

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: October 28, 2014

FINDINGS DATE: November 4, 2014

PROJECT ANALYST: Gloria C. Hale

ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: F-10287-14/ OrthoCarolina, PA d/b/a OrthoCarolina Ballantyne/
Acquire one fixed MRI/ Mecklenburg County

F-10292-14/ Presbyterian Hospital Mint Hill, LLC d/b/a Novant
Health Mint Hill Medical Center/ Acquire one fixed MRI scanner/
Mecklenburg County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C - OrthoCarolina Ballantyne

NC - Novant Health Mint Hill

Need Determination

The 2014 State Medical Facilities Plan (2014 SMFP) includes a methodology for determining the need for additional fixed MRI scanners by service area. Application of the need methodology in the 2014 SMFP identified a need for one additional fixed MRI scanner in the Mecklenburg County MRI Service Area. Two applications were submitted to the Certificate of Need Section, each proposing to acquire a fixed MRI scanner for Mecklenburg County. Each proposal is briefly described below.

OrthoCarolina, PA d/b/a OrthoCarolina Ballantyne (OrthoCarolina Ballantyne) - proposes to acquire one fixed MRI scanner to operate at its OrthoCarolina Ballantyne location in Charlotte in Mecklenburg County. The applicant, OrthoCarolina, PA, provides outpatient orthopedic care to patients at 33 locations throughout the state. OrthoCarolina, PA owns and operates one fixed MRI scanner at its OrthoCarolina Spine Center location in Mecklenburg County and one mobile MRI scanner which it operates at three sites in Mecklenburg County: OrthoCarolina Huntersville, OrthoCarolina Ballantyne, and OrthoCarolina Spine Center. In addition, OrthoCarolina, PA provides mobile MRI services, through a service agreement with Alliance Imaging, at three of its locations in Mecklenburg County: OrthoCarolina Spine Center, OrthoCarolina Matthews, and OrthoCarolina University. The applicant states, in Section I, page 15, that the Ballantyne location provides services four days per week, 12 hours per day and is “*OrthoCarolina’s highest volume mobile MRI site*”. The applicant proposes to reallocate the mobile MRI days currently used at the Ballantyne location to its Spine Center and Huntersville locations. OrthoCarolina Ballantyne does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2014 SMFP for Mecklenburg County. Therefore, the application is consistent with the need determination.

Presbyterian Hospital Mint Hill, LLC d/b/a Novant Health Mint Hill Medical Center (Novant Health Mint Hill) proposes to acquire one fixed MRI scanner to operate at Novant Health Mint Hill Medical Center, a CON-approved but not yet developed 50-bed acute care hospital to be located in Mint Hill (Project I.D. #F-7648-06). The parent company of Novant Health Mint Hill, Novant Health, Inc., owns and operates nine fixed MRI scanners and operates two mobile MRI scanners at two sites in Charlotte in Mecklenburg County and one site in Mooresville in Iredell County. Novant Health Mint Hill does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2014 SMFP for Mecklenburg County. Therefore, the application is consistent with the need determination.

Policies

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. Both policies are located on page 38 of the 2014 SMFP.

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 applicants responded to Policy GEN-3 as follows:

OrthoCarolina Ballantyne

Promote Safety and Quality

In Section III.2, page 49, the applicant discusses its safety and quality improvement benefits. The applicant states:

- *“One of the most important goals of the project is to provide MRI capacity that will safely provide high quality scans and timely utilization.”*
- *The MRI equipment installation will be completed in accordance with all local, state and federal requirement regarding MRI safety, electrical safety and building codes.*
- *Staff training, continued ACR accreditation, and the continued use of performance improvement policies will ensure quality service and high levels of patient and physician satisfaction.”*

In addition, the applicant states, in Section II.7, page 20, that OrthoCarolina has a quality assurance policy that includes *“ongoing review for quality, correct imaging parameters, and slice positioning that includes review of films with Victor Ho, MD radiologist.”* An annual physics evaluation of each MRI scanner is planned along with the implementation of the manufacturer’s maintenance service agreements to further ensure and maintain quality of care. Lastly, patient satisfaction surveys are also administered. The applicant provides its quality assurance and safety policies in Exhibit 10 and its corporate compliance/risk management policy in Exhibit 12.

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

Promote Equitable Access

In Section III.2, page 49, the applicant discusses how they will promote equitable access. The applicant states:

- *“OrthoCarolina intends to add MRI capacity at OC Ballantyne and provide MRI procedures with contrast.*

- *The proposed project will reduce the need for OrthoCarolina patients to be referred to other MRI scanners due to limitations of the existing schedule of the mobile MRI.*
- *OrthoCarolina will continue to provide a broad range of MRI procedures to all payor categories of patients regardless of their ability to pay for services.”*

In addition, in Section VI.2, page 65, the applicant states that it “*does not discriminate against anyone due to age, race, color, religion, ethnicity, gender, disability, or ability to pay.*” Moreover, OrthoCarolina provides access to MRI services through Physician Reach Out and Care Ring to provide specialty care to uninsured patients and also provides care to low income and uninsured patients at the CMC Myers Clinic. Documentation for these two programs is provided in Exhibits 21 and 22, respectively. Furthermore, the applicant provides a copy of its financial and charity care policies in Exhibit 23.

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

Maximize Healthcare Value

In Section III.2, page 49, the applicant states how the proposed project will maximize healthcare value. The applicant states:

- *“The proposed 1.5T MRI scanner has an excellent range of capabilities and will be covered by a warranty in the first year to reduce maintenance costs.*
- *OrthoCarolina staff will be trained to utilize the new scanner to support clinical excellence, higher staff productivity and patient safety.*
- *OC Ballantyne has the existing facilities, support staff and resources to implement the proposed fixed MRI scanner which will improve overall cost effectiveness.*
- *OrthoCarolina has extensive experience in managing MRI services in a cost effective manner. No increases in MRI charges are predicted for the first three years of operation.”*

OrthoCarolina Ballantyne adequately demonstrates the need the population to be served has for the proposed fixed MRI scanner. The applicant adequately demonstrates that projected utilization of the proposed fixed MRI scanner is based on reasonable, credible and supported assumptions. See Section III.1 of the application. Therefore, OrthoCarolina Ballantyne adequately demonstrates that the proposal would maximize healthcare value for resources expended.

Novant Health Mint Hill

Promote Safety and Quality

In Section III.2, page 67, and in Exhibit 14, the applicant discusses how it will promote safety and quality. The applicant states, on page 67:

“NHMHMC [Novant Health Mint Hill Medical Center] will have, similar to the other Novant Health acute care facilities in Mecklenburg County, a focused quality management program dedicated to ongoing quality assessment and improvement to provide high quality, cost-effective health care that meets the needs of all patients and enhances clinical effectiveness and health outcomes for the population.”

In addition, Exhibit 14 includes sample policies and procedures from three of its acute care hospitals in Mecklenburg County and two policies from Novant Health, Inc. The applicant states, on page 67, that the Novant Health Mint Hill facility will actively participate in these, *“including those applicable to MRI diagnostic imaging programs.”* The policies include a Clinical Improvement & Patient Safety Plan, Infection Prevention Plan, a Risk Management Plan and Utilization Review Plan.

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

Promote Equitable Access

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

“The primary focus for this project is improving geographic access to MRI services for residents in Eastern Mecklenburg County and the surrounding areas. The fixed MRI scanner is the only MRI scanner operating in the Mint Hill service area of Mecklenburg County, an area that has seen significant population growth in recent years. The proposed project ...brings these services much closer to a population that is underserved and lacks local access to an MRI scanner.”

In Section III.2, page 68, the applicant states that instead of having a mobile MRI scanner at Novant Health Mint Hill a few days a week as it had originally planned in its CON-approved project to develop the Novant Health Mint Hill Medical Center (Project I.D. #F-7648-06), its proposal for a fixed MRI scanner *“will promote enhanced and expanded local access to the residents of the 5-zip code Mint Hill service area.”*

In addition, in Exhibit 6, the applicant provides copies of Novant Health’s Charity Care policies and the Novant Health Medical Group Charity Care policy which it states will be in effect once the Novant Health Mint Hill Medical Center, along with the proposed fixed MRI scanner, become operational.

Moreover, the applicant states, in Section VI.2, on page 105,

“It is the policy of all the Novant Health facilities and programs, including Novant Health Mint Hill Medical Center, to provide necessary services to all individuals without regard to race, creed, color, or handicap. Novant Health facilities and programs do not discriminate against the above-listed persons, or other medically underserved persons, regardless of their ability to pay.”

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

Maximize Healthcare Value

In Section III.2, pages 73-75, the applicant discusses how the proposed project will maximize healthcare value. On page 74, the applicant states that Novant’s “*Payer Neutral Revenue (PNR) System*”, in which all payers are considered “*as if they were Medicare*” to prepare for lower payer reimbursement levels from all payers, and its “*Remarkable Patient Experience*” strategy, resulting in improved services, will continue to decrease costs and improve quality. As stated on page 74,

“Novant’s goal was and continues to be to develop services that are:

- *Safer and higher quality*
- *More patient-focused*
- *More integrated*
- *More affordable”*

In addition, on page 75, the applicant states that Novant Health employs various environmental protection methods that “*...supports Novant Health’s mission to ‘improve the health of communities and results in cost savings, which helps Novant Health achieve affordability...’*”

However, the applicant does not demonstrate how its projected volumes incorporate these concepts in meeting the need identified in the SMFP and, therefore, does not demonstrate how it maximizes healthcare value for resources expended. The discussion regarding historical and projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is not consistent with Policy GEN-3 and is not conforming to this criterion.

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."

OrthoCarolina Ballantyne - In Section III.2, page 50, the applicant states that its project architect and facility engineering and administration departments will research and develop "*specific design features to ensure improved energy efficiency and water conservation*" and discusses how the proposed project will address energy efficiency and sustainability for health services facilities through the following systems and features:

- Lighting systems, water systems, and heating, ventilation, and air-conditioning systems – the areas to be renovated for the project will provide higher energy efficiency, including water conservation standards, in accordance with the North Carolina State Building Codes. These include "*energy efficient LED lighting*" and modifications, additions, or upgrades to water systems, hand wash facilities, and toilets.
- "*Minor Equipment will be evaluated prior to purchase and implementation based on energy efficiency and water conservation.*"
- "*Operational policies and systems related to the building including staff training, preventive maintenance, environmental services and landscape maintenance will be followed to promote energy efficiency and water conservation.*"

The applicant further states, on page 50, "*The changes will not adversely affect patient or resident health, safety or infection control.*"

In summary, the application is consistent with the need determination in the 2014 SMFP and Policy GEN-4. Therefore, the application is conforming to this criterion.

Novant Health Mint Hill – Exhibit 12 contains a copy of Novant Health’s Sustainable Energy Management Plan, dated May 2, 2014. The applicant states, in Section III.2, page 76, that this plan “*will be applicable when NHMHMC [Novant Health Mint Hill Medical Center] opens.*” The plan’s Executive Summary, included in Exhibit 12, states,

“Novant Health proposes to improve the efficient use of energy resources by creating and implementing an effective Sustainable Energy Management Plan. This plan and its implementation will demonstrate both fiscal and environmental responsibility to our employees, patients, visitors and the general public. Our energy management program will target operating cost reduction, promote stewardship of natural resources, and enhance patient satisfaction. Novant Health’s Sustainable Energy Management Plan aligns with our Brand Promise to make the healthcare experience simpler, more convenient, and more affordable.”

Further, the applicant states, on page 76,

“This plan is a starting point for this future requirement. In addition, upon approval of this project and as construction/renovation is beginning, NH Mint Hill Medical Center will work with DHSR Construction Section to ensure that NHMHMC’s plan addresses energy efficiency and water conservation, in a manner conforming to the rules, codes and standards of the DHSR Construction Section.”

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.

In summary, the application is consistent with the need determination in the 2014 SMFP and Policy GEN-4, but is not consistent with Policy GEN-3. Consequently, the application is not conforming to this criterion.

Conclusion

Both applications are conforming to the need determination in the 2014 SMFP for an additional MRI scanner in Mecklenburg County. However, the limit on the number of MRI scanners that may be approved in this review is one MRI scanner. Collectively, the two applicants propose a total of two MRI scanners. Therefore, even if both applications are conforming to all statutory and regulatory review criteria, both applications cannot be approved.

Both applications are conforming to Policy GEN-4.

OrthoCarolina Ballantyne’s application is conforming to Policy GEN-3. Novant Health Mint Hill’s application is nonconforming to Policy GEN-3.

Therefore, the OrthoCarolina Ballantyne application is conforming to this criterion and the Novant Health Mint Hill application is nonconforming to this criterion.

See the Summary following the Comparative Analysis for the decision.

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

C - OrthoCarolina Ballantyne
NC - Novant Health Mint Hill

OrthoCarolina Ballantyne proposes to acquire one fixed MRI scanner to expand outpatient MRI services. Existing mobile MRI services at the Ballantyne location will be reallocated to OrthoCarolina's Spine Center and Huntersville sites. Through the planned acquisition of a fixed, wide bore MRI scanner, the needs of obese patients will be addressed and an increased number of contrast MRI procedures will be able to be performed. The proposed imaging services would operate 12 hours a day, six days a week, for a total of 72 hours per week. The applicant proposes to add a modular unit adjacent to the OrthoCarolina Ballantyne office to accommodate the fixed MRI scanner. In Section II, page 17, the applicant states, "*The space is in close proximity to the existing MRI waiting, registration and support spaces.*"

The applicant already owns and operates one fixed MRI scanner at OrthoCarolina Spine Center in Charlotte and one mobile MRI scanner that is utilized at three host sites, OrthoCarolina Spine Center, OrthoCarolina Huntersville and OrthoCarolina Ballantyne in Mecklenburg County, as stated in Section I, page 7. In addition, as stated in Section I, page 8, OrthoCarolina, PA provides mobile MRI services to the following three locations through a service agreement with Alliance Imaging: OrthoCarolina Spine Center, OrthoCarolina Matthews, and OrthoCarolina University.

Population to be Served

In Sections III.4 and III.5, pages 52-53, the applicant provides the current and projected patient origin for fixed MRI services at OrthoCarolina Ballantyne, as illustrated in the following table:

County or States*	FY13 Percent of Total	1st Operating Year CY 2016 Percent of Total**	2nd Operating Year CY 2017 Percent of Total**
Mecklenburg	46.02%	46.01%	46.02%
Union	20.38%	20.38%	20.38%
Gaston	0.68%	0.67%	0.67%
Cabarrus	0.23%	0.25%	0.24%
Anson	0.23%	0.25%	0.24%
Iredell	0.18%	0.18%	0.17%
Stanly	0.18%	0.18%	0.17%
Cleveland	0.12%	0.11%	0.11%
Other NC*	0.53%	0.57%	0.54%
South Carolina	30.98%	30.98%	30.99%
Other States	0.47%	0.48%	0.47%
Total	100.00%	100.00%	100.00%

*Other counties include Brunswick, Catawba, Craven, Davidson, Forsyth, Lincoln, McDowell, Pitt, Rutherford, Swain, Transylvania, and Wake. Other States include GA, CO, FL, IA, MI, NY, OH, PA, TX.

