



**Atrium Health**

**Comments on  
NHI Matthews, LLC's and Novant Health, Inc.'s  
Fixed MRI Scanner Certificate of Need Application,  
Project ID # F-12113-21**

**October 1, 2021**

## Competitive Comments on Mecklenburg County MRI Applications

*submitted by*

### **The Charlotte-Mecklenburg Hospital Authority**

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), The Charlotte-Mecklenburg Hospital Authority (CMHA) submits the following comments related to the application filed by NHI Matthews, LLC<sup>1</sup> and Novant Health, Inc. (collectively referred to herein as Novant Health) to acquire a fixed MRI scanner in Mecklenburg County to be located at a new health service facility, Novant Health Imaging Matthews (NHI Matthews), which will be an independent diagnostic treatment facility (IDTF) and a diagnostic center. CMHA's comments include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards.*" See N.C. GEN. STAT. § 131E-185(a1)(1)(c).<sup>2</sup> In order to facilitate the Agency's ease in reviewing these comments, CMHA has organized its discussion by issue, specifically noting the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity relative to each issue, as they relate to Novant Health's NHI Matthews application, Project ID # F-12113-21. The following comments include general comments on this review, as well as specific comments on Novant Health's application and a comparative analysis including CMHA's application to acquire a fixed MRI scanner to be located at Carolinas Medical Center (CMC), Project ID # F-12117-21. Based on the following comments, Novant Health's NHI Matthews application should be denied.

#### **GENERAL COMMENTS**

The *2021 State Medical Facilities (2021 SMFP)* identifies a need for an additional fixed MRI scanner in Mecklenburg County, and CMHA demonstrates the greatest need for additional capacity. As shown below in a table excerpted from page 42 of CMHA's application, CMHA's fixed MRI scanners in Federal Fiscal Year (FFY) 2020 performed more than 3,900 adjusted MRI scans above Mecklenburg County's threshold of 4,805 scans per fixed unit. By comparison, Novant Health currently operates with excess capacity of fixed MRI scanners.

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<sup>1</sup> NHI Matthews, LLC has one member, Foundation Health Systems Corp., which is a wholly owned subsidiary of Novant Health.

<sup>2</sup> CMHA is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to its application filed on August 16, 2021 (Project ID # F-12117-21).

**FFY 2020 Fixed MRI Scans and Capacity by Provider**

	<i>Weighted Fixed MRI Scans</i>	<i>Existing and Approved Fixed Units</i>	<i>Total Weighted Scans in Excess of 4,805 per Unit*</i>
CMHA	47,198	9**	3,953
CIS	13,182	3	-1,233
Novant Health	49,710	11***	-3,145
OrthoCarolina	14,204	2	4,594
CNSA	4,028	1	-777

Source: *Proposed 2022 SMFP*.

\*Weighted MRI Scans - (Fixed Units x 4,805 Planning Threshold); negative indicates a surplus of capacity.

\*\*Conservatively includes the fixed MRI scanner at Atrium Health Kenilworth, which was approved, but not yet operational during FFY 2020 and therefore had no reported volume in FFY 2020. Exclusion of the Kenilworth MRI, for which there was no volume, would result in CMHA’s eight operational scanners operating at 8,758 weighted scans in excess of 4,805 per unit.

\*\*\*Does not include the fixed MRI scanner at Novant Health Imaging SouthPark, which was not awarded until February 11, 2021. Inclusion of the Novant Health Imaging SouthPark MRI, for which there was no volume, would result in Novant Health’s 12 existing and approved scanners operating at 7,950 weighted scans below 4,805 per unit.

In addition, given the higher population per MRI scanner in Charlotte as opposed to Matthews (detailed in the Comparative Analysis below), the Charlotte location proposed by CMHA – as opposed to the Matthews location proposed by Novant Health – is the most effective alternative for the development of an additional fixed MRI scanner to be located in Mecklenburg County.

Further, as noted in CMHA’s application (see Section C.4 and Form C Assumptions and Methodology), CMHA believes that adding fixed MRI capacity at CMC is the most effective alternative for the development of an additional fixed MRI scanner to be located in Mecklenburg County based on the following factors:

- CMHA has historically performed the highest volume of adjusted MRI scans among the county’s providers;
- Of the applicants, CMHA has the highest number of adjusted MRI scans in excess of the planning threshold indicating the greatest need for additional capacity;
- CMHA provides the broadest geographic access to patients seeking MRI scans in Mecklenburg County; and,
- CMHA has the highest complexity mix among all MRI providers in Mecklenburg County.

## APPLICATION-SPECIFIC COMMENTS

The Novant Health application to acquire a fixed MRI scanner to be developed at a new health service facility, NHI Matthews, which will be an IDTF and diagnostic center, should not be approved as proposed. CMHA identified the following specific issues, each of which contributes to NHI Matthews' non-conformity:

- (1) Failure to conform with performance standards**
- (2) Failure to provide reasonable utilization projections**
- (3) Failure to demonstrate financial feasibility**

Each of the issues listed above is discussed in turn below. Please note that relative to each issue, CMHA has identified the statutory review criteria and specific regulatory criteria and standards creating the non-conformity.

### Failure to Conform with Performance Standards

#### *Inconsistent Information Provided*

As discussed below, the NHI Matthews application fails to meet the performance standards for historical and projected utilization of mobile MRI scanners.

The historical standard, 10A NCAC 14C .2703(b)(2), states that an applicant proposing to acquire a fixed MRI scanner shall:

*demonstrate that each existing mobile MRI scanner<sup>3</sup> 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 to be performed on all of the applicant's mobile MRI scanners.]*

The projected standard, 10A NCAC 14C .2703(b)(5), states that an applicant proposing to acquire a fixed MRI scanner shall:

*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.]*

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<sup>3</sup> "Existing MRI scanner" means "an MRI scanner in operation prior to the beginning of the review period." See 10A NCAC 14C .2701(5).

Novant Health's responses to the historical and projected performance standards (found on pages 56 and 58 of its application, respectively) are identical. In its responses, Novant Health states:

**RESPONSE:** At the time of this CON application submission, neither of the applicants is operating a mobile MRI scanner in the proposed MRI service Area, Mecklenburg County, in which the applicants or a related entity owns a controlling interest.

Novant Health's responses to the historical and projected performance standards simply state that there are no mobile MRI scanners owned or operated by Novant Health or a related entity in the MRI service area. While some of Novant Health's mobile MRI scanners may have been removed from Mecklenburg County host sites on the day prior to submitting its NHI Matthews application (as documented by its Material Compliance Requests included in Exhibit C.1), as discussed in more detail to follow, it is questionable that Novant Health has removed all of its mobile MRI scanners from the service area (specifically those owned by Kings Medical Group, which appear to service NHI Steele Creek and NHI University in Mecklenburg County) or that it intends to keep its mobile MRI scanners out of the service area. As such, Novant Health's responses to the performance standards are seemingly inconsistent with responses provided in Section A and Form O Facilities of its application as discussed further below and call into question whether or not Novant Health will operate mobile MRI scanners in the service area after the date of submission of its application. Given information provided by Novant Health in Section A and Form O Facilities – namely, where Novant Health identifies mobile MRI scanners owned by Novant Health in Mecklenburg County – it appears that Novant Health fails to properly account for the mobile MRI scanners owned by Novant Health or a related entity in response to the historical and projected performance standards.

As shown in Section A and Form O Facilities on pages 22 and 141 of the NHI Matthews application (each of which is excerpted below), Novant Health is operating mobile MRI scanners at two sites in the service area – NHI University and NHI Steele Creek – and as discussed in more detail below, the Kings Medical Group mobile MRI scanners that service those sites appear to be owned by the applicants and Novant Health is the ultimate parent entity. Notably, Novant Health provides no rationale or basis for its exclusion of NHI University and NHI Steele Creek in its responses to the historical and projected performance standards. Clarity regarding the seemingly conflicting information provided by Novant Health in its responses to the performance standards and Section A and Form O Facilities is vital to the Agency's review of the application under the historical and projected performance standards, which require applicants to:

- 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; and
- demonstrate that the annual utilization of each existing, approved, and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and is located 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 and (ii) .

However, as noted above, rather than provide clarity, Novant Health simply states that there are no mobile MRI scanners owned or operated by Novant Health or a related entity in the MRI service area.

As shown in Section A on page 22 of the NHI Matthews application, excerpted below with purple highlights added, contrary to its responses to the performance standards, Novant Health is operating mobile MRI scanners at two sites in the service area – NHI University and NHI Steele Creek.

**Novant Health  
North Carolina MRI IDTF and HOPD Providers**

	County	Name of Facility	Type of Health Service Facility	MRI Service
1	Mecklenburg	NHI Ballantyne	IDTF	Fixed MRI
2	Mecklenburg	NHI Museum	HOPD	Fixed MRI
3	Mecklenburg	NHI Southpark	IDTF	Fixed MRI
4	Mecklenburg	NHI Steele Creek	IDTF	Mobile Service
5	Mecklenburg	NHI University	HOPD	Mobile Service
6	Mecklenburg	Novant Health Breast Center Charlotte	IDTF	
7	Buncombe	NCDI Open MRI & Imaging of Asheville	IDTF	Fixed MRI
8	Cabarrus	NHI Cabarrus	IDTF	Fixed MRI
9	Cumberland	NCDI Carolina Imaging	IDTF	Fixed MRI
10	Durham	NCDI Durham Diagnostic Imaging (Independence)	IDTF	Fixed MRI
11	Durham	NCDI Durham Diagnostic Imaging (South Point)	IDTF	Mobile Service
12	Forsyth	NHI Kernersville	HOPD	Fixed MRI
13	Forsyth	NHI Maplewood	HOPD	Fixed MRI
14	Forsyth	NHI Piedmont	IDTF	Fixed MRI
15	Forsyth	Novant Health Breast Center Winston Salem	HOPD	
16	Gaston	NHI Gastonia	IDTF	Fixed MRI
17	Guilford	NHI Triad	IDTF	Fixed MRI
18	Iredell	NHI Mooresville	IDTF	Mobile Service
19	New Hanover	Novant Health New Hanover Regional Medical Center - Medical Mall	HOPD	Fixed MRI
20	New Hanover	Novant Health New Hanover Regional Medical Center - Orthopedic Hospital	HOPD	Fixed MRI
21	Onslow	NCDI Coastal Diagnostic Imaging	IDTF	Fixed MRI
22	Orange	Chapel Hill Diagnostic Imaging	Diagnostic Center	Fixed MRI
23	Rowan	NHI Julian Road	HOPD	Fixed MRI
24	Union	NHI Monroe	HOPD	Mobile Service

The information provided in Section A on page 22 of the NHI Matthews application (excerpted above) is consistent with information provided in response to Form O Facilities in the NHI Matthews application. As shown in Form O Facilities on page 141 of the NHI Matthews application, excerpted below with purple highlights added, contrary to its responses to the performance standards, Novant Health is operating two mobile MRI scanners in the service area – NHI University and NHI Steele Creek. Moreover, Novant Health indicates in Form O Facilities on page 141 of its application that both NHI University and NHI Steele Creek are owned by the applicants, not a third-party mobile vendor, and that Novant Health is the ultimate parent entity.

**Form O Facilities**

	County	Name of Facility	Type of Health Service Facility	MRI Scanners	Owned by the Applicant(s)?	Provide the Name of the Related Entity if Not Owned by the Applicant
1	Brunswick	Novant Health Brunswick Medical Center	Hospital	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
2	Buncombe	NCDI Open MRI & Imaging of Asheville	IDTF	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
3	Cabarrus	NHI Cabarrus	IDTF	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
4	Cumberland	NCDI Carolina Imaging	IDTF	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
5	Davidson	Novant Health Thomasville Medical Center	Hospital	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
6	Durham	NCDI Durham Diagnostic Imaging (Independence)	IDTF	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
7	Durham	NCDI Durham Diagnostic Imaging (South Point)	IDTF	Mobile Service	Yes	Novant Health, Inc. - Ultimate Parent Company
8	Forsyth	NHI Kernersville	HOPD	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
9	Forsyth	NHI Maplewood	HOPD	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
10	Forsyth	Novant Health Breast Center Winston Salem	HOPD		Yes	Novant Health, Inc. - Ultimate Parent Company
11	Forsyth	Novant Health Clemmons Medical Center	Hospital	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
12	Forsyth	Novant Health Forsyth Medical Center	Hospital	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
13	Forsyth	Novant Health Kernesville Medical Center	Hospital	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
14	Forsyth	NHI Piedmont	IDTF	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
15	Gaston	NHI Gastonia	IDTF	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
16	Guilford	NHI Triad	IDTF	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
17	Iredell	NHI Mooresville	IDTF	Mobile Service	Yes	Novant Health, Inc. - Ultimate Parent Company
18	Mecklenburg	NHI Museum	HOPD	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
19	Mecklenburg	NHI University	HOPD	Mobile Service	Yes	Novant Health, Inc. - Ultimate Parent Company
20	Mecklenburg	Novant Health Huntersville Medical Center	Hospital	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
21	Mecklenburg	Novant Health Matthews Medical Center	Hospital	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
22	Mecklenburg	Novant Health Mint Hill Medical Center	Hospital	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
23	Mecklenburg	Novant Health Presbyterian Medical Center - Charlotte Orthopedic Hospital	Hospital	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
24	Mecklenburg	Novant Health Presbyterian Medical Center - Main	Hospital	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
25	Mecklenburg	NHI Ballantyne	IDTF	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
26	Mecklenburg	NHI Southpark	IDTF	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
27	Mecklenburg	NHI Steele Creek	IDTF	Mobile Service	Yes	Novant Health, Inc. - Ultimate Parent Company
28	Mecklenburg	Novant Health Breast Center Charlotte	IDTF		Yes	Novant Health, Inc. - Ultimate Parent Company
29	New Hanover	Novant Health New Hanover Regional Medical Center - Medical Mall	HOPD	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
30	New Hanover	Novant Health New Hanover Regional Medical Center - Orthopedic Hospital	HOPD	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
31	New Hanover	Novant Health New Hanover Regional Medical Center	Hospital	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
32	Onslow	NCDI Coastal Diagnostic Imaging	IDTF	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
33	Orange	Chapel Hill Diagnostic Imaging	Diagnostic Center	Fixed MRI*	Yes	Novant Health, Inc. - Ultimate Parent Company
34	Rowan	NHI Julian Road	HOPD	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
35	Rowan	Novant Health Rowan Medical Center	Hospital	Fixed MRI	Yes	Novant Health, Inc. - Ultimate Parent Company
36	Union	NHI Monroe	HOPD	Mobile Service	Yes	Novant Health, Inc. - Ultimate Parent Company

\* Novant Health owns the fixed MRI scanner but does not operate or manage Chapel Hill Diagnostic Imaging.

As noted above, Novant Health provides no rationale or basis for its exclusion of its mobile units serving NHI University and NHI Steele Creek in its responses to the performance standards. Absent any explanation, Novant Health’s responses to the performance standards are seemingly inconsistent with responses provided by Novant Health in Section A and Form O Facilities of its application.

*Failure to Address Mobile MRI Scanners in Mecklenburg County as Identified in the SMFP*

Novant Health’s responses to the performance standards are not only seemingly inconsistent with responses provided by Novant Health in Section A and Form O Facilities of its application, but also data provided in the *2021 SMFP* and the *Proposed 2022 SMFP*. According to the *2021 SMFP*, as well as the *Proposed 2022 SMFP* (each of which will be discussed in turn below), these service sites – NHI University and NHI Steele Creek – appear to be served by multiple mobile MRI scanners.

As illustrated on page 357 of the *2021 SMFP*, excerpted below with purple highlights added, NHI University appears to have been served by two grandfathered mobile MRI scanners owned by Kings Medical Group<sup>4</sup>, which as explained in more detail later in this document, Novant Health previously has indicated is a related entity. NHI Steele Creek appears to be served by two mobile MRI scanners – one grandfathered

<sup>4</sup> These mobile MRI scanners are identified as MQ9 and MQ25, respectively. The MQ designation seems to suggest that these scanners may be MedQuest MRI scanners. Moreover, information provided in the Registration and Inventory of Medical Equipment forms for the Kings Medical Group mobile MRI scanners was compiled and prepared by MedQuest personnel. Of note, Novant Health is MedQuest’s ultimate parent entity.

mobile MRI owned by Kings Medical Group and one mobile MRI owned by Jacksonville Diagnostic Imaging, LLC,<sup>5</sup> an affiliate and related entity of Novant Health. Novant Health included in Exhibit C.1 of the NHI Matthews application documentation that the Jacksonville Diagnostic Imaging, LLC mobile scanner would no longer service NHI Steele Creek as of August 14, 2021 but included no such documentation for the Kings Medical Group scanners that service NHI University and NHI Steele Creek. Moreover, regardless of whether the volumes are looked at separately or consolidated by service site or mobile MRI unit, each of these scanners performed less than 3,328 weighted MRI procedures historically, and as such, each is non-conforming with the historical performance standards found at 10A NCAC 14C .2703(b)(2).

**Table 17E-1: MRI Fixed and Mobile Procedures by MRI Service Area with Tiered Thresholds and Fixed Equivalents**

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
Service Area	Service Type	CON #	Service Site (Provider/Owner)	Fixed Magnet	Fixed Equiv	Total MRI Scans	Outprt No Contrast	Outprt Contrast	Inprt No Contrast	Inprt Contrast	Adjusted Total	Area Avg Procs	Threshold	MRI Need
Mecklenburg	Mobile	F-6734-03	Charlotte (Carolina Neurology & Spine Associates)	0	1.00	4,900	3,789	1,111	0	0	5,344			
Mecklenburg	Mobile	Grandfathered	Charlotte Eye, Ear, Nose & Throat (Alliance HealthCare Services)	0	0.17	805	82	723	0	0	1,094			
Mecklenburg	Mobile	Grandfathered	Novant Health Ballantyne (Kings Medical Group)	0	0.00	19	19	0	0	0	19			
Mecklenburg	Mobile	Grandfathered	Novant Health Huntersville Medical Center (Kings Medical Group)	0	0.24	1,138	740	398	0	0	1,297			
Mecklenburg	Mobile	Grandfathered	Novant Health Huntersville Medical Center (Kings Medical Group)	0	0.03	162	101	61	0	0	186			
Mecklenburg	Mobile	F-6626-02	Novant Health Imaging - Steele Creek (Jacksonville Diagnostic Imaging, LLC)	0	0.12	598	394	204	0	0	680			
Mecklenburg	Mobile	Grandfathered	Novant Health Imaging Steele Creek (Kings Medical Group)	0	0.10	470	375	95	0	0	508			
Mecklenburg	Mobile	Grandfathered	Novant Health Imaging University (Kings Medical Group)	0	0.18	877	589	288	0	0	992			
Mecklenburg	Mobile	Grandfathered	Novant Health Imaging University (Kings Medical Group)	0	0.05	242	166	76	0	0	272			
Mecklenburg	Mobile	Grandfathered	Novant Health Matthew Medical Center (Kings Medical Group)	0	0.12	566	340	226	0	0	656			

As illustrated on page 356 of the *Proposed 2022 SMFP*, excerpted below with purple highlights added, NHI University appears now to be served by four mobile MRI scanners – two grandfathered mobile MRIs owned by Kings Medical Group<sup>6</sup>, which Novant Health previously has indicated is a related entity, one mobile MRI owned by Jacksonville Diagnostic Imaging, LLC,<sup>7</sup> an affiliate and related entity of Novant Health, and one mobile MRI owned by Presbyterian Mobile Imaging, LLC,<sup>8</sup> an affiliate and related entity of Novant Health, while NHI Steele Creek appears to be served by two grandfathered mobile MRIs owned by Kings Medical Group.<sup>9</sup> Exhibit C.1 of the NHI Matthews application included documentation that the Jacksonville Diagnostic Imaging, LLC and Presbyterian Mobile Imaging, LLC mobile MRI scanners would no longer serve NHI University as of August 14, 2021 but included no such documentation for the Kings Medical Group scanners that serve NHI University and NHI Steele Creek.

<sup>5</sup> Jacksonville Diagnostic Imaging, LLC is a wholly owned subsidiary of Novant Health. Pursuant to Project ID # F-6626-02, Jacksonville Diagnostic Imaging, LLC was approved to acquire a mobile MRI scanner.

<sup>6</sup> As noted previously, these mobile MRI scanners are identified as MQ9 and MQ25, respectively.

<sup>7</sup> As noted previously, Jacksonville Diagnostic Imaging, LLC is a wholly owned subsidiary of Novant Health. Pursuant to Project ID # F-6626-02, Jacksonville Diagnostic Imaging, LLC was approved to acquire a mobile MRI scanner.

