,225	1.10	3,554
2017	3,291	1.10	3,626
2018	3,358	1.10	3,700

Totals may not foot due to rounding.

Step 5 – Project Randolph Hospital’s Total MRI Outpatient Procedures

Randolph Hospital states that it analyzed the historical percentage of outpatient MRI patients by county of origin receiving care at its facility to determine a reasonable in-migration percentage for its outpatient MRI service. The applicant provides the following table to demonstrate the percent of patients from Randolph County and the percent of patients from outside Randolph County over the last three years, based on internal data.

**Randolph Hospital Historical In-migration
 for Outpatient MRI Services**

FY	% of Patients from Randolph County	% of Patients from Outside Randolph County	Total
2011	88.8%	11.2%	100.0%
2012	88.5%	11.5%	100.0%
2013	89.7%	10.3%	100.0%

Randolph Hospital states that it determined the most recent data with an in-migration rate of 10.3% of total patients was a reasonable and conservative rate and has assumed that 10.3 % of total outpatient procedures at Randolph Hospital will be provided to patients who reside outside of Randolph County. Therefore, the outpatient procedures performed on Randolph County residents represents 89.7% of the total outpatient procedures to be performed by Randolph Hospital. On page 28, the applicant states, “*Thus the following table shows Randolph Hospital’s total number of projected outpatient MRI procedures through the third project year.*”

Randolph Hospital Total Projected Outpatient Procedures

FY	Outpatient Procedures for Randolph Co. Patients	Outpatient Procedures for Other Co. Patients	Total Outpatient Procedures
2014	3,413	392	3,805
2015	3,483	400	3,883
2016	3,554	408	3,962
2017	3,626	416	4,043
2018	3,700	425	4,125

Totals may not foot due to rounding.

Step 6 – Project MRI of Asheboro’s Projected MRI Procedures

MRI of Asheboro’s first full fiscal year is projected to be FY 2016. Upon becoming operational, MRI of Asheboro will provide all projected Randolph Hospital outpatient MRI procedures, shifting 100% of Randolph Hospital’s outpatient MRI procedures to MRI of Asheboro. The following table shows the outpatient procedures projected to be performed at MRI of Asheboro during the first three project years.

MRI of Asheboro Projected MRI Procedures

FY	Randolph Hospital Outpatient Procedures	Shift to MRI of Asheboro	MRI of Asheboro Outpatient Procedures
2014	3,805		
2015	3,883		
2016	3,962	100%	3,962
2017	4,043	100%	4,043
2018	4,125	100%	4,125

On page 29, the applicant states:

“The proposed development of one previously awarded unit of MRI equipment at MRI of Asheboro will provide a convenient, lower cost alternative to residents of Randolph County and surrounding areas. As demonstrated above, the facility is projected to be well utilized through the third project year.”

The applicant adequately demonstrates projected utilization of the proposed MRI scanner is based upon reasonable, credible and supported assumptions.

Access

In Section IV.2, page 41, the applicant states that the proposed facility will follow the established policies of Randolph Hospital regarding access to services, stating:

“Randolph Hospital does not discriminate against low-income persons, racial or ethnic minorities, women handicapped persons, the elderly, or other underserved persons, including the medically indigent.”

In Section IV.4, page 42, the applicant states, “*Yes, all medically appropriate referrals are accepted, regardless of their financial circumstances.*”

In Section V.6, pages 47-48, the applicant says the proposed project will promote access to healthcare services in the service area, stating:

“The freestanding facility will offer patients a new convenient location for MRI services which will not only expand access geographically but also financially, as discussed above. Many patients may find a lower-cost alternative to be more suitable for their needs and financial circumstances.

...

Further, MRI of Asheboro is located less than half a mile (0.3 miles) from a public transportation bus station. Thus, the proposed facility will be accessible for residents of Randolph County that may not have access to a personal vehicle.”

In Section IV.6, page 43, the applicant provides the expected payor mix for the outpatient MRI service, with 41.5% and 14.2% of total utilization being Medicare/Medicare Managed Care and Medicaid, respectively.