**Percentages calculated by Project Analyst based on data provided on page 53.

As illustrated in the table above, the applicant does not project a change in the patient origin for the proposed fixed MRI scanner.

The applicant adequately identifies the population to be served.

Need Analysis

In Section III.1, pages 34-40, the applicant states the need for the proposed fixed MRI scanner at the OrthoCarolina Ballantyne location is based on the following factors:

- *“The 2014 State Medical Facilities Plan includes a need determination for an additional fixed MRI scanner in Mecklenburg County based on the standard methodology. [see page 35]*
- *The growth and aging of the population of Mecklenburg County is expected to increase demand for healthcare services, including MRI procedures. [see pages 35-36]*

- *Physician recruitment will increase utilization of MRI at the OrthoCarolina Ballantyne office. [see page 37 and Exhibits 13 and 15]*
- *The high utilization of the existing fixed and mobile MRI scanners owned by OrthoCarolina is causing scheduling backlogs. [see pages 38-39]*
- *The acquisition of the fixed MRI scanner will allow OrthoCarolina to change the schedule for the existing mobile MRI scanner to provide increased days of service and access at the OrthoCarolina Spine Center and OrthoCarolina Huntersville offices. [see page 40]”*

Projected Utilization

Step 1:

In Section IV.1, pages 39-48, the applicant provides the assumptions and methodology used to project utilization for each of its MRI scanners, and states it is using a conservative annual growth rate that is less than the compound annual growth rates (CAGRs) of each of its MRI scanners. However, the 2% annual growth rate the applicant uses to project utilization in years 2013-2014 and 2014-2015 for its fixed MRI scanner and the two mobile MRI scanners utilized at its Spine Center is higher than the corrected CAGR of 0.25% calculated by the Project Analyst. The applicant provides utilization projections for each of its MRI scanners on page 41, illustrated in the following table:

OrthoCarolina Fixed and Mobile MRIs in Mecklenburg County	2010- 2011	2011- 2012	2012- 2013	CAGR	Assumption of annual growth for current and interim years	Current	Interim
						2013- 2014	2014- 2015
Ballantyne OrthoCarolina (OC) Mobile	2,260 [2,560]	3,108	3,768	29.12% [21.32%]	5%	3,956	4,154
Spine Center MRI Totals	9,408 [10,067]	10,377	10,118	3.70% [0.25%]	2%	10,320	10,527
a. OC Fixed	7,985	8,260	8,037		2%	8,198	8,260
b. OC Mobile	1,423 [1,432]	1,323 [794]	584		2%	596	608
c. Alliance Mobile Units	0 [650]	794 [1,323]	1,497		2%	1,527	1,658
Huntersville OC Mobile	1,215	1,667	1,511	11.52%	3%	1,556	1,603
University OC (Alliance Mobile Units)	1,181	1,393	1,298	4.84%	2%	1,324	1,350
Matthews OC (Alliance Mobile Units)	768	362	1,292	29.70%	5%	1,357	1,424
Total OC Fixed and Mobile MRI in Mecklenburg County	14,832 [15,791]	16,907	17,987	10.12% [6.73%]		18,514	19,059
						2.9%	2.9%

*Totals may not foot due to rounding. Corrections made by the Project Analyst are in brackets.

In Section IV.1, page 41, the applicant stated that it used a conservative growth rate assumption for 2013-2014 and “...then at max of 8260” for 2014-2015 for the projected utilization for its fixed MRI scanner at the Spine Center. Once the maximum of 8,260 MRI scans is reached, the “...overflow from OC Fixed” would be performed by the mobile MRI scanner operated by Alliance Imaging at the Spine Center. However, as stated above, the applicant’s annual growth rate used for projecting utilization of the Spine Center’s MRI scanners was not less than the corrected CAGR as the applicant states in its assumptions. If an annual growth rate was used that was equal to or lower than the corrected CAGR of 0.25%, a maximum of 8,260 scans would not be reached in fiscal year 2014-2015.

Step 2:

The applicant adjusts the projections based on a project start date of January 1, 2016, stating, in Section III, page 42, “The historical data and the projections in Step 1 are based on the October 1 through September 30 reporting periods.”

The applicant describes the assumptions used in calculating the calendar year 2014 MRI utilization in Step 2a, page 42, and Step 2b, page 43, as follows:

Step 2a: *“The CY 2014 MRI scan volumes are based on Step 1 Values for 2013-14 multiplied times 0.75 plus the 2014-15 scan values multiplied times 0.25. The 0.75 factor is based on 9 months (Jan to Sept 2014) of the 12 month period in Step 1 for Current Year. The 0.25 factor is based on 3 months (Oct to Dec 2014) of the 12 month period in Step 1 for Interim Year”*

Step 2b: *“provides the Calendar Year 2015 projections. The CY 2015 MRI scan volumes are based on the same annual growth assumptions as provided in Step 1 above except once the OC Spine Center fixed MRI reaches maximum [sic] utilization the Alliance mobile MRI increases by 9.5% due to shift of MRI procedures.”*

In addition, in regard to the calendar year 2015 projections for the Spine Center’s fixed MRI scanner, the applicant states, on page 43,

“The fixed OC MRI reached maximum capacity 8260 based on 99 hrs per week.”

In regard to the calendar year 2015 projections for the Spine Center’s Alliance Mobile MRI, the applicant states, on page 43,

“The Alliance mobile MRI is used to perform the ‘overflow’ MRI cases that do not have to be performed on the OC Spine fixed MRI that require contrast.”

The applicant provides the projected interim MRI utilization for CY 2015 on page 43, illustrated as follows:

	Current CY 2014	Annual Growth Assumptions for Interim CY 2015	Interim CY 2015
Ballantyne OrthoCarolina (OC) Mobile	4,006	5%	4,206
Spine Center MRI Totals	10,372	2.0%	10,579
a. OC Fixed	8,213	0.6%	8,260
b. OC Mobile	599	2.0%	611
c. Alliance Mobile Units	1,560	9.5%	1,708
Huntersville OC Mobile	1,568	3.0%	1,615
University OC (Alliance Mobile Units)	1,331	2.0%	1,357
Matthews OC (Alliance Mobile Units)	1,374	5.0%	1,442
Total OC Fixed & Mobile in Mecklenburg County	18,650		19,200

Totals may not foot due to rounding.

Step 3:

The following table, from page 44, provides the applicant's growth assumptions and projected utilization for the first three years of the project, adjusted for calendar years:

	Interim CY 2015	Growth Assumptions for Years 1, 2 and 3 Following Installation of Fixed MRI	Year 1 CY 2016	Year 2 CY 2017	Year 3 CY 2018
Ballantyne OrthoCarolina (OC) Mobile MRI, then fixed MRI Yrs. 1-3	4,206	Installation Fixed MRI; 5% annual growth	4,416	4,637	4,869
Spine Center MRI Totals	10,579	2% annual growth	10,791	11,007	11,227
a. OC Fixed	8,260	At maximum capacity of 8,260	8,260	8,260	8,260
b. OC Mobile	611	Add 3 days/week to serve 20% total OC Spine Center MRI scans	2,158	2,201	2,245
c. Alliance Mobile Units	1,708	Decrease to 1 day/week to serve 3.5% (Yr.1), 5.0% (Yr.2) and 6.4% (Yr.3) of total OC Spine Center MRI scans	373	545	722
Huntersville OC Mobile	1,615	Add 1 day/week; 3% annual growth	1,663	1,713	1,765
University OC (Alliance Mobile Units)	1,357	No change in # of days; 2% annual growth	1,384	1,412	1,440
Matthews OC (Alliance Mobile Units)	1,442	No change in # of days; 2% annual growth	1,471	1,501	1,531
Total OC Fixed & Mobile in Mecklenburg County	19,200		19,726	20,270	20,832

The applicant provides the following assumptions, on page 44, to project OrthoCarolina's MRI utilization for each of the first three years following project completion,

“The proposed fixed MRI increases at 5 percent annually consistent with the assumptions for previous years and less than the CAGR percentage. Once the fixed MRI scanner is installed at Ballantyne the OC mobile MRI will be scheduled to be utilized at the Spine Center 3 additional days per week and utilized at OC Huntersville one additional day per week.

Consistent with the previous Step 2, the OC Spine Center’s total combined MRI utilization increases by 2 percent annually and the fixed MRI remains at its maximum capacity of 8,260 annual MRI scans. Once the fixed MRI is installed at OC Ballantyne the OC mobile MRI will add three days of service per week at the Spine Center (for a total of 4 days / week). The OC mobile MRI will perform an estimated 20 percent [sic] the total Spine Center MRI procedures. As a result OC Spine Center will have less need to utilize the Alliance mobile MRI scanners. Therefore, the Alliance MRI scanner will be reduced to one day per week to perform the remaining overflow MRI which is projected at 3.5 percent, 5.0 percent and 6.4 percent of the total OC Spine Center volume.

OC Huntersville will also gain one additional day of service from the OC mobile MRI (for a total of 3 days / week) with 3 percent annual growth in utilization.

OC University and OC Matthews will continue to obtain mobile MRI service with Alliance with annual increases of 2 percent and 5 percent respectively.”

Step 4:

The following table, from page 46, provides the breakdown of MRI procedures with and without contrast for OrthoCarolina’s existing and proposed fixed MRI scanners and its mobile scanner:

	YR 1	YR 2	YR 3	%
Ballantyne OC Proposed Fixed MRI				
with contrast	856	898	943	19.4%
without contrast	3,561	3,739	3,926	80.6%
Total	4,416	4,637	4,869	100.0%
Spine Center OC Existing Fixed MRI				
with contrast	1,600	1,600	1,600	19.4%
without contrast	6,660	6,660	6,660	80.6%
Total	8,260	8,260	8,260	100.0%
Mobile OC Existing MRI				
with contrast	109	112	114	2.8%
without contrast	3,713	3,803	3,896	97.2%
Total*	3,822	3,915	4,010	100.0%

*Includes OC mobile MRI scanner procedures from the Spine Center and Huntersville locations.

The applicant provides the assumptions for calculating the weighted MRI procedures in the above table on page 46, as follows:

“The applicant assumes that all MRI procedures will be outpatient scans (no inpatient MRIs are performed) and that the percentage mix at OC Ballantyne will be 19.4 percent with contrast and 80.6 percent without contrast based on the historical data for the existing fixed MRI at the OC Spine Center. The OC mobile MRI is expected to have 2.8 percent with contrast and 97.2 percent without contrast consistent with its historical utilization data for 2012-13. MRI total volumes for each MRI scanner are from Step 3.” (Emphasis in original)

Step 4b:

The applicant applies the weighting factor of 0.4 to the MRI procedures with contrast to obtain the total weighted MRI procedures for the proposed fixed MRI scanner, its existing MRI scanner and its mobile MRI scanner, illustrated as follows:

	YR 1	YR 2	YR 3
Ballantyne OC Proposed Fixed MRI			
with contrast	1,198	1,258	1,320
without contrast	3,561	3,739	3,926
Total	4,759	4,997	5,246
Spine Center OC Existing Fixed MRI			
with contrast	2,240	2,240	2,240
without contrast	6,660	6,660	6,660
Total	8,900	8,900	8,900
Mobile OC Existing MRI			
with contrast	152	156	160
without contrast	3,713	3,803	3,896
Total	3,865	3,959	4,056

As shown in the table above, OrthoCarolina Ballantyne projects that its proposed fixed MRI scanner at its Ballantyne location and its existing fixed MRI scanner at its Spine Center will exceed 4,805 weighted MRI procedures in the third year of the project as required by 10A NCAC 14C .2703(b)(3). The applicant’s existing mobile MRI scanner is projected to exceed 3,328 weighted MRI procedures in the third year of the project as required by 10A NCAC 14C .2703(b)(2).

Although the applicant's growth assumption for projecting utilization of its fixed MRI scanner at the Spine Center for the project's interim and operational years was based on an error in calculating the CAGR, the Spine Center's fixed MRI scanner's current utilization of 8,037 in fiscal year 2012-2013, on page 41, far exceeds the performance standard of 4,805 MRI procedures required in 10A NCAC .2703(b)(3). Furthermore, based on the Spine Center's fixed MRI scanner's corrected CAGR of 0.33%, as calculated by the Project Analyst, the utilization of this scanner would still be expected to increase through the first three operating years of the proposed MRI scanner and continue to meet the performance standard.

In addition, it is reasonable to expect an increase in the use of the Spine Center's OrthoCarolina mobile MRI scanner due to the reallocation of three days of mobile MRI services from the OrthoCarolina Ballantyne location to the Spine Center and the decrease of the use of the Alliance mobile MRI unit there to one day per week. It is also reasonable to expect an increase in the use of OrthoCarolina's mobile MRI scanner due to the reallocation of one day of mobile MRI services to the Huntersville location. Therefore, it is reasonable to expect increased access to the OrthoCarolina mobile MRI scanner due to an increase in availability of mobile MRI services at the Spine Center and the Huntersville locations.

Access

In Section VI, pages 65-66, the applicant states that is committed to providing access to its services to all underserved groups, including patients with low incomes, Medicaid patients, indigent and charity care patients, racial and ethnic minorities, women, persons with disabilities, elderly persons, and all other underserved persons. In addition, in Section VI.15, page 71, the applicant projects that 22.8% of OrthoCarolina Ballantyne's MRI patients will be covered by Medicare (20.1%) and Medicaid (2.7%).

Conclusion

In summary, the applicant adequately identified the population to be served and adequately demonstrates the need the population to be served has for the proposed fixed MRI scanner. Furthermore, the applicant adequately demonstrates the extent to which all residents of the area, including medically underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

Novant Health Mint Hill - proposes to acquire one fixed MRI scanner and operate it at its CON-approved 50-bed acute care hospital (Project I.D. #F-7648-06), Novant Health Mint Hill Medical Center, to be located in the eastern portion of Mecklenburg County. Novant Health Mint Hill Medical Center has not yet been developed, however according to its most recent progress report dated April 3, 2014, the hospital will begin offering services on December 31, 2017. In its application to develop the hospital, Novant Health proposed to obtain MRI services on site from a mobile MRI provider two to three days a week. The applicant now proposes to use the fixed MRI scanner instead of mobile MRI services.