<sup>8</sup> Novant Health is the ultimate parent entity of Presbyterian Mobile Imaging, LLC. Pursuant to Project ID # F-7164-04, Presbyterian Mobile Imaging, LLC was approved to acquire a mobile MRI scanner.

<sup>9</sup> As noted previously, these mobile MRI scanners are identified as MQ9 and MQ25, respectively.



Proposed 2022 SMFP

Table 17E-1: MRI Fixed and Mobile Procedures by MRI Service Area with Tiered Thresholds and Fixed Equivalents

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
Service Area	Service Type	CON #	Service Site (Provider/Owner)	Fixed Magnet	Fixed Equiv	Total MRI Scans	Outpt No Contrast	Outpt Contrast	Inpt No Contrast	Inpt Contrast	Adjusted Total	Area Avg Procs	Threshold	MRI Need
Mecklenburg	Mobile	F-006734-03	Carolina Neurosurgery & Spine Associates-Charlotte (Carolina Neurosurgery & Spine Associates)	0	1.00	5,728	4,490	1,238	0	0	6,223			
Mecklenburg	Mobile	Legacy	Charlotte Eye, Ear, Nose & Throat (Alliance HealthCare Services)	0	0.04	357	44	313	0	0	482			
Mecklenburg	Mobile	Legacy	Charlotte Eye, Ear, Nose & Throat (Alliance HealthCare Services)	0	0.11	517	79	438	0	0	692			
Mecklenburg	Mobile	Legacy	Novant Health Ballantyne (Kings Medical Group)	0	0.02	111	111	0	0	0	111			
Mecklenburg	Mobile	F-007164-04	Novant Health Imaging - Ballantyne (Presbyterian Mobile Imaging)	0	0.04	213	104	109	0	0	257			
Mecklenburg	Mobile	F-006626-02	Novant Health Imaging - University (Jacksonville Diagnostic Imaging)	0	0.03	158	95	63	0	0	183			
Mecklenburg	Mobile	F-007164-04	Novant Health Imaging - University (Presbyterian Mobile Imaging)	0	0.07	336	210	126	0	0	386			
Mecklenburg	Mobile	Legacy	Novant Health Imaging Steele Creek (Kings Medical Group)	0	0.12	575	401	174	0	0	645			
Mecklenburg	Mobile	Legacy	Novant Health Imaging Steele Creek (Kings Medical Group)	0	0.00	875	633	242	0	0	972			
Mecklenburg	Mobile	Legacy	Novant Health Imaging University (Kings Medical Group)	0	0.15	735	519	216	0	0	821			
Mecklenburg	Mobile	Legacy	Novant Health Imaging University (Kings Medical Group)	0	0.14	688	479	209	0	0	772			
Mecklenburg	Mobile	G-007065-04	Novant Health Matthews Medical Center (Forsyth Medical Hospital)	0	0.05	230	140	90	0	0	266			
Mecklenburg	Mobile		Novant Health Mint Hill Medical Center	0	0.06	299	197	78	18	6	342			
Mecklenburg	Mobile	F-007987-07	OrthoCarolina Huntersville (OrthoCarolina, PA)	0	0.30	1,427	1,227	200	0	0	1,507			
Mecklenburg	Mobile	F-007987-07	OrthoCarolina Matthews (OrthoCarolina, PA)	0	0.47	2,260	2,260	0	0	0	2,260			
Mecklenburg	Mobile	Legacy	OrthoCarolina Randolph Spine Center (Alliance Healthcare Services)	0	0.12	590	495	95	0	0	628			
Mecklenburg	Mobile	F-007987-07	OrthoCarolina Spine Center (OrthoCarolina, PA)	0	0.28	1,354	1,253	101	0	0	1,394			
Mecklenburg	Mobile	Legacy	OrthoCarolina, P. A. (Alliance Healthcare Services)	0	0.21	990	990	0	0	0	990			
Mecklenburg	Mobile	Legacy	OrthoCarolina, PA (Alliance Healthcare Services)	0	0.00	15	15	0	0	0	15			
Mecklenburg	Mobile		Presbyterian Mobile MRI	0	0.46	2,204	1,634	570	0	0	2,432			
Mecklenburg			2021 Need Determination	1	1.00	0	0	0	0	0	0			
Mecklenburg				27	31.23	127,152					152,584	4,886	4,805	1

As noted above, Novant Health provides no rationale or basis for its exclusion of its mobile units serving NHI University and NHI Steele Creek in its responses to the performance standards. Absent any explanation, Novant Health’s responses to the performance standards are seemingly inconsistent with responses provided by Novant Health in Section A and Form O Facilities of its application as well as the 2021 SMFP and the Proposed 2022 SMFP.

*Failure to Provide Information Necessary Relative to Novant Health’s Mobile MRI Scanners for the Analyst to Properly Evaluate the Performance Standards*

As noted above, Novant Health’s responses to the historical and projected performance standards simply state that there are no mobile MRI scanners owned or operated by Novant Health or a related entity in the MRI service area. Novant Health does reference a change from its prior Mecklenburg County MRI application in Section C of its application, stating that:

It should be noted that several Novant Health facilities located in Mecklenburg County have been host sites for mobile MRI scanners that are ultimately owned by Novant Health; however, at the time of this CON application’s submission, there are no mobile MRI scanners located in or operated in the SMFP-defined Mecklenburg County MRI service area.

However, under the performance standards, a mobile MRI should be accounted for if it is used in the MRI service area either: (a) between the filing date and the start of the review; or (b) during the review. Notably, **Novant Health provides no evidence, data, or documentation to substantiate its statement**

**that “there are no mobile MRI scanners located in or operated in the SMFP-defined Mecklenburg County MRI service area”** – in particular relative to the Kings Medical Group mobile MRI scanners that serve NHI University and NHI Steele Creek. While Novant Health does provide copies of Material Compliance Requests in Exhibit C.1 which document the removal of various Mecklenburg County host sites from its mobile routes, Novant Health provides no evidence or documentation to indicate its intent and commitment not to operate any of its mobile MRI scanners at any of the host sites in Mecklenburg County between the filing date and start of the review or during the review. Rather, Novant Health’s responses to the performance standards simply indicate that “[a]t the time of this CON application submission,” there are no mobile MRI scanners owned or operated by Novant Health or a related entity in the MRI service area.

While some of Novant Health’s mobile MRI scanners may have been removed from Mecklenburg County host sites the day prior to submitting its NHI Matthews application (as documented by its Material Compliance Requests included in Exhibit C.1), Novant Health provides no documentation which would indicate that – from the day of submission until the end of the review – its mobile MRI scanners will not add any Mecklenburg County host sites back to its mobile MRI scanner routes, nor does it provide any documentation that its Kings Medical Group mobile scanners will no longer serve NHI University and NHI Steele Creek. In fact, and as discussed below, **there is publicly available information which would suggest that Novant Health has operated its mobile MRI scanners at host sites in Mecklenburg County during the timeframe relevant to the performance standards.**

As depicted in the photographs below, **a mobile MRI scanner was parked on the NHI Steele Creek site and in operation on August 26, 2021 (a date which falls between the filing date of August 16, 2021 and the start of the review on September 1, 2021).** The photograph below shows the outside of the NHI Steele Creek facility on August 26, 2021. Visible in the photograph is a mobile MRI scanner parked on the site.



The two photographs below show zoomed in views of the mobile MRI scanner parked on the NHI Steele Creek site on August 26, 2021. In the first photograph, “MQ25” can be seen on the side of the mobile unit. As noted previously, one of the Kings Medical Group mobile MRI scanners is identified as MQ25. While Novant Health has historically argued that grandfathered MRI units – such as the mobile MRI

scanners owned by Kings Medical Group – are exempt from meeting the performance standards<sup>10</sup>, such view is contradicted by the language of the MRI rules and past Agency decisions for MRI reviews, as discussed in detail below. Moreover, Novant Health fails to proactively address whether Kings Medical Group, which owns several mobile MRI scanners serving Mecklenburg County (including the MQ25 mobile unit pictured below), is an affiliate or related entity of Novant Health in its current application – rather it simply states that there are no mobile MRI scanners owned or operated by Novant Health or a related entity in the MRI service area. As discussed in detail below, Novant Health historically has taken a different view regarding the relation of Kings Medical Group to Novant Health. The second photograph below, which shows staff coming in and out of the mobile MRI unit – MQ25 – parked on the NHI Steele Creek site on August 26, 2021, suggests that not only was the mobile MRI scanner parked on the NHI Steele Creek site on August 26, 2021, but it also was in operation.



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<sup>10</sup> Please note that Novant Health does not proactively make such an argument in its current application – rather it simply states that there are no mobile MRI scanners owned or operated by Novant Health or a related entity in the MRI service area.



Given the lack of information and documentation provided by Novant Health in its current application – detail that is vital to the Agency’s review of the application under the performance standards – Novant Health should be found non-conforming with the performance standards.

#### *Failure to Address Grandfathered MRI Units*

Historically, Novant Health has argued that grandfathered MRI units – such as the mobile MRI scanners owned by Kings Medical Group – are exempt from meeting the performance standards. While Novant Health does not proactively make such an argument in its current application – rather it simply states that “[a]t the time of this CON application submission, neither of the applicants is operating a mobile MRI scanner in the proposed MRI service Area, Mecklenburg County, in which the applicants or a related entity owns a controlling interest” – it is nonetheless important to note that the view that grandfathered MRI units are exempt from meeting performance standards is contradicted by the language of the MRI rules and past Agency decisions for MRI reviews, as discussed below.

There is no language in the MRI performance standards at 10 NCAC 14C .2703(b) demonstrating that grandfathered MRI units are exempt from meeting the historical or projected standards. The rules clearly state that “each existing mobile MRI scanner” and “each existing, approved and proposed mobile MRI scanner” are to be considered and make no references to any exclusions for grandfathered units. Further, in its current application, Novant Health assumes that the performance standards apply to a grandfathered unit. Specifically, in its response to the projected performance standard for fixed MRI units at 10A NCAC 14C .2703(b)(3), Novant Health’s data includes the grandfathered mobile unit that is approved to be converted to fixed at Novant Health Presbyterian Medical Center,<sup>11</sup> as shown on pages 122 through 123 of the NHI Matthews application. It is not clear why Novant Health believes (incorrectly)

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<sup>11</sup> Pursuant to Exemption Record #2983 approved on August 17, 2019, a grandfathered mobile MRI will be replaced with a grandfathered fixed MRI at Novant Health Presbyterian Medical Center resulting in a total of five MRIs on that campus.

in its currently proposed application that the performance standards apply to grandfathered MRI units when approved to be operated as fixed units but not when operated as mobile units.

Moreover, there is nothing in the *SMFP* need methodology to suggest that grandfathered MRI units are not subject to the CON rules. Grandfathered units, both fixed and mobile, are included in the inventory of MRI scanners, which is used to determine the need for additional MRI scanners. If the *SMFP* was not concerned with the utilization of grandfathered units in determining need for additional units, it would not include those units in the inventory.

In addition, past Agency decisions in MRI reviews have applied the MRI rules to grandfathered MRI units, fixed and mobile. CMHA is aware of the following instances, and there may be many more.

- In its review of Project ID # J-7442-05 (see Attachment 1), the Agency applied the MRI rules to Alliance Imaging's grandfathered mobile units. The Agency noted that Alliance Imaging failed to provide the host sites of each of its 29 mobile MRI scanners and noted that at least three of the 29 were acquired pursuant to a certificate of need, suggesting that as many as 26 units were grandfathered units. Further, the Agency found Alliance Imaging non-conforming with the projected mobile MRI performance standards because no utilization projections were provided for its mobile MRI scanners in the eastern mobile MRI region. The Agency made no exclusions at all for any grandfathered scanners.
- In the 2009 Forsyth County MRI review (see Attachment 2), the Agency applied the MRI rules to grandfathered fixed MRI units operated at Forsyth Medical Center (two), Excel Imaging-Maplewood (one), and Piedmont Imaging Center (one). While the 2009 *SMFP* did not distinguish between grandfathered and CON-awarded scanners, the 2019 *SMFP* and earlier *SMFP*s show that these units are grandfathered. The Agency applied the historical and projected fixed MRI performance standards in the review and made no exclusions for the grandfathered scanners.
- In the 2016 Guilford County MRI review (see Attachment 3), the Agency applied the mobile MRI performance standards to grandfathered mobile MRI scanners owned by Alliance HealthCare Services (AHS) in the service area (known as SOS and CNSA). As shown in the 2016 *SMFP*, these units are grandfathered. The Agency applied the historical and projected mobile MRI performance standards in the review and made no exclusions for the grandfathered scanners.
- In the 2016 Wake County MRI review (see Attachment 4), the Agency applied the fixed MRI performance standards to both Wake Radiology's and Duke Raleigh's grandfathered fixed MRI units. As shown in the 2016 *SMFP*, both Duke Raleigh and Wake Radiology operated fixed grandfathered units at Duke Raleigh Hospital and Wake Radiology Raleigh MRI (Wake Radiology Diagnostic Imaging), respectively. The Agency applied the historical and projected fixed MRI performance standards in the review and made no exclusions for the grandfathered scanners.
- In the 2016, 2017, and 2019 Mecklenburg County MRI reviews (see Attachments 5, 6, and 7, respectively), the Agency applied the fixed MRI performance standards to CMC's grandfathered fixed MRI units. As shown on its 2019 Hospital License Renewal Application (HLRA), CMC reported one grandfathered fixed MRI scanner and determined through research that another one of its units is grandfathered, which was reported on its 2020 HLRA. The Agency applied the historical and projected fixed MRI performance standards in these reviews and made no exclusions for the grandfathered scanners.

Moreover, such an exclusion would run contrary to the intent of the MRI rules and the premise of the CON law. As the Agency stated in the 2016 Wake County MRI review (cited above), *“the [historical mobile MRI performance standard at 10 NCAC 14C .2703(b)(2)] Rule is necessary as it would not be consistent with the premise of the CON Law to approve an applicant to acquire an additional MRI scanner (fixed or mobile) when the applicant has access to an existing mobile MRI scanner which has the capacity to serve more patients than it is currently serving.”* See the 2016 Wake County MRI review Findings, page 63.

Further, there is no language in any CON rule exempting or excluding grandfathered assets. CMHA is not aware of any instance where the Agency has exempted grandfathered beds, operating rooms, cardiac catheterization equipment, linear accelerators, PET scanners, MRI scanners, CT scanners, or any other asset in evaluating conformity with any Rule. CMHA is aware of myriad examples of the Agency applying CON rules to grandfathered assets, outside of the MRI examples listed above. For example, any hospital, like CMC, that existed prior to 1977 would have grandfathered acute care beds and/or operating rooms. The Agency has applied the operating room and acute care bed rules to CMC’s grandfathered assets in many acute care and operating room reviews without any exemption or exclusion. Simply put, there is no such exemption for grandfathered assets.

Finally, while Novant Health does not proactively address whether Kings Medical Group, which owns several mobile MRI scanners serving Mecklenburg County, is an affiliate or related entity of Novant Health in its current application – rather it simply states that *“[a]t the time of this CON application submission, neither of the applicants is operating a mobile MRI scanner in the proposed MRI service Area, Mecklenburg County, in which the applicants or a related entity owns a controlling interest”* – it is important to note that historically, Novant Health has identified the grandfathered mobile MRI units owned by Kings Medical Group as mobile MRI scanners in which Novant Health or a related entity owns a controlling interest – please see the excerpt below from page 53 of Novant Health’s 2019 MRI CON (Project ID # F-11755-19 – to develop an additional fixed MRI scanner at Novant Health Matthews Medical Center) wherein, in response to the historical performance standards, Novant Health identified two existing mobile MRI scanners – NHI Steele Creek (owned by King’s Medical Group, MQ 9) and NHI University (owned by King’s Medical Group, MQ 25) as mobile MRI scanners *“in which Novant Health or a related entity owns a controlling interest that are currently located in the proposed MRI service area of Mecklenburg County.”* Novant Health went on to indicate in its 2019 MRI CON that both of these units are grandfathered units and as such are exempt from meeting the performance standards.

**(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];**

As a provider of both fixed and mobile MRI services, Novant Health and its affiliates MedQuest Associates have access to several mobile MRI scanners that are used interchangeably at host sites throughout the state of North Carolina. This is particularly important to ensure that all communities within Novant Health's service area have adequate access to MRI services. Other than temporary MRI scanners, there are two existing mobile MRI scanners in which Novant Health or a related entity owns a controlling interest that are currently located in the proposed MRI service area of Mecklenburg County. Both mobile MRI units operating in Mecklenburg County are grandfathered units that are exempt from meeting the performance standards.

Host Site	Unit Name	Status
NHI Steele Creek	King's Medical Group (MQ 9)	Grandfathered
NHI University	King's Medical Group (MQ 25)	Grandfathered

Clearly, Novant Health historically has indicated that it (or a related entity) owns a controlling interest in Kings Medical Group. Most recently, however, in its current application, Novant Health simply states that “[a]t the time of this CON application submission, neither of the applicants is operating a mobile MRI scanner in the proposed MRI service Area, Mecklenburg County, in which the applicants or a related entity owns a controlling interest.” Notably, Novant Health provides no information which would explain why its prior position regarding the relation of Kings Medical Group to Novant Health is no longer accurate.

If the ownership of Kings Medical Group changed (from Novant's earlier representation), Novant Health nonetheless fails to provide adequate documentation indicating as much. Given the lack of information and documentation provided by Novant Health in its current application regarding the relation of Kings Medical Group to Novant Health – information and documentation that is vital to the Agency's review of the application under the performance standards – Novant Health should be found non-conforming with the performance standards. Moreover, regardless of the ownership status of the Kings Medical Group's mobile units, there are several other mobile units owned by Novant Health or a related entity that are shown to be operating in the service area.

*Failure to Account for Novant Health Ballantyne in Response to the Performance Standards*

Additionally, **Novant Health fails to mention anywhere in its application the approved development of Novant Health Ballantyne Medical Center (Novant Health Ballantyne), a new Novant Health acute care hospital in Ballantyne, which will offer mobile MRI services.** As stated on page 15 of the Novant Health Ballantyne application (Project ID # F-11625-18), Novant Health Ballantyne “will also contract with an existing mobile imaging services vendor for Mobile MRI scanner services on-site initially for one to two days per week. [Novant Health Ballantyne] has secured a commitment from MedQuest<sup>12</sup> to provide these services.” Notwithstanding the fact that Novant Health Ballantyne is currently under construction, Novant Health includes no discussion in its current application regarding how the site will be served and whether it will be fully utilized. Of note, Novant Health does not indicate whether Ballantyne would be served by a grandfathered or non-grandfathered scanner. However, according to the *Proposed 2022 SMFP*,

<sup>12</sup> As noted previously, MedQuest is an affiliate and related entity of Novant Health.

excerpted below with purple highlights added, Novant Health Ballantyne appears to be served by one legacy<sup>13</sup> mobile MRI scanner owned by Kings Medical Group.