The applicant adequately demonstrates 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 proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need the population to be served has for the proposed change of scope for the approved MRI scanner, and demonstrates that all residents of the area will have adequate 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.

C

The applicant proposes to develop the previously approved MRI scanner as a non-hospital based service, located in separate, leased space in Asheboro, within a half of a mile from Randolph Hospital. Thus, there will be no additional burden on patients who are accustomed to receiving MRI services at Randolph Hospital. In fact, the relocated MRI

service will enable the applicant to provide outpatient MRI services to patients at a more convenient location and at a lower cost.

The applicant states in Section II, page 18 of the application, that MRI of Asheboro will provide all projected Randolph Hospital outpatient MRI procedures, representing a 100% shift from Randolph Hospital's main campus, thereby providing these patients easier and more cost-effective access to services. In addition, on page 19, the applicant states that some patients currently leave Randolph County for MRI services in outpatient facilities. Some of these patients will likely shift to MRI of Asheboro, since those services will now be offered on a lower-cost freestanding basis.

Furthermore, in Section II, page 23, the applicant states that existing MRI equipment at Randolph Hospital is inadequate to meet the growing outpatient MRI demand; shifting the outpatient MRI services to MRI of Asheboro will therefore prevent the overutilization of the one remaining scanner at the hospital. The applicant adequately demonstrates that Randolph County patients who continue to use Randolph Hospital inpatient MRI services will not be adversely affected by the relocation of the approved MRI scanner to MRI of Asheboro. Consequently, the application is conforming to this criterion.

- (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 II.5, pages 30-31, the applicant describes several alternatives it considered prior to submitting this change of scope application, which include:

- 1) Maintain the Status Quo – continue to develop the project as it was approved in Project I.D. #G-8342-09. The applicant states that it believes that the previously approved project can no longer be developed as originally proposed within the approved capital cost amount. Also, states the applicant, because there is a need for freestanding MRI services in Randolph County, this alternative does not propose the most efficient use of hospital resources, and does not propose cost-effective MRI services for Randolph County patients. Thus, maintaining the status quo was not considered a viable alternative.
- 2) Develop the Project as a Joint Venture – the applicant states that Randolph Hospital rejected this alternative after determining that a joint venture would not provide any benefits related to quality, access, or value of the service.
- 3) Pursue the Proposed Change in Scope Project – given the technological advances in MRI equipment since the approval of the original application, particularly regarding aspects such as imaging quality and patient comfort, the applicant states, *“the change in scope will allow for more efficient patient-centered care. Additionally, the proposed project is a more cost effective alternative for developing the MRI unit.”*

The applicant states that in addition to better value to patients and payors, the freestanding MRI facility will offer patients a new convenient location for MRI services, thereby expanding access both geographically and financially.

The applicant adequately demonstrates that the proposal to develop the approved MRI service as a non-hospital based diagnostic center is the most effective alternative for the development of the approved MRI scanner. Furthermore, 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.

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

- 1. MRI of Asheboro, LLC d/b/a MRI of Asheboro shall materially comply with the representations made in this certificate of need application, Project ID# G-10355-14, the certificate of need application Project ID# G-8342-09 as amended by this project and supplemental information provided during the expedited review of this application. In those instances in which representations conflict, MRI of Asheboro, LLC d/b/a MRI of Asheboro shall materially comply with the last made representation.**
 - 2. MRI of Asheboro, LLC d/b/a MRI of Asheboro shall acquire no more than one fixed MRI scanner.**
 - 3. MRI of Asheboro, LLC d/b/a MRI of Asheboro 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 or that would otherwise require a certificate of need.**
 - 4. MRI of Asheboro, LLC d/b/a MRI of Asheboro shall obtain accreditation from the American College of Radiology or a comparable accreditation authority, as determined by the Certificate of Need Section, for magnetic resonance imaging within two years following operation of the proposed MRI scanner.**
 - 5. MRI of Asheboro, LLC d/b/a MRI of Asheboro 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 Project I.D. #G-8342-09, the applicants were previously approved for a capital cost of \$2,505,618. In this application, the applicants project a capital cost of \$2,532,009, which represents a one percent increase of \$26,391. In Section VI.4, pages 52-53, the applicant provides a table to illustrate the difference in capital costs between the two applications, as summarized below.