Population to be Served

In Section III.1, page 44, the applicant states that its proposed service area will be a five zip code area surrounding Novant Health Mint Hill Medical Center, stating that the service area is consistent with the service area proposed for the development of the hospital (Project I.D. #F-7648-06). The zip code areas, provided on page 44, are as follows:

*“28227 – Mint Hill
28213 – Charlotte
28215 – Charlotte
28075 – Harrisburg (Cabarrus County)
28107 – Midland (Cabarrus County)”*

In Section III.4(a), page 78, the applicant provides the projected patient origin for the proposed fixed MRI scanner at Novant Health Mint Hill Medical Center, illustrated as follows:

Zip Code Areas	% Patient Origin
28227 - Mecklenburg	23.5%
28215 - Mecklenburg	45.1%
28213 - Mecklenburg	15.1%
28107 - Cabarrus	2.7%
28075 - Cabarrus	3.5%
Other In-migration*	10.0%
Total	100.0%

**Includes “zip codes in Mecklenburg and Cabarrus Counties outside the Mint Hill 5-Zip Code Primary Service Area”*

Therefore, the applicant projects that the majority of its MRI patients, 83.7%, will come from Mecklenburg County and 6.2% will come from Cabarrus County.

The applicant adequately identified the population to be served.

Need Analysis

In Section III.1, pages 44-59, the applicant states that the need for the proposed fixed MRI scanner at Novant Health Mint Hill is based on the following factors:

- *“Increasing Population in the NHMHMC Service Area [see pages 44-46];*
- *Increasing Population in Mecklenburg and Contiguous Counties [see pages 47-49];*

- *Growth in Business, Housing, and Transportation in the NHMHC Primary Service Area* [see pages 50-55];
- *Projected Need for one Fixed MRI Scanner in Mecklenburg County in 2014 SMFP* [see page 55];
- *Anticipated MRI Utilization at NHMHC* [see pages 57-59]; and
- *Physician Support for Fixed MRI Services at NHMHC* [see Exhibit 4]”

Projected Utilization – Novant Health Mint Hill

In Section III.1, pages 57-59, the applicant provides projected utilization for the proposed fixed MRI scanner at Novant Health Mint Hill.

On page 57, the applicant states that since Novant Health Mint Hill Medical Center is not yet developed, and thus has no historical utilization of MRI services, it bases its projections on historical MRI data from its acute care hospitals and outpatient imaging centers in Mecklenburg County.

Step 1:

On page 57, the applicant states that it expects the proposed fixed MRI scanner to become operational on 1/01/2018 and that its MRI patients will come from Novant Health Mint Hill’s five zip code primary service area, which consists of zip codes 28213, 28215, 28227, 28075, and 28107. Also on page 57, the applicant states that over 2,700 residents of the primary service area utilized MRI services at Novant Health facilities during CY 2013.

Step 2:

The applicant utilizes a CAGR of 1.56%, based on the population growth of the primary service area between 2010 and 2020, to project the number of MRI patients at Novant Health Mint Hill for CY2013-CY2020. The applicant provides the population data used to calculate the CAGR, on page 46, as follows:

City	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	CAGR*
28075 Harrisburg -C	16,143	16,497	16,185	17,204	17,558	17,912	18,266	18,619	18,973	19,327	19,681	2.00%
28107 Midland-C	6,422	6,470	6,518	6,566	6,614	6,662	6,710	6,758	6,806	6,854	6,902	0.72%
28213 Charlotte - M	37,309	38,069	38,829	38,588	40,248	41,108	41,868	42,627	43,387	44,147	44,907	1.87%
28215 Charlotte - M	53,269	54,433	55,237	56,040	56,844	57,648	58,542	59,255	60,059	60,863	61,667	1.47%
28227 Mint Hill - M	49,635	50,409	51,182	51,956	52,370	53,503	54,277	55,051	55,824	56,598	57,372	1.46%
Totals*	162,778	165,878	167,951	170,354	173,634	176,833	179,663	182,310	185,049	187,789	190,529	1.59%

*Totals and CAGRs calculated by Project Analyst.

"Sources: Year 2010 – www.zip-code.com 2010 zeta database

Growth Rates = Sg2 Market Demographics"

On page 57, the applicant provides the projected number of MRI patients from Novant Health Mint Hill's primary service area as follows:

**Novant Health MRI Patients
from Proposed Primary Service Area**

Year	# of MRI patients	Population Growth Factor
CY 2013 – Actual	3,221	
CY 2014 – Estimated	3,271	1.56%
CY 2015 - Estimated	3,322	1.56%
CY 2016 - Estimated	2,274	1.56%
CY 2017 - Estimated	3,427	1.56%
CY 2018 - Estimated	3,480	1.56%
CY 2019 - Estimated	3,534	1.56%
CY 2020 - Estimated	3,590	1.56%

'Source: CY2013 MRI patient data collected from Novant Health facilities (hospitals & imaging centers) for the Primary Service Area. Population data from Sg2'

Step 3:

The applicant estimates that 55% of the projected number of MRI patients from the primary service area will shift from other Novant Health facilities to Novant Health Mint Hill in Project Year 1 (CY2018), 70% in CY2019, and 80% in CY2020, as depicted in the following table from page 58:

Project Year	Estimated MRI Patients	Projected Market Capture	Projected Number of MRI Patients
CY2018	3,480	55%	1,914
CY2019	3,534	70%	2,476 [2,474]
CY2020	3,590	80%	2,872

The applicant provides its assumptions for the “*market capture*” of its primary service area as follows from page 58:

- *“there are no existing fixed MRI scanners in the five zip code service area;*
- *Projected population growth in the defined zip code service area is projected to exceed 16% between 2010 and 2020;*
- *NHMHMC will offer a choice for fixed MRI services in the suburban Charlotte market area;*
- *The proposed location adjacent to the I-485 Beltway will result in ease of access to existing population; and*
- *The new I-485 Beltway will result in population growth in areas of the zip codes closer to NHMHMC.”*

Step 3a:

The applicant anticipates there will be 10% in-migration of MRI patients from other areas outside of the primary service area and states, “*This percentage is consistent with NHMHMC’s prior CON application to develop the acute care facility in Mint Hill (CON Project I.D. #F-7648-06).*” The addition of in-migration MRI patients is illustrated in the following table from page 58:

Project Year	Projected Number of MRI Patients from Primary Service Area	Number of In-migration MRI Patients	Estimated Total Number of MRI Patients
CY2018	1,914	213	2,127
CY2019	2,474	275	2,691 [2,749]
CY2020	2,872	319	3,191

Step 4:

The applicant applies a MRI scan ratio of 1.26, based on the average number of scans per patient at all four of its acute care facilities in Mecklenburg County during CY2013, to the estimated total number of MRI patients to obtain the unweighted MRI volume, as follows:

Project Year	Estimated Total Number of MRI Patients	Average Number of Scans per Patient	Estimated Unweighted MRI Volume
CY2018	2,127	1.26	2,680
CY2019	2,749	1.26	3,464
CY2020	3,191	1.26	4,021

Step 5:

As discussed on page 59, the applicant determined the percentages of inpatient and outpatient MRI scans, and percentages of contrast studies, performed at two of its community hospitals in Mecklenburg County, Novant Health Matthews Medical Center and Novant Health Huntersville Medical Center, in CY2013. The applicant then calculated the averages of these percentages and applied them to the unweighted MRI volume to determine the weighted MRI volume for Novant Health Mint Hill.

Step 6:

The applicant provides the weighted volume for Novant Health Mint Hill in the following table:

Project Year	Unweighted MRI Volume	Inpatient MRI Volume	Outpatient MRI Volume	Total Contrast Scans	Inpatient Adjustment	Contrast Adjustment	Weighted MRI Volume
		17.45%	82.55%	38.2%			
CY2018	2,680	468	2,212	1,024	187.2	409.6	3,277 [3,191]
CY2019	3,464	605	2,859	1,323	242.0	529.2	4,235
CY2020	4,021	702	3,319	1,536	280.8	614.4	4,916

Projected Utilization – Other Novant Health Hospitals

In Section III.1, pages 60-62, the applicant provides projected utilization for Novant Health's other acute care hospitals located in Mecklenburg County.

Step 1:

The applicant provides the historical unweighted MRI volume for each of its acute care facilities in Mecklenburg County, as follows:

Facility	CY2010	CY2011	CY2012	CY2013	% Distribution
Novant Health (NH) Presbyterian Medical Center	8,472	8,512	8,124	8,374	36.4%
NH Huntersville Medical Center	6,160	6,010	6,372	6,099	26.5%
NH Matthews Medical Center	6,371	6,138	5,684	5,421	23.5%
NH Charlotte Orthopedic Hospital	3,144	2,718	1,845	3,138	13.6%
Totals	24,147	23,378	22,025	23,032	
Annual Growth Rate*		-3.18%	-5.79%	4.57%	

"Source: Trendstar Internal MRI data for each facility."

*Project Analyst calculated annual growth rates.

Step 2:

The applicant states that the growth rate in total unweighted MRI procedures for the facilities listed in Step 1 was 4.6% from CY2012 and CY2013. The applicant applied the 4.6% growth rate to the total CY2013 volume for its hospitals in Mecklenburg County and for each subsequent project year to obtain the following total unweighted MRI volumes by project year:

Year	Total Unweighted MRI Volume	Percent Change
CY2014 - Interim	24,091	4.6%
CY2015 - Interim	25,200	4.6%
CY2016 - Interim	26,359	4.6%
CY2017 - Interim	27,571	4.6%
CY2018 - Year 1	28,840	4.6%
CY2019 - Year 2	30,166	4.6%
CY2010 - Year 3	31,554	4.6%

However, the applicant does not adequately demonstrate that the 4.6% projected growth rate is reasonable and adequately supported. The total unweighted MRI procedures performed at its acute care facilities with fixed MRI scanners actually declined from CY2010 to CY2011 by -3.18% and by -5.79% from CY2011 to CY2012 as depicted in the table in Step 1 above. The 4.6% growth rate that was used to project utilization is the percent change in total unweighted MRI volume between CY2012 and CY2013. Of the

three annual periods that change can be calculated for, that is the only period showing positive growth. The applicant does not adequately explain why it provided three years of data but chose to rely only on the one year that volume increased. Furthermore, the applicant does not adequately explain why it assumes a positive growth rate going forward given that the CAGR for the time period CY2010 – CY2013 is a negative CAGR of -1.17%.

Step 3:

On page 61, the applicant states that it distributes the unweighted MRI volume among each Novant Health hospital based on its historical utilization and consideration of “(1) the CON approved fixed MRI scanner at NHMMC becomes operational in CY 2016 for a total of two inpatient fixed MRI scanners, and (2) the proposed fixed MRI unit at NHMMC becomes operational in CY 2018.” The applicant provides its distribution of unweighted MRI volume as follows:

	Interim CY2014	Interim CY2015	Interim CY2016	Interim CY2017	PY1 CY2018	PY2 CY2019	PY3 CY2020	% Distribution PY3
NH Presbyterian Medical Center (MC)	8,759	9,162	8,698	9,167	8,856	9,130	9,468	30%
NH Huntersville MC	6,380	6,431	6,326	6,272	6,056	6,033	6,074	19%
NH Matthews MC	5,670	6,174	8,013	8,823	7,931	8,145	8,520	27%
NH Charlotte Orthopedic Hospital	3,282	3,433	3,321	3,309	3,317	3,394	3,471	11%
NH Mint Hill MC	n/a	n/a	n/a	n/a	2,680	3,464	4,021	13%
Totals	24,091	25,200	26,359	27,571	28,840	30,166	31,554	

The applicant provides the following assumptions on pages 61-62,

“1. NHMMC’s CON-approved second inpatient fixed MRI scanner is projected to be operational beginning in CY 2016. The availability of two fixed MRI scanners at NHMMC will increase capacity for MRI services at that facility, as well as relieve the increasing volumes at NHPMC which also operates two fixed MRI scanners.”

2. *NHHMC operates one fixed MRI scanner that is performing well over 6,000 unweighted MRI scans. As such, NHHMC's MRI scanner is reaching maximum capacity and will not be capable of maintaining increasing MRI volumes through CY 2020. With additional fixed MRI capacity available at NHMMC and NHMHMC, the excess capacity at NHHMC can be somewhat alleviated.*
3. *NHCOH is a specialty orthopedic hospital, which recently replaced its one fixed MRI scanner. The volume estimated for this facility is consistent with its historical operating experience.*
4. *NHPMC operates two fixed MRI scanners at a consistently high volume, which has averaged 8,370 unweighted annual MRI procedures from CY 2010-CY2013. With two fixed MRI scanners, NHPMC is better suited to increase its MRI volume in the future. In CY 2016 and CY 2018, NHPMC's MRI volume will decline slightly as patients are able to have increased accessibility to MRI services closer to home at the Novant Health Mint Hill MRI scanner.*
5. *In order to determine weighted volume for each hospital, the facility-specific inpatient/outpatient percentages and contrast percentages for CY 2013 were applied to the estimated unweighted MRI totals for each facility."*

The applicant provides the weighted MRI volume for each of Novant's hospitals in Mecklenburg County, on page 62, as follows:

Novant Health Presbyterian Medical Center

Project Year	Unweighted MRI Volume	Inpatient MRI Volume	Outpatient MRI Volume	Total Contrast Scans	Inpatient Adjustment	Contrast Adjustment	Weighted MRI Volume*
		43.5%	56.5%	45.1%			
PY 1	8,856	3,852	5,004	3,994	1,541	1,598	11,995
PY 2	9,130	3,972	5,158	4,118	1,589	1,647	12,366
PY 3	9,468	4,119	5,349	4,270	1,648	1,708	12,823

*Totals may not foot due to rounding.

Novant Health Huntersville Medical Center

Project Year	Unweighted MRI Volume	Inpatient MRI Volume	Outpatient MRI Volume	Total Contrast Scans	Inpatient Adjustment	Contrast Adjustment	Weighted MRI Volume*
		13.4%	86.6%	32.95%			
PY 1	6,056	812	5,244	1,995	325	798	7,179
PY 2	6,033	808	5,225	1,988	323	795	7,152
PY 3	6,074	814	5,260	2,001	326	800	7,200

*Totals may not foot due to rounding.

Novant Health Matthews Medical Center

Project Year	Unweighted MRI Volume	Inpatient MRI Volume	Outpatient MRI Volume	Total Contrast Scans	Inpatient Adjustment	Contrast Adjustment	Weighted MRI Volume*
		21.5%	78.5%	43.5%			
PY 1	7,931	1,705	6,226	3,450	682	1,380	9,993
PY 2	8,145	1,751	6,394	3,543	700	1,417	10,263
PY 3	8,520	1,832	6,688	3,706	733	1,482	10,735

*Totals may not foot due to rounding.

