

Competitive Comments on Mecklenburg County MRI Applications

submitted by

Carolinas Physicians Network, Inc. (CPN)

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Carolinas Physicians Network, Inc. (CPN) submits the following comments related to Novant Health Matthews Medical Center's (NH Matthews) application to acquire a fixed MRI scanner in Mecklenburg County. CPN'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). In order to facilitate the Agency's ease in reviewing the comments, CPN 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 the NH Matthews application, Project ID # F-11755-19. The following comments include general comments on this review, as well as specific comments on the NH Matthews' application and a comparative analysis including CPN's application to acquire a fixed MRI scanner at Atrium Health Kenilworth Diagnostic Center #1, Project ID # F-11760-19. Based on the following comments, it is clear that NH Matthews' application should be denied.

GENERAL COMMENTS

The *2019 State Medical Facilities (SMFP)* identifies a need for an additional fixed MRI scanner in Mecklenburg County, and Atrium Health, CPN's parent, demonstrates the greatest need for additional capacity. As shown below in a table excerpted from page 32 of CPN's application, which has been updated to reflect Novant Health's July 2019 conversion of grandfathered mobile MRI scanner to a fixed MRI scanner at NH Presbyterian as discussed below, Atrium Health's fixed MRI scanners in FFY 2018 performed more than 7,600 adjusted MRI scans above Mecklenburg County's threshold of 4,805 scans per fixed unit. **Said another way, Atrium Health has enough volume today to support almost two more fixed MRI scanners (1.6 more).** By comparison, Novant Health currently operates with excess capacity of fixed MRI scanners.

FFY 2018 Fixed MRI Scans and Capacity by Provider

	<i>Adjusted Fixed MRI Scans</i>	<i>Fixed Units</i>	<i>Adjusted Scans in Excess of 4,805 per Unit*</i>
Atrium Health	46,123	8.0	7,683
CIS	9,821	3.0	-4,594
Atrium Health/CIS	55,944	11.0	3,089
Novant Health**	46,755	11.0	-6,100
OrthoCarolina	15,581	2.0	5,971
CNSA	4,471	1.0	-334

Source: *Proposed 2020 SMFP* as well as corrected data. See Exhibit C.4-1 of CPN's application.

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

**Novant Health's fixed inventory has been updated to include the recent conversion of a grandfathered mobile MRI scanner to a fixed MRI scanner at NH Presbyterian. As such, Novant Health's has 11 fixed units and its adjusted scans in excess of 4,805 per Unit was recalculated.

In its application, NH Matthews incorrectly and repeatedly states that Novant Health fixed MRI units are the most highly utilized in Mecklenburg County (see pages 30, 33, 45, and 62). In support of this erroneous statement, NH Matthews provided the following table on page 33 of its application.

Figure 3
FY 2018 Fixed MRI Utilization of Mecklenburg County Acute Care Hospitals

Provider	No. of Fixed MRI Scanners	MRI Scan Volume	Weighted MRI Volume	Weight Volume/Unit	% Capacity
Novant Health Matthews Medical Center	1	7,011	8,564	8,564	124.8%
Novant Health Huntersville Medical Center	1	6,328	7,617	7,617	111.0%
Carolinas Medical Center – Mercy	1	5,269	6,619	6,619	96.4%
Carolinas Medical Center – Main	4	17,984	24,709	6,177	90.0%
Atrium Health University City	1	4,722	5,760	5,760	83.9%
Novant Health Presbyterian Medical Center*	3	12,969	16,675	5,558	81.0%
Atrium Health Pineville	2	7,164	9,035	4,518	65.8%
Novant Health Mint Hill Medical Center**	1	0	0	0	0.0%
Combined Health System Utilization – Hospital Fixed					
Novant Health	5	26,308	32,856	6,571	95.7%
Atrium Health	8	35,139	46,123	5,765	84.0%

Source: 2020 Proposed SMFP

*Includes Presbyterian Medical Center - Main and The Charlotte Orthopedic Hospital. Novant Health Imaging Museum operates as a department of Presbyterian Medical Center but only provides outpatients diagnostic services during regular business hours like a freestanding facility.

**NH Mint Hill Opened in October 2018 and will show utilization for FY 2019 in the 2021 SMFP.

Note: The chart above identifies the providers of fixed MRI services and the volumes performed during October 1, 2017-September 30, 2018 as reported in the draft 2020 SMFP.

Capacity = weighted volume/ (# of fixed units x 6,864)

Note: NHHMC and NHHMC volumes edited based on corrections to the LRA. See Exhibit C-4.2 (Tab 3) pages 84 to 91.

There are significant issues with this analysis. To determine the most highly utilized providers and those most in need of additional capacity, the analysis must be based on an accurate inventory. NH Matthews fails to accurately record the inventory of MRI scanners in Mecklenburg County.