Comparison of Capital Expense

	Previously Approved	Proposed Change of Scope
Site Costs	\$ 0	\$ 206,800
Construction Contract	\$ 827,830	\$ 0
MRI Scanner	\$ 1,475,988	\$ 1,674,379
Moveable Equip/furniture	\$ 8,000	\$ 0
PDC Cassette	\$ 0	\$ 507,280
Caring Suite	\$ 0	\$ 79,000
Consultant Fees	\$ 150,600	\$ 63,800
Financing	\$ 0	\$ 750
Other	\$ 43,200	\$ 0
Total Cap Costs	\$ 2,505,618	\$ 2,532,009
Amount Above Previously Approved Capital Cost		\$ 26,391

In Section VII.1, page 56, the applicant states the start-up expenses for this change of scope application are \$182,294. There were no start-up expenses associated with the original application; therefore, the costs of this change of scope application are projected to be \$208,685 higher than was originally approved. In Exhibit 13, the applicant provides a September 15, 2014 letter signed by the Chief Financial Officer of Randolph Hospital, which confirms the total capital costs and the start-up costs reported in Sections VI and VII of the application. Additionally, the letter documents availability of funding for the total capital cost of \$2,532,009, with a capital lease in the amount of \$1,674,379 and accumulated reserves estimated at \$857,630. Start-up costs will also be funded from accumulated reserves. A copy of the proposed capital lease by GE Capital is provided in Exhibit 14.

Exhibit 16 contains the financial statements for Randolph Hospital for the years ending September 30, 2013 and 2012. As of September 30, 2013, Randolph Hospital had cash and cash equivalents of \$6,258,257, total current assets of \$39,072,243 and total net assets of \$65,860,769 (total assets – total liabilities).

The applicant provides pro forma financial statements for the first three years of the project, beginning October 1, 2015. The applicant projects revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below.

MRI of Asheboro MRI Services	Project Year 1	Project Year 2	Project Year 3
Projected # of Procedures	3,962	4,043	4,125
Projected Average Charge (Gross Patient Revenue / Projected # of MRIs)	\$ 2,077	\$ 2,139	\$ 2,204
Gross Patient Revenue	\$ 8,228,762	\$ 8,648,552	\$ 9,089,757
Deductions from Gross Patient Revenue	\$ 6,872,620	\$ 7,223,226	\$ 7,591,718
Net Patient Revenue	\$ 1,356,142	\$ 1,425,325	\$ 1,498,038
Total Expenses	\$ 1,177,060	\$ 1,145,630	\$ 1,176,168
Net Income	\$ 179,082	\$ 279,695	\$ 321,870

The above revenue and expenses are representative of the entire facility, as MRI of Asheboro provides only MRI services. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See pages 77-79 for the assumptions regarding costs and charges. See discussion regarding projected utilization in Criterion (3), which 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, and therefore, the application is conforming to this criterion.

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

C

The original application, Project I.D. #G-8342-09, was conforming to this criterion. In this application, the applicant proposes to develop the approved MRI as a non-hospital based diagnostic center. The proposed location is within the same county and less than one half a mile from the hospital, the originally approved location for the scanner. The applicant is not proposing to increase the number of MRI scanners in the service area. Thus, the inventory of MRI scanners in Randolph County will not change. The applicant states that the population presently served will continue to be served following the development of the freestanding diagnostic center; with greater geographical and financial access. 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 V.2, page 44, the applicant provides a table, reproduced below, to illustrate projected staffing for the MRI service at MRI of Asheboro.

EMPLOYEE CATEGORY	PROJECTED FTES
Receptionist	2.30
Technologist	2.25
Supervisor	0.50
Technologist Aide	2.00
Total	7.05

In Section V.1, page 44, the applicant states:

“Some of the proposed staff will be shifted from Randolph Hospital’s existing MRI service. In total, Randolph Hospital and MRI of Asheboro will add 2.67 FTEs from current staffing levels.”