Novant Health Charlotte Orthopedic Hospital

Project Year	Unweighted MRI Volume	Inpatient MRI Volume	Outpatient MRI Volume	Total Contrast Scans	Inpatient Adjustment	Contrast Adjustment	Weighted MRI Volume*
		1.43%	98.57%	25.55%			
PY 1	3,317	47	3,269	847	19	339	3,674
PY 2	3,394	49	3,345	867	19	347	3,760
PY 3	3,471	50	3,421	887	20	355	3,846

*Totals may not foot due to rounding.

Projected Utilization – Novant Health’s Outpatient Imaging Centers

In Section III.1, pages 63-65, the applicant provides its projections for its fixed MRI services provided at Novant’s three outpatient imaging centers in Mecklenburg County.

Step 1:

The applicant states that during 2012 one fixed MRI scanner was relocated from its South Park Imaging Center to its Ballantyne Imaging Center. The applicant provides the historical, unweighted MRI volume for each outpatient imaging center and provides the CAGR, on page 63, as follows:

	CY2011	CY2012	CY2013	CAGR
Ballantyne	1,483	1,624	1,934	
Museum	1,550	2,562	2,339	
South Park	3,921	4,158	3,579	
Totals	6,954	8,344	7,852	4.13%

Step 2:

The applicant applies the CAGR of 4.13% to the unweighted MRI volume for each outpatient imaging center, illustrated as follows:

	CY2014	CY2015	CY2016	CY2017	CY2018	CY2019	CY2020
Ballantyne	2,014	2,097	2,184	2,274	2,368	2,466	2,567
Museum	2,436	2,536	2,641	2,750	2,864	2,982	3,105
South Park	3,727	3,881	4,041	4,208	4,382	4,563	4,751
Totals	8,176	8,514	8,866	9,232	9,613	10,010	10,423

Step 3:

The applicant applies the weighting factors based on each of the outpatient imaging center's specific contrast percentages for CY2013 to obtain the weighted MRI volume, as illustrated below:

Ballantyne	Unweighted MRI Volume	Contrast Percentage	Contrast Scans	Weighted MRI Volume*
Project Year 1	2,368	24%	568	2,595
Project Year 2	2,466	24%	592	2,702
Project Year 3	2,567	24%	616	2,813
Museum				
Project Year 1	2,864	28%	802	3,184
Project Year 2	2,982	28%	835	3,316
Project Year 3	3,105	28%	869	3,453
South Park				
Project Year 1	4,382	15%	657	4,645
Project Year 2	4,563	15%	684	4,836
Project Year 3	4,751	15%	713	5,036

*Totals may not foot due to rounding.

On page 64, the applicant combines the projected weighted MRI volume for each of its fixed MRI scanners in Mecklenburg County and calculates the average weighted MRI volume per fixed MRI scanner, as follows:

Projected Weighted, Fixed MRI Volume by Novant Health Facility

	Number of Fixed MRI Scanners	Project Year 1	Project Year 2	Project Year 3
Hospitals:				
NH Presbyterian MC	2	11,995	12,366	12,823
NH Huntersville MC	1	7,179	7,152	7,200
NH Matthews MC	2	9,993	10,263	10,735
NH Charlotte Orthopedic Hospital	1	3,674	3,760	3,846
NH Mint Hill MC	1	3,277 [3,191]	4,235	4,916
Outpatient Centers				
Ballantyne	1	2,595	2,702	2,813
Museum	1	3,184	3,316	3,453
South Park	1	4,645	4,836	5,036
Totals	10	46,542 [46,456]	48,630	50,822
Average Per Scanner		4,654 [4,646]	4,863	5,082

The applicant states, on page 65,

“Based on ten fixed scanners (8 existing units, 1 approved but not operational, and 1 proposed), the average annual weighted volume is 5,082 MRI procedures per fixed MRI scanner. Pursuant to 10A NCAC .2703, the proposed MRI scanner at NHMHMC will perform 5,082 [4,916] weighted MRI procedures in Year 3 of operation, which exceeds the required 4,805 weighted MRI procedures in YR 3 of operation.”

However, as stated previously, the growth rate of 4.6% used by the applicant to project unweighted MRI volume at other Novant Health hospitals in Mecklenburg County is not reasonable and adequately supported. See the discussion on pages 23-24 of these findings.

Utilization of Novant Health’s Mobile MRI Scanners Operating in Mecklenburg County

In Section II, pages 29 and 32, the applicant states that related entities own two mobile MRI scanners that serve the following sites in Mecklenburg County:

Mobile MRI Unit	Host Sites	Location	Service Provided
MQ 16	Novant Health (NH) Imaging – University NH Imaging – Steele Creek	Charlotte Charlotte	2 days/wk. 5 days/wk.
Presbyterian Hospital Unit	Mooresville Diagnostic Imaging NH Imaging – University NH Imaging – Steele Creek	Mooresville, Iredell County Charlotte Charlotte	1 day/wk. 5 days/wk. 1 day/wk.

In Section II, pages 29-30, the applicant states that related entities own two mobile MRI scanners that provide MRI services in Mecklenburg County. The MQ 16 unit performed only 2,286 weighted MRI scans in FFY 2013 and the Presbyterian Hospital Mobile Unit performed only 1,796 weighted MRI scans in FFY 2013. Therefore, neither scanner performed the 3,328 weighed MRI scans required by 10A NCAC 14C .2703(b)(2).

On page 33, the applicant provides historical total unweighted MRI volume for both fixed and mobile MRI scanners for all providers of MRI services in Mecklenburg County for fiscal years 2010-2011 through fiscal years 2012-2013, and calculates an average annual growth rate of 2.20%, illustrated as follows:

All Providers	FY 2010-2011	FY 2011-2012	FY 2012-2013
Mecklenburg County	91,734	94,174	95,807
Percent Change		2.66%	1.73%
Average Growth Rate			2.20%

The applicant calculates its total unweighted MRI volume through project year three, FY 2020-2021, using an average annual growth rate of 2.2%, illustrated as follows:

Time Period	Total Unweighted MRI Volume (All Providers)	Percent Change
FY 2012-2013	95,807	
FY 2013-2014	97,915	2.2%
FY 2014-2015	100,069	2.2%
FY 2015-2016	102,271	2.2%
FY 2016-2017	104,521	2.2%
FY 2017-2018	106,820	2.2%
FY 2018-2019	109,170	2.2%
FY 2019-2020	111,572	2.2%
FY 2020-2021	114,027	2.2%

Novant Health’s MQ 16 Mobile MRI Scanner

The applicant converted the data to calendar years to be consistent with the proposed project years, calculated the market capture for the MQ 16 mobile MRI scanner, and increased market share by 0.20% each project year based on “...continued population increase, the aging of the population, high demand at the mobile MRI host sites as well as other Novant sites and the addition of new mobile host sites in the coming years due to marketing and development efforts.” The applicant provides the following table illustrating these calculations on page 33:

**Projected Unweighted MRI Volume
 MQ 16 Mobile MRI Scanner**

Mecklenburg County	CY 2018	CY 2019	CY 2020
Unweighted MRI Volume	107,412	109,776	112,188
MQ 16 – Market Capture	2.41%	2.61%	2.81%
Projected Unweighted MRI Volume	2,589	2,865	3,152

The applicant utilized its contrast percentage from FY 2012-2013 for the MQ 16 of 20.5% to calculate the weighted scan volume for each of the project years, as follows:

Mecklenburg County	CY 2018	CY 2019	CY 2020
Projected Unweighted MRI Volume	2,589	2,865	3,152
Contrast Percentage	20.5%	20.5%	20.5%
Contrast Scans	531	587	646
Contrast Adjustment	212	235	258
Projected Weighted MRI Volume	2,801	3,100	3,410

Novant Health’s Presbyterian Hospital Unit Mobile MRI Scanner

Next, the applicant projected utilization of its second mobile MRI scanner, the Presbyterian Hospital Unit. The applicant determined that based on FY 2012-2013 data, the Presbyterian Hospital Unit captured approximately 1.0% of the Mecklenburg County unweighted MRI volume and approximately 4.2% of the Iredell County total unweighted MRI volume. The applicant assumed the following market capture increase each year for the Presbyterian Hospital Unit, as stated on page 34, “...market capture will increase by 0.50% beginning in CY 2018 in light of the additional day of service at Novant Health Imaging – Steele Creek, the anticipated high demand for MRI services in Mecklenburg County, the increase in the resident population, the aging of the population and the increase in demand for MRI services at Novant Health facilities.” The applicant provides these calculations in the following table from page 34:

Mecklenburg County	CY 2018	CY 2019	CY 2020
Unweighted MRI Volume	107,412	109,776	112,188
Presbyterian Hospital Unit – Market Capture	1.50%	2.0%	2.50%
Projected Unweighted MRI Volume – Mecklenburg County Host Sites	1,611	2,196	2,805

The applicant states, on page 35, that the Presbyterian Hospital Unit will continue to serve MRI patients at its Mooresville Diagnostic Imaging Center in Iredell County. The overall volume of unweighted MRI procedures in Iredell County declined by -6.8% from FY 2010-2011 to FY 2011-2012 and increased by 7.1% from FY 2011-2012 to FY 2012-2013, as illustrated in the table below:

All Providers	FY 2010-2011 Total Unweighted MRI Volume	FY 2011-2012 Total Unweighted MRI Volume	FY 2012-2013 Total Unweighted MRI Volume
Iredell County	16,569	15,522	16,635
Percent Change		-6.8%	7.1%

The applicant states, *“In order to be conservative, Novant Health utilized the estimated annual population increase of 1.2%.”* The applicant used this percentage to project total unweighted MRI volume for Iredell County through FY 2020-2021, illustrated in the following table:

Time Period	Total Unweighted MRI Volume – Iredell County	Percent Change
FY 2012-2013	16,635	
FY 2013-2014	16,835	1.2%
FY 2014-2015	17,037	1.2%
FY 2015-2016	17,241	1.2%
FY 2016-2017	17,448	1.2%
FY 2017-2018	17,657	1.2%
FY 2018-2019	17,869	1.2%
FY 2019-2020	18,083	1.2%
FY 2020-2021	18,300	1.2%

The Project Analyst determined that the CAGR for the total unweighted MRI volume for Iredell County from FY 2010-2011 to FY 2012-2013 was 0.2%. The applicant did not adequately explain why it was reasonable to assume volume would increase 1.2% per year given that actual volume only increased 0.2% per year between FY 2010-2011 and FY 2012-2013. Thus, projected volume for Iredell County (all providers) is potentially overstated.

The applicant converted the data to calendar year data and estimated market capture at 4.2% for the Presbyterian Hospital Unit for MRI scans in Iredell County, based on data for FY 2012-2013. The projected unweighted MRI volume is illustrated in the following table:

Iredell County	CY 2018	CY 2019	CY 2020
Unweighted MRI Volume	17,869	18,083	18,300
Presbyterian Hospital Unit – Market Capture	4.2%	4.2%	4.2%
Projected Unweighted MRI Volume –Iredell County Host Site	750	760	769

The applicant totals the unweighted MRI volume for its Mecklenburg County and Iredell County host sites served by the Presbyterian Hospital Unit, and calculates and applies the contrast percentage based on data from FY 2012-2013 to determine the projected weighted MRI volume, illustrated in the following table:

Presbyterian Hospital Unit	CY 2018	CY 2019	CY 2020
Mecklenburg County - Projected Unweighted MRI Volume	1,611	2,196	2,805
Iredell County – Projected Unweighted Volume	750	760	769
Presbyterian Hospital Unit – Total Unweighted Volume all Host Sites	2,361	2,956	3,574
Percent Contrast	22.2%	22.2%	22.2%
Contrast Scans	524	656	793
Contrast Adjustment	210	262	317
Projected Weighted MRI Volume	2,571	3,218	3,891

The applicant states that each of its two mobile MRI scanners, MQ 16 and the Presbyterian Hospital Unit, will perform over 3,328 weighted MRI scans in the third year of the proposed project, as required by 10 A NCAC 14C .2703(b)(2). The MQ 16 mobile unit is projected to perform a total of 3,410 weighted MRI scans and the Presbyterian Hospital Unit is projected to perform a total of 3,891 weighted MRI scans.

In summary, the applicant does not adequately demonstrate that:

- 1) Each existing mobile MRI scanner owned by a related entity and operating at host sites in Mecklenburg County performed at least 3,328 weighted MRI scans in the most recent 12 month period for which the applicant has data; and
- 2) Projected utilization of all existing, approved and proposed fixed MRI scanners owned by the applicant or a related entity and operating in Mecklenburg County is reasonably expected to average 4,805 weighted MRI scans per scanner.

Access

In Section VI.15, page 124, the applicant states that its projected payor mix for the fixed MRI scanner is expected to be similar to its historical payor mix for Mint Hill patients who have received MRI services at Novant Health's acute care hospitals in Mecklenburg County. The applicant projects that 51.9% of its proposed patients will be covered by Medicare (41.9%) and Medicaid (10.0%).

Conclusion

In summary, the applicant adequately identifies the population to be served and the extent to which all residents of the service area, including medically underserved groups, are likely to have access to the proposed services. However, the applicant does not adequately demonstrate the need the population to be served has for the proposed fixed MRI scanner. Consequently, the application is not 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 – Both Applications

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C - OrthoCarolina Ballantyne
NC - Novant Health Mint Hill

OrthoCarolina Ballantyne - In Section III.3, pages 51-52, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – the applicant determined that this is not an effective alternative because of the high volume of MRI scans being done at the OrthoCarolina Ballantyne site. The site has the highest rate of growth of all the OrthoCarolina offices with mobile MRI scanners and has a fully booked schedule one week out. In addition, many patients are referred to other MRI scanners for MRI procedures requiring contrast since the mobile MRI at the Ballantyne site has operational limitations.
- 2) Acquire a second fixed MRI scanner at the OrthoCarolina Spine Center – this alternative would require extensive renovations and therefore would

increase costs. In addition, it would be disruptive to operations. The applicant states that this alternative has merit based on the volume of MRI procedures, however additional days of mobile MRI services may be obtained from either the OrthoCarolina mobile MRI scanner or the Alliance Imaging mobile scanner to increase capacity.

- 3) Acquire a fixed MRI scanner for either OrthoCarolina Matthews or OrthoCarolina University – this alternative was not considered effective because neither location has an MRI utilization that would support a full time fixed MRI scanner.

The applicant concluded that acquiring a fixed MRI scanner at OrthoCarolina Ballantyne would be the least costly and most effective alternative.

