

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

DECISION DATE: August 28, 2012
FINDINGS DATE: September 5, 2012
PROJECT ANALYST: Bernetta Thorne-Williams
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: F-8789-12/ CaroMont Health, Inc. and Gaston Memorial Hospital, Inc./ Acquire one fixed MRI scanner to be located at its satellite emergency department in Mount Holly/ Gaston County

F-8793-12/ Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center – Gastonia/ Acquire one fixed MRI scanner to operate at its existing imaging center and develop a diagnostic center/ Gaston County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NC – CaroMont and GMH
C – PIC-Gastonia

The 2011 State Medical Facilities Plan (2011 SMFP) includes a methodology for determining the need for additional fixed MRI scanners by service area. Application of the need methodology in the 2011 SMFP identified a need for one additional fixed MRI scanner in the Gaston County MRI Service Area. No applications were submitted in 2011. The need determination in the 2011 SMFP was reallocated by the Certificate of Need Section pursuant to Policy GEN-1: Reallocations and a review was scheduled in the second Category I review for HSA III in 2012. Two applications were submitted to the Certificate of Need Section, each proposing to acquire a fixed MRI scanner for Gaston County. Each proposal is briefly described below.

CaroMont Health, Inc. (CaroMont) and Gaston Memorial Hospital (GMH) propose to acquire one fixed MRI scanner to operate at the approved Mount Holly MedPlex (Gaston County). The MedPlex will be a satellite expansion of GMH's existing emergency department (See Project I.D. # F-8586-10). The applicants own and operate four fixed MRI scanners in Gaston County and one mobile MRI scanner which serves two sites in Gaston County. CaroMont and GMH do not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2011 SMFP for Gaston County. Therefore, the application is consistent with the need determination.

Mecklenburg Diagnostic Imaging, LLC (MDI) d/b/a Presbyterian Imaging Center - Gastonia (PIC-Gastonia) proposes to acquire one fixed MRI scanner to replace its existing mobile MRI scanner currently operating at its existing outpatient imaging center in Gastonia and to develop a diagnostic center, as that term is defined in G.S .131E-176(7a). PIC-Gastonia currently offers mobile MRI, CT and ultrasound services at its imaging center. PIC-Gastonia does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2011 SMFP for Gaston County. Therefore, the application is consistent with the need determination.

In addition, there are two policies in the 2012 SMFP that are applicable to this review, Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities. Both policies are located on page 40 of the 2012 SMFP.

Policy GEN-3 states:

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

The applicants responded to Policy GEN-3 as follows:

CaroMont and GMH - Promote Safety and Quality

In Section III.2, page 67, the applicants discuss their safety and quality improvement plan. The applicants state:

“The proposed project will promote ..., and encourage quality health care services by providing more efficient health care services to the patient population served by CaroMont Health and GMH.”

In Section V.7, page 104, the applicants state:

“The GMH MRI service will provide patients of the service area with quality care in the most patient-friendly setting. GMH will provide the management of the proposed project and the experience radiologists of Gaston Radiology will provide clinical interpretation and will ensure the quality of MRI is available. The patient will receive the required imaging as part of a full continuum of care offered by CaroMont Health without the added time and inconvenience associated with traveling outside the service area.

GMH will recruit and retain highly skilled and experienced MRI Technologists to provide the MRI services proposed in this application.”

In Section II.7(a), pages 27-29, the applicants provide additional information concerning the methods CaroMont and GMH will use to insure and maintain quality care. See Exhibit 7 for copies of the applicants’ Improvement, Risk Management and Patient Safety Plans.

The applicants adequately demonstrate that the proposal will promote safety and quality care.

Promote Equitable Access

In Section III.2, page 67, the applicants discuss how they will promote equitable access. The applicants state:

“The proposed project will promote ... [and] expand health care services to the medically underserved, ... by providing more efficient health care services to the patient population served by CaroMont Health and GMH.”

In Section V.7, page 103, the applicants state:

“CaroMont Health attempts to address every barrier to access its services. CaroMont Health and GMH is a not for profit hospital that does not discriminate against any class of patient based on age, sex, religion, race, handicap, ethnicity, or ability to pay. GMH actively participates in both the Medicaid and Medicare programs. GMH has also negotiated with the following private insurance providers:

- *Aetna*
- *Beech Street*
- *Blue Medicare HMO and Blue Medicare PPO (PARTNERS National Health Plan of North Carolina*
- *BlueCross BlueShield of North Carolina*
- *BlueCross BlueShield of South Carolina (via Blue Card)*
- *Carolina Behavioral Health Alliance, LLC*
- *CCN (First Health)*
- *ChoiceCare Network PPO*
- *CIGNA*
- *CIGNA Behavioral Health*
- *First Health*

- *Gaston Hospice and Grief Counseling Services*
- *Great-West Healthcare*
- *Hospice and Palliative Care of Cleveland County*
- *Humana*
- *Inclusive Health (NC Health Insurance Risk Pool)*
- *Medicare/Medicaid*
- *MedCost*
- *MultiPlan*
- *North Carolina State Health Plan*
- *OneNet (formerly Alliance PPO/MAMSI)*
- *Premier Health, Inc*
- *Primary Physician Care Network*
- *Private Healthcare Systems (PHCS)*
- *Southcare Healthcare Preferred (First Health)*
- *Stabilus Inc. (direct employer contract)*
- *United Healthcare*
- *United Behavioral Health*
- *WellPath Community Health Plans”*

The applicants adequately demonstrate that the proposal will promote adequate access.

Maximize Healthcare Value

In Section III.2, page 104, the applicants state how the proposed project will maximize healthcare value. The applicants state:

“The state-of-the-art equipment that is proposed will enhance cost-efficiency of MRI Services. This equipment will reduce the need for duplicative MRI scans because of high quality imaging and standardized clinical protocols.”

In Section X.1, page 129, the applicants state:

“GMH is committed to and actively involved in efforts to contain costs in the development of the MedPlex as such [sic] MRI services. ... [T]his project represents either expanding the MedPlex or developing a separate building to house the MRI scanner on the MedPlex’s campus. The project will be developed in the most cost-effective manner.

The following methods will be incorporated in the design of the facility to maintain energy operations and contain costs of utilities:

- *Vegetation will be incorporated on the site around the perimeter of the building to help deter heat gain in the summer months and allow for the hear gain in the winter months.*
- *The facility will include low-emissive, double-insulated exterior glazing.*

- *Building materials will be selected that have reduced chemical emissions, such as low-VOC paint, adhesives, finishes, and formaldehyde-free wood products.*
- *Energy-efficient lighting will be integrated with central controls.*
- *Plumbing fixtures will be low water consuming fixtures.*
- *The facility will have a centralized, automated building management system, to assist in reducing energy consumption.*
- *High efficiency gas-fire, water heater will be incorporated into the facility.”*

However, CaroMont and GMH did not adequately demonstrate the need the population to be served has for the proposed fixed MRI scanner. CaroMont owns a mobile MRI scanner which operates at two sites in Gaston County. According to the applicants, this mobile performed only 1,970 weighted MRI procedures during FFY 2011. The applicants did not adequately explain why they need an additional fixed MRI scanner to serve the population they propose to serve when they have a mobile MRI scanner which they own and control that has unused capacity. Therefore, the applicants do not adequately demonstrate that acquiring an additional fixed MRI scanner would maximize healthcare value for resources expanded.

Consequently, CaroMont and GMH did not adequately demonstrate that the proposal would maximize healthcare value.

PIC-Gastonia - Promote Safety and Quality

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

“In addition to all of the policies that will be in place to promote the safety of PIC-Gastonia’s patients and staff as well as the quality of services provided, PIC-Gastonia’s patients will benefit from the availability of a full-time fixed MRI scanner that offers high quality, state-of-the-art imaging. ... Specially, PIC-Gastonia will promote safety and quality in the delivery of healthcare services by utilizing the following:

- *Verbal and written instructions related to patient safety prior to the MRI procedure.*
- *Regular maintenance schedule for the proposed equipment to ensure the equipment is maintained in proper working order at all times.*
- *Adherence with all applicable ADA and state/local policies related to the physical structure of the building.*
- *Quality interpretation of the MRI images by a board-certified radiologist.*
- *Interpretation results within 24-48 hours of exam time in order to facilitate the healthcare delivery process with the referring physician.”*

In Section II.4, pages 18-19, the applicant discusses additional methods in which PIC-Gastonia will ensure quality care. See Attachment 7 for a copy of MedQuest’s Quality Assurance Plan. (MedQuest, a related entity to PIC-Gastonia, manages the center.)

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

Promote Equitable Access

In Section III.2, pages 49-50, the applicant states how the proposed project will promote equitable access. The applicant states:

“PIC-Gastonia will provide equal access to all patients in need of MRI imaging without regard for the patient’s ability to pay for the services. PIC-Gastonia will adopt a generous charity care policy consistent with requirements of its ultimate non-profit parent company, Novant Health, Inc. ... PIC-Gastonia offers access not only geographically but also financially. PIC-Gastonia does not propose any increase in its MRI charges for 36 months during Project Years 1-3. It is PIC-Gastonia’s goal to provide high quality service for a reasonable charge. ...

PIC-Gastonia & Charity Care

..., PIC-Gastonia will partner with the local healthcare providers of Gaston County and the surrounding areas to extend its services to those patients in need. ... The proposed project will promote cost-effective approaches:

- *By maintaining the same charges, with no increases in charges, for each of the first three project years,*
- *By expanding health care services to the medically underserved in Gaston County, and*
- *Through the partnership with local healthcare providers, and encouraging quality health care services by providing more accessible health care services.”*

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

Maximize Healthcare Value

In Section III.2, page 51, the applicant states how the proposed project will maximize healthcare value.

“PIC-Gastonia will maximize healthcare value for resources expended in a number of ways, including but not limited to, the following:

- *PIC-Gastonia leases space in an existing medical office building, which is more cost effective than proposing new construction for the proposed space to accommodate the new fixed MRI scanner.*
- *Due to the volume of imaging equipment purchased by Novant and MedQuest, the applicant will utilize its purchasing power to obtain a reasonable and very competitive price for the proposed MRI scanner.*

- *PIC-Gastonia proposes to maintain the same charges for its MRI services for the first three years of the project, which means patients and payors will benefit by no increase in charges for a 36-month period.*
- *PIC-Gastonia proposes to provide a substantial amount of charity care for service area residents, based on the Novant Charity Care policy which provides care at no charge for eligible charity care patients with annual household incomes up to 300% of the Federal Poverty Level.”*

PIC-Gastonia adequately demonstrates the need the population to be served has for the proposed fixed MRI scanner. The applicant adequately demonstrates that projected utilization of the proposed fixed MRI scanner is based on reasonable, credible and supported assumptions. The applicant adequately demonstrates the fixed MRI scanner will be well utilized. See Section III.1 of the application. The mobile scanner now serving PIC-Gastonia, which is owned by a related entity, only began service 10 days before the application was submitted. This mobile MRI scanner will be replaced by the proposed fixed MRI scanner. Therefore, PIC-Gastonia adequately demonstrates that the proposal would maximize healthcare value for resources expended.

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.”

CaroMont and GMH- In Section III.2, page 67, the applicants discuss how the proposed project will provide energy efficiency and sustainability for health services facilities. The applicants state:

“The design of both the expanded MedPlex (Option 1) and the separate MRI building (Option 2) will conform to all local, state and federal codes and regulations for energy compliance.

Design to support the minimization of waste in construction and operation and allocation of adequate space for recycling will be incorporated.

The design will not adversely affect the patient health, safety or infection control.

Building design materials will be chosen to reduce energy consumption and the building will be well insulated to conserve energy. Exterior materials anticipated will be a combination of stone, brick and glass for longevity, protection and safety of occupants and energy conservation.

Building glass will be Low E to reduce solar glare and minimize heat infiltration into the interior of the building.

...

*Efficient mechanical and electrical systems will be selected and sized to meet loads, efficiently utilize space and in consideration of climate characteristics.
Energy efficiency goals will be considered in all phases of facility development.*

The design in addition to reducing consumption and use will enhance the users’ well-being.

Building materials will be selected to reduce the emission of greenhouses [sic], gases, whenever possible.

The applicants state how they plan to assure improved energy consumption. However, the applicants do not state how they plan to assure improved water consumption. Therefore, the application is not consistent with Policy GEN-4.

In summary, the application is consistent with the need determination in the 2011 SMFP but is not consistent with either Policy GEN-3 or Policy GEN-4. Consequently, the application is nonconforming to this criterion.

PIC-Gastonia- In Section III.2, page 51, the applicant discusses how the proposed project will provide energy efficiency and sustainability for health services facilities. The applicant states:

“PIC-Gastonia’s project will be developed in accordance with Novant’s Energy Plan which includes energy efficiency and water conservation.... Novant Health’s Energy Management objectives include fostering an energy management culture that identifies and supports awareness programs designed to educate employees about opportunities to contain costs and protect the environment through improved energy efficiency. Novant

Health strives to create and continually foster a business environment that will support sustainable efforts and best practices in energy efficiency, along with construction and resource management.”

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

In summary, the application is consistent with the need determination in the 2011 SMFP and Policy GEN-3 and Policy GEN-4. Consequently, the application is conforming to this criterion.

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

NC – CaroMont and GMH
C – PIC-Gastonia

CaroMont and Gaston Memorial Health, Inc were issued a certificate of need on May 9, 2012 to develop a satellite emergency department, also known as the “Mount Holly MedPlex,” which is an expansion of GMH’s existing emergency department to be operated as a department of GMH. In Project I.D. # F-8586-10, the applicants proposed the 46,108 square foot facility would include:

- 6 Rapid Medical Evaluation (Triage) Bays
- 12 treatment rooms (10 general purpose treatment rooms; 1 trauma room; and 1 resuscitation room)
- 1 CT scanner
- 1 fixed general radiography unit
- 1 mobile general radiography unit
- 1 ultrasound unit

In this application, CaroMont Health and GMH propose to acquire one fixed MRI scanner to expand the services provided at the Mount Holly MedPlex (Gaston County). The proposed imaging services would operate 24 hours a day, 7 days a week under GMH’s current license and be billed under GMH’s provider number. The applicants purpose two possible options for the proposed fixed MRI scanner, as follows:

Option 1: The applicants would construct a 1,600 square foot expansion “bump out” of the previously approved MedPlex for a construction cost \$485,100. In Section II.1, page 18, the applicants report this option would involve constructing the following:

- MRI Room
- Control Room
- MRI Prep Room
- Computer Room
- Toilet
- Dressing Room

Option 2: The applicants would construct a separate building on the MedPlex campus to house the proposed MRI scanner and services for a construction cost of \$694,975. In Section II.1, page, the applicants report this option would involve constructing the following:

- MRI Room
- Control Room
- Computer Room
- 3 Toilets
- Waiting Room
- Reception
- Office
- Storage
- Break Room
- Conference Room

The applicants already own and operate four fixed MRI scanners in Gaston County. See Section I.12(d), page 13. A related entity owns a mobile MRI scanner which operates at two sites in Gaston County. See Section II.8, page 48.

