

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: October 10, 2014

PROJECT ANALYST: Celia C. Inman

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10314-14/ University of North Carolina Hospitals at Chapel Hill/  
Acquire ninth MRI/ Orange County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

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The University of North Carolina Hospitals at Chapel Hill (UNC Hospitals) proposes to acquire one additional fixed magnetic resonance imaging (MRI) scanner for a total of nine MRI scanners upon project completion. The project does not require new construction; however there will be minimal renovation for the installation of the ninth MRI scanner at the UNC campus hospital. The 2014 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional fixed magnetic resonance imaging (MRI) scanners by service area. Page 171 of the SMFP identifies a need for one fixed MRI scanner in Orange County. UNC Hospitals proposes to acquire one fixed MRI scanner to be located on the UNC Hospitals campus in Orange County. Therefore, the application is consistent with the need determination.

In addition, there are two policies in the 2014 SMFP that are applicable to this review, Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

The applicant responds to Policy GEN-3 as follows:

#### Promote Safety and Quality

In Section III.2, page 62, the applicant states that patient safety and quality of care are priority objectives. The applicant further states:

*“The project will be planned and developed to incorporate patient safety features, advanced imaging capabilities and enhanced staff training. Adding the MRI scanner will enable UNC Hospitals to accept patient referrals, accommodate clinical and teaching objectives and provide timely and efficient care.”*

Exhibits 7, 8, 9 and 10 contain UNC Health Care policies on quality improvement, performance improvement studies, safety policies and risk management policies, respectively.

The applicant adequately demonstrates that the proposal will promote safety and quality care.

#### Promote Equitable Access

In Section III.2, page 62, the applicant discusses how the proposed project will promote equitable access. The applicant states:

*“Access to MRI services will continue to follow the existing policies that UNC Hospitals has in place. As North Carolina’s only state-owned referral, tertiary and quaternary care center, UNC Hospitals has the obligation to accept any North Carolina citizen requiring treatment. No North Carolina citizen is denied access to non-elective care due to race, sex, creed, age, handicap, financial status or lack of medical insurance. The facility is designed in accordance with the latest State of North Carolina and federal guidelines for handicapped accessibility. The project will incorporate all applicable provisions of the Americans with Disabilities Act.”*

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In Section VI.2, page 86, the applicant states that UNC Hospitals traditionally provides services to a wide variety of patient groups and provides the following supporting FY 2014 data.

	<b>Low Income</b>	<b>Racial &amp; Ethnic Minorities</b>	<b>Women</b>	<b>Elderly</b>	<b>Other Underserved</b>
Total Hospital	17.0%	36.3%	58.6%	23.8%	10.9%
MRI	16.6%	34.2%	54.0%	20.4%	10.1%

Low Income = Medicaid and ½ of Medicaid Pending; Other Underserved = Self Pay and ½ of Medicaid Pending

In Section VI.8, page 89, the applicant discusses charity care and bad debt, stating that UNC Hospitals’ MRI service will provide more than \$200,000,000 in charity care in project years one and two; and approximately \$100,000,000 in bad debt each year. The applicant further states:

*“Charity care is defined in accordance with UNC Hospitals’ Credit and Collection Policy based upon the guarantor’s ability to pay. The guarantor’s ability to pay is determined after a financial statement is obtained, with the required verification documentation, and a credit rating is assigned. Provision for bad debts represents services for which individuals have refused to make payment even though they have the financial ability to pay or have not completed documentation of financial need. These are incurred on uninsured (self pay) patients and on portions of the copayments and deductibles that are the patient’s liability under commercial indemnity insurance policies. Please see Exhibit 21 for the Credit and Collection Policy”*

The applicant adequately demonstrates that the proposal will promote adequate access.

Maximize Healthcare Value

In Section III.2, page 62-63, the applicant states that the proposed project will maximize healthcare value because:

- The project will utilize existing facility space in the hospital.
- Ancillary and support services are currently in place to support additional MRI capacity.
- UNC Hospitals works diligently to contain operating costs through quality improvement, management of staffing expenses, purchasing contracts for supplies and medications, and enhancing facility maintenance and energy cost savings.
- The applicant makes special efforts to contain costs, including appropriate staffing levels, installation of MRI equipment consistent with UNC Hospital’s Energy Efficiency and Sustainability Plan, staffing efficiency and improved scheduling, and group purchasing, cost effective distribution and delivery systems.

The applicant adequately demonstrates that the proposal will maximize healthcare value. Therefore the application is conforming to Policy GEN-3.

Policy GEN-4 states:

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

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

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”*

In Section III.2, pages 63-64, the applicant addresses Policy GEN-4, stating:

*“UNC Hospitals will develop and implement an Energy Efficiency and Sustainability Plan for the MRI project that conforms to or exceeds the energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The Plan shall not adversely affect patient or resident health, safety or infection control.*

*UNC Hospitals proposes to acquire and install one unit of additional MRI equipment. No facility construction of additional building space is involved.*

*The facility and equipment installation plans and specifications for the project shall be researched and developed by the project architect, with input from facility engineering and administration, to include specific design features to ensure improved energy efficiency and water conservation. UNC Hospitals will develop and implement an Energy Efficiency and Sustainability Plan that is specific to the project and will address the following systems and features:*

1. *Lighting Systems – Lighting systems will be renovated, added and upgraded as needed within the scope of the project to provide higher energy efficiency in accordance with energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The changes to the lighting systems shall not adversely affect patient or resident health, safety or infection control.*
2. *Water Systems – Water systems, hand wash facilities, and toilets will be modified, added and upgraded as needed within the scope of the project to provide higher energy efficiency ...*
3. *Heating, Ventilation, and Air-conditioning (HVAC) Systems – HVAC systems will be renovated, added or upgraded as needed within the scope of the areas of renovation for the project to provide higher energy efficiency ...*
4. *Minor Equipment will be evaluated prior to purchase and implementation based on energy efficiency and water conservation. ...*
5. *Other potential energy conservation measures for the project will be researched and evaluated by the project engineer and architect as well as UNCH administration.”*

The applicant adequately demonstrates the proposal includes a plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4 and conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

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UNC Hospitals proposes to renovate space at 101 Manning Drive, Chapel Hill and acquire one additional fixed MRI scanner for a total of nine fixed MRI scanners. The charts on pages 11 and 25 of the application show five of the existing eight fixed MRI scanners are located at 101 Manning Drive, one MRI is located at the Ambulatory Care Center on Mason Farm Road and two are at UNC’s Imaging Center on Raleigh Road. This list of eight excludes UNC Hospitals’ 3.0 Tesla MRI and multi-slice PET/CT (as described on page 12 of the application). This piece of equipment is included in the PET inventory in the 2014 SMFP.

UNC Hospitals plans to relocate one of its existing scanners from 101 Manning Drive to the UNC Hillsborough campus. On page 25, the applicant states:

*“CON Project ID # J-8330-09 approved the relocation of one existing Magnetom Avanto 1.5T MRI Scanner to the Hillsborough campus at 460 Waterstone Dr, Hillsborough, NC 27278 in 2015.”*

Thus, at project completion, UNC Hospitals expects to operate five fixed MRIs at the 101 Manning Drive location (including the proposed MRI in this application), one at the Ambulatory Care Center on Mason Farm Road, two at the Imaging Center on Raleigh Road and one in Hillsborough, relocated from 101 Manning Drive, as approved in Project ID # J-8330-09. This is a total of nine MRIs at UNC Hospitals, excluding the PET/MR.

**Population to be Served**

In Section III.4(a), pages 66-67, the applicant identifies the population it served, as of March 31, 2014 (9 months data, annualized). As North Carolina’s only state-owned, tertiary care referral center, UNC Hospitals provided care to residents residing in counties throughout North Carolina with the majority of that care being provided to residents of Orange County. The 2014 SMFP identifies the MRI service area of UNC Hospitals at Chapel Hill as Orange County. The table below summarizes the historical percentage of patient origin, based on the applicant’s information as reported on pages 67-70 of the application.

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County of Residence	AC Services	MRI Services
Orange	23.96%	16.89%
Wake	13.92%	12.96%
Durham	10.57%	6.40%
Alamance	9.46%	9.97%
Chatham	6.77%	5.30%
Cumberland	3.72%	5.33%
Lee	3.43%	3.31%
Harnett	2.10%	2.80%
Guilford	1.85%	2.41%
Johnston	1.82%	2.18%
All Other NC Counties	20.65%	29.33%
Total NC	98.25%	96.88%
Other US Total	1.73%	3.12%
International Total	0.01%	0.01%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>

Totals may not sum due to rounding.