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

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

Novant Health Mint Hill - In Section III.3, page 77, the applicant discusses two alternatives Novant Health Mint Hill considered, which are:

- 1) Contract for mobile MRI scanner services – this alternative had been included in Novant’s application for a new hospital, Novant Health Mint Hill Medical Center (Project I.D. #F-7648-06), which included a proposal to contract with a mobile MRI scanner vendor to provide MRI services two to three days per week. When the application was filed, however, there was no need determination in the SMFP for a fixed MRI scanner in Mecklenburg County. The applicant states that since it will be a full-service community hospital, a full-time fixed MRI scanner would be preferable since it would provide local accessibility and avoid the cost of providing mobile MRI services.
- 2) Relocate an existing fixed MRI scanner – the applicant states that Novant and its affiliate, MedQuest Associates, own and operate five fixed MRI scanners at acute care hospitals and three fixed MRI scanners at outpatient imaging centers. However, most of these sites have only one fixed MRI scanner. Therefore, relocating one of them to Novant Health Mint Hill would leave one site with no fixed MRI scanner. Therefore, this was not considered to be an effective alternative.

The applicant concluded that acquiring a fixed MRI scanner at Novant Health Mint Hill would be the least costly and most effective alternative.

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

In summary, the applicant did not adequately demonstrate that its proposal is its least costly or most effective alternative to meet the need. Therefore, the application is not conforming to this criterion.

- (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.

CA - OrthoCarolina Ballantyne
NC - Novant Health Mint Hill

OrthoCarolina Ballantyne - In Section VIII.1, page 80, the applicant states the capital cost for the project will be \$2,421,147, comprised as follows:

Site Costs	\$267,000
Modular Building Delivered Cost	\$430,240
Miscellaneous Project Costs	
Fixed MRI Scanner Equipment	\$1,539,915
Architect/Engineering Fees	\$30,000
Sales Tax (7.5%) and Contingency (2.5%)	\$153,992
Sub-Total Miscellaneous	\$1,723,907
Total Capital Cost of Project	\$2,421,147

In Section IX, page 84, the applicant states there will be no start-up or initial operating expenses since OrthoCarolina currently provides mobile MRI services at the OrthoCarolina Ballantyne location where the proposed fixed MRI scanner will be installed. In Section VIII.3, page 81, the applicant states that the project will be funded through a conventional loan. Exhibit 28 contains a letter dated May 1, 2014 from the Vice President of Wells Fargo Bank, which states:

“I am writing to confirm our recent discussions about capital expense financing for the purchase and installation of a fixed MRI scanner at the OrthoCarolina Ballantyne office in Mecklenburg County. You have indicated that the total capital cost to be incurred to purchase and install the MRI scanner is budgeted at approximately \$2,300,000.

...

Based on our discussions and a review of your request for financing, Wells Fargo Bank will consider providing OrthoCarolina, PA with the financing briefly

described...This letter is an expression of our strong interest in providing this financing based on the arrangements described above.”

However, the applicant states, in Section VIII, page 80, that the total capital cost of the project will be \$2,421,147. The difference between the approximate commercial loan amount of \$2,300,000 and the projected capital cost of \$2,421,147 is \$121,147. The applicant does not provide documentation on how this cost difference will be funded.

Exhibit 29 contains audited financial statements for OrthoCarolina, PA for the years ending December 31, 2013 and December 31, 2012. As of December 30, 2013, OrthoCarolina, PA had net revenues of \$187,404,202 and total operating expenses of \$108,915,875. Net assets were equal to \$78,488,327 (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project subject to Condition #2 found at the end of the Findings.

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

OrthoCarolina Ballantyne Fixed MRI Scanner	Project Year 1 1/01/2016- 12/31/2016	Project Year 2 1/01/2017- 12/31/2017	Project Year 3 1/01/2018- 12/31/2018
Projected # of Unweighted Scans	4,416	4,637	4,869
Projected Average Charge (Gross Patient Revenue/Projected # of Unweighted Scans)	\$1,548	\$1,548	\$1,548
Gross Patient Revenue	\$6,835,968	\$7,178,076	\$7,537,212
Deductions from Gross Patient Revenue	\$4,570,720	\$4,799,463	\$5,039,591
Net Patient Revenue	\$2,265,248	\$2,378,613	\$2,497,621
Total Expenses	\$1,102,612	\$1,302,588	\$1,329,701
Net Income	\$1,162,636	\$1,076,026	\$1,167,920

As shown in the table above, the applicant projects a positive net income in each of the first three operating years of the project. The applicant also projects a positive net income for all of OrthoCarolina’s services, including all MRI services. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. The discussion of projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. The application is conforming to this criterion as conditioned.

Novant Health Mint Hill - In Section VIII.1, page 138, the applicant states that the total capital cost of the project will be \$2,421,102, including \$14,544 for site costs, \$420,185 for a construction contract, \$1,806,823 for fixed equipment purchase/lease, \$36,000 for

information technology, \$12,150 for furniture costs, \$81,400 for consultant fees inclusive of architect/engineering fees, and \$50,000 for Other (Project Contingency). In Section IX, page 147, the applicant states that there will be start up expenses associated with the proposed project but there will not be any initial operating expenses. In Section VIII.3, page 139, the applicant states that the project will be funded by the accumulated reserves of its parent company, Novant Health, Inc. Exhibit 8 contains a letter dated May 5, 2014 and signed by the Senior Vice President of Novant Health, Inc. which states:

“This letter will serve to confirm that Novant Health, Inc. will be funding the capital cost of \$2,421,402 from the Accumulated Reserves of Novant Health, Inc. The start-up and working capital needs for this MRI scanner project are defined in the applicant’s responses in CON Application Section IX. Novant Health reserves the right to seek tax exempt bond funding for all or part of this project as discussed in Section VIII of our CON Application.”

Exhibit 8 of the application contains the combined financial statements for Novant Health, Inc. and Affiliates for the years ending December 31, 2012 and December 31, 2013. As of December 31, 2013, Novant Health and Affiliates had \$249,182,000 in cash and cash equivalents, unrestricted net assets of \$2,499,333,000 and \$2,558,393,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

The applicant provides pro forma financial statements for the first three years of the project for the proposed fixed MRI scanner. In Form C, the applicant projects revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below.

Novant Health Mint Hill Fixed MRI Scanner	Project Yr 1 1/01/2018- 12/31/2018	Project Yr 2 1/01/2019- 12/31/2019	Project Yr 3 1/01/2020- 12/31/2020
Projected # of Unweighted MRI Scans	2,680	3,464	4,021
Projected Average Charge (Gross Patient Revenue/ Projected # of Unweighted MRI Scans)	\$2,937	\$3,025	\$3,116
Gross Patient Revenue	\$7,871,485	\$10,479,414	\$12,529,404
Deductions from Gross Patient Revenue	\$5,531,766	\$7,364,514	\$8,85,166
Net Patient Revenue	\$2,339,719	\$3,114,900	\$3,724,238
Total Expenses	\$970,616	\$1,061,163	\$1,136,500
Net Income	\$1,369,103	\$2,053,737	\$2,587,739

The applicant also projects a positive net income for the entire hospital in each of the first three operating years of the project.

However, the applicant's utilization projections are unsupported and unreliable. Consequently, operating expenses and revenues that are based on the applicant's projected utilization are also unreliable. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the applicant did not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Consequently, the application is not 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 - OrthoCarolina Ballantyne
NC - Novant Health Mint Hill

There are 19 existing fixed MRI scanners in Mecklenburg County according to the 2014 SMFP. The following table provides the number, location, and average utilization of each of the fixed MRI scanners, summarized from Table 9P of the 2014 SMFP.

Fixed MRI Scanners in Mecklenburg County

Facility	# of Fixed MRI Scanners	Weighted # of MRI Scans	Average # of MRI Scans per Scanner*	Threshold per MRI Scanner
Carolinas Medical Center	4	22,409	5,602	4,805
Carolinas Medical Center – University	1	6,066	6,066	4,805
Carolinas Medical Center Mercy/Pineville	2	13,569	6,785	4,805
Novant Health Charlotte Orthopedic Hospital	1	2,775	2,775	4,805
Novant Health Huntersville Medical Center	1	7,356	7,356	4,805
Novant Health Imaging Museum	1	2,686	2,686	4,805
Novant Health Matthews Medical Center	2	7,238	3,619	4,805
Novant Health Presbyterian Medical Center	2	10,465	5,233	4,805
Carolinas Imaging Services – Ballantyne (Carolinas Imaging Services, LLC)	1	2,391	2,391	4,805
Carolinas Imaging Services – Southpark (Carolinas Imaging Services, LLC)	1	3,135	3,135	4,805
Novant Health Imaging Southpark (Mecklenburg Diagnostic Imaging, Inc.)	1	660	660	4,805
Novant Health Imaging Southpark (Mecklenburg Diagnostic Imaging, Inc.)	1	3,722	3,722	4,805
OrthoCarolina Spine Center (OrthoCarolina, P.A.)	1	8,900	8,900	4,805

*Average number of MRI scans are rounded to nearest whole number.

OrthoCarolina Ballantyne adequately demonstrates that its proposed project would not result in unnecessary duplication of existing or approved MRI services in Mecklenburg County based on the following analysis:

- 1) The State Health Coordinating Council and Governor determined a need for one additional fixed MRI scanner in Mecklenburg County. See Table 9P of the 2014 SMFP. OrthoCarolina Ballantyne submitted its application in response to the need determination in the 2014 SMFP.
- 2) The applicant proposes to acquire one fixed MRI scanner to replace mobile MRI scanner services provided at its Ballantyne location. The applicant adequately demonstrates in its application that the fixed MRI scanner it proposes to develop in Mecklenburg County is needed in addition to the existing fixed MRI scanners in Mecklenburg County. The applicant adequately demonstrates that its projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Consequently, the application is conforming to this criterion.

Novant Health Mint Hill does not adequately demonstrate that its proposed project would not result in unnecessary duplication of existing or approved MRI services in Mecklenburg County based on the following analysis:

- 1) The State Health Coordinating Council and Governor determined a need for one additional fixed MRI scanner in Mecklenburg County. See Table 9P of the 2014 SMFP. Novant Health Mint Hill submitted its application in response to the need determination in the 2014 SMFP.
- 2) However, Novant Health Mint Hill does not adequately demonstrate in its application that the fixed MRI scanner it proposes to develop in Mecklenburg County is needed in addition to the existing fixed MRI scanners in Mecklenburg County. In particular, Novant Health Mint Hill does not adequately demonstrate that the two mobile MRI scanners owned by a related entity and operated at host sites located in Mecklenburg County each performed at least 3,328 weighted MRI scans during the most recent 12-month period for which the applicant has data as required by 10A NCAC 14C .2703(b)(2). In addition, the applicant does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Consequently, the application is not 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

OrthoCarolina Ballantyne
Novant Health Mint Hill

OrthoCarolina Ballantyne - In Section VII.3(a), page 74, the applicant provides the projected staffing for the proposed fixed MRI scanner at the OrthoCarolina Ballantyne location. The applicant projects to employ 2.0 full-time equivalent (FTE) MRI Technicians and 2.0 FTE Technician Assistants, 1.0 FTE MRI scheduler and a 0.25 of a FTE MRI supervisor. The applicant states that the remaining 75 percent of the supervisor's time will be dedicated to the Ballantyne mobile MRI service to be provided at the other OrthoCarolina sites. Only the two FTE MRI Technicians and two FTE Technician Assistants will be new positions. The MRI scheduler and MRI supervisor are existing positions with the Ballantyne mobile MRI service. In Section VII.3, page 74, the applicant states, "...*OrthoCarolina management has current knowledge of the wage rates, benefits and education, and training requirements to recruit and evaluate candidates.*" In Exhibit 3, the applicant provides a letter from Dr. Victor Ho, which states, "*This letter is to provide assurance that if OrthoCarolina receives approval for the project; I am willing to continue to provide Head Radiology Medical Directorship for the MRI unit.*"

The applicant adequately demonstrates the availability of health manpower and management personnel for the provision of the proposed services. Therefore, the application is conforming to this criterion.

Novant Health Mint Hill - In Section VII.1(b), page 125, the applicant provides the projected staffing for the proposed fixed MRI scanner. The applicant projects staffing will consist of 4.0 FTE MRI Technologists and 0.4 of a FTE MRI Radiology Manager in project year two, (1/01/2019 – 12/31/2019). In Section VII.3, page 127, the applicant discusses its established recruitment process and policies pertaining to retention of staff. In Exhibit 5, the applicant provides a letter from Dr. Erik K. Insko documenting his intent to serve as Medical Director for MRI Imaging at Novant Health Mint Hill.

The applicant adequately demonstrates the availability of health manpower and management personnel for the provision of the proposed services. Therefore, the application is conforming to this criterion.

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

C

OrthoCarolina Ballantyne
Novant Health Mint Hill

OrthoCarolina Ballantyne – OrthoCarolina Ballantyne is an existing healthcare office in Charlotte that currently provides mobile MRI services four days a week. The applicant states, in Section II.2(a), that it, “...has existing ancillary and support services that are sufficient to support the proposed fixed MRI scanner.” The applicant provides a listing of these services in Section II.1(a), page 18.

In Section V.2(a), page 60, the applicant states that it does not have transfer agreements with other facilities since it does not admit patients. Rather, it provides services as an outpatient facility. The applicant states, on page 60, that its physicians have admitting privileges at multiple hospitals in Mecklenburg County. In addition, Exhibit 9 contains an outline of the applicant’s procedures in the event of a medical emergency.

In Section V.4(a), the applicant describes how the proposed service will be coordinated with the existing healthcare system as follows:

“As one of the largest practices in the region, OrthoCarolina physicians have already established positive relationships with local hospitals, physicians, rehabilitation facilities and other healthcare providers. OrthoCarolina physicians are members of the Mecklenburg County Medical Society and also participate in Physician Reach Out which provides charity care to thousands of patients.”

In addition, Exhibit 13 contains letters of support from OrthoCarolina physicians.

The applicant adequately demonstrates the availability of the necessary ancillary and support services and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

Novant Health Mint Hill – In Section II.2, page 12, the applicant states that all necessary ancillary and support services will be available for the proposed project, including, but not limited to, pharmacy, laboratory, code blue team support, emergency services, housekeeping, and respiratory therapy.

In Section V.2(a), page 87, the applicant states that it has a transfer agreement already in place with Novant Health Presbyterian Medical Center and that “Novant Health and its Greater Charlotte Market acute care facilities have established patient transfer agreements (PTAs), and NHMHMC and the proposed fixed MRI scanner will be included in these agreements once the hospital is open.” Exhibit 10 contains a copy of the patient transfer agreement between Novant Health Presbyterian Medical Center and Novant Health Mint Hill Medical Center. In addition, on page 88, the applicant states that Novant Health Mint Hill will “accept all clinically appropriate referral from physicians, as well as transfers from other hospitals based on patient transfer agreements and

protocols.” Moreover, the applicant states that Novant Health and its hospitals have long-standing physician support and that it has a large network of physician and surgeon specialties in the greater Charlotte market. Letters of support from area physicians are provided in Exhibit 4.