Population to be Served

In Section III.4(b) and Section III.5(c), pages 75-77, the applicants provide the current and project patient origin for fixed MRI services at GMH, as illustrated in the table below:

County	FY11 Percent of Total	CY1 2014 and CY2 2015 Percent of Total
Primary Service Area		
Gaston	76.1%	76.1%
Secondary Service Area		
Cleveland	9.2%	9.2%
Lincoln	5.4%	5.4%
Mecklenburg	2.0%	2.0%
In-Migration	7.3%	7.3%
Total	100.0%	100.0%

As illustrated in the table above, the applicants do not project a change in the patient origin for MRI services.

The applicants adequately identified the population to be served.

Need Analysis

In Section III.1, page 56, the applicants state the need for the proposed fixed MRI scanner at the MedPlex facility in Mount Holly is based on the following factors:

- *“Meet the expected demand for MRI services and will achieve sufficient volumes to maintain the operation of five MRI scanners in Gaston County.*

- *Increase patient access to fixed MRI services in Gaston County by increasing MRI capacity.*
- *Meet the demand for motionless imaging and faster scan time.'*

In Section III.1(b), pages 56-64, the applicants discuss other factors that they state support the need for the proposed fixed MRI scanner, which are summarized below:

“In projecting demand for the proposed MRI scanner, CaroMont Health and GMH reviewed:

1. *Service Area Population Growth Trends*
 - a. *Gaston County*
 - b. *CaroMont Health and GMC MRI Service Area*
2. *Physician Referral Patterns and Support*
 - a. *Physician Growth*
3. *MRI Utilization Rates*
 - a. *Utilization*

1. *Service Area Population Growth Trends*

a. *Gaston County*

From 2004 to 2012, the population of Gaston County grew by 7.1 percent. Based on projections, Gaston County’s population is projected to grow by an additional 3.8 percent from 2010 to 2016. In particular:

- *... The NC State Office of Budget and Management projects that the 45-64 population will increase by 5.2 percent from 2010 to 2012, to become 27.9 percent of Gaston’s total population.*
- *... The NC State Office of Budget and Management projects that the elderly population [65+ years old] will be the fastest growing population, increasing by 18.9 percent from 2010 – 2016.*

Gaston County Population Growth

	2004	2010	2016	2004-2012	2010-2016
			<i>(Projected)</i>	<i>Percent Growth</i>	<i>Percent Growth</i>
<i><18 Population</i>	46,366	49,198	49,540	6.11%	0.70%
<i>18-44 Population</i>	73,170	72,806	72,242	-0.50%	-0.77%
<i>45-64 Population</i>	48,813	56,900	59,836	16.57%	5.16%
<i>65+ Population</i>	24,301	27,480	32,663	13.08%	18.86%
<i>Total Population</i>	192,650	206,384	214,281	7.13%	3.83%
<i><18 Population</i>	24.07%	23.84%	23.12%		
<i>18-44 Population</i>	37.98%	35.28%	33.71%		
<i>45-64 Population</i>	25.34%	27.57%	27.92%		
<i>65+ Population</i>	12.61%	13.31%	15.24%		

Source: NC Office of State Budget and Management, February 2012

b. CaroMont Health and GMH MRI Service Area

From 2004 to 2010 the population of the MRI service area, which includes Cleveland, Gaston, Lincoln, and Mecklenburg Counties grew by 15.7 percent. Based on projections, the service area’s population is projected to grow by an additional 9.4 percent from 2010 to 2012. In particular:

- ... The NC State Office of Budget and Management projects that the 45-64 population will increase by 12.5 percent from 2010 to 2016, to become 25.7 of the service area’s total population.
- ... The NC State Office of Budget and Management projects that the elderly population [65+] will be the fastest growing population, increasing by 28.2 percent from 2010 to 2016.

CaroMont Health and GMH MRI Service Area Population Growth

	2004	2010	2016 (Projected)	2004-2010 Percent Growth	2010-2016 Percent Growth
<18 Population	286,813	324,284	349,134	13.06%	7.66%
18-44 Population	474,298	521,320	540,870	9.91%	3.75%
45-64 Population	259,704	326,754	367,540	25.82%	12.48%
65+ Population	108,805	134,903	172,952	23.99%	28.20%
Total Population	1,129,620	1,307,261	1,430,496	15.73%	9.43%
<18 Population	25.39%	24.81%	24.41%		
18-44 Population	41.99%	39.88%	37.81%		
45-64 Population	22.99%	25.00%	25.69%		
65+ Population	9.63%	10.32%	12.09%		

Source: NC Office of State Budget and Management, February 2012

The four-county CaroMont Health–defined, MRI service area’s population is expected to increase by 9.4 percent over the next six year period represented in the table, from 1.3 million in 2010 to 1.4 million in 2016.

...[T]he 65+ age group accounts for only 10.3 percent of the CaroMont Health-defined MRI service area’s population in 2010 and 13.3 percent of the state-defined MRI service area’s population, the 65+ age group accounts for than 39.7 percent of the OP MRI scans 58.7 percent of the OP MRI scans performed by CaroMont Health. This high demand for MRI services is due to increased orthopedic and neurological scans that this age group requires. Additionally, since GMH is a tertiary referral hospital a larger percentage of the Medicare population travels to GMH to receive healthcare services, including inpatient, surgical, diagnostic imaging, and rehabilitation. ... [I]n addition to GMH’s recent designation as a Level III Trauma Center.

2. Physician Referral Patterns and Support

a. Physician Growth

... Since 2005, GMH has added more than 60 physicians to its active Medical Staff, including six radiologists. ... GMC expects continued growth in the physician community over the next few years.

2. MRI Utilization Rates

a. Utilization Growth

... Diagnostic Imaging Services, which are predominantly outpatient, have experienced considerable growth. Radiology procedures and studies increased 25.0 percent, from about 124,000 to more than 155,000 in 2011. ...

...
...

The need methodology ..., which is based on historical and projected MRI utilization rates, produces projected CaroMont Health/GMH MRI Service scans for all fixed MRI scanners from FY2012 through FY 2017, as follows:

FY2012 – FY2017 Projected CaroMont Health MRI Scans

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
MRI Scans	15,665	16,623	17,639	18,718	19,863	21,078

Between 2002 and 2009, Total MRI volume at CaroMont Health increased at an average rate of 22.1 percent; more recently due to the recession, unemployment, and pre-certification requirements MRI Imaging volume at CaroMont Health has decreased at an average annual rate of 12.1 percent. Considering the aging of and the growth of the population, the addition of Medical staff physicians to continue to meet healthcare access needs over the next five years, the decrease in unemployment, and the results of the Affordable Care Act, a projected annual growth averaging 6.1 percent is a reasonable assumption as shown in the following table. The following table also highlights the average number of CaroMont Health (non-weighted) MRI scans performed per scanner.

FY202-FY2016 CaroMont Health MRI Volumes and Annual % Change

	MRI Scan Volume	Annual MRI Scan Change	MRI Scanners	MRI Scans per Scanner	
ACTUAL	FY2002	5,475	1	5,475	
	FY2003	9,897	80.8%	2	4,949
	FY2004	10,449	5.6%	2	5,225
	FY2005	11,257	7.7%	4	2,814
	FY2006	14,889	32.3%	4	3,722
	FY2007	18,310	23.0%	4	4,578
	FY2008	18,721	2.2%	4	4,680
	FY2009	19,361	3.4%	4	4,840
	FY2010	15,073	-22.1%	4	3,768
	FY2011	14,762	-2.1%	4	3,691

PROJECTED	<i>FY2012</i>	<i>15,664</i>	<i>6.1%</i>	<i>4</i>	<i>3,916</i>
	<i>FY2013</i>	<i>16,622</i>	<i>6.1%</i>	<i>4</i>	<i>4,156</i>
	<i>FY2014</i>	<i>17,639</i>	<i>6.1%</i>	<i>5</i>	<i>3,528</i>
	<i>FY2015</i>	<i>18,717</i>	<i>6.1%</i>	<i>5</i>	<i>3,743</i>
	<i>FY2016</i>	<i>19,862</i>	<i>6.1%</i>	<i>5</i>	<i>3,972</i>
	<i>FY2017</i>	<i>21,078</i>	<i>6.1%</i>	<i>5</i>	<i>4,216</i>

Projected Utilization

In Section IV.1, pages 82-90, the applicants provide the assumptions and methodology used to project utilization for the fixed MRI scanners, as follows:

“Step 1.

CaroMont Health Historical MRI Scan Change

CaroMont Health and GMH identified the MRI scans performed at its four locations as reported in the 2006-2012 Hospital License Renewal Applications to determine the annual change percentage over the last seven years. ...

CaroMont Health calculated the average annual change percentage during this time period to be 6.1 percent. CaroMont Health used the average annual change percentage to project the FY2012 through FY2017 MRI scan volume performed at CaroMont Health. ...

	<i>Year</i>	<i>GMH</i>	<i>DX</i>	<i>CIS-Summit</i>	<i>CIS-Belmont</i>	<i>Total</i>	<i>% Change</i>
HISTORICAL	<i>FY2005</i>	<i>7,459</i>	<i>3,377</i>	<i>251</i>	<i>170</i>	<i>11,257</i>	
	<i>FY2006</i>	<i>6,761</i>	<i>2,232</i>	<i>2,750</i>	<i>3,146</i>	<i>14,889</i>	<i>32.3%</i>
	<i>FY2007</i>	<i>7,626</i>	<i>2,477</i>	<i>3,876</i>	<i>4,331</i>	<i>18,310</i>	<i>23.0%</i>
	<i>FY2008</i>	<i>7,532</i>	<i>2,734</i>	<i>3,897</i>	<i>4,558</i>	<i>18,721</i>	<i>2.2%</i>
	<i>FY2009</i>	<i>7,452</i>	<i>3,462</i>	<i>3,598</i>	<i>4,849</i>	<i>19,361</i>	<i>3.4%</i>
	<i>FY2010</i>	<i>6,568</i>	<i>2,099</i>	<i>2,655</i>	<i>3,751</i>	<i>15,073</i>	<i>-22.1%</i>
	<i>FY2011</i>	<i>6,976</i>	<i>1,167</i>	<i>3,054</i>	<i>3,565</i>	<i>14,762</i>	<i>-2.1%</i>
PROJECTED	<i>FY2012</i>					<i>15,665</i>	<i>6.1%</i>
	<i>FY2013</i>					<i>16,623</i>	<i>6.1%</i>
	<i>FY2014</i>					<i>17,639</i>	<i>6.1%</i>

	FY2015	18,718	6.1%
	FY2016	19,863	6.1%
	FY2017	21,078	6.1%

Step 2.

CaroMont Health FY2011 MRI Scan Type Breakdown

CaroMont Health and GMH calculated the MRI type breakdown by adding all scans by type performed at CaroMont Health's four locations as reported in the 2012 Hospital License Renewal Application.

...

CaroMont Health applied these percentages to the annual MRI scans projected in Step 1. [See the tables on page 83.]

...

Next, CaroMont Health adjusted the MRI scan projections to account for the fact that the MRI scanner will become operational on January 1, 2014. To accomplish this CaroMont Health calculates FY2014Q1 by multiplying FY2014 by 25 percent. Each projected calendar year (CY) is calculated by multiplying the same FY MRI scan volume by 75% and adding 25% of the MRI scan volume from the following FY. The following table highlights the full FY, partial FY and full CY MRI scan projects.

	IPw	IPwo	OPw	OPwo	Total
FY2012	1,530	1,386	5,026	7,723	15,665
FY2013	1,624	1,471	5,333	8,195	16,623
FY2014Q1	431	390	1,415	2,174	4,410
CY2014	1,749	1,585	5,746	8,829	17,909
CY2015	1,856	1,682	6,097	9,369	19,004
CY2016	1,970	1,785	6,470	9,972	20,166

Step 3.

CaroMont Health MRI Scan Type % Breakdown by Site

CaroMont Health and GMH calculated the MRI scan type percentage breakdown by dividing the number of MRI scans reported by type by each site in FY2011 by the total MRI scans by type performed at CaroMont Health's four locations as reported in the 2012 License Renewal Application.

Next, CaroMont Health applied these percentages to the MRI scans projected in Step 1 for FY2012, FY2013, and FY2014Q1. [See tables of pages 85-86]

...

Step 4.

CaroMont Health MRI Scan Type % Breakdown by Site by site

CaroMont Health and GMH projected the MRI scan type percentage breakdown for the five sites, when the proposed MRI scanner becomes operational. The following projects also assume that the MRI scanner at The Diagnostic Center is replaced by 2014.

... [A]ll IP MRI scans will be performed at GMH and the OP MRI scans will be scheduled among GMH and the four other sites. During the process of scheduling and MRI scan through GMH's central scheduling, patients will be given their preferred location to receive their MRI scan; however, patients will be encouraged to utilize the new MedPlex MRI scanner and move away from receiving OP MRI scans at GMH. [See table on page 87.]

...

Next, CaroMont Health applied these percentages to the MRI scans projected in Step 2 for CY2014 to CY2016. The following tables shows the number of MRI scans by type projected to be performed at the five CaroMont Health sites after the operation of the proposed MRI scanner at the MedPlex.

CY2014

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>GMH</i>	1,749	1,585	632	971	4,937
<i>DX</i>			1,264	1,942	3,206
<i>CIS-Belmont</i>			1,092	1,678	2,769
<i>CIS-Summit</i>			1,264	1,942	3,206
<i>MedPlex</i>			1,494	2,296	3,789
<i>Total</i>	1,749	1,585	5,746	8,829	17,909

CY2015

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>GMH</i>	1,856	1,682	671	1,031	5,239
<i>DX</i>			1,341	2,061	3,403
<i>CIS-Belmont</i>			1,158	1,780	2,939
<i>CIS-Summit</i>			1,341	2,061	3,403
<i>MedPlex</i>			1,585	2,436	4,021
<i>Total</i>	1,856	1,682	6,097	9,369	19,004

CY2016

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>

<i>GMH</i>	<i>1,970</i>	<i>1,785</i>	<i>712</i>	<i>1,094</i>	<i>5,560</i>
<i>DX</i>			<i>1,423</i>	<i>2,187</i>	<i>3,611</i>
<i>CIS-Belmont</i>			<i>1,229</i>	<i>1,889</i>	<i>3,118</i>
<i>CIS-Summit</i>			<i>1,423</i>	<i>2,187</i>	<i>3,611</i>
<i>MedPlex</i>			<i>1,682</i>	<i>2,585</i>	<i>4,267</i>
Total	1,970	1,785	6,470	9,942	20,168

Step 5.

Weighted MRI Scans by Site

CaroMont Health and GMH projected the weighted MRI scans for the five sites by applying the MRI weights identified in 10A NCAC 14C .2701(18) ...

...

