

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: October 28, 2016
Findings Date: November 1, 2016

Project Analyst: Julie Halatek
Co-Signer: Lisa Pittman
Assistant Chief: Martha J. Frisone

COMPETITIVE REVIEW

Project ID #: F-11182-16
Facility: Carolinas Imaging Services – Huntersville
FID #: 020284
County: Mecklenburg
Applicant: Carolinas Imaging Services, LLC
Project: Acquire a fixed MRI scanner to add to an existing diagnostic center

Project ID #: F-11184-16
Facility: Novant Health Huntersville Medical Center
FID #: 990440
County: Mecklenburg
Applicant: The Presbyterian Hospital
Project: Acquire a second fixed MRI scanner

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C – CIS
NC - Novant

The 2016 State Medical Facilities Plan (2016 SMFP) includes a methodology for determining the need for additional fixed MRI scanners by service area. Application of the need methodology in the 2016 SMFP identified a need for one additional fixed MRI scanner in the Mecklenburg County MRI Service Area. Two applications were submitted to the Healthcare Planning and Certificate of Need Section (Agency), each proposing to acquire a fixed MRI scanner for Mecklenburg County.

Need Determination

Carolinas Imaging Services, LLC (CIS) proposes to acquire one fixed MRI scanner to be installed at its Huntersville (CIS-H) location, which is already a diagnostic center, to replace the use of an existing CIS-owned mobile MRI scanner. CIS does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2016 SMFP for Mecklenburg County. Therefore, the application is consistent with the need determination.

The Presbyterian Hospital (Novant) proposes to acquire a fixed MRI scanner which will be located at Novant Health Huntersville Medical Center (NHHMC) for a total of two fixed MRI scanners. The applicant does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2016 SMFP for Mecklenburg County. Therefore, the application is consistent with the need determination.

Policies

There are two policies in the 2016 SMFP which are applicable to this review: Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-3: Basic Principles, 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.”

CIS.

Promote Safety and Quality - In Section I, pages 14-17, Section II.3, page 22, Sections II.5-7, pages 23-26, Section III.2, pages 64-65, and Section V.7, page 84, the applicant

describes how it believes the proposed project would promote safety and quality. Exhibits 7, 12, and 15 contain copies of CIS's Professional QI Program, CHS Clinical Training Affiliations, and Continuing Education Plan and Policies. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access - In Section III.2, page 65, Section VI, pages 88-98, and Exhibits 14 and 20, the applicant describes how it believes the project would promote equitable access to MRI scanner services. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will promote equitable access.

Maximizing Healthcare Value - The applicant describes how it believes the proposed project would maximize healthcare value in Section III.2, page 66, stating:

“Given that the physical space will only require upfit, the proposed project will allow CIS-Huntersville to quickly meet the needs of the market while also remaining cost-effective. Further, as the Carolinas HealthCare System Huntersville freestanding emergency department grows and serves patients requiring MRI services, the proposed fixed scanner at CIS-Huntersville, which is located within the same building as the freestanding emergency department, will be able to serve these patients in a timely, cost-effective manner.

Additionally, the proposed project presents a cost-effective alternative for patients who need MRI services. CIS-Huntersville is the only freestanding facility in northern Mecklenburg County...”

The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how the projected volumes incorporate the concepts of quality, equitable access, and maximum value for resources expended in meeting the need identified in the 2016 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. The discussion regarding revenues and costs found in Criterion (5) is incorporated herein by reference. Therefore, the application is consistent with Policy GEN-3.

Novant.

Promote Safety and Quality - In Section I, pages 4-8, Section II.1, pages 9-11, Section II.5, II.6, and II.7, pages 13-17, Section III.2, pages 48-55, and Section V.7, pages 68-72, the applicant describes how it believes the proposed project would promote safety and quality. Exhibits 2, 4, 5, and 6 contain information on the proposed scanner, quality and safety related policies and procedures, hospital licensure, and clinical improvement plans, respectively. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access - In Section III.2, pages 51-52, Section V.7, pages 71-72, Section VI, pages 74-86, and Exhibits 6, 13, and 14, the applicant describes how it believes the project would promote equitable access to MRI scanner services. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will promote equitable access. The discussion regarding access found in Criterion (18a) is incorporated herein by reference.

Maximizing Healthcare Value – In Section III.2, pages 53-54, Section V.7, pages 68-69, and Exhibits 16 and 22, the applicant describes how it believes the proposed project would maximize healthcare value.

However, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum value for resources expended. The applicant does not adequately demonstrate the need to acquire a fixed MRI scanner. Therefore, the applicant fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2016 SMFP. The discussion regarding analysis of need, including historical and projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not consistent with Policy GEN-3.

Policy GEN-4 states:

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

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

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

CIS. The proposed capital expenditure for this project is greater than \$2 million and less than \$5 million. In Section III.2, pages 66-67, the applicant states that it is committed to energy efficiency and sustainability and provides a written statement, including five guiding principles, describing its plan to ensure energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Novant. The proposed capital expenditure for this project is greater than \$2 million and less than \$5 million. In Section XI.7, page 119, the applicant states that the project will be designed in compliance with all applicable requirements for energy efficiency and consumption. Exhibit 10 contains a copy of the applicant's 2016 Sustainable Energy Management Plan. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

In summary, both applicants adequately demonstrate that their proposals are consistent with the need determination in the 2016 SMFP for one fixed MRI scanner for Mecklenburg County. However, the limit on the number of MRI scanners that may be approved in this review is one MRI scanner. Collectively, both applicants propose a total of two MRI scanners. Therefore, even if both applications were conforming to all statutory and regulatory review criteria, both applications cannot be approved.

The application submitted by CIS is conforming to Policy GEN-3. The application submitted by Novant is not conforming to Policy GEN-3. Both applications are conforming to Policy GEN-4. Therefore, the CIS application is conforming to this criterion and the Novant 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 – CIS
NC – Novant

CIS proposes to acquire a fixed MRI scanner to be installed at its Huntersville (CIS-H) location to replace its existing mobile MRI scanner service. In Section I.12(e), page 14, the applicant states that CIS was formed as a joint venture between The Charlotte-

Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System (CHS) and Charlotte Radiology (CR). The CHS system includes the following separately licensed hospitals:

- Carolinas HealthCare System Anson in Wadesboro (Anson County)
- Carolinas Medical Center in Charlotte (Mecklenburg County)
- Carolinas HealthCare System Lincoln in Lincoln (Lincoln County)
- Carolinas HealthCare System Pineville in Pineville (Mecklenburg County)
- Carolinas HealthCare System NorthEast in Concord (Cabarrus County)
- Carolinas HealthCare System Union in Monroe (Union County)
- Carolinas HealthCare System University in Charlotte (Mecklenburg County)
- Carolinas HealthCare System Cleveland in Shelby (Cleveland County)
- Carolinas HealthCare System Kings Mountain in Kings Mountain (Cleveland County)
- Stanly Regional Medical Center in Albemarle (Stanly County)

The licensed hospitals in Mecklenburg County have the following associated facilities included on their 2016 License Renewal Application (LRA):

- Carolinas Medical Center in Charlotte – License #H0071 (CMC)
 - CMC – Mercy (acute care hospital campus)
 - CHS Southpark (satellite ED)
 - CHS Behavioral Health Charlotte (psychiatric hospital)
 - CHS Behavioral Health Davidson (psychiatric hospital)
- Carolinas HealthCare System Pineville in Pineville – License #H0042
 - CHS Pineville (acute care hospital)
 - CHS Steele Creek (satellite ED)
- Carolinas HealthCare System University in Charlotte – License #H0255
 - CHS University (acute care hospital)
 - CHS Huntersville (surgery center)
 - Carolinas Sleep Services University (sleep services)
 - CHS Huntersville Emergency Department (satellite ED)
 - Southeast Pain Care Center University (pain center)

In Section I.12(c), pages 11-14, CR provides a list of the outpatient imaging centers, breast centers, and vascular and interventional centers that it manages and operates.

In addition to CIS-H, CIS owns and operates the following outpatient imaging centers, all located in Mecklenburg County (all of which are designated as diagnostic centers):

- Carolinas Imaging Services – Ballantyne in Charlotte
- Carolinas Imaging Services – Matthews in Matthews
- Carolinas Imaging Services – South Park in Charlotte

According to the application and the 2016 Registration and Inventory of Medical Equipment forms, CIS owns and operates the following MRI scanners:

Serial Number	Type	Site/Location	County	City
R1308*	Fixed	CIS-South Park	Mecklenburg	Charlotte
54940	Fixed	CIS-Ballantyne	Mecklenburg	Charlotte
R4016**	Mobile	CHS Anson Carolina Neurological Clinic	Anson Mecklenburg	Wadesboro Charlotte
R6099	Mobile	CIS-Huntersville St. Luke's Hospital	Mecklenburg Polk	Huntersville Columbus

*The applicant states on page 14 that the MRI scanner is leased from CHS.

**The information about this scanner was obtained from the 2016 forms. The applicant states on page 32 that this scanner no longer operates in Mecklenburg County.

Additionally, CMC owns five fixed MRI scanners, CHS Pineville owns one fixed MRI scanner, and CMC University owns one fixed MRI scanner.

At project completion, CIS will be licensed for three fixed and two mobile MRI scanners operating in Mecklenburg County. In Section II.8, page 35, the applicant states that at project completion, it proposes that the existing mobile MRI scanner currently serving CIS-H will serve CMC and CHS Pineville.

Patient Origin

On page 154, the 2016 SMFP defines the service area for fixed MRI scanners as “a single county, except where there is no licensed acute care hospital located within the county.” Thus, the service area for this project consists of Mecklenburg County. Providers may serve residents of counties not included in their service area.

In Section III.4(b), page 71, the applicant provides the historical patient origin for CIS-H MRI scanner patients, as shown in the table below.

CIS-H MRI Patient Origin by County Historical – CY 2015**	
County	% Patients
Mecklenburg	59.6%
Iredell	15.2%
Lincoln	6.6%
Gaston	5.0%
Cabarrus	4.6%
Catawba	2.6%
Rowan	1.6%
Other*	4.8%
Total	100.0%

*The applicant identifies “Other” as 20 counties in North Carolina, eight counties in South Carolina, and other states.

**The applicant does not provide information on what time period is measured in this patient origin information. However, on page 54, the applicant states that it uses calendar year information to project utilization because it correlates with the most recent data as well as CIS’s fiscal year. Thus, the Project Analyst believes this data is from CY 2015.

In Section III.5(c), page 74, the applicant provides the projected patient origin for the first two years of operation after project completion, as shown in the table below.

CIS-H MRI Patient Origin by County Projected OY1 & OY2 – CY 2018 & CY 2019				
County	# Patients OY1	% Total Patients OY1	# Patients OY2	% Total Patients OY2
Mecklenburg	2,577	66.7%	2,853	67.3%
Iredell	536	13.9%	583	13.8%
Lincoln	198	5.1%	211	5.0%
Gaston	148	3.8%	158	3.7%
Cabarrus	136	3.5%	145	3.4%
Catawba	79	2.0%	84	2.0%
Rowan	49	1.3%	52	1.2%
Other*	142	3.7%	151	3.6%
Total	3,864	100.0%	4,237	100.0%

*The applicant identifies “Other” as 20 counties in North Carolina, eight counties in South Carolina, and other states.

In Section III.5(d), page 74, the applicant states it based its projected patient origin on the current patient origin as well as the patient origin of a projected shift in volume (discussed further below).

The applicant adequately identifies the population proposed to be served.

Analysis of Need

In Section III.1(a) of the application, the applicant states the identified need is to replace mobile MRI service with fixed MRI service, expand available hours, and enhance service to its patients. The applicant describes the factors which it states result in the need for the proposed project, including:

- Increased utilization of MRI services at CIS and CHS facilities for both fixed and mobile MRI services (pages 38-41 and pages 43-44).
- When combined with data from CHS facilities, an increase in utilization at a higher rate than other providers of MRI services in Mecklenburg County (pages 41-45).
- Mobile MRI scanners are less effective than fixed scanners at higher volume sites because of their limited availability, limited space in a trailer, and location outside of a building (pages 45-46).
- The proposed fixed MRI scanner has additional features over the current mobile MRI scanner, including noise reduction technology, additional space, artifact reduction software, and other software features (page 47).
- A fixed MRI scanner will allow for an increase in available hours and days which will reduce an existing two-day patient wait for services (pages 46-48).
- Growth and aging of the Mecklenburg County population is expected to continue (pages 50-53).

The information in the pages referenced above is reasonable and adequately supported for the following reasons:

- Population growth occurring in Mecklenburg County;
- The applicant provides sufficient evidence of MRI services growth at its facilities and at CHS facilities at a higher rate than other providers of MRI services in Mecklenburg County; and
- Limitations of existing mobile MRI scanner with regard to technological capability and physical structure.