Proposed 2022 SMFP

Table 17E-1: MRI Fixed and Mobile Procedures by MRI Service Area with Tiered Thresholds and Fixed Equivalents

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
Service Area	Service Type	CON #	Service Site (Provider/Owner)	Fixed Magnet	Fixed Equiv	Total MRI Scans	Outpt No Contrast	Outpt Contrast	Inpt No Contrast	Inpt Contrast	Adjusted Total	Area Avg Procs	Threshold	MRI Need
Mecklenburg	Mobile	F-006734-03	Carolina Neurosurgery & Spine Associates-Charlotte (Carolina Neurosurgery & Spine Associates)	0	1.00	5,728	4,490	1,238	0	0	6,223			
Mecklenburg	Mobile	Legacy	Charlotte Eye, Ear, Nose & Throat (Alliance HealthCare Services)	0	0.04	357	44	313	0	0	482			
Mecklenburg	Mobile	Legacy	Charlotte Eye, Ear, Nose & Throat (Alliance HealthCare Services)	0	0.11	517	79	438	0	0	692			
Mecklenburg	Mobile	Legacy	Novant Health Ballantyne (Kings Medical Group)	0	0.02	111	111	0	0	0	111			
Mecklenburg	Mobile	F-007164-04	Novant Health Imaging - Ballantyne (Presbyterian Mobile Imaging)	0	0.04	213	104	109	0	0	257			
Mecklenburg	Mobile	F-006626-02	Novant Health Imaging - University (Jacksonville Diagnostic Imaging)	0	0.03	158	95	63	0	0	183			
Mecklenburg	Mobile	F-007164-04	Novant Health Imaging - University (Presbyterian Mobile Imaging)	0	0.07	336	210	126	0	0	386			
Mecklenburg	Mobile	Legacy	Novant Health Imaging Steele Creek (Kings Medical Group)	0	0.12	575	401	174	0	0	645			
Mecklenburg	Mobile	Legacy	Novant Health Imaging Steele Creek (Kings Medical Group)	0	0.00	875	633	242	0	0	972			
Mecklenburg	Mobile	Legacy	Novant Health Imaging University (Kings Medical Group)	0	0.15	735	519	216	0	0	821			
Mecklenburg	Mobile	Legacy	Novant Health Imaging University (Kings Medical Group)	0	0.14	688	479	209	0	0	772			
Mecklenburg	Mobile	G-007065-04	Novant Health Matthews Medical Center (Forsyth Medical Hospital)	0	0.05	230	140	90	0	0	266			
Mecklenburg	Mobile		Novant Health Mint Hill Medical Center	0	0.06	299	197	78	18	6	342			
Mecklenburg	Mobile	F-007987-07	OrthoCarolina Huntersville (OrthoCarolina, PA)	0	0.30	1,427	1,227	200	0	0	1,507			
Mecklenburg	Mobile	F-007987-07	OrthoCarolina Matthews (OrthoCarolina, PA)	0	0.47	2,260	2,260	0	0	0	2,260			
Mecklenburg	Mobile	Legacy	OrthoCarolina Randolph Spine Center (Alliance Healthcare Services)	0	0.12	590	495	95	0	0	628			
Mecklenburg	Mobile	F-007987-07	OrthoCarolina Spine Center (OrthoCarolina, PA)	0	0.28	1,354	1,253	101	0	0	1,394			
Mecklenburg	Mobile	Legacy	OrthoCarolina, P. A. (Alliance Healthcare Services)	0	0.21	990	990	0	0	0	990			
Mecklenburg	Mobile	Legacy	OrthoCarolina, PA (Alliance Healthcare services)	0	0.00	15	15	0	0	0	15			
Mecklenburg	Mobile		Presbyterian Mobile MRI	0	0.46	2,204	1,634	570	0	0	2,432			
Mecklenburg			2021 Need Determination	1	1.00	0	0	0	0	0	0			

Based on the discussions above, given conflicting information provided in Novant Health’s application and in statements made by Novant Health on the public record, as well as its failure to explain its exclusion of various mobile MRI scanners in the MRI service area, Novant Health’s ability to meet the performance standards is unsupported. As such, **the NHI Matthews application should be found non-conforming with the performance standards in the MRI rules (10A NCAC 14C .2703, particularly .2703(b)(2) and (b)(5)) as well as non-conforming with Criteria 1, 3, 4, 5, 6, and 18a and should be denied.**

Failure to Provide Reasonable Utilization Projections

*Unreasonable and Unsupported Assumptions*

The volume for Novant Health’s proposed IDTF and diagnostic center – NHI Matthews – is based on unreasonable and unsupported assumptions. Namely, Novant Health assumes that NHI Matthews will be open 312 days per year and will average 14 patients per day.

As stated on page 124 of Novant Health’s application, it assumes that NHI Matthews will operate six days per week, Monday through Saturday, for a total of 312 days per year (note: the 312 days per year is

<sup>13</sup> “Legacy” is not defined in the *Proposed 2022 SMFP*; however, it appears to refer to MRI scanners that were referenced in earlier *SMFP* versions as “grandfathered.”



calculated by multiplying six days per week by 52 weeks per year). Using these assumptions, Novant Health's projections show 4,828 weighted procedures in project year 3. This is just over the performance standard of 4,805 procedures by 23 weighted scans. Of note, Novant Health's assumptions fail to account for or to factor in any downtime and/or location closures. That is, Novant Health's assumptions fail to build in downtime for system maintenance and/or weather or holiday closures. Based on Novant Health's assumptions, downtime and/or office closures of more than 1.5 days (which would not be uncommon based on the experience of CMHA), will result in Novant Health's failure to meet performance standards.

The other key assumption in determining volume is Novant Health's project year 3 assumed average of 14 patients per day. This assumption is unsupported. Per page 124 of the NHI Matthews application, "Novant Health IDTFs frequently perform up to 20 MRI scans in a day." However, Novant Health fails to provide any evidence to support either claim. In addition, and interestingly enough, **14 patients per day is the exact number of patients Novant Health needs in order to meet the performance standards.** If Novant Health were to drop the average patients per day to 13.9, Novant Health would no longer meet the performance standards. Given that Novant Health provided no evidence to support its assumption of 14 patients per day, it is likely that this number was simply chosen by Novant Health in order for it to meet the performance standards. More importantly, the number of hours the scanner will operate and the number of patients that can be accommodated on the scanner per day do not demonstrate the need the population has for the services proposed and it is impossible for the Agency to determine whether or not patients Novant Health is proposing to serve need the proposed MRI scanner at the rate of six days per week at 14 patients per day.

Further, Novant Health indicates on pages 133 and 137 of its application that its assumptions relative to revenues, contractuals, and expenses rely on an existing Novant Health IDTF, NHI Southpark.<sup>14</sup> However, and in contrast, Novant Health's volume projections ignore the historical experience of NHI Southpark as well as NHI Ballantyne, its two local IDTFs. Notably, based on the data on pages 120 and 121 of the NHI Matthews application, NHI Ballantyne did not meet the historical performance standard a single time from 2014 through 2020 and NHI Southpark only met the historical performance standard once during that period.

#### *Unsupported Growth Rate*

The MRI volume for Novant Health facilities in Mecklenburg County is projected using a growth rate of 5.69 percent based on Novant Health's Mecklenburg County experience from 2014 through 2020. See the NHI Matthews application, page 122. An analysis of the various compound annual growth rates (CAGRs) that Novant Health could have selected is provided in the table below.

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<sup>14</sup> While Novant Health indicates on pages 133 and 137 of its application that its assumptions relative to revenues, contractuals, and expenses rely on an existing Novant Health IDTF, NHI Southpark, it should be noted that Novant Health also provides conflicting information on pages 133 and 137 of its application in which it states "NHI Matthews data was used because NHI Matthews is an IDTF." Not only are such statements inconsistent with statements made on the same pages regarding NHI Southpark serving as the basis for these assumptions, but also, such statements are simply false as NHI Matthews is not an existing IDTF (as noted by Novant Health in its application – see page 29 where Novant Health states "NHI Matthews **will be both an independent diagnostic treatment facility and a diagnostic center and will operate a single fixed MRI scanner.**" **[emphasis added]**).

CAGR	Historical Utilization*		Population Growth*
	Novant Health	Mecklenburg County	
2014-2020	5.69%	3.70%	
2015-2020	4.36%	3.41%	
2016-2020	5.36%	2.71%	
2017-2020	5.25%	-0.01%	
2018-2020	4.75%	0.14%	
2019-2020	-2.29%	-3.62%	
2016-2021			1.56%
2021-2026			1.80%

\*Calculated based on data provided pages 41, 45, and 122 of the NHI Matthews application.

As shown above, Novant Health’s selected growth rate is 54 percent higher than the county’s utilization growth rate during the same period of time and is more than three times the county’s projected population growth rate. Using more recent growth yields a lower growth rate. This further calls into question the reasonableness of Novant Health’s assumptions.

Additionally, and as noted previously, Novant Health fails to mention anywhere in its application the approved development of Novant Health Ballantyne, a new Novant Health acute care hospital in Ballantyne, which will offer mobile MRI services. As stated on page 15 of the Novant Health Ballantyne application (Project ID # F-11625-18), Novant Health Ballantyne “*will also contract with an existing mobile imaging services vendor for Mobile MRI scanner services on-site initially for one to two days per week. [Novant Health Ballantyne] has secured a commitment from MedQuest<sup>15</sup> to provide these services.*” There is no discussion whatsoever of whether the development of hospital-based MRI services at Novant Health Ballantyne will impact the utilization of other Novant Health sites. This is a particular issue as the projected utilization of Novant Health Ballantyne included a shift of patients from other Novant Health hospitals, thereby impacting the projected MRI volume of those facilities.

Based on the discussions above, it is clear that Novant Health’s projected utilization is unsupported. As such, **the NHI Matthews application is non-conforming with Criteria 1, 3, 4, 5, 6, 18a, and the performance standards in the MRI rules (10A NCAC 14C .2703, particularly .2703(b)(2) and (b)(5)) and should be denied.**

#### Failure to Demonstrate Financial Feasibility

Novant Health fails to demonstrate the financial feasibility of its proposed project. As discussed above, Novant Health’s utilization projections are not based on reasonable assumptions – as such, Novant Health is nonconforming with Criterion 5. Notably, Novant Health provides inconsistent information regarding the basis of its financial assumptions. While Novant Health indicates on pages 133 and 137 of its application that its assumptions relative to revenues and expenses rely on an existing Novant Health IDTF, NHI Southpark, Novant Health also provides conflicting information on the same pages of its application – pages 133 and 137 – in which it states “*NHI Matthews data was used because NHI Matthews is an IDTF.*” Not only are such statements inconsistent with statements made on the same pages regarding NHI Southpark serving as the basis for these assumptions, but also, such statements are simply false as NHI

<sup>15</sup> Please note that Novant Health is MedQuest’s ultimate parent entity.

Matthews is not an existing IDTF (as noted by Novant Health in its application). These inconsistent statements call into question the reasonableness of Novant Health's assumptions.

Given inconsistent information regarding financial assumptions provided in its application, **Novant Health fails to demonstrate that the financial feasibility of its project is based on reasonable projections of costs and should be found non-conforming with Criterion 5 as well as non-conforming with Criteria 1, 4, and 18a and should be denied.**

## COMPARATIVE COMMENTS

Given that both CMHA and Novant Health propose to meet the need for the additional fixed MRI in Mecklenburg County, only one of the applications can be approved as proposed. In reviewing comparative factors that are applicable to this review, CMHA compared the applications on the following factors:

- Conformity with Applicable Statutory and Regulatory Review Criteria
- Scope of Services
- Historical Utilization
- Meeting the Need for Additional MRI Capacity
- Demonstration of Need
- Geographical Accessibility (Location within the Service Area)
- Geographic Reach
- Access by Underserved Groups
- Revenues
- Operating Expenses

CMHA believes that the factors presented above and discussed in turn below should be considered by the Agency in reviewing the competing applications.

### Conformity with Applicable Statutory and Regulatory Review Criteria

As discussed in the application-specific comments above, the NHI Matthews application is non-conforming with multiple statutory and regulatory review criteria. In contrast, the CMHA application is conforming with all applicable statutory and regulatory review criteria. Therefore, with regard to conformity with applicable statutory and regulatory review criteria, the CMHA application is the most effective alternative.

### Scope of Services

With regard to scope of services, the applications submitted by CMHA and NHI Matthews are both in response to the *2021 SMFP*, which includes a need determination for one additional fixed MRI scanner in Mecklenburg County. CMC is an existing acute care hospital that provides primarily inpatient services. Novant Health's proposed facility, NHI Matthews, is not existing – its proposal would result in a new diagnostic facility that provides only outpatient services. An inpatient acute care hospital is able to provide a much broader scope of services than an outpatient diagnostic facility. As noted on page 44 of CMHA's application, CMHA facilities – particularly CMC – provide a comprehensive scope of MRI services while other providers in Mecklenburg County offer more limited services. Of note, CMC is an academic medical center with over 1,100 physicians and providers specializing in all areas of medicine; thus, CMC's size and scope of services will be much broader than an outpatient diagnostic facility such as that proposed by Novant Health. While there are times that a freestanding scanner may be a better alternative, the current review is not such a time – as such, a comparison of scope of services is meaningful given the need in Mecklenburg County.

Moreover, the application submitted by CMHA proposes to acquire a 3.0 Tesla (3.0T) MRI scanner with BioMatrix and Turbo Suite technology, while the application submitted by Novant Health proposes to acquire a 1.5T MRI scanner. As noted on page 33 of CMHA's application, a Tesla is the unit of

measurement that is used to quantify the strength of a magnetic field. Originally, the high-field standard was 1.5T. A 3.0T scanner is twice the strength of a 1.5T and produces exceptionally detailed images. As noted in Section E of CMHA’s application, while CMHA considered acquiring a 1.5T MRI to meet the need for an additional fixed MRI scanner at CMC, CMHA determined that acquiring a 1.5T scanner was not the most effective alternative. As discussed in Section C.4 of CMHA’s application, 3.0T scans show more detail than other scanners and are especially helpful when a more sensitive diagnostic tool is needed – as often is the case for CMC patients. Smaller abnormalities in the brain and spine are less likely to be missed, which can lead to a more accurate diagnosis of epilepsy, tumors, and strokes. Orthopedic physicians can use this enhanced sensitivity to assess joint fractures, joint stability, and sometimes even bleeding associated with fractures. Further, 3.0T scans are one of the best diagnostic tools for both infections and other types of tissue changes like prostate cancer, allowing for earlier diagnosis.

Given the foregoing discussion, with regard to scope of services, CMHA is the more effective alternative.

Historical Utilization

The following table illustrates the total MRI scans and the adjusted total of MRI scans performed by Novant Health and its affiliates and CMHA and its affiliates for all fixed MRIs in Mecklenburg County as identified in Table 17E-1 of the *Proposed 2022 SMFP*.

	<b>Total Fixed MRI Scans</b>	<b>Adjusted Total Fixed MRI Scans</b>
CMHA	46,785*	60,380**
Novant Health	40,578	49,710

Source: *Proposed 2022 SMFP*.

\* Includes 35,357 total fixed MRI scans performed by CMHA and 11,428 total fixed MRI scans performed by CIS (35,357 + 11,428 = 46,785).

\*\*Includes 47,198 adjusted total fixed MRI scans performed by CMHA and 13,182 adjusted total fixed MRI scans performed by CIS (47,198 + 13,182 = 60,380).

As indicated in the table above, Novant Health and its affiliates performed 40,578 total MRI scans and 49,710 adjusted MRI scans in Mecklenburg County and CMHA and its affiliates performed 46,785 total MRI scans and 60,380 adjusted MRI scans in Mecklenburg County. Based on the table above, CMHA has a higher historical MRI utilization in Mecklenburg County. Therefore, with regard to this factor, CMHA is the more effective alternative.

## Meeting the Need for Additional Fixed MRI Capacity

Within Mecklenburg County, CMHA operates eight fixed MRI units at three licensed acute care hospitals. In addition, CMHA and Charlotte Radiology jointly own Carolinas Imaging Services, LLC (CIS), which operates three freestanding fixed MRI scanners. Historically, Novant Health has owned 10 existing or approved fixed MRI scanners; however, it received approval in July 2019 to convert a grandfathered mobile MRI scanner to a grandfathered fixed MRI scanner at Novant Health Presbyterian Medical Center. **Please note that any comparative evaluation of Novant Health's fixed MRI capacity should include this additional grandfathered unit, for a total of 11 fixed MRI units.**

As shown in the table below, CMHA's volume of weighted scans in excess of the planning threshold is higher than any other provider in Mecklenburg County, with the exception of OrthoCarolina, which is the only other provider with *any* volume in excess of the per unit planning threshold. Of note, CMHA's inventory of nine fixed units in the table below includes the fixed scanner operated by Carolinas Physicians Network, Inc. (CPN) (of which CMHA is the parent) at Atrium Health Kenilworth Diagnostic Center #1, which became operational on April 5, 2021 (pursuant to Project ID # F-11760-19) and therefore had no volume in FFY 2020. As such, because CMHA's inventory below includes one scanner that was approved, but not yet operational and had no volume in the time period reported, CMHA's total weighted scans per unit appear artificially low. **If the calculation was made using only CMHA's eight MRI scanners in operation in FFY 2020, the total weighted scans in excess of the threshold per unit would be 8,758.** Moreover, if the calculation was made using CMHA's eight MRI scanners in operation in FFY 2020 plus CIS's three MRI scanners in operation in FFY 2020, **the combined CMHA related entity total volume of weighted scans in excess of the planning threshold would be 7,525 – the highest of all the providers in Mecklenburg County.**

Please note that Novant Health's inventory of 11 fixed units in the table below does not include the fixed scanner awarded to Novant Health following the appeal of its denial to develop an additional MRI scanner at Novant Health Imaging SouthPark in 2020, Project ID # F-11946-20, whereby it received approval via settlement to develop an additional fixed MRI for a total of two fixed MRI scanners at Novant Health Imaging SouthPark. A certificate was issued for Novant Health Imaging SouthPark to acquire a second MRI scanner on February 11, 2021. Given that the twelfth MRI scanner was not approved in FFY 2020 and had no volume in the time period reported, it is excluded from the calculation in the table below. As such, and as indicated in the table below, Novant Health's 11 operational fixed MRI scanners in FFY 2020 performed only 4,519 adjusted MRI scans per unit on average which is approximately 286 adjusted MRI scans below the threshold of 4,805 scans per fixed unit.

**FFY 2020 Fixed MRI Scans and Capacity by Provider**

	<i>Weighted Fixed MRI Scans</i>	<i>Existing and Approved Fixed Units</i>	<i>Weighted Scans per Unit*</i>	<i>Weighted Scans in Excess of 4,805 per Unit*</i>	<i>Total Weighted Scans in Excess of 4,805 per Unit*</i>
	<b>A</b>	<b>B</b>	<b>C = A/B</b>	<b>D = C – 4,805</b>	<b>E = D x B</b>
CMHA	47,198	9**	5,244	439	3,953
CIS	13,182	3	4,394	-411	-1,233
<b>CMHA Related Entity Total (CMHA and CIS combined)</b>	<b>60,380</b>	<b>12**</b>	<b>5,032</b>	<b>227</b>	<b>2,720</b>
Novant Health	49,710	11***	4,519	-286	-3,145
OrthoCarolina	14,204	2	7,102	2,297	4,594
CNSA	4,028	1	4,028	-777	-777

Source: *Proposed 2022 SMFP*.

\*Weighted MRI Scans – (Fixed Units x 4,805 Planning Threshold); negative indicates a surplus of capacity.

\*\*Includes the fixed MRI scanner at Atrium Health Kenilworth, which was approved, but not yet operational during FFY 2020 and therefore had no reported volume in FFY 2020.

\*\*\*Does not include the fixed MRI scanner at Novant Health Imaging SouthPark, which was not awarded until February 11, 2021.

As shown above, Novant Health currently operates with excess capacity of fixed MRI scanners. Therefore, with regard to meeting the need for additional fixed MRI capacity, CMHA is the more effective alternative.

Demonstration of Need

CMHA adequately demonstrates that the projected utilization of CMHA’s (and its affiliates) existing, approved, and proposed MRI scanners is based on reasonable and supported assumptions. Therefore, CMHA demonstrates the need the population it projects to serve has for the proposed fixed MRI scanner. NHI Matthews does not demonstrate that the projected utilization of Novant Health’s (and its affiliates) existing, approved, and proposed MRI scanners is based on reasonable and adequately supported assumptions, as discussed previously. Therefore, NHI Matthews did not demonstrate the need the population it projects to serve has for the proposed fixed MRI scanner. Therefore, the proposal submitted by CMHA is the most effective with regard to demonstration of need.

Geographic Accessibility (Location within the Service Area)

The service area for the MRI is Mecklenburg County. The table below follows the same analysis the Agency conducted in its 2019 Mecklenburg County MRI review and provides the location of the existing fixed MRI scanners in Mecklenburg County, summarized from Table 9P of the *Proposed 2022 SMFP* and publicly available information.

<b>Facility</b>	<b>Location</b>	<b># of Scanners Per Facility</b>	<b>Population Estimate as of July 2019</b>	<b>Population Per Scanner</b>
Atrium Health Pineville	Charlotte	2		
Atrium Health University City	Charlotte	1		
CMC/Atrium Health Mercy	Charlotte	5		
Novant Health Presbyterian Medical Center*	Charlotte	5 <sup>^</sup>		
Atrium Health Kenilworth Diagnostic Center #1	Charlotte	1		
CIS Ballantyne	Charlotte	1		
CIS SouthPark	Charlotte	1		
NHI Ballantyne	Charlotte	1		
NHI SouthPark	Charlotte	2		
OrthoCarolina Ballantyne	Charlotte	1		
OrthoCarolina Spine Center	Charlotte	1		
Carolina Neurosurgery & Spine Associates	Charlotte	1		
<b>Total Charlotte</b>		<b>22</b>	<b>885,708</b>	<b>40,259</b>
CIS Huntersville	Huntersville	1		
Novant Health Huntersville Medical Center	Huntersville	2		
<b>Total Huntersville</b>		<b>3</b>	<b>58,098</b>	<b>19,366</b>
Novant Health Mint Hill Medical Center	Mint Hill	1		
<b>Total Mint Hill</b>		<b>1</b>	<b>27,617</b>	<b>27,617</b>
Novant Health Matthews Medical Center	Matthews	1		
<b>Total Matthews</b>		<b>1</b>	<b>33,138</b>	<b>33,138</b>
<b>Total MRI Scanners</b>		<b>27</b>		

Source: *Proposed 2022 SMFP*.