Next, CaroMont Health applied these weights to the MRI scans projected in Step 1 and assigned to a site in Steps 3 and 4. The following table shows the number of weighed MRI scans by type projected to be performed at the five CaroMont Health sites after the operation of the proposed MRI scanner on the MedPlex campus.

FY2012

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>GMH</i>	<i>2,754</i>	<i>1,941</i>	<i>2,718</i>	<i>2,515</i>	<i>9,927</i>
<i>DX</i>			<i>549</i>	<i>851</i>	<i>1,400</i>
<i>CIS-Belmont</i>			<i>2,126</i>	<i>2,277</i>	<i>4,403</i>
<i>CIS-Summit</i>			<i>1,644</i>	<i>2,080</i>	<i>3,724</i>
Total	2,754	1,941	7,036	7,723	19,454

FY2013

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>GMH</i>	<i>2,922</i>	<i>2,059</i>	<i>2,884</i>	<i>2,668</i>	<i>10,534</i>
<i>DX</i>			<i>583</i>	<i>903</i>	<i>1,486</i>
<i>CIS-Belmont</i>			<i>2,256</i>	<i>2,416</i>	<i>4,672</i>
<i>CIS-Summit</i>			<i>1,744</i>	<i>2,207</i>	<i>3,951</i>
Total	2,922	2,059	7,467	8,195	20,643

FY2014Q1

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>GMH</i>	<i>775</i>	<i>546</i>	<i>765</i>	<i>708</i>	<i>2,795</i>
<i>DX</i>			<i>155</i>	<i>240</i>	<i>394</i>
<i>CIS-Belmont</i>			<i>598</i>	<i>641</i>	<i>1,239</i>

<i>CIS-Summit</i>			463	585	1,048
Total	775	546	1,981	2,174	5,476

CY2014

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>GMH</i>	3,149	2,219	885	971	7,223
<i>DX</i>			1,770	1,942	3,712
<i>CIS-Belmont</i>			1,528	1,678	3,206
<i>CIS-Summit</i>			1,770	1,942	3,712
<i>MedPlex</i>			2,092	2,296	4,387
Total	3,149	2,219	8,044	8,829	22,241

CY2015

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>GMH</i>	3,341	2,354	939	1,031	7,665
<i>DX</i>			1,878	2,061	3,939
<i>CIS-Belmont</i>			1,622	1,780	3,402
<i>CIS-Summit</i>			1,878	2,061	3,939
<i>MedPlex</i>			2,219	2,436	4,655
Total	3,341	2,354	8,536	9,369	23,601

CY2016

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>GMH</i>	3,546	2,498	996	1,094	8,134
<i>DX</i>			1,993	2,187	4,180
<i>CIS-Belmont</i>			1,721	1,889	3,610
<i>CIS-Summit</i>			1,993	2,187	4,180
<i>MedPlex</i>			2,355	2,585	4,940
Total	3,546	2,498	9,058	9,942	25,044

As shown in the tables above, CaroMont Health and GMH project that the proposed fixed MRI scanner will perform 4,940 weighted MRI procedures during Project Year 3 (CY2016), which exceeds the 4,805 weighted MRI procedures required by 10A NCAC 14C .2703(b)(4). Additionally, as shown in the table above, the applicants project that GMH will perform 8,134 weighted MRI procedures, CIS-Belmont will perform 3,610 weighted MRI procedures and CIS-Summit will perform 4,180 weighted MRI procedures during Project Year 3 (CY2016). Therefore, the applicants project that the existing, approved and proposed fixed MRI scanners owned by CaroMont Health and GMH or one of its subsidiaries and located in Gaston County will perform 25,044 weighted MRI procedures in the third project year [8,134 + 4,180 + 3,610 + 4,180 + 4,940 = 25,044] or an average of 5,009 weighted procedures [25,044/5 = 5008.8], which exceeds the 4,805 required by 10A NCAC 14C .2703(b)(3). However, see discussion below regarding the reasonableness of the projected utilization, particularly the 6.1% growth rate.

In Section IV.1, pages 91-96, the applicants provide the assumptions and methodology used to project utilization of the related entity’s mobile MRI scanner, as follows:

“Mobile MRI Need Methodology

CaroMont Health and GMH used the following need methodology to project MRI scan volumes for each mobile MRI site through 2016.

Step 1.

MRI Specialists Historical MRI Scan Change

CaroMont Health and GMH identified the MRI scans performed at the two mobile sites and as reported in the 2010-2012 SMFP to determine the annual change percentage over the last year. The following table shows considerable growth since initiation of services.

CaroMont Health calculated the annual change percentage during this time period to be 66.5 percent for Opw and 14.0 percent for OPwo. CaroMont Health used just 1/4th of the annual change percentage to project the FY2012 through FY2016 mobile MRI scan volume performed by the mobile MRI scanner. CaroMont Health believes that this percent increase is reasonable because the mobile MRI scanners are becoming better utilized at the host sites.

Year	OPw	OPwo	Total
FY2009	124	221	345
FY2010	472	763	1,235
FY2011	786	870	1,656
<i>Source: 2010-2012 State Medical Facilities Plan</i>			
<i>Actual Growth</i>	66.5%	14.0%	
<i>1/4” Actual Growth</i>	16.6%	3.5%	
FY2012	917	901	1,817
FY2013	1,069	932	2,001
FY2014	1,247	965	2,212
FT2015	1,454	999	2,453
FY2016	1,696	1,034	2,730
FY2017	1,978	1,070	3,048

Next, CaroMont Health adjusted the mobile MRI scan projections to account for the fact that the proposed MRI scanner will become operational on January 1, 2014. To accomplish this CaroMont Health calculated the FY2014Q1 by multiplying FY2014 by 25%. Each projected calendar year (CY) is calculated by multiplying the same FYMRI scan volume by 75% and adding 25% of the MRI scan volume from the following FY. For example, CY2014 equals (75%

x FY2014 MRI scans) + (25% x FY2015 MRI scans). The following table highlights the full FY, partial FY and full CY.

Year	OPw	OPwo	Total
FY2012	917	901	1,817
FY2013	1,069	932	2,001
FY2014QI	312	241	553
CY2014	1,299	973	2,272
CY2015	1,515	1,007	2,522
CY2016	1,767	1,043	2,809

Step 2.

MRI Specialists MRI Scan Type % Breakdown by Site

CaroMont Health and GMH calculated the MRI scan type percentage breakdown by dividing the number of MRI scans reported by typed by each site in FY2011 by the total MRI scans by type performed at both sites as reported in the 2012 Equipment Information form.

Next, CaroMont Health applied these percentages to the mobile MRI scans projected in Step 1 for FY2012 through CY2016. [See tables on pages 93-94.]

[There are no Steps 3 and 4 in this methodology.]

Step 5.

Weighted MRI Scans by Site

CaroMont Health and GMH projected the weighted MRI scans for the two sites applying the MRI weights identified in 10A NCAC 14C .2701(18) ...

...

Next CaroMont Health applied these weights to the mobile MRI scans projected in Step 1 and assigned to be a site in Step 2. The following table shows the number of weighted MRI scans by type projected to be performed at the two mobile sites.

FY2012

	IPw	IPwo	OPw	OPwo	Total
<i>Gastonia</i>			1,073	759	1831
<i>Belmont</i>			211	142	352
Total			1,284	901	2,184

FY2013

	IPw	IPwo	OPw	OPwo	Total

<i>Gastonia</i>			1,251	785	2,036
<i>Belmont</i>			246	147	392
Total			1,497	932	2,429

FY2014Q1

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>Gastonia</i>			365	203	568
<i>Belmont</i>			72	38	110
Total			436	241	678

CY2014

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>Gastonia</i>			1,520	820	2,340
<i>Belmont</i>			298	153	452
Total			1,818	973	2,792

CY2015

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>Gastonia</i>			1,773	849	2,621
<i>Belmont</i>			348	159	507
Total			2,121	1,007	3,128

CY2016

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>Gastonia</i>			2,068	878	2,946
<i>Belmont</i>			406	164	570
Total			2,474	1,043	3,516

A related entity owns an existing mobile MRI scanner which operates at two sites in Gaston County (Gastonia and Belmont). Therefore, pursuant to 10A NCAC 14C .2703(b)(2), the applicants are required to demonstrate that this existing mobile MRI scanner performed at least 3,328 weighted MRI procedures in the most recent 12-month period for which the applicant has data. In Section II.8, page 48, the applicants provided the number of weighted MRI scans performed on this mobile MRI scanner from 10/01/10 – 9/30/2011, as illustrated in the table below.

<i>MRI Procedure</i>	<i>Procedures</i>	<i>Weights</i>	<i>Weighted Procedures</i>
<i>OP/With Contrast/Sedation</i>	786	1.4	1,100
<i>OP/NO Contrast</i>	870	1.0	870
Total	1,656		1,970

Source: CaroMont Decision Support and Planning

As illustrated in the table above, the applicants report that only 1,970 weighted MRI procedures were performed by the mobile MRI scanner from October 1, 2010 to September 30, 2011. This is 41% less than the 3,328 weighted MRI procedures required by 10A NCAC 14C .2703(b)(2) [$3,328 - 1,970 = 1,358$; $1,358 / 3,328 = 0.408$]. The applicants do not explain why the existing mobile MRI scanner could not provide MRI services at the Mount Holly MedPlex, given that it is not being fully utilized.

Furthermore, the applicants do not adequately demonstrate that the 6.1% projected growth rate is reasonable, credible and supported. This rate was calculated by the applicants by averaging the annual percentage changes for the 6-year period between FY 2005 and FY 2011. Note: this is not a “compound annual growth rate” (CAGR), which would be only 4.6% for the same 6-year period. Moreover, the applicants used GMH’s hospital license renewal applications (LRAs) to obtain the data for the table on page 82 of the application. There is an addition error in GMH’s 2012 LRA which was carried over into the table on page 82 of the certificate of need application. Specifically, the total number of MRI procedures for FY 2011 is not 14,762. The correct total is 14,702. This error does not materially affect the calculation of either the average of the percentage changes or the CAGR. However, what does materially affect these percentages is the inclusion of FY 2005 data in both calculations. If FY 2005 data is excluded and the correct number of MRI procedures for FY 2011 is used, the average of the percentage changes for the 5-year period between FY 2006 and FY 2011 is only 0.81% (not 6.1%) and the CAGR is a negative 0.25% (not 4.6%). An examination of the number of MRI procedures performed between FY 2006 and FY 2011 shows that utilization increased through FY 2009 and then began declining. As of FY 2011, utilization was slightly less than utilization in FY 2006 (14,702 procedures in FY 2011 compared to 14,889 procedures in FY 2006). Given that the CAGR for the 5-year period from FY 2006 to FY 2011 is a negative 0.25% and the average of the percentage changes is only 0.81% for the same time period, the applicants do not adequately demonstrate that it was reasonable to use a growth rate of 6.1% to calculate projected utilization of their fixed MRI scanners. Thus, the applicants do not adequately demonstrate that projected utilization of the fixed MRI scanners is based on reasonable, credible and supported assumptions. Consequently, the applicants do not adequately demonstrate the need to acquire a fifth fixed MRI scanner.

Moreover, the projected utilization of the mobile MRI scanner owned by a related entity is questionable. In Section IV.1, page 91, the applicants provide historical utilization data for the mobile MRI scanner for FY 2009 through FY 2011. According to records in the Certificate of Need Section (CON Section), the mobile MRI scanner did not begin operating until April of 2009. FY 2009 began on October 1, 2008 and ended on September 30, 2009. Thus, the mobile MRI scanner only operated for half of FY 2009. In Section IV.1, page 91, the applicants do not state that it was in operation for only six months of FY 2009. However, the applicants did not include the utilization during FY 2009 in calculating the rates of growth for the mobile MRI scanner. Instead, they calculated the rate of growth for procedures with contrast and procedures without contrast between FY 2010 and FY 2012, a one year period. They assume that utilization of the mobile MRI scanner will increase at $\frac{1}{4}$ of each of these rates. A one year increase is not sufficient to establish a trend. Also, at the time this application was submitted it appears that the applicants only had 18 months (1.5 years) of utilization data for this mobile MRI scanner. During the first years of operation it is not unusual for an MRI scanner to

experience significant growth which then slows once the equipment has been in use for a few years. The applicants do not adequately demonstrate that utilization of this mobile MRI scanner will increase 16.6% each year for procedures with contrast and 3.5% each year for procedures without contrast between FY 2011 and FY 2017 (the third operating year of the proposed fixed MRI scanner). Particularly, given the rate of growth between FY 2006 and FY 2011 for the four fixed MRI scanners located in Gaston County, which are all owned by the applicants.

In summary, the applicants did not adequately demonstrate the need the population to be served has for the proposed fixed MRI scanner given the underutilization of the existing mobile MRI scanner owned by a related entity which operates at two sites in Gaston County and the unreliability of the projected utilization of the fixed and mobile MRI scanners. Therefore, the application is nonconforming with this criterion.

Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center – Gastonia, is operated and managed by MedQuest Associates, Inc, whose parent company is Novant Health, Inc. They propose to acquire one fixed MRI scanner to operate at the existing imaging center in Gastonia. Mecklenburg Diagnostic Imaging, LLC, in Project I.D. # F-8237-08, was approved to acquire a mobile MRI scanner to serve the Gastonia site 920 Cox Road (PIC-Gastonia). The certificate of need was issued with an effective date of January 10, 2012. The equipment did not begin operating until March 5, 2012. The proposed fixed MRI scanner would replace this mobile MRI scanner. Prior to March 5, 2012, mobile MRI services were provided at PIC-Gastonia by two other mobile MRI scanners owned by a related entity. These mobile MRI scanners no longer provide services at PIC-Gastonia.

Population to be Served

In Section III.4(b) and Section III.5(b), pages 53-54, the applicant provides the current and projected patient origin for its existing mobile and proposed fixed MRI services at PIC-Gastonia, as illustrated in the table below.

County	Historical % of Total Patients CY 2011	Projected % of Total Patients FY 2015	Projected % of Total Patients FY 2016
Gaston	64.3%	64.3%	64.3%
Cleveland	12.9%	12.9%	12.9%
Lincoln	7.2%	7.2%	7.2%
Mecklenburg	6.2%	6.2%	6.2%
Other	9.4%	9.4%	9.4%
Total	100%	100%	100%

Other includes: Catawba, Rutherford, Cabarrus, Caldwell, Alexander, other North Carolina counties, South Carolina and unknown.

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

The applicant adequately identified the population to be served.

Need Analysis

In Section III.1, pages 39-42, the applicant states the need for the proposed fixed MRI scanner at PIC-Gastonia is based on the following factors which are briefly discussed below:

- Limitations to the use of mobile MRI services
- Service Area Growth
- Aging Population

Limitations to the use of mobile MRI services

“The use of mobile MRI services has limitations, which include:

- *Mobiles are not easily accessible for all patients.*
- *Mobile MRI scanners are less effective in accommodating obese patients.*
- *Patients are inevitably exposed to the elements ...*
- *Technological advances are available in the latest MRI scanners that are not available on the mobile MRI scanner.*
- *Mobiles are not as efficient – moving patients outside means inherently slower processes.*
- *Mobile systems are not quite as easily accessible to emergency personnel in the event of a medical emergency.*
- *Mobile scanners tend to be more costly to service and recognize more downtime than fixed MRI scanners due to the wear and tear associated with the constant movement of the trailers.*

...