First, the table incorrectly states the fixed MRI capacity of Novant Health Huntersville Medical Center (NH Huntersville) as one fixed MRI scanner; NH Huntersville has an approved and existing capacity of two fixed MRI scanners. The *Proposed 2020 State Medical Facilities Plan* also incorrectly stated NH Huntersville’s fixed MRI capacity; however, the Healthcare Planning and Certificate of Need Section has corrected this error and the most recent version of Table 17E-1 dated September 11, 2019 (see Attachment 1) shows that NH Huntersville has two fixed MRI units. Moreover, NH Matthews understands that it has been approved for a second fixed scanner, as it states on page 34 that “*Novant Health Huntersville Medical Center (“NHHMC”) had a mobile MRI unit onsite until August 2019, as its second fixed unit becomes operational in August 2019” (emphasis added)*. Further, the Novant Health total line does not include NH Mint Hill’s fixed unit but does include Atrium Health Pineville’s second fixed unit, neither of which was operational during the FFY 2018 time period; to remain consistent with the *2019 SMFP* and provide an accurate comparison, CPN believes both should be included. Additionally, as NH Matthews states on page

40 of its application, “Novant Health has submitted and been granted a request for exemption for NHPMC to convert a mobile MRI unit to a fixed unit on its main campus.” However, NH Matthews’ analysis fails to include that additional fixed unit, which would bring its total hospital fixed capacity to eight units and result in lower utilization per unit and as a percent of capacity than shown above.

When the second fixed unit at NH Huntersville, the NH Mint Hill unit, and the recently converted grandfathered fixed unit at NH Presbyterian are included in the analysis above, the subtotal of the Novant Health fixed MRI units in the table demonstrates lower utilization than the Atrium Health scanners.

Figure 3
FY 2018 Fixed MRI Utilization of Mecklenburg County Acute Care Hospitals

Provider	No. of Fixed MRI Scanners	MRI Scan Volume	Weighted MRI Volume	Weight Volume/Unit	% Capacity
Novant Health Matthews Medical Center	1	7,011	8,564	8,564	124.8%
Novant Health Huntersville Medical Center	2 1	6,328	7,617	3,809 7,617	55.4% 111.0%
Carolinas Medical Center – Mercy	1	5,269	6,619	6,619	96.4%
Carolinas Medical Center – Main	4	17,984	24,709	6,177	90.0%
Atrium Health University City	1	4,722	5,760	5,760	83.9%
Novant Health Presbyterian Medical Center*	4 3	12,969	16,675	4,169 5,558	60.7% 81.0%
Atrium Health Pineville	2	7,164	9,035	4,518	65.8%
Novant Health Mint Hill Medical Center**	Added below 1	0	0	0	0.0%
Combined Health System Utilization – Hospital Fixed				4,107	59.8%
Novant Health	8 5	26,308	32,856	6,571	95.7%
Atrium Health	8	35,139	46,123	5,765	84.0%

Source: 2020 Proposed SMFP

*Includes Presbyterian Medical Center - Main and The Charlotte Orthopedic Hospital. Novant Health Imaging Museum operates as a department of Presbyterian Medical Center but only provides outpatients diagnostic services during regular business hours like a freestanding facility.

**NH Mint Hill Opened in October 2018 and will show utilization for FY 2019 in the 2021 SMFP.

Note: The chart above identifies the providers of fixed MRI services and the volumes performed during October 1, 2017-September 30, 2018 as reported in the draft 2020 SMFP.

Capacity = weighted volume/ (# of fixed units x 6,864)

Note: NHMMC and NHHMC volumes edited based on corrections to the LRA. See Exhibit C-4.2 (Tab 3) pages 84 to 91.

The second issue with this analysis is that it excludes three of Novant Health’s existing fixed scanners (Novant Health Imaging Museum, Novant Health Imaging Southpark, and Novant Health Imaging Ballantyne), which have lower utilization rates than the scanners that are included in the NH Matthews’ analysis, and it also excludes all other freestanding fixed MRI scanners in Mecklenburg County operated by Atrium Health and others. By comparison, the table provided on page 1 of these comments which is based on a table included in CPN’s application that includes the two NH Huntersville MRI units, the NH Mint Hill unit, as well as all other fixed MRI scanners in Mecklenburg County, and has been updated to include the NH Presbyterian converted fixed unit. CPN’s analysis, which is based on the correct inventory, shows that Atrium Health has the greatest need for additional capacity while Novant Health has excess capacity. Further, as noted in CPN’s application, CPN believes additional fixed MRI capacity within Atrium

Health is the most effective alternative for the development of an additional fixed MRI scanner located in Mecklenburg County based on the following factors:

- Atrium Health/Carolinas Imaging Services (CIS) has historically performed the highest volume of adjusted MRI scans among the county's providers;
- Atrium Health has the highest number of adjusted MRI scans in excess of the planning threshold indicating the greatest need for additional capacity;
- Atrium Health/CIS provides the broadest geographic access to patients seeking MRI scans in Mecklenburg County; and,
- Atrium Health/CIS has the highest complexity mix among all MRI providers in Mecklenburg County.

Cardiac MRI

NH Matthews' application includes a short discussion of cardiac MRI technology and states that "the proposed MRI scanner will offer more advanced technology that will allow [NH Matthews] to increase its capacity for cardiac studies" (page 36). Please note that any cardiac MRI program at NH Matthews, if it exists today, is far less advanced than the cardiac MRI program operated by Atrium Health and CPN. As noted in CPN's application, Atrium Health and CPN initiated the development of an advanced, robust cardiac MRI program five years ago with the hiring of a fellowship-trained cardiac MRI physician, currently based at CMC. Atrium Health and CPN have now added a second fellowship-trained cardiac MRI physician and will add a third in the fall of 2019. These additional physicians will support the additional exam interpretation duties expected based on the dramatic historical growth of Atrium Health and CPN's cardiac MRI program. Referrals from CPN physicians alone resulted in more than 1,200 outpatient cardiac MRI scans to CMC in CY 2019 and these scans grew 31.8 percent annually from CY 2016 to 2019. NH Matthews' statement that "[a] cardiac MRI study including prep time and procedure time can require two or more hours" suggests that it would be treating the most complex pediatric congenital heart scans performed under anesthesia, as these are the types of cardiac MRI scans that take that length of time. Typically, adult cardiac MRI scans require an hour or less. It is unlikely that pediatric patients of that acuity would be scanned at NH Matthews given the resource requirements such as a pediatric cardiac anesthesiologist and pediatric emergency response resources. Rather, it appears that NH Matthews' application included generic, common features of its proposed scanner and would not be at all comparable to CPN's proposed cardiac MRI program at Atrium Health Kenilworth Diagnostic Center #1.