\*Includes Charlotte Orthopedic Hospital and Novant Health Imaging Museum.

<sup>^</sup>Pursuant to Exemption Record #2983 approved on August 17, 2019, a grandfathered mobile MRI will be replaced with a grandfathered fixed MRI at Novant Health Presbyterian Medical Center resulting in a total of five MRIs on that campus.

Novant Health proposes to locate the additional fixed MRI scanner in Matthews, Mecklenburg County. In contrast, CMHA proposes to locate the additional fixed MRI scanner in Charlotte, Mecklenburg County. Neither applicant is proposing to locate the additional scanner in Huntersville or Mint Hill. Based on the Mecklenburg County population estimates as of July 1, 2019, the most recently available information from the US Census Bureau, 40,259 people are using the MRI scanners located in Charlotte on a per capita basis as opposed to only 33,138 people using the MRI scanner in Matthews on a per capita basis, as illustrated in the table above. Based on the same analysis as in the 2019 review, the geographic location of the MRI



scanner in Charlotte is a more effective alternative for MRI services in Mecklenburg County for the reasons stated above.

Thus, the Charlotte location proposed by CMHA – as opposed to the Matthews location proposed by Novant Health – is the most effective alternative for the development of an additional fixed MRI scanner located in Mecklenburg County under this analysis.

Geographic Reach

According to patient origin data submitted on license renewal applications (LRAs), only 58.5 percent of patients served by Mecklenburg County fixed MRI providers originate from within the county. As shown in the table below, South Carolina patients comprise 12.4 percent of total MRI scans performed by Mecklenburg County fixed MRI providers followed by neighboring North Carolina counties.

**FFY 2019 Total Patient Origin for  
Mecklenburg County Fixed MRI Providers**

<i>NC County/State of Origin</i>	<i>Percent of Total</i>
Mecklenburg	58.5%
South Carolina	12.4%
Union	9.9%
All Others^	5.2%
Gaston	4.0%
Cabarrus	2.6%
Iredell	2.0%
Lincoln	2.0%
Other States	1.6%
Cleveland	1.0%
Rowan	0.8%
<b>Total</b>	<b>100.0%</b>

Source: 2020 LRAs as compiled in the Healthcare Planning Section 2020 LRA Database, the most recent available.

^Includes all other North Carolina counties not listed on the table.

As noted on pages 43-44 of CMHA’s application, without the demand for MRI services originating from outside of Mecklenburg County, there would not be a need for additional fixed MRI capacity to be located in Mecklenburg County. As CMHA demonstrates in its application, Mecklenburg County would have a surplus of 10.5 fixed equivalents or more than one-third of its existing capacity, if not for the demand for MRI services originating from outside of the county. Under these circumstances, CMHA believes the Agency should recognize that the need for additional MRI capacity in Mecklenburg County is driven by residents across the region and evaluate an applicant’s geographic reach in assessing the need for additional MRI capacity in Mecklenburg County.

As noted on page 36 of the NHI Matthews application, Novant Health assumes that its service area will be similar to that of Novant Health Matthews Medical Center’s outpatient MRI patient origin and indicates that as such, it projects that Mecklenburg and Union counties will represent 90 percent of its MRI patients. In contrast, CMHA projects that Mecklenburg and Union counties will represent 56.5 percent of its MRI

patients. Of note, CMHA overall, and CMC in particular, serves a significant number of patients from the entirety of Health Service Area (HSA) III counties (Cabarrus, Cleveland, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, and Union) as well as from South Carolina. In fact, more than 40 percent of CMC’s MRI patients originate from the seven counties in the HSA other than Mecklenburg and from South Carolina, highlighting the extent of CMC’s geographic reach and its service to those patients that utilize Mecklenburg County MRI units.

Based on the discussion above, with regard to geographic reach, CMHA is the most effective alternative.

Access by Underserved Groups

The following table illustrates the percent of total MRI procedures to be provided to Medicaid, Medicare, and Self Pay patients as stated in Section L.3 of the respective applications:

	<b>CMHA – CMC</b>	<b>Novant Health – NHI Matthews</b>
Percent of Total MRIs to be provided to Medicare Recipients	29.5%	39.3%
Percent of Total MRIs to be provided to Medicaid Recipients	18.7%	5.6%
Percent of Total MRIs to be provided to Self Pay Patients	15.3%	3.7%

Source: Sections L.3 of the respective applications.

As shown above, NHI Matthews projects to serve a higher percentage of Medicare MRI patients compared to CMHA. However, CMHA proposes to serve more Medicaid and Self Pay MRI patients.

The following table illustrates the percent of total MRI procedures to be provided to women, individuals aged 65 and older, and racial minorities as stated in Section C.6 of the respective applications:

	<b>CMHA – CMC</b>	<b>Novant Health – NHI Matthews</b>
Percent of Total MRIs to be provided to Women Recipients	59.4%	51.9%
Percent of Total MRIs to be provided to Age 65+ Recipients	22.6%	39.3%
Percent of Total MRIs to be provided to Racial Minority Patients	59.8%	42.7%

Source: Sections C.6 of the respective applications.

As shown above, NHI Matthews projects to serve more individuals aged 65 and older compared to CMHA. However, CMHA proposes to serve more women and racial minorities.

On page 133 of its application, Novant Health indicates that it utilized Novant Health Matthews Medical Center data to project charity care patients. Namely, Novant Health states “Charity care is estimated to be 2.5% for services based on the actual gross revenue value of charity care provided in CY2020 at Novant

*Health Matthews Medical Center outpatients receiving an MRI scan.”* However, Novant Health then goes on to note (also on page 133 of its application) that *“Novant Health Matthews Medical Center data was used because the hospital-based MRI service provides a higher level of charity care.”* Therefore, by Novant Health’s own admission, its charity care projections are overstated. Given Novant Health’s overstated charity care projections – which it acknowledges on page 133 of its application – NHI Matthews failed to demonstrate the reasonableness of its assumptions with regard to its projection of charity care patients. Moreover, it bears mention that Novant Health’s assumptions relative to charity care, which rely on an acute care hospital facility, are inconsistent with its assumptions relative to revenues, contractuals, and expenses, which rely on an existing Novant Health IDTF, NHI Southpark.<sup>16</sup>

Given the discussion above, CMHA is the more effective alternative with regard to access to underserved groups.

Revenues

The following table illustrates each applicant’s projected total gross revenue and total net revenue per procedure in the third project year.

	<b>CMHA – CMC (PY3)</b>	<b>Novant Health – NHI Matthews (PY3)</b>
Unweighted MRI Procedures	17,882	4,368
Gross Revenue	\$101,482,803	\$12,052,764
<b>Gross Revenue per Procedure</b>	<b>\$5,675</b>	<b>\$2,759</b>
Net Revenue	\$27,467,845	\$2,268,554
<b>Net Revenue per Procedure</b>	<b>\$1,536</b>	<b>\$519</b>

As shown above, NHI Matthews projects lower average net revenue per MRI procedure. However, the scope of service differs significantly between CMC, a quaternary facility providing inpatient services, and NHI Matthews, a diagnostic center providing only outpatient services. Inpatient services will generate a higher net revenue per procedure due to the higher acuity and complexity of services. As discussed on page 44 of CMC’s application, Atrium Health’s MRI scanners have the highest MRI complexity mix of any MRI provider in Mecklenburg County, including Novant Health. Differences in the type of facility and the services offered by each of the facilities impacts the averages shown in the table above. Thus, the result of this analysis is inconclusive.

Notwithstanding the foregoing discussion, it bears mention that relative to its revenue assumptions, Novant Health provides inconsistent information regarding the basis of its assumptions. While Novant Health indicates on page 133 of its application that its assumptions relative to revenues rely on an existing Novant Health IDTF, NHI Southpark, Novant Health also provides conflicting information on the same page

<sup>16</sup> While Novant Health indicates on pages 133 and 137 of its application that its assumptions relative to revenues, contractuals, and expenses rely on an existing Novant Health IDTF, NHI Southpark, it should be noted that Novant Health also provides conflicting information on pages 133 and 137 of its application in which it states *“NHI Matthews data was used because NHI Matthews is an IDTF.”* Not only are such statements inconsistent with statements made on the same pages regarding NHI Southpark serving as the basis for these assumptions, but also, such statements are simply false as NHI Matthews is not an existing IDTF.

of its application – page 133 – in which it states “NHI Matthews data was used because NHI Matthews is an IDTF.” Not only are such statements inconsistent with statements made on the same page regarding NHI Southpark serving as the basis for these assumptions, but also, such statements are simply false as NHI Matthews is not an existing IDTF. These inconsistent statements call into question the reasonableness of Novant Health’s financial assumptions.

Operating Expenses

The following table illustrates each applicant’s operating expenses per procedure in the third project year.

	<b>CMHA – CMC (PY3)</b>	<b>Novant Health – NHI Matthews (PY3)</b>
Operating Expenses	\$7,589,545	\$1,658,736
Unweighted MRI Procedures	17,882	4,368
Operating Expenses per Procedure	<b>\$424</b>	<b>\$380</b>

As shown above, NHI Matthews projects lower average operating cost per MRI procedure. However, the scope of service differs significantly between CMC, a quaternary facility providing inpatient services, and NHI Matthews, a diagnostic center providing only outpatient services. Inpatient services will generate a higher operating cost per procedure due to the higher acuity and complexity of services. As discussed on page 44 of CMC’s application, Atrium Health’s MRI scanners have the highest MRI complexity mix of any MRI provider in Mecklenburg County, including Novant Health. Differences in the type of facility and the services offered by each of the facilities impacts the averages shown in the table above. Thus, the result of this analysis is inconclusive.

Further, and as noted above relative to its revenue assumptions, Novant Health also provides inconsistent information regarding the basis of its expense assumptions. While Novant Health indicates on page 137 of its application that its assumptions relative to expenses rely on an existing Novant Health IDTF, NHI Southpark, Novant Health also provides conflicting information on the same page of its application – page 137 – in which it states “NHI Matthews data was used because NHI Matthews is an IDTF.” Not only are such statements inconsistent with statements made on the same page regarding NHI Southpark serving as the basis for these assumptions, but also, such statements are simply false as NHI Matthews is not an existing IDTF. These inconsistent statements call into question the reasonableness of Novant Health’s financial assumptions.

**SUMMARY**

As noted previously, CMHA maintains that the NHI Matthews application cannot be approved as proposed given its non-conformity with Criteria 1, 3, 4, 5, 6, 18a, and 10A NCAC 14C .2703. As such, CMHA is the only approvable application. Based on the comparative analysis summarized below, CMHA believes that its application represents the most effective alternative for meeting the need in the 2021 SMFP for an additional fixed MRI scanner in Mecklenburg County.

<i>Comparative Factor</i>	<i>CMHA – CMC</i>	<i>Novant Health – NHI Matthews</i>
Conformity with Applicable Statutory and Regulatory Review Criteria	More Effective	Less Effective
Scope of Services	More Effective	Less Effective
Historical Utilization	More Effective	Less Effective
Meeting the Need for Additional MRI Capacity	More Effective	Less Effective
Demonstration of Need	More Effective	Less Effective
Geographical Accessibility (Location within the Service Area)	More Effective	Less Effective
Geographic Reach	More Effective	Less Effective
Access by Underserved Groups	More Effective	Less Effective
Revenues	Inconclusive	Inconclusive
Operating Expenses	Inconclusive	Inconclusive

In summary, CMHA believes that its application is clearly the most effective alternative for an additional fixed MRI scanner needed in Mecklenburg County. CMHA’s application is also fully conforming to all applicable statutory and regulatory review criteria and comparatively superior on the relevant factors in this review. As such, the proposal by CMHA to develop an additional fixed MRI scanner at CMC can and should be approved.

***Please note that in no way does CMHA intend for these comments to change or amend its application filed on August 16, 2021. If the Agency considers any of these comments to be amending CMHA’s application, those responses should not be considered.***

ATTACHMENT - REQUIRED STATES AGENCY FINDINGS  
FINDINGS

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

DECISION DATE: April 28, 2006  
FINDINGS DATE: May 5, 2006

PROJECT ANALYST: Ronald Loftin  
SECTION CHIEF: Lee Hoffman

PROJECT I.D. NUMBER: J-7442-05/ Alliance Imaging, Inc. (Lessor) and Atlantic Diagnostic Center (Lessee) / Acquire by lease a mobile 1.5 Tesla MRI scanner to serve sites in Alamance, Durham and Duplin Counties

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

Alliance Imaging, Inc. (“**Alliance Imaging**”) proposes to purchase a new mobile MRI scanner and lease it to Atlantic Diagnostic Center, PA (“**ADC**”). There are no policies in the 2005 State Medical Facilities Plan (SMFP) applicable to the review of applications for acquisition of mobile MRI scanners. Further, because the 2005 SMFP does not contain a methodology for determining need for a mobile MRI scanner, there is no applicable need determination for mobile MRI scanners. Consequently, this criterion is not applicable to the proposal to acquire a mobile MRI scanner.

- (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

the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

NC

The applicants failed to adequately demonstrate that their proposal to acquire a mobile MRI scanner will have a positive impact upon the cost effectiveness and access to the proposed services. Therefore, the applicants are not conforming with this criterion. See Criteria (3), (5), and (13) for discussion.

- (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.

NA

- (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 States 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

The proposal does not conform with all applicable Criteria and Standards for Magnetic Resonance Imaging Services required by 10A NCAC 14C Section .2700, as indicated below.

**.2702**

**Information Required of Applicant**

- (a) *“An applicant proposing to acquire an MRI scanner, including a Mobile MRI scanner, shall use the Acute Care Facility/Medical Equipment application form.”*
  - C- The applicants used the appropriate 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 services shall be named as co-applicant in the application form.”*
  - NA- The applicants propose a mobile MRI scanner.

- (c) *“An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall also provide the following additional information:*
- (1) *documentation that the MRI scanner shall be available and staffed for use at least 66 hours per week, with the exception of a mobile MRI scanner;”*
- NA- The applicants propose an mobile MRI scanner.
- (2) *“documentation that the proposed mobile MRI scanner shall be available and staffed for use at least 40 hours per week;”*
- C- The applicants propose the mobile MRI scanner will operate seven days per week, twelve hours per day.
- (3) *“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 fees is included in the charge, provide the dollar amount for the professional fee;*
- NC- The applicants provided the average global charge to the patient for only 18 MRI procedures to be performed most frequently in the first three years of operation at each of the three proposed sites, in Section X.2 of the application. [Note: Twenty procedures are listed but two are duplicates.] The applicants state that the projected global MRI charges include the procedure charge and the radiology interpretation fee. The radiology interpretation fee ranges from \$109 to \$522 depending upon the MRI procedure. However, because charges for 20 procedures were not provided, the applicants are not conforming with this rule.
- (4) *“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;*
- C- The applicants state on page 18 of the application: *“Not applicable. A service agreement is not proposed because the proposed mobile MRI host sites are owned by the applicant.”* However, the application contains in Exhibit 25 an unsigned MRI service agreement between Alliance Imaging and ADC, which lists a fee of \$1,000 per day to be billed by Alliance Imaging to ADC.
- (5) *“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”*
- NC- In Exhibit 10 of the application, the applicants provide 15 letters from physicians, which include 12 physicians in Durham County and 3 physicians



in Duplin County indicating their intent to refer patients to the proposed mobile MRI sites. However, none of the letters provide an estimate of the number of patients to be referred to the scanner. Also, no letters are provided from physicians regarding referrals to the mobile MRI scanner located in Alamance County. Therefore, the applicants are not conforming with this rule.

- (6) *“for each location at which the service will be provided, projections of the annual number of weighted MRI procedures to be performed for each of the four types of weighted MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project.”*

- C- The 2005 SMFP, on page 114, introduces a system of weighting values by procedure type, as shown in the table below. As defined in 10A NCAC 14C .2700, *“‘Weighted MRI procedures’ means MRI procedures which are adjusted to account for the length of time to complete the procedure, based on the following weights: one outpatient MRI procedure without contrast or sedation is valued at 1.0 weighted MRI procedure, one outpatient MRI procedure with contrast or sedation is valued at 1.4 weighted MRI procedures, one inpatient MRI procedure without contrast or sedation is valued at 1.4 weighted MRI procedures; and one inpatient MRI procedure with contrast or sedation is valued at 1.8 weighted MRI procedures.”*

MRI Procedure Type	Base Weight	Inpatient Weight	Contrast Weight	Procedure Time Minutes
<b>Outpatient/ No Contrast/ Sedation</b>	1.0	0.0	0.0	30
<b>Outpatient/ With Contrast/ Sedation</b>	1.0	0.0	.4 (Add 12 minutes)	42
<b>Inpatient/ No Contrast/ Sedation</b>	1.0	.4 (Add 12 minutes)	0.0	42
<b>Inpatient/ With Contrast/ Sedation</b>	1.0	.4 (Add 12 minutes)	.4 (Add 12 minutes)	54

Using the four types of weighted MRI procedures as identified in the SMFP, the applicants provide in Section IV, the following projections for the first three operating years of the proposed project at the three proposed host sites. See Criterion (3) for discussions of reasonableness of projections.

<b>Site: ADC Burlington</b>	Year 1 2007	Year 2 2008	Year 3 2009
<b>Outpatient Without Contrast</b>	1170	1346	1463
<b>Outpatient With Contrast</b>	546	628	683
<b>Inpatient Without Contrast</b>	0	0	0
<b>Inpatient With Contrast</b>	0	0	0
<b>Totals</b>	1716	1973	2145

Source: Section IV of the application.

<b>Site: ADC Durham</b>	Year 1 2007	Year 2 2008	Year 3 2009
<b>Outpatient Without Contrast</b>	1053	1229	1346
<b>Outpatient With Contrast</b>	491	573	628
<b>Inpatient Without Contrast</b>	0	0	0
<b>Inpatient With Contrast</b>	0	0	0
<b>Totals</b>	1544	1802	1973

Source: Section IV of the application.

<b>Site: ADC Wallace</b>	Year 1 2007	Year 2 2008	Year 3 2009
<b>Outpatient Without Contrast</b>	351	390	429
<b>Outpatient With Contrast</b>	164	182	200
<b>Inpatient Without Contrast</b>	0	0	0
<b>Inpatient With Contrast</b>	0	0	0
<b>Totals</b>	515	572	629

Source: Section IV of the application.

<b>ADC mobile MRI scanner Total for Three Sites</b>	Year 1 2007	Year 2 2008	Year 3 2009
<b>Outpatient Without Contrast</b>	2574	2964	3237
<b>Outpatient With Contrast</b>	1201	1383	1511
<b>Inpatient Without Contrast</b>	0	0	0
<b>Inpatient With Contrast</b>	0	0	0
<b>Totals</b>	3775	4347	4748

Source: Section IV of the application.

- (7) *“a detailed description of the methodology used to project the number of weighted MRI procedures to be performed;”*
- C- The applicants’ methodology used to project the number of weighted MRI procedures is described in Section III, pages 31-37 of the application. See Criterion (3) for discussion regarding reasonableness of methodology.
- (8) *“documentation to support each assumption used in projecting the number of procedures to be performed;”*

- NC- The applicants failed to provide adequate documentation to support each of their assumptions. See Criterion (3) for discussion.
- (9) *“for each existing fixed or 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, physical location for fixed MRI scanners, and host sites for mobile MRI scanners;”*
- NC- The applicants state on page 19 that ADC has no fixed or mobile MRI scanners. In Exhibit 4, Alliance Imaging lists 29 MRI scanners, which includes fixed and mobile units owned by Alliance Imaging and related companies in North Carolina. Alliance Imaging provides the vendor, Tesla strength, and serial number for its MRI scanners. However, Alliance Imaging does not provide the host sites for each of its mobile MRI scanners, operated in the month the application was submitted, as required by this rule. Further, the applicants do not provide the location for Alliance’s fixed MRI scanners. In addition, although at least three of the MRI scanners on Alliance’s list were acquired pursuant to a certificate of need, the applicants did not provide the CON project identification number. Therefore, the applicants are not conforming with this rule.
- (10) *“for each approved fixed or mobile MRI scanner to be owned by the applicant or a related entity and approved to be operated in North Carolina, the proposed vendor, proposed tesla strength, CON project identification number, physical location for fixed MRI scanners, and host sites for mobile MRI scanners;”*
- NA- In Section II.8, page 19, the applicants state, in response to 10A NCAC 14C .2702(c)(10), *“Not applicable. The applicant has no approved fixed or mobile MRI equipment in North Carolina.”* However, the word *“applicant,”* as used by the applicants in that sentence, refers only to ADC. The application does not include a statement as to whether Alliance or its related entities have any approved fixed or mobile MRI scanners that were not operational prior to the beginning of the review. Nevertheless, a review of the records in the Certificate of Need Section indicates that Alliance and its related entities had no undeveloped approved MRI scanners prior to the beginning of the review.
- (11) *“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.”*
- C- The applicants propose to provide MRI service to one host site in Burlington in Alamance County, one host site in Durham County and one host site in Wallace in Duplin County. There are fixed MRI scanners currently located in both Alamance and Durham Counties. In Section II of

the application, the applicants state the selection of the proposed host sites is based on: *“high demand for MRI service by an underserved population; strong market potential and physician referral relationships; availability of appropriate host site facility.”* See Criterion (3) for discussion of the reasonableness of the applicants’ assumptions for selection of the host sites.