The applicant adequately demonstrates the availability of the necessary ancillary and support services and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA – Both Applications

- (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 – Both Applications

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

C

OrthoCarolina Ballantyne
Novant Health Mint Hill

OrthoCarolina Ballantyne - In Section XI.4, page 89, the applicant states that its services are currently provided in leased space totaling 16,682 square feet. The applicant proposes to add a modular building consisting of 700 square feet to provide the proposed fixed MRI scanner services. The proposed square footage for each of the sections of the modular building is described as follows on page 89:

Section	Gross Square Feet (S.F.)
Mechanical Room	320 S.F.
Control Room	230 S. F.
Scanner Room	120 S. F.
Total	700 S. F.

In Section XI.4(f), page 90, the applicant projects the following cost per square foot for the modular building, as illustrated in the following table:

	Estimated Square Feet	Construction Cost Per Square Foot*	Total Cost per Square Foot
Total	700	\$697,240/ 700 = \$996.06	\$2,421,147/ 700 = \$3,458.78

*Construction cost includes site preparation costs and modular building cost, (\$267,000 + \$430,240 = \$697,240), as indicated on page 80.

In Section XI.7, page 91, the applicant states that the modular building housing the proposed fixed MRI scanner will be energy efficient and “...will be maintained to provide patient comfort and allow the imaging equipment to operate at optimal performance levels.”

The applicant adequately demonstrates that the cost, design, and means of construction represent the most reasonable alternative and would not unduly increase the costs and charges of providing MRI services. The discussion of costs and charges found in Criterion (5) is incorporated herein by reference. Therefore, the application is conforming to this criterion.

Novant Health Mint Hill – In Section XI.4, page 153, the applicant states it will add 963 square feet to its CON-approved, but not yet developed, Novant Mint Hill Medical Center, to accommodate the proposed fixed MRI scanner services. The proposed square footage for each area of this addition, as stated on page 154, is as follows:

Area	Gross Square Feet (S.F.)
MRI Scanner Room	361 S.F.
Control Room	122 S. F.
Equipment Room	118 S. F.
Vestibule	130 S.F.
Patient Hold	232 S.F.
Total	963 S. F.

A letter regarding the certified cost estimate of the construction cost is provided by BBH Design in Exhibit 11 which states:

“This is to certify that we have reviewed the Construction Costs for the referenced project. Based on our review and comparison of this project with similar projects, we believe the costs indicated are a reasonable estimate of the costs to be expected on a project of the scope defined. The project provides for a small building addition to contain a fixed site MRI to replace the mobile unit at this facility.”

The Anticipated Construction Cost of \$434,729 has been provided by Vannoy Construction, General Contractors. In addition to the construction estimate, the anticipated architectural/engineering fee is \$ 43,400.”

In Section XI.4(f), page 154, the applicant projects the cost per square foot for the addition, as illustrated below:

	Estimated Square Feet	Construction Cost per SF	Total Cost per SF
Total	963	\$436.33	\$2,421,102/963 = \$2,514.12

In Section III.7, page 76, the applicant states that it will use Novant Health’s “Sustainable Energy Management Plan”, provided in Exhibit 12, as a starting point for compliance with the 2014 SMFP Policy GEN-4 and will work with the Construction Section of the Division of Health Service Regulation to ensure the plan addresses energy efficiency and water conservation that conforms to the rules, codes and standards required.

The applicant adequately demonstrates that the cost, design, and means of construction represent the most reasonable alternative and would not unduly increase the costs and charges of providing MRI services. The discussion of costs and charges found in Criterion (5) is incorporated herein by reference. Therefore, the application is conforming to this criterion.

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

C - OrthoCarolina Ballantyne
NA - Novant Health Mint Hill

OrthoCarolina Ballantyne - In Section VI.13, page 70, the applicant provides the payor mix for its mobile MRI services at the Ballantyne location for Federal Fiscal Year 2013, as illustrated in the table below.

**OrthoCarolina Ballantyne Mobile MRI Services
October 1, 2012 to September 30, 2013
Current Patient Days/ Procedures
as Percent of Total Utilization**

Self Pay/Indigent/Charity	1.94%
Medicare/Medicare Managed Care	20.08%
Medicaid	2.73%
Commercial Insurance	39.35%
Managed Care	32.18%
Other (Worker's Comp, Other)	3.72%
Total	100.0%

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

	Total # of Medicaid Eligibles as % of Total Population June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Mecklenburg	14.7%	5.1%	20.1%
Statewide	16.5%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the proposed MRI services at the same rate as older segments of the population likely to utilize the proposed MRI services.

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 applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities 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 have adequate access to OrthoCarolina Ballantyne's existing mobile MRI services and 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 - OrthoCarolina Ballantyne
 NA - Novant Health Mint Hill

OrthoCarolina Ballantyne – The applicant states, in Section VI.11, page 69, that while it has no federal obligation to provide uncompensated care, many of its physicians provide uncompensated care at local hospitals. Exhibits 21, 22 and 23 contain information on healthcare programs that many OrthoCarolina physicians participate in to provide healthcare to low income or uninsured people.

In Section VI.10, page 69, the applicant indicates that no civil rights equal access complaints have been filed against OrthoCarolina, PA in the past five years.

The application is conforming to this criterion.

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

C

OrthoCarolina Ballantyne
Novant Health Mint Hill

OrthoCarolina Ballantyne - In Section VI.14, page 70, the applicant provides the projected payor mix for the second operating year following completion of the project (CY 2017), as illustrated in the table below:

OrthoCarolina (OC) Ballantyne Mobile MRI Projected Payor Mix CY 2017	
Self Pay/Indigent/Charity	1.94%
Medicare/Medicare Managed Care	20.8%
Medicaid	2.73%
Commercial Insurance	39.35%
Managed Care	32.18%
Other (Worker's Comp, Other)	3.72%
Total	100.0%

As illustrated in the table above, the applicant assumes the payor mix for fixed MRI services will remain the same as the historical payor mix for mobile MRI services.

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

Novant Health Mint Hill - In Section VI.15, page 124, the applicant provides the projected payor mix for the proposed fixed MRI scanner during the second operating year following completion of the project (CY 2019), as illustrated in the table below:

Novant Health Mint Hill Projected Payor Mix CY 2019	
Payor	% of Total Procedures
Self Pay / Indigent / Charity	5.35%
Medicare / Medicare Managed Care	41.92%
Medicaid	9.99%
Commercial Insurance	1.53%
Managed Care	39.21%
Other	2.00%
Total	100.00%

In Section VI.15, page 124, the applicant states that its projected payor mix for the proposed fixed MRI scanner *“is based on weighted average of the MRI patient payor mix for all Mint Hill Medical Primary Service Area patients served at MRI scanners operated at Novant Health’s four existing acute care hospitals in Mecklenburg County during CY 2013.”*

The applicant demonstrates that medically underserved groups will have adequate access to the proposed fixed MRI scanner. 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

OrthoCarolina Ballantyne
Novant Health Mint Hill

OrthoCarolina Ballantyne - In Section VI.9(a), page 68, the applicant states that MRI services are accessed through an OrthoCarolina physician or physician assistant’s order. The applicant states,

“Primary care physicians in Mecklenburg County and nearby communities also refer MRI patients to OrthoCarolina physicians because

these patients have need for the diagnosis of musculoskeletal diseases or injuries that will require treatment.”

The applicant adequately demonstrates it will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

Novant Health Mint Hill - In Section VI.9(a), page 120, the applicant states that access to the proposed fixed MRI services will be available only upon physician referral. This may occur in several different ways, including through physician referral by a Novant Health Mint Hill medical staff member for outpatient services, physician referral and inpatient admission, the patient’s primary care physician to a physician member of Novant Health Mint Hill’s staff, physician referral from other Novant Health acute care hospitals, and through outside physicians referring to members of Novant Health Mint Hill’s medical staff.

The applicant adequately demonstrates it will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

OrthoCarolina Ballantyne
Novant Health Mint Hill

OrthoCarolina Ballantyne - In Section V.1(a), page 60, the applicant states that it has an existing clinical training agreement with Cabarrus College Medical Imaging Program. A copy of its agreement with Cabarrus College is provided in Exhibit 17. In addition, the applicant states that the OrthoCarolina Foundation provides several other training programs for health professionals including a mini-fellowship program for orthopedic surgeons from developing countries, continuing education for nurses, and funding opportunities for allied health students in disciplines such as nursing, physical therapy, and athletic training. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

Novant Health Mint Hill - In Section V.1(a), page 86, the applicant states that its Novant Health facilities in the greater Charlotte area have many clinical education agreements in place and that these will include the fixed MRI scanner at Novant Health Mint Hill once it is approved and operational. A full listing of Novant Health’s clinical education agreements with health professions training programs is provided in Exhibit 3. This listing includes, but is not limited to, Cabarrus College, Charlotte-Mecklenburg Board of Education Health Occupations program, Stanly Community College, and UNC-

Charlotte. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C - OrthoCarolina Ballantyne
NC - Novant Health Mint Hill

OrthoCarolina Ballantyne – There are 19 existing fixed MRI scanners in Mecklenburg County according to the 2014 SMFP. The following table provides the number, location, and average utilization of each of the fixed MRI scanners, summarized from Table 9P of the 2014 SMFP.

Fixed MRI Scanners in Mecklenburg County

Facility	# of Fixed MRI Scanners	Weighted # of MRI Scans	Average # of MRI Scans per Scanner*	Threshold per MRI Scanner
Carolinas Medical Center	4	22,409	5,602	4,805
Carolinas Medical Center – University	1	6,066	6,066	4,805
Carolinas Medical Center Mercy/Pineville	2	13,569	6,785	4,805
Novant Health Charlotte Orthopedic Hospital	1	2,775	2,775	4,805
Novant Health Huntersville Medical Center	1	7,356	7,356	4,805
Novant Health Imaging Museum	1	2,686	2,686	4,805
Novant Health Matthews Medical Center	2	7,238	3,619	4,805
Novant Health Presbyterian Medical Center	2	10,465	5,233	4,805
Carolinas Imaging Services – Ballantyne (Carolinas Imaging Services, LLC)	1	2,391	2,391	4,805
Carolinas Imaging Services – Southpark (Carolinas Imaging Services, LLC)	1	3,135	3,135	4,805
Novant Health Imaging Southpark (Mecklenburg Diagnostic Imaging, Inc.)	1	660	660	4,805
Novant Health Imaging Southpark (Mecklenburg Diagnostic Imaging, Inc.)	1	3,722	3,722	4,805
OrthoCarolina Spine Center (OrthoCarolina, P.A.)	1	8,900	8,900	4,805

*Average number of MRI scans are rounded to nearest whole number.

The applicant proposes to acquire a fixed MRI scanner for use at OrthoCarolina Ballantyne in Charlotte, Mecklenburg County. In Sections II.7, page 20, V.7, page 63, VI.2, pages 65-68, and X.1, page 85, the applicant discusses how the proposed project

will enhance competition in the service area, including how it will have a positive impact on the cost effectiveness, quality and access to MRI services in Mecklenburg County. The applicant states, in Section V.7, in page 63,

“The proposed fixed MRI scanner will enhance competition by promoting cost effective care and great access to services.

...

The current four days per week (48 hours/week) of mobile MRI service at Ballantyne is fully utilized with the MRI schedule completely booked for the next week. The proposed project will support patient access by providing appointment options six days per week (84 hours/week) with less delay and greater flexibility as compared to the current mobile service. The project will support cost effective care by expediting the diagnostic imaging interpretation and allow physicians to implement medical treatment or schedule surgery. Quality of care will be enhanced through this project. The proposed project will bolster staff training and focus on MRI safety, policies and procedures, equipment quality assurance and image quality.”

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 applicant adequately demonstrates that any enhanced competition will have a positive impact on cost effectiveness, quality and access to MRI services in Mecklenburg County based on the information in the application and the following analysis:

- ◆ Projected utilization of the fixed MRI scanner is based on reasonable and adequately supported assumptions. See Section III of the application. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates the financial feasibility of the proposal is based upon reasonable projections of costs and charges. See the Pro Formas. The discussion regarding financial feasibility found in Criterion (5) is incorporated herein by reference. Therefore the applicant adequately demonstrates the cost effectiveness of its proposal.
- ◆ The applicant projects to provide adequate access to medically underserved groups including self-pay/charity care patients, Medicare beneficiaries and Medicaid recipients. See Section VI of the application. The discussion regarding projected access by these groups found in Criterion (13) is incorporated herein by reference.
- ◆ The applicant adequately documents that it will provide quality care. See Sections II and VII of the application.

Therefore, the application is conforming to this criterion.

Novant Health Mint Hill – The applicant proposes to acquire a fixed MRI scanner for use at Novant Health Mint Hill Medical Center in Mint Hill, Mecklenburg County. In Section V.7, pages 92-104, the applicant explains why its proposal to acquire a fixed MRI scanner to be located at the approved Novant Health Mint Hill Medical Center will enhance competition by promoting cost effectiveness, quality and access to MRI services in Mecklenburg County. See also Sections II, III, VI and VII of the application for additional discussion by the applicant about the impact of its proposal on cost effectiveness, quality and access to MRI services in Mecklenburg County.

However, the applicant does not adequately demonstrate that any enhanced competition will have a positive impact on cost effectiveness. This determination is based on the information in the application and the following analysis:

- The applicant does not adequately demonstrate that each existing mobile MRI scanner owned by a related entity and operating at host sites in Mecklenburg County performed at least 3,328 weighted MRI scans in the most recent 12-month period for which the applicant has data.
- Projected utilization is not based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- The applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

Therefore, the application is not 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 – OrthoCarolina Ballantyne
NA – Novant Health Mint Hill

OrthoCarolina Ballantyne – In Section II.7, page 20, the applicant states that it has a quality assurance policy which includes scheduled reviews of quality of services and that it conducts patient satisfaction surveys. Copies of the applicant's quality assurance and safety policies are provided in Exhibit 10. In addition, the applicant states that staff are trained in all policies and procedures, including those pertaining to applicable OSHA standards, infection control standards, and conditions of participation for Medicare and Medicaid. The applicant provides a copy of its staff training policy and training documents in Exhibit 11. Moreover, the applicant states, on page 20, that none of its OrthoCarolina facilities' licenses have been revoked. 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 - OrthoCarolina Ballantyne
NC - Novant Health Mint Hill

OrthoCarolina Ballantyne proposes to acquire a new fixed MRI scanner pursuant to a need determination in the 2014 SMFP for one fixed MRI scanner in Mecklenburg County. Therefore, the Criteria and Standards for Magnetic Resonance Imaging Scanner in 10A NCAC 14C .2700 are applicable to this review. The application is conforming to all applicable Criteria and Standards for Magnetic Resonance Imaging Scanner.