Service Area Growth

“Gaston County is the proposed service area for the proposed project. Located west of Charlotte ..., Gaston County is experiencing relatively steady population growth. According to the North Carolina Office of State Budget and Management, Gaston County’s population increased by 8.86% from April 2000 to July 2009. From July 2010 to July 2019, Gaston’s County’s population is expected to increase from 206,384 to 218,372 or 5.8%.

The majority of the municipal growth is occurring in the central and eastern portions of Gaston County in the areas of Gastonia, Belmont, Mount Holly and Ranlo. Gastonia is the most populated area in Gaston County. The population growth in Gastonia alone represents 53% of the county’s total growth from 2000 to 2009. The majority of the growth is occurring along the I-85 corridor with an emphasis in the areas of Gastonia and east towards Charlotte. The location of the proposed fixed MRI scanner in Gastonia at PIC-Gastonia is ideally situated to provide convenient access to all residents in Gaston County.

[See map on page 41 of the application].

Aging Population

“... The elderly population is expected to grow at a rate faster than the population overall, increasing nearly 10% between 2010 and 2013, from 27,480 residents aged 65 and older to 30,189 residents aged [sic] 65 and older. Population growth among residents 65 and older is significant because this age group tends to utilize health care services, including imaging services, at a rate higher than younger age groups.

	2010	2011	2012	2013	%Change
<i>Residents 65 years old +</i>	27,480	28,134	29,213	30,189	9.85%
<i>Total Population</i>	206,384	207,465	208,828	210,191	1.84%
<i>Residents 65+ as a % of Total Population</i>	13.3%	13.6%	14.0%	14.4%	1.1%

Source: NC OBSM: Projected County Total – Standard Age Groups

In Section III.1, pages 43-44, the applicant discusses expected business development in Gaston County.

Projected Utilization

In Section III.1, pages 44-46, the applicant provides projected utilization for the proposed fixed MRI scanner. The applicants state the decrease in utilization of mobile MRI services in FFY 2007-08 and FFY 2009-10 is “most likely a result of the extreme and sustained economic recession Factors such as high unemployment, loss of health coverage and reductions in income.”

The applicant provides the assumptions and methodology used to project utilization of the proposed fixed MRI scanner in Section III.1, pages 44-46, as follows:

“PIC-Gastonia currently offers mobile MRI services at its existing outpatient imaging center. The following chart provides the historical utilization of MRI services in Gaston County.

Gaston County Historical MRI Utilization – All Sites

	FY2000-05	FY2005-06	FY2006-07	FY2007-08	FY2008-09	FY2009-10
<i>Unweighted MRI Volume</i>	17,1746	19,488	21,508	20,709	21,563	18,634
<i>Weighted MRI Volume</i>	22,504	24,700	26,778	25,746	26,857	22,894
<i>% change in Unweighted Volume</i>	---	12.41%	10.37%	-3.71%	4.12%	-13.58%

Note: FY 2009-10 is 10/1/2009-9/30/2010

PIC-Gastonia also reviewed the historical MRI utilization for North Carolina (unweighted MRI volume for all sites, mobile, and fixed). A comparison of Gaston County and North Carolina shows a similar trend in that both Gaston County and North Carolina experienced decreases in MRI volume during FY 2007-08 and FY 2009-10. In the positive growth, Gaston County's growth rates were significantly higher than North Carolina as a whole.

North Carolina Historical MRI Utilization – All Sites

	FY2000-05	FY2005-06	FY2006-07	FY2007-08	FY2008-09	FY2009-10
<i>Unweighted MRI Volume</i>	719,447	786,694	821,829	814,048	828,805	777,609
<i>Weighted MRI Volume</i>	---	9.35%	4.47%	-1.0%	1.81%	-6.18%

Note: FY 2009-10 is 10/1/2009-9/30/2010

During FFY2005-2007 and FY2008-2009, Gaston County posted increases in MRI volume that outperformed the percentages for North Carolina. ...

...

... [T]he use rate per thousand for North Carolina during FY 2009-10 was 81.2 scans per thousand residents, while Gaston County's use rate was 90.7.

...

The average use rate during the three year period [FY 2007-10] was 99.2 scans per 1,000 residents. By applying this average to the projected population totals of Gaston County, it will provide a conservative estimate of the MRI volume for Gaston County during the project time period.

Estimated MRI Volume in Gaston County (10/1/2014-9/30/2016)

Year	Gaston County Population	Use Rate	Projected Unweighted MRI Volume
2014	211,557	99.2	20,986
2015	212,919	99.2	21,122

The MRI volumes estimated for 2014-2017 using the three-year average use rate of 99.2 produce reasonable projections each year that are consistent with Gaston County's historical experience. During the last six reporting periods, the lowest unweighted MRI volume was 17,746 scans in FY 04-05 and the highest volume was 21,563 scans in FY 2008-09.

PIC-Gastonia's Market Share

During FY 2009-10, PIC-Gastonia reported 1,415 unweighted scans, which is a market share of 7.56% (1,415 scans/18,720 total scans). This market share percentage was obtained with partial mobile MRI services, with service available at the PIC-Gastonia site only 4 days a week, approximately 9 hours per day. As a result of the proposed project with a fixed MRI scanner in operation 6 days and 70 hours per week, PIC-Gastonia estimates it will increase its market share as follows:

	Year 1 – 10/14-9/15	Year 2 – 10/15-9/16	Year 3 – 10/16-9/17
<i>Projected Gaston County MRI volume</i>	21,122	21,257	21,392
<i>PIC-Gastonia Market Share</i>	15.1%	18.8%	21.3%
<i>PIC-Gastonia Unweighted</i>	3,189	3,996	4,561

PIC-Gastonia assumed in Year 1 (10/14-9/15) that it would double its FY 2009-10 market share of 7.56% ($7.56\% \times 2 = 15.1\%$) due to the implementation of the full-time fixed MRI scanner. In Years 2 and 3, PIC-Gastonia estimates a smaller increase of 3.78% (1/2 of 7.56%) in Year 2 and 2.52% (1/3 of 7.56%). There are several factors that support the projected market share percentages, including but not limited to the following:

- ...
- *Increased availability of MRI services at PIC-Gastonia due to an increase in service from 4 days per week on the current mobile MRI scanner to 6 days per week on the proposed fixed MRI scanner, an increase of 50% in terms of days of MRI access per week.*
- *Letters of support from local providers indicating willingness to refer patients to the proposed facility*
- ...
- ...
- ...
- *The outmigration of Gaston County residents to Mecklenburg County for MRI services. Based on FY 2009-10 data from Novant’s fixed MRI scanners in Mecklenburg County, 990 Gaston County patients received MRI services at Novant’s facilities in Mecklenburg County. ...*

Weighted MRI Volume at PIC-Gastonia

In order to estimate weighted volume, PIC-Gastonia utilized its FY 2009-10 contrast percentage, 23%, and applied it to the projected unweighted volume from the chart above. The contrast scans were adjusted by the outpatient/contrast factor of .4 to determine the number of weighted MRI scans.

	Year 1 – 10/14-9/15	Year 2 – 10/15-9/16	Year 3 – 10/16-9/17
<i>PIC-Gastonia Unweighted MRI Volume</i>	3,189	3,996	4,561
<i>Contrast %</i>	23%	23%	23%
<i>Contrast Scans</i>	732	919	1,049
<i>Adjustment</i>	293	367	420
<i>Weighted Volume</i>	3,482	4,364	4,981

PIC-Gastonia is projected to provide 3,482, 4,364 and 4,981 weighted MRI procedures during the first three years of operation for the proposed MRI.”

As shown in the table above, PIC-Gastonia projects that the proposed fixed MRI scanner will perform 4,981 weighted MRI procedures during Project Year 3, which exceeds the 4,805 weighted MRI procedures required by 10A NCAC 14C .2703(b)(3). Projected utilization is based on reasonable, credible and supported assumptions regarding the use rate per 1,000 population and projected market share growth due primarily to additional hours of operation and the advantage of a fixed MRI scanner over a mobile MRI scanner. Therefore, the applicant adequately demonstrates the need to acquire the proposed fixed MRI scanner.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need the population has for the proposed MRI scanner. Consequently, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA – Both Applications

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

NC – CaroMont and GMC
C – PIC-Gastonia

CaroMont & GMC- In Section III.3, pages 69-73, the applicants describe several alternatives considered which include the following:

- 1) Maintain the Status Quo – the applicants decided to do nothing would not address the need determination identified in the 2011 SMFP for Gaston County for one additional fixed MRI in the Gaston County service area;
- 2) Joint Venture – the applicants concluded that a joint venture was not their best alternative for several reasons including: the MRI would have to be classified as an IDTF and Medicaid does not currently reimburse IDTF's and with a joint venture, significant overhead would have to be duplicated [See page 70, for a complete list of bullet points concerning the reasons identified by the applicants as to why a joint venture was not their most effective alternative];
- 3) Locate the fixed MRI in another location in Gaston County – the applicants considered possibly locating the proposed fixed MRI scanner in southern Gaston County, however, the applicants concluded that MRI services are currently available in that area of the county via

MRI services in Mecklenburg County or at Tenet Hospital in SC. The applicants also considered the Cherryville area, however, the applicants concluded CaroMont has a smaller presence in the area and that patients have established a referral pattern to both Lincolnton (CMC-Lincoln) and Shelby (Cleveland Regional). The applicants concluded those locations were not their best alternatives; and

4) Build a new freestanding diagnostic center – the applicants concluded building a new freestanding diagnostic center would involve a higher capital cost and would not allow for the sharing of staff. Thus, the applicants concluded that this was not their most effective alternative.

The applicants concluded that the approved Mount Holly MedPlex would be their least costly and most effective alternative.

However, a related entity owns a mobile MRI scanner which operates at two sites in Gaston County. This mobile MRI scanner is not fully utilized and could provide services at the Mount Holly MedPlex. The applicants do not discuss this alternative, and thus, do not adequately explain why utilization of the mobile MRI scanner at the Mount Holly MedPlex would not be a less costly or more effective alternative.

Moreover, the application is not conforming with all other applicable statutory and regulatory review criteria, and therefore, it is not approvable. An application that can not be approved can not be an effective alternative.

In summary, the applicants did not adequately demonstrate that the proposal is their least costly or most effective alternative to meet the need and the application is nonconforming to this criterion.

PIC-Gastonia- In Section III.3, page 52, the applicant discusses the two alternatives PIC-Gastonia considered, which are:

1) Continue to Utilize Mobile MRI Service – the applicants concluded that the use of continued mobile MRI services had short term benefits, but did not represent an effective long-term solution for an established imaging center; and

2) A new fixed MRI scanner – which the applicants conclude would increase competition and accessibility to services in Gaston County.

The applicant adequately demonstrates that acquiring the fixed MRI scanner to be located at its existing imaging center in Gastonia is its most effective alternative to meet the need for fixed MRI services in Gaston County.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and therefore, the application is approvable.

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

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C – CaroMont and GMC
C – PIC-Gastonia

CaroMont and GMC- In Section VIII.1, page 123, the applicants state the capital cost for the project will either be \$2,363,716 or \$2,676,900 depending on which option is selected, as illustrated in the table below.

	<i>Option 1</i>	<i>Option 2</i>
<i>Description</i>	<i>Expansion</i>	<i>New Building</i>
<i>Construction Contract Cost of Materials (including Cost of Labor and inflation)</i>		
<i>Sub-Total Construction Contract</i>	\$485,100	\$694,975
<i>Miscellaneous Project Costs</i>		
<i>Equipment Purchase/Lease</i>	\$1,559,498	\$1,559,498
<i>Furniture and Equipment [not previously listed]</i>	\$20,000	\$75,000
<i>Consultant Fees:</i>		
<i>Architect & Engineering</i>	\$41,234	\$59,073
<i>Legal Fees/Market Analysis</i>	\$35,000	\$35,000
<i>Reimbursable Expenses</i>	\$8,000	\$10,000
<i>Other (Contingency 10.0% of project costs)</i>	\$214,884	\$243,354
<i>Sub-Total Miscellaneous</i>	\$1,878,616	\$1,981,925
<i>Total Capital Cost of Project</i>	\$2,363,716	\$2,676,900

In Section IX, page 128, the applicants state there will be \$20,958 in start-up expenses to include one month of salary expenses and \$5,000 for medical supplies. The applicants further state on page 128, that there will be no initial operating expenses associated with the proposed project. In Section VIII.3, page 124, the applicants state that the project will be funded by CaroMont Health, Inc accumulated reserves and in Section IX, page 128 the applicants state that the working capital for the proposed project will be funded by CaroMont Health, Inc, unrestricted cash. Exhibit 21, contains a letter dated March 10, 2012 from the Executive Vice President & CFO CaroMont Health, Inc, which states:

“CaroMont Health, Inc. will obligate and commit \$2,676,900 million for the sole purpose of acquiring an MRI scanner and developing an MRI Service at its approved Mount Holly MedPlex. CaroMont Health plans to provide the funds through Accumulated Reserves.

CaroMont Health, Inc, will also obligate and commit \$20,958 for the sole purpose of funding the working capital required to make the MRI scanner operational. CaroMont Health plans to provide the funds through Accumulated Reserves.

CaroMont Health, Inc. has sufficient Accumulated Reserves to provide the funding required for this project. ...

...”

Exhibit 22 of the application contains the audited financial statements for CaroMont Health, Inc. and Affiliates for the years ending June 30, 2010 and June 30, 2011. As of June 30, 2011, CaroMont Health, Inc. and Affiliates had \$1,412,181 in cash and cash equivalents, unrestricted net assets of \$526,544,273 and \$547,041,551 in net assets (total assets less total liabilities). The applicants adequately demonstrated the availability of sufficient funds for the capital needs of the project.

In Section XIII, the pro forma tab, the applicants provide financial statements for the first three years of the proposed project for Gaston Memorial Hospital. The following table illustrates revenues and expenses for the entire hospital. The proposed fixed MRI scanner, like all the other services to be provided at the Mount Holly MedPlex, will be provided as a service of the hospital.

	Project Yr 1 FY 1/1/14-12/31/14	Project Yr 2 FY 1/1/15-12/31/15	Project Yr 3 FY 1/1/16-12/31/16
Projected # of weighted healthcare units (see page 146 of the application for how this was calculated)	104,207	104,877	105,547
Gross Patient Revenue	\$542,272,251	\$562,130,513	\$582,694,262
Deductions from Gross Patient Revenue	\$9,589,166	\$9,940,326	\$10,303,961
Net Patient Revenue	\$542,274,025	\$562,132,352	\$582,696,168
Total Expenses	\$524,476,121	\$546,793,776	\$569,865,626
Net Income	\$17,797,904	\$15,338,576	\$12,830,542

As shown in the table above, the applicants project that net revenues will exceed expenses during each of the first three operating years.