As illustrated in the above table, Orange, Wake, Durham, Alamance, Chatham, Cumberland, Lee, Harnett, Guilford, and Johnston Counties represent approximately 78% of the acute care patient origin at UNC at Chapel Hill, and approximately 68% of its MRI patient origin. The tables on pages 67 and 70 illustrate that UNC Hospitals treats patients from all over North Carolina and from outside the State. In Section III.5(a), page 70, the applicant states:

*“Consistent with the 2014 State Medical Facilities Plan, the MRI service area is Orange County. The proposed project to add MRI equipment does not involve a change in the population to be served or a change in the service area definition.”*

In Section III.5(c), pages 71-73, the applicant provides the projected patient origin for MRI services for the first two years following completion of the proposed project. The table below illustrates the ten North Carolina counties projected to have patient origin of at least two percent of the total patient origin.

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County of Residence	Percent Patient Origin
Orange	16.89%
Wake	12.96%
Alamance	9.97%
Durham	6.40%
Cumberland	5.33%
Chatham	5.30%
Lee	3.31%
Harnett	2.80%
Guilford	2.41%
Johnston	2.18%
Total Top Ten Counties	67.55%
Other NC Counties	29.33%
Out of State	3.12%
International	0.01%
<b>Total</b>	<b>100.00%</b>

Totals may not sum due to rounding.

As illustrated in the table above, the applicant projects that approximately 68% of its MRI patient's will originate from Orange, Wake, Alamance, Durham, Cumberland, Chatham, Lee, Harnett, Guilford and Johnston Counties. Another 29% of its total patients will originate from other North Carolina counties. An additional 3% of its patient origin is projected to come from residents residing in the US but outside of North Carolina and less than 0.02% from outside the US. The applicant states that its MRI patient origin for the proposed project will remain consistent with its FY 2014 MRI patient origin.

The applicant adequately identifies the population it proposes to serve.

### **Need Analysis**

In Section III.1, page 41, the applicant states:

*“The need to acquire additional MRI equipment is due to multiple factors, including:*

- The growth and aging of the population of Orange County, HSA IV and North Carolina is expected to increase demand for healthcare services including MRI procedures.*
- Expansion of UNC Hospitals' acute care capacity will increase inpatient and outpatient utilization as the hospital can accept additional transfer requests from other facilities.*



- *High utilization of the eight existing MRI scanners supports the need to add capacity.*
- *The expanded availability of specialized care with additional inpatient beds at UNC Hospital will serve high acuity patients who often require advanced diagnostic imaging including MRI procedures.*
- *Additional MRI referrals are expected due to the growth in the number of physicians within the UNC Physicians Network and additional hospital affiliations.*
- *Growth in the number of MRI Radiology faculty positions supports increased MRI utilization.*
- *Future utilization projections based on reasonable and conservative assumptions support the need for one additional fixed MRI scanner.”*

The applicant discusses the above factors on pages 41-47 of the application, as summarized below.

#### Population Growth

In Section III.1, page 42, the applicant provides population data for Orange County and Health Service Area (HSA) IV. HSA IV is projected to increase by 6.66 % or 130,054 persons between 2014 and 2018. The projection table compiled with North Carolina Office of State Budget and Management (OSBM) data for the 11 counties that comprise HSA IV illustrates a consistent growth in population of 1.6% annually. The table further illustrates a projected population growth for Orange County of 4.8% between 2014 and 2018, or 1.2% annually. The applicant further states on page 42, that the need for MRI services in Orange County will be greater as the population continues to age, “*as the senior population segments (ages 65 years and older) have the highest incidence of diseases and disorders*”. The Orange County population of age 65+ is projected to increase from 16,236 persons in 2014 to 20,366 persons in 2018 which is a 25.4 percent increase in the 65+ age group. Thus, says the applicant, “*Accordingly the demand for diagnostic imaging services including MRI procedures is likely to increase in future years.*”

#### Expansion of UNC Hospitals’ Acute Care Capacity and Specialized Care for High Acuity Patients

On page 44 of the application, the applicant states that UNC Hospitals has multiple projects in development to increase total acute care bed capacity. UNC Hospitals completed licensure of an additional 23 acute care beds in October 2012 for a total number of 724 licensed acute care beds. An additional 32 CON-approved beds are scheduled to be licensed and operational in the spring of 2015. On page 44, the applicant states:

*“As the bed capacity increases, UNC Hospitals will be positioned to accept more transfers of high acuity patients from other hospitals; the ongoing increases in UNC acute care capacity will generate higher demand for MRI procedures to provide timely and appropriate patient care.”*

On page 43, the applicant states its belief that the need for additional MRI capacity relates to the high acuity of UNC Hospitals’ patients and the depth of specialized acute care services that are provided by UNC Hospitals. The applicant provides the following UNC Hospitals facts to demonstrate the acuity of its patients:

- UNC at Chapel Hill is home to UNC Hospital’s ACS-verified Level 1 Trauma Center with 2000 multiply-injured patients admitted annually.
- UNC Hospitals is designated as an Advanced Comprehensive Stroke Center.
- The North Carolina Neurosciences Hospital, within UNC Hospitals, serves as the inpatient and outpatient facility for Neurology, Neurosurgery, Otolaryngology and Psychiatry.
- The Neurosciences Intensive Care Unit (NSICU) provides care for critically ill patients with injury or disease of the central and peripheral nervous system. The NSICU expanded to 16 beds in the spring of 2010.

#### Utilization of Existing Equipment

In Section III.1, page 45, the applicant discusses the growth of its MRI utilization over the last ten years, stating that MRI procedures are available 24 hours per day 7 days per week, with the eight fixed MRI scanners operating a combined total of 864 hours per week for an average of 108 hours per week per scanner. The applicant further states:

*“The eight existing MRI scanners (excluding the PET/MRI) are currently operating at high utilization due to the:*

- *High utilization by both inpatients and outpatients*
- *High percentage of advanced MR procedures that utilize contrast*
- *Use of the MR procedure rooms and equipment for teaching*
- *Continued expansion of UNC Hospitals’ acute care capacity*

- *Increased referral sources due to additional hospitals affiliated with UNC Health Care System and growth in the number of physicians in the UNC Physicians Network [sic]*”

The 2014 SMFP includes a need determination for one fixed MRI scanner in Orange County based on the standard methodology. The applicant states:

*“The high utilization of the existing fixed MRI scanners at UNC Hospitals supports the need for an additional MRI scanner.*

*The growth in demand for MRI services at UNC Hospitals is also demonstrated by the increases in the numbers of MRI patients in recent years.”*

On pages 46-47, the applicant demonstrates its two year compound annual growth rate (CAGR) in its MRI service and its most recent 12 month utilization. UNC Hospitals had a 6.42 CAGR of MRI patients for the two year period from 2011 to 2013 as reported on its 2012 and 2014 License Renewal Applications (LRAs).

**Calculation of Two-Year CAGR**

<b>Historical Data</b>	<b>2010-11 (2012 LRA)</b>	<b>2012-13 (2014 LRA)</b>
Total MRI Patients	18,474	20,922
MRI Patients CAGR		6.42%

CAGR:  $fx=Rate((2013-2011), , -18474, 20922)$

The applicant reports a total of 27,596 unweighted scans, 38,112 weighted scans and 20,596 patients for the most recent 12 month period from April 1, 2013 through March 31, 2014. On page 46, the applicant states:

*“The eight existing fixed MRI scanners at UNC Hospitals in Orange County performed an average of 3449.5 unweighted annual procedures. UNC Hospitals’ current average of MRI procedures per patient for all the fixed MRI scanners is 1.34 procedures with 1.394 procedures per patient at the Main Hospital and 1.178 procedures per patient at the Imaging Center.”*

The Analyst calculated the most recent 3-year CAGR using the data provided by the applicant on page 49, the applicant’s assumed FY 2014 utilization, as shown below.

**Calculation of Three-Year CAGR**

<b>Historical Data</b>	<b>FY 2011</b>	<b>FY 2014</b>
Total MRI Patients	18,474	20,596
MRI Patients CAGR		3.96%

CAGR:  $fx=Rate((2014-2011), , -18474, 20596)$

The above table illustrates that the applicant's assumption of MRI patients for FY 2014, which is lower than the number of MRI patients in 2013, results in a 3-year CAGR that is significantly lower than the 2-year CAGR at the end of FY 2013.

Additional MRI Referrals / UNC Physicians Network and Hospital Affiliations / UNC School of Medicine Radiology Faculty and Fellows

On pages 44-45, the applicant states that UNC Hospitals has a strong network of providers who will refer patients to the hospital for MRI procedures. The applicant further states:

*"The dramatic growth in the number of physician members of UNC Physicians Network combined with the increase in affiliate hospitals supports future increases in patient transfers and referrals to UNC Hospitals."*

The applicant states that affiliates of the UNC Health Care System, in addition to UNC Hospitals and UNC School of Medicine, include Caldwell Memorial Hospital, Chatham Hospital, High Point Regional Hospital, Johnston Health, Nash Healthcare, Rex Healthcare, Pardee Hospital and the UNC Physicians Network.