Projected Utilization

In Section IV.1, page 78, the applicant provides the historical utilization for its mobile MRI scanner and projected utilization for the proposed fixed MRI scanner. In Section III.1(b), the applicant discusses the assumptions and methodology used to project MRI utilization at CIS-H, summarized as follows:

- Historical CY 2013-2015 utilization increased at a compound annual growth rate (CAGR) of 26.6 percent for unweighted scans and 26.2 percent for weighted scans. (page 54).
- MRI scans for CY 2016 through CY 2020, the third full fiscal year following completion of the proposed project, are projected forward at 7.0 percent for outpatient scans without contrast or sedation and 5.8 percent for outpatient scans with contrast and/or sedation, an annual growth rate of one fourth of its CY 2013-2015 CAGR. The applicant states that it chose the projected growth rate to be conservative in its assumptions. The applicant states that this projected growth is reasonable due to the historic growth experienced at CIS-H as well as overall CIS and CHS average annual utilization increases of more than six percent (pages 55-56). The applicant provides a table showing the overall CIS and CHS CAGR on page 56.

On page 55, the applicant provides the most recent utilization data, interim year utilization projections, and projected utilization for Project Years 1-3, as shown in the table below.

CIS-H CY 2015-2020 Historical and Projected Patient Utilization (prior to patient shift)							
	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CAGR
OP w/o Contrast/Sedation	1,755	1,878	2,010	2,151	2,302	2,463	7.0%
OP w/ Contrast/Sedation	700	740	783	828	876	927	5.8%
Total Scans	2,455	2,618	2,793	2,979	3,178	3,390	6.7%
Total Weighted	2,735	2,915	3,106	3,311	3,529	3,761	6.6%

The applicant projects a shift in patient referrals to occur when patients currently receiving MRI services at other facilities are referred to CIS-H for MRI services. The applicant states that a shift in patient referrals is reasonable for the following reasons:

- CIS and CHS have experienced increased utilization of their fixed MRI services (page 56).
- The mobile MRI scanner at CIS-H cannot offer the same patient convenience as a fixed MRI scanner because mobile MRI scanners are generally less effective. The reasons its mobile MRI scanner is not as effective as a fixed MRI scanner are discussed in Section III.1(a) of the application (pages 56-57).
- The proposed fixed MRI scanner will be in operation for 66 hours of service per week instead of the current 48 hours. It will also allow for MRI services to be offered on Wednesdays, which is currently not available, because a mobile lithotripsy unit occupies the mobile pad on Wednesdays (page 57).

The applicant provides the following assumptions and methodology for calculating the proposed shift in patient referrals (pages 57-62):

- In CY 2015 approximately 60 percent of CIS-H patients originated in seven contiguous zip codes (28078, 28031, 28269, 28117, 28216, 28115, and 28036).
- The applicant defined these seven zip codes as its primary market for the proposed project. Future increases in patient referrals will originate only from this primary market.
- The shift in patient referrals will come from patients being served at one of three hospitals affiliated with CHS (CMC, CMC-Mercy, and CHS University) and no referrals are expected to come from any other providers.
- The MRI units at the referenced facilities are all operating above 4,805 weighted MRI scans per unit per year; therefore, it will be easier for patients to schedule a time at CIS-H for services rather than at the existing facilities.
- Only scheduled outpatient MRI scans will be involved in any patient shifts to CIS-H because CIS-H does not offer inpatient services and therefore no inpatient MRI scans would be performed there.
- Medicaid patients are excluded from projections of shifting patient referrals because Medicaid does not reimburse for MRI scans outside of hospitals. Therefore, Medicaid patients are not likely to come to CIS-H for MRI services.

- The applicant used the same percentages to project growth for the shift in patient referrals as it used for projecting future utilization at CIS-H.
- 50 percent of the identified patients will shift from where they currently receive services to CIS-H.
- The 50 percent of patients who shift will do so with a “ramp-up” period, where 80 percent, 90 percent, and 100 percent of the estimated patient shift will receive services at CIS-H in Project Years One, Two, and Three, respectively.

On page 61, the applicant identifies 1,834 MRI scans from CY 2015, broken down by facility and type of scan, which it projects will be part of the patient shift. On page 62, the applicant provides the most recent utilization data, interim year utilization projections, and projected utilization for Project Years 1-3 for the projected patient shift, as shown in the table below.

CIS-H CY 2015-2020 Historical and Projected Patient Utilization – Patient Shift						
	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020
OP w/o Contrast/Sedation	970	1,038	1,111	1,189	1,272	1,362
OP w/ Contrast/Sedation	864	914	967	1,022	1,081	1,144
Projected Shift	NA	NA	NA	50%	50%	50%
Ramp-Up	NA	NA	NA	80%	90%	100%
Shifted OP w/o Contrast/Sedation	0	0	0	476	573	681
Shifted OP w/ Contrast/Sedation	0	0	0	409	487	572

Finally, the applicant provides the total projected utilization for CIS-H during Project Years 1-3, including projections based on historical utilization at CIS-H as well as the projections for patient shift, as shown in the table below.

CIS-H CY 2015-2020 Historical and Projected Patient Utilization – Total						
	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020
Existing OP w/o Contrast/Sedation	1,755	1,878	2,010	2,151	2,302	2,463
Existing OP w/ Contrast/Sedation	700	740	783	828	876	927
Shifted OP w/o Contrast/Sedation	0	0	0	476	573	681
Shifted OP w/ Contrast/Sedation	0	0	0	409	487	572
Total Scans	2,455	2,619	2,793	3,864	4,237	4,643
Total Weighted	2,735	2,915	3,106	4,359	4,782	5,242

Projected utilization is based on reasonable and adequately supported assumptions, summarized as follows:

- Historical MRI utilization;
- Projected growth rate that is lower than historical growth rates;
- Increased hours of operation; and
- Sufficient evidence to support patient shift in location of services.

Based on review of: 1) the information provided by the applicant in Section III, pages 38-77, Section IV, pages 78-79, and referenced exhibits; 2) comments received during the first 30 days of the review cycle; and 3) the applicant’s response to the comments received at the public hearing, the applicant adequately documents the need for the project for the reasons discussed above.

Access

In Section VI.2, page 88, the applicant states:

“CIS will continue to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay, or any other factor that would classify a patient as underserved. Diagnostic imaging services at CIS-Huntersville will continue to be available to and accessible by any patient who has a clinical need for such services.”

On pages 88-89, the applicant states that while CIS-H does accept Medicaid patients for certain types of imaging services, Medicaid does not authorize payments to independent diagnostic testing facilities (IDTFs) like CIS-H for MRI services. The applicant states, *“Medicaid patients referred to CIS for services that are not authorized by IDTFs are referred to hospital-based [sic]. CIS has to [sic] the ability to and does directly schedule these patients at hospital-based providers.”*

The applicant further addresses access to CIS’s MRI services in Sections VI.13 and VI.15. On pages 96-97, the applicant provides the CY 2015 payor mix and the projected payor mix for the MRI service component for the second full fiscal year of the proposed project.

CIS-H MRI Historical/Projected Payor Mix		
	CY 2015	CY 2019
Self-Pay/Indigent/Charity	0.7%	0.7%
Medicare/Medicare Managed Care	21.1%	21.1%
Medicaid	0.0%	0.0%
Commercial/Managed Care	63.9%	63.9%
Other*	14.3%	14.3%
Total	100.0%	100.0%

*Other includes Worker’s Compensation, Champus/TRICARE, and Veteran’s Administration

Exhibit 14 contains a copy of the applicant’s financial policies.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed.

Conclusion

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

Novant proposes to add a second fixed MRI scanner to its Huntersville campus, to be located in an outpatient setting. In Section I.12(b), pages 4-5, the applicant states that in addition to NHHMC, its parent company, Novant Health, Inc., owns, operates, and/or manages the following hospitals in North Carolina:

- Novant Health Charlotte Orthopaedic Hospital in Charlotte (Mecklenburg County)
- Novant Health Presbyterian Hospital in Charlotte (Mecklenburg County)
- Novant Health Matthews Medical Center in Matthews (Mecklenburg County)
- Novant Health Rowan Medical Center in Salisbury (Rowan County)
- Novant Health Thomasville Medical Center in Thomasville (Davidson County)
- Novant Health Forsyth Medical Center in Winston-Salem (Forsyth County)
 - Novant Health Kernersville Medical Center in Kernersville
 - Novant Health Clemmons Medical Center in Clemmons
- Novant Health Medical Park Hospital in Winston-Salem (Forsyth County)
- Novant Health Brunswick Medical Center in Bolivia (Brunswick County)
- Halifax Regional Medical Center in Roanoke Rapids (Halifax County)
- Ashe Memorial Hospital in Jefferson (Ashe County)
- Hugh Chatham Memorial Hospital in Elkin (Surry County)
- Morehead Memorial Hospital in Eden (Rockingham County)
- Carteret Health Care in Morehead City (Carteret County)

Additionally, Novant Health, Inc. has received CON approval to construct Novant Health Mint Hill Medical Center, a community hospital to be located in Charlotte (Mecklenburg County).

The licensed hospitals in Mecklenburg County have the following associated facilities included on their 2016 License Renewal Application (LRA):

- Novant Health Presbyterian Hospital in Charlotte – License #H0010
 - Novant Health Midtown (surgery center)
 - Novant Health Charlotte (surgery center)
 - Novant Health Imaging Museum (freestanding diagnostic imaging center)
 - Novant Health Imaging University (freestanding diagnostic imaging center)
 - Novant Health Charlotte Orthopedic Hospital (orthopedic hospital)

On page 5, the applicant lists the following facilities it owns and operates in the greater Charlotte area:

- Southpark Outpatient Surgery – Charlotte
- Novant Health Ballantyne Outpatient Surgery – Charlotte
- Novant Health Monroe Outpatient Surgery – Monroe
- Novant Health Huntersville Outpatient Surgery – Huntersville
- Matthews Surgery Center – Matthews

On pages 5-6, the applicant states that MedQuest is an affiliated company and manages or operates 25 diagnostic imaging centers in various locations throughout North Carolina, including these eight facilities in the greater Charlotte area:

- Novant Health Imaging Cabarrus – Concord
- Novant Health Imaging Gastonia – Gastonia
- Novant Health Imaging South Park – Charlotte
- Novant Health Imaging Ballantyne – Charlotte
- Novant Health Imaging Steele Creek – Charlotte
- Novant Health Imaging Monroe – Monroe
- Novant Health Breast Center – Charlotte
- Novant Health Breast Center – Huntersville

According to the application, pages 7-8, and the 2016 Registration and Inventory of Medical Equipment forms, Novant Health, Inc. owns and operates the following fixed and mobile MRI scanners in Mecklenburg County:

Serial Number	Type	Site/Location	County	City
963112YM8	Fixed	Novant Health Imaging Museum	Mecklenburg	Charlotte
R0801	Fixed	Novant Health Imaging Ballantyne	Mecklenburg	Charlotte
30563	Fixed	Novant Health Imaging South Park	Mecklenburg	Charlotte
26489	Fixed	NHHMC	Mecklenburg	Huntersville
240317MR8	Fixed	Novant Health Matthews Medical Center	Mecklenburg	Matthews
M135	Fixed	Novant Health Charlotte Orthopaedic Hospital	Mecklenburg	Charlotte
WB0156	Fixed	Novant Health Presbyterian Medical Center	Mecklenburg	Charlotte
HM0406	Fixed	Novant Health Presbyterian Medical Center	Mecklenburg	Charlotte
R3980	Mobile	PIC University	Mecklenburg	Charlotte
		PIC Steele Creek	Mecklenburg	Charlotte
		PIC Ballantyne	Mecklenburg	Charlotte
235487	Mobile	Mooreville Diagnostic Imaging	Iredell	Mooreville
		Novant Health Imaging University	Mecklenburg	Charlotte
		PIC Steele Creek	Mecklenburg	Charlotte

Note: An approved fixed MRI scanner to be located at NHMCMC is expected to be operational in 2018.

Also on pages 7-8, the applicant states that Novant owns 25 additional fixed MRI scanners elsewhere around the country.

At project completion, Novant will be licensed for two fixed MRI scanners on the NHHMC campus and a total of ten fixed MRI scanners and two mobile MRI scanners operating in Mecklenburg County.

Patient Origin

On page 154, the 2016 SMFP defines the service area for fixed MRI scanners as “a single county, except where there is no licensed acute care hospital located within the county.” Thus, the service area for this project consists of Mecklenburg County. Providers may serve residents of counties not included in their service area.

NHHMC currently has one fixed MRI scanner, which the applicant states performed more than 7,495 weighted MRI scans during CY 2015. In Section III.4 and III.5, pages 58 and 59, the applicant provides the current patient origin by county for the existing MRI services at NHHMC and the projected patient origin by county for the first two years following project completion, as shown in the table below.

NHHMC Historical/Projected Patient Origin – MRI Services			
County	CY 2015	CY 2018	CY 2019
Mecklenburg	66.73%	66.73%	66.73%
Lincoln	10.56%	10.56%	10.56%
Iredell	7.62%	7.62%	7.62%
Gaston	5.48%	5.48%	5.48%
Cabarrus	3.46%	3.46%	3.46%
All Other In-Migration*	6.15%	6.15%	6.15%
Total	100.00%	100.00%	100.00%

*The applicant states that this category includes other North Carolina counties and U.S. states.

In Section III.5(d), page 60, with regard to the assumptions for projected patient origin, the applicant states: “The proposed patient origin by county is based upon historical patient origin for MRI service at NHHMC.” The applicant adequately identifies the population proposed to be served.