Novant Health Mint Hill proposes to acquire a new fixed MRI scanner pursuant to a need determination in the 2014 SMFP for one fixed MRI scanner in Mecklenburg County. Therefore, the Criteria and Standards for Magnetic Resonance Imaging Scanner in 10A NCAC 14C .2700 are applicable to this review. The application is not conforming to all applicable Criteria and Standards for Magnetic Resonance Imaging Scanner.

The specific criteria for both applications 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- Both applications were submitted on the Acute Care Facility/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- **OrthoCarolina Ballantyne** - In Section II, page 22, the applicant states, *“The application names OrthoCarolina, PA as the sole applicant as it is the entity that will own the MRI scanner and bill patients for the procedures.”*

- C- **Novant Health Mint Hill** - In Section II, page 19, the applicant indicates that Presbyterian Hospital Mint Hill, LLC d/b/a Novant Health Mint Hill Medical Center is the applicant and the entity that will bill the patients for MRI services.

- (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- **OrthoCarolina Ballantyne** - In Section II, pages 17 and 22, the applicant states the proposed fixed MRI scanner will be available and staffed 7:00 am to 7:00 pm Monday through Saturday for a total of 72 hours per week.

 - C- **Novant Health Mint Hill** – In Exhibit 5, the applicant provides a letter documenting that the proposed MRI scanner will be available and staffed for use at least 66 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- Neither of the applicants 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- Neither of the applicants 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 fee;*

 - C- **OrthoCarolina Ballantyne** - The applicant provides the projected charges for the 20 MRI procedures to be performed most frequently during each of the first three years of operation in Section II, page 23. In Section II.1,

page 18, the applicant states that professional services, including image interpretation, will be provided by radiologists with Mecklenburg Radiology and that these services will be directly billed to the patient.

- C- **Novant Health Mint Hill** - In Section II, page 20, the applicant provides the projected charges for the 20 MRI procedures to be performed most frequently during each of the first three years of operation. The applicant states that these charges represent the facility charges and indicates that the radiologists' professional fee will be directly billed to the patient.

(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- Neither of the applicants 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- **OrthoCarolina Ballantyne** - Exhibit 13 contains letters from physicians indicating their support for the project, their intent to refer patients to the proposed fixed MRI scanner, and their estimates of the number of patients proposed to be referred per year, which is based on the physicians' historical number of referrals to the Ballantyne location for MRI scans.

- C- **Novant Health Mint Hill** – In Exhibit 4, the applicant provides a listing of physicians indicating intent to refer patients to the proposed fixed MRI scanner and their estimates of the number of patients proposed to be referred per year.

(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- **OrthoCarolina Ballantyne** - In Section II, page 24, the applicant states that OrthoCarolina, PA currently operates one fixed MRI scanner at the OrthoCarolina Spine Center located at 2001 Randolph Road in Charlotte, Mecklenburg County. The proposed fixed MRI scanner will be located at OrthoCarolina Ballantyne, 15825 John J. Delaney Drive in Charlotte, Mecklenburg County.

- C- **Novant Health Mint Hill** - In Section II, page 21, the applicant states it operates 10 existing, approved, or proposed fixed MRI scanners in Mecklenburg County, the proposed MRI service area. The following table, from page 21, indicates its fixed MRI scanner locations.

Hospitals	Location	Number of Fixed MRI Scanners	MRI Scanner Status
Novant Health (NH) Presbyterian Medical Center (MC)	Charlotte	2	Existing
NH Huntersville MC	Huntersville	1	Existing
NH Matthews MC	Matthews	2	1 Existing 1 Approved*
NH Charlotte Orthopedic Hospital	Charlotte	1	Existing
NH Mint Hill MC	Mint Hill	1	Proposed
Outpatient Centers			
Ballantyne	Charlotte	1	Existing
Museum	Charlotte	1	Existing
South Park	Charlotte	1	Existing
Total		10	

*NHMMC was approved for a second fixed MRI scanner pursuant to a CON issued for Project I.D. #F-8688-11.

(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- **OrthoCarolina Ballantyne** - In Section II, page 24, the applicant provides the projected number of unweighted annual MRI procedures to be performed for each of the four types of MRI procedures, for each of its facilities with existing or proposed fixed MRI scanners, for each of the first three years of operation following completion of the proposed project as illustrated in the table below. See the discussion regarding the reasonableness of the projected utilization in Criterion (3).

Unweighted Projected Annual MRI Procedures

	Year 1 2016	Year 2 2017	Year 3 2018
OrthoCarolina Ballantyne Proposed Fixed MRI			
Inpatient with contrast	0	0	0
Inpatient without contrast	0	0	0
Outpatient with contrast	856	898	943
Outpatient without contrast	3,561	3,739	3,926
Total	4,416	4,637	4,869
OrthoCarolina Spine Center Existing Fixed MRI			
Inpatient with contrast	0	0	0
Inpatient without contrast	0	0	0
Outpatient with contrast	1,600	1,600	1,600
Outpatient without contrast	6,660	6,600	6,600
Total	8,260	8,260	8,260

- C- **Novant Health Mint Hill** - In Section II, pages 22-23, the applicant provides the projected number of unweighted MRI procedures to be performed at each of Novant Health’s facilities with fixed MRI scanners in Mecklenburg County, for the first three years of operation following completion of the proposed project, as illustrated in the table below:

Unweighted Projected Annual MRI Procedures

	Year 1 2018	Year 2 2019	Year 3 2020
NH Mint Hill MC			
Inpatient with contrast	179	231	268
Inpatient without contrast	289	374	434
Outpatient with contrast	845	1,092	1,268
Outpatient without contrast	1,367	1,767	2,051
Total	2,680	3,464	4,021
NH Presbyterian MC			
Inpatient with contrast	1,737	1,791	1,858
Inpatient without contrast	2,115	2,181	2,261
Outpatient with contrast	2,257	2,326	2,412
Outpatient without contrast	2,747	2,832	2,937
Total	8,856	9,130	9,468
NH Huntersville MC			
Inpatient with contrast	267	265	267
Inpatient without contrast	545	543	547
Outpatient with contrast	1,728	1,722	1,733
Outpatient without contrast	3,516	3,502	3,527
Total	6,056	6,033	6,074
NH Matthews MC			
Inpatient with contrast	742	766	801
Inpatient without contrast	963	986	1,031
Outpatient with contrast	2,708	2,777	2,905
Outpatient without contrast	3,518	3,616	3,783
Total	7,931	8,145	8,520
NH Charlotte Orthopedic Hospital			
Inpatient with contrast	12	13	13
Inpatient without contrast	35	36	37
Outpatient with contrast	835	855	874
Outpatient without contrast	2,435	2,490	2,547
Total	3,317	3,394	3,471
NH Imaging Center Museum			
Outpatient with contrast	802	835	869
Outpatient without contrast	2,062	2,147	2,236
Total	2,864	2,982	3,105
NH Imaging South Park			

Outpatient with contrast	657	684	713
Outpatient without contrast	3,725	3,879	4,038
Total	4,382	4,563	4,751
NH Imaging Ballantyne			
Outpatient with contrast	568	592	616
Outpatient without contrast	1,800	1,874	1,951
Total	2,368	2,466	2,567

However, see the discussion regarding the reasonableness of the projected utilization in Criterion (3).

(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- **OrthoCarolina Ballantyne** - In Section II, page 25, the applicant provides the number of weighted procedures by type for the first three years of operation, following completion of the proposed project, as illustrated below. See the discussion regarding the reasonableness of the projected utilization in Criterion (3).

Weighted Projected Annual MRI Procedures

	Year 1 2016	Year 2 2017	Year 3 2018
OrthoCarolina Ballantyne Proposed Fixed MRI			
Inpatient with contrast	0	0	0
Inpatient without contrast	0	0	0
Outpatient with contrast	1,198	1,257	1,320
Outpatient without contrast	3,561	3,739	3,926
Total	4,759	4,997	5,246
OrthoCarolina Spine Center Existing Fixed MRI			
Inpatient with contrast	0	0	0
Inpatient without contrast	0	0	0
Outpatient with contrast	2,240	2,240	2,240
Outpatient without contrast	6,660	6,600	6,600
Total	8,900	8,900	8,900

- C- **Novant Health Mint Hill** - In Section II, pages 22-23, the applicant provides the projected number of weighted MRI procedures to be performed at each of its locations for the first three years of operation following completion of the proposed project, as illustrated in the table below. However, see the discussion regarding the reasonableness of the projected utilization in Criterion (3).

Weighted Projected Annual MRI Procedures*

	Year 1 2018	Year 2 2019	Year 3 2020
NH Mint Hill MC			
Total unweighted MRI scans	2,680	3,464	4,021
Inpatient adjustment for contrast	187	242	281
Contrast adjustment	410	529	614
Total	3,277	4,235	4,916
NH Presbyterian MC			
Total unweighted MRI scans	8,856	9,130	9,468
Inpatient adjustment for contrast	1,541	1,589	1,648
Contrast adjustment	1,598	1,647	1,707
Total	11,995	12,366	12,823
NH Huntersville MC			
Total unweighted MRI scans	6,056	6,033	6,074
Inpatient adjustment for contrast	325	323	326
Contrast adjustment	798	795	800
Total	7,179	7,152	7,200
NH Matthews MC			
Total unweighted MRI scans	7,931	8,145	8,520
Inpatient adjustment for contrast	682	701	733
Contrast adjustment	1,380	1,417	1,482
Total	9,993	10,263	10,735
NH Charlotte Orthopedic Hospital			
Total unweighted MRI scans	3,317	3,394	3,471
Inpatient adjustment for contrast	19	19	20
Contrast adjustment	340	347	355
Total	3,674	3,760	3,846
NH Imaging Center Museum			
Total unweighted MRI scans	2,864	2,982	3,105
Contrast adjustment	320	334	348
Total	3,184	3,316	3,453

NH Imaging South Park			
Total unweighted MRI scans	4,382	4,563	4,751
Contrast adjustment	263	273	285
Total	4,645	4,836	5,036
NH Imaging Ballantyne			
Total unweighted MRI scans	2,368	2,466	2,567
Contrast adjustment	227	236	246
Total	2,595	2,702	2,813

*Totals may not foot due to rounding.

(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- **OrthoCarolina Ballantyne** - The applicant provides a detailed description of the methodology and assumptions used to project the number of unweighted MRI procedures, including the number of contrast versus non-contrast procedures, in Section III, pages 41-48. See the discussion regarding the reasonableness of the methodology and assumptions used to project utilization in Criterion (3).

-C- **Novant Health Mint Hill** - The applicant provides a detailed description of the methodology and assumptions used to project the number of unweighted MRI procedures, including the number of contrast versus non-contrast procedures, in Section III.1, pages 57-61. However, see the discussion regarding the reasonableness of the methodology and assumptions used to project utilization in Criterion (3).

(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- **OrthoCarolina Ballantyne** - The applicant provides a detailed description of the methodology and assumptions used to project the number of weighted MRI procedures in Section III, pages 41-48. See the discussion of the reasonableness of the methodology and assumptions used to project utilization in Criterion (3).

-C- **Novant Health Mint Hill** - The applicant provides a detailed description of the methodology and assumptions used to project the number of weighted MRI procedures in Section III.1, pages 62-65. However, see the discussion

regarding the reasonableness of the methodology and assumptions used to project utilization in Criterion (3).

(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- **OrthoCarolina Ballantyne-** In Section II, page 25, and in Exhibit 2 the applicant provides the vendor, tesla strength, serial number, CON project number and host sites for the mobile MRI scanner that is owned by OrthoCarolina, PA, the applicant.

-C- **Novant Health Mint Hill -** In Section II, page 25, the applicant provides the vendor, tesla strength, serial number, CON project number and host site for the mobile MRI scanners owned by Novant Health, Inc. or a related entity.

(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- Neither application proposes the acquisition of a mobile MRI scanner.

(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- Neither application proposes the acquisition of a mobile MRI scanner.

(15) identity of the accreditation authority the applicant proposes to use.

-C- **OrthoCarolina Ballantyne -** The applicant proposes to use the accreditation authority, American College of Radiology, as identified in Section II, page 26 of the application.

-C- **Novant Health Mint Hill -** The applicant proposes to use either the accreditation authority, American College of Radiology or The Joint Commission, for the proposed MRI scanner, as stated in Section II, page 26.

(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- Neither application proposes 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- Neither application proposes 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- Neither application proposes 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- Neither application proposes the acquisition of a multi-position MRI scanner.

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- Neither application proposes 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- **OrthoCarolina Ballantyne** - In Section II, page 28, and in Exhibit 2 the applicant states that its one fixed MRI performed 8,660 weighted MRI procedures in the most recent 12 month period for which the applicant had data.

-C- **Novant Health Mint Hill** - In Section II, page 29, the applicant states that its eight existing fixed MRI scanners performed an average of 4,669 weighted MRI procedures in CY 2013.

- (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.];*

- C- **OrthoCarolina Ballantyne** - In Section II, page 28, and in Exhibit 2, the applicant states that its one owned mobile MRI scanner, which operated at three sites in Mecklenburg County, performed 5,930 weighted MRI procedures during the most recent 12 month period for which the applicant had data.

- NC- **Novant Health Mint Hill** – In Section II, pages 29-30, the applicant states that related entities own two mobile MRI scanners that provide MRI services in Mecklenburg County. The MQ 16 unit performed only 2,286 weighted MRI scans in FFY 2013 and the Presbyterian Hospital Mobile Unit performed only 1,796 weighted MRI scans in FFY 2013. Therefore, the application is not conforming to this Rule.

(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;*

The 2014 SMFP shows that there are more than four (4) fixed MRI scanners located in the MRI service area of Mecklenburg County. Therefore, each applicant must demonstrate that the average annual utilization for the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns and locates in Mecklenburg County is reasonably expected to perform 4,805 weighted MRI procedures in the third operating year.

- C- **OrthoCarolina Ballantyne** - The applicant owns and operates one existing fixed MRI scanner and proposes to acquire one additional fixed MRI scanner in Mecklenburg County, for a total of two fixed MRI scanners. In Section III.1, page 47, the applicant provides the number of weighted MRI

procedures projected to be performed on the proposed fixed MRI scanner and on the existing fixed MRI scanner.

The average annual utilization for the applicant's existing, approved and proposed MRI scanners is projected to be 7,073 weighted MRI procedures in the third operating year. The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

-NC- **Novant Health Mint Hill-** In Section II, page 30, the applicant states its annual average weighted MRI scan volume for its existing, approved, and proposed fixed MRI scanners is projected to be 5,082 weighted MRI procedures in the third operating year. However, the applicant does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming to this Rule.