UNC Physicians Network (UNCPN) is a regional network of more than 36 practices and over 180 physicians and advanced practice practitioners who deliver a full range of primary care and specialty services to communities in nine counties throughout North Carolina. UNCPN was originally launched in 2010 under the name of Triangle Physicians Network with 15 practices and 60 physicians. Per the applicant, UNCPN provides physician practices access to operational support, specialty and subspecialty care providers and UNC Health Care System's electronic medical records system.

In addition to the UNC Physician Network and its hospital affiliations, the applicant states that UNC's growing number of radiology faculty and fellows utilize UNC Hospitals' eight existing fixed MRI scanners.

Exhibit 31 contains letters from physicians in support of UNC Hospitals' proposal to acquire a ninth MRI scanner. Many of the letters include projected numbers of referrals.

**Projected Utilization**

On page 44, the applicant states that the proposed expansion of MRI capacity is consistent with the expected increases in inpatient and outpatient hospital utilization. On page 61, the applicant provides a summary of its projected utilization for the nine fixed MRIs at UNC Hospitals, as shown below.

**UNC Hospitals Combined Fixed MRI Utilization**

	<b>Intervening FY 2015</b>	<b>Year 1 FY 2016</b>	<b>Year 2 FY 2017</b>	<b>Year 3 FY 2018</b>
	<b>7/1/14-6/30/15</b>	<b>7/1/15-6/30/16</b>	<b>7/1/16-6/30/17</b>	<b>7/1/17-6/30/18</b>
Total Unweighted MRI Procedures	28,565	29,565	30,599	31,670
Total Weighted MRI Procedures	39,450	40,831	42,260	43,739
# Fixed MRI Scanners	9	9	9	9
Weighted MRI Procedures per MRI	4,383	4,537	4,696	4,860

The table above shows nine MRIs in the intervening year, FY 2015, with weighted MRI procedures per MRI at 4,383. There will be only eight MRIs in FY 2015 with weighted MRI procedures per MRI at 4,931.

The applicant states that UNC Hospitals’ projected MRI calculations are based on the most recent 12 month utilization data and conservative growth assumptions. The applicant’s assumptions and methodology used to project utilization are provided in Section III, pages 48-61 and summarized below.

Step 1. Distribution by type of procedure based on the MRI utilization per patient from April 1, 2013 through March 31, 2014 (as calculated by the Analyst with the utilization data provided in the application).

<b>Type of Procedure</b>	<b>UNC Hospitals Campus</b>	<b>Imaging Center</b>	<b>Total UNC Hospitals Procedures</b>	<b>Combined Percent</b>	<b>UNC Campus Percent</b>	<b>Imaging Center Percent</b>
OP WO Contrast	3,712	2,088	5,800	21.02%	17.30%	33.80%
OP With Contrast	11,109	4,019	15,128	54.82%	51.80%	65.10%
IP WO Contrast	2,156	18	2,174	7.88%	10.10%	0.30%
IP With Contrast	4,450	44	4,494	16.28%	20.80%	0.70%
<b>Total MRI Procedures</b>	<b>21,427</b>	<b>6,169</b>	<b>27,596</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

Totals may not sum due to rounding.

Note: The “Distribution by Type of Procedures” table provided by the applicant on page 48 contains errors in the “Combined” column.

Step 2. Project current FY 2014 MRI utilization. The applicant assumes a FY 2014 patient and procedure utilization equal to the most recent available 12-month data, April 2013 – March 2014.

	<b>Most Recent 12 Months 4/1/13 to 3/31/14</b>	<b>Assumed FY 2014</b>
Total MRI Patients	20,596	20,596
Total MRI Procedures	27,596	27,596

On page 49, the applicant states:

*“This assumption is reasonable and conservative because UNC Hospital’s scope of services has remained unchanged and the number of referring physicians and faculty continues to increase.”*

The applicant makes the same assumption for its Alamance County mobile MRI service at Burlington Imaging and Breast Center (BIBC), resulting in 534 MRI patients and 583 MRI procedures.

Step 3. Project UNC Hospitals’ future MRI patients and annual unweighted MRI procedures based on 3.5 percent annual growth in MRI patients and 1.34 MRI procedures per patient.

**Projected MRI Patients and Unweighted MRI Procedures**

	<b>Current</b>	<b>Intervening</b>	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>
	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>	<b>FY 2018</b>
Total MRI Patients	20,596	21,317	22,063	22,835	23,634
Total MRI Procedures	27,596	28,565	29,564	30,599	31,670

The applicant states that the assumption of a 3.5% annual increase in patients is more conservative than the 2-year CAGR of 6.42%, takes into consideration a short-term dip in utilization, and is supported by the following factors:

- Population growth and aging for Orange County and HSA IV;
- Addition of 32 licensed acute care beds which will allow more transfers of high acuity patients;
- Expansion of the UNC Physician Network and addition of hospital affiliates, which expands the referral base; and
- Growth in the number of radiology department faculty positions.

The 3.5% annual increase is consistent with the Project Analyst’s calculation of UNC Hospitals’ fixed MRI services’ 3-year CAGR of 3.96%.

The assumption of 1.34 MRI procedures per patient is based on the applicant’s most recent 12 month experience for its existing eight MRI scanners. The applicant states that the assumption of 1.34 procedures per patient is less than both North Carolina Baptist Medical Center (1.49) and Duke University Hospital (1.78).

The applicant uses a 1.5% annual increase in mobile MRI patients at BIBC and 1.0917 procedures per patient based on actual historical BIBC data.

Step 4. Project future annual unweighted MRI procedures by type of procedure based on Step 1 percentages.

**Projected Unweighted Procedures by Type  
 UNC Hospitals Fixed MRI Service**

		<b>Intervening</b>	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>
		<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>	<b>FY 2018</b>
Total Unweighted Procedures from Step 3		28,565	29,564	30,599	31,670
Procedures by Type	Percent				
OP WO Contrast Weighted	21.02%	6,004	6,214	6,432	6,657
OP With Contrast Weighted	54.82%	15,659	16,207	16,774	17,362
IP WO Contrast Weighted	7.88%	2,251	2,330	2,411	2,496
IP With Contrast Weighted	16.28%	4,650	4,813	4,982	5,156

Totals may not sum due to rounding.

The applicant states that the assumption for percentages of procedures by type of procedure being the same as the most recent 12 months is reasonable because UNC Hospitals expects that the overall scope of MRI imaging service is not likely to change in terms of the mix of inpatients and outpatients.

The applicant projects unweighted procedures for BIBC based on the most recent 12-month data for BIBC procedure by type as stated on page 52.

Step 5. Convert projected annual unweighted MRI procedures by type to weighted procedures by type using the weight factors provided in the 2014 SMFP.

**Projected Weighted Procedures by Type  
 UNC Hospitals Fixed MRI Service**

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		<b>Intervening FY 2015</b>	<b>Year 1 FY 2016</b>	<b>Year 2 FY 2017</b>	<b>Year 3 FY 2018</b>
		<b>7/1/14-6/30/15</b>	<b>7/1/15-6/30/16</b>	<b>7/1/16-6/30/17</b>	<b>7/1/17-6/30/18</b>
<b>Procedures by Type</b>	<b>Factor</b>				
OP WO Contrast Weighted	1.0	6,004	6,214	6,432	6,657
OP With Contrast Weighted	1.4	21,923	22,690	23,484	24,306
IP WO Contrast Weighted	1.4	3,151	3,262	3,376	3,494
IP With Contrast Weighted	1.8	8,371	8,664	8,967	9,281
<b>Total Weighted Procedures</b>		<b>39,449</b>	<b>40,830</b>	<b>42,259</b>	<b>43,738</b>

Totals may not sum due to rounding.

In the third year following the completion of the proposed project, UNC Hospitals projects to perform 43,738 weighted procedures on its nine fixed MRI scanners in Orange County, which equals 4,860 procedures per scanner.

Step 5A. Project future annual numbers of weighted MRI procedures for each UNC Hospitals MRI location in Orange County, based on the most recent 12 months data, April 1, 2013 through March 31, 2014.

**Historical Distribution of MRI Patients between UNC  
 Hospital Campus and Imaging Center Scanners**

	<b>UNC Hospital Campus (6 MRI Scanners)</b>	<b>Imaging Center (2 MRI Scanners)</b>	<b>Total</b>
Total MRI Patients	15,358	5,238	20,596
Percentages	74.57%	25.43%	100.00%

Based on the percentages above, the applicant distributes the total projected MRI patients between the MRIs on the UNC Campus (six existing MRI scanners, including the existing scanner approved to be moved to Hillsborough in Project ID# J-8330-09: 74.57%) and the Imaging Center (two MRI scanners: 25.43%) for the intervening year, FY 2015. For the first three project years, the applicant distributes the total projected MRI patients, using the percentages above, with 74.57% of the patients attributed to the seven MRI scanners at UNC Hospitals and 25.43% of the patients attributed to the two scanners at the Imaging Center. At this point in the methodology, the seven scanners at UNC Hospitals include the one scanner being relocated to Hillsborough in Project ID# J-8330-09 and the proposed scanner in this application.