Projected utilization for the fixed MRI scanner is unsupported and unreliable. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby by reference as if fully set forth herein. However, although projected revenues and expenses for the fixed MRI scanners would be unreliable to the extent they are based on unreliable projected utilization, in this case, the impact on the projected revenue and expenses for the hospital as a whole would be de minimis.

In summary, the applicants adequately demonstrate that the financial feasibility of the proposal, as part of the entire hospital, is based upon reasonable projections of costs and charges for the hospital as a whole. Thus, the application is conforming with this criterion.

PIC-Gastonia- In Section VIII.1, page 88, the applicant states that the total capital cost of the project will be \$2,662,155, including \$800,000 for construction contract, \$1,732,155 for fixed equipment purchase/lease, \$25,000 for furniture costs, \$80,000 for architect/engineering fees, and \$25,000 for Other (Contingency). In Section IX, page 96, the applicant states that there will be no start up or initial operating expenses associated with the proposed project. In Section VIII.3, page 89, the applicant states that the project will be funded by the accumulated reserves of its parent company, Novant Health, Inc. Attachment 16 contains a March 5, 2012 letter signed by the Executive Vice President & Chief Financial Officer for Novant Health, which states:

“This letter will serve to confirm that Novant Health, Inc. (“Novant”) will be funding the capital cost of \$2,662,155 of [sic] the Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center – Gastonia’s MRI project from Novant’s accumulated reserves. As the Chief Financial Officer for Novant, I have the authority to obligate funds from the accumulated reserves of Novant for projects undertaken by MedQuest, Inc. and Mecklenburg Diagnostic Imaging, LLC, both affiliates of Novant. Novant is the not-for-profit parent company of MedQuest, Inc., and the ultimate parent company of Mecklenburg Diagnostic Imaging, LLC, I can and will commit Novant’s reserves to cover all of the capital costs associated with this project. There will be no start-up or working capital associated with this project since Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center – Gastonia is an existing facility.”

Attachment 16 also contains a letter dated March 13, 2012, from the Vice President, Finance for MedQuest Associates, which states:

“This letter confirms the availability of funds for Mecklenburg Diagnostic Imaging, LLC a/b/a Presbyterian Imaging Center – Gastonia (“PIC-Gastonia”) to support the capital expenditure required for the acquisition of the fixed MRI as proposed in the PIC-Gastonia CON application. The total capital expenditure required for the proposed project is \$2,622,155, which includes the total cost of the MR system and other related equipment, construction, expenses and common consulting fees. The project will not require any start-up or initial operating expenses as it is an existing outpatient imaging center.

MedQuest, Inc., an affiliate of PIC-Gastonia, will make available all funds necessary to finance the proposed project and required working capital, as well any unforeseen expenses related to the CON application, through its accumulated reserves and through MedQuest’s Inc.’s \$425 million Revolving Credit with Novant Health, Inc. “

Attachment 17 of the application contains the combined financial statements for Novant Health, Inc. and Affiliates for the years ending December 31, 2009 and December 31, 2010. As of December 31, 2010, Novant Health and Affiliates had \$507,879,000 in cash and cash equivalents, unrestricted net assets of \$4,619,087,000 and \$1,951,802,000 in net assets (total

assets less total liabilities). The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

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

	Project Yr 1 10/1/14-9/30/15	Project Yr 2 10/1/15-9/30/16	Project Yr 3 10/1/16-9/30/17
Projected # of Unweighted MRI Procedures	3,189	3,996	4,561
Projected Average Charge (Gross Patient Revenue/ Projected # of Procedures)	\$1,522	\$1,522	\$1,522
Gross Patient Revenue	4,853,173	6,081,304	6,941,148
Deductions from Gross Patient Revenue	2,578,211	3,230,647	3,687,432
Net Patient Revenue	2,274,961	2,850,657	3,253,715
Total Expenses	1,356,447	1,561,028	1,626,256
Net Income	918,515	1,289,629	1,627,459

The applicant also projects a positive net income for the entire diagnostic center 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 for the assumptions regarding cost and charges. See Criterion (3) for discussion of utilization projections which is hereby incorporated hereby as if fully set forth herein. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and charges, and therefore, the application is conforming to this criterion.

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

NC – CaroMont and GMH
C – PIC-Gastonia

CaroMont and GMH currently own and operate four existing fixed MRI scanners in Gaston County. The 2011 SMFP identified a need for one additional fixed MRI scanner in Gaston

County. No applications were received and the need determination was reallocated by the CON Section pursuant to Policy GEN-1 in the second category I review cycle for CY 2012. The applicants propose to acquire a fifth fixed MRI scanner to be located at the approved Mount Holly MedPlex. However, a related entity owns an underutilized mobile MRI scanner which operates at two sites in Gaston County. This mobile performed only 1,970 weighted MRI procedures in FY 2011, the most recent 12-month period for which the applicants had data. Full utilization of a mobile MRI scanner is at least 3,328 weighted MRI procedures per year (80% of capacity which is 4,160 weighted MRI procedures per year). In addition, projected utilization of the existing and proposed fixed MRI scanners and the existing mobile MRI scanner is not credible. See Criterion (3) for discussion which is incorporated hereby as if fully set forth herein. The applicants did not adequately demonstrate the need to acquire a fifth MRI scanner. Thus, the applicants did not adequately demonstrate that the proposal would not result in the unnecessary duplication of existing or approved MRI scanners. Consequently, the application is nonconforming to this criterion.

PIC-Gastonia- The 2011 SMFP identified a need for one additional fixed MRI scanner in Gaston County. No applications were received and the need determination was reallocated by the CON Section pursuant to Policy GEN-1 in the second category I review cycle for CY 2012. The applicant proposes to acquire one fixed MRI scanner to replace its existing mobile MRI scanner at its existing imaging center in Gastonia. The applicant adequately demonstrates the need to replace the mobile MRI services at PIC-Gastonia with a fixed MRI scanner. The 2011 SMFP identified a need for a fifth fixed MRI scanner and the applicant adequately demonstrates the need for its proposed fixed MRI scanner based on reasonable, credible and supported projected utilization. See Criterion (3) for discussion which is incorporated hereby as if fully set forth herein. Thus, the applicant adequately demonstrates the addition of a fixed MRI scanner at PIC-Gastonia will not result in the unnecessary duplication of fixed MRI scanners in Gaston County. Consequently, the application is conforming to this criterion.

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

C – CaroMont Health and GMH
C – PIC-Gastonia

CaroMont and GMH- In Section VII.1(b), page 115, the applicants provide the projected staffing for the proposed fixed MRI scanner at the approved Mount Holly MedPlex. The applicants project to employ 3.0 full-time equivalents (FTEs) for the proposed MRI project. (2.0 FTE MRI technologist positions and 1.0 FTE clerical position). In Section VII.6, page 188, the applicants discuss their experience in the recruitment and retention of staff. In Exhibit 14, the applicants provide a letter from Dr. Kevin Dul, which states, *“I am currently the Medical Director of Imaging Services at Gaston Memorial Hospital and I am willing to continue in that role at Gaston Memorial Hospital and the approved Mount Holly MedPlex.”*

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

PIC-Gastonia- In Section VII.1(a)(b), pages 77-78, the applicant provides the projected staffing for the proposed fixed MRI scanner. The applicant projects staffing will increase from 8.09 FTE positions to 9.84 FTE positions at the beginning of the second year (FY2012) (1.75 will be FTE MR technologist positions). In Section VII.6, page 83, the applicant discusses its experience in the recruitment and retention of staff. In Attachment 8, the applicant provides a letter from Dr. Jay Patti agreeing to provide Medical Director Services to PIC-Gastonia.

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

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

C – CaroMont and GMH
C – PIC-Gastonia

CaroMont and GMH- GMH is an existing hospital located in Gastonia. The applicants were previously approved to develop a MedPlex in Mount Holly which will provide emergency and imaging (CT, x-ray and ultrasound) services. In Section II.2(a), the applicants state:

“The ancillary and support services needed to support this proposed project include

- *Housekeeping*
- *Security*
- *Finance/Registration*
- *Administration*
- *Guest Services*
- *Bio Medical*
- *Risk Management*
- *Purchasing”*

In Section V.2(a), page 98, the applicants identify the facilities with which they have transfer agreements, as follows:

“Transfer agreements currently exist between GMH and the provider facilities listed. GMH expects these arrangements to continue into the foreseeable future.

- *Cleveland Regional Medical Center*
- *Carolinas Medical Center – Lincoln*
- *Carolinas Medical Center”*

Exhibit 12 contains a listing of Education Affiliation Agreements and see Exhibit 13 for copies of the applicants transfer agreements. Exhibit 25 contains copies of physicians and community support letters.

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

PIC-Gastonia- The applicant is an existing provider of imaging services, currently offering CT, ultrasound and mobile MRI services. In Section II.2(a), page 16, the applicant states:

“The only support services needed for the proposed project are staff training, accounting, purchasing, and human resources. No other support services or ancillary services are required for efficient and effective utilization of the proposed project. MedQuest, the management company for PIC-Gastonia, provides these services.”

In Section V.2(a), pages 61-62, the applicant states that as a freestanding imaging center, it does not have established transfer agreements. The applicant also states:

“PIC-Gastonia works with the closest appropriate provider to transfer a patient who developed an emergent problem while undergoing a diagnostic procedure at PIC-Gastonia. In addition, the PIC-Gastonia MRI Technologists will be required to be trained in CPR, and can contact 911 for an ambulance and will support the patient until the ambulance arrives.”

See Attachment 6 for a copy of PIC-Gastonia’s Emergency Policy and Attachment 13 for a copy of Novant Health’s Clinical Education Arrangements. Attachment 24 contains copies of letters of support from physicians.

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

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

NA – Both Applications

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

(iv) would be available in a manner which is administratively feasible to the HMO.

NA – Both Applications

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

C – CaroMont and GMH
 NA – PIC-Gastonia

CaroMont and GMH- In Section XI.4, page 137, the applicants provide the existing and proposed square footage for both options considered for the MRI suite, as illustrated in the tables below:

Expansion

<i>Department/Section</i>	<i>SF</i>	<i>New Construction Estimated SF</i>	<i>Total Projected Project SF</i>
<i>MRI Services</i>	<i>1,600</i>	<i>1,600</i>	<i>1,600</i>

New Building

<i>Department/Section</i>	<i>SF</i>	<i>New Construction Estimated SF</i>	<i>Total Projected Project SF</i>
<i>MRI Services</i>	<i>2,800</i>	<i>2,800</i>	<i>2,800</i>

Exhibit 24 of the application contains two certified cost estimates from Robert C. Aull, AIA, ACHA, one for each option. The first cost estimate letter states:

“This correspondence is written to document various design and construction budget information related to the planned MRI addition to the current design for the Freestanding Emergency Care Center for CaroMont Health in Mount Holly, NC. The overall project size is approximately 1,600 square feet of additional enclosed space. There is also construction associated with the design and exterior, lower level parking/service areas.

The Concept Design documentation has been developed in order to define the overall scope of the project and has been utilized to establish a projected estimate of construction cost. The design and cost projections are both program and site specific. The construction cost is projected to be \$485,100. This budget figure includes 5% construction contingency and escalation to the anticipated start of construction has also been included.

...”

The second certified cost estimate letter states:

“This correspondence is written to document various design and construction budget information related to the planned Freestanding MRI located adjacent to the Freestanding Emergency Care Center for CaroMont Health in Mount Holly, NC. The overall project size is approximately 2,800 square feet of new enclosed interior space and associated site development.

The Concept Design documentation has been developed in order to define the overall scope of the project and has been utilized to establish a projected estimate of construction cost. The design and cost projections are both program and site specific. The construction cost is projected to be \$694,975. This budget figure includes 5% construction contingency and escalation to the anticipated start of construction has also been included.

...”

In Section XI.4(f), page 138, the applicants project the following cost per square foot for each option, as illustrated in the tables below.

Expansion

	<i>Estimated Square Feet</i>	<i>Construction Cost Per SF</i>	<i>Total Cost per SF</i>
<i>Total</i>	<i>1,600</i>	<i>\$303.19</i>	<i>\$1,477.32</i>

New Building

	<i>Estimated Square Feet</i>	<i>Construction Cost Per SF</i>	<i>Total Cost per SF</i>
<i>Total</i>	<i>2,800</i>	<i>\$248.21</i>	<i>\$956.04</i>

In Section XI.7, pages 140, the applicants provide a list of several steps that will be taken to ensure the facility is energy efficient. On page 40, the applicants also state:

“CaroMont Health and GMH have designed the proposed project to be in compliance with all applicable federal, state, and local requirements for energy efficiency and consumption. The facility will be operated by computerized energy and building management systems designed for the most effective and efficient operations.”

The applicants propose two alternatives or options. For each option, the applicants adequately demonstrate that the cost, design, and means of construction represent the most reasonable alternative for that option and that neither option would unduly increase the costs and charges of providing MRI services. See Criterion (5) for discussion of costs and charges which is hereby incorporated by reference as if fully set forth herein. 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 – CaroMont and GMH
C – PIC-Gastonia

CaroMont and GMH- In Section VI.12 and VI.13, pages 109-110, the applicants provide the payor mix during Fiscal Year 2010 for the entire hospital and for MRI services, as illustrated in the table below:

Gaston Memorial Hospital 10/01/10 – 9/30/11 Payor Mix			
	Entire Facility	Outpatient MRI Imaging	Inpatient MRI Imaging
Self Pay/Indigent/Charity	4.7%	4.5%	8.9%
Medicare/Medicare Managed Care	57.3%	39.7%	58.7%
Medicaid	19.8%	11.7%	13.5%
Commercial Insurance	0.6%	0.8%	0.5%
Managed Care	15.3%	41.6%	16.8%
Other (Government)	2.3%	1.7%	1.7%
Total	100.0%	100.0%	100.0%

In Section VI.2, page 105, the applicants state:

“Low-income persons needing Imaging Services will have access to MRI Services at the MedPlex. CaroMont Health is committed to providing care for the under/uninsured and charity care patients.”

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY 2009, respectively. The data in the table was obtained on August 23, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2008 (Estimate by Cecil G. Sheps Center)
Gaston	20%	8.6%	19.0%
Statewide	17%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by CaroMont and GMH.

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

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

The applicants demonstrated that medically underserved populations currently have adequate access to Gaston Memorial Hospital and its MRI services. Therefore, the application is conforming to this criterion.

PIC-Gastonia- In Section VI.12, page 74, the applicant provides the following payor mix during FY 2010 for the entire imaging center, as illustrated in the table below:

PIC-Gastonia FY 2010 Payor Mix	
Payor	% of Total Procedures
Self Pay / Indigent / Charity	4.4%
Medicare / Medicare Managed Care	23.6%
Medicaid	5.7%
Commercial Insurance	46.0%
Managed Care	8.4%
Other (CHAMPUS, Auto liability, etc.)	11.9%
Total	100.0%

In Section VI.2, page 67, the applicant states *“The imaging services provided by PIC-Gastonia are readily available to all patient groups.”*

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and

estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY 2009, respectively. The data in the table was obtained on August 23, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2008 (Estimate by Cecil G. Sheps Center)
Gaston	20%	8.6%	19.0%
Statewide	17%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by PIC-Gastonia.