Analysis of Need

In Section III.1(a), page 30, the applicant states:

“Since 2004, NHHMC has experienced exceptional growth as a community-based hospital serving northern Mecklenburg County and the surrounding areas. The historical MRI volume at NHHMC speaks for itself. The State’s definition of 100% capacity for a fixed MRI scanner is 6,864 weighted MRI procedures. In the last six reporting periods (FY 2009-FY 2015), NHHMC has repeatedly performed in excess of 7,000 weighted MRI scans annually. The demand for MRI services at this facility continues to push the limits of capacity at such a rate that NHHMC recently added mobile MRI capacity as a short-term, temporary means of increasing capacity.

...

Year after year, NHHMC's existing scanner pushes past the practical limits of capacity to provide these necessary imaging services to its patients and their referring physicians. Currently, NHHMC's existing fixed MRI scanner operates from 6:30am to 12:00am Monday – Friday and 6:30am to 7:30pm Saturday – Sunday. On a weekly basis, NHHMC's sole fixed MRI unit is running more than 100 hours. This level of operation over time can create higher maintenance demands and issues. At this current level of service, an equipment downtime event represents a serious accessibility issue for NHHMC's patients."

On page 31, the applicant states that it was approved to relocate a total of 48 acute care beds and one operating room from Novant Health Presbyterian Medical Center to NHHMC. The applicant states that the project represents an increase in bed capacity of 53 percent, and that because of increasing MRI volumes, the expected growth in inpatient services, and the fact that the existing fixed MRI scanner services both inpatients and outpatients, there is a need for a second fixed MRI scanner dedicated to serving outpatients.

In Section III.1(a), pages 29-40, the applicant describes the factors it believes influence the demand for the proposed project, including:

- Historical MRI demand at NHHMC in excess of practical capacity (page 30)
- Approved expansion plans for NHHMC through Project I.D. #F-11110-15 and the impact of that expansion (pages 31-32)
- Growth of active medical staff (pages 33-35)
- Population growth in the NHHMC service area (pages 35-39)
- Aging of the population in the NHHMC service area (pages 39-40)

The information in the pages referenced above is reasonable and adequately supported for the following reasons:

- Historical growth in MRI procedures;
- Approval of Project I.D. #F-11110-15, relocating 48 acute care beds and one operating room; and
- Population growth occurring in Mecklenburg County.

Projected Utilization

In calculating its projected total utilization for its fixed and mobile MRI scanners, the applicant separately projects utilization for acute care facility-based fixed MRI scanners, outpatient facility-based fixed MRI scanners, and mobile MRI scanners.

In Section II.8, page 19, the applicant provides the historical utilization for the existing fixed MRI scanners it or its parent company owns and operates in Mecklenburg County. In Section III.2, page 47, the applicant provides projected utilization including the proposed additional fixed MRI scanner through the first three years of operation following completion of the project (CY 2018 through CY 2020), as shown in the table below.

Novant Health Patient Utilization of Fixed MRI Services – Historical and Project Years 1-3 Weighted Volume by Facility					
Facility	# Fixed MRI Scanners	Weighted MRI Volume			
		CY 2015	CY 2018	CY 2019	CY 2020
HOSPITALS					
NHPMC	2	11,810	13,326	13,662	13,796
NHHMC*	2	7,495	8,785	9,339	10,107
NHMMC	1	7,739	6,976	6,581	5,758
NHCOH	1	3,857	4,369	4,558	4,753
NHMHMC**	1	--	1,722	2,513	3,744
OUTPATIENT IMAGING CENTERS					
Ballantyne	1	2,638	3,032	3,187	3,349
Museum	1	2,412	2,793	2,935	3,086
South Park	1	3,683	4,266	4,483	4,712
Totals*	10	39,634	45,269	47,258	49,305

*In CY 2015, there was only one fixed MRI scanner at NHHMC for a total of nine existing and approved fixed MRI scanners at Novant Health facilities in Mecklenburg County.

**On page 44, the applicant states that the approved fixed MRI scanner to be located at NHMHMC is not expected to be operational until mid-2018.

As shown in the above table, the applicant projects the existing and proposed fixed MRI scanners at NHHMC will perform a total of 10,107 weighted MRI procedures in the third operating year, for an average of 5,053 weighted MRI procedures per machine. Furthermore, the applicant projects the 10 existing, approved, and proposed fixed MRI scanners will perform an average of 4,931 weighted MRI procedures during the third operating year, which exceeds the utilization standards required in 10A NCAC 14C .2703(b). The applicant describes the assumptions and methodology used to project utilization in Section III.1(b), pages 41-47, which are summarized below.

Novant Health Acute Care Facility-Based Fixed MRI Scanners

Step 1. The applicant determined the historical unweighted MRI volume for all Novant hospitals in Mecklenburg County for CYs 2012-2015 to calculate an average annual growth rate for all Novant facilities, as shown in the table below.

Novant Health Historical Unweighted MRI Volume – Mecklenburg County					
Acute Care Facility-Based Fixed MRI Scanners					
Hospital	# of Fixed Units	CY 2012	CY 2013	CY 2014	CY 2015
NHPMC	2	8,124	8,443	8,683	8,904
NHCOH	1	1,845	3,136	3,470	3,527
NHHMC	1	6,372	6,098	5,991	6,298
NHMMC	1	5,684	5,420	5,635	6,260
Total		22,025	23,097	23,779	24,989
% Change			4.87%	2.95%	5.09%
AAGR CY 2012 – CY 2014					4.30%

The applicant determined that the Novant acute care facility Average Annual Growth Rate (AAGR) was 4.30 percent (4.87% + 2.95% + 5.09% = 12.91%; 12.91% / 3 years = 4.30%). *Step 2.* The applicant applied the 4.30 percent AAGR to the total Novant unweighted MRI volume for CY 2015 and projected those totals forward through CY 2020 (the third year of operation for the proposed project), as shown in the table below.

Novant Health Historical Unweighted MRI Volume – Mecklenburg County						
Acute Care Facility-Based Fixed MRI Scanners						
	Actual	Estimated	Estimated	Project Year 1	Project Year 2	Project Year 3
Time Period	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020
Unweighted MRI Volume	24,989	26,064	27,184	28,353	29,572	30,844
% Change		4.30%	4.30%	4.30%	4.30%	4.30%

Step 3. The applicant determined the unweighted MRI volume distribution between the different hospitals. The applicant states that changes from the historical distribution rates are expected when NHMHMC becomes operation in mid-2018 and NHHMC’s proposed fixed MRI scanner becomes operational for CY 2018. The applicant then distributes the unweighted MRI volume among the different facilities for each of the first three project years (CY 2018 – CY 2020), while factoring in the aforementioned changes to the distribution rates, as shown in the table below.

Novant Health Historical/Projected Unweighted MRI Volume – Mecklenburg County						
Acute Care Facility-Based Fixed MRI Scanners						
Hospital	CY 2015	Distribution %	CY 2018	CY 2019	CY 2020	PY 3 Distribution %
Volume	24,989	100.0%	28,353	29,572	30,844	100.0%
NHPMC	8,904	35.6%	9,952	10,202	10,302	33.4%
NHCOH	3,527	14.1%	3,969	4,140	4,318	14.0%
NHHMC	6,298	25.2%	7,372	7,837	8,482	27.5%
NHMMC	6,260	25.1%	5,642	5,323	4,657	15.1%
NHMHMC*	--	0%	1,418	2,070	3,084	10.0%

*The approved fixed MRI scanner to be located at NHMHMC was not in operation in CY 2015 and is not expected to be operational until mid-2018.

Step 4. The applicant determined the specific contrast and inpatient adjustments to the unweighted MRI volume for each facility based on a three-year average and then applied that ratio to the unweighted MRI volume to project weighted MRI volume. The

calculations for NHHMC are shown in the table below. The applicant repeated the process with each of the facilities listed in the previous tables, and those calculations can be found on pages 43-44 of the application.

NHHMC – Weighted MRI Volume Projections – CY 2018 - 2020				
Acute Care Facility-Based Fixed MRI Scanners				
	Percentages	CY 2018	CY 2019	CY 2020
Total Unweighted Volume		7,372	7,837	8,482
Estimated IP	13.9%	1,025	1,089	1,179
Estimated OP	86.1%	6,347	6,748	7,303
Contrast Scans	34.0%	2,507	2,665	2,884
Weights*				
IP		410.0	435.6	471.6
Contrast Scans		1,002.8	1,066.0	1,153.6
Weighted MRI Volume		8,785	9,339	10,107

*One weighted scan is equal to 1.4 unweighted scans, per the methodology in the 2016 SMFP.

As shown above, the applicant’s utilization projections are based on the historical utilization of Novant’s existing fixed MRI scanners from CY 2012 through CY 2015, increased by reasonable and adequately supported growth rates.

Novant Health Outpatient Facility-Based Fixed MRI Scanners

Step 1. The applicant determined the historical unweighted MRI volume for all Novant outpatient facilities with a fixed MRI scanner in Mecklenburg County for CYs 2012-2015, as shown in the table below (see page 45).

Novant Health Historical Unweighted MRI Volume – OP Facilities (w/Fixed MRI Scanners)					
Facility	# of Fixed Units	CY 2012	CY 2013	CY 2014	CY 2015
Ballantyne	1	1,625	1,934	2,219	2,406
Museum	1	2,562	2,339	2,218	2,157
South Park	1	4,158	3,579	3,167	3,429
Total	3	8,345	7,852	7,604	7,992
% Change			-5.91%	-3.16%	5.10%
AAGR CY 2012 – CY 2015					-1.32%

Step 2. The applicant then applies a growth rate of 5.1 percent, starting with the most recent calendar year information, and then projects outpatient fixed MRI procedure utilization going forward through the end of the third operating year.

Novant Health Projected Unweighted MRI Volume – OP Facilities (w/Fixed MRI Scanners)						
	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	Distribution
Unweighted Scans	8,400	8,828	9,278	9,751	10,249	
Ballantyne	2,529	2,657	2,793	2,936	3,085	30.1%
Museum	2,267	2,383	2,505	2,632	2,767	27.0%
South Park	3,604	3,788	3,980	4,183	4,397	42.9%

However, the applicant does not adequately demonstrate that a growth rate of 5.1 percent is reasonable and adequately supported. The total unweighted MRI procedures performed at its outpatient facilities with fixed MRI scanners actually declined by -5.91 percent from CY 2012 to CY 2013 and by -3.16 percent from CY 2013 to CY 2014 as depicted in the table in Step 1 above. The 5.1 percent growth rate that was used to project utilization is the percent change in total unweighted MRI volume between CY 2014 and CY 2015. 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 four years of data but chose to rely only on the one year that volume increased. Moreover, the applicant used an average of the same four year period to project growth in the outpatient facility-based MRI scanners. Furthermore, the applicant does not adequately explain why it assumes a positive growth rate going forward given that the CAGR for the three year time period (CY 2012 – CY 2015) is -1.32 percent.

Thus, projected utilization for outpatient facility fixed MRI scanners is not based on reasonable and adequately supported assumptions. However, if the applicant had provided data that included CY 2011, the AACR would rise to four percent. Calculations performed by the Project Analyst demonstrate that an AACR of four percent would result in the Novant outpatient fixed MRI scanners reasonably projecting to perform an average of 4,873 annual weighted procedures, which would also meet the regulatory threshold set out in 10A NCAC 14C .2703(b)(3).

Novant Health Mobile MRI Scanners

In Section II.8, pages 21-26, the applicant projects utilization for the mobile MRI scanners it owns and operates in Mecklenburg County during the first three years of operation following project completion.

On page 22, the applicant states that it owns and operates two mobile MRI scanners in the service area, known as MQ 2 and PMI. The applicant has received approval to relocate MQ 2 permanently to Gaston County as part of Project I.D. #F-8793-12. Therefore, the historical and proposed utilization of MQ 2 is not applicable to this review. The applicant states that a different mobile MRI scanner, MQ 26, will be brought in to take over MQ 2's former route. MQ 26's projected utilization is relevant to this review, but not its historical utilization, because it was not operating in Mecklenburg County at the time this application was submitted.

The Registration and Inventory of Medical Equipment (RIME) forms filed by Presbyterian Mobile Imaging, LLC (PMI) show the historical utilization of the PMI mobile scanner, as illustrated in the table below.

PMI Mobile MRI Scanner Historical Utilization (Weighted Procedures*) FY 2013 – FY 2015				
Year	NHI – Mooresville**	NHI – University	NHI – Steele Creek	Total
FY 2013	742	1,055	--***	1,757
FY 2014	822	1,178	118	2,118
FY 2015	444	1,255	367	2,066

*Note: Weighted procedures calculated by multiplying MRI scans with contrast or sedating by 1.4, per the methodology in the 2016 SMFP, and adding that number to the raw number of MRI scans without contrast or sedation.

**While the data in the table above shows an almost 50 percent decline in the number of procedures from FY 2014 to FY 2015, the FY 2014 RIME states that the Mooresville site was in service for 817 hours and the FY 2015 RIME states that the Mooresville site was in service for 425 hours.

***According to the FY 2013 RIME form filed by PMI, the NHI – Steele Creek site was not serviced by PMI.

On page 24, the applicant provides the average number of scans per day for CY 2015 for each of the four sites the mobile scanners currently serve, as shown in the table below.