APPLICATION-SPECIFIC COMMENTS

NH Matthews's application to acquire a fixed MRI scanner should not be approved as proposed. CPN identified the following specific issues, each of which contributes to NH Matthews's non-conformity:

- (1) Failure to conform with performance standards**
- (2) Failure to provide reasonable utilization projections**
- (3) Failure to demonstrate that the least costly or most effective alternative is proposed**
- (4) Failure to demonstrate financial feasibility**

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

Failure to conform with performance standards

NH Matthews’ application fails to meet the performance standards for historical and projected utilization of mobile MRI scanners. The historical standard, 10 NCAC 14C .2703(b)(2), states that an applicant proposing to acquire a fixed MRI scanner shall:

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.

NH Matthews’ response on page 53 of its application states:

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

As shown on page 44 of the NH Matthews application, excerpted below with red circles added, each of these scanners performed less than 3,328 weighted MRI procedures historically, and as such, each is non-conforming with 10 NCAC 14C .2703(b)(2).

Adjusted Total Scans									
						Project Years			
	FY 2017	FY 2018	FY 2019 Annualized	Interim FY 2020	Interim Q1- Q3 2021	7/1/2021 - 6/30/2022	7/1/2022 - 6/30/2023	7/1/2023 - 6/30/2024	
Hospitals									
<i>Presbyterian Medical Center</i>									
Fixed*	18,918	20,180	21,584	23,026	18,423	25,786	27,509	29,847	
<i>Huntersville Medical Center</i>									
Fixed	7,728	7,617	8,031	10,760	8,587	11,995	12,764	13,581	
Mobile	526	1,252	1,985	-	-	-	-	-	
Total	8,254	8,869	10,015	10,760	8,587	11,995	12,764	13,581	
<i>Matthews Medical Center</i>									
Fixed	8,604	8,564	8,126	9,049	6,883	9,871	10,374	10,902	
Mobile	87	732	765	-	-	-	-	-	
Total	8,691	9,296	8,891	9,049	6,883	9,871	10,374	10,902	
<i>Mint Hill Medical Center</i>									
Fixed	-	-	4,045	4,251	3,351	4,637	4,874	5,122	
Freestanding Mobile									
NHI University	3,864	1,738	1,445	1,879	1,832	2,050	2,154	2,264	
NHI Steele Creek	1,133	949	2,144	2,253	1,776	2,458	2,583	2,715	
Freestanding Fixed									
NHI Ballantyne	2,691	3,743	3,698	4,067	3,539	5,274	6,117	7,096	
NHI Southpark	4,035	4,657	4,880	5,357	4,427	6,341	6,975	7,673	

*Includes Presbyterian Main, Charlotte Orthopedic Hospital, and Novant Health Imaging Museum
 Note: Data presented is based on corrected LRAs. See Exhibit C-4.2 (Tab 3) pages 84-91.

The projected performance 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.]

NH Matthews' response on page 55 of its application states:

As a provider of both fixed and mobile MRI services, Novant Health has 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 own 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.

As shown on page 44 of the NH Matthews application, excerpted below with orange circles added, each of these scanners is projected to perform less than 3,328 weighted MRI procedures, and as such, each is non-conforming with 10A NCAC 14C .2703(b)(5).

Adjusted Total Scans								
	FY 2017	FY 2018	FY 2019 Annualized	Interim FY 2020	Interim Q1- Q3 2021	Project Years 7/1/2021 - 6/30/2022	7/1/2022 - 6/30/2023	7/1/2023 - 6/30/2024
Hospitals								
<i>Presbyterian Medical Center</i>								
Fixed*	18,918	20,180	21,584	23,026	18,423	25,786	27,509	29,347
<i>Huntersville Medical Center</i>								
Fixed	7,728	7,517	8,031	10,760	8,587	11,995	12,764	13,581
Mobile	526	1,252	1,985	-	-	-	-	-
Total	8,254	8,869	10,015	10,760	8,587	11,995	12,764	13,581
<i>Matthews Medical Center</i>								
Fixed	8,604	8,564	8,126	9,049	6,883	9,871	10,374	10,902
Mobile	87	732	765	-	-	-	-	-
Total	8,691	9,296	8,891	9,049	6,883	9,871	10,374	10,902
<i>Mint Hill Medical Center</i>								
Fixed	-	-	4,045	4,251	3,351	4,637	4,874	5,122
Freestanding Mobile								
NHI University	3,864	1,738	1,445	1,879	1,832	2,050	2,154	2,264
NHI Steele Creek	1,133	949	2,144	2,259	1,776	2,458	2,583	2,715
Freestanding Fixed								
NHI Ballantyne	2,691	3,743	3,698	4,067	3,539	5,274	6,117	7,096
NHI Southpark	4,035	4,667	4,880	5,367	4,427	6,341	6,975	7,673

*Includes Presbyterian Main, Charlotte Orthopedic Hospital, and Novant Health Imaging Museum
 Note: Data presented is based on corrected LRAs. See Exhibit C-4.2 (Tab 3) pages 84-91.