**Distribution of Projected UNC Hospitals MRI Patients**

		<b>Intervening FY 2015</b>	<b>Year 1 FY 2016</b>	<b>Year 2 FY 2017</b>	<b>Year 3 FY 2018</b>
	<b>Assumptions</b>	<b>7/1/14-6/30/15</b>	<b>7/1/15-6/30/16</b>	<b>7/1/16-6/30/17</b>	<b>7/1/17-6/30/18</b>
UNC Hospitals MRI Patients	100.00%	21,317	22,063	22,835	23,634
UNC Campus and Hillsborough	74.57%	15,896	16,452	17,028	17,624
Imaging Center	25.43%	5,421	5,611	5,807	6,010

Totals may not sum due to rounding.

To project MRI procedures for the UNC Campus and Hillsborough scanners (7 scanners) and the Imaging Center scanners (2 scanners), the applicant states the use of the most recent historical procedures per patient for the UNC Campus and Hillsborough scanners (1.395) and the Imaging Center scanners (1.178).

**Distribution of Projected UNC Hospitals MRI Procedures**

	<b>Assumptions</b>	<b>Intervening FY2015</b>	<b>Year 1 FY2016</b>	<b>Year 2 FY2017</b>	<b>Year 3 FY2018</b>
UNC Campus and Hillsborough Patients		15,896	16,452	17,028	17,624
Procedures	1.395 Scans per Patient	22,178	22,954	23,758	24,589
Imaging Center Patients		5,421	5,611	5,807	6,010
Procedures	1.178 Scans per Patient	6,387	6,610	6,842	7,081

Totals may not sum due to rounding.

Steps 5B – 5E. Projected MRI procedures after development of Project ID # J-8330-09 as of July 2015 (relocate one UNC Hospitals Campus MRI scanner to the Hillsborough Campus) and the addition of the MRI in this application; projected MRI procedures at the Imaging Center; and projected MRI procedures for UNC Hospitals Burlington Imaging and Breast Center mobile MRI services.

On pages 55-56, the applicant provides a methodology for distributing the projected unweighted MRI procedures between the UNC Campus and the Hillsborough Campus based on what it says was the projected unweighted procedures for the relocated Hillsborough scanner in the previously-approved Project ID # J-8330-09. The Year 1 unweighted figure of 3,432 does not correspond with figures the Project Analyst finds in Project ID # J-8330-09, however, it does calculate to be “14.95 percent of the UNC Hospitals total MRI utilization excluding that of the Imaging Center” as stated by the applicant. Furthermore, the difference between the 3,432 unweighted procedures used by the applicant on page 55 and the projected Project ID # J-8330-09 unweighted procedures for project year one was less than two percent and therefore immaterial.

In addition, the weighted MRI procedures provided by the applicant on page 55 are calculated erroneously, as is evident when comparing the “OP with Contrast” row in the weighted

procedures table with the “OP with Contrast” row in the unweighted procedures table. The error results in the total weighted procedures per year being 29% understated in the Hillsborough utilization calculation on page 55. However, the applicant provides the correct totals in the table on page 28 of the application. Thus, Steps 5B - 5E are not significant to the outcome of the projected utilization methodology, as shown in the table below in the Project Analyst’s recalculation of the applicant’s summary table on page 59, using the applicant’s projected 3,432 unweighted procedures for Hillsborough in the first year after completion of both projects, FY 2016 (July 1, 2015 – June 30, 2016); the distribution of unweighted scans provided by the applicant in Step 4 on page 52; and the procedure by type weights provided in Step 5. The summary table illustrates the total UNC Hospitals Orange County MRI utilization, first reduced by the Imaging Center projected utilization, then by the Hillsborough campus projected utilization, leaving the UNC Hospitals campus projected MRI utilization. The summary table also includes the projected Alamance County mobile MRI utilization.

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**Summary Table, Application Page 59, Recalculated**

	<b>Intervening</b>	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>
	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>	<b>FY 2018</b>
<b>UNC Orange County Fixed MRI Services</b>				
UNC Orange County Number of MRI Scanners	8	9	9	9
Total MRI Patients	21,317	22,063	22,835	23,634
Total MRI Unweighted Procedures	28,565	29,564	30,599	31,670
Total Weighted MRI Procedures	39,449	40,830	42,259	43,738
Imaging Center Number of MRI Scanners	2	2	2	2
Imaging Center MRI Patients (2 scanners)	5,421	5,611	5,807	6,010
Imaging Center MRI Unweighted Procedures	6,387	6,610	6,842	7,081
Imaging Center MRI Weighted Procedures	8,095	8,378	8,672	8,975
Hillsborough Campus Number of MRI Scanners	0	1	1	1
Hillsborough MRI Patients (1 scanner)	0	2,460	2,546	2,635
Hillsborough MRI Unweighted Procedures	0	3,432	3,552	3,676
Hillsborough MRI Weighted Procedures	0	4,852	5,022	5,198
UNC Hospitals Campus Number of MRI Scanners	6	6	6	6
UNC Campus MRI Patients (6 scanners)	15,896	13,992	14,482	14,989
UNC Campus MRI Unweighted Procedures	22,178	19,522	20,206	20,913
UNC Campus MRI Weighted Procedures	31,355	27,600	28,566	29,566
<b>UNC Alamance County Mobile MRI -Burlington Imaging and Breast Center</b>				
BIBC Mobile MRI Patients	542	550	558	567
BIBC Mobile MRI Unweighted Procedures	592	601	610	619
BIBC Mobile MRI Weighted Procedures	675	685	695	706
<b>All UNC Orange and Alamance County Fixed and Mobile MRI Services</b>				
All UNC MRI Patients	21,859	22,613	23,394	24,201
All UNC MRI Unweighted Procedures	29,156	30,165	31,209	32,288
Total All UNC MRI Weighted Procedures	40,124	41,515	42,955	44,445

Totals may not sum due to rounding.

The applicant adequately demonstrates the need to acquire one additional MRI Scanner for a total of nine MRI scanners to expand capacity and patient access to MRI procedures.

Furthermore, the applicant adequately demonstrates the need for the proposal for all of the following reasons:

- 1) The applicant does not propose new construction or expansion of the existing facility, only minor renovation;
- 2) University of North Carolina Hospitals at Chapel Hill is one of five academic medical center teaching hospitals in North Carolina and the only state-owned teaching hospital in North Carolina; and
- 3) The addition of a ninth MRI scanner will maximize efficiency for patients requiring inpatient and outpatient MRI procedures.

### Access

In Section III.2, page 62, the applicant discusses how the proposed project will promote equitable access. The applicant states:

*“Access to MRI services will continue to follow the existing policies that UNC Hospitals has in place. As North Carolina’s only state-owned referral, tertiary and quaternary care center, UNC Hospitals has the obligation to accept any North Carolina citizen requiring treatment. No North Carolina citizen is denied access to non-elective care due to race, sex, creed, age, handicap, financial status or lack of medical insurance. The facility is designed in accordance with the latest State of North Carolina and federal guidelines for handicapped accessibility. The project will incorporate all applicable provisions of the Americans with Disabilities Act.”*

In Section VI.2, page 86, the applicant states that UNC Hospitals has traditionally provided services to a wide variety of patient groups and provides the following table, based on FY 2014 data.

	<b>Low Income</b>	<b>Racial &amp; Ethnic Minorities</b>	<b>Women</b>	<b>Elderly</b>	<b>Other Underserved</b>
Total Hospital	17.0%	36.3%	58.6%	23.8%	10.9%
MRI	16.6%	34.2%	54.0%	20.4%	10.1%

Low Income = Medicaid and ½ of Medicaid Pending; Other Underserved = Self Pay and ½ of Medicaid Pending

In Section VI.8, page 89, the applicant discusses charity care and bad debt, stating that UNC Hospitals’ MRI service will provide more than \$200,000,000 in charity care in project years one and two; and approximately \$100,000,000 in bad debt each year.

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need the population projected to be served has for the proposed project, and demonstrates all residents of the service area, and, in particular, underserved groups, are likely to have access to the services proposed. 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 64-66, the applicant describes several alternatives considered which include the following:

- 1) Maintain Status Quo – UNC Hospitals considered maintaining the status quo, however, the applicant concluded this option fails to improve access to MRI services and does not respond to the increased demand for MRI services that is being generated by the patient population plus the increased numbers of patient transfers and referrals.
- 2) Alternative Location – the applicant evaluated alternative locations exterior to the hospital campus and the Imaging Center at 1350 Raleigh Road. However, the applicant determined that it was the MRI utilization that centered on the UNC Hospitals campus that generated the peak in utilization that merits additional capacity. Other areas of the county were judged to have adequate MRI capacity. The Imaging Center alternative was rejected as it would have required additional capital costs to renovate the facility. The applicant further states that recent MRI placements have been made off-campus at the Imaging Center and soon the Hillsborough location will be operational.
- 3) Alternate MRI Specifications – The applicant states on page 65 that UNC Hospitals also rejected the options to acquire an upright MRI scanner, an open bore type MRI scanner and an extremity MRI scanner due to the following disadvantages:
  - The upright MRI scanner is not widely endorsed by radiologists and referring physicians.
  - The open bore MRI scanner cannot provide the desired image quality for certain procedures.
  - An extremity MRI scanner could not accommodate the head, spine, abdominal and shoulder MRI procedures that are routinely ordered by UNC physicians.