Novant Mobile MRI Host Site Average Scans/Day CY 2015	
Mobile Host Site	Average Scans/Day
NHI – University	7.5
NHI – Steele Creek	6.4
NHI – Mooresville	9.0
NHI – Monroe	5.9

The applicant describes its assumptions and methodology for projecting future utilization of its mobile MRI scanners on page 24. The applicant states:

“Utilizing the current average scans/day of service, Novant Health projected unweighted volume by mobile host site for CY 2018-CY 2020 based on the projected days of service for each facility. Considering the increasing demands in each county for imaging services, Novant Health conservatively projected a growth factor of 1 scan per day of service each project year.”

On pages 24-26, the applicant projects utilization for each of the mobile MRI scanners that will be operating in Mecklenburg County during the first three operating years of the proposed fixed MRI scanner, as shown in the tables below.

Mobile Unit: MQ 26 – Unweighted MRI Volume – CYs 2018-2020										
Site	Days/Week	CY 2018			CY 2019			CY 2020		
		Scans/Day	Scans/Week	Volume	Scans/Day	Scans/Week	Volume	Scans/Day	Scans/Week	Volume
Steele Creek	2	6.4	12.8	640	7.4	14.8	740	8.4	16.8	840
University	4	7.5	30	1,500	8.5	34	1,700	9.5	38	1,900
Monroe	1	5.9	5.9	295	6.9	6.9	345	7.9	7.9	395
Total				2,435			2,785			3,135

Mobile Unit: PMI – Unweighted MRI Volume – CYs 2018-2020										
Site	Days/ Week	CY 2018			CY 2019			CY 2020		
		Scans/Day	Scans/Week	Volume	Scans/Day	Scans/Week	Volume	Scans/Day	Scans/Week	Volume
Steele Creek	3	6.4	19.2	960	7.4	22.2	1,110	8.4	25.2	1,260
University	1	7.5	7.5	375	8.5	8.5	425	9.5	9.5	475
Mooreville*	3	9.0	27	1,350	10.0	30.0	1,500	10.0	30.0	1,500
Total				2,685			3,035			3,235

*On page 25, the applicant states that it assumed that 10.0 scans per day of service would be approaching maximum capacity.

The applicant then used the average contrast percentage for each mobile unit from CY 2015 to determine the weighted MRI volume for each mobile MRI unit, as shown in the tables below.

Weighted MRI Projections – Mobile Unit: MQ 26			
	CY 2018	CY 2019	CY 2020
Estimated MRI Scan Volume	2,435	2,785	3,135
Contrast Scans – 24.4%	594	679.5	764.9
Contrast Weight	237.7	271.8	306.0
Total Weighted MRI Volume	2,673	3,057	3,441

Weighted MRI Projections – Mobile Unit: PMI			
	CY 2018	CY 2019	CY 2020
Estimated MRI Scan Volume	2,685	3,035	3,235
Contrast Scans – 20.22%	543	614	654
Contrast Weight	217.2	245.6	261.6
Total Weighted MRI Volume	2,902	3,281	3,497

However, the applicant does not adequately support its assumption of one additional scan per day at each location. The following table, prepared by the Project Analyst, shows the projected percentage increases in utilization of its mobile MRI scanners in the first three operational years:

Novant Mobile MRI Scanner Utilization Projection Percentage Increases		
Year	MRI Scan Volume	Percent Change
Steele Creek		
CY 2018	1,600	--
CY 2019	1,850	15.6%
CY 2020	2,100	13.5%
Average Annual Change Rate		14.6%
University		
CY 2018	1,875	--
CY 2019	2,125	13.3%
CY 2020	2,375	11.8%
Average Annual Change Rate		12.6%
Monroe		
CY 2018	295	--
CY 2019	345	16.9%
CY 2020	395	14.5%
Average Annual Change Rate		15.7%
Mooresville		
CY 2018	1,350	--
CY 2019	1,500	10.0%
CY 2020	1,500	0.0%
Average Annual Change Rate		5.0%

The projected increase in mobile MRI utilization ranges from five percent to more than 15 percent during each of the first three operating years. However, the applicant projects growth rates of 4.30 percent and 5.1 percent for its fixed hospital-based and its fixed outpatient MRI scanners. The applicant does not provide enough information in the application as submitted to adequately demonstrate that projected utilization of the mobile MRI scanners is reasonable and adequately supported.

The applicant does not adequately demonstrate the need to acquire a fixed MRI scanner to be located in Mecklenburg County, as explained in the following discussion. The Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700, require the applicant to demonstrate that any mobile MRI scanners owned and/or operated by the applicant or related entities in the service area performed at least 3,328 weighted MRI procedures during the most recent 12-month period for which the applicant has data. In Section II.8, page 20, the applicant states:

“As of the filing date of this application, Novant Health owns and operates two mobile MRI units that provide service in Mecklenburg County, among other counties: MQ 2 and Presbyterian Mobile Imaging (PMI). The weighted MRI volume for CY 2015 (January 1, 2015-December 31, 2015) was 1,781 scans for MQ 2 and 1,972 scans for Presbyterian.

It should be noted Novant Health’s two mobile MRI units that serve sites in Mecklenburg Couty [sic] are not operating in Mecklenburg County exclusively. Issues that are unique to mobile units like travel time, equipment downtime,

changes in host sites, etc. are factors that have a direct impact on MRI volume by mobile unit. The demand for a fixed MRI unit at a facility like NHHMC is entirely independent of whether or not a mobile MRI unit has reached or exceeded the 3,328 weighted threshold level. As explained in this application, a mobile unit cannot substitute for the second fixed MRI unit needed at NHHMC.”

The applicant’s two mobile MRI scanners performed only 1,781 and 1,972 weighted MRI procedures in the applicant’s most recent 12-month period for which it has data (CY 2015) anywhere in the state, not just in Mecklenburg County. Therefore, neither scanner performed a minimum of 3,328 weighted MRI scans as required by 10A NCAC 14C .2703(b)(2). The Rule is necessary as it would not be consistent with the premise of the CON Law to approve an applicant to acquire an additional MRI scanner (fixed or mobile) when the applicant has access to an existing mobile MRI scanner which has the capacity to serve more patients than it is currently serving.

In summary, the applicant adequately demonstrates that its existing fixed MRI scanners which it or a related entity owns a controlling interest in and which are located in Mecklenburg County performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data. The applicant also adequately demonstrates the average annual utilization of the existing, approved, and proposed fixed MRI scanners which it or a related entity owns a controlling interest in and which are located in Mecklenburg County are reasonably expected to perform 4,805 weighted MRI procedures in the third year of operation following completion of the proposed project.

However, the applicant does not adequately demonstrate that:

- Each existing mobile MRI scanner owned by the applicant or a related entity and operating at host sites in the proposed service area performed at least 3,328 weighted MRI scans in the most recent 12 month period for which the applicant has data, as required by 10A NCAC 14C .2703(b)(2); and
- The annual utilization of each existing, approved, and proposed mobile MRI scanner which the applicant or a related entity owns and will operate at host sites in the proposed service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project, as required by 10A NCAC 14C .2703(b)(5).

Based on review of: 1) the information provided by the applicant in Section III, pages 29-61, Section IV, pages 62-63, and referenced exhibits; 2) comments received during the first 30 days of the review cycle; and 3) the applicant’s response to the comments received at the public hearing, the applicant does not adequately document the need for the project for the reasons discussed above.

Access

In Section VI, pages 74-77, the applicant states that it is committed to continuing to provide services for low income persons, racial and ethnic minorities, women, handicapped persons, elderly, and other underserved persons, including medically indigent patients referred by physicians. The applicant also states it will provide services to all persons regardless of ability to pay.

The applicant further addresses access to Novant’s MRI services in Sections VI.13 and VI.15. On pages 85-86, the applicant provides the CY 2015 payor mix and the projected payor mix for the MRI service component for the second full fiscal year of the proposed project.

NHHMC Historical/Projected Payor Mix MRI Services – CY 2015/2019	
Self Pay/Indigent/Charity	1.91%
Medicare/Medicare Managed Care	33.51%
Medicaid	3.96%
Commercial Insurance	0.70%
Managed Care	57.95%
Other*	1.97%
Total	100.00%

*Other includes Worker’s Compensation, Champus/TRICARE, and Veteran’s Administration

Exhibit 13 contains a copy of the applicant’s charity care and business office policies.

The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served and demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services. However, the applicant does not adequately demonstrate the need to acquire a fixed MRI scanner to be located in Mecklenburg County. Therefore, the application is nonconforming 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.

Neither applicant proposes to relocate, eliminate, or otherwise reduce an existing service. Therefore, this criterion is not applicable to this review.

- (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 – CIS
NC – Novant

CIS. In Section III.3, pages 67-69, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- Maintain the Status Quo – The applicant states that maintaining the status quo would not provide state-of-the-art MRI technology. The applicant also states that the existing mobile MRI scanner is smaller than the proposed MRI scanner which is uncomfortable for larger patients and anyone who is claustrophobic. Finally, maintaining the status quo would not accommodate the projected future growth in utilization of the MRI service at CIS-H. Therefore, this alternative was rejected.
- Acquire a Fixed MRI Scanner at a Hospital-Based Location - The applicant states that it did not believe that demand for lower-cost alternatives would be met by placing an MRI at a hospital-based location. The applicant also states that while there is increasing utilization at hospital-based locations, it believes that the need for a fixed MRI scanner at CIS-H is more immediate and that the increased demand at hospital-based facilities can be met by using mobile MRI services. Therefore, this alternative was rejected.
- Acquire a Fixed MRI Scanner at Another Freestanding Location – The applicant states that not only would there be significant challenges to adding fixed MRI scanner capacity to other freestanding locations, including needing new construction, but additionally other freestanding locations currently have fixed MRI scanner capacity. Therefore, this alternative was rejected.
- Proposed Project – Acquire a Fixed MRI Scanner at CIS-H – The applicant states that the project as proposed provides the most effective alternative for meeting CIS-H patients’ need for an additional MRI scanner.

After considering the above alternatives, the applicant states the proposed alternative represents the most effective alternative to meet the identified need.

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

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

Novant. In Section III.3, pages 55-57, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- Contract for Mobile MRI Scanner Services at NHHMC – The applicant states that it has recently added mobile MRI service to NHHMC due to the ongoing high demand for MRI services. The applicant states that while it is a short-term solution, it is not viable as a long-term solution because “*a mobile MRI unit is not an optimal alternative for the imaging of inpatients.*” Therefore, the applicant rejected this alternative. However, the applicant proposed to utilize the proposed scanner for outpatients, not inpatients.
- Redirect NHHMC MRI Patients to Other Facilities – The applicant states that while it currently owns and operates five fixed MRI scanners located in hospitals, three fixed MRI scanners located in imaging centers, and two mobile MRI host sites, the majority of Novant’s MRI capacity is located in central and southern Mecklenburg County. The applicant states that the closest site to NHHMC is more than 10 miles away from NHHMC and only offers mobile MRI service at this time, and the remaining facilities are significantly further away from NHHMC and heavily utilized already. Therefore, the applicant rejected this alternative.
- Acquire a Second Fixed MRI Scanner Identified in the 2016 SMFP – The applicant states that the project as proposed, acquiring a second fixed MRI scanner to be located in outpatient space on the campus of NHHMC, provides the most cost effective alternative to meeting the need for additional fixed MRI services.

After considering the above alternatives, the applicant states the proposed alternative represents the most effective alternative to meet the identified need.

However, the application is not conforming to all other statutory and regulatory review criteria, and thus, is not approvable. A project that cannot be approved cannot be an effective alternative. The applicant does not adequately demonstrate the need for the proposed fixed MRI scanner given the additional capacity available on the mobile MRI scanners owned and operated by the applicant or a related entity in Mecklenburg County.

In summary, the applicant does not adequately demonstrate that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is nonconforming 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.

C – Both Applications

CIS.

Capital and Working Capital Costs

In Section VIII.1, pages 105-106, the applicant states the total capital cost of the proposed project is projected to be \$2,193,750, comprised of the following costs:

Project Capital Cost – CIS-H Fixed MRI Scanner	
Construction Contract	\$382,100
Equipment/Furniture – MRI	\$1,651,650
Equipment/Furniture – Other	\$35,000
Consultant Fees	\$125,000
Total	\$2,193,750

In Section IX.1, page 110, the applicant states there will be no start-up expenses and no initial operating expenses associated with the project.

Availability of Funds

In Section VIII.3, page 106, the applicant states that the total capital cost will be funded with \$2,193,750 in CIS accumulated reserves. Exhibit 18 contains a letter from the Manager of CIS which documents its commitment to fund the proposed project and the availability of funds. Exhibit 19 contains the unaudited current balance sheet and financial position of all CIS entities. According to the financial statements, as of March 31, 2016, CIS had \$5,681,950 in total cash, \$8,174,445 in total assets, and \$7,798,317 in total net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

In the pro forma financial statements (Form C), the applicant projects a positive net income for the proposed CIS-H MRI service component in each of the first three operating years of the project, as shown in the table below.