(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- **OrthoCarolina Ballantyne -** The proposed fixed MRI scanner would be located at a different site from the applicant's existing fixed MRI scanner. The applicant states, in Section III.1, page 47, that the projected utilization of its proposed fixed MRI scanner will be 5,246 weighted MRI procedures in the third operating year. The applicant adequately demonstrates that projected utilization of its proposed fixed MRI scanner is based on

reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- C- **Novant Health Mint Hill** - The proposed fixed MRI scanner will be located at Novant Health Mint Hill Medical Center, currently under development. The applicant projects that the proposed fixed MRI scanner will perform 4,916 weighted MRI procedures in the third operating year. The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization of the proposed fixed MRI scanner found in Criterion (3) is incorporated herein by reference.

(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

- C- **OrthoCarolina Ballantyne** - The applicant owns one mobile MRI scanner. In Section III.1, page 47, the applicant projects that it will perform 4,056 weighted MRI procedures in the third operating year of the proposed project. The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is conforming to this Rule.

- NC- **Novant Health Mint Hill** - In Section II, page 34, the applicant states that the weighted MRI scan volume for its MQ 16 mobile MRI scanner is projected to be 3,410 in CY 2020, the third year of operation of the proposed project. In Section II, page 36, the applicant projects that its other mobile MRI scanner, its Presbyterian Hospital Unit mobile MRI scanner, will perform 3,891 weighted MRI scans in CY 2020, the third year of operation of the proposed project. However, the applicant does not adequately demonstrate projected utilization of the existing Presbyterian Hospital mobile MRI scanner is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization of the Presbyterian Hospital mobile MRI scanner found in Criterion (3) is incorporated herein by reference. The application is not conforming to this Rule.

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

-C- **OrthoCarolina Ballantyne** - The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section III, pages 41-48. The applicant adequately documents assumptions and provides data supporting the methodology used for each projection. The discussion regarding the methodology and assumptions used to project utilization found in Criterion (3) is incorporated herein by reference.

-NC- **Novant Health Mint Hill** - The applicant's assumptions and data used to support the methodology used for each projection required by this Rule are described in Section II, pages 32-37. However, the applicant does not adequately document assumptions or provide data supporting the methodology used for each projection. The discussion regarding the methodology and assumptions used to project utilization found in Criterion (3) is incorporated herein by reference. The application is not conforming to this Rule.

(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- Neither application proposes the acquisition of a dedicated fixed 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- Neither application proposes 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- Neither application proposes the acquisition of a fixed multi-position MRI scanner.

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- Neither application proposes 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- **OrthoCarolina Ballantyne** – In Exhibit 14, the applicant states that it intends to obtain accreditation for the fixed MRI scanner from the American College of Radiology.

-C- **Novant Health Mint Hill** - The applicant proposes to use either the American College of Radiology or The Joint Commission for accreditation, as stated in Section II, page 26.

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- **OrthoCarolina Ballantyne** - Exhibit 3 contains a letter from Dr. Victor Ho, with Mecklenburg Radiology Associates, stating that Mecklenburg Radiology Associates currently meets all of the above criteria and will continue to meet it for the proposed MRI service. In addition, Dr. Ho states he is willing to continue to serve as Head Radiology Medical Director for the MRI service.

-C- **Novant Health Mint Hill** – Exhibit 5 contains a letter from Dr. Erik K. Insko stating that he is the proposed MRI Medical Director for the Novant Health Mint Hill Medical Center and that he meets the criteria set forth in the MRI CON regulations. His curriculum vitae is provided in Exhibit 5.

(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 of operation of the dedicated breast MRI scanner.*

-NA- Neither application proposes 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- **OrthoCarolina Ballantyne** - In Section VII.1(b), page 73, the applicant states that it will employ two FTE MRI technologist positions for the proposed fixed MRI scanner at the OrthoCarolina Ballantyne location and

that one of the MRI technologists will be present during the hours of operation of the MRI scanner.

- C- **Novant Health Mint Hill** – Exhibit 5 contains a letter stating that two full-time MRI technologist-radiographers will be available and that one of them will be present during the hours the MRI scanner is in operation.
- (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- **OrthoCarolina Ballantyne** - Exhibit 11 contains a copy of OrthoCarolina’s Basic Life Support for Healthcare Providers Initial Certification Agenda and New Hire Orientation Agenda, documenting required staff training and certification in CPR and basic cardiac life support.
 - C- **Novant Health Mint Hill** – Exhibit 5 contains a letter from the Radiology Manager at Novant Health Matthews Medical Center stating that MRI staff training at Novant Health Mint Hill Medical Center will include certification in cardiopulmonary resuscitation and basic cardiac life support from either the American Red Cross or American Heart Association.
 - (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- **OrthoCarolina Ballantyne** - Exhibit 11 contains a copy of OrthoCarolina’s staff education and training program policies, including annual compliance training.
 - C- **Novant Health Mint Hill** – Exhibit 5 contains a letter from the Radiology Manager at Novant Health Matthews Medical Center stating that MRI staff at Novant Health Mint Hill Medical Center will include “*an organized program of MRI staff education and training which is integral [sic] the services program and ensures improvement in technique and the proper training of new personnel.*”
- (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- Neither application proposes the acquisition of 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- Neither application proposes the acquisition of 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.

-NA- Neither application proposes to perform cardiac MRI procedures.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2014 State Medical Facilities Plan, no more than one additional fixed MRI scanner may be approved in this review for Mecklenburg County. Because the two applications in this review collectively propose to acquire two additional fixed MRI scanners, only one of the applications can be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the analyst conducted a comparative analysis of the proposals to decide which proposal should be approved. For the reasons set forth below and in the rest of the findings, the application submitted by OrthoCarolina, PA, Project I.D. #F-10287-14, is approved and the other application, submitted by Presbyterian Hospital Mint Hill, LLC d/b/a Novant Health Mint Hill Medical Center, is denied.

Geographic Distribution

The 2014 SMFP identifies the need for one fixed MRI scanner in Mecklenburg County. The following table identifies the location of the existing and approved fixed MRI scanners in Mecklenburg County.

Facility	City/Town	# of Existing and Approved Fixed MRI Units
Carolinas Medical Center	Charlotte	4
Carolinas Medical Center - University	Charlotte	1
Carolinas Medical Center Mercy/ Pineville	Charlotte/Pineville	2
Novant Health (NH) Presbyterian Medical Center	Charlotte	2
NH Huntersville Medical Center	Huntersville	2
NH Matthews Medical Center	Matthews	2
NH Charlotte Orthopedic Hospital	Charlotte	1
NH Imaging Museum	Charlotte	1
NH Imaging Southpark	Charlotte/Southpark	1
Carolinas Imaging Services - Ballantyne	Charlotte/Ballantyne	1
Carolinas Imaging Services - Southpark	Charlotte/Southpark	1
OrthoCarolina Spine Center	Charlotte	1
Total		19

As shown in the table above, there are 19 existing and approved fixed MRI scanners located in Mecklenburg County. Fifteen are located in Charlotte, two are located in Huntersville, and two are located in Matthews. There are no fixed MRI scanners located in other Mecklenburg County cities.

OrthoCarolina Ballantyne proposes to locate an additional fixed MRI scanner in Charlotte at OrthoCarolina's Ballantyne office located in the Ballantyne area in the southern part of Mecklenburg County. Novant Health Mint Hill proposes to locate a fixed MRI scanner at its approved Novant Health Mint Hill Medical Center to be located in Mint Hill in the eastern part of Mecklenburg County. Thus, with respect to geographic distribution, the proposal submitted by Novant Health Mint Hill is the more effective alternative since there are no fixed MRI scanners in Mint Hill, but there is one already in the Ballantyne area of Charlotte.

Demonstration of Need

OrthoCarolina Ballantyne adequately demonstrated that projected utilization of the proposed fixed MRI scanner was based on reasonable and adequately supported assumptions. Therefore, OrthoCarolina Ballantyne adequately demonstrated the need the population it projects to serve has for the proposed fixed MRI scanner. See Criterion (3) for discussion. However, Novant Health Mint Hill did not demonstrate that each of the existing mobile MRI scanners owned by related entities and operated at host sites in Mecklenburg County performed at least 3,328 weighted MRI scans during the most recent 12 month period for which the applicant has data as required by 10A NCAC 14C .2703(b)(2). Moreover, Novant Health Mint Hill did not adequately demonstrate that projected utilization of its existing fixed and mobile MRI scanners was based on reasonable and adequately supported assumptions. Therefore, Novant Health Mint Hill did not adequately demonstrate the need the population it projects to serve has for the proposed fixed MRI scanner. See Criterion (3) for discussion. Therefore the proposal submitted by OrthoCarolina Ballantyne is the more effective alternative with regard to demonstration of need.

Access by Underserved Groups

The following table illustrates the percentage of total MRI procedures projected to be provided to Medicaid and Medicare recipients in Project Year 2, as stated in Section VI.15 of the respective applications.

Application	Percentage of Total Procedures to be Provided to Medicaid Recipients	Percentage of Total Procedures to be Provided to Medicare Recipients
OrthoCarolina Ballantyne	2.73%	20.08%
Novant Health Mint Hill	9.99%	41.92%

As shown in the table above, Novant Health Mint Hill proposes to serve the highest percentage of both Medicaid and Medicare recipients. Therefore, the proposal submitted by Novant Health Mint Hill is the more effective alternative with regard to access by Medicaid and Medicare recipients.

Revenues

OrthoCarolina Ballantyne's proposed fixed MRI scanner is projected to begin operating 1/01/2016. **Novant Health Mint Hill's** proposed fixed MRI scanner is projected to begin operating 1/01/2018. Therefore, the only overlapping year of operation is CY 2018, which is OrthoCarolina Ballantyne's third operating year and Novant Health Mint Hill's first operating year. Neither applicant includes professional fees (i.e., charges for interpretation of the images by a radiologist). Both applicants deduct bad debt from gross revenue.

Gross Revenue per Procedure

Application	# of MRI Procedures	Gross Revenue	Gross Revenue Per Procedure
OrthoCarolina Ballantyne (Year Three – 1/01/2018 – 12/31/2018)	4,869	\$7,537,212	\$1,548
Novant Health Mint Hill (Year One – 1/01/2018 – 12/31/2018)	2,680	\$7,871,485	\$2,937

As shown in the table above, OrthoCarolina Ballantyne projects the lowest gross revenue per procedure. Novant Health Mint Hill projects the highest gross revenue per procedure. Furthermore, Novant Health Mint Hill did not adequately demonstrate that projected utilization was based on reasonable and adequately supported assumptions. See Criteria (3) for discussion. Consequently, projected revenues based on that projected utilization, are not reliable. Therefore, with regard to projected gross revenue per procedure, the proposal submitted by OrthoCarolina Ballantyne is the most effective alternative.

Average Net Revenue per Procedure

Application	# of MRI Procedures	Net Revenue	Average Net Revenue Per Procedure
OrthoCarolina Ballantyne (Year Three – 1/01/2018 – 12/31/2018)	4,869	\$1,162,636	\$239
Novant Health Mint Hill (Year One – 1/01/2018 – 12/31/2018)	2,680	\$2,339,719	\$481

As shown in the above table, OrthoCarolina Ballantyne projects the lowest average net revenue per procedure. Novant Health Mint Hill projects the highest average net revenue per procedure. Furthermore, Novant Health Mint Hill did not adequately demonstrate that projected utilization was based on reasonable and adequately supported assumptions. See Criteria (3) for discussion. Consequently, projected revenues based on that projected utilization, are not reliable. Therefore, with regard to projected average net revenue per procedure, the proposal submitted by OrthoCarolina Ballantyne is the most effective alternative.

Operating Expenses

Average Operating Expense per Procedure

Application	# of MRI Procedures	Total Operating Expenses	Average Operating Expense Per Procedure
OrthoCarolina Ballantyne (Year Three – 1/01/2018 – 12/31/2018)	4,869	\$1,102,612	\$226
Novant Health Mint Hill (Year One – 1/01/2018 – 12/31/2018)	2,680	\$970,616	\$362

As shown in the table above, OrthoCarolina Ballantyne projects the lowest average operating expense per procedure. Novant Health Mint Hill projects the highest average operating expense per procedure. Furthermore, Novant Health Mint Hill did not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. See Criterion (3) for discussion. Consequently, projected operating expenses based on that utilization are not reliable. Therefore, with regard to projected operating cost per procedure, the proposal submitted by OrthoCarolina Ballantyne is the most effective alternative.

SUMMARY

The application submitted by OrthoCarolina Ballantyne was determined to be conforming or conditionally conforming to all applicable statutory and regulatory review criteria.

In contrast, the application submitted by Novant Health Mint Hill was determined to be nonconforming to Criteria (1), (3), (4), (5), (6), (18a) and 10A NCAC 14C .2703(b)(2), (3), (5) and (6).

For each of the comparative analysis factors listed below, the application submitted by Novant Health Mint Hill was determined to be the more effective alternative than the application submitted by OrthoCarolina Ballantyne:

- Geographic Distribution
- Access by Underserved Groups

For each of the comparative analysis factors listed below, the application submitted by OrthoCarolina Ballantyne was determined to be the more effective alternative than the application submitted by Novant Health Mint Hill:

- Demonstration of Need
- Gross Revenue per Procedure
- Net Revenue per Procedure
- Operating Expense per Procedure

CONCLUSION

Each application is individually conforming to the need determination in the 2014 SMFP for one fixed MRI scanner in Mecklenburg County. However, N.C.G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed MRI scanners that can be approved the CON Section. The CON Section determined that the application submitted by OrthoCarolina, PA is the most effective alternative proposed in this review for one additional fixed MRI scanner for Mecklenburg County and is approved. The approval of any other application would result in the approval of MRI scanners in excess of the need determination in the 2014 SMFP and therefore, the application submitted by Presbyterian Hospital Mint Hill, LLC d/b/a Novant Health Mint Hill Medical Center is denied.

The application submitted by OrthoCarolina, PA is approved subject to the following conditions:

- 1. OrthoCarolina, PA shall materially comply with all representations made in the certificate of need application.**
- 2. Prior to issuance of the certificate of need, OrthoCarolina, PA shall provide documentation of the availability of sufficient funds for the capital cost of the project.**
- 3. OrthoCarolina, PA shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**
- 4. OrthoCarolina, PA shall acquire no more than one fixed MRI scanner for a total of no more than one fixed MRI scanner at OrthoCarolina Ballantyne.**
- 5. OrthoCarolina, PA shall obtain accreditation from The Joint Commission, 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.**
- 6. OrthoCarolina, PA shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**