(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.”*

-C- The applicants state: *“Not applicable. The proposed MRI scanner will serve host sites that are owned by the applicant.”* However, the applicants did provide a copy of the contract between Alliance Imaging and ADC for provision of services at each of ADC’s host sites.

(e) *“An applicant proposing to acquire a dedicated fixed breast MRI scanner shall: (1) provide a copy of a contract or working agreement with a radiologist or practice group that is competent, qualified, and trained to interpret images produced by an MRI scanner configured exclusively for mammographic studies; (2) document that the applicant performed mammograms continuously for the last year; and (3) document that the applicant’s existing mammography equipment is in compliance with the U.S. Food and Drug Administration Mammography Quality Standards Act.”*

-NA- The applicants are not proposing a dedicated fixed breast MRI scanner.

(f) *“An applicant proposing to acquire a dedicated fixed pediatric MRI scanner shall: (1) provide a copy of a contract or working agreement with two pediatric radiologists qualified as described in 10A NCAC 14C .2705(f)(1); (2) provide a copy of the facility’s emergency plan for pediatric and special needs patients that outline all emergency procedures including acute care transfers and a copy of a contract with an ambulance service for transportation during any emergencies; (3) commit that the proposed MRI scanner shall be used exclusively to perform procedures on pediatric MRI patients; (4) provide a description of the scope of the research studies that shall be conducted to develop protocols related to MRI scanning of pediatric MRI patients; which includes special needs patients, and (5) commit to prepare an annual report, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, which shall include the protocols for scanning pediatric MRI patients and the annual volume of weighted MRI procedures performed, by type.”*

-NA- The applicants are not proposing a dedicated pediatric MRI scanner.

- (a) *“An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner.*
- (1) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns 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.];*

-NC- The applicants state *“Not applicable. The applicant does not own or operate any mobile MRI scanners in North Carolina.”* However, Alliance Imaging is one of the applicants. Specifically, the application contains a certification page signed by Alliance Imaging and identifies the mobile MRI scanners owned and operated by Alliance Imaging in response to 10A NCAC 14C .2702(c)(9). Also, Alliance Imaging will purchase the proposed MRI scanner. Therefore, Alliance Imaging is required to provide the requested information on its mobile MRI scanners operated in the applicable mobile MRI region which is defined in 10A NCAC .2701 (8). In this review the applicants propose to locate the mobile MRI scanner in HSA II which is in the western part of the state, and in HSAs IV and VI in the eastern part of the state. Therefore, the applicants must provide the requested utilization data for all MRI scanners operated in the western (I, II, III) and eastern (IV, V, VI) mobile MRI regions. However, the applicants provide no utilization data for the mobile MRI scanners Alliance Imaging owns and operates in the two mobile MRI regions. Therefore, the applicants are not conforming with this rule.

- (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.];*

-NC- The rule requires Alliance to provide projections for its existing, approved and proposed mobile MRI scanners operated in the eastern mobile MRI region (IV, V, VI). In Section II.8, page 19, the applicants state, in response to 10A NCAC 14C .2702(c)(10), that *“The applicant has no approved fixed or mobile MRI equipment in North Carolina.”* However, the word *“applicant,”* as used by the applicants in that sentence, refers only to ADC. The application does not include a statement as to whether Alliance or its related entities have any approved fixed or mobile MRI scanners that were not operational prior to the beginning of the review. Nevertheless, a review of the records in the Certificate of Need Section indicates that Alliance and

its related entities had no undeveloped approved MRI scanners prior to the beginning of the review. However, Alliance does operate numerous mobile MRI scanners in the eastern mobile MRI region, but no projections were provided for these MRI scanners.

With regard to the applicants' "proposed" mobile MRI scanner, the applicants project in Section IV of the application that it will perform a total of 4,748 weighted MRI procedures in "Year 3 10/08 –9/09." However, the applicants did not adequately demonstrate that the projections are reasonable and therefore did not demonstrate that the proposed mobile MRI scanner is reasonably projected to perform at least 3,328 weighted MRI procedures. See Criterion (3) for discussion. In summary, the applicants are not conforming with this rule.

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

-NC- The applicants failed to provide adequate documentation to support each assumption. See Criterion (3) for discussion. Therefore, the applicants are not conforming with this rule.

- (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 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; (2) demonstrate that each existing mobile MRI scanner, which the applicant or a related entity owns and operates in the proposed mobile MRI region, 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.]; (3) demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns 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;

(4) demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns 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.]; (5) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.”

-NA- The applicants propose to acquire a mobile MRI scanner.

(c) “An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner for which the need determination in the States 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 1,716 weighted MRI procedures per year; and” (2) “document the assumptions and provide data supporting the methodology used for each projection required in this Rule.”

-NA- The applicants do not propose a fixed MRI scanner as described in Paragraph (c) of this rule.

(d) “An applicant proposing to acquire a dedicated fixed pediatric MRI scanner shall: (1) demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 2746 weighted MRI procedures (i.e., 80 percent of one procedure per hour, 66 hours per week, 52 weeks per year); and (2) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.”

-NA- The applicants are not proposing to acquire a dedicated pediatric MRI scanner.

#### .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 proposed MRI service area to document the availability of MRI services if patients require them when the mobile unit is not in service at that host site.”

-NC- The applicants provide in Exhibit 15 a letter from ADC stating that informal agreements exist between ADC and local hospitals with local hospitals agreeing to accept patients for MRI services. However, the applicants do not provide a copy of a referral agreement between each host site and another provider of MRI services in the service area for referral of patients needing an MRI scan on days when the proposed mobile MRI scanner is not available at the host site. Therefore, the applicants are not conforming to this rule.

(b) *“An applicant proposing to acquire a dedicated fixed pediatric MRI scanner shall provide a written policy regarding pediatric sedation which outlines the criteria for sedating a pediatric patient, including the special needs patients, and identifies the staff that will administer and supervise the sedation process.”*

-NA- The applicants are not proposing to acquire a dedicated pediatric MRI scanner.

(c) *“An applicant proposing to acquire a dedicated fixed pediatric MRI scanner shall provide evidence of the availability of a pediatric code cart at the facility where the proposed pediatric MRI scanner will be located and a plan for emergency situations as described in 10A NCAC 14C .2702(f)(2).”*

-NA- The applicants are not proposing to acquire a dedicated pediatric MRI scanner.

(d) *“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- The applicants state in Exhibit 8 that ADC will obtain accreditation from the Joint Commission for the Accreditation of Healthcare Organizations for MRI services within two years following completion of the project.

**.2705**

**Staffing and Staff Training**

(a) *“An applicant proposing to acquire an MRI scanner shall demonstrate that one diagnostic radiologist certified by the American Board of Radiologists shall be available to provide the proposed services 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- The applicants provide in Exhibits 5 and 18 of the application documentation of MRI trained board certified diagnostic radiologists for the proposed MRI scanner at each of the three proposed host sites. The applicants state George Eason, M.D. has agreed to serve as Medical Director at all three proposed sites.
  
- (b) *“An applicant proposing to acquire a dedicated fixed breast MRI scanner shall provide documentation that the radiologist is trained and has experience in interpreting images produced by an MRI scanner configured exclusively to perform mammographic studies.”*
- NA- The applicants are not proposing to acquire a dedicated fixed breast MRI scanner.
  
- (c) *“An applicant proposing to acquire a MRI scanner shall provide evidence of the availability of two full-time MRI technologist-radiographers and that one of these technologists shall be present during the hours of operation of the MRI scanner.”*
- C- In Sections II and VII.2 of the application, ADC states it will contract with Alliance Imaging for 2.5 FTE MRI technologists. The applicants state this will enable at least one of the MRI technologists to be on site during operating hours. The applicants are conforming with this criterion.
  
- (d) *“An applicant proposing to acquire an MRI scanner 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- The applicants state in Section II that all radiology technologists are required to be certified in CPR and basic life support training.
  
  - (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- The applicants state that it *“provides an organized program of staff education that relates to MRI services for each of the host sites.”*
  
- (e) *“An applicant proposing to acquire a mobile MRI scanner shall document that the requirements in Paragraphs (a) and (c) of this Rule shall be met at each host facility.”*
- C- The applicants document that radiology coverage will be available at each site and that at least one of the MRI technologists will be on site at each host facility during operating hours of the mobile MRI scanner.
  
- (f) *“An applicant proposing to acquire a dedicated fixed pediatric MRI scanner shall: (1) provide documentation of the availability of at least two*

*radiologists, certified by the American Board of Radiology, with a pediatric fellowship or two years of specialized training in pediatrics; (2) provide evidence that the applicant will have at least one licensed physician on-site during the hours of operation of the proposed MRI scanner; (3) provide documentation that the applicant will employ at least two licensed registered nurses and that one of these nurses shall be present during the hours of operation of the proposed MRI scanner; (4) provide a description of a research group for the project including a radiologist, neurologist, pediatric sedation specialist and research coordinator; (5) provide documentation of the availability of the research group to conduct research studies on the proposed MRI scanner; and (6) provide letters from the proposed members of the research group indicating their qualifications, experience and willingness to participate on the research team.”*

-NA- The applicants are not proposing to acquire a dedicated pediatric 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- The applicants state in Section II of the application that they are not proposing to perform cardiac MRI studies.

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

## FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 28, 2009  
 FINDINGS DATE: January 5, 2010  
 PROJECT ANALYST: Gregory F. Yakaboski  
 TEAM LEADER: Martha J. Frisone

PROJECT I.D. NUMBER: G-8372-09/ North Carolina Baptist Hospital, Inc./ Acquire a sixth fixed MRI scanner/ Forsyth County

G-8376-09/ Piedmont Imaging, LLC/Acquire a fixed MRI scanner and develop a diagnostic center/ Forsyth County

## REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C – NCBH

NC- PI-North

The 2009 State Medical Facilities Plan (2009 SMFP) provides a methodology for determining the need for additional fixed MRI scanners in North Carolina by service area. Application of the need methodology in the 2009 SMFP identified a need for one fixed MRI scanner in Forsyth County. Two applications were submitted to the Certificate of Need Section, each proposing to acquire a fixed MRI scanner for Forsyth County. Each proposal is briefly described below.

**North Carolina Baptist Hospital, Inc. (“NCBH”)** currently owns and operates 5 fixed MRI scanners on the NCBH campus. In this application, the applicant proposes to obtain a sixth fixed MRI scanner to be located in an existing radiology suite on the 4<sup>th</sup> floor of the Comprehensive Cancer Center. The applicant proposes to acquire no more than one fixed MRI scanner to be located in Forsyth County. Consequently, the application is conforming to the need determination in the 2009 SMFP.

C – NCBH  
NC – PI-NORTH

**NCBH** adequately demonstrated that the proposal will have a positive impact upon the cost effectiveness, quality, and access to the proposed services. See Criteria (1), (3), (5), (7), (8) (13) and (20). Therefore, the application is conforming to this criterion.

**PI-NORTH** did not adequately demonstrate that the proposal will have a positive impact upon the cost effectiveness of the proposed services. See Criteria (1) and (5). Therefore, the application is nonconforming 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- NCBH  
NA – PI North

North Carolina Baptist Hospital is accredited by the Joint Commission (formerly the Joint Commission on Accreditation of Health Care Organizations) and certified for Medicare and Medicaid participation. According to the Acute and Home Care Licensure and Certification Section, DHSR, 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 with this criterion.

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

C – Both Applications

**NCBH** The proposal is conforming to all Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700. The specific criteria are discussed below.

**PI-NORTH** The proposal is conforming to all Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700. The specific criteria are discussed below.

**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 Facility/Medical Equipment application form.

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

-C- **NCBH** – In Section II.8, page 29, NCBH states it will bill the patients for MRI services.

-C- **PI-North**– In Section II.8, page 26, PI-North states it will bill the patients for MRI services.

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

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

-C- **NCBH** – In Section II.8, page 29, the applicant states the proposed MRI scanner will be available and staffed at least 70 hours per week.

-C- **PI-North** – In Section II.8, page 26, the applicant states the proposed MRI scanner will be available and staffed at least 68 hours per week.

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

-NA- **Both Applicants** – The applicants do not propose 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- **Both Applicants** – The applicants do not propose 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- **NCBH** – In Section II.8, page 30, and in Exhibit 5, the applicant provides the projected charges for the 20 MRI procedures to be performed most frequently during the first three years of operation.
  
- C- **PI-NORTH** – In Section II.8, pages 26-27, the applicant provides the projected charges for the 20 MRI procedures to be performed most frequently during the first three years of operation. In Section II.8, page 26, the applicant states the charges include both the technical and professional fee components. The dollar amount is provided for the professional fee component.
  - (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- **Both Applicants** – The applicants do not propose to provide the 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- **NCBH** – Exhibit 6 of the application 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 scans.
  
- C- **PI-NORTH** – Attachment 29 of the application 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 each year, which is based on the physicians' historical number of referrals for MRI studies to Piedmont.
  - (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- **NCBH** – In Section II.8, page 30, the applicant states NCBH currently operates five fixed MRI scanners. The applicant proposes to locate and operate a sixth fixed MRI scanner at NCBH. The applicant also states that the “*The AC-3 MRI acquired in 2004 is not included in this inventory as it is not a clinical scanner and is not counted in NCBH's MRI inventory in the North Carolina State Medical Facilities Plan.*” The applicant also states that the “*WFUBMC Outpatient Imaging, LLC, of which NCBH is 33% owner will operate one MRI scanner.*”
  
- C- **PI-NORTH** – In Section II.8, pages 28-29, the applicant states that Novant and its related entities “*own a total of nine existing and approved fixed MRI scanners*” which are located in

Forsyth County. These 9 fixed MRI scanners and the proposed fixed MRI scanner are located as follows:

Location	Units
Forsyth Medical Center (1)	3
MedQuest Piedmont Imaging-Winston Salem	2
Forsyth Medical Center Imaging- Salem MRI Center (2) (3)	1
Forsyth Medical Center Imaging- Maplewood	2
MedQuest Piedmont Imaging- Kernersville (approved but not operational)	1
Piedmont Imaging- North (proposed) (4)	1
Total	10

- (1) Forsyth Medical Center is approved for one additional MRI that is not yet operational for a total of 3 fixed MRI scanners at FMC.
- (2) One MRI scanner was relocated from FMCI-Salem to FMCI-Maplewood in June 2008.
- (3) A dedicated breast MRI scanner is operational at Forsyth Medical Center Imaging-Salem but has not been included in this summary or in the analyses presented in this application for general MRI services.
- (4) With this application the PI-North proposes to locate a fixed MRI scanner at 985 Pinebrook Knolls Drive, Winston-Salem, NC.

(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- **NCBH** – In Section II.8, page 31, Section III.1(b), page 50, and Exhibit 7, the applicant provides projections of the number of unweighted MRI procedures to be performed on its existing fixed MRI scanners and on the proposed fixed MRI scanner for the first three years following completion of the project, as illustrated in the following table:

**NCBH: Projected Unweighted MRI procedures**

		Year 1	Year 2	Year 3
# of Units*		6	6	6
Outpatient	Without Contrast	5,196.72	5,326.56	5,459.76
Outpatient	With Contrast	10,393.44	10,653.12	10,919.52
Inpatient	Without Contrast	1,602.322	1,642.356	1,683.426
Inpatient	With contrast	4,460.518	4571.964	4,686.294
<b>TOTALS</b>		21,653	22,194	22,749

\*5 existing and 1 proposed.

In Exhibit 7, the applicant provides the projected number of unweighted MRI procedures to be performed on the existing fixed MRI scanner at WFUBMC Outpatient Imaging, which is a related entity of NCBH, as illustrated in the table below.

**WFUBMC Outpatient Imaging: Unweighted MRI Procedures**

		FY 2009 Actual (Nov 2008-Jun 2009/ 8 months)	FY 2010 Interim	FY 2011 Projected	FY 2012 Projected	FY 2013 Projected
# of Units				1	1	1
Outpatient	Without Contrast	717	1,440	1,896	2,432	2,493
Outpatient	With Contrast	522	1,049	1,380	1,771	1,815
Totals		1,239 / 8 mo = 154.9 x 12 mo = 1,859 annualized	2,489	3,276	4,203	4,308
Percentage growth year to year		-na-	33.9%	31.6%	28.3%	2.5%

However, the project analyst notes that in Exhibit 7 the applicant states that “A conservative growth rate of 2.5% was used to project future volumes, which is consistent with the NCBH rate used in this CON applic.” However, as shown in the table above, the applicant did not use a 2.5% growth rate. The table below illustrates projected volumes utilizing a 2.5% growth rate.

**WFUBMC Outpatient Imaging: Unweighted MRI Procedures**

		FY 2009 Actual (Nov 2008-Jun 2009/ 8 months)	FY 2010 Interim	FY 2011 Projected	FY 2012 Projected	FY 2013 Projected
# of Units				1	1	1
Outpatient	Without Contrast	717/8 mo = 89.6 x 12 mo = 1,075 annualized	1,102	1,130	1,158	1,187
Outpatient	With Contrast	522/8 mo = 65.3 x 12 mo = 784 annualized	804	824	845	866
Totals		1,239 / 8 mo = 154.9 x 12 mo = 1,859 annualized	1,906	1,954	2,003	2,053
Percentage growth year to year		-na-	2.5%	2.5%	2.5%	2.5%

See Criterion (3) for discussion.

- C- **PI-NORTH** – In Section II.8, pages 30-32, the applicant provides projections of the number of unweighted MRI procedures to be performed on the existing, approved or proposed fixed MRI



scanners owned by Novant or its related entities for the first three years following completion of the project, as illustrated in the following table:

**Forsyth Medical Center: Projected Unweighted MRI procedures (3 existing fixed scanners)**

		Year 1	Year 2	Year 3
Outpatient	Without Contrast	847	858.55	862.4
Outpatient	With Contrast	1,749	1,772.85	1,780.8
Inpatient	Without Contrast	2,343	2,374.95	2,385.6
Inpatient	With contrast	6,061	6,143.65	6,171.2
TOTALS		11,000	11,150	11,200

**Piedmont Imaging: Winston-Salem: Projected Unweighted MRI procedures (2 existing fixed scanners)**

		Year 1	Year 2	Year 3
Outpatient	Without Contrast	7,617.61	7,572.711	7,465.41
Outpatient	With Contrast	2,392.39	2,378.289	2,344.59
Inpatient	Without Contrast	-na-	-na-	-na-
Inpatient	With contrast	-na-	-na-	-na-
TOTALS		10,010	9,951	9,810

**Maplewood: Projected Unweighted MRI procedures (2 existing fixed scanners)**

		Year 1	Year 2	Year 3
Outpatient	Without Contrast	6,533.468	6,438.726	6,693.858
Outpatient	With Contrast	2,224.532	2,192.274	2,279.142
Inpatient	Without Contrast	-na-	-na-	-na-
Inpatient	With contrast	-na-	-na-	-na-
TOTALS		8,758	8,631	8,973

**Salem MRI: Projected Unweighted MRI procedures (1 existing fixed scanner)**

		Year 1	Year 2	Year 3
Outpatient	Without Contrast	3,936.24	3,915.934	3,920.62
Outpatient	With Contrast	1,103.76	1,098.066	1,099.38
Inpatient	Without Contrast	-na-	-na-	-na-
Inpatient	With contrast	-na-	-na-	-na-
TOTALS		5,040	5,014	5,020

**PI-Kernersville (CON Approved): Projected Unweighted MRI procedures (1 approved fixed scanner)**

		Year 1	Year 2	Year 3
Outpatient	Without Contrast	2,449.265	2,759.484	3,106.649
Outpatient	With Contrast	1,395.735	1,572.516	1,770.351
Inpatient	Without Contrast	-na-	-na-	-na-
Inpatient	With contrast	-na-	-na-	-na-
TOTALS		3,845	4,332	4,877

**Piedmont Imaging- North (Proposed): Projected Unweighted MRI procedures  
(1 proposed fixed scanner)**

		<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>
Outpatient	Without Contrast	2,907.02	3,340	3,524.952
Outpatient	With Contrast	912.98	1,048.971	1,107.048
Inpatient	Without Contrast	-na-	-na-	-na-
Inpatient	With contrast	-na-	-na-	-na-
<b>TOTALS</b>		<b>3,820</b>	<b>4,389</b>	<b>4,632</b>

See Criterion (3) for discussion.