CIS-H Projected Revenue/Expenses – Project Years 1-3			
MRI Service	Project Year 1 CY 2018	Project Year 2 CY 2019	Project Year 3 CY 2020
Projected # of MRI Scans	3,864	4,237	4,643
Projected Average Charge	\$1,463	\$1,463	\$1,463
Gross Patient Revenue	\$5,651,394	\$6,197,587	\$6,790,919
Deductions from Gross Patient Revenue	\$2,758,150	\$3,024,718	\$3,314,292
Net Patient Revenue	\$2,893,245	\$3,172,870	\$3,476,627
Total Expenses	\$2,014,030	\$2,282,457	\$2,463,693
Net Income	\$879,215	\$890,413	\$1,012,934

Furthermore, the CIS-H Forecasted Consolidated Income Statement (Form B) projects that revenues for CIS-H will exceed operating expenses in each of the first three operating years

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

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

Novant.

Capital and Working Capital Costs

In Section VIII, page 100, the applicant states the total capital cost is projected to be \$2,334,327, as shown in the table below.

Project Capital Cost – Novant Fixed MRI Scanner	
Construction Contract	\$520,299
Equipment/Furniture – MRI	\$1,601,181
Equipment/Furniture – Other	\$30,312
Consultant Fees	\$122,701
Project Contingency	\$59,834
Total	\$2,334,327

In Section IX.1, page 109, the applicant states there will be no start-up or initial operating expenses associated with the project.

Availability of Funds

In Section VIII.3, page 101, the applicant states that the total capital cost of the project will be funded through the accumulated reserves of Novant Health, Inc. Exhibit 17 contains a letter dated May 9, 2016, from a Senior Vice President of Finance of Novant Health, Inc., documenting its intention to fund the capital costs for the proposed project. Exhibit 18 contains the audited financial statements for Novant Health, Inc. and Affiliates for the years ending December 31, 2015 and 2014. According to the financial statements, as of December 31, 2015, Novant Health, Inc. had \$354,403,000 in cash and cash equivalents, \$5,605,759,000 in total assets, and \$2,888,769,000 in total net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

In the pro forma financial statements for NHHMC’s MRI services (Form C), the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as shown in the table below.

NHHMC – MRI Service Projected Revenue/Expenses – Project Years 1-3			
MRI Service	Project Year 1 CY 2018	Project Year 2 CY 2019	Project Year 3 CY 2020
Projected # of MRI Scans	7,372	7,837	8,482
Projected Average Charge	\$6,860	\$7,135	\$7,420
Gross Patient Revenue	\$22,703,729	\$24,859,874	\$27,713,066
Deductions from Gross Patient Revenue	\$13,669,465	\$15,013,115	\$16,785,405
Net Patient Revenue	\$9,034,264	\$9,846,760	\$10,927,661
Total Expenses	\$1,732,808	\$1,801,350	\$1,875,211
Net Income	\$7,301,456	\$8,045,410	\$9,052,450

Furthermore, the NHHMC Forecasted Consolidated Income Statement (Form B) projects that revenues for NHHMC will exceed operating expenses in each of the first three operating years of the project. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization of the fixed MRI scanners at NHHMC, costs, and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding utilization projections for the fixed MRI scanners at NHHMC found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C – CIS
 NC – Novant

The 2016 SMFP includes a methodology for determining the need for additional fixed MRI scanners by service area. Step 12, on page 157 of the 2016 SMFP, states:

“If the area average procedure per magnet is greater than or equal to the service area threshold, a need is determined for one additional MRI scanner in the service area.”

On page 154, the 2016 SMFP defines the service area for fixed MRI scanners as “*a single county, except where there is no licensed acute care hospital located within the county.*” Thus, the service area for this project consists of Mecklenburg County. Providers may serve residents of counties not included in their service area.

The 2016 SMFP identifies the need for one fixed MRI scanner in Mecklenburg County, based on the following data presented on pages 168-169 of the 2016 SFMP.

Mecklenburg County MRI Scanner Review
 Project I.D. #: F-11182-16 and F-11184-16

Mecklenburg County MRI Scanner Inventory & Utilization – Table 9P, 2016 SMFP (FY 2014)						
Service Type	Service Site	Provider	# Fixed and Fixed Equiv	Total Scans	Weighted Scans	Avg Scans / Magnet
Hosp. Fixed	CMC	CMC	5.00	21,896	30,045	6,009
Hosp. Fixed	CMC-Pineville	CMC-Pineville	1.00	8,091	10,601	10,601
Hosp. Fixed	CMC-University	CMC-University	1.00	4,963	6,276	6,276
Hosp. Fixed	NHHMC	NHHMC	1.00	5,998	7,173	7,173
Hosp. Fixed	NHI-Museum**	NHI-Museum	1.00	2,359	2,699	2,699
Hosp. Fixed	NHMMC***	NHMMC	2.00	5,569	6,850	3,425
Hosp. Fixed	NHPMC	NHPMC	3.00	10,155	13,206	4,402
FS* Fixed	CIS-Ballantyne	CIS	1.00	2,653	2,946	2,946
FS Fixed	CIS-South Park	CIS	1.00	2,543	2,878	2,878
FS Fixed	NHI-Ballantyne	MDI, Inc.	1.00	1,789	1,942	1,942
FS Fixed	NHI-South Park	MDI, Inc.	1.00	3,242	3,463	3,463
FS Fixed	OrthoCarolina Spine Center	OrthoCarolina	1.00	8,442	9,079	9,079
Mobile	Carolina Neuro Clinic	CIS	0.21	995	1,132	
Mobile	Carolina Neurosurgery & Spine-Baldwin	Carolina Neurosurgery & Spine	0.69	3,307	3,701	
Mobile	Carolina Neurosurgery & Spine-Ballantyne	Carolina Neurosurgery & Spine	0.27	1,295	1,378	
Mobile	CIS-Huntersville	CIS	0.38	1,815	2,018	
Mobile	Mecklenburg Neuro Assoc.	InSight Imaging	0.43	2,052	2,443	
Mobile	NHI-University	NHI-University	0.32	1,535	1,686	
Mobile	NHI-University	PMI	0.22	1,065	1,178	
Mobile	OrthoCarolina	Alliance	0.27	1,296	1,296	
Mobile	OrthoCarolina	Alliance	0.00	20	20	
Mobile	OrthoCarolina	Alliance	0.00	17	17	
Mobile	OrthoCarolina-Ballantyne	OrthoCarolina	0.80	3,830	3,830	
Mobile	OrthoCarolina-Huntersville	OrthoCarolina	0.34	1,650	1,728	
Mobile	OrthoCarolina-Matthews	Alliance	0.01	43	43	
Mobile	OrthoCarolina-Matthews	Alliance	0.26	1,265	1,265	
Mobile	OrthoCarolina-Matthews	OrthoCarolina	0.06	273	273	
Mobile	OrthoCarolina Spine	OrthoCarolina	0.10	495	495	
Mobile	PIC-University	JDI, Inc.	0.05	263	289	
Mobile	PIC-Ballantyne	FHMI	0.01	36	36	
Mobile	PIC-Ballantyne	JDI, Inc.	0.06	308	331	
Mobile	PIC-Ballantyne	Kings Med. Group	0.00	12	13	
Mobile	PIC-Steele Creek	JDI, Inc	0.12	566	611	
Mobile	PIC-Steele Creek	Kings Med. Group	0.00	13	14	
Mobile	PIC-Steele Creek	PMI	0.02	107	118	
Mobile	PIC-University	Kings Med. Group	0.04	200	212	
Mobile	Randolph Spine	Alliance	0.00	13	15	
Mobile	Randolph Spine	Alliance	0.31	1,509	1,593	
Total Fixed Scanners and Scans			19.00	77,700	97,158	5,114
Total Mobile Fixed Equivalent and Scans			4.97	23,980	25,735	5,178
Total Mecklenburg Co Fixed Scanners and Fixed Equiv Scanners and Scans Performed			23.97	101,680	122,893	5,127
Threshold for Scans per Scanner						4,805

*FS = Free-Standing

**NHI-Museum is located away from the main campus of NHPMC, and essentially functions as a free-standing facility, but is licensed as part of NHPMC.

***One of the approved MRI scanners is not yet operational. It will be located at NHMMC and is expected to be operational in mid-2018.

There are 20 existing and approved fixed MRI scanners in Mecklenburg County. The following table identifies the provider, the number of scanners, and average weighted utilization of the fixed MRI scanners, summarized from Table 9P of the 2016 SMFP (based on FFY 2014 utilization data submitted by providers).

Mecklenburg County Fixed MRI Scanner Inventory/Scans – FFY 2014			
Provider	Number of Fixed MRIs	Total Number of Weighted Scans	Average Weighted Scans per Scanner
CMC	5	30,045	6,009
CMC-Pineville	1	10,601	10,601
CMC-University	1	6,276	6,276
NHHMC	1	7,173	7,173
Novant Health Imaging Museum	1	2,699	2,699
Novant Health Matthews MC*	2	6,850	3,425
Novant Health Presbyterian MC	3	13,206	4,402
CIS-Ballantyne	1	2,946	2,946
CIS-SouthPark	1	2,878	2,878
Novant Health Imaging-Ballantyne	1	1,942	1,942
Novant Health Imaging SouthPark	1	3,463	3,463
OrthoCarolina Spine Center	1	9,079	9,079
OrthoCarolina Ballantyne**	1	n/a	n/a
Total	20	97,158	5,114

Source: 2016 SMFP, 2015 License Renewal Applications and 2015 Equipment and Inventory of Medical Equipment

*The approved MRI scanner is not yet operational. Moreover, it will be located at NHHMC and is not expected to be operational until mid-2018.

**The MRI scanner did not become operational until October 26, 2015. Therefore, there is no data to report from FFY 2014.

CIS. In Section III.1, pages 40-53, the applicant states that CIS’s identified need is to replace mobile MRI scanner services with fixed MRI services, expand available hours, and enhance service to its patients. On page 31, the applicant shows that it owns nine existing fixed MRI scanners in Mecklenburg County. Unweighted volume performed on the nine scanners increased by a CAGR of 7.3 percent from FFY 2013-2015. The applicant also states that while other providers in Mecklenburg County have also experienced growth in utilization, the average CAGR experienced by all of the non-CIS/CHS providers is smaller than at its own facilities. Unweighted volume at the non-CIS/CHS providers increased by a CAGR of 5.2 percent from FFY 2013-2015. The applicant states on page 43 that in FFY 2015, CHS and CIS-affiliated fixed MRI scanners performed an average of 6,165 weighted scans per year.

The applicant adequately demonstrates that the fixed MRI scanner it proposes to develop in Mecklenburg County is needed in addition to the existing and approved 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 need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

Therefore, the applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved MRI services in Mecklenburg County. Consequently, the application is conforming to this criterion.

Novant proposes to acquire a second fixed MRI scanner to be located in outpatient space on the campus of NHHMC. On page 19, the applicant states that it owns eight existing fixed MRI scanners in Mecklenburg County. One additional scanner is approved but not yet operational. Unweighted volume performed on the eight existing MRI scanners increased 2.9 percent annually from CY 2012-2015 (see pages 41 and 45). The applicant states on page 20 that it owns and operates two mobile MRI scanners in Mecklenburg County – MQ2 and Presbyterian Mobile Imaging, LLC (PMI). The weighted MRI volume for CY 2015 was 1,781 scans for MQ2 and 1,972 scans for PMI, which is all the procedures performed by these scanners anywhere in the state, not just Mecklenburg County.

The Registration and Inventory of Medical Equipment (RIME) forms filed by PMI show the historical utilization of the PMI mobile scanner, as shown in the table below.

PMI Mobile MRI Scanner Historical Utilization (Weighted Procedures*)				
FY 2013 – FY 2015				
Year	NHI – Mooresville**	NHI – University	NHI – Steele Creek	Total
FY 2013	742	1,055	--***	1,757
FY 2014	822	1,178	118	2,118
FY 2015	444	1,255	367	2,066

*Note: Weighted procedures calculated by multiplying MRI scans with contrast or sedating by 1.4, per the methodology in the 2016 SMFP, and adding that number to the raw number of MRI scans without contrast or sedation.

**While the data in the table above shows an almost 50 percent decline in the number of procedures from FY 2014 to FY 2015, the FY 2014 RIME states that the Mooresville site was in service for 817 hours and the FY 2015 RIME states that the Mooresville site was in service for 425 hours.

***According to the FY 2013 RIME form filed by PMI, the NHI – Steele Creek site was not serviced by PMI.

Neither the FY 2015 utilization nor the CY 2015 utilization meets the required threshold of 3,328 weighted scans per mobile MRI unit as required by 10A NCAC 14C .2703(b)(3). The discussion regarding utilization of the mobile MRI scanners found in Criterion (3) is incorporated herein by reference. The applicant does not adequately demonstrate that the fixed MRI scanner it proposes to develop in Mecklenburg County is needed in addition to the existing and approved fixed MRI scanners in Mecklenburg County, given the additional capacity available on the mobile MRI scanners owned and operated by the applicant or a related entity in Mecklenburg County and the approved but not yet developed fixed MRI scanner which will belong to Novant.

The applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved MRI services in Mecklenburg County. Therefore, the application is nonconforming 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 – Both Applications

CIS. In Section VII.1, page 99, the applicant provides CIS-H's current and projected MRI staffing, which shows it currently employs 3.02 full-time equivalent (FTE) MRI technologists and 1.06 FTE clerical positions, and that it projects to employ 4.53 FTE MRI technologists and 1.59 FTE clerical positions to staff the existing fixed scanners and the proposed fixed MRI scanner in the second year of the project. In Section VII, pages 99-102, the applicant describes its experience and process for recruiting and retaining staff. Ken Wolfson, M.D., serves as the Medical Director (see page 103). Exhibit 13 contains a letter from Dr. Wolfson, supporting the proposed project, as well as documenting his intention to continue to serve as Medical Director. Exhibit 20 contains copies of letters from area physicians expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

Novant. In Section VII.1, pages 87-88, the applicant provides NHHMC's current and projected MRI staffing. NHHMC currently employs 5.0 full-time equivalent (FTE) MRI technologists and 0.15 FTE radiology manager positions, and projects to employ 9.0 FTE MRI technologists and 0.20 FTE radiology manager positions to staff the existing fixed scanner and the proposed fixed MRI scanner in the second year of the project. In Section VII, pages 91-94, the applicant describes its experience and process for recruiting and retaining staff. Erik Insko, M.D., serves as the Medical Director (see page 95). Exhibit 12 contains a letter from Dr. Insko, supporting the proposed project, as well as documenting his intention to continue to serve as Medical Director. Exhibit 8 contains copies of letters from area physicians expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C – Both Applications

CIS. In Section II.2, pages 21-22, the applicant describes the necessary ancillary and support services and states that all necessary ancillary and support services are currently available at CIS-H. Exhibit 6 contains a letter from the Manager of CIS documenting the availability of the necessary ancillary and support services. Exhibit 20 contains letters of support from physicians. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

Novant. In Section II.2, page 12, and Section VII.1, pages 87-89, the applicant describes the necessary ancillary and support services required to operate the proposed MRI service and describes from where and how those services are provided. Exhibit 8 contains letters

of support from physicians. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

C – Both Applications

CIS proposes to develop the fixed MRI scanner in existing space which previously supported the operation of a fixed MRI scanner (until it was relocated in 2008). Exhibit 17 contains a letter from an architect that estimates construction costs that are consistent with the project capital cost projections provided by the applicant in Section VIII.1, pages 105-106 of the application. In Section XI.7, page 118, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design, and means

of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

Novant proposes to develop the fixed MRI scanner by renovating existing space in a medical office building on the grounds of NHHMC. Exhibit 21 contains a letter from an architect that estimates construction costs that are consistent with the project capital cost projections provided by the applicant in Section VIII.1, page 100, of the application. In Section XI.7, page 119, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. Exhibit 10 contains the Sustainable Energy Management Plan which is already in place at NHHMC. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design, and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

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

C – Both Applications

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

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

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

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

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

However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race, or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

CIS. In Sections VI.12 and VI.13, pages 95-96, the applicant provides the payor mix during CY 2015 for the entire CIS-H facility as well as the MRI service component for CIS-H, as illustrated in the tables below:

CIS-H Historical Payor Mix MRI Services – CY 2015	
Self Pay/Indigent/Charity	0.7%
Medicare/Medicare Managed Care	21.1%
Medicaid	0.0%
Commercial/Managed Care	63.9%
Other*	14.3%
Total	100.0%

*Other includes Worker's Compensation, Champus/TRICARE, and Veteran's Administration

CIS-H Historical Payor Mix Entire Facility – CY 2015	
Self Pay/Indigent/Charity	2.5%
Medicare/Medicare Managed Care	28.0%
Medicaid	0.03%
Commercial/Managed Care	65.2%
Other*	4.2%
Total	100.0%

*Other includes Worker's Compensation, Champus/TRICARE, and Veteran's Administration

On pages 96 and 98, the applicant states that it does not serve Medicaid patients and does not project to serve Medicaid patients because Medicaid does not reimburse for MRI scans outside of hospitals and therefore Medicaid patients are not likely to come to CIS-H for MRI services. The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and is conforming to this criterion.

Novant. In Sections VI.12 and VI.13, page 85, the applicant provides the payor mix during CY 2015 for the entire NHHMC facility as well as the MRI service component for NHHMC, as illustrated in the tables below:

NHHMC Historical Payor Mix MRI Services – CY 2015	
Self Pay/Indigent/Charity	1.91%
Medicare/Medicare Managed Care	33.51%
Medicaid	3.96%
Commercial Insurance	0.70%
Managed Care	57.95%
Other*	1.97%
Total	100.00%

*Other includes Worker's Compensation, Champus/TRICARE, and Veteran's Administration

NHHMC Historical Payor Mix Entire Facility – CY 2015	
Self Pay/Indigent/Charity	7.78%
Medicare/Medicare Managed Care	26.81%
Medicaid	10.40%
Commercial Insurance	0.90%
Managed Care	51.56%
Other*	2.55%
Total	100.00%

*Other includes Worker's Compensation, Champus/TRICARE, and Veteran's Administration

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and 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 – Both Applications

Recipients of Hill-Burton funds were required to provide uncompensated care, community service, and access by minorities and handicapped persons.

CIS. In Section VI.11, page 95, the applicant states,
“CIS-Huntersville is not obligated to provide uncompensated care, community service, or access to care by medically underserved, minorities, or handicapped persons under public regulations.”

The applicant states that it will continue to be accessible to persons with physical disabilities and handicaps, and will not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay. See Exhibit 14 for CIS's patient financial policies. In Section VI.10(a), page 94, the applicant

states that it has not had any civil rights access complaints or violations filed against CIS in the last five years. The application is conforming to this criterion.

Novant. In Section VI.11, pages 84-85, the applicant states:

“NHFMC fulfilled its Hill-Burton obligations in 1991. At that time, the obligation for the remainder of the 20-year term to expire in 1993 was \$144,343. NH Forsyth Medical Center [sic] had contributed \$236,289 in excess of the required amount and subsequently satisfied all obligations under 42 CFR 124, Subpart F. The quota was exceeded as of 1982. As required by the former Hill-Burton program, the NH Presbyterian Medical Center has far exceeded its requirements for delivering uncompensated care pursuant to that program and its regulations. NHHMC and all Novant facilities in North Carolina continue to comply with the community service obligation and there is no denial, restriction, or limitation of access to minorities or handicapped persons.”

In Section VI.10(a), page 84, the applicant states there have been no civil rights access complaints or violations filed against Novant in the last 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 – Both Applications

CIS addresses access to services in Section VI. On pages 96-97, the applicant provides the following payor mix for the second full fiscal year of the proposed project.

CIS-H Projected Payor Mix – MRI CY 2019	
Self Pay/Indigent/Charity	0.7%
Medicare/Medicare Managed Care	21.1%
Medicaid	0.0%
Commercial/Managed Care	63.9%
Other*	14.3%
Total	100.0%

*Other includes Worker's Compensation, Champus/TRICARE, and Veteran's Administration

CIS-H Projected Payor Mix – Total CY 2019	
Self Pay/Indigent/Charity	2.5%
Medicare/Medicare Managed Care	28.0%
Medicaid	0.03%
Commercial/Managed Care	65.2%
Other*	4.2%
Total	100.0%

*Other includes Worker's Compensation, Champus/TRICARE, and Veteran's Administration

On pages 97-98, the applicant states that it based its projections on historical data and does not anticipate any changes in payor mix as a result of this project. The applicant demonstrates that medically underserved groups are likely to have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

Novant. In Sections VI.14 and VI.15, page 86, the applicant projects the following payor mix for the second operating year (CY 2019):

NHHMC Projected Payor Mix MRI Services – CY 2019	
Self Pay/Indigent/Charity	1.91%
Medicare/Medicare Managed Care	33.51%
Medicaid	3.96%
Commercial Insurance	0.70%
Managed Care	57.95%
Other*	1.97%
Total	100.00%

*Other includes Worker's Compensation, Champus/TRICARE, and Veteran's Administration

NHHMC Projected Payor Mix Entire Facility – CY 2019	
Self Pay/Indigent/Charity	7.78%
Medicare/Medicare Managed Care	26.81%
Medicaid	10.40%
Commercial Insurance	0.90%
Managed Care	51.56%
Other*	2.55%
Total	100.00%

*Other includes Worker's Compensation, Champus/TRICARE, and Veteran's Administration

On page 86, the applicant states that it based its projections on the payor mix data for CY 2015. The applicant demonstrates that medically underserved groups are likely to have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C – Both Applications

CIS. In Section VI.9, pages 93-94, the applicant documents the range of means by which patients will have access to the proposed services. The applicant states that patients typically are referred by area physicians. The applicant states that it does not have any formal working arrangements with other healthcare facilities or agencies, because physicians direct patient care, but that it works closely with CHS facilities in Mecklenburg County to ensure comprehensive services are available to all patients. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

Novant. In Section VI.9, page 83, the applicant documents the range of means by which patients have access to the proposed services. The applicant states that a physician referral is necessary for an MRI procedure and that its existing fixed MRI scanner is highly utilized by local physicians. Exhibit 8 contains letters of support from area physicians. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C – Both Applications

CIS. In Section V.1, pages 80-83, the applicant documents that CIS accommodates the clinical needs of health professional training programs in the area and that it will continue to do so. The applicant provides a list of the health professional training programs that currently utilize the training opportunities at CIS in Exhibit 12. The information provided is reasonable and supports a finding of conformity with this criterion.

Novant. In Section V.1, page 64, the applicant states that it has many established clinical education agreements with area health education programs. Exhibit 3 contains a list of all affiliations with area health education programs and a sample clinical education agreement. The information provided is reasonable 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 – CIS
 NC – Novant

The 2016 SMFP includes a methodology for determining the need for additional fixed MRI scanners by service area. Application of the need methodology in the 2016 SMFP identified a need for one additional fixed MRI scanner in the Mecklenburg County MRI Service Area.

On page 154, the 2016 SMFP defines the service area for fixed MRI scanners as “*a single county, except where there is no licensed acute care hospital located within the county.*” Thus, the service area for this project consists of Mecklenburg County. Providers may serve residents of counties not included in their service area.

There are 20 existing and approved fixed MRI scanners in Mecklenburg County. The following table identifies the provider, the number of scanners, and average weighted utilization of the fixed MRI scanners, summarized from Table 9P of the 2016 SMFP (based on FFY 2014 utilization data submitted by providers).

Mecklenburg County Fixed MRI Scanner Inventory/Scans – FFY 2014			
Provider	Number of Fixed MRIs	Total Number of Weighted Scans	Average Weighted Scans per Scanner
CMC	5	30,045	6,009
CMC-Pineville	1	10,601	10,601
CMC-University	1	6,276	6,276
NHHMC	1	7,173	7,173
Novant Health Imaging Museum	1	2,699	2,699
Novant Health Matthews MC*	2	6,850	3,425
Novant Health Presbyterian MC	3	13,206	4,402
CIS-Ballantyne	1	2,946	2,946
CIS-SouthPark	1	2,878	2,878
Novant Health Imaging-Ballantyne	1	1,942	1,942
Novant Health Imaging SouthPark	1	3,463	3,463
OrthoCarolina Spine Center	1	9,079	9,079
OrthoCarolina Ballantyne**	1	n/a	n/a
Total	20	97,158	5,114

Source: 2016 SMFP, 2015 License Renewal Applications and 2015 Equipment and Inventory of Medical Equipment

*The approved MRI scanner is not yet operational. Moreover, it will be located at NHHMC and is not expected to be operational until mid-2018.

**The MRI scanner did not become operational until October 26, 2015. Therefore, there is no data to report from FFY 2014.

CIS proposes to add one fixed MRI scanner at its Huntersville location. In Section V.7, pages 84-86, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality, and access to the proposed services, stating:

“The proposed project will foster competition by promoting value, safety and quality, and access to services in the proposed service area and thus will be in compliance with the spirit and legislative intent of the CON Law.

...

CIS currently provides quality care to the residents of Mecklenburg County and surrounding areas. CIS seeks to continue its mission of providing locally available state-of-the-art diagnostic imaging services through the proposed project. ...

...

As a freestanding facility, CIS-Huntersville can provide services at a lower out-of-pocket cost to patients. Insurance companies tier out-of-pocket requirements depending on the type of facility where patients receive care. Insurance companies categorize hospital-based services in a higher out-of-pocket tier than they do freestanding outpatient services, meaning that the patient’s out-of-pocket expenses are greater when receiving hospital-based care, regardless of whether the service is classified as inpatient or outpatient care. Since freestanding facilities are categorized in a lower tier, reduced out-of-pocket expenses are passed along to the patient.”

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

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

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3), and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

Novant proposes to acquire a second fixed MRI scanner to be located in outpatient space on the campus of NHHMC. In Section V.7, pages 68-72, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality, and access to the proposed services. The applicant discusses its various accolades from national organizations regarding excellence in community hospitals, strong financial health systems, and quality of care. The applicant emphasizes its Charity Care and related policies contained in Exhibit 13.