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

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

The applicant demonstrated that medically underserved populations currently have adequate access to PIC-Gastonia. Therefore, the application is conforming to this criterion.

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

C – PIC-Gastonia

CaroMont and GMH- Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 109, the applicants state:

“GMH fulfilled its Hill-Burton obligation and does not have any related obligation under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and the handicapped. As 501 (c)(3) tax-exempt entities, CaroMont Health and GMH are charities organized, among other things, to promote the health of their communities. Accordingly, they provide charity care. However, there are no federal regulations per se applicable to them that require the provision of uncompensated care. Nevertheless, CaroMont Health affiliated entities strive to provide services to all persons in need of health care services.”

In Section VI.2 and VI.3, pages 105-106, the applicants state:

“CaroMont Health’s obligations under its lease agreement with Gaston County and its nonprofit status guarantee non-discriminatory access to services. ...

Elderly persons needing imaging Services will have access to MRI Services at the MedPlex. CaroMont Health is committed to providing care to elderly patients.

Medically indigent persons needing Imaging Services will have access to MRI Services at the MedPlex.

The expanded MedPlex or the separate MRI building will be physically designed for use by handicapped persons and will meet all American with Disability Act provisions. Specifically, the facility will have handicapped operated doors, wide hallways, patient elevators, and Braille signage.”

In Section VI.10, page 108, the applicants state, *“No complaints have been filed against GMH in the last five years.”*

The application is conforming to this criterion.

PIC-Gastonia- Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 73, the applicant states:

“PIC-Gastonia has no current obligation or any prior obligation under any Federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. PIC-Gastonia does not and will not discriminate on the basis of race, creed, color, sex, age, religion, national origin, mental or physical handicap, or ability to pay.”

In Section VI.2, page 67, the applicant states:

“Novant, the ultimate parent company of PIC-Gastonia, has as its mission, ‘to improve the health of communities, one person at a time’. Novant is available to take care of each person’s physical and mental health needs, as well as their financial health related to the consumption of healthcare services provided at Novant facilities.”

In Section VI.10(a), page 73, the applicant states:

“There have been no civil rights equal access complaints filed against any facilities or services owned by MedQuest, or Novant Healthcare in North Carolina in the past five years.”

The application is conforming to this criterion.

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

C- CaroMont and GMH
 C –PIC-Gastonia

CaroMont and GMH- In Section VI.14(b) and VI.15(b), pages 111-112, the applicants provide the projected payor mix for the second full fiscal year (1/1/15-1/31/15) of operations for the entire hospital and MRI services, as illustrated in the table below.

Gaston Memorial Hospital Projected Payor Mix Second Full Fiscal Year As a % of Total Procedures			
	Entire Facility	MRI Outpatient	MRI Inpatient
Self Pay/Indigent/Charity	4.7%	4.5%	8.9%
Medicare/Medicare Managed Care	57.3%	39.7%	58.7%
Medicaid	19.8%	11.7%	13.5%
Commercial Insurance	0.6%	0.8%	0.5%
Managed Care	15.3%	41.6%	16.8%
Other (Government)	2.3%	1.7%	1.7%
Total	100.0%	100.0%	100.0%

As illustrated in the table above, the applicants do not project a change in the payor mix for MRI services.

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

PIC-Gastonia- In Section VI.14, page 75, and Section VI.15, page 75, the applicant provides the projected payor mix for the entire facility and the proposed fixed MRI scanner during the second operating year, as illustrated in the table below:

PIC-Gastonia Year Two Payor Mix	
Payor	% of Total Procedures
Self Pay / Indigent / Charity	4.5%
Medicare / Medicare Managed Care	22.7%
Medicaid	8.9%
Commercial Insurance	50.2%
Managed Care	9.3%
Other (CHAMPUS, Auto liability, etc.)	4.4%
Total	100.0%

In Section VI.15, page 75, the applicant states that its projected payor mix “*is based on historical payor mix for PIC-Gastonia.*” It does not say it is exactly the same, and indeed, there are some differences between the FY 2010 percentages and the Year Two percentages, as illustrated in the table below.

PIC-Gastonia Payor Mix		
Payor	% of Total Procedures	
	FY 2010	Year Two
Self Pay / Indigent / Charity	4.4%	4.5%
Medicare / Medicare Managed Care	23.6%	22.7%
Medicaid	5.7%	8.9%
Commercial Insurance	46.0%	50.2%
Managed Care	8.4%	9.3%
Other (CHAMPUS, Auto liability, etc.)	11.9%	4.4%
Total	100.0%	100.0%

The projected percentages for Self Pay / Indigent / Charity and Medicaid are higher in Year Two than what was reported for FY 2010. The projected percentage for Medicare is slightly lower. The differences are not material.

For certain payors, the projected payor mix reported in the tables in Section VI.14, page 75, and Section VI.15, page 75, differs from the percentages actually used to project gross and net revenues, as illustrated in the table below.

PIC-Gastonia Payor Mix		
Payor	% of Total Procedures	
	Pro Formas	Sections VI.14 and VI.15
Self Pay / Indigent / Charity	4.5%	4.5%

Medicare / Medicare Managed Care	22.7%	22.7%
Medicaid	8.9%	8.9%
Commercial Insurance	7.6%	50.2%
Managed Care	35.7%	9.3%
Other (CHAMPUS, Auto liability, etc.)	20.7%	4.4%
Total	100.0%	100.0%

As shown in the table above, the projected percentages for Self Pay / Indigent / Charity, Medicare / Medicare Managed Care and Medicaid are identical in Sections VI.14-15 and the Pro Formas. There is a substantial difference in the percentages for Commercial Insurance, Managed Care and Other. However, an examination of the Pro Formas shows that the projected average gross and net revenues for those three payors is the same, and thus, the total projected gross and net revenues for the entire facility would be the same regardless of the percentage for each of those three payors. Moreover, it appears that the percentages for each of those three payors may not be matched to the correct payor. For example, it appears that Other should be 7.6% while Commercial Insurance would more likely be 35.7% or possibly 20.7%.

The applicant demonstrates that medically underserved groups (Self Pay / Indigent / Charity, Medicare and Medicaid) will have adequate access to the proposed fixed MRI scanner. Therefore, the application is conforming to this criterion.

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

C – CaroMont and GMH
C – PIC-Gastonia

CaroMont and GMH- In Section VI.9(a), page, 108, the applicants state:

“Access to MRI Services is by physician’s order; however, patients have the ability to choose where they receive their MRI scan.”

The applicants adequately demonstrate they will provide a range of means by which patients will have access to the proposed services. Therefore, the application is conforming with this criterion.

PIC-Gastonia- In Section VI.9(a), page 72, the applicant states.

“A referral from a licensed physician is required to access the MRI services proposed in this application.”

The applicant adequately demonstrates it will provide a range of means by which patients will have access to the proposed services. Therefore, the application is conforming with 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 – CaroMont and GMH
C – PIC-Gastonia

CaroMont and GMH- In Section V.1(a)(b)(c), page 97, the applicants provide documentation that they will continue to accommodate the clinical needs of area health professional training programs. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

PIC-Gastonia- In Section V.1(a)(b)(c), page 61, the applicant provides documentation that PIC-Gastonia will accommodate the clinical needs of area health professional training programs. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

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

NC – CaroMont and GMH
C – PIC-Gastonia

CaroMont and GMH – The applicants own and operate the four existing fixed MRI scanners located in Gaston County. A related entity owns a mobile MRI scanner which operates at two sites in Gaston County, one in Gastonia and one in Belmont.

CaroMont and GMH propose to acquire a fixed MRI scanner to be located at the approved Mount Holly MedPlex, which will provide emergency services and other imaging services, including CT, x-ray and US. The Mount Holly MedPlex will be licensed as part of the hospital. There is no fixed MRI scanner in Mount Holly, but there is one in Belmont. The three other existing fixed MRI scanners are located in Gastonia, one in the hospital and two in imaging centers.

In Section V.7, pages 64-65, the applicants explain why they believe that their proposal to acquire a fixed MRI scanner and locate it at the approved Mount Holly MedPlex will enhance

competition by promoting cost effectiveness, quality and access to MRI services in Gaston County. See also Sections II, III, V.6, VI and VII of the application for additional discussion by the applicants about the impact of their proposal on cost effectiveness, quality and access to MRI services in Gaston County.

The applicants adequately demonstrate that their proposal would enhance competition by promoting quality and access to MRI services. However, the applicants do not adequately demonstrate that their proposal would enhance competition by promoting cost effectiveness for the following reasons:

- 1) A related entity owns a mobile MRI scanner, which operates at two sites in Gaston County, that performed only 1,970 weighted MRI procedures during FFY 2011. Thus, it operated at only 47.4% of capacity [$1,970 / (3,328 / 0.8) = 0.474$]. See Section II.8, page 48, and 10A NCAC 14C .2703(b)(2).
- 2) The applicants fail to discuss the option of utilizing the mobile MRI scanner to meet the need in Mount Holly rather than acquiring a fixed MRI scanner given that the mobile MRI scanner appears to have unused capacity. See Section III.3, pages 69-71.
- 3) Projected utilization of the fixed and mobile MRI scanners is not based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein.

Therefore, the applicants did not adequately demonstrate that their proposal is conforming to this criterion.

PIC-Gastonia – The applicant does not own and operate a fixed MRI scanner in Gaston County. A related entity does own a mobile MRI scanner which it began operating at PIC-Gastonia on March 5, 2012 (10 days before this application was submitted). Prior to March 5, 2012, mobile MRI services were provided at PIC-Gastonia by a different related entity. Those mobile MRI scanners no longer provide services at PIC-Gastonia. If this application is approved, PIC-Gastonia would no longer contract for mobile MRI services.

PIC-Gastonia proposes to acquire a fixed MRI scanner and locate it in its existing imaging center in Gastonia, which results in the development of a new diagnostic center as that term is defined in G.S. 131E-176(7a).

In Section V.7, pages 64-65, the applicant explains why it believes that its proposal to acquire a fixed MRI scanner and locate it in its existing imaging center in Gastonia will enhance competition by promoting cost effectiveness, quality and access to MRI services in Gaston County. See also Sections II, III, VI and VII of the application for additional discussion by the applicant about the impact of its proposal on cost effectiveness, quality and access to MRI services in Gaston County.

The applicant adequately demonstrates that its proposal would enhance competition by promoting cost effectiveness, quality and access to MRI services based on the following analysis:

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

Therefore, the applicant adequately demonstrates that its proposal is conforming to this criterion.

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

C – CaroMont and GMH
NA – PIC-Gastonia

CaroMont and GMH- According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, no incidents occurred within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

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

NC – CaroMont and GMH
C – PIC-Gastonia

The application submitted by CaroMont and GMH is not conforming with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700. The application submitted by PIC-Gastonia is conforming with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700. The specific criteria are discussed below.

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

10A NCAC 14C .2702 INFORMATION REQUIRED OF APPLICANT

(a) *An applicant proposing to acquire an MRI scanner, including a mobile MRI scanner, shall use the Acute Care Facility/Medical Equipment application form.*

-C- Both applicants used the Acute Care/Medical Equipment application form.

(b) *Except for proposals to acquire mobile MRI scanners that serve two or more host facilities, both the applicant and the person billing the patients for the MRI service shall be named as co-applicants in the application form.*

-C- **CaroMont and GMH-** In Section II.8, page 33, the applicants state, “*GMH is an applicant and the biller of MRI services.*”

-C- **PIC-Gastonia-** In Section II.8, page 23, the applicant states, “*Mecklenburg Diagnostic Imaging, LLC d/b/a PIC-Gastonia, the applicant, will bill patients for the technical portion of the MRI services. Mecklenburg Radiology Associates will bill patients separately for its professional services.*”

(c) *An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall provide the following information:*

(1) *documentation that the proposed fixed MRI scanner, excluding fixed extremity and breast MRI scanners, will be available and staffed for use at least 66 hours per week;*

-C- **CaroMont and GMH-** In Section II.8, page 33, the applicants state the proposed MRI scanner will be available and staffed 24 hours per day/ 7 days per week. The applicants further state the purposed scanner will be operational Monday through Friday from 9:00 a.m. to 5:00 p.m. for scheduled outpatient services.

-C- **PIC-Gastonia-** In Section II.8, page 23, that applicant states the proposed MRI scanner will be available and staffed at least 70 hours per week, Monday through Friday 8:00 a.m. to 8:00 p.m. and on Saturday from 8:00 a.m. to 6:00 p.m.

(2) *documentation that the proposed mobile MRI scanner will be available and staffed for use at least 40 hours per week;*

- NA- Neither of the applicants propose to acquire a mobile MRI scanner.
- (3) *documentation that the proposed fixed extremity or dedicated breast MRI scanner shall be available and staffed for use at least 40 hours per week;*
- NA- Neither of the applicants propose to acquire a fixed extremity or dedicated breast MRI scanner.
- (4) *the average charge to the patient, regardless of who bills the patient, for each of the 20 most frequent MRI procedures to be performed for each of the first three years of operation after completion of the project and a description of items included in the charge; if the professional fee is included in the charge, provide the dollar amount for the professional fee;*
- C- **CaroMont and GMH-** In Section II.8, page 34, the applicants state, “*GMH does not charge the patient professional fees, that charge is billed directly by the radiologist.*” Also in Section II.8, page 34, the applicants provide the projected charges for the 20 MRI procedures to be performed most frequently during each of the first three years of operation.
- C- **PIC-Gastonia-** In Section II.8, page 24, the applicant states, “*PIC-Gastonia will bill patients for the technical portion of the proposed MRI service MRA will bill patients separately for its professional services.*” Also in Section 11.8, page 24, the applicant provides the projected charges for the 20 MRI procedures to be performed most frequently during each of the first three years of operation.
- (5) *if the proposed MRI service will be provided pursuant to a service agreement, the dollar amount of the service contract fee billed by the applicant to the contracting party for each of the first three years of operation;*
- NA- Neither of the applicants propose to provide MRI services pursuant to a service agreement.
- (6) *letters from physicians indicating their intent to refer patients to the proposed magnetic resonance imaging scanner and their estimate of the number of patients proposed to be referred per year, which is based on the physicians' historical number of referrals;*
- C- **CaroMont and GMH-** Exhibit 25 contains letters from physicians indicating their intent to refer patients to the proposed fixed MRI scanner and their estimate of the number of patients proposed to be referred per year, which is based on the physicians’ historical number of referrals for MRI studies. In Section II.8, page 35, the applicants state, “*It should be noted that physicians refer patients for MRI scan, but the patient is free to receive their MRI scan at any provider in*

Gaston or in a surrounding county. ... As such the physician does not direct the patient as to which MRI scanner they should receive their MRI scan.”