The applicant states the proposed 1.5 Tesla MRI was determined to be the most effective alternative in equipment because it provides the optimal range of clinical capabilities for the inpatients and outpatients who utilize UNC Hospitals.

- 4) Develop the Project as Proposed –the applicant concludes that the project as proposed is UNC’s least costly and most effective alternative to increase fixed MRI capacity to serve the needs of patients, radiologists and students.

The applicant adequately demonstrates that acquiring the fixed MRI scanner to be located at 101 Manning Drive on the UNC Hospitals campus is its most effective alternative to meet the need for fixed MRI services in Orange County.

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

In summary, the applicant adequately demonstrates that its 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. University of North Carolina Hospitals at Chapel Hill shall materially comply with all representations made in its certificate of need application.**
  - 2. University of North Carolina Hospitals at Chapel Hill 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.**
  - 3. University of North Carolina Hospitals at Chapel Hill shall acquire no more than one fixed MRI scanner for a total of no more than nine fixed MRI scanners.**
  - 4. Prior to issuance of the certificate of need, University of North Carolina Hospitals at Chapel Hill shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing to the Certificate of Need Section.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 107, the applicant states that the total capital cost of the project will be \$3,210,288, as shown in the table below.

**Project Capital Cost**

Construction Contract	\$607,425
Fixed Equipment	\$2,352,863
Architect & Engineering Fees	\$50,000
Contingency	\$200,000
<b>Total Capital Cost</b>	<b>\$ 3,210,288</b>

In Section IX, page 112, the applicant states there will be no start-up or initial operating expenses associated with the proposed project. In Section VIII.3, page 108, the applicant states that the project will be funded through UNC Hospitals' accumulated reserves. Exhibit 26 contains an August 12, 2014 letter signed by the President for UNC Hospitals, which states:

*“This letter is to confirm the availability of funding in excess of \$3,210,288 specifically for use for the capital costs associated with the development of the above referenced project. ...”*

Exhibit 27 of the application contains the audited financial statements for UNC Hospitals for the year ending June 30, 2013. As of June 30, 2013, UNC had \$142,371,338 in cash and cash equivalents and \$1,240,579,117 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In pro forma financial statements for UNC Hospitals MRI services (Form C), the applicant projects revenues will exceed expenses in each of the first three operating years, as shown in the table below:

**Projected UNC Hospitals MRI Services**

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	<b>Project Year 1 FY2016</b>	<b>Project Year 2 FY2017</b>	<b>Project Year 3 FY2018</b>
Projected # of Unweighted MRI Procedures	30,165	31,209	32,289
Projected Average Charge (Gross Patient Revenue/ Projected # of Procedures)	\$ 3,063	\$ 3,216	\$ 3,377
Gross Patient Revenue	\$ 92,398,472	\$ 100,376,168	\$ 109,042,212
Deductions from Gross Patient Revenue	\$ 53,351,822	\$ 57,958,225	\$ 62,962,087
Net Patient Revenue	\$ 39,046,650	\$ 42,417,943	\$ 46,080,125
Total Expenses	\$ 12,681,406	\$ 13,618,980	\$ 13,937,951
Net Income	\$ 26,365,244	\$ 28,798,963	\$ 32,142,174

The applicant also projects a positive net income for the UNC Hospitals in each of the first three operating years of the project. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including the projected utilization. See the pro forma financial statements in the application for the assumptions. See Criterion (3) for discussion of utilization projections which is incorporated hereby by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues, 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 applicant proposes to acquire a ninth MRI scanner. The applicant does not propose to acquire any new beds or to offer any new services. The applicant adequately demonstrates the need for an additional MRI scanner. See Criterion (3) for the discussion regarding the need for the proposal which is incorporated hereby by reference.

The applicant currently provides MRI services in Orange County. The eight existing fixed MRI scanners at UNC Hospitals in Orange County performed 38,112 weighted procedures, an average of 4,764 procedures per scanner from April 1, 2013 to March 31, 2014. 4,764 is 99% of the 4,805 planning threshold (70% for four scanners and over) in the 2014 SMFP. UNC Hospitals' nine MRI scanners are projected to operate at 71% of capacity in the third year of operations ( $43,739 / 9 = 4,860$  weighted scans per scanner / 6,864 defined capacity of one scanner = .7080).

The applicant adequately demonstrates the project will not result in the unnecessary duplication of existing or approved MRI services in the Orange County service area. Consequently, the application is conforming to this criterion.



- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.1(a and b), page 98, the applicant provides the current staffing for its eight existing MRI scanners and the projected staffing during the second full fiscal year following the installation of the ninth MRI scanner, as illustrated in the table below.

**Current and Proposed Staffing**

	<b>CURRENT FTES</b>	<b>PROJECTED FTES FY 2017</b>
Radiology Manager	0.2	0.2
MRI Supervisor	1.0	1.0
MRI Technologist	30.6	36.5
Clinical Nurse II/Tier I	1.5	1.5
Scheduler	1.0	2.0
Transport	1.0	1.0
<b>Total</b>	<b>35.3</b>	<b>42.2</b>

As illustrated in the above table, the applicant projects to add 5.9 full-time equivalent (FTE) MRI technologist positions and 1.0 FTE scheduler position by the second full fiscal year following completion of the proposed project. Furthermore, in Section VII.3(a), page 100, the applicant states:

*“The total of 36.5 FTE MRI technologists will provide continuous availability of service and ensure the availability of two full-time MRI technologists and one or more of these technologists will be present during the hours of operation for all of the existing plus the additional fixed MRI scanner. The proposed scanner will operate 128 hours per week. The staffing tables do not include any MRI technologist positions for UNC Hospitals Burlington Imaging and Breast Center; these mobile MRI scanners are provided by contract service owned and staffed by Alliance Imaging.”*

In Section VII.6(a and b), page 102, the applicant provides UNC’s recruitment and staff retention plans. In Section VII.8(a), page 104, the applicant states Dr. Matthew Mauro serves as Professor and Chair of the Department of Radiology and Dr. Richard Semelka serves as the Director of MR Services, Professor and Vice Chair of Clinical Research and Vice Chair of Quality and Safety. The applicant states that the 40 full-time faculty members of the Department of Radiology cover many areas of expertise within interventional and diagnostic radiology. See Exhibit 30 for copies of the physicians’ curricula vitae. The applicant demonstrates the availability of adequate health manpower and management personnel to provide the proposed services, and therefore, the application is conforming to this criterion.

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

C

The applicant currently provides MRI services and the necessary ancillary and support services are currently available. In Section II.2(a), page 17, the applicant states:

*“The proposed project is for the expansion of an existing service with the addition of one MRI scanner. All ancillary and support services are currently available. No additional staff is needed for the ancillary and support services.”*

See Exhibit 3 of the application for a copy of a letter from Dr. Brian P. Goldstein attesting to the availability of ancillary and support services. Exhibit 31 contains letters of support from physicians for the proposed additional MRI scanner. The applicant adequately demonstrates the availability of the necessary ancillary and support services and that the proposed services would be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing

the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.12 and VI.13, pages 95-96, the applicant provides the payor mix during FY 2013 for the entire hospital and the MRI services department, as illustrated in the table below:

**UNC Hospitals**  
**FY 2013(7/1/12-6/30/13)**  
**Patient Days/Procedures as a % of Total Utilization**

	<b>Entire Facility</b>	<b>MRI Volume</b>
Self-Pay / Indigent / Charity	5.7%	10.5 %
Medicare/Medicare Managed Care	31.7%	27.4%
Medicaid	29.8%	16.6%
Commercial Insurance	1.0%	1.1 %
Managed Care	26.0%	36.5%
Other*	5.8%	8.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Totals may not sum due to rounding.

\*Other includes N.C. Department of Corrections, Tricare and Workers Compensation.

In Section VI.2, page 86, the applicant states:

*“As North Carolina’s only state-owned comprehensive, full service hospital-based program, UNC Hospitals has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is*

*denied access to non-elective care because of race, sex, creed, age, handicap, financial status or lack of medical insurance.*

*The facility is designed in accordance with the latest State of North Carolina and Federal guidelines for handicapped accessibility. The project incorporates all applicable provisions of the Americans with Disabilities Act.”*

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population</b>	<b>2009 % Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)</b>
Orange County	8.6%	3.5%	18.9%
Statewide	16.5%	6.7%	19.7%

\*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the imaging services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to the services offered at UNC Hospitals at Chapel Hill. Therefore, the application is conforming to this criterion.