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

However, the applicant does not adequately demonstrate how any enhanced competition in the service area includes a positive impact on the cost-effectiveness of the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant does not adequately demonstrate that the mobile MRI scanners owned by the applicant or a related entity and operated at host sites in the service area performed at least 3,328 weighted MRI scans in the most recent 12-month period for which the applicant has data.
- The applicant does not adequately demonstrate that the projected utilization of the mobile MRI scanners operating at host sites in the service area are reasonably expected to perform at least 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project.
- The discussion regarding historical and projected utilization found in Criterion (3) 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 – Both Applications

CIS. In Section II.7, pages 24-26, and Exhibit 7, the applicant describes the methods used to ensure and maintain quality care. In Section I.12(b), pages 10-11, the applicant provides a list of CIS-owned health care facilities in North Carolina. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System (CHS) manages CIS. In Section I.12(c), pages 11-14, the applicant provides a partial list of Carolinas HealthCare System owned and/or managed healthcare facilities in North Carolina. In Section II.7(c), pages 25-26, the applicant states that none of the licensed health service facilities owned or operated by the applicant, as identified by the applicant in Section I.12, pages 10-14, have had their licenses revoked or had their Medicare or Medicaid provider agreements revoked. According to the files in the Acute and Home Care Licensure and Certification Section,

DHSR, one incident occurred at two of the 22 CIS/CHS owned or managed facilities within the eighteen months immediately preceding submission of the application through the date of this decision related to quality of care. As of the date of this decision, the problems have been corrected. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at CIS and CHS facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Novant. In Section II.7, pages 14-17, and Exhibit 6, the applicant describes the methods used to ensure and maintain quality care. In Section II.7(c), page 17, the applicant indicates that there have been no quality of care issues at the healthcare facilities identified in Section I.12. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, one incident occurred at three of the 11 Novant owned or managed facilities and three incidents occurred at one of the 11 Novant owned or managed facilities within the eighteen months immediately preceding submission of the application through the date of this decision related to quality of care. As of the date of this decision, two of the three problems at one facility have been corrected and a single problem at another facility has been corrected. Three incidents remain under investigation by the Centers for Medicare and Medicaid Services for potential violations with no timetable for any decision or outcome. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at Novant facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C – CIS
NC – Novant

The application submitted by CIS was determined to be conforming with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700. The application submitted by Novant was found to not be in conformity with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700. The specific criteria are discussed below.

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

10A NCAC 14C .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- **Both Applicants.** The applicants do not propose the acquisition of a mobile MRI scanner.

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

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

-C- **CIS** owns and operates two existing fixed MRI scanners located in Mecklenburg County. CHS, the parent company of CIS, owns and operates seven existing fixed MRI scanners located in Mecklenburg County. In Section II.8, page 31, the applicant provides the following table and states that CIS and CHS performed an average of 5,913 weighted scans per

machine during the most recent 12 month period for which data was available (March 2015 – February 2016), well in excess of the required average of 3,328 scans.

CIS/CHS Fixed MRI Scanner Historical Utilization for March 2015-February 2016							
	OP No Contrast	OP Contrast	IP No Contrast	IP Contrast	Total Weighted	Fixed Magnet	Total Average
CMC	5,024	5,088	4,820	2,449	23,303	4	
CMC-Mercy	2,223	1,371	924	346	6,059	1	
CHS University	2,710	1,215	802	188	5,872	1	
CHS Pineville	4,463	1,880	1,990	423	10,642	1	
CIS-Ballantyne	2,398	1,020	0	0	3,826	1	
CIS-SouthPark	1,955	1,111	0	0	3,510	1	
Total					53,213	9	5,913

- C- **Novant** owns and operates eight existing fixed MRI scanners in Mecklenburg County. In Section II.8, page 19, the applicant provides the following table and states that Novant performed an average of 4,954 weighted scans per machine during the most recent 12 month period for which data was available (CY 2015), well in excess of the required average of 3,328 scans.

Novant Fixed MRI Scanner Historical Utilization for CY 2015							
	# Fixed Scanners	Unweighted IP Volume	Unweighted OP Volume	Total Contrast Scans	IP Adjustment	Contrast Adjustment	Weighted MRI Volume
Hospitals							
NHPMC	2	2,939	5,965	4,327	1175.6	1730.8	11,810
NHHMC	1	813	5,485	2,179	325.2	871.6	7,495
NHMMC	1	1,229	5,032	2,467	491.6	986.8	7,739
NHCOH	1	38	3,489	786	15.2	314.4	3,857
Outpatient Centers							
Ballantyne	1	0	2,406	579	0	231.6	2,638
Museum	1	0	2,157	638	0	255.2	2,412
South Park	1	0	3,429	634	0	253.6	3,683
Total	8						39,634
Average Weighted MRI Volume Per Scanner							4,954

- (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- **CIS.** In Section II.8, page 32, the applicant states that it operates one existing mobile MRI scanner in Mecklenburg County, the proposed service

area, which served both CIS-H and St. Luke's Hospital in Polk County. The applicant states that this mobile MRI scanner performed 3,714 weighted MRI procedures for the most recent 12 month period for which data was available (March 2015 – February 2016).

CIS also owns a mobile MRI scanner which, until recently, was servicing CHS Anson in Anson County as well as Carolina Neurological Clinic in Mecklenburg County. According to the most recent Registration and Inventory of Medical Equipment form, the mobile MRI scanner performed 1,216 weighted MRI scans during the most recent period that data is available (October 2014 – September 2015). However, on page 32, the applicant states that it removed the mobile MRI scanner discussed above from service. Information received from NHHMC during the public comment period suggests that this mobile MRI scanner is still located within Mecklenburg County. The Agency has not independently verified this assertion. Nonetheless, the scanner is not operating in Mecklenburg County at this time, and on October 12, 2016, the Agency issued a Declaratory Ruling authorizing CIS to change host sites. None are located in Mecklenburg County. The performance standards in this Rule apply to “*existing mobile MRI scanner[s] which the applicant or a related entity...operates in the proposed MRI service area...*” (emphasis added) Because the scanner is not currently operating in Mecklenburg County, its previous utilization numbers are not applicable to this Rule.

-NC- **Novant.** In Section II.8, page 20, the applicant states:

“As of the filing date of this application, Novant Health owns and operates two mobile MRI units that provide service in Mecklenburg County, among other counties: MQ 2 and Presbyterian Mobile Imaging (PMI). The weighted MRI volume for CY 2015 (January 1, 2015-December 31, 2015) was 1,781 scans for MQ 2 and 1,972 scans for Presbyterian.

It should be noted Novant Health's two mobile MRI units that serve sites in Mecklenburg Couty [sic] are not operating in Mecklenburg County exclusively. Issues that are unique to mobile units like travel time, equipment downtime, changes in host sites, etc. are factors that have a direct impact on MRI volume by mobile unit. The demand for a fixed MRI unit at a facility like NHHMC is entirely independent of whether or not a mobile MRI unit has reached or exceeded the 3,328 weighted threshold level. As explained in this application, a mobile unit cannot substitute for the second fixed MRI unit needed at NHHMC.”

On page 22, the applicant states that it owns and operates two mobile MRI scanners in the service area, known as MQ 2 and PMI. The applicant has

received approval to relocate MQ 2 permanently to Gaston County as part of Project I.D. #F-8793-12. Therefore, the historical and proposed utilization of MQ 2 is not applicable to this review. The applicant states that a different mobile MRI scanner, MQ 26, will be brought in to take over MQ 2's former route. MQ 26's projected utilization is relevant to this review, but not its historical utilization, because it was not operating in Mecklenburg County at the time this application was submitted.

The Registration and Inventory of Medical Equipment (RIME) forms filed by Presbyterian Mobile Imaging, LLC (PMI) show the historical utilization of the PMI mobile scanner, as illustrated in the table below.

PMI Mobile MRI Scanner Historical Utilization (Weighted Procedures*) FY 2013 – FY 2015				
Year	NHI – Mooresville**	NHI – University	NHI – Steele Creek	Total
FY 2013	742	1,055	--***	1,757
FY 2014	822	1,178	118	2,118
FY 2015	444	1,255	367	2,066

*Note: Weighted procedures calculated by multiplying MRI scans with contrast or sedating by 1.4, per the methodology in the 2016 SMFP, and adding that number to the raw number of MRI scans without contrast or sedation.

**While the data in the table above shows an almost 50 percent decline in the number of procedures from FY 2014 to FY 2015, the FY 2014 RIME states that the Mooresville site was in service for 817 hours and the FY 2015 RIME states that the Mooresville site was in service for 425 hours.

***According to the FY 2013 RIME form filed by PMI, the NHI – Steele Creek site was not serviced by PMI.

The applicant does not demonstrate that each existing mobile MRI scanner owned by the applicant or a related entity and operating in Mecklenburg County performed at least 3,328 weighted MRI procedures during the most recent 12 months for which the applicant has data. 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 2016 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- **CIS.** In Section II.8, page 33, the applicant provides a table showing CIS’s and CHS’s projected MRI utilization for the proposed project’s third project year, CY 2020, as shown below. CIS-H will own and operate three fixed MRI scanners: one existing scanner at both the CIS-Ballantyne office and the CIS-SouthPark office, as well as a new scanner at CIS-H. CHS will own and operate seven existing fixed MRI scanners.

CIS/CHS Fixed MRI Scanner Projected Utilization for Project Year 3 (CY 2020)							
	OP No Contrast	OP Contrast	IP No Contrast	IP Contrast	Total Weighted	Fixed Magnet	Total Average
CMC	4,000	4,028	4,820	2,449	20,795	4	
CMC-Mercy	2,100	1,279	924	346	5,807	1	
CHS University	2,444	1,054	802	188	5,381	1	
CHS Pineville	3,427	1,443	1,990	423	8,995	1	
CIS-Ballantyne	2,398	1,020	0	0	3,826	1	
CIS-SouthPark	1,955	1,111	0	0	3,510	1	
CIS-Huntersville	3,144	1,499	0	0	5,242	1	
Total					53,557	10	5,356

The applicant states that the average annual weighted MRI scan volume for the ten fixed MRI scanners owned by CHS and CIS will be 5,356 weighted MRI procedures at the end of the third operating year. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is conforming to this Rule.

- C- **Novant.** In Section II.8, page 21, the applicant states the average annual weighted MRI scan volume for Novant’s 10 fixed MRI scanners in Mecklenburg County is projected to be 4,931 weighted MRI procedures in the third operating year, in excess of the 4,805 weighted MRI procedures required by the Rule.

Novant Health Projected Patient Utilization of Fixed MRI Services – Project Years 1-3 Projected Weighted Volume by Facility				
Facility	# Fixed MRI Scanners	Weighted MRI Volume		
		CY 2018	CY 2019	CY 2020
HOSPITALS				
NHPMC	2	13,326	13,662	13,796
NHHMC	2	8,785	9,339	10,107
NHMMC	1	6,976	6,581	5,758
NHCOH	1	4,369	4,558	4,753
NHMHMC*	1	1,722	2,513	3,744
OUTPATIENT IMAGING CENTERS				
Ballantyne	1	3,032	3,187	3,349
Museum	1	2,793	2,935	3,086
South Park	1	4,266	4,483	4,712
Totals	10	45,269	47,258	49,305
Average Weighted Volume per Fixed MRI Scanner		4,527	4,726	4,931

*The approved fixed MRI scanner to be located on the NHMHMC campus is not yet operational. It is expected to become operational in mid-2018.

Even though the application does not adequately support projected utilization of the existing MRI scanners in the outpatient imaging centers, publicly available data, combined with the information provided by the applicant in the application, nevertheless supports the applicant's assertion that all the existing and proposed fixed MRI scanners would average more than the 4,805 weighted MRI procedures per scanner as required by this Rule. Therefore, the application is 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;*
- NA- **CIS.** In Section II.1, page 18, the applicant states that the proposed fixed MRI scanner will be located at the existing CIS-H facility, which currently operates a mobile MRI scanner.
- NA- **Novant.** In Section II.8, page 21, the applicant states that the proposed fixed MRI scanner will be located on the campus of NHHMC, which currently operates an existing fixed MRI scanner.
- (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- **CIS.** In Section II.8, page 35, the applicant states that it proposes to relocate its existing mobile MRI currently servicing CIS-H to service CMC and CHS Pineville three days per week at each facility. The applicant projects that the mobile MRI scanner will perform 3,417 weighted MRI procedures during the third operating year following project completion. The applicant's assumptions and methodology for projecting the mobile MRI scanner utilization are found in Exhibit 8.
- NC- **Novant.** The applicant does not demonstrate that each existing mobile MRI scanner it or a related entity owns and operates within Mecklenburg County is reasonably projected to perform at least 3,328 weighted MRI procedures in the third operating year following project completion. The discussion regarding projected utilization of the existing mobile MRI scanner units found in Criterion (3) is incorporated herein by reference. Therefore, 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- **CIS's** methodology and assumptions used for the above CIS projections are described in Section III.1(b), pages 53-62, and Exhibit 8.
- C- **Novant's** methodology and assumptions used for these projections are described in Section II.8, pages 21-26, and Section III.1(b), pages 41-47.
- (b) *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- **Both Applicants.** The applicants do not propose the acquisition of a fixed dedicated breast MRI scanner.

(c) 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- **Both Applicants.** The applicants do not propose the acquisition of a fixed extremity MRI scanner.

(d) 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- **Both Applicants.** The applicants do not propose the acquisition of a fixed multi-position MRI scanner.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2016 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 Project 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 CIS is approved and the application submitted by Novant is denied.