In addition, the applicant discusses its existing relationships with area training schools and its past hiring experience, stating:

“Randolph County is a highly desirable setting to live and work and Randolph Hospital does not anticipate any significant challenges in recruiting and retaining employees.”

Furthermore, the applicant states on page 46 that Randolph Hospital has had significant experience in recruiting physicians to the area and that it expects that to continue. Exhibit 18 contains support letters from local physicians. Exhibit 12 contains a letter from Dr. Thomas Lawrence, Randolph Hospital’s Medical Director of Radiology stating his support and intent to serve as MRI of Asheboro’s Medical Director. The applicant adequately documents the availability of sufficient health manpower and management personnel to provide the proposed MRI services at MRI of Asheboro. Therefore, the application is conforming to this criterion.

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

C

The original application, Project I.D. #G-8342-09, was conforming to this criterion. Form B-1 on page 74 includes “Other Direct Expenses” and “Housekeeping /Laundry” expense. The assumptions on page 77, identify “Other Direct Expenses” to include costs associated with scheduling, registration, pre certification, pre call to patients, MRI check in, coding, billing, and other costs necessary for operation. On page 15 of the application, the applicant states that support space is provided in the proposed location, including reception area, a business office, staff break room, staff and patient restroom, a nurses station, lab space, computer/telephone room, multiple physician offices and multiple exam rooms. The applicant adequately demonstrates the provision of the necessary ancillary and support services. Exhibit 18 contains letters from approximately 40 area physicians and other

healthcare providers expressing support for the proposed project and demonstrating that the proposed service will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers: (i) would be available under a contract of at least 5 years duration; (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO; (iii) would cost no more than if the services were provided by the HMO; and (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

C

The original application, Project I.D. #G-8342-09, was conforming to this criterion, wherein the applicants proposed to renovate 276 square feet and construct an additional 2,040 new square feet, thereby expanding the hospital campus MRI suite. In the current application, the applicant proposes to develop the freestanding service at an existing medical office building (MOB) within a PDC Cassette with Caring MR Suite, a pre-engineered hospital-grade building which the applicant says can be developed quickly and at a lower cost, averaging between 25 to 30 percent below the costs associated with developing similar MRI space within a hospital.

Exhibit 3 provides a copy of the PDC Cassette quote and the Caring MR Suite quote, along with descriptions and documentation of construction type. Exhibit 4 provides the line drawings for the MOB space and the PDC Cassette.

In Section IX.5, on page 68, the applicant states:

“Automation systems with remote tie-in to the building will be implemented with the goal to conserve energy based on time of day setbacks to ensure that office utilities are not in use during evening and other unoccupied hours. The thermostat will be set at a temperature that is comfortable to patients yet mindful of energy consumption. MRI of Asheboro will also feature modern T8 LED lighting systems.”

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative for the project they propose, and that the construction costs will not unduly increase costs and charges for health services. See the discussion of costs and charges in Criterion (5), which is incorporated herein by reference. 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

The original application, Project I.D. #G-8342-09, was conforming to this criterion and the applicant proposes no changes in this current application to affect that determination. 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

The original application, Project I.D. #G-8342-09, was conforming to this criterion and the applicant proposes no changes in this current application to affect that determination. 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

The following table illustrates the projected payor mix for MRI services at MRI of Asheboro during the second operating year, as reported by the applicant in Section IV, page 43 and in the financial section of the application, on page 75. The applicant states that the projection is based on Randolph Hospital's FY 2013 outpatient MRI service.

SECOND FULL PROJECT FISCAL YEAR PROJECTED PROCEDURES AS % OF TOTAL UTILIZATION	
Self Pay / Indigent / Charity	3.9%
Medicare / Medicare Managed Care	41.4%
Medicaid	14.2%
Managed Care / Commercial	37.5%
Other (includes other government and worker's comp)	2.9%
Total	100.0%

Totals may not sum due to rounding.