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 95, the applicant states:

*“UNC Hospitals has long since satisfied its “free care” obligation under the Hill-Burton Act. Charity care provided by UNC Hospitals for the year ending June 30, 2014 was \$191,354,929 (15.64% of Net Revenue)[sic] UNC Hospitals provides care to all persons based only on their need for care and without regard to minority status or handicap/disability.”*

See Exhibit 22 for a copy of the applicant’s policies and procedures regarding admissions and discharges.

In Section VI.10 (a), page 94, the applicant states that it has not been notified of any civil rights equal access complaints being filed against the hospital and/or any facilities or services owned by the hospital within the past 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(a and b) and VI.15(a and b), pages 96-97, the applicant provides the projected payor mix for the second full fiscal year of operations for the entire hospital and the MRI services department for the proposed second year of service FY 2017 (July 1, 2016 – June 30, 2017), as illustrated in the table below:

**UNC Hospitals Projected FY 2017 Payor Mix  
Patient Days/Procedures as a % of Total Utilization**

	<b>Entire Facility</b>	<b>MRI Volume</b>
Self-Pay / Indigent / Charity	5.7%	10.5 %
Medicare/Medicare Managed Care	31.7%	27.4%
Medicaid	29.8%	16.6%
Commercial Insurance	1.0%	1.1 %
Managed Care	26.0%	36.5%
Other*	5.8%	8.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Totals may not sum due to rounding.

\*Other includes N.C. Department of Corrections, Tricare and Workers Compensation.

On page 97, the applicant states the projected payor percentages are based on the assumption that future payor percentages will be the same as the most recent fiscal year 2013.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. 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(a), page 90, the applicant describes the range of means by which a person will have access to its services. The information provided is reasonable and credible and supports a finding of conformity 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(b), page 79, the applicant states UNC Hospitals MRI equipment is used for medical rotations and educational experiences for radiology residents and fellows as well as multiple health professional training programs and it will continue to be used for these purposes. The applicant further states that its MRI scanners are also utilized by clinical training programs with the UNC Radiology Program and the UNC Nursing Program. Exhibit 19 contains documentation of a UNC training program affiliation agreement. The information

provided in Section V.1 is reasonable and credible 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

The applicant operates the only state-owned academic medical center in North Carolina and is the only acute care hospital in the Orange County service area. UNC Hospitals owns and operates eight existing MRI scanners (excluding its PET/MR) and is the only provider of inpatient MRI services in the applicant's service area. The applicant proposes to acquire an additional MRI scanner for a total of nine (excluding UNC Hospitals' PET/MR).

In Section V.7, page 84, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states:

*“UNC Hospitals is an existing provider of MRI procedures. This project is designed to enhance the provision of timely, quality patient care, and to assist UNC Hospitals in meeting its four-fold mission of patient care, teaching, research and community service. The project will foster competition by promoting improved patient access and advance the cost effectiveness and quality of MRI services.*

*The UNC MRI service has achieved full utilization of its existing MRI scanners. This high utilization causes scheduling difficulties and diminishes staff productivity. The proposed project will greatly improve scheduling and allow the staff to achieve greater productivity and improve patient satisfaction.*

*One of the competitive strengths of the UNC MRI service is the depth of the faculty physicians' expertise. Approval of the proposed project will add needed MRI capacity and improve access for residents and fellows. This arrangement bolsters the clinical capabilities of the Department as well as the teaching and research resources of the program.”*



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

- The applicant adequately demonstrates the need to acquire an additional MRI scanner;
- The applicant adequately demonstrates that UNC Hospitals at Chapel Hill has and will continue to provide quality services; and
- The applicant demonstrates that UNC Hospitals at Chapel Hill has and will continue to provide adequate access to medically underserved populations.

The application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The University of North Carolina Hospitals at Chapel Hill is accredited by the Joint Commission and certified for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, no incidents occurred within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

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

C

The application submitted by University of North Carolina Hospitals at Chapel Hill is conforming with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700. The specific criteria are discussed below.

**SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER**

**10A NCAC 14C .2702 INFORMATION REQUIRED OF APPLICANT**

- (a) *An applicant proposing to acquire an MRI scanner, including a mobile MRI scanner, shall use the Acute Care Facility/Medical Equipment application form.*
- C- The applicant used the Acute Care/Medical Equipment application form.
- (b) *Except for proposals to acquire mobile MRI scanners that serve two or more host facilities, both the applicant and the person billing the patients for the MRI service shall be named as co-applicants in the application form.*
- C- In Section II.8, page 22, the applicant states, “*University of North Carolina Hospitals at Chapel Hill is the sole applicant as it is the entity that will own the MRI scanner and bill patients for the procedures.*”
- (c) An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall provide the following information:
  - (1) *documentation that the proposed fixed MRI scanner, excluding fixed extremity and breast MRI scanners, will be available and staffed for use at least 66 hours per week;*
  - C- In Section II.8, page 23, the applicant states that the proposed MRI scanner will be staffed and operational 5:30 am to 11:30 pm, seven days per week for a total of 126 hours per week.
  - (2) *documentation that the proposed mobile MRI scanner will be available and staffed for use at least 40 hours per week;*
  - NA- The applicant does not propose to acquire a mobile MRI scanner.
  - (3) *documentation that the proposed fixed extremity or dedicated breast MRI scanner shall be available and staffed for use at least 40 hours per week;*
  - NA- The applicant does not propose to acquire a fixed extremity or dedicated breast MRI scanner.

- (4) *the average charge to the patient, regardless of who bills the patient, for each of the 20 most frequent MRI procedures to be performed for each of the first three years of operation after completion of the project and a description of items included in the charge; if the professional fee is included in the charge, provide the dollar amount for the professional*
- C- In Section II.8, page 24, the applicant provides the projected charges for the 20 most frequent procedures to be performed in the first three years of operation after completion of the project.
- (5) *if the proposed MRI service will be provided pursuant to a service agreement, the dollar amount of the service contract fee billed by the applicant to the contracting party for each of the first three years of operation;*
- NA- The applicant does not propose to provide MRI services pursuant to a service agreement.
- (6) *letters from physicians indicating their intent to refer patients to the proposed magnetic resonance imaging scanner and their estimate of the number of patients proposed to be referred per year, which is based on the physicians' historical number of referrals;*
- C- Exhibit 31 contains letters from more than 25 physicians indicating their support for the proposed project and their intent to refer patients to UNC for MRI scans. Approximately 70% of the letters estimate the annual number of patients which may be referred to UNC Hospitals for their MRI scans.
- (7) *for each location in the MRI service area at which the applicant or a related entity will provide MRI services, utilizing existing, approved, or proposed fixed MRI scanners, the number of fixed MRI scanners operated or to be operated at each location;*
- C- In Section II, page 25, the applicant provides a table listing its eight existing UNC Hospitals fixed MRI scanners and their locations.
- (8) *for each location in the MRI service area at which the applicant or a related entity will provide MRI services, utilizing existing, approved, or proposed fixed MRI scanners, projections of the annual number of unweighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project;*
- C- In Section II.8, page 26, the applicant states:

*“The projections for the annual number of unweighted MRI procedures by each of the four types of MRI procedures for each location in the Orange County Service Area are provided in the tables below.”*

The applicant provides *“projections of the annual number of unweighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project”* on pages 26-27 of the application.

- (9) *for each location in the MRI service area at which the applicant or a related entity will provide services, utilizing existing, approved, or proposed fixed MRI scanners, projections of the annual number of weighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project;*
- C- In Section II.9, pages 28-29, the applicant provides *“projections of the annual number of weighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project.”*
- (10) *a detailed description of the methodology and assumptions used to project the number of unweighted MRI procedures to be performed at each location, including the number of contrast versus non-contrast procedures, sedation versus non-sedation procedures, and inpatient versus outpatient procedures;*
- C- The applicant’s methodology and assumptions used to project the number of unweighted and weighted MRI procedures are described in Section III, pages 48-61.
- (11) *a detailed description of the methodology and assumptions used to project the number of weighted MRI procedures to be performed at each location;*
- C- The applicant’s methodology and assumptions used to project the number of unweighted and weighted MRI procedures are described in Section III, pages 48-61.
- (12) *for each existing, approved or proposed mobile MRI scanner owned by the applicant or a related entity and operated in North Carolina in the month the application is submitted, the vendor, tesla strength, serial number or vehicle identification number, CON project identification number, and host sites;*