Geographic Accessibility

The following table identifies the location of the existing and approved fixed MRI scanners in Mecklenburg County.

Existing and Approved Fixed MRI Scanners By Location – Mecklenburg County (FY 2014)			
Facility	City/Town	Number of Fixed MRIs	Number of Scans
CMC – Mercy	1000 Blythe Boulevard, Charlotte, 28203	5	30,045
CMC – Pineville	10628 Park Road, Charlotte, 28210	1	10,601
CMC – University	8800 North Tryon Street, Charlotte, 28262	1	6,276
Novant Health Huntersville Med Ctr	10030 Gilead Road, Huntersville, 28078	1	7,173
NHI – Museum	2900 Randolph Road, Charlotte, 28211	1	2,699
Novant Health Matthews Med Ctr	1500 Matthews Township Parkway, Matthews, 28105	1	6,850
Novant Health Presbyterian Med Ctr	200 Hawthorne Lane, Charlotte, 28204	3	13,206
CIS – Ballantyne	15110 John J Delaney Drive, Charlotte, 28277	1	2,946
CIS – South Park	4525 Cameron Valley Parkway, Charlotte, 28203	1	2,878
NHI – Ballantyne	14215 Ballantyne Corporate Place, Charlotte, 28211	1	1,942
NHI – South Park	6324 Fairview Road, Charlotte, 28210	1	3,463
OrthoCarolina Spine Center	2001 Randolph Road, Charlotte, 28207	1	9,079
OrthoCarolina Ballantyne*	15825 Ballantyne Medical Place, Charlotte, 28277	1	N/A
Novant Health Mint Hill Med Ctr**	State Route 24 and Interstate 485 North, Charlotte	1	N/A
Total		20	97,158

Sources: 2016 SMFP (number of fixed MRI scanners and number of scans), 2016 and 2015 Registration and Inventory of Medical Equipment forms (addresses), 2016 Hospital License Renewal Application forms (addresses)

*The fixed MRI scanner became operational on October 26, 2015 and no data has been reported to the Agency yet.

**The approved fixed MRI scanner will be located at NHMHMC and is expected to become operational in mid-2018.

As shown in the tables above, there are 20 existing and approved fixed MRI scanners located in Mecklenburg County: 17 in Charlotte, two in Matthews, and one in Huntersville. Both applicants propose to locate the fixed MRI scanner in Huntersville. Novant proposes to add a fixed MRI scanner to its existing campus where one existing fixed MRI scanner is currently located. CIS proposes to add a fixed MRI scanner to its existing campus less than three miles away. Both applicants propose to add a fixed MRI scanner in a town (Huntersville) within Mecklenburg County where a fixed MRI scanner currently exists. Therefore, with regard to improving

geographic accessibility to fixed MRI scanner services in Mecklenburg County, both proposals are comparable.

Demonstration of Need

CIS adequately demonstrates that projected utilization of the proposed fixed MRI scanner is reasonable, adequately documents its assumptions and methodologies, and demonstrates the need the population it projects to serve has for the proposed fixed MRI scanner. Novant does not adequately demonstrate the need the population it proposes to serve has for the proposed fixed MRI scanner. The discussion regarding demonstration of need found in Criterion (3) is incorporated herein by reference. Therefore, the application submitted by CIS is the most effective alternative with regard to demonstration of need.

Ownership of Fixed MRI Scanners in Mecklenburg County

There are 20 existing and approved fixed MRI in Mecklenburg County, owned by three different providers. The following table identifies the provider, number of MRI scanners, and average utilization of each of the fixed MRI scanners.

Ownership of Existing and Approved Fixed MRI Scanners in Mecklenburg County (FY 2014)			
Provider	Number of Fixed MRIs	Total Number of Weighted Scans	Average Weighted Scans per Scanner
CIS/CHS	9	52,746	5,861
Novant	9	35,333	3,926
OrthoCarolina	2	9,079	9,079
Total	20	100,524	5,291

Source: Table 9P, 2016 SMFP

Thirteen of the 19 existing Mecklenburg County fixed MRI scanners are hospital-based and five are in freestanding outpatient imaging centers. Hospital-based MRI scans are provided at six different hospital sites (seven, once NHMHMC opens in mid-2018) and freestanding outpatient scans are provided at five different sites (and a sixth site at NHI-Museum). In addition, mobile MRI services are offered at 15 sites in Mecklenburg County.

CIS/CHS owns nine of the 19 existing fixed MRI scanners in Mecklenburg County. Novant owns eight of the 19 existing fixed MRI scanners in Mecklenburg County but has an approved fixed MRI scanner projected to be operational in 2018. Both CIS and Novant already provide both fixed and mobile MRI scanner services at various locations in Mecklenburg County, and each location proposed for the fixed MRI scanner currently provides either fixed or mobile MRI scanner access. There will be no change in the number of providers of MRI scanner service. Therefore, with regard to improving accessibility to an increased number of providers of MRI services in Mecklenburg County, both proposals are comparable.

Access by a Diverse Patient Population / Broad Range of Clinical Needs and Acuity

Both applicants propose to provide additional fixed MRI scanner service in an outpatient, non-emergency setting. CIS proposes to add the fixed MRI scanner to its freestanding outpatient imaging center. Novant proposes to add the fixed MRI scanner in outpatient office space on its main campus specifically for use by outpatients who currently use the fixed MRI scanner shared with inpatients. Both applications propose to provide MRI services to patients suitable to be served in a freestanding outpatient setting.

The quote for the fixed MRI scanner in Exhibit 5 of the CIS application is for a fixed MRI scanner of industry standard sizing – a 60 centimeter bore opening and a maximum patient weight of 350 pounds. Novant states that it plans to acquire a wide-bore MRI scanner (70 centimeters) with a maximum patient weight of 550 pounds (see Exhibit 2). Novant further states that it plans to provide MRI scanner access to Medicaid patients, something which CIS states in its application that it cannot do because of the way Medicaid reimbursements work for freestanding diagnostic imaging centers.

Both applicants propose to provide MRI services to patients suitable to be served in a freestanding outpatient setting only. Novant proposes to provide MRI scanner services to a more diverse group of patients with more diverse clinical needs. However, Novant did not adequately demonstrate the need to acquire a fixed MRI scanner to be located in Mecklenburg County and therefore cannot be approved. The discussion regarding need and projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, with regard to improving access to a more diverse patient population based on clinical needs and acuity, CIS is the most effective alternative.

Access by Underserved Groups

The following table shows each application’s projected percentages of MRI procedures to be provided to Medicaid and Medicare recipients, and to self-pay, indigent and charity patients in the second full fiscal year of operation following completion of the project, based on the information provided by the applicants in Section VI.15(a) of the applications. Generally, the application proposing to serve the higher percentages of underserved groups of patients is the more effective alternative with regard to this comparative factor. CIS has stated in its application that it cannot provide MRI scanner services to Medicaid patients due to reimbursement guidelines, but that Medicaid patients are seen at that location for other covered services. Both the percentages for MRI services as well as for all services at the specific location proposed are provided in the table below.

Projections of Percentage of Total Procedures Provided to Underserved Groups			
Applicant	Medicare	Medicaid	Self-Pay/ Indigent/Charity
CIS – MRI only	21.1%	0.0%	0.7%
CIS – all	28.0%	0.03%	2.5%
Novant – MRI only	33.51%	3.96%	1.91%
Novant - all	26.81%	10.40%	7.78%

As shown in the table above, CIS projects the highest percentage of services to be provided to Medicare recipients by its entire facility, but Novant projects the highest percentage of services to be provided to Medicare recipients for MRI services only, the highest percentage of services to be provided to Medicaid recipients in both categories, and the highest percentage of services to be provided to Self-pay/Indigent/Charity in both categories. However, Novant did not adequately demonstrate the need to acquire a fixed MRI scanner to be located in Mecklenburg County and therefore cannot be approved. The discussion regarding need and projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application submitted by CIS is the most effective alternative with regard to access by underserved groups.

Projected Average Gross Revenue per MRI Procedure

The following table shows the projected gross revenue per MRI procedure in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements (Form C). Novant does not include professional fees (i.e., charges for interpretation of the images by a radiologist) in its pro formas. CIS does include professional fees in its pro formas. Generally, the application proposing the lowest gross revenue per MRI procedure is the most effective alternative with regard to this comparative factor.

Application	Gross Revenue	Deduct Professional Fees	Gross Revenue less Professional Fees	# of Unweighted MRI procedures	Average Gross Revenue per Procedure
CIS	\$6,790,919	(\$1,156,105)	\$5,634,814	4,643	\$1,214
Novant	\$27,713,066	N/A	\$27,713,066	8,482	\$3,267

Source: Applicants’ Form C and accompanying assumptions

As shown in the table above, CIS projects the lowest average gross revenue per MRI procedure in the third operating year. Therefore, the application submitted by CIS is the more effective alternative with regard to projected average gross revenue per MRI procedure.

Charges for MRI services provided at a freestanding outpatient facility are typically less than those provided at a hospital. However, a hospital provides services to a broader patient population, including emergency and inpatients or patients with co-morbidities. Therefore, a comparison of gross revenue per procedure between a hospital and freestanding outpatient facilities must be viewed with caution.

Projected Average Net Revenue per MRI Procedure

The following table shows the projected net revenue per MRI procedure in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements (Form C). Novant does not include professional fees (i.e., charges for interpretation of the images by a radiologist) in its pro formas. CIS does include professional fees in its pro formas. Generally, the application proposing the lowest net revenue per MRI procedure is the most effective alternative with regard to this comparative factor.

Application	Net Revenue	Deduct Professional Fees	Net Revenue less Professional Fees	# of Unweighted MRI procedures	Average Net Revenue per Procedure
CIS	\$3,476,627	(\$1,156,105)	\$2,320,522	4,643	\$500
Novant	\$10,927,661	N/A	\$10,927,661	8,482	\$1,288

Source: Applicants' Form C and accompanying assumptions

As shown in the table above, CIS projects the lowest average net revenue per MRI procedure in the third operating year. Therefore, the application submitted by CIS is the more effective alternative with regard to projected average net revenue per MRI procedure.

Charges for MRI services provided at a freestanding outpatient facility are typically less than those provided at a hospital. However, a hospital provides services to a broader patient population, including emergency and inpatients or patients with co-morbidities. Therefore, a comparison of net revenue per procedure between a hospital and freestanding outpatient facilities must be viewed with caution.

Projected Average Operating Expense per MRI Procedure

The following table shows the projected average operating expense per MRI procedure in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements (Form C). Generally, the application proposing the lowest average operating expense per MRI procedure is the more effective alternative with regard to this comparative factor. Generally, the application proposing the lowest net revenue per MRI procedure is the most effective alternative with regard to this comparative factor.

Projected Average Operating Expense per MRI Procedure – OY 3		
Third Operating Year	CIS	Novant
Total Operating Expenses	\$2,463,693	\$1,875,211
Deduct Professional Fees	(\$1,156,105)	N/A
Operating Expenses Less Professional Fees	\$1,307,588	\$1,875,211
Unweighted MRI Procedures	4,643	8,482
Operating Expense/Procedure	\$282	\$221

Source: Applicants' Form C and accompanying assumptions

As shown in the table above, Novant projects the lowest average operating expense per MRI procedure in the third operating year. However, hospital-based facilities and freestanding facilities account for expenses differently; therefore, a direct comparison of average expense per procedure by a hospital and a freestanding outpatient facility must be viewed with caution. Furthermore, Novant did not adequately demonstrate the need to acquire a fixed MRI scanner to be located in Mecklenburg County and therefore cannot be approved. The discussion regarding need and projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application submitted by CIS is the most effective alternative with regard to projected average operating expense per MRI procedure.

SUMMARY

The following is a summary of the reasons the proposal submitted by CIS is determined to be the most effective alternative in this review:

- CIS projects the lowest average gross revenue and average net revenue per MRI procedure.
- The application submitted by CIS was determined to be conforming to all applicable statutory and regulatory review criteria.

The following is a summary of the reasons the proposal submitted by Novant is determined to be a less effective alternative in this review than the approved applicant:

- Novant did not demonstrate the need to acquire the proposed fixed MRI scanner. The discussion regarding need found in Criterion (3) is incorporated herein by reference.
- The application submitted by Novant was determined to be nonconforming to Criteria (1), (3), (4), (6), (18a) and 10A NCAC 14C .2703(b)(2) and (5).

CONCLUSION

Both of the applications are conforming to the need determination in the 2016 SMFP for one fixed MRI scanner in Mecklenburg County. 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 by the Agency. The Agency determined that the application submitted by CIS is the most effective alternative proposed in this review for one additional fixed MRI scanner for Mecklenburg County and is approved. The approval of the other application would result in the approval of MRI scanners in excess of the need determination in the 2016 SMFP and therefore, the application submitted by Novant is denied.

The application submitted by CIS is approved subject to the following conditions.

- 1. Carolinas Imaging Services, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Carolinas Imaging Services, Inc. shall acquire no more than one fixed MRI scanner as part of this project.**
- 3. Carolinas Imaging Services, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VIII of the application and that would otherwise require a certificate of need.**
- 4. Carolinas Imaging Services, Inc. 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.**