- C- **PIC-Gastonia-** Attachment 24 contains letters from physicians indicating their intent to refer patients to the proposed fixed MRI scanner and their estimate of the number of patients proposed to be referred per year, which is based on the physicians’ historical number of referrals. Also see Section II.8, page 25, for further discussion on the physician referral letters.

(7) *for each location in the MRI service area at which the applicant or a related entity will provide MRI services, utilizing existing, approved, or proposed fixed MRI scanners, the number of fixed MRI scanners operated or to be operated at each location;*

- C- **CaroMont and GMH-** In Section II.8, page 35, the applicants state CaroMont and GMH currently operate four fixed MRI scanners in Gaston County, the proposed service area, as illustrated in the following table.

Location	
GMH	
The Diagnostic Center	
CaroMont Imaging Services - Summit	
CaroMont Imaging Services - Belmont	
Total	4

- C- **PIC-Gastonia-** In Section II.8, page 25, the applicant states neither Novant Health, Inc. nor a related entity operates any fixed MRI scanners in Gaston County, the proposed MRI service area.

(8) *for each location in the MRI service area at which the applicant or a related entity will provide MRI services, utilizing existing, approved, or proposed fixed MRI scanners, projections of the annual number of unweighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project;*

- C- **CaroMont and GMH-** In Section II.8, page 36, the applicants provide the projected number of unweighted MRI procedures to be performed for each of the four types of MRI procedures, for each facility, for the first three years of operation following completion of the proposed project, as illustrated in the tables below.

Unweighted MRI Projections

CY2014

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>GMH</i>	1,749	1,585	632	971	4,937
<i>DX</i>			1,264	1,942	3,206
<i>CIS-Belmont</i>			1,092	1,678	2,769
<i>CIS-Summit</i>			1,264	1,942	3,206
<i>MedPlex</i>			1,494	2,296	3,789
Total	1,749	1,585	5,746	8,829	17,909

CY2015

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>GMH</i>	1,856	1,682	671	1,031	5,239
<i>DX</i>			1,341	2,061	3,403
<i>CIS-Belmont</i>			1,158	1,780	2,939
<i>CIS-Summit</i>			1,341	2,061	3,403
<i>MedPlex</i>			1,585	2,436	4,021
Total	1,856	1,682	6,097	9,369	19,004

CY2016

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>GMH</i>	1,970	1,785	712	1,094	5,560
<i>DX</i>			1,423	2,157	3,611
<i>CIS-Belmont</i>			1,229	1,889	3,118
<i>CIS-Summit</i>			1,423	2,187	3,611
<i>MedPlex</i>			1,682	2,585	4,267
Total	1,970	1,785	6,470	9,942	20,166

The application is conforming to this rule. However, see Criterion (3) for discussion regarding the reasonableness of the applicants' projections.

- C- **PIC-Gastonia-** In Section II.8, page 25, the applicant states, “[T]he applicant has no related entities in the MRI service area, Gaston County, other than PIC-Gastonia.” The applicant provides the projected number of unweighted outpatient MRI procedures to be performed at PIC-Gastonia, for the first three years of operation following completion of the proposed project, as illustrated in the table below.

PIC-Gastonia: Years 1-3 (10/01/2014 through 09/30/2017)

<i>Year</i>	<i>Outpatient/No Contrast/ Sedation</i>	<i>Outpatient/With Contrast/ Sedation</i>	<i>Total Unweighted Volume</i>
<i>Year 1</i>	2,456	733	3,189
<i>Year 2</i>	3,077	919	3,996
<i>Year 3</i>	3,512	1,049	4,561

- (9) for each location in the MRI service area at which the applicant or a related entity will provide services, utilizing existing, approved, or

proposed fixed MRI scanners, projections of the annual number of weighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project;

- C- **CaroMont and GMH-** In Section II.8, page 37, the applicants provide the number of weighted procedures by type for the first three years of operation, following completion of the proposed project, as illustrated below.

*Weighted MRI Projections
CY2014*

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>GMH</i>	3,149	2,219	855	971	7,223
<i>DX</i>			1,770	1,942	3,712
<i>CIS-Belmont</i>			1,528	1,678	3,206
<i>CIS-Summit</i>			1,770	1,942	3,712
<i>MedPlex</i>			2,092	2,296	4,387
Total	3,149	2,219	8,044	8,829	22,241

CY2015

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>GMH</i>	3,341	2,354	939	1,031	7,665
<i>DX</i>			1,878	2,061	3,939
<i>CIS-Belmont</i>			1,662	1,780	3,402
<i>CIS-Summit</i>			1,878	2,061	3,939
<i>MedPlex</i>			2,219	2,436	4,655
Total	3,341	2,354	8,536	9,369	23,601

CY2016

	<i>IPw</i>	<i>IPwo</i>	<i>OPw</i>	<i>OPwo</i>	<i>Total</i>
<i>GMH</i>	3,564	2,498	996	1,094	8,134
<i>DX</i>			1,993	2,187	4,180
<i>CIS-Belmont</i>			1,721	1,889	3,610
<i>CIS-Summit</i>			1,993	2,187	4,180
<i>MedPlex</i>			2,355	2,585	4,940
Total	3,564	2,498	9,058	9,942	25,044

The application is conforming to this Rule. However, see Criterion (3) for discussion regarding the reasonableness of the applicant's projections.

- C- **PIC-Gastonia-** In Section II.8, page 25, the applicant provides the projected number of weighted outpatient MRI procedures to be performed at PIC-Gastonia, for the first three years of operation following completion of the proposed project, as illustrated in the table below.

PIC-Gastonia: Years 1-3 (10/01/2014 through 09/30/2017)

<i>Year</i>	<i>Outpatient/No Contrast/</i>	<i>Outpatient/With Contrast/</i>	<i>Total Weighted</i>

	<i>Sedation</i>	<i>Sedation</i>	<i>Volume</i>
<i>Year 1</i>	2,456	733	3,482
<i>Year 2</i>	3,077	919	4,364
<i>Year 3</i>	3,512	1049	4,981

(10) *a detailed description of the methodology and assumptions used to project the number of unweighted MRI procedures to be performed at each location, including the number of contrast versus non-contrast procedures, sedation versus non-sedation procedures, and inpatient versus outpatient procedures;*

- C- **CaroMont and GMH-** The applicants' methodology and assumptions used to project the number of unweighted MRI procedures, including the number of contrast versus non-contrast procedures are described in Section IV, pages 82-90.
- C- **PIC-Gastonia-** The applicant's methodology and assumptions used to project the number of unweighted MRI procedures are described in Section III.1 and Section IV, page 58.

(11) *a detailed description of the methodology and assumptions used to project the number of weighted MRI procedures to be performed at each location;*

- C- **CaroMont and GMH-** The applicant's methodology and assumptions used to project the number of weighted MRI procedures are described in Section IV, pages 82-90.
- C- **PIC-Gastonia-** The applicant's methodology and assumptions used to project the number of weighted MRI procedures are described in Section III.1 and Section IV, page 58.

(12) *for each existing, approved or proposed mobile MRI scanner owned by the applicant or a related entity and operated in North Carolina in the month the application is submitted, the vendor, tesla strength, serial number or vehicle identification number, CON project identification number, and host sites;*

- C- **CaroMont and GMH-** In Section II.8, page 39, the applicants provide the vendor, tesla strength, serial number, CON project number and host site for the mobile MRI scanner that is owned by CaroMont and operated at MRI Specialist in Belmont and Gastonia.
- C- **PIC-Gastonia-** In Section II.8, pages 26-27, the applicant provides the vendor, tesla strength, serial number, CON project number and host site for the mobile MRI scanners owned by the applicant's related entities, (such as MedQuest or Novant Health).

(13) *for each host site in the mobile MRI region in which the applicant or a related entity will provide the proposed mobile MRI services, utilizing existing, approved, or proposed mobile MRI scanners, projections of the annual number of unweighted and weighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project;*

-NA- **CaroMont and GMH-** Neither application propose the acquisition of a mobile MRI scanner.

-NA- **PIC-Gastonia-** The applicant or a related entity does not propose to provide mobile MRI services.

(14) *if proposing to acquire a mobile MRI scanner, an explanation of the basis for selection of the proposed host sites if the host sites are not located in MRI service areas that lack a fixed MRI scanner; and*

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

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

-C- **CaroMont and GMH-** The applicants identify the accreditation authority they propose to use in Section II.8, page 42 of the application.

-C- **PIC-Gastonia-** The applicant identifies the accreditation authority it proposes to use in Section II.8, page 28 of the application.

(d) *An applicant proposing to acquire a mobile MRI scanner shall provide copies of letters of intent from, and proposed contracts with, all of the proposed host facilities of the new MRI scanner.*

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

(e) *An applicant proposing to acquire a dedicated fixed breast MRI scanner shall demonstrate that:*

(1) *it has an existing and ongoing working relationship with a breast-imaging radiologist or radiology practice group that has experience interpreting breast images provided by mammography, ultrasound, and MRI scanner equipment, and that is trained to interpret images produced by a MRI scanner configured exclusively for mammographic studies;*

(2) *for the last 12 months it has performed the following services, without interruption in the provision of these services: breast MRI procedures on a fixed MRI scanner with a breast coil, mammograms, breast ultrasound*

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

-NA- Neither application proposes the acquisition of a dedicated fixed breast MRI scanner.

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

- (7) *provide documentation of the capacity of the proposed scanner based on the number of days to be operated each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of unweighted MRI procedures the scanner is capable of performing each hour;*
- (8) *identify the types of MRI procedures by CPT code that are appropriate to be performed on an extremity MRI scanner as opposed to a whole body MRI scanner;*
- (9) *provide copies of the operational and safety requirements set by the manufacturer; and*
- (10) *describe the criteria and methodology to be implemented for utilization review to ensure the medical necessity of the procedures performed.*

-NA- Neither application proposes the acquisition of an extremity MRI scanner.

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

- (6) *demonstrate that at least 50 percent of the patients to be served on the multi-position MRI scanner will be spine patients who are examined in an upright or nonstandard position; and*
- (7) *provide documentation of the capacity of the proposed fixed multi-position MRI scanner based on the number of days to be operated each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of unweighted MRI procedures the scanner is capable of performing each hour.*

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

10A NCAC 14C .2703 PERFORMANCE STANDARDS

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

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

- (b) *An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:*
 - (1) *demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;*

-C- **CaroMont and GMH-** In Section II.8, page 47, the applicants state that the 4 fixed MRIs operated by CaroMont Health performed 18,258 weighted MRI procedures in the most recent 12 month period for which the applicants have data, which is an average of 4,564 weighted MRI procedures per MRI scanner [18,258/4=4,564.5].

-NA- **PIC-Gastonia-** In Section II.8, page 32, the applicant states, “*Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center- Gastonia, or its ultimate parent company, Novant Health Inc, does not own a controlling interest in a fixed MRI scanner in Gaston County.*

(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.];*

-NC- **CaroMont and GMH-** In Section II.8, page 48, the applicants state that the mobile MRI scanner owned by a related entity and operated at two sites in Gaston County performed only 1,970 weighted MRI procedures from 10/1/2010 - 9/30/2011, which is substantially less than the 3,328 weighted MRI procedures required by this rule. See the table below:

MRI Specialists – Belmont

MRI Specialist - Gastonia

<i>MRI Procedures</i>	<i>Procedures</i>	<i>Weights</i>	<i>Weighted Procedures</i>
<i>IP/With Contrast/Sedation</i>		<i>1.8</i>	
<i>IP/No Contrast/Sedation</i>		<i>1.4</i>	
<i>OP/With Contrast/Sedation</i>	<i>786</i>	<i>1.4</i>	<i>1,100</i>
<i>OP/No Contrast</i>	<i>870</i>	<i>1.0</i>	<i>870</i>
<i>Total</i>	<i>1,656</i>		<i>1,970</i>

The application is nonconforming with this rule.

-NA- **PIC-Gastonia-** The only mobile MRI scanner owned by the applicant or a related entity which currently provides services in Gaston County did not begin operations until March 5, 2012 (10 days before this application was submitted). See Project I.D. # F-8237-08.

(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 2011 SMFP shows more than four (4) fixed MRI scanners located in the MRI service area of Gaston County. Therefore, each applicant must demonstrate that the average annual utilization for the existing, approved and proposed MRI scanners which the applicant or a related entity owns and locates in Gaston MRI County is reasonably expected to perform 4,805 weight MRI procedures per scanner in the third operating year.

-NC- **CaroMont and GMH-** The applicants would have a total of 5 existing, approved and proposed fixed MRI scanners located in Gaston County. In Section II.8, page 49, the applicants project to perform a total of 25,044 weighted MRI procedures in the third operating year (CY2016), which is an average utilization of 5,008 weighted procedures per scanner [25,044/5=5,008.8]. However, the applicants did not adequately demonstrate that projected utilization is based on reasonable, credible and supported assumptions. The discussion in Criterion (3) regarding projected utilization is incorporated hereby as if fully set forth herein. Therefore, the applicants do not adequately demonstrate that five fixed MRI scanners would perform an average of at least 4,805 weighted MRI procedures per scanner in the third operating year. The application is nonconforming with this Rule.

-C- **PIC-Gastonia-** In Section II.8, page 33, the applicant provides the number of weighted MRI procedures projected to be performed on the proposed fixed MRI scanner, as illustrated below.

	<i>Year 1 – 10/14-9/15</i>	<i>Year 2 – 10/15-9/16</i>	<i>Year 3 – 10/16 – 9/17</i>
<i>PIC-Gastonia Unweighted MRI Volume</i>	3,189	3,996	4,561
<i>Contrast %</i>	23%	23%	23%
<i>Contrast Scans</i>	733	919	1,049
<i>Adjustment</i>	293	368	420
<i>Weighted Volume</i>	3,482	4,364	4,981

The applicant projects it will perform 4,981 weighted MRI procedures in the third operating year. The applicant adequately demonstrates that projected

utilization is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein.

- (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;*

-NC- **CaroMont and GMH-** The proposed fixed MRI scanner would be located at a different site from the applicants' existing fixed MRI scanners. In Section II.8, page 50, the applicants project the proposed fixed MRI scanner at the Mount Holly MedPlex will perform 4,940 weighted MRI procedures in the third year operating year. However, projected utilization is not based on reasonable, credible and supported assumptions. See Criterion (3) for discussion of projected utilization which is incorporated hereby as if fully set forth herein. Therefore, the applicants did not adequately demonstrate that the proposed fixed MRI scanner would perform at least 4,805 weighted MRI procedures in the third operating year. The application is nonconforming with this Rule.

-NA- **PIC-Gastonia-** The applicant will only own and operate one fixed MRI scanner in Gaston County.