NH Matthews provides no basis for its statements that grandfathered MRI units are exempt from meeting these performance standards. NH Matthews' statement is contradicted by the language of the MRI rules, its own application, 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 standard. 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 own application, NH Matthews assumes that the performance standards apply to a grandfathered unit. Specifically, in its response to the projected performance standard for fixed MRI units at 10 NCAC 14C .2703(b)(3), NH Matthews’ response includes the grandfathered mobile unit that is approved to be converted to fixed at Presbyterian Medical Center, as shown in the excerpt below from page 54:

All existing, approved, and proposed fixed MRI scanners, which NHMMC or a related entity own a controlling interest in, located in Mecklenburg County are projected to perform at least 4,805 weighted MRI procedures in the third year of operation following completion of the proposed project. This includes the second unit at NHMMC proposes in this application. Please see Figure 10 presented below. Additionally, see the detailed projected utilization presented above for the specific assumptions supporting these projections.

Figure 10
Novant Health Weighted MRI Procedures Third Year of Operation

Facility	Total Projected MRI Scans	Adjusted Total	Number of Units	Adjusted Total/Unit
Presbyterian Medical Center*	23,283	29,347	5	5,869
Huntersville Medical Center	11,283	13,581	2	6,791
Matthews Medical Center	8,926	10,902	2	5,451
Mint Hill Medical Center	4,233	5,122	1	5,122
NHI Ballantyne	6,277	7,096	1	7,096
NHI Southpark	7,099	7,673	1	7,673

Source: Internal Data

*Includes Presbyterian Main (two existing units and one additional unit per request of exemption to convert a mobile unit to a fixed unit – Record #2983), Charlotte Orthopedic Hospital (one unit), and Novant Health Imaging Museum (one unit).

It is not clear why NH Matthews believes (incorrectly) in its currently proposed application that the performance standards apply to grandfathered MRI units when 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 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. CPN is aware of the following instances, and there may be many more.

- In its review of J-7442-05 (see Attachment 2), 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 3), 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 SMFPs 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 and 2017 Mecklenburg County MRI reviews (see Attachment 4), the Agency applied the fixed MRI performance standards to Carolinas Medical Center's (CMC) grandfathered fixed MRI units. As shown on its 2019 Hospital License Renewal Application (HLRA), CMC reported one grandfathered fixed MRI scanner and has determined through recent research that another one of its units is grandfathered, which will be 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 scanner.
- In the 2016 Guilford County MRI review (see Attachment 5), the Agency applied the mobile MRI performance standards to Alliance HealthCare Services' (AHS) grandfathered mobile MRI scanners 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 6), 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.

Again, NH Matthews provides no basis for its statement that the grandfathered units are exempt from meeting the performance standards. Moreover, such an exclusion would run contrary to the intent of the MRI rules and **the premise of the CON Law**. As the Agency states 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 page 63).

Finally, there is no language in any CON rule exempting or excluding grandfathered assets. CPN 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. CPN 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 as NH Matthews asserts.

NH Matthews should be found non-conforming with 10A NCAC 14C .2703(b)(2) and (5). As such, NH Matthews should be denied.

Failure to provide reasonable utilization projections

As shown in the table on page 41 of its application (excerpted below), NH Matthews experienced a 4.4 percent decline in total MRI scans from 2018 to 2019 (circled in red).

Number of MRI Scans – Novant Health Mecklenburg County				
	FY 2017	FY 2018	FY 2019 Annualized	2-Year CAGR
Hospitals				
<i>Presbyterian Medical Center</i>				
Fixed*	15,046	16,010	17,124	6.7%
<i>Huntersville Medical Center</i>				
Fixed**	6,530	6,328	6,184	
Mobile***	459	1,091	1,729	
Total	6,989	7,419	7,913	6.4%
<i>Matthews Medical Center</i>				
Fixed	7,024	7,011	6,653	
Mobile	78	624	652	
Total	7,102	7,635	7,305	1.4%
<i>Mint Hill Medical Center</i>				
Fixed†	-	-	3,343	
Freestanding Mobile				
NHI University††	1,744	1,632	1,358	-11.8%
NHI Steele Creek	1,029	883	1,995	39.2%
Freestanding Fixed				
NHI Ballantyne	2,431	3,311	3,272	16.0%
NHI Southpark	3,733	4,318	4,515	10.0%
Novant Health Hospitals in Mecklenburg County†††	26,474	28,023	29,241	5.1%

Source: NHMMC Internal Data

Of note, this decline occurred at the same time as NH Mint Hill began offering MRI services, suggesting that some of NH Matthews’ historical volume may have shifted to and is now being served by NH Mint Hill reducing the demand at NH Matthews. NH Matthews fails to discuss the decline anywhere in its application. Note, it is not clear how long NH Mint Hill’s MRI service has been operational and how its annualized FY 2019 volumes were derived.