In Section IV.2, page 41, the applicant states:

“The proposed facility will follow the established policies of Randolph Hospital regarding the accessibility of services. Randolph Hospital does not discriminate against low-income persons, racial or ethnic minorities, women, handicapped persons, the elderly, or other underserved persons, including the medically indigent.”

The applicant demonstrates it will provide adequate access to the medically underserved population. 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

The original application, Project I.D. #G-8342-09, was conforming to this criterion and as in the original application, a referral from a licensed physician is required for access to the proposed MRI services. On page 42, the applicant states, “*Yes, all medically appropriate referrals are accepted, regardless of their financial circumstances.*” 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

The original application, Project I.D. #G-8342-09, was conforming to this criterion and the applicants propose no changes in this current application to affect that determination. In Section V.3, page 45 of this change of scope application, the applicant states that all area schools have access to and are encouraged to participate in Randolph Hospital’s professional training programs. The applicant further states:

“The expansion of MRI services will enhance existing relationships. Randolph Hospital currently maintains a close working relationship and provides a clinical site for students of Wake Technical Community College, Sandhills Community College, and Randolph Community College.”

The applicant adequately demonstrates that the proposed MRI service will accommodate the clinical needs of health professional training programs in the area. Therefore, the application is conforming 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

Effective September 26, 2009, Randolph Hospital was issued a certificate of need to acquire a second fixed MRI scanner to locate in its hospital campus MRI suite.

In this application, the applicant proposes to develop the previously approved MRI in a freestanding diagnostic center to offer Randolph County patients better geographical and financial access to MRI services.

In Section II.4, page 19, the applicant discusses the benefits of offering the MRI service as a freestanding facility, such as lower out-of-pocket expenses for patients. The applicant provides study data on pages 20-21 that shows:

“As patients began opting for the most cost-effective alternative (freestanding facilities), hospital-based outpatient facilities also lowered prices to remain competitive in the markets, which resulted in lower MRI-related healthcare costs overall.”

In addition, in Section V.6, page 47, the applicant states:

“In addition to better value to patients and payors, the freestanding MRI facility will offer patients a new convenient location for this service thereby expanding access both geographically and financially.”

The applicant states that it also believes that the proposed project will promote the provision of quality healthcare services to patients in the service area, stating:

“The IDTF entity, as a subsidiary of Randolph Hospital, will adhere to the hospital’s existing performance improvement and patient safety plan, shown in Exhibit 10, and utilization review plan, shown in Exhibit 11.”

See also Sections II, III, V, VI and VII of the original application, Project I.D. #G-8342-09. The original application was conforming to this criterion and the applicants propose no changes in this current application that would reverse that determination. In fact, this application has a more positive impact upon the cost effectiveness, quality, and access to the services proposed.

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

- The applicant adequately demonstrates the need to develop the MRI scanner previously approved in Project ID #G-8342-09 as a non-hospital based service, and that it is a cost-effective alternative;

- Randolph Hospital, parent company of MRI of Asheboro, LLC, has and will continue to provide quality services and MRI of Asheboro will provide quality service; and
- Randolph Hospital, parent company of MRI of Asheboro, LLC, has and will continue to provide adequate access to medical underserved populations and MRI of Asheboro will provide adequate access to medically underserved populations.

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

MRI of Asheboro will be a new facility, owned and operated by MRI of Asheboro, LLC, a newly established LLC. Randolph Hospital is the sole owner and parent company of MRI of Asheboro, LLC. Randolph Hospital is accredited by the Joint Commission and certified by CMS for Medicare and Medicaid participation. According to the records in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents have occurred at Randolph Hospital within the eighteen months immediately preceding the date of this decision for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

There are no Criteria and Standards applicable to the review of this application for a Change of Scope for Project ID# G-8342-09 (acquire a 2nd MRI scanner). The Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700 were applicable in the conditional approval of Project ID# G-8342-09 (acquire a 2nd MRI scanner). The Criteria and Standards for Diagnostic Centers, promulgated in 10A NCAC 14C .1800 are not applicable to this review as they *“shall apply to applications for diagnostic centers for which specific criteria and standards have not otherwise been promulgated in 10A NCAC 14C”* (emphasis added).