- (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*

-NC- **CaroMont and GMH-** In Section II.8, page 51, the applicants project that the mobile owned by a related entity and operated at two sites in Gaston County will

perform 3,516 weighted MRI procedures in the third operating year. However, projected utilization is not based on reasonable, credible or supported assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein. Therefore, the applicants did not adequately demonstrate the mobile MRI would perform at least 3,328 weighted MRI procedures during the third operating year. The application is nonconforming with this Rule.

-NA- **PIC-Gastonia-** In Section II.8, page 34, the applicant states, “*If awarded the certificate of need to acquire a fixed MRI scanner in Gaston County, PIC-Gastonia would no longer utilize mobile MRI services. Therefore, Novant’s mobile MRI scanner would continue to serve PIC-Monroe and be redeployed to another Novant facility within the mobile’s service area but outside of Gaston County, pending the appropriate regulatory approval from the Department of Health and Human Services and the installation of the proposed fixed MRI scanner.*”

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

-NC- **CaroMont and GMH-** The applicants’ assumptions and data used to support the methodology for each projection required by this Rule are described in Section IV, pages 82-96. However, the assumptions and data used to support the methodology for each projection are not credible or supported. See Criterion (3) for discussion regarding the applicants’ assumptions and data used to support the methodology for each projection which is incorporated hereby as if fully set forth herein. The application is nonconforming with this Rule.

-C- **PIC-Gastonia-** The applicant’s assumptions and data used to support the methodology used for each projection required by this Rule are described in Section III.1 and Section IV, page 58. The assumptions and data used to support the methodology for each projection are credible and supported. See Criterion (3) for discussion regarding the applicant’s assumptions and data used to support the methodology for each projection which is incorporated hereby as if fully set forth herein.

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

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

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

-NA- Neither application proposes the acquisition of a dedicated fixed breast MRI scanner.

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

- (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(f)(7); and*
- (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- Neither application proposes the acquisition of a fixed extremity MRI scanner.

(e) *An applicant proposing to acquire a fixed multi-position MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for a demonstration project shall:*

- (1) *demonstrate annual utilization of the proposed multi-position MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(g)(7); and*
- (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

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

10A NCAC 14C .2704 SUPPORT SERVICES

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

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

(b) *An applicant proposing to acquire a fixed or mobile MRI scanner shall obtain accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the American College of Radiology or a comparable accreditation authority, as determined by the Certificate of Need Section, for magnetic resonance imaging within two years following operation of the proposed MRI scanner.*

- C- **CaroMont and GMH-** In Section II.8, page 53, the applicants state, “*GMH is accredited through the Joint Commission.*”
- C- **PIC-Gastonia-** In Section II.8, page 36, the applicant states, “*PIC-Gastonia will obtain accreditation from the American College of Radiology (“ACR”) for the proposed MRI services.*”

10A NCAC 14C .2705 STAFFING AND STAFF TRAINING

- (a) *An applicant proposing to acquire an MRI scanner, including extremity and breast MRI scanners, shall demonstrate that one diagnostic radiologist certified by the American Board of Radiologists shall be available to interpret the images who has had:*
 - (1) *training in magnetic resonance imaging as an integral part of his or her residency training program; or*
 - (2) *six months of supervised MRI experience under the direction of a certified diagnostic radiologist; or*
 - (3) *at least six months of fellowship training, or its equivalent, in MRI; or*
 - (4) *a combination of MRI experience and fellowship training equivalent to Subparagraph (a)(1), (2) or (3) of this Rule.*
- C- **CaroMont and GMH-** See Exhibit 4 for a copy of Dr. Kevin Dul’s, curriculum vitae and Exhibit 8 for a letter from Dr. Stephen Losletter with Gaston Radiology expressing an intention to continue providing interpretive services.
- C- **PIC-Gastonia-** In Section II.8, the applicant states that radiology services will be provided by Mecklenburg Radiology Associates, PLLC (MRA) and that Dr. Jay Patti, a board-certified radiologist, will serve as the Medical Director for PIC-Gastonia. See Attachment 8 for a letter from Dr. Patti agreeing to serve as the Medical Director and a copy of his curriculum vitae.
 - (b) *An applicant proposing to acquire a dedicated breast MRI scanner shall provide documentation that:*
 - (1) *the radiologist is trained and has expertise in breast imaging, including mammography, breast ultrasound and breast MRI procedures; and*
 - (2) *two full time MRI technologists or two mammography technologists are available with training in breast MRI imaging and that one of these technologists shall be present during the hours operation of the dedicated breast MRI scanner.*
- NA- Neither application proposes the acquisition of a dedicated breast MRI scanner.
 - (c) *An applicant proposing to acquire a MRI scanner, including extremity but excluding dedicated breast MRI scanners, shall provide evidence of the availability of two full-time MRI technologist-radiographers and that one of these technologists shall be present during the hours of operation of the MRI scanner.*

- C- **CaroMont and GMH-** In Section VII.1, page 115, the applicants indicate that it will employ two FTE MRI technologist positions for the proposed fixed MRI scanner at the Mount Holly MedPlex.
- C- **PIC-Gastonia-** In Section VII.1, page 79, the applicant states the facility will employ 2.5 FTE MRI technologist positions dedicated to the operation of the proposed fixed MRI and a total of 3.8 FTE technologist positions for the entire facility. The applicant states that at least one MRI technologist will be on duty at the facility during all hours of operations.
- (d) *An applicant proposing to acquire an MRI scanner, including extremity and breast MRI scanners, shall demonstrate that the following staff training is provided:*
 - (1) *American Red Cross or American Heart Association certification in cardiopulmonary resuscitation (CPR) and basic cardiac life support; and*
 - C- **CaroMont and GMH-** See Exhibit 9 for the 2012 BCLS and ACLS training schedule and for additional training including cardiopulmonary resuscitation (CPR) training.
 - C- **PIC-Gastonia-** In Section II.8, page 37, the applicant states that its entire clinical staff maintain certifications in cardiopulmonary resuscitation (CPR) training. See Attachment 9 for documentation on staff training and education programs.
 - (2) *the availability of an organized program of staff education and training which is integral to the services program and ensures improvement in technique and the proper training of new personnel.*
 - C- **CaroMont and GMH-** See Exhibit 9 for documentation that GMH has an organized staff education program.
 - C- **PIC-Gastonia-** See Attachment 9 for documentation that PIC-Gastonia has an organized staff education program. See also Section II.8, page 37.
- (e) *An applicant proposing to acquire a mobile MRI scanner shall document that the requirements in Paragraph (a) of this Rule shall be met at each host facility, and that one full time MRI technologist-radiographer shall be present at each host facility during all hours of operation of the proposed mobile MRI scanner.*
- NA- Neither application proposes the acquisition of a mobile MRI scanner.
- (f) *An applicant proposing to acquire an extremity MRI scanner, pursuant to a need determination in the State Medical Facilities Plan for a demonstration project, also shall provide:*

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

-NA- Neither application proposes the acquisition of an extremity MRI scanner.

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

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

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2011 State Medical Facilities Plan, no more than one additional fixed MRI scanner may be approved in this review for Gaston County. Because the two applications in this review collectively propose to acquire two additional fixed MRI scanners, only one of the applications can be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the analyst conducted a comparative analysis of the proposals to decide which proposal should be approved. For the reasons set forth below and in the rest of the findings, the application submitted by Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center – Gastonia, Project I.D. #J-F-8793-12, is approved and the other application is denied.

Geographic Distribution

The 2011 SMFP identifies the need for one fixed MRI scanner in Gaston County. The following table identifies the location of the existing and approved fixed MRI scanners in Gaston County.

Facility	City/Town	# of Existing and Approved Fixed MRI Units
Gaston Memorial Hospital	Gastonia	1
GMH/CaroMont Imaging Services	Gastonia	1
GMH/CaroMont Imaging Services	Belmont	1
GMH – The Diagnostic Center	Gastonia	1
Total		4

As shown in the table above, there are 4 existing and approved fixed MRI scanners located in Gaston County. Three are located in Gastonia and one is located in Belmont. There are no fixed MRI scanners located in other Gaston County cities including Bessemer City, Cherryville, Cramerton, Dallas, Dellview, High Shoals, Lowell, McAdenville, Mount Holly, Ranlo, Spencer Mountain or Stanley.

PIC-Gastonia proposes to locate an additional fixed MRI scanner in Gastonia and CaroMount and GMH propose to locate a fixed MRI scanner at the approved MedPlex in Mount Holly. Thus, with respect to geographic distribution, the proposal submitted by CaroMont and GMH is the more effective alternative. Since there are no fixed MRI scanners in Mount Holly, but there are three already in Gastonia.

Demonstration of Need

PIC-Gastonia adequately demonstrated that projected utilization of the proposed fixed MRI scanner is based on reasonable, credible and supported assumptions. Therefore, PIC-Gastonia adequately demonstrated the need the population it projects to serve has for the proposed fixed MRI scanner. See Criterion (3) for discussion. However, CaroMont and GMH did not adequately demonstrate that projected utilization of its existing and proposed fixed MRI scanners is based on reasonable, credible and supported assumptions. Moreover, a related entity to CaroMont and GMH owns and operates an underutilized mobile MRI scanner which operates at two sites in Gaston County. Therefore, CaroMont and GMH did not adequately demonstrate the need the population they project to serve has for the proposed fixed MRI scanner. See Criterion (3) for discussion. Therefore, the proposal submitted by PIC-Gastonia is the more effective alternative with regard to demonstration of need.

Access by Underserved Groups

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

Application	Percentage of Total Procedures to be Provided to Medicaid Recipients	Percentage of Total Procedures to be Provided to Medicare Recipients
PIC-Gastonia	8.9%	22.7%
CaroMont and GMH	11.7%	39.7%

As shown in the table above, CaroMont / GMH propose to serve the highest percentage of both Medicaid and Medicare recipients. Therefore, the proposal submitted by CaroMont / GMH is the more effective alternative with regard to access by Medicaid and Medicare recipients.

Revenues

The third full fiscal year of operation (Project Year 3) for PIC-Gastonia is October 1, 2016 to September 30, 2017. Project Year 3 for CaroMont / GMH is January 1, 2016 to December 31, 2016.

Neither PIC-Gastonia nor CaroMont / GMH include professional fees (i.e. charges for interpretation of the images by a radiologist) in their respective charges. Both PIC-Gastonia and CaroMont / GMH deduct bad debt from gross revenue.

The average gross revenue per procedure for Project Year 3 was calculated by dividing total gross revenue by total unweighted MRI procedures. See the following table.

**Project Year 3
Average Gross Revenue per Unweighted MRI procedure**

Application	Total Gross Revenue	# of Unweighted MRI Procedures	Average Gross Revenue per Procedure
PIC-Gastonia	\$6,941,148	4,561	\$1,522
CaroMont & GMH	\$61,156,168	20,166	\$3,033

As shown in the table above, PIC-Gastonia projects the lowest average gross revenue per unweighted MRI procedure.

The average net revenue per procedure for Project Year 3 was calculated by dividing total net revenue by total unweighted MRI procedures. See the following table.

**Project Year 3
Average Net Revenue per Unweighted MRI Procedure**

Application	Net Revenue	# of Unweighted MRI Procedures	Average Net Revenue Per Procedure
PIC-Gastonia	\$3,253,715	4,561	\$713
CaroMont & GMH	\$13,146,737	20,166	\$652

As shown in the table above, CaroMont / GMH projects the lowest average net revenue per unweighted MRI procedure.

The average gross revenue per procedure and average net revenue per procedure for the CaroMont / GMH application are both questionable because projected utilization is not based on reasonable, credible and supported assumptions. See Criterion (3) for discussion.

On the other hand, the average gross revenue per procedure and average net revenue per procedure for the PIC-Gastonia application are not questionable because the projected utilization is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion.

Therefore, with regard to projected revenues, the proposal submitted by PIC-Gastonia is the most effective alternative.

Operating Costs

Neither PIC-Gastonia nor CaroMont / GMH include professional fees (i.e. charges for interpretation of the images by a radiologist) in their respective charges. Both PIC-Gastonia and CaroMont / GMH deduct bad debt from gross revenue.

The average operating cost per procedure for Project Year 3 was calculated by dividing total operating expenses by total unweighted MRI procedures.

**Project Year 3
 Average Operating Cost per Unweighted Procedure**

Application	# of Unweighted MRI Procedures	Total Operating Costs	Average Cost Per Procedure (less Professional Fee Component per procedure)
PIC-Gastonia	4,561	\$1,626,256	\$357
CaroMont & GMH	20,166	\$4,578,445	\$227

As shown in the table above, CaroMont / GMH projects the lowest average operating cost per unweighted MRI procedure.

However, CaroMont / GMH’s projected operating cost per unweighted procedure is questionable because projected utilization is not based on reasonable, credible and supported assumptions. See Criterion (3) for discussion.

On the other hand, PIC-Gastonia’s projected operating cost per unweighted MRI procedure is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion.

Therefore, with regard to projected operating costs, the proposal submitted by PIC-Gastonia is the most effective alternative.

SUMMARY

The following is a summary of the reasons the application submitted by **PIC-Gastonia** is determined to be the most effective alternative in this review:

PIC-Gastonia

- adequately demonstrates the need the population to be served has for the proposed fixed MRI scanner. See Criterion (3) and Comparative Analysis for discussion.
- adequately demonstrates projected revenues and costs for proposed MRI services are based on projected utilization which is based on reasonable, credible and supported assumptions. See Comparative Analysis.

The following is a summary of the reasons the application submitted by CaroMont and GMH is found to be a less effective alternative than the application submitted by PIC-Gastonia.

CaroMont and GMH

- did not adequately demonstrate the need the population to be served has for the proposed fixed MRI scanner. See Criterion (3) and Comparative Analysis for discussion.
- projected revenues and costs for the proposed MRI services are questionable because they are based on projected utilization which is questionable because it is not based on reasonable, credible and supported assumptions. See Comparative Analysis.

CONCLUSION

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 CON Section. The CON Section determined that the application submitted by Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center – Gastonia is the most effective alternative proposed in this review for one additional fixed MRI scanner for Gaston County and is approved. The approval of any other application would result in the approval of MRI scanners in excess of the need determination in the 2011 SMFP and therefore, the application submitted by CaroMont Health, Inc., and Gaston Memorial Hospital is denied.

The application submitted by Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center – Gastonia is approved subject to the following conditions.

- 1. Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center – Gastonia shall materially comply with all representations made in its certificate of need application.**
- 2. Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center – Gastonia shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**
- 3. Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center – Gastonia shall acquire no more than one fixed MRI scanner for a total of no more than one fixed MRI scanners.**
- 4. Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center – Gastonia obtain accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the American College of Radiology or a comparable accreditation authority,**

as determined by the Certificate of Need Section, for magnetic resonance imaging within two years following operation of the proposed MRI scanner.

- 5. Upon completion of the proposed project, Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center – Gastonia shall redeploy the mobile MRI to a site outside of the Gaston County MRI service area.**
- 6. Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center – Gastonia shall not exceed the representation made in the application for MRI charges for the facility related component in any of the first three operating years of the project.**
- 7. Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center – Gastonia 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.**