Additionally, NH Matthews fails to mention anywhere in its application the approved development of Novant Ballantyne Medical Center (NH Ballantyne), a new Novant Health acute care hospital in Ballantyne, which will offer mobile MRI services. As stated on page 15 of the NH Ballantyne application (Project ID # F-11625-18), NH 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. [NH Ballantyne] has secured a commitment from MedQuest to provide these services.” There is no discussion whatsoever of whether the development of hospital-based MRI services at NH Ballantyne will impact the utilization of other Novant Health sites. This is a particular issue as the projected utilization of NH Ballantyne included a shift of patients from other Novant hospitals. Further, NH Matthews states that only two existing

grandfathered mobile MRI units owned by Novant Health or a related entity will operate in Mecklenburg County in the future. As NH Matthews makes no mention of NH Ballantyne in its application, it does not indicate whether NH Ballantyne would be served by one of those scanners or perhaps by a non-grandfathered scanner.

Based on the discussion above, it is clear that NH Matthews' projected utilization is unsupported. As such, NH 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(3) and (6)) and should be denied.

Failure to demonstrate that the least costly or most effective alternative is proposed

On pages 61-62 of its application, NH Matthews discusses three alternatives it considered regarding the development of a fixed MRI:

1. Maintain the status quo
2. Add additional mobile MRI days
3. Seek the State's approval of NHMMC for a new fixed MRI unit

In addition to failing to demonstrate the need for a second fixed MRI scanner, NH Matthews does not address an additional alternative relevant to this review. NH Matthews does not consider the alternative of developing the proposed MRI scanner as a part of a freestanding imaging center, rather than a hospital-based unit. MRI units operated by freestanding imaging centers provide lower patient charges, as evidenced by the comparison of gross and net revenues shown in the comparative analysis below. As stated on pages 37-38 of its application, NH Matthews "has seen a dramatic increase in outpatient MRI procedures in particular over the past five years. Note that while total fixed MRI scans have grown by 31.1 percent, or 5.6 percent annually, over the past five years, outpatient fixed MRI scans account for the majority of that growth with an increase of 38.6 percent, or 6.7 percent annually, from FY 2013 to 2018" (emphasis added). NH Matthews continues by stating that it "operates a full schedule of outpatient MRIs on a daily basis. The MRI outpatient schedule is so full that patients who are admitted through the emergency department (ED) and STAT inpatients must be worked into the schedule" (page 38). Based on these representations in particular, Novant Health could have proposed a freestanding imaging center to address NH Matthews' outpatient MRI needs and provide patients with outpatient-only access and convenience with lower patient charges while also relieving purported scheduling constraints that affect ED and inpatient needs.

Based on these issues, NH Matthews failed to demonstrate that its proposal is the least costly or most effective alternative. NH Matthews should be found non-conforming with Criterion 4. As such, its application should be denied.

Failure to demonstrate financial feasibility

NH Matthews fails to demonstrate the financial feasibility of its proposed project. NH Matthews' financial projections understate expenses, as they do not include any indirect expenses associated with corporate overhead, scheduling, registration, billing, etc. As shown in NH Matthews' Form F.3-Operating Costs, less than \$2,000 annually is projected for Other Expenses-Miscellaneous and no other line item lists other indirect expenses.

Form F.3 Operating Costs	Prior Full FY	Interim* Full FY	Interim* Full FY	Interim* Partial FY	1st Full FY	2nd Full FY	3rd Full FY
Criterion (5)	From (10/1/2017)	From (10/1/2018)	From (10/1/2019)	From (10/1/2020)	From (07/01/2021)	From (07/01/2022)	From (07/01/2023)
Complete a separate Form F.3 for the entire facility and each service component	To (9/30/2018)	To (9/30/2019)	To (9/30/2020)	To (6/30/2021)	To (06/30/2022)	To (06/30/2023)	To (06/30/2024)
Salaries (from Form H Staffing)	\$409,194	\$480,141	\$494,545	\$382,036	\$938,292	\$966,441	\$995,434
Taxes and Benefits	\$119,883	\$140,668	\$144,889	\$111,926	\$274,895	\$283,141	\$291,636
Independent Contractors (1)	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Medical Supplies	\$103,885	\$116,714	\$120,735	\$93,670	\$136,349	\$146,162	\$156,682
Other Supplies	\$997	\$4,851	\$4,948	\$3,785	\$5,122	\$5,225	\$5,329
Dietary (2)	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Housekeeping/Laundry (2)	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Equipment Maintenance	\$270,779	\$325,617	\$0	\$12,500	\$37,500	\$37,500	\$37,500
Building & Grounds Maintenance (2)	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Utilities	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Insurance	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Professional Fees	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Interest Expense	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Rental Expense	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Property and Other Taxes (except Income)	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Depreciation - Buildings	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Depreciation - Equipment	\$17,203	\$12,274	\$176,213	\$ 234,951	\$ 634,518	\$ 634,518	\$634,518
Other Expenses (specify) Miscellaneous	\$74	\$1,388	\$1,415	\$1,083	\$1,465	\$1,494	\$1,524
Other Expenses (specify)	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Other Expenses (specify)	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Total Expenses	\$922,015	\$1,081,653	\$942,745	\$839,951	\$2,028,142	\$2,074,483	\$2,122,624

By comparison, previous Novant Health applications for hospital-based fixed MRI services in Mecklenburg County have included a significant amount of indirect expense. For example, Novant Health’s 2017 CON for an additional MRI scanner at NH Presbyterian Medical Center included Outside Services and Other Indirect/Corporate Overhead Expenses totaling \$450,000 or more annually, comprising 23 to 25 percent of total expenses (see Attachment 7). NH Presbyterian’s financial assumptions described these expenses as follows:

- Corporate Overhead and Other Indirect Expenses include, but are not limited to the following, inflated 3 to 4 percent annually: Cable Services, Community Outreach, Dues/Memberships, Education Fees, Employee Activities, Food Catering, Freight, Mileage, Mobile Phone Services, Pager Services, Postage, Seminars, infectious Waste Disposal, Licenses, Marketing, Telephone, Travel & Conference, and Miscellaneous/Other Expenses.
- Outside Services, included but are not limited to the following, inflated 3 to 4 percent annually: Ambulance Services, Armored Car Services, Banking Services, Billing Fees, Collection Fees, Consulting Fees, Courier Services, Contract Labor, Environmental Services, Extermination, Food Services, Infection Control, Lab Services, Mobile Services, Outside Record Storage, Patient Escort Services, Recruitment, Sterile Processing, Software Contract Agreement, Surgical & Diagnostic Services, Uniform Cleaning, Housekeeping, Miscellaneous and Other Expenses
- Corporate Overhead for NHPMC is based on the cost incurred by Novant Health for providing services and any additional costs required for: Human resources, Information Technology, Courier Services, Accounting and Finance Services, Facility Services, Materials Management, Patient Accounting, and Other Corporate Services.

NH Matthews’ 2011 CON to develop a fixed MRI scanner included Other Indirect Expenses totaling \$350,000 to \$416,000 annually, comprising 20 to 30 percent of total expenses (see Attachment 8). NH Matthews’s 2011 financial assumption described these expenses as follows:

Indirect Expenses include but are not limited to the following expenses inflated 2.5% to 4% annually.

Housekeeping	Accounting	Seminars	Licenses
Laundry	Billings	Education Fees	Travel & Conference
Utilities	Collections	Facility Overhead	
Insurance	Pager Service	Other	

It appears as though the financial statements included in NH Matthews' currently proposed application fail to include any such expenses for items that are necessary to provide the proposed service. As such, NH Matthews' expenses are significantly understated.

Given its understated expenses, NH Matthews' application fails to demonstrate the financial feasibility of the project is based on reasonable projections of costs and should be found non-conforming with Criterion 5. As such, its application should be denied.

COMPARATIVE COMMENTS

Given that both CPN and NH Matthews 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, CPN compared the applications on the following factors:

- Meeting the Need for Additional MRI Capacity
- Geographic Reach
- Demonstration of Need
- Access by Underserved Groups
- Revenues
- Operating Expenses

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

Meeting the Need for Additional Fixed MRI Capacity

Within Mecklenburg County, CPN’s parent, Atrium Health, operates eight fixed MRI units at three licensed acute care hospitals. In addition, Atrium Health 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 NH Presbyterian. **Please note that any comparative evaluation of Novant Health’s fixed MRI capacity should include this additional grandfathered unit.** As such, Novant Health now has 11 fixed MRI units in Mecklenburg County-the same number as Atrium Health/CIS. As shown in the table below, Atrium Health and CIS perform the highest volume of adjusted fixed MRI scans in Mecklenburg County, approximately 56,000 in FFY 2018, or nearly 10,000 more than the next largest provider. Atrium Health’s fixed MRI scanners in FFY 2018 performed more than 7,600 adjusted MRI scans above Mecklenburg County’s threshold of 4,805 scans per fixed unit. Said another way, Atrium Health has enough volume today to support almost two more fixed MRI scanners (1.6 more). Additionally, Atrium Health and CIS’s scanners perform 5,086 adjusted MRI scans per unit on average. By comparison, Novant Health’s fixed MRI scanners performed only 4,250 adjusted MRI scans per unit on average which is 6,100 adjusted MRI scans below the threshold of 4,805 scans per fixed unit.

FFY 2018 Fixed MRI Scans and Capacity by Provider

	<i>Adjusted Fixed MRI Scans</i>	<i>Fixed Units</i>	<i>Adjusted Scans in Excess of 4,805 per Unit*</i>	<i>Adjusted Scans per Fixed Unit</i>
Atrium Health	46,123	8.0	7,683	5,765
CIS	9,821	3.0	-4,594	3,274
Atrium Health/CIS	55,944	11.0	3,089	5,086
Novant Health	46,755	11.0	-6,100	4,250

Source: *Proposed 2020 SMFP* as well as corrected data.

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

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, CPN is the more effective alternative.

Geographic Reach

According to patient origin data submitted on license renewal applications (LRAs), less than 60 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 13.3 percent of total MRI scans performed by Mecklenburg County fixed MRI providers followed by neighboring North Carolina counties.

Total Patient Origin for Mecklenburg County Fixed MRI Providers

<i>NC County/State of Origin</i>	<i>Percent of Total</i>
Mecklenburg	57.6%
South Carolina	13.3%
Union	10.1%
All Others	5.0%
Gaston	4.1%
Cabarrus	2.4%
Iredell	2.0%
Lincoln	1.9%
Other States	1.8%
Cleveland	1.2%
Rowan	0.7%
Total	100.0%

Source: 2019 LRAs.

As noted on pages 34-35 of CPN’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 CPN demonstrates, Mecklenburg County would have a surplus of more than 11 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, CPN 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 shown in the table below, CPN projects to serve a higher percentage of Mecklenburg, South Carolina, Gaston, Cabarrus, Iredell, Lincoln, and Cleveland County residents than NH Matthews.