(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- **NCBH** – In Section II.8, page 31, the applicant provides projections of the number of weighted MRI procedures to be performed on its existing fixed MRI scanners and on the proposed fixed MRI scanner for the first three years following completion of the project, as illustrated in the table below:

**NCBH: Projected Weighted MRI procedures at NCBH**

		<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>
# of Units*		<b>6</b>	<b>6</b>	<b>6</b>
Outpatient	Without Contrast	5,197	5,327	5,460
Outpatient	With Contrast (plus contrast adjustment)	14,551	14,914	15,287
Inpatient	Without Contrast	2,243	2,299	2,357
Inpatient	With contrast (plus contrast adjustment)	8,029	8,230	8,435
<b>TOTALS</b>		<b>30,020</b>	<b>30,770</b>	<b>31,539</b>

\* 5 existing and 1 proposed.

In Exhibit 7, the applicant provides the projected number of weighted MRI procedures to be performed on the existing fixed MRI scanner at WFUBMC Outpatient Imaging, which is a related entity of NCBH, as illustrated in the table below.

**WFUBMC Outpatient Imaging: Weighted MRI Procedures (1 existing fixed MRI Scanner)**

		FY 2009 Actual (Nov 2008-Jun 2009/ 8 months)	FY 2010 Interim	FY 2011 Projected	FY 2012 Projected	FY 2013 Projected
# of Units (fixed)		1	1	1	1	1
Outpatient	Without Contrast	717	1,440	1,896	2,432	2,493
Outpatient	With Contrast (plus contrast adjustment)	731	1,468	1,932	2,479	2,541
Totals		1,448 / 8 months = 181 x 12 months = 2,172 annualized	2,908	3,828	4,911	5,034
Percentage Growth Year to Year		-na-	33.9%	31.6%	28.3%	2.5%

The project analyst notes that in Exhibit 7 the applicant states that “A conservative growth rate of 2.5% was used to project future volumes, which is consistent with the NCBH rate used in this CON applic.” However, as shown in the table above, the percentage growth is not 2.5% year to year. Specifically, the growth rate is 33.9% between FY 2009 and FY 2010, 31.6% between FY 2010 and FY 2011, 28.3% between FY 2011 and FY2012; and 2.5% between FY 2012 and FY 2013. It should be noted however, that projected utilization in FY 2011 (3,276) is the same utilization projected in Project I.D. # G-7780-07 for FY 2009 (3,276). Moreover, projected utilization in FY 2012 (4,203) appears to be a transposition of the utilization projected in Project I.D. # G-7780-07 for FY 2010 (4,032). Furthermore, the growth rate between FY 2012 and FY 2013 is 2.5% as stated by the applicant.

As shown in the table above, projected future volumes of MRI scans at WFUBMC did not use a 2.5% growth rate. In the table below the project analyst projects the future volumes utilizing a 2.5% growth rate.

**WFUBMC Outpatient Imaging: Weighted MRI Procedures (1 existing fixed MRI Scanner)**

		FY 2009 Actual (Nov 2008-Jun 2009/ 8 months)	FY 2010 Interim	FY 2011 Projected	FY 2012 Projected	FY 2013 Projected
# of Units (fixed)		1	1	1	1	1
Outpatient	Without Contrast	717/8 mo = 89.6 x 12 mo = 1,075 annualized	1,102	1,130	1,158	1,187
Outpatient	With Contrast (plus contrast adjustment)	731/8 mo = 91.4 x 12 mo = 1,097	1,124	1,152	1,181	1,211
Totals		1,448 / 8 months = 181 x 12 months = 2,172 annualized	2,226	2,282	2,339	2,398
Percentage Growth Year to Year		-na-	2.5%	2.5%	2.5%	2.5%

See Criterion (3) for additional discussion.

- C- **PI-NORTH** – In Section II.8, pages 30-32, the applicant provides projections of the number of weighted MRI procedures to be performed on the existing, approved and proposed fixed MRI scanners owned by Novant or its related entities for the first three years following completion of the project, as illustrated in the table below:

**Forsyth Medical Center: Projected Weighted MRI procedures (3 existing scanners)**

		Year 1	Year 2	Year 3
Outpatient	Without Contrast	847	858.55	862.4
Outpatient	With Contrast	2,448.6	2,481.99	2,493.12
Inpatient	Without Contrast	3,280.2	3,324.93	3,339.84
Inpatient	With contrast	10,909.8	11,058.57	11,108.16
Total		17,486	17,724	17,804

**Piedmont Imaging: Winston-Salem: Weighted MRI procedures  
(2 existing fixed scanners)**

		Year 1	Year 2	Year 3
Outpatient	Without Contrast	7,617.61	7,572.711	7,465.41
Outpatient	With Contrast	3,349.912	3,329.6046	3,282,426
Inpatient	Without Contrast	-na-	-na-	-na-
Inpatient	With contrast	-na-	-na-	-na-
TOTALS		10,967	10,902	10,748

**Maplewood: Projected Weighted MRI procedures (2 existing fixed scanners)**

		Year 1	Year 2	Year 3
Outpatient	Without Contrast	6,533.468	6,438.726	6,693.858
Outpatient	With Contrast	3,114.3448	3,069.1836	3,190.7988
Inpatient	Without Contrast	-na-	-na-	-na-
Inpatient	With contrast	-na-	-na-	-na-
<b>TOTALS</b>		<b>9,648</b>	<b>9,508</b>	<b>9,885</b>

**Salem MRI: Projected Weighted MRI procedures (1 existing fixed scanner)**

		Year 1	Year 2	Year 3
Outpatient	Without Contrast	3,936.24	3,915.934	3,920.62
Outpatient	With Contrast	1,545.264	1,537.2924	1,539.132
Inpatient	Without Contrast	-na-	-na-	-na-
Inpatient	With contrast	-na-	-na-	-na-
<b>TOTALS</b>		<b>5,482</b>	<b>5,453</b>	<b>5,460</b>

**PI-Kernersville: Projected Weighted MRI procedures (1 approved fixed scanner)**

		Year 1	Year 2	Year 3
Outpatient	Without Contrast	2,449.265	2,759.484	3,106.649
Outpatient	With Contrast	1,954.029	2,201.5224	2,478.4914
Inpatient	Without Contrast	-na-	-na-	-na-
Inpatient	With contrast	-na-	-na-	-na-
<b>TOTALS</b>		<b>4,403</b>	<b>4,961</b>	<b>5,585</b>

**Piedmont Imaging- North (Proposed) : Projected Weighted MRI procedures (1 proposed fixed scanner)**

		Year 1	Year 2	Year 3
Outpatient	Without Contrast	2,907.02	3,340	3,524.952
Outpatient	With Contrast	1,278.172	1,468.5594	1,549.8672
Inpatient	Without Contrast	-na-	-na-	-na-
Inpatient	With contrast	-na-	-na-	-na-
<b>TOTALS</b>		<b>4,185</b>	<b>4,809</b>	<b>5,075</b>

See Criterion (3) for additional discussion.

(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- **NCBH** – The applicant’s methodology and assumptions used to project the number of unweighted MRI procedures are described in Section II.8, page 31 and Section III.1, pages 43-55 of the application, including the number of contrast versus non-contrast procedures. See Criterion (3) for discussion of reasonableness of the methodology and assumptions.

-C- **PI-NORTH** – The applicant’s methodology and assumptions used to project the number of unweighted MRI procedures are described in Section II.8, pages 33-34 and Section III.1, pages

51-68 of the application, including the number of contrast versus non-contrast procedures. PI-NORTH does not propose to provide sedation or serve inpatients. See Criterion (3) for discussion of reasonableness of the methodology and assumptions.

(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- **NCBH** – The applicant’s methodology and assumptions used to project the number of weighted MRI procedures are described in Section II.8, page 32 and Section III.1, pages 43-55 of the application. See Criterion (3) for discussion of reasonableness of the methodology and assumptions.

-C- **PI-NORTH** – The applicant’s methodology and assumptions used to project the number of weighted MRI procedures are described in Section II.8, page 34 and Section III.1, pages 51-68 of the application. See Criterion (3) for discussion of reasonableness of the methodology and assumptions.

(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;*

-NA- **NCBH** – The applicant does not own a mobile MRI scanner.

-C- **PI-NORTH** – In Section II.8, pages 34-36, the applicant identifies six mobile MRI scanners that MedQuest Associates, Inc., Novant Health or its related entities own and which are operated in North Carolina.

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

-NA- **Both Applicants** – The applicants do not propose to acquire a mobile MRI scanner.

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

-NA- **Both Applicants** – The applicants do not propose to acquire a mobile MRI scanner.

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

-C- **NCBH** – In Section II.8, page 33, the applicant states it is accredited by the Joint Commission. See Exhibit 8 for documentation.

-C- **PI-NORTH** – In Section II.8, page 37, the applicant states it will seek American College of Radiology (ACR) accreditation for the proposed fixed MRI scanner.

*(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- **Both Applicants** – The applicants do not propose to acquire 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- **Both Applicants** – The applicants do not propose to acquire 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 shall 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 shall 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- Both Applicants** – The applicants do not propose to acquire 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 shall 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- **Both Applicants** – The applicants do not propose to acquire 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 3,328 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.];*
  - (3) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- **Both Applicants** – The applicants do not propose to acquire 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- **NCBH** – In Section II.8, page 36, the applicant states that “NCBH performed a total of 21,903 unweighted and 30,709 weighted procedures in Fiscal Year 2009 (July 1, 2008 – June 30, 2009) which equates to 6,142 scans per MRI scanner which exceeds 3,328. NCBH does not have a controlling interest in WFUBMC Outpatient Imaging Center, LLC, as it owns a 33% share of ownership.” However, WFUBMC Outpatient Imaging Center (OPIC) is a related entity to NCBH. See Project I.D. # G-7780-07. In Exhibit 7, the applicant provides the actual number of unweighted and weighted MRI procedures performed at WFUBMC OPIC in FY 2009 as set forth in the table below:

**WFUBMC OPIC: Weighted MRI Procedures  
(1 existing fixed MRI Scanner)**

	FY 2009 Actual (Nov 2008-Jun 2009/ 8 months)
# of Units (fixed)	1
# of Weighted Scans	1,448 / 8 months = 181 x 12 months = 2,172 annualized

During Fiscal Year 2009, the 5 fixed MRI scanners at NCBH performed a total of 30,709 weighted MRI procedures. These weighted procedures added to the 2,172 weighted MRI procedures performed at WFUBMC OPIC totals 32,881 weighted MRI procedures or 5,480 weighted MRI procedures per scanner  $(30,709 + 2,172 = 32,881) / 6$  MRI scanners = 5,480 which exceeds the 3,328 required by this rule.

-C- **PI-NORTH** – In Section II.8, page 41, the applicant states “PI-North and its related entities including Novant Health and FMC currently operate a total of 7 operational MRI units in the service area (2 at FMC, 1 at Salem MRI Center, 2 at Maplewood Imaging, 2 at PI in Winston Salem). These MRI units all operated at well above the average required level of 3,328 weighted MRI procedures for the 12 month period ending September 30, 2008. These 7 fixed MRI units operated at over 100 percent of capacity as shown below in Exhibit 4. Novant also is CON-approved for two additional MRI scanners, which are under development (1 at FMC, 1 at PI-Kernersville) for a total of 9 existing and approved MRI scanners.”

The table below illustrates the number of weighted MRI procedures performed during FFY 2008.

Location	Units	Weighted MRI Procedures	Average Per Unit
Forsyth Medical Center (1)	2	20,254	10,127
Piedmont Imaging Center	2	12,229	6,115
Excel Imaging- Salem MRI Center (2)	1	8,198	8,198
Excel Imaging- Maplewood (2)	2	8,544	4,272
Total	7	49,225	7,032

- (1) Forsyth Medical Center was approved for one additional fixed MRI scanner which is not yet operational.  
 (2) Effective July 1, 2009, the Excel Imaging sites have been renamed Forsyth Medical Center Imaging

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

-NA- **NCBH** – In Section II.8, page 36, the applicant states that it “*does not have a controlling interest in or own any mobile MRI scanners.*”

-C- **PI-NORTH** – In Section II.8, page 43, the applicant states that the only mobile MRI scanner owned by MedQuest or Novant that operates in Forsyth County is the Forsyth Medical Center-Siemens Avanto, 1.5 Tesla mobile MRI; Serial Number- 25479; G-7065-04; Host Sites: Winston-Salem Health Care, Mountainview Medical (recently discontinued), Central Triad Imaging Center and Medical Associates of Davie. The number of weighted MRI procedures performed during the most recent 12-month period is illustrated in the table below:

FMC Mobile	# of Units	Weighted MRI Procedures
5/1/08-4/30/09	1	3,462

(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 2009 SMFP shows 14 existing fixed MRI scanners located in the proposed service area, which is Forsyth County. Therefore, each applicant must demonstrate that the average annual utilization for the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns and locates in Forsyth County are reasonably expected to perform 4,805 weighted MRI procedures per scanner.

- C- **NCBH** – In Section II.8, page 37, the applicant projects to perform 31,540 weighted MRI procedures with six fixed MRI scanners (five existing and one proposed) in the third year of operation for an average utilization of 5,257 weighted procedures per MRI scanner [31,540 weighted procedures / 6 scanners = 5,257]. However, the projected number of weighted MRI procedures reported by the applicant for Fiscal Year’s 2011-2013 (the first 3 years following completion of the proposed project) does not include the weighted MRI procedures performed on the existing fixed MRI scanner at WFUBMC OPIC, which is a related entity to NCBH. In Exhibit 7, the applicant provides the projected number of weighted MRI procedures to be performed at WFUBMC OPIC for each of the first three years following completion of the proposed project. The applicant states in Exhibit 7 that a 2.5% growth rate was applied to project utilization at WFUBMC OPIC. However, the applicant did not apply the 2.5% growth rate each year. In the table below, the project analyst calculated the number of weighted MRI procedures projected to be performed on the fixed MRI scanner at WFUBMC OPIC assuming a growth rate of 2.5% each year.

**WFUBMC OPIC: Weighted MRI Procedures**

	FY 2009 Actual (Nov 2008- Jun 2009/ 8 months)	FY 2010 Interim	FY 2011 Projected	FY 2012 Projected	FY 2013 Projected
# of Units (fixed)	1	1	1	1	1
# of Weighted Procedures	1,448 / 8 months = 181 x 12 months = 2,172 annualized	2,226	2,282	2,339	2,398

When the projected weighted WFUBMC OPIC MRI procedures for Year 3 are added to those projected to be performed at NCBH, the average weighted procedures per MRI unit equals 4,848 [31,540 + 2,398 = 33,938/ 7 scanners (6 existing fixed + 1 proposed) = 4,848, which exceeds the 4,805 required by this rule. See criterion (3) for discussion regarding the reasonableness of projected utilization.

- C- **PI-NORTH** – In Section II.8, page 44, the applicant projects to perform 54,557 weighted MRI procedures with 10 fixed MRI scanners (8 existing, 1 approved and 1 proposed) in the third year of operation for an average of 5,456 weighted procedures per MRI scanner [54,557 weighted procedures / 10 scanners = 5,455.7], which exceeds the 4,805 required by this rule. See criterion (3) for discussion regarding the reasonableness of projected utilization.

- (4) *if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*
- (A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
  - (B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
  - (C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
  - (D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*
  - (E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

-NA- **NCBH** – In Section II.8, page 37, the applicant states the proposed MRI scanner will be located on the NCBH campus.

-C- **PI-NORTH** – 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. In Section II.8, page 45, and in Section IV, page 79, the applicant states that the proposed PI-North MRI scanner will perform 5,075 weighted MRI procedures in the third year following completion of the proposed project. See Criterion (3) for discussion regarding the reasonableness of projected utilization.

- (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.];*

-NA- **NCBH** – The applicant does not own a mobile MRI scanner.

-C- **PI-NORTH** – In Section II.8, pages 45-46, the applicant states “FMC, a related entity to PI and Novant Health, operates one mobile MRI unit in the Forsyth County service area. Currently, the FMC mobile MRI unit is approved to serve host sites in Forsyth, Stokes and Davie Counties. This unit is expected to provide more than 3,328 weighted MRI procedures in 2013, the third year of operation following completion of the proposed project.” The applicant projects the existing mobile MRI scanner will perform 3,731 weighted MRI procedures in Project Year 3.

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

-C- **NCBH** – The applicant adequately documented the assumptions and provided data supporting the methodology used for each projection required in this rule. See Criterion (3) for discussion.

-C- **PI-NORTH** – The applicant adequately documented the assumptions and provided data supporting the methodology used for each projection required in this rule. See Criterion (3) for discussion.

(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- **Both Applicants** – The applicants do not propose to acquire a fixed dedicated breast MRI scanner.

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

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

-NA- **Both Applicants** – The applicants do not propose to acquire 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- **Both Applicants** – The applicants do not propose to acquire 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- **Both Applicants** – The applicants do not propose to acquire 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- **NCBH** – The hospital is currently accredited by the Joint Commission. See Exhibit 8 for documentation.

-C- **PI-NORTH** – In Section II.8, page 48, the applicant states it will obtain accreditation by the American College of Radiology within two years following operation of the proposed MRI scanner.

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

*(a) An applicant proposing to acquire an MRI scanner, including extremity and breast MRI scanners, shall demonstrate that one diagnostic radiologist certified by the American Board of Radiologists shall be available to interpret the images who has had:*

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

-C- **NCBH** – In Section II.8, page 40, the applicant states “*Medical coverage for the proposed service will be provided in the same manner that coverage is provided for NCBH’s existing scanners. The Medical Director of Magnetic Resonance Imaging, Dr. John R. Leyendecker, provides departmental direction.*” Exhibit 2 contains a copy of the curriculum vitae for Dr. Leyendecker. The applicant states that it has a total of 44 radiologists on staff.

-C- **PI-NORTH** – In Section II.8, page 48, the applicant states, “*Radiology coverage for PI-North will be provided by Forsyth Radiological Associates. Dr. Vito Basile, who is a board-certified radiologist with specialty training in MRI [sic].*” Attachment 10 contains a copy of the curriculum vitae for Dr. Basile. Attachment 11 contains a letter expressing Dr. Basile’s willingness to “*provide Medical Director services and image interpretation*” for the proposed MRI scanner.

*(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- Both Applicants** – The applicants do not propose to acquire 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- NCBH** – In Section II.8, page 40, the applicant states that it is an existing MRI provider which currently employs 24.6 FTE MRI technologists. By the second full year following completion of the project, NCBH anticipates employing 30.4 MRI technologists. (See staffing tables in Section VII.). The applicant states at least one of the MRI technologists will be on site during the operating hours of the MRI scanner.

**-C- PI-NORTH** – In Section II.8, page 49, and Section VII.1, page 101, the applicant proposes to employ 2.0 FTE MRI technologist positions for operation of the fixed MRI scanner. The applicant states at least one of the MRI technologists will be on site during the operating hours of the MRI scanner.

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

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

**-C- NCBH** – In Section II.8, page 41, the applicant states that its staff will continue to provide continuing education programs for staff, including cardiopulmonary resuscitation (CPR) and basic life support (BLS). The applicant states “*All MRI technologists at NCBH are certified in CPR and basic cardiac life support (BCLS).*”

**-C- PI-NORTH** – In Section II.8, page 49, the applicant states it will require its staff to be certified in cardiopulmonary resuscitation (CPR) and basic cardiac life support and that all training will be provided by MedQuest Associates, Inc.

- (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- NCBH** – In Section II.8, page 41, the applicant states, “*NCBH has a comprehensive orientation and training program for all radiology staff and includes MRI technologists in this plan.*”



Exhibit 10 for information regarding NCBH's continuing education policy for the Radiology Department.

- C- **PI-NORTH** – In Section II.8, page 49, the applicant states “*All staff education and training will be provided by MedQuest Associates, Inc. MedQuest Associates, Inc. has an established training program that is implemented in each of its managed facilities.*” Attachment 12 contains a letter from MedQuest Associates, Inc. stating that PI-North's employees will have access to training and continuing education programs.

*(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- **Both Applicants** – The applicants do not propose to acquire a mobile MRI scanner.

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

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

- NA- **Both Applicants** – The applicants do not propose to acquire an extremity MRI scanner.

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

- NA- **NCBH** – The applicant states that it does not propose to perform cardiac MRI procedures on the proposed MRI scanner.

- NA- **PI-North**- The applicant states that it does not proposed to perform cardiac MRI procedures on the proposed MRI scanner.