- C- In Section II.8, page 29, the applicant states: *“UNC Hospitals has no existing, approved or proposed mobile MRI scanners in North Carolina.”*
- (13) *for each host site in the mobile MRI region in which the applicant or a related entity will provide the proposed mobile MRI services, utilizing existing, approved, or proposed mobile MRI scanners, projections of the annual number of unweighted and weighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project;*
- NA- This applicant does not propose to provide mobile MRI services.
- (14) *if proposing to acquire a mobile MRI scanner, an explanation of the basis for selection of the proposed host sites if the host sites are not located in MRI service areas that lack a fixed MRI scanner; and*
- NA- The applicant does not propose the acquisition of a mobile MRI scanner.
- (15) *identity of the accreditation authority the applicant proposes to use.*
- C- The applicant identifies the accreditation authority it proposes to use in Section II.8, page 30 of the application. The applicant states:
- “The proposed fixed MRI scanner will be accredited by the American College of Radiology and The Joint Commission.”*
- (d) *An applicant proposing to acquire a mobile MRI scanner shall provide copies of letters of intent from, and proposed contracts with, all of the proposed host facilities of the new MRI scanner.*
- NA- The applicant does not propose the acquisition of a mobile MRI scanner.
- (e) *An applicant proposing to acquire a dedicated fixed breast MRI scanner shall demonstrate that:*
- (1) *it has an existing and ongoing working relationship with a breast-imaging radiologist or radiology practice group that has experience interpreting breast images provided by mammography, ultrasound, and MRI scanner equipment, and that is trained to interpret images produced by a MRI scanner configured exclusively for mammographic studies;*
- (2) *for the last 12 months it has performed the following services, without interruption in the provision of these services: breast MRI procedures on a fixed MRI scanner with a breast coil, mammograms, breast ultrasound procedures, breast needle core biopsies, breast cyst aspirations, and pre-surgical breast needle localizations;*

- (3) *its existing mammography equipment, breast ultrasound equipment, and the proposed dedicated breast MRI scanner is in compliance with the federal Mammography Quality Standards Act;*
- (4) *it is part of an existing healthcare system that provides comprehensive cancer care, including radiation oncology, medical oncology, surgical oncology and an established breast cancer treatment program that is based in the geographic area proposed to be served by the applicant; and,*
- (5) *it has an existing relationship with an established collaborative team for the treatment of breast cancer that includes, radiologists, pathologists, radiation oncologists, hematologists/oncologists, surgeons, obstetricians/gynecologists, and primary care providers.*

-NA- The applicant does not propose the acquisition of a dedicated fixed breast MRI scanner.

- (f) *An applicant proposing to acquire an extremity MRI scanner, pursuant to a need determination in the State Medical Facilities Plan for a demonstration project, shall:*
- (1) *provide a detailed description of the scope of the research studies that will be conducted to demonstrate the convenience, cost effectiveness and improved access resulting from utilization of extremity MRI scanning;*
  - (2) *provide projections of estimated cost savings from utilization of an extremity MRI scanner based on comparison of "total dollars received per procedure" performed on the proposed scanner in comparison to "total dollars received per procedure" performed on whole body scanners;*
  - (3) *provide projections of estimated cost savings to the patient from utilization of an extremity MRI scanner;*
  - (4) *commit to prepare an annual report at the end of each of the first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that will include:*
    - (A) *a detailed description of the research studies completed;*
    - (B) *a description of the results of the studies;*
    - (C) *the cost per procedure to the patient and billing entity;*
    - (D) *the cost savings to the patient attributed to utilization of an extremity MRI scanner;*
    - (E) *an analysis of "total dollars received per procedure" performed on the extremity MRI scanner in comparison to "total dollars received per procedure" performed on whole body scanners; and*
    - (F) *the annual volume of unweighted and weighted MRI procedures performed, by CPT code;*
  - (5) *identify the operating hours of the proposed scanner;*
  - (6) *provide a description of the capabilities of the proposed scanner;*
  - (7) *provide documentation of the capacity of the proposed scanner based on the number of days to be operated each week, the number of days to be operated each year, the number of hours to be operated each day, and the average*

*number of unweighted MRI procedures the scanner is capable of performing each hour;*

- (8) *identify the types of MRI procedures by CPT code that are appropriate to be performed on an extremity MRI scanner as opposed to a whole body MRI scanner;*
- (9) *provide copies of the operational and safety requirements set by the manufacturer; and*
- (10) *describe the criteria and methodology to be implemented for utilization review to ensure the medical necessity of the procedures performed.*

-NA- The applicant does not propose the acquisition of an extremity MRI scanner.

- (g) *An applicant proposing to acquire a multi-position MRI scanner, pursuant to a need determination in the State Medical Facilities Plan for a demonstration project, shall:*
  - (1) *commit to prepare an annual report at the end of each of the first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that will include:*
    - (A) *the number of exams by CPT code performed on the multi-position MRI scanner in an upright or nonstandard position;*
    - (B) *the total number of examinations by CPT code performed on the multi-position MRI scanner in any position;*
    - (C) *the number of doctors by specialty that referred patients for an MRI scan in an upright or nonstandard position;*
    - (D) *documentation to demonstrate compliance with the Basic Principles policy included in the State Medical Facilities Plan;*
    - (E) *a detailed description of the unique information that was acquired only by use of the multi-position capability of the multi-position MRI scanner; and*
    - (F) *the number of insured, underinsured, and uninsured patients served by type of payment category;*
  - (2) *provide the specific criteria that will be used to determine which patients will be examined in other than routine supine or prone imaging positions;*
  - (3) *project the number of exams by CPT code performed on the multi-position MRI scanner in an upright or nonstandard position;*
  - (4) *project the total number of examinations by CPT code performed on the multi-position MRI scanner in any position;*
  - (5) *demonstrate that access to the multi-position MRI scanner will be made available to all spine surgeons in the proposed service area, regardless of ownership in the applicant's facility;*
  - (6) *demonstrate that at least 50 percent of the patients to be served on the multi-position MRI scanner will be spine patients who are examined in an upright or nonstandard position; and*
  - (7) *provide documentation of the capacity of the proposed fixed multi-position MRI scanner based on the number of days to be operated each week, the*

*number of days to be operated each year, the number of hours to be operated each day, and the average number of unweighted MRI procedures the scanner is capable of performing each hour.*

-NA- The application does not propose the acquisition of a multi-position MRI scanner pursuant to a need determination.

**10A NCAC 14C .2703 PERFORMANCE STANDARDS**

(a) *An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner shall:*

- (1) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the mobile MRI region in which the proposed equipment will be located, except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; with the exception that in the event an existing mobile MRI scanner has been in operation less than 12 months at the time the application is filed, the applicant shall demonstrate that this mobile MRI scanner performed an average of at least 277 weighted MRI procedures per month for the period in which it has been in operation;*
- (2) *demonstrate annual utilization in the third year of operation is reasonably projected to be at least 3328 weighted MRI procedures on each of the existing, approved and proposed mobile MRI scanners owned by the applicant or a related entity to be operated in the mobile MRI region in which the proposed equipment will be located [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; and*
- (3) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- The applicant does not propose the acquisition of a mobile MRI scanner.

(b) *An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:*

- (1) *demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;*

-C- In Section II.8, page 32, the applicant states, “The table below shows that UNC Hospitals’ eight existing fixed MRI scanners performed more than 3,328



*weighted MRI procedures in the most recent 12 month period (April 1, 2013 to March 31, 2014) for which the applicant has reliable data.”*

The eight existing fixed MRI scanners at UNC Hospitals in Orange County performed an average of 4,764 weighted annual procedures per MRI scanner as shown in the table on page 33 and below.

	UNC Campus	Imaging Center	Unweighted Total Scans	% of Total Scans	Weighted Total Scans
Number of Fixed MRI Scanners	6	2			
OP WO Contrast	3,712	2,088	5,800	21.02%	5,800
OP With Contrast	11,109	4,019	15,128	54.82%	21,179
IP WO Contrast	2,156	18	2,174	7.88%	3,044
IP With Contrast	4,450	44	4,494	16.28%	8,089
Total MRI Procedures	21,427	6,169	27,596	100%	38,112
Weighted Annual Procedures per MRI Scanner					4,764

Source: The applicant states the use of the most recent 12 months data by type of scan to calculate percentages and numbers of MRI procedures per patient.

(2) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];*

-NA- The applicant states that UNC Hospitals has no existing, approved or proposed mobile MRI scanner.

(3) *demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*

- (A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
- (B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
- (C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*

- (D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*
  - (E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*
- C- The applicant states that the proposed fixed MRI scanner will be located at 101 Manning Drive in Chapel Hill, in the Orange County service area. The applicant also states that the annual utilization of the proposed fixed MRI scanner and all of UNC Hospitals' existing fixed MRI scanners in the service area are reasonably expected to exceed 4,805 weighted procedures as shown in the tables on pages 28-29 and 34-37. The methodology for the projections is provided on pages 48-61 of the application. The applicant adequately demonstrates that projected utilization is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding projected utilization which is hereby incorporated by reference.
- (4) *if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*
- (A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
  - (B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
  - (C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
  - (D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*
  - (E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*
- C- The applicant states that the proposed fixed MRI scanner will be located at 101 Manning Drive, a location at which the applicant already has existing fixed MRI scanners. The applicant also states that the annual utilization of the proposed fixed MRI scanner and all of UNC Hospitals' existing fixed MRI scanners are reasonably expected to exceed 4,805 weighted procedures as shown in the tables on pages 28-29 and 34-37.
- (5) *demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of*

*operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and*

-NA- The applicant does not own or operate any mobile MRI scanners. Upon approval of the project, the applicant will own and operate nine fixed MRI scanners in Orange County, not including the UNC Hospitals PET/MR.