NC County/State of Origin	CPN	NH Matthews
Mecklenburg	55.0%	53.01%
South Carolina	8.8%	3.93%
Union	6.5%	36.27%
Gaston	7.0%	0.52%
Cabarrus	3.4%	1.71%
Iredell	1.7%	0.18%
Lincoln	1.7%	Less than 0.92%
Cleveland	2.7%	Less than 0.92%
Rowan	0.8%	Less than 0.92%

Source: Section C.3.(a).

Therefore, with regard to geographic reach of the population served by MRI units located in Mecklenburg County, CPN is the most effective alternative.

Demonstration of Need

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

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:

	CPN	NH Matthews
Percent of Total MRIs to be provided to Medicare Recipients	29.2%	42.8%
Percent of Total MRIs to be provided to Medicaid Recipients	15.2%	4.9%
Percent of Total MRIs to be provided to Self Pay Patients	6.8%	3.7%

Source: Section L.3.

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

Please note that NH Matthews failed to provide the estimated percentage of total patients for each group during the third full fiscal year of the project as requested in Section C.11 NH Matthews' response to L.1 is for its entire facility and not its MRI service. CPN provided the requested information for C.11 in its application, as shown below.

	<i>Women MRI Patients</i>	<i>Age 65+ MRI Patients</i>	<i>Racial Minorities MRI Patients</i>
CPN MRI	53.8%	23.8%	42.6%
NH Matthews	Not provided	Not provided	Not provided

Source: Section C.11.

Therefore, with regard to access to underserved groups, CPN is the more effective alternative.

Revenues

The following table illustrates each applicant's projected total gross revenue (technical component only) per procedure in the third project year.

	<i>CPN (PY3)</i>	<i>NH Matthews (PY3)</i>
Gross Revenue	\$8,302,392	\$33,772,732
Unweighted MRI Procedures	4,011	8,926
Gross Revenue per Procedure	\$2,070	\$3,784

As shown above, CPN projects lower average gross revenue per MRI procedure. Therefore, CPN is the more effective alternative with regard to gross revenue.

The following table illustrates each applicant's projected total net revenue (technical component only) per procedure in these years.

	<i>CPN (PY3)</i>	<i>NH Matthews (PY3)</i>
Net Revenue	\$1,785,730	\$7,021,351
Unweighted MRI Procedures	4,011	8,926
Net Revenue per Procedure	\$445	\$787

As shown above, CPN projects lower average net revenue per MRI procedure. Therefore, CPN is the most effective alternative with regard to net revenue.

Operating Expenses

The following table illustrates each applicant's operating expenses (technical component only) per procedure in the third project year.

	CPN (PY3)	NH Matthews (PY3)
Operating Expenses	\$1,456,984	\$2,122,624
Unweighted MRI Procedures	4,011	8,926
Operating Expenses per Procedure	\$363	\$238

As demonstrated in the discussion above on the failure to demonstrate financial feasibility, NH Matthews understated its expenses throughout the project period and failed to include the costs necessary to provide the proposed MRI service. As such, CPN is the more effective alternative with regard to operating expenses.

SUMMARY

As noted previously, CPN maintains that NH 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, CPN is the only approvable application. Based on the comparative analysis summarize below, CPN believes that its application represents the most effective alternative for meeting the need in the 2019 SMFP for an additional fixed MRI scanner in Mecklenburg County.

Comparative Factor	CPN	NH Matthews
Meeting the Need for Additional MRI Capacity	More Effective	Less Effective
Geographic Reach	More Effective	Less Effective
Demonstration of Need	More Effective	Less Effective
Access by Underserved Groups	More Effective	Less Effective
Revenues	More Effective	Less Effective
Operating Expenses	More Effective	Less Effective

As such, the Agency can and should approve CPN.

Attachment 1

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
Macon	Hospital Fixed		Angel Medical Center	1	1.00	2,060	1,455	513	73	19	2,310			
Macon	Hospital Fixed	A-007197-05	Highlands-Cashiers Hospital	1	1.00	457	354	94	5	4	500			
Macon	Mobile	Grandfathered	Duke LifePoint Harris Regional At Franklin Med (Alliance Healthcare Services)	0	0.08	319	299	20	0	0	327			
Macon				2	2.08	2,836					3,136	1,508	4,118	0
Martin	Mobile	Grandfathered	CHS - Martin General Hospital (Alliance Healthcare Services)	0	0.00	3	2	1	0	0	3			
Martin	Mobile	Q-6884-03	CHS Martin General Hospital (Alliance Healthcare Services & University Health Systems of Eastern NC)	0	0.27	464	406	50	5	3	488			
Martin				0	0.27	467					492	492	1,716	0
McDowell	Hospital Fixed	C-007304-05	Mission Hospital McDowell	1	1.00	1,803	1,155	526	63	59	2,086			
McDowell	Mobile	E-007066-04	Blue Ridge Marion (Blue Ridge Radiology Associates, P.A.)	0	0.19	731	608	123	0	0	780			
McDowell				1	1.19	2,534					2,866	2,408	3,775	0
Mecklenburg	Hospital Fixed	F-006830-03; F-011425-17	Atrium Health Pineville	2	2.00	7,164	3,141	1,606	1,763	654	9,035			
Mecklenburg	Hospital Fixed	F-005919-98	Atrium Health University City	1	1.00	4,722	2,423	1,218	786	295	5,760			
Mecklenburg	Hospital Fixed		Carolinas Medical Center - Main	4	4.00	17,984	4,424	6,079	4,229	3,252	24,709			
Mecklenburg	Hospital Fixed		Carolinas Medical Center - Mercy	1	1.00	5,269	2,345	1,023	1,451	450	6,619			
Mecklenburg	Hospital Fixed	F-005580-97; F-008237-08	Novant Health Huntersville Medical Center	2	2.00	6,328	3,388	2,119	539	282	7,617			
Mecklenburg	Hospital Fixed	F-006379-01; F-008688-11	Novant Health Matthews Medical Center	1	1.00	7,011	3,478	2,350	834	349	8,564			
Mecklenburg	Hospital Fixed		Novant Health Mint Hill Medical Center	1	1.00	0	0	0	0	0	0			
Mecklenburg	Hospital Fixed		Novant Health Presbyterian Medical Center-Charlotte Orthopedic Hospital	1	1.00	3,002	2,045	938	12	7	3,388			
Mecklenburg	Hospital Fixed	F-002332-85	Novant Health Presbyterian Medical Center-Main	2	2.00	9,967	2,983	3,533	2,135	1,316	13,287			
Mecklenburg	Hospital Fixed		Novant Health Presbyterian Medical Center-Novant Health Imaging Museum	1	1.00	3,041	1,881	1,160	0	0	3,505			
Mecklenburg	Freestanding Fixed	F-008106-08	Carolina NeuroSurgery & Spine Associates Charlotte (Carolina NeuroSurgery & Spine Associates)	1	1.00	4,276	3,789	487	0	0	4,471			
Mecklenburg	Freestanding Fixed	F-007167-04	Carolinas Imaging Services-Ballantyne (Carolinas Imaging Services, LLC)	1	1.00	4,097	2,738	1,359	0	0	4,641			