**ATTACHMENT - REQUIRED STATE AGENCY FINDINGS****FINDINGS**

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 26, 2016

Findings Date: August 26, 2016

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Assistant Chief: Martha J. Frisone

**COMPETITIVE REVIEW**


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Project ID #: G-11147-16  
 Facility: Cone Health  
 FID #: 943494  
 County: Guilford  
 Applicant(s): The Moses H. Cone Memorial Hospital  
 The Moses H. Cone Memorial Hospital Operating Corporation  
 Project: Acquire a fourth fixed MRI scanner

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Project ID #: G-11148-16  
 Facility: Southeastern Orthopaedic Specialists  
 FID #: 090353  
 County: Guilford  
 Applicant(s): Southeastern Orthopaedic Specialists, P.A.  
 Alliance HealthCare Services, Inc.  
 Project: Acquire a fixed MRI scanner

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Project ID #: G-11149-16  
 Facility: Wake Forest Baptist Imaging, LLC  
 FID #: 160116  
 County: Guilford  
 Applicant(s): Wake Forest Baptist Imaging, LLC  
 Project: Acquire a fixed MRI scanner

**REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES**

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

determination that the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**WFBI.** In Section II.6 and 7, pages 22-25, and Exhibit 8, the applicant describes the methods used by WFBI to insure and maintain quality care. In Section I.12, page 12, the applicant describes WFBH's acute care network as including Brenner Children's Hospital, Wake Forest Baptist Medical Center, Davie Medical Center and Lexington Medical Center. On page 12, the applicant states, "*WFBH also holds the Gold Seal of Approval from the Joint Commission, the nation's esteemed standards-setting and accrediting body for health care quality.*" In Section II.7(c), page 25, the applicant states that no license has ever been revoked for any of the healthcare facilities identified in Section I.12. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, two incidents occurred at North Carolina Baptist Hospital and one at Lexington Medical Center within the eighteen months immediately preceding submission of the application through the date of this decision related to quality of care. As of the date of this decision, the problems had been corrected. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at WFBH System facilities, WFUHS, and OIA, the applicant provided sufficient evidence that quality care has been provided in the past. The information provided by the applicant is reasonable and supports the determination that the applicant is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C- Cone Health and WFBI  
NC- SOS

The applications submitted by Cone Health and WFBI were determined to be conforming with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700. The application submitted by SOS was found not to be 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 .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- **All Applicants.** The applicants do not propose the acquisition of a mobile MRI scanner.

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

-C- **Cone Health.** Cone Health owns and operates three existing fixed MRI scanners located in Guilford County. Diagnostic Radiology and Imaging,

LLC (DRI) is a joint venture between Cone Health and Greensboro Radiology P.A. and, therefore, is a related entity. DRI owns and operates three fixed MRI scanners in Guilford County. In Section II.8, page 29, the applicants provide the following table and state that Cone Health and DRI performed an average of 5,367 weighted scans per machine in FY2015, well in excess of the required average of 3,328 scans.

	# Scanners	Outpatient		Inpatient		Total Weighted Scans *	Average Weighted Scans
		W/O Contrast	W/ Contrast	W/O Contrast	W/ Contrast		
Moses Cone	2	3,128	1,234	4,008	1,217	12,657	6,329
Wesley Long	1	894	1,837	518	481	5,057	5,057
DRI	3	7,627	4,899	0	0	14,486	4,829
<b>Total</b>	<b>6</b>	<b>11,649</b>	<b>7,970</b>	<b>4,526</b>	<b>1,698</b>	<b>32,200</b>	<b>5,367</b>

\*The applicants state that scans are weighted per the weighting system described on page 156 of the 2016 SMFP

- NA- **SOS.** In Section II.8, page 41, the applicants state that neither SOS nor AHS owns a controlling interest in a fixed MRI scanner in the proposed service area.
- C- **WFBI.** In Section II.8, page 29, the applicant states that neither WFBI nor a related entity owns a controlling interest in any fixed MRI scanners.

As of March 15, 2016, neither the applicant nor any related entity owned a controlling interest in any fixed MRI scanners in Guilford County. However, on page 30, the applicant states that it expects WFBH will acquire Cornerstone, gaining control of Cornerstone’s existing assets, including its existing fixed MRI scanner in Guilford County during the review of this application. Therefore, as WFBH is a related entity, the applicant provides the relevant historical utilization for Cornerstone’s fixed MRI scanner, stating:

*“During FY2015, Cornerstone’s fixed MRI scanner performed 4,509 unweighted MRI procedures (1,593 procedures with contrast + 2,916 procedures without contrast), or 5,146 weighted MRI procedures.”*

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

- NA- **Cone Health.** In Section II.8, page 29, the applicants state that neither Cone Health nor any related entities operate a mobile MRI scanner in Guilford County, the proposed service area.
  
- NC- **SOS.** In Section II.8, pages 42-43, the applicants state that AHS currently operates two mobile MRI scanners in the service area, one at SOS (Signa 447) and one at CNSA (Signa 451). The applicants provide spreadsheets in Exhibit 14 showing both scanners performed over 3,328 weighted MRI scans in the most recent 12-month period for which their data was available, March 1, 2015 through February 29, 2016. However, the applicant provides a table in Exhibit 4 identifying AHS-owned North Carolina MRI scanners, which shows that AHS operates six mobile scanners in Guilford County: ESP 27, Signa 294, Signa 413, Signa 447, Signa 451, and Signa 470. Furthermore, the 2016 Registration and Inventory of Medical Equipment for AHS's Signa 407 shows that scanner also operated in Guilford County, in addition to the counties listed in the applicant's table in Exhibit 4. Therefore, there appear to be seven AHS mobile MRI scanners which served host sites in Guilford County in the last reporting period. The applicant discussed only two of the seven. Nothing in the application as submitted documents that five of the seven mobile MRI scanners are no longer operating in Guilford County.

The Project Analyst was able to access the 2016 RIME submitted to the Healthcare Planning and Certificate of Need Section (Agency) by AHS on only three of the seven scanners listed above: Signa 407, Signa 447, and ESP 27.

On its 2016 RIME for Signa 447, AHS reported 5,341 procedures at SOS in Greensboro, Guilford County, which is above the 3,328 scan threshold, as required in 10A NCAC 14C .2703(b)(2). The following tables show the utilization reported for Signa 407 and ESP 27, as adjusted by the 2016 SMFP methodology for weighting MRI scans.

**SIGNA 407**  
**10/1/2014-9/30/2015**

Sites Served	County	Unweighted Procedures	Outpt w Contrast	Outpt w/o Contrast	Inpt w Contrast	Inpt w/o Contrast	Weighted Procedures
UNC	Alamance	272	60	212			296
MRI Specialists of the Carolinas	Cleveland	266	42	224			283
Yadkin Valley Community Hospital	Yadkin	57	7	49		1	60
WFBH Med Plaza	Forsyth	206	21	185			214
Moses Cone MedCenter High Point	Guilford	49	10	39			53
SOS	Guilford	124	1	123			124
Davie County Hospital	Davie	751	193	556	1	1	829
OrthoCarolina PA	Scotland	19	0	19			19
Randolph Spine Center	Mecklenburg	16	1	15			16
OrthoCarolina PA	Union	21	0	21			21
Total Procedures Reported on Signa 407 and Weighted		<b>1,781</b>					<b>1,917</b>

Source: January 2016 Registration and Inventory of Medical Equipment and 2016 SMFP Methodology  
 Totals may not sum due to rounding

**ESP 27**  
**10/1/2014-9/30/2015**

Sites Served	County	Unweighted Procedures	Outpt w Contrast	Outpt w/o Contrast	Weighted Procedures
Moses Cone MedCenter High Point	Guilford	645	152	493	706
UNC	Alamance	343	81	262	375
Carolina Neurosurgery & Spine	Guilford	194	64	130	220
Cone Health MedCenter-Kernersville	Forsyth	95	11	84	99
Wake Radiology Services	Wake	7	0	7	7
Onslow Memorial Hospital	Onslow	9	0	9	9
SOS	Guilford	31	0	31	31
Triangle Orthopedic	Wake	404	8	394	405
Duke Health Raleigh	Wake	188	90	98	224
Wake Radiology Services	Johnston	119	0	119	119
Total Procedures Reported on ESP 27 and Weighted		<b>2,035</b>			<b>2,195</b>

Source: January 2016 Registration and Inventory of Medical Equipment and the 2016 SMFP Methodology  
 Totals may not sum due to rounding

As the tables above show, both the Signa 407 and ESP 27 scanners performed below the 3,328 weighted scan threshold, per the January 2016 RIME. It appears AHS did not submit the 2016 RIME forms for the other AHS scanners reported in Exhibit 4 as operating in Guilford County.

The applicant does not demonstrate that each existing mobile MRI scanner owned by the applicant or a related entity and operating in Guilford County performed at least 3,328 weighted scans during the most recent 12-month period for which the applicant has data. Therefore, the application is not conforming with this Rule.

-NA- **WFBI.** In Section II.8, page 30, the applicant states that neither WFBI nor any related entities have ownership in a mobile MRI scanner that operates in Guilford County.

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

(A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*

(B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*

(C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*

(D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*

(E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

The 2016 SMFP shows that there are more than four (4) fixed MRI scanners located in the MRI service area of Guilford County. Therefore, each applicant must demonstrate that the average annual utilization for the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns and locates in Guilford County is reasonably expected to perform 4,805 weighted MRI procedures in the third operating year.

C- **Cone Health.** In Section II.8, page 30, the applicants provide tables showing Cone Health's and DRI's projected MRI utilization for the proposed project's first three project years, FFY2018 through FFY2020, as shown below. Cone Health-Greensboro will own and operate four fixed



MRI scanners: Moses Cone Hospital main campus - two existing fixed scanners and one proposed fixed scanner; and Wesley Long – one existing fixed scanner. DRI will own and operate three existing fixed MRI scanners.

**Cone Health Projected MRI Scans**

Type of Scan	FFY2018	FFY2019	FFY2020
OP W/O Contrast	4,144	4,185	4,227
OP W/ Contrast	3,164	3,196	3,228
IP W/O Contrast	4,874	4,996	5,121
IP W/ Contrast	1,829	1,874	1,921
Total Scans	14,010	14,251	14,497
Weighted Scan Totals*	18,689	19,027	19,373
<b>Average Weighted Scans</b>	<b>4,672</b>	<b>4,757</b>	<b>4,843</b>

\*The applicants state that scans are weighted per the weighting system described on page 156 of the 2016 SMFP.

**Diagnostic Radiology and Imaging Projected Scans**

Type of Scan	FFY2018	FFY2019	FFY2020
OP W/O Contrast	7,858	7,937	8,016
OP W/ Contrast	5,047	5,098	5,149
Totals	12,905	13,035	13,165
Weighted Totals*	14,925	15,074	15,225
<b>Average Weighted Total</b>	<b>4,975</b>	<b>5,025</b>	<b>5,075</b>

\*The applicants state that scans are weighted per the weighting system described on page 156 of the 2016 SMFP

The applicants state that the average annual weighted MRI scan volume for Cone Health’s four fixed MRI scanners is projected to be 4,843 weighted MRI procedures per MRI scanner in the third operating year. The applicants further state that DRI, a related entity is projected to provide 5,075 weighted MRI scans per fixed MRI scanner in the proposed project’s third operating year. The application is conforming to this Rule.

- C- **SOS.** In Section II.8, page 44, the applicants state the annual weighted MRI scan volume for SOS’s proposed, and only, fixed MRI scanner is projected to be 5,409 weighted MRI procedures in the third operating year. The application is conforming to this Rule.
- C- **WFBI.** In Section II.8, page 31, the applicant states WFBI projects to perform 5,282 weighted MRI procedures during the third year of the proposed project. The applicant further states that Cornerstone will perform 5,302 weighted MRI procedures during CY2019, the proposed project’s third project year. The application is conforming to this Rule.

(4) *if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*

(A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*

(B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*

(C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*

(D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*

(E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

-NA- **Cone Health.** In Section II.8, page 31, the applicants state that the proposed scanner will be located on the Moses Cone Hospital main campus with the existing fixed MRI service.

-NA- **SOS.** In Section II.8, page 45, the applicants state that the proposed fixed MRI scanner will be located at SOS, which is currently serviced by the AHS mobile MRI scanner.

-C- **WFBI.** In Section II.8, page 31, the applicant refers to 10A NCAC 14C .2703(b)(3), where it projects WFBI will perform 5,282 weighted MRI procedures and Cornerstone will perform 5,302 weighted procedures in CY2019, the third project year. The application is conforming with this Rule.

(5) *demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and*

- NA- **Cone Health.** In Section II.8, page 31, the applicants state that neither Cone Health nor any related entities currently operate a mobile MRI scanner in Guilford County, the proposed MRI service area.
- NC- **SOS.** In Section II.8, page 46, the applicants state that AHS's mobile scanner at CNSA (Signa 451) will perform 3,580 weighted scans in FFY2020, the proposed project's third year of operation. The applicants are proposing that the Signa 407 mobile MRI will be upgraded to fixed; and correctly do not provide utilization for that scanner in response to this question. However, the applicants fail to discuss the utilization for the mobile scanner currently serving SOS (Signa 447) and the other AHS-owned mobile scanners that operate in Guilford County, as identified in the applicants' table in Exhibit 4 of the application. The applicants provide projections for the proposed fixed and only one mobile. Therefore the application is not conforming to this Rule.
- NA- **WFBI.** In Section II.8, page 32, the applicant states that neither WFBI nor any related entities have ownership in a mobile MRI scanner that operates in Guilford County.
  - (6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- C- **Cone Health.** The applicants' methodology and assumptions used for the above Cone Health projections are described in Section IV.1, pages 61-67. The applicants state on page 32, that the DRI projections are based on a 1.0% annual growth rate, which the applicants state essentially mirrors projected population growth in Guilford County from 2015 to 2020.
- NC- **SOS.** The applicants' methodology and assumptions used for these projections are described in Section IV.1(d), pages 67-74. However, the applicants fail to discuss the utilization for the mobile currently serving SOS (Signa 447) and the other AHS-owned mobile scanners that operate in Guilford County, as identified in Exhibit 4 of the application. The applicants provide projections for the proposed fixed and only one mobile. Therefore the application is not conforming to this Rule.
- C- **WFBI.** The applicant describes the methodology and assumptions used for its projections in Section III.1, pages 35-59.
  - (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- **All Applicants.** The applicants do not propose the acquisition of a fixed dedicated breast MRI scanner.

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

-NA- **All Applicants.** The applicants do not propose the acquisition of a fixed extremity MRI scanner.

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

-NA- **All Applicants.** The applicants do not propose the acquisition of a fixed multi-position MRI scanner.

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

## FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2016

Findings Date: September 29, 2016

Project Analyst: Gloria C. Hale

Team Leader: Fatimah Wilson

Assistant Chief: Martha J. Frisone

**COMPETITIVE REVIEW**


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Project ID #: J-011167-16  
 Facility: Duke Radiology Holly Springs  
 FID #: 160156  
 County: Wake  
 Applicant: Duke University Health System, Inc.  
 Project: Acquire one fixed MRI scanner and develop a diagnostic center

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Project ID #: J-11159-16  
 Facility: Raleigh Radiology Cary  
 FID #: 080405  
 County: Wake  
 Applicant: Raleigh Radiology, LLC  
 Project: Acquire one fixed MRI scanner

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Project ID #: J-11172-16  
 Facility: Wake Radiology - Wake Forest MRI Office  
 FID #: 160160  
 County: Wake  
 Applicants: Wake Radiology Services LLC and Wake Radiology Diagnostic Imaging, Inc.  
 Project: Acquire one fixed MRI scanner and develop a diagnostic center

**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.

**Raleigh Radiology.** In Section II.5, page 27, the applicant discusses how the proposed 3T fixed MRI scanner will improve quality of care. In Section II.6, page 27, the applicant states that its MRI services at RR Cary are accredited by the American College of Radiology. See Exhibit 8 for documentation of ACR accreditation. In Section II.7, page 28, and Exhibit 9, the applicant discusses its quality of care processes. In Section III.2, page 72, the applicant discusses additional methods it uses to ensure quality. After reviewing and considering information provided by the applicant, and considering the quality of care provided at all of its offices, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**Wake Radiology.** In Sections II.5, II.6, and II.7, pages 23-24, the applicants state that all of its offices are accredited by the American College of Radiology (ACR), including the mobile MRI service at WRWF, and that the proposed, fixed MRI services will also adhere to these standards. In addition, as stated on page 24, Wake Radiology has internal quality of care processes and procedures in place to assure quality of care, including its Wake Radiology Peer Review process. See Attachment F for documentation of accreditation and Attachment H for documentation of the applicants' Peer Review process and policies. After reviewing and considering information provided by the applicants and considering the quality of care provided, the applicants provide sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C  
DRHS  
Raleigh Radiology

NC  
Wake Radiology

**DRHS** proposes to acquire a new fixed MRI scanner pursuant to a need determination in the 2016 SMFP for one fixed MRI scanner in Wake County. Therefore, the Criteria and Standards for Magnetic Resonance Imaging Scanner in 10A NCAC 14C .2700 are applicable to this review. The application is conforming to all applicable Criteria and Standards for Magnetic Resonance Imaging Scanner.

**Raleigh Radiology** proposes to acquire a new fixed MRI scanner pursuant to a need determination in the 2016 SMFP for one fixed MRI scanner in Wake County. Therefore, the Criteria and Standards for Magnetic Resonance Imaging Scanner in 10A NCAC 14C .2700 are applicable to this review. The application is conforming to all applicable Criteria and Standards for Magnetic Resonance Imaging Scanner.

**Wake Radiology** proposes to acquire a new fixed MRI scanner pursuant to a need determination in the 2016 SMFP for one fixed MRI scanner in Wake County. Therefore, the Criteria and Standards for Magnetic Resonance Imaging Scanner in 10A NCAC 14C .2700 are applicable to this review. The application is not conforming to all applicable Criteria and Standards for Magnetic Resonance Imaging Scanner.

The specific criteria for all three applications are discussed below.

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

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

- (a) *An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner shall:*
- (1) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the mobile MRI region in which the proposed equipment will be located, except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; with the exception that in the event an existing mobile MRI scanner has been in operation less than 12 months at the*

*time the application is filed, the applicant shall demonstrate that this mobile MRI scanner performed an average of at least 277 weighted MRI procedures per month for the period in which it has been in operation;*

- (2) demonstrate annual utilization in the third year of operation is reasonably projected to be at least 3328 weighted MRI procedures on each of the existing, approved and proposed mobile MRI scanners owned by the applicant or a related entity to be operated in the mobile MRI region in which the proposed equipment will be located [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; and*
- (3) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- None of the applications propose the acquisition of a mobile MRI scanner.

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

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

-C- **DRHS.** In Section II, page 28, the applicant states that its two fixed MRI scanners at Duke Raleigh Hospital performed a total of 10,391 weighted MRI procedures from February 2015 – January 2016, for an average of 5,196 weighted MRI procedures per scanner.

-NA- **Raleigh Radiology.** Neither the applicant nor a related entity owns or has a controlling interest in any fixed MRI scanners located in Wake County.

-C- **Wake Radiology.** In Section III.1, page 48, the applicants state that their four fixed MRI scanners performed 14,455 weighted MRI procedures from 4/01/15 – 3/31/16, for an average of 3,611 weighted MRI procedures per scanner.

- (2) demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This*



*is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];*

- NA- **DRHS.** Neither the applicant nor a related entity owns or has a controlling interest in any mobile MRI scanners operated in Wake County.
- NA- **Raleigh Radiology.** Neither the applicant nor a related entity owns or has a controlling interest in any mobile MRI scanners operated in Wake County.
- NC- **Wake Radiology.** In Section III.1, page 45, the applicants state that their mobile MRI scanner performed 1,402 weighted MRI procedures at the WRWF location from 4/01/15 – 3/31/16. In Section III.1, page 50, the applicants state that their mobile MRI scanner performed 791 weighted MRI procedures at WRDI Cary, Fuquay-Varina and North Raleigh sites from 4/01/15 – 3/31/16, for a combined total of 2,193 weighted MRI procedures. Therefore, the applicants do not adequately demonstrate that their mobile MRI scanner performed at least 3,328 weighted MRI procedures in the most recent 12 month period for which they had data. The application is not conforming to this Rule.

In their response to comments, the applicants argue that this Rule should be void as not reasonably necessary for the Agency to determine whether the applicants demonstrate a need for the proposed fixed MRI scanner. However, the Rule is necessary as it would not be consistent with the premise of the CON Law to approve an applicant to acquire an additional MRI scanner (fixed or mobile) when the applicant has access to an existing mobile MRI scanner which has the capacity to serve more patients than it is currently serving.