(6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-C- The applicant's assumptions and data used to support the methodology for each projection required by this Rule are described in Section III.1, pages 48-61. The assumptions and data used to support the methodology for each projection are reasonable, credible and supported. See Criterion (3) for discussion regarding the applicant's assumptions and data used to support the methodology for each projection which is hereby incorporated by reference.

(c) *An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*

(1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure per hour times 40 hours per week times 52 weeks per year; and*

(2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- The applicant does not propose the acquisition of a fixed dedicated breast MRI scanner.

(d) *An applicant proposing to acquire a fixed extremity MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*

(1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(f)(7); and*

(2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- The applicant does not propose the acquisition of a fixed extremity MRI scanner.

- (e) *An applicant proposing to acquire a fixed multi-position MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for a demonstration project shall:*
- (1) *demonstrate annual utilization of the proposed multi-position MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(g)(7); and*
  - (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- The application does not propose the acquisition of a fixed multi-position MRI scanner for which the need determination in the SMFP was based on an approved petition for a demonstration project.

#### **10A NCAC 14C .2704 SUPPORT SERVICES**

- (a) *An applicant proposing to acquire a mobile MRI scanner shall provide referral agreements between each host site and at least one other provider of MRI services in the geographic area to be served by the host site, to document the availability of MRI services if patients require them when the mobile unit is not in service at that host site.*

-NA- The applicant does not propose the acquisition of a mobile MRI scanner.

- (b) *An applicant proposing to acquire a fixed or mobile MRI scanner shall obtain accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, 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.*

-C- In Section II.8, page 39 of the application, the applicant states:

*“Please see Exhibit 13 for documentation regarding UNC Hospital’s commitment to obtain accreditation for the MRI scanner.”*

Exhibit 13 contains a letter from the UNC Hospitals’ Director of Radiology stating that UNC’s existing MRIs are accredited by the American College of Radiology (ACR) and The Joint Commission. It also states a commitment to obtain ACR accreditation for the proposed scanner.

#### **10A NCAC 14C .2705 STAFFING AND STAFF TRAINING**

- (a) *An applicant proposing to acquire an MRI scanner, including extremity and breast MRI scanners, shall demonstrate that one diagnostic radiologist certified by the*

*American Board of Radiologists shall be available to interpret the images who has had:*

- (1) training in magnetic resonance imaging as an integral part of his or her residency training program; or*
- (2) six months of supervised MRI experience under the direction of a certified diagnostic radiologist; or*
- (3) at least six months of fellowship training, or its equivalent, in MRI; or*
- (4) a combination of MRI experience and fellowship training equivalent to Subparagraph (a)(1), (2) or (3) of this Rule.*

-C- In Section II.1, page 14, the applicant states:

*“UNC Hospitals Department of Radiology provides a tremendous range of magnetic resonance imaging procedures to view all areas of the body. In addition the highly trained staff and physicians perform specialized types of procedures including MRI cardiac morphology, MRI spectroscopy, MRI guidance for needle placement, and MR functional imaging.*

*Matthew Mauro, MD is Professor and Chair of the Department of Radiology. Richard Semelka, MD is the Director of MR Services, Professor and Vice Chair of Clinical Research and Vice Chari of Quality and Safety. The 40 full-time faculty members in the Department of Radiology cover many areas of expertise within interventional and diagnostic radiology. Additional part-time faculty and fellows in the Department provide extensive clinical expertise, research and training related to MRI procedures.”*

In Section II.8, page 39, the applicant refers to Exhibit 14 for a letter of support from a board-certified radiologist who meets all of the above qualifications. Exhibit 14 contains a letter of support from Matthew Mauro, MD, Chairman of the Department of Radiology. Exhibit 30 contains the CVs for Dr. Mauro and Dr. Semelka, among others, documenting Board Certification, training and experience.

In Section VII.6 (b), page 102, the applicant states, “*...the many existing MRI-trained radiologists will staff the proposed additional MRI scanner at UNC Hospitals.*”

In Section VII.7 (a), page 103, the applicant states:

*“Currently the Department of Radiology is staffed with 40 full-time licensed physicians, six part time physicians and six Radiology Fellows. In addition to this, other physicians will utilize the hospital MRI scanners as required by clinical training programs.”*

- (b) *An applicant proposing to acquire a dedicated breast MRI scanner shall provide documentation that:*
- (1) *the radiologist is trained and has expertise in breast imaging, including mammography, breast ultrasound and breast MRI procedures; and*
  - (2) *two full time MRI technologists or two mammography technologists are available with training in breast MRI imaging and that one of these technologists shall be present during the hours operation of the dedicated breast MRI scanner.*

-NA- The proposed project does not involve the acquisition of a dedicated breast MRI scanner.

- (c) *An applicant proposing to acquire a MRI scanner, including extremity but excluding dedicated breast MRI scanners, shall provide evidence of the availability of two full-time MRI technologist-radiographers and that one of these technologists shall be present during the hours of operation of the MRI scanner.*

-C- In Section II.8, page 39, the applicant states,

*“Please see Section VII, page 97 of the application that documents the availability of two full-time MRI technologists and that one of these technologists shall be present during the hours of operation of the MRI scanner.”*

Section VII does not contain page 97, nor does page 97 discuss technologists. However, in Section VII.1, page 98, the applicant provides tables showing current and projected staffing levels, with 36.5 FTE positions shown for MRI technologists in project year two. In Section VII.3(a), page 100, the applicant states:

*“The total of 36.5 FTE MRI technologists will provide continuous availability of service and ensure the availability of two full-time MRI technologists and one or more of these technologists will be present during the hours of operation for all of the existing plus the additional fixed MRI scanner.”*

- (d) *An applicant proposing to acquire an MRI scanner, including extremity and breast MRI scanners, shall demonstrate that the following staff training is provided:*

- (1) *American Red Cross or American Heart Association certification in cardiopulmonary resuscitation (CPR) and basic cardiac life support; and*

-C- In Section II, page 39, the applicant states, *“Please see Exhibit 15 for the letter that documents staff training for CPR and basic cardiac life support.”*

Exhibit 15 does not appear to contain a letter *“that documents staff training for CPR and basic cardiac life support.”* However, Exhibit 15 does contain UNC

Health Care policies relative to staff training and competencies. It also contains copies of employees' certification cards for completion of the American Heart Association BLS for Healthcare Providers (CPR and AED) Program.

(2) *the availability of an organized program of staff education and training which is integral to the services program and ensures improvement in technique and the proper training of new personnel.*

-C- In Section II, page 40, the applicant states that Exhibit 16 contains documentation of staff education and training. Exhibit 16 contains copies of UNC Health Care policies for Employee Safety Education and Training and Orientation. In addition, Exhibit 15 contains policies relative to staff training and competencies.

(e) *An applicant proposing to acquire a mobile MRI scanner shall document that the requirements in Paragraph (a) of this Rule shall be met at each host facility, and that one full time MRI technologist-radiographer shall be present at each host facility during all hours of operation of the proposed mobile MRI scanner.*

-NA- The applicant is not proposing to acquire a mobile MRI scanner.

(f) *An applicant proposing to acquire an extremity MRI scanner, pursuant to a need determination in the State Medical Facilities Plan for a demonstration project, also shall provide:*

- (1) *evidence that at least one licensed physician shall be on-site during the hours of operation of the proposed MRI scanner;*
- (2) *a description of a research group for the project including a radiologist, orthopaedic surgeon, and research coordinator; and*
- (3) *letters from the proposed members of the research group indicating their qualifications, experience and willingness to participate on the research team.*

-NA- The applicant is not proposing to acquire an extremity MRI scanner.

(g) *An applicant proposing to perform cardiac MRI procedures shall provide documentation of the availability of a radiologist, certified by the American Board of Radiology, with training and experience in interpreting images produced by an MRI scanner configured to perform cardiac MRI studies.*

-C- In Section II, page 40, the applicant states:

*“UNC Hospitals currently performs cardiac MRI studies utilizing the existing MRI scanners. The proposed additional 1.5 Tesla scanner will also have cardiac MRI capabilities.*

*UNC Hospitals has multiple radiologists certified by the American Board of Radiology with training and experience in interpreting images produced by an MRI scanner configured to perform cardiac MRI studies. Please see Exhibit 30 for Radiologists' training and certification and credentials."*

Exhibit 30 contains documentation of the required training and experience in interpreting cardiac MRI studies for numerous radiologists.