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

- (A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
- (B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
- (C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
- (D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*

*(E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

The 2016 SMFP shows that there are more than four (4) fixed MRI scanners located in the fixed MRI service area of Wake County. Therefore, each applicant must demonstrate that the average annual utilization for the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns and locates in Wake County is reasonably expected to perform 4,805 weighted MRI procedures in the third operating year.

- C- **DRHS.** The applicant owns and operates two existing fixed MRI scanners and proposes to acquire one additional fixed MRI scanner in Wake County, for a total of three fixed MRI scanners. In Section III.1, page 76, the applicant projects that its proposed fixed MRI scanner will perform 5,193 weighted MRI procedures in the third operating year. In Section IV.1, page 100, the applicant projects that its two existing fixed MRI scanners will perform a total of 14,413 weighted MRI procedures in the third operating year, for an average of 7,207, rounded up.

The application is conforming to this Rule.

- C- **Raleigh Radiology.** In Section IV.1, page 99, the applicant projects that its proposed fixed MRI scanner will perform 8,496 weighted MRI procedures in the third year of operation following project completion.

The application is conforming to this Rule.

- NC- **Wake Radiology.** In Section II, page 30, the applicants state that the average number of weighted MRI procedures for its proposed fixed MRI scanner and its four existing fixed MRI scanners will be 4,860. However, the applicants do not adequately demonstrate that projected utilization of the proposed, fixed MRI scanner or their four existing fixed MRI scanners are based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is not conforming to this Rule.

*(4) if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is*

*applicable, in the third year of operation following completion of the proposed project:*

- (A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
- (B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
- (C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
- (D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*
- (E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

-C- **DRHS.** The proposed fixed MRI scanner would be located at a different site from the applicant's two existing fixed MRI scanners. In Section III.1, page 76, the applicant projects that it's proposed fixed MRI scanner to be located in Holly Springs will perform 5,193 weighted MRI procedures in the third operating year.

-NA- **Raleigh Radiology.** The applicant does not own or operate any fixed MRI scanners in Wake County.

-NC- **Wake Radiology.** The applicants' proposed fixed MRI scanner will be located at the Wake Forest site where the applicants do not currently have a fixed MRI scanner. In Section IV, page 62, the applicants project to perform 4,835 weighted MRI procedures on the proposed fixed MRI scanner in the third operating year. However, the applicants do not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions regarding growth. The discussion regarding projected utilization of the proposed fixed MRI scanner found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming to this Rule.

- (5) demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and*

- NA- **DRHS.** The applicant does not own any mobile MRI scanners in Wake County.
- NA- **Raleigh Radiology.** The applicant does not own any mobile MRI scanners in Wake County.
- NC- **Wake Radiology.** In Section III.1, page 51, the applicants project that their mobile MRI scanner will perform 3,532 weighted MRI procedures in operating year three. However, the applicants do not adequately demonstrate that the projected utilization of their mobile MRI scanner is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization of their mobile MRI scanner found in Criterion (3) is incorporated herein by reference. The application is not conforming to this Rule.
  - (6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- C- **DRHS.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section III, pages 54-76, and Section IV, pages 99-100.
- C- **Raleigh Radiology.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section IV.1, pages 94-101.
- C- **Wake Radiology.** The applicants' assumptions and data supporting the methodology used for each projection required by this Rule are described in Section II.8, pages 31-32, and Section III.1, pages 44-51.
- (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- None of the applications propose 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- None of the applications propose the acquisition of a fixed extremity MRI scanner.

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

-NA- None of the applications propose the acquisition of a fixed multi-position MRI scanner.

### **COMPARATIVE ANALYSIS**

Pursuant to G.S. 131E-183(a)(1) and the 2016 State Medical Facilities Plan, no more than one additional fixed MRI scanner may be approved in this review for Wake County. Because the three applications in this review collectively propose to acquire three additional fixed MRI scanners, only one of the applications can be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved. For the reasons set forth below and in the rest of the findings, the application submitted by Duke University Health System, Inc., Project I.D. #J-11167-16, is approved and the other applications, submitted by Raleigh Radiology, LLC, and Wake Radiology Services, LLC and Wake Radiology Diagnostic Imaging, Inc., are denied.

#### **Geographic Distribution**

The 2016 SMFP identifies the need for one fixed MRI scanner in Wake County. The following table identifies the location of the existing and approved fixed MRI scanners in Wake County.

**ATTACHMENT - REQUIRED STATE AGENCY FINDINGS****FINDINGS**

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

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

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

**COMPETITIVE REVIEW**


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

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

**REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES**

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

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

C – CIS  
 NC - Novant

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

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

(21) Repealed effective July 1, 1987.

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

C – CIS  
NC – Novant

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

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

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

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

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

-NA- **Both Applicants.** The applicants do not propose the acquisition of a mobile MRI scanner.

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

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

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



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

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

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

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

- (2) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];*
- C- **CIS.** In Section II.8, page 32, the applicant states that it operates one existing mobile MRI scanner in Mecklenburg County, the proposed service

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

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

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

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

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

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

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

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

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

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

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

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

The applicant does not demonstrate that each existing mobile MRI scanner owned by the applicant or a related entity and operating in Mecklenburg County performed at least 3,328 weighted MRI procedures during the most recent 12 months for which the applicant has data. Therefore, the application is not conforming to this Rule.

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

(A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*

(B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*

(C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*

- (D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or
- (E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;

The 2016 SMFP shows that there are more than four (4) fixed MRI scanners located in the MRI service area of Mecklenburg County. Therefore, each applicant must demonstrate that the average annual utilization for the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns and locates in Mecklenburg County is reasonably expected to perform 4,805 weighted MRI procedures in the third operating year.

- C- **CIS.** In Section II.8, page 33, the applicant provides a table showing CIS’s and CHS’s projected MRI utilization for the proposed project’s third project year, CY 2020, as shown below. CIS-H will own and operate three fixed MRI scanners: one existing scanner at both the CIS-Ballantyne office and the CIS-SouthPark office, as well as a new scanner at CIS-H. CHS will own and operate seven existing fixed MRI scanners.

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

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

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

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

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

Even though the application does not adequately support projected utilization of the existing MRI scanners in the outpatient imaging centers, publicly available data, combined with the information provided by the applicant in the application, nevertheless supports the applicant's assertion that all the existing and proposed fixed MRI scanners would average more than the 4,805 weighted MRI procedures per scanner as required by this Rule. Therefore, the application is conforming to this Rule.

(4) *If the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*

- (A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
- (B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
- (C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
- (D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*

- (E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*
- NA- **CIS.** In Section II.1, page 18, the applicant states that the proposed fixed MRI scanner will be located at the existing CIS-H facility, which currently operates a mobile MRI scanner.
- NA- **Novant.** In Section II.8, page 21, the applicant states that the proposed fixed MRI scanner will be located on the campus of NHHMC, which currently operates an existing fixed MRI scanner.
- (5) *demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and*
- C- **CIS.** In Section II.8, page 35, the applicant states that it proposes to relocate its existing mobile MRI currently servicing CIS-H to service CMC and CHS Pineville three days per week at each facility. The applicant projects that the mobile MRI scanner will perform 3,417 weighted MRI procedures during the third operating year following project completion. The applicant's assumptions and methodology for projecting the mobile MRI scanner utilization are found in Exhibit 8.
- NC- **Novant.** The applicant does not demonstrate that each existing mobile MRI scanner it or a related entity owns and operates within Mecklenburg County is reasonably projected to perform at least 3,328 weighted MRI procedures in the third operating year following project completion. The discussion regarding projected utilization of the existing mobile MRI scanner units found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming to this Rule.
- (6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- C- **CIS's** methodology and assumptions used for the above CIS projections are described in Section III.1(b), pages 53-62, and Exhibit 8.
- C- **Novant's** methodology and assumptions used for these projections are described in Section II.8, pages 21-26, and Section III.1(b), pages 41-47.
- (b) *An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical*

*Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*

- (1) demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure per hour times 40 hours per week times 52 weeks per year; and*
- (2) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- **Both Applicants.** The applicants do not propose the acquisition of a fixed dedicated breast MRI scanner.

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

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

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

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

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

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

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

## FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 29, 2018

Findings Date: March 29, 2018

Team Leader: Gloria C. Hale

Co-Signer: Lisa Pittman

**COMPETITIVE REVIEW**

Project ID #: F-11433-17

Facility: Novant Health Presbyterian Medical Center

FID #: 943501

County: Mecklenburg

Applicant: The Presbyterian Hospital

Project: Acquire one new fixed MRI scanner pursuant to the Need Determination in the 2017 SMFP

Project ID #: F-11425-17

Facility: Carolinas HealthCare System Pineville

FID #: 110878

County: Mecklenburg

Applicant: Mercy Hospital, Inc.

Project: Acquire a second fixed MRI scanner at Carolinas HealthCare System Pineville pursuant to a Need Determination in the 2017 SMFP

**REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES**

N.C. Gen. Stat. 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



in any of these facilities. However, according to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of the application through the date of this decision, four incidents related to quality of care occurred in three of these facilities and they have not yet been deemed to be back in compliance. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 12 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

NC – The Presbyterian Hospital  
C – Mercy Hospital

**The Presbyterian Hospital.** The application submitted by The Presbyterian Hospital was found to not be in conformity with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700.

**Mercy Hospital.** The application submitted by Mercy Hospital was determined to be conforming with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700.

The specific criteria for both applications are discussed below.

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

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

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

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

-NA- Neither of the applicants propose to acquire a mobile MRI scanner. Therefore, this rule is not applicable to this review.

- (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- **The Presbyterian Hospital.** In Section C, pages 55-56, the applicant states that Novant Health's fixed MRI scanners in Mecklenburg County performed an average of 5,339 weighted MRI procedures from July 1, 2016 through June 30, 2017.

-C- **Mercy Hospital.** In Section C, page 62, the applicant states that CHS/CIS' fixed MRI scanners in Mecklenburg County performed an average of 6,399 weighted MRI procedures from August 2016 through July 2017.

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

-NA- **The Presbyterian Hospital.** The applicant does not currently own or have a controlling interest in any mobile MRI scanners operated in Mecklenburg County. Therefore, this Rule is not applicable to this application.

-C- **Mercy Hospital.** The applicant states, in Section C, page 63, that it operates one mobile MRI scanner in the service area which services two sites, CIS-Huntersville in Mecklenburg County and St. Luke's Hospital in Polk County. The applicant provides the historical utilization for the mobile MRI scanner for the period, August 2016 through July 2017, on page 63, illustrated as follows:

**CIS Mobile MRI Scanner Weighted MRI Procedures  
August 2016 through July 2017**

	CIS-Huntersville	St. Luke's	Total
Total Weighted MRI Procedures	3,189	877	4,066

*(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 2017 SMFP shows that there are more than four (4) fixed MRI scanners located in the fixed MRI service area of Mecklenburg County. Therefore, each applicant must demonstrate that the average annual utilization for the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns and locates in Mecklenburg County will be at least 4,805 weighted MRI procedures in the third operating year.

**-NC- The Presbyterian Hospital.** The applicant states, in Section C, page 57, that it projects its annual average weighted MRI scan volume for each of its existing, approved, and proposed fixed MRI scanners to be 5,006 weighted MRI procedures per fixed MRI scanner in project year three. However, the applicant does not provide its methodology, assumptions, or projected utilization for all of Novant Health's existing and approved fixed MRI scanners it owns and operates at its acute care facilities and outpatient sites in Mecklenburg County. Therefore, the applicant does not adequately demonstrate that the annual average weighted MRI scan volume for each existing, approved, and proposed fixed MRI scanner owned and operated by Novant Health in Mecklenburg County will be at least 4,805 weighted MRI procedures in the third year of operation following completion of the proposed project, pursuant to 10A NCAC 14C .2703(b)(3).

**-C- Mercy Hospital.** In a table provided in Section C.11, page 64, the applicant states that the average annual weighted MRI procedures that all CHS/CIS existing, approved, and proposed fixed MRI scanners are projected to perform in the third year of operation of the proposed project is 5,918.

*(4) if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*

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

*(D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*

*(E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

**-NA- Both Applications.** Neither applicant proposes to locate an additional fixed MRI scanner at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity. Therefore, this Rule is not applicable this review.

*(5) demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and*

**-NA- The Presbyterian Hospital.** The applicant does not own any mobile MRI scanners in Mecklenburg County. Therefore, this Rule is not applicable to this review.

**-C- Mercy Hospital.** In Section C.11, page 65, and Exhibit C.11-1, page 15, the applicant projects the annual utilization of its one existing mobile MRI scanner located in Mecklenburg County will perform 3,848 weighted MRI procedures in CY2021, the third year of operation of the proposed project.

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

**-NC- The Presbyterian Hospital.** The applicant's assumptions and data supporting the methodology used for the projection required in 10 A NCAC 14C .2703(b)(1) are provided in Section C, pages 55-56. However, the applicant does not provide assumptions nor data supporting a methodology used for the projection required in 10A NCAC 14C .2703(b)(3). Therefore, the application is not conforming to this Rule.

**-C- Mercy Hospital.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q, page 1, Section C.11, page 63, Section Q, page 2-3, and Exhibit C.11-1, pages 1-15.

*(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 of the applicants propose the acquisition of a dedicated fixed breast MRI scanner. Therefore, this Rule is not applicable to this review.

*(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 of the applicants propose the acquisition of a fixed extremity MRI scanner. Therefore, this Rule is not applicable to this review.

*(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 of the applicants propose the acquisition of a fixed multi-position MRI scanner. Therefore, this Rule is not applicable to this review.

**ATTACHMENT - REQUIRED STATE AGENCY FINDINGS****FINDINGS**

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 28, 2020

Findings Date: February 4, 2020

Project Analyst: Ena Lightbourne

Team Leader: Fatimah Wilson

Assistant Chief: Lisa Pittman

**COMPETITIVE REVIEW**


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Project ID #:	F-11755-19
Facility:	Novant Health Matthews Medical Center
FID #:	945076
County:	Mecklenburg
Applicant(s):	Presbyterian Medical Care Corp.
Project:	Acquire a second fixed MRI scanner pursuant to the need determination in the 2019 SMFP

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Project ID #:	F-11760-19
Facility:	Atrium Health Kenilworth Diagnostic Center #1
FID #:	190165
County:	Mecklenburg
Applicant(s):	Carolinas Physicians Network, Inc.
Project:	Acquire one fixed MRI scanner pursuant to the need determination in the 2019 SMFP

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**REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES**

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

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

C – Both Applications

**Project ID# F-11760-19/Atrium Health Kenilworth Diagnostic Center #1/Acquire One Fixed MRI Scanner**

In Section O, Form A, the applicant identifies all other healthcare facilities in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant does not specifically identify which facilities are diagnostic centers, but the information in Form A suggests there are nine such diagnostic centers located in North Carolina.

On page 94, the applicant states,

*“Each of the facilities identified...has continually maintained all relevant licensure, certification, and accreditation...for the 18 months preceding the submission of this application.”*

After reviewing and considering information provided by the applicant regarding the quality of care provided at Sanger and the other seven facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

**C-Both Applications**

The Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700, are applicable to this review.

The specific criteria for both applications are discussed below.

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

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

- (a) *An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner shall:*
  - (1) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the mobile MRI region in which*



*the proposed equipment will be located, except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; with the exception that in the event an existing mobile MRI scanner has been in operation less than 12 months at the time the application is filed, the applicant shall demonstrate that this mobile MRI scanner performed an average of at least 277 weighted MRI procedures per month for the period in which it has been in operation;*

- (2) *demonstrate annual utilization in the third year of operation is reasonably projected to be at least 3328 weighted MRI procedures on each of the existing, approved and proposed mobile MRI scanners owned by the applicant or a related entity to be operated in the mobile MRI region in which the proposed equipment will be located [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; and*
- (3) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule*

**-NA-** Neither of the applicants propose to acquire a mobile MRI scanner. Therefore, this rule is not applicable to this review.

(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-** Novant Health, Inc. owned nine existing fixed MRI scanners in Mecklenburg County. In Section C, page 53, the applicant reports in the most recent 12 months of operation (January 2018 through December 2018) for which data was available, the eight fixed MRI scanners in Mecklenburg County performed 44,771 weighted MRI procedures or an average of 4,975 weighted MRI procedures per MRI scanner which is greater than the 3,328 weighted MRI procedures per scanner required by the Rule.

**-C-** CMHA and CIS owned eleven existing fixed MRI scanners in Mecklenburg County. In Section C, page 51, the applicant reports in the most recent 12 months of operation (July 2018 through June 2018) for which data was available, the eleven fixed MRI scanners in Mecklenburg County performed 60,372 weighted MRI procedures or an average of 5,488 weighted MRI procedures per MRI scanner which is greater than the 3,328 weighted MRI procedures per scanner required by the Rule.

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

*average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];*

- NA- Novant Health, Inc. owned two existing mobile MRI scanners in Mecklenburg County. However, pursuant to a Material Compliance determination issued by the CON Section on August 16, 2019, mobile MRI services at Novant Health Imaging University and Novant Health Imaging Steele Creek was discontinued effective August 15, 2019.
- NA- CMHA and CIS do not own controlling interest in and operate a mobile MRI in the proposed MRI service area. Therefore, this rule is not applicable to this review.
  - (3) *demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*
    - (A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
    - (B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
    - (C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
    - (D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*
    - (E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*
- C- Novant Health, Inc. owned 11 existing and proposes one new fixed MRI scanner in Mecklenburg County. Therefore, pursuant to the Rule, the applicant must demonstrate that the eleven existing and one proposed fixed MRI scanners are reasonably expected to perform 4,805 weighted MRI procedures in the third year following completion of the proposed project. The third OY is CY2023. In Section C.12, page 54, the applicant projects the 11 existing and one proposed fixed MRI scanner will perform 73,721 weighted MRI procedures in the third year of operation (CY2023) for an average of 6,143 weighted MRI procedures which is greater than the 4,805 weighted MRI procedures required by the Rule.
- C- CMHA and CIS owned 11 existing and proposes one new fixed MRI scanner in Mecklenburg County. Therefore, pursuant to the Rule, the applicant must demonstrate that the eleven existing and one proposed fixed MRI scanners are reasonably expected to perform 4,805 weighted MRI procedures in the third year following completion of the proposed project. The third OY is CY2023. In Section C.12, page 53, the applicant projects the 11 existing and one proposed fixed MRI scanner will perform 61,087 weighted MRI procedures in the third year of operation (CY2023) for an average of 5,091 weighted MRI procedures which is greater than the 4,805 weighted MRI procedures required by the Rule.

- (4) *if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*
- (A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
  - (B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
  - (C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
  - (D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*
  - (E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

**-NA-** Presbyterian Medical Care Corp. does not propose to locate an additional fixed MRI scanner at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity. Therefore, this Rule is not applicable to this review. The applicant proposes to locate the MRI unit at a location of an existing MRI unit.

**-C-** CHMA and CIS owns eleven existing fixed MRI scanners in Mecklenburg County. 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 related entity. Therefore, pursuant to the rule, the applicant must demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform 4,805 weighted MRI procedures in the third year following completion of the proposed project. The third OY is CY2023. In Section C.12, page 53, the applicant projects that the proposed MRI scanner will perform 4,975 weighted MRI procedures in the third year of operation (CY2023), which is greater than the 4,805 weighted MRI procedures required by the Rule.

- (5) *demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and*

**-NA-** Novant Health, Inc. owned two existing mobile MRI scanners in Mecklenburg County. However, pursuant to a Material compliance determination issued by the CON Section on August 16, 2019, mobile MRI services at Novant Health Imaging University and Novant Health Imaging Steele Creek was discontinued August 15, 2019.

**-NA-** CMHA and CIS does not own a controlling interest in and operate a mobile MRI in the proposed MRI service area. Therefore, this rule is not applicable to this review.

- (6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- (c) *An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*
- (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure per hour times 40 hours per week times 52 weeks per year; and*
  - (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- NA-** Neither of the applicants propose the acquisition of a dedicated fixed breast MRI scanner. Therefore, this Rule is not applicable to this review.
- (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 of the applicants propose the acquisition of a dedicated fixed extremity MRI scanner. Therefore, this Rule is not applicable to this review.
- (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 of the applicants propose the acquisition of a dedicated fixed multi-position MRI scanner. Therefore, this Rule is not applicable to this review.

### COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2019 SMFP, no more than one additional fixed MRI scanner may be approved for Mecklenburg County in this review. Because the two applications in this review collectively propose to acquire two additional fixed MRI scanners to be located in Mecklenburg County, all of the applications cannot be approved for the total of number of MRI scanners proposed.