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	Freestanding Fixed	F-011182-16	Carolinas Imaging Services-Huntersville (Carolinas Imaging Services, LLC)	1	1.00	883	601	255	21	6	998			
Mecklenburg	Freestanding Fixed	F-005918-98	Carolinas Imaging Services-Southpark (Carolinas Imaging Services, LLC)	1	1.00	3,547	1,959	1,588	0	0	4,182			
Mecklenburg	Freestanding Fixed	F-007068-04	Novant Health Imaging Southpark(Mecklenburg) (Mecklenburg Diagnostic Imaging, Inc.)	1	1.00	4,318	3,445	873	0	0	4,667			
Mecklenburg	Freestanding Fixed	F-10287-14	OrthoCarolina Ballantyne (OrthoCarolina, P.A.)	1	1.00	8,028	7,651	377	0	0	8,179			
Mecklenburg	Freestanding Fixed	J-006698-02	OrthoCarolina Spine Center (OrthoCarolina, P.A.)	1	1.00	6,760	5,155	1,605	0	0	7,402			
Mecklenburg	Freestanding Fixed	F-005748-97	PIC- Ballantyne (Novant Health Imaging Ballantyne)	1	1.00	3,311	2,231	1,080	0	0	3,743			
Mecklenburg	Mobile	F-006830-03; F-011425-17	Atrium Health Pineville	0	0.21	997	477	520	0	0	1,205			
Mecklenburg	Mobile	F-006868-03	Atrium Health- Pineville (Carolinas Imaging Services, LLC)	0	0.01	37	11	26	0	0	47			
Mecklenburg	Mobile	F-005919-98	Atrium Health University City	0	0.16	791	454	141	166	30	938			
Mecklenburg	Mobile	F-006868-03	Atrium Health,Carolina Neurological (Carolinas Imaging Services, LLC)	0	0.08	399	269	130	0	0	451			
Mecklenburg	Mobile	F-006734-03	Ballantyne (Carolina NeuroSurgery & Spine Associates)	0	0.31	1,479	1,286	193	0	0	1,556			
Mecklenburg	Mobile		Carolina Neurosurgery & Spine Associates Charlotte (Alliance Healthcare Services)	0	0.16	767	679	88	0	0	802			
Mecklenburg	Mobile	F-006734-03	Carolina NeuroSurgery & Spine Associates-Charlotte (Carolina NeuroSurgery & Spine Associates)	0	0.99	4,772	3,793	979	0	0	5,164			
Mecklenburg	Mobile	F-007040-04	Carolinas Imaging Services-Huntersville (Carolinas Imaging Services, LLC)	0	0.45	2,165	1,455	683	18	6	2,447			
Mecklenburg	Mobile		Carolinas Medical Center - Main	0	0.03	123	45	78	0	0	154			
Mecklenburg	Mobile	Grandfathered	Charlotte Eye, Eart, Nose & Throat (Alliance Healthcare Services)	0	0.10	464	47	417	0	0	631			
Mecklenburg	Mobile	F-005723-97	Mecklenburg Neurological Associates (InSight Imaging)	0	0.09	431	195	236	0	0	525			
Mecklenburg	Mobile	Grandfathered mobile unit	Novant Health Huntersville Medical Center (King's Medical Group)	0	0.18	887	583	304	0	0	1,009			
Mecklenburg	Mobile	Grandfathered	Novant Health Huntersville Medical Center (King's Medical Group)	0	0.04	204	106	98	0	0	243			
Mecklenburg	Mobile	Grandfathered	Novant Health Imaging Steele Creek (King's Medical Group)	0	0.15	703	607	96	0	0	741			
Mecklenburg	Mobile	Grandfathered	Novant Health Imaging University (King's Medical Group)	0	0.15	712	530	182	0	0	785			
Mecklenburg	Mobile	Grandfathered mobile unit	Novant Health Imaging University (King's Medical Group)	0	0.14	660	478	182	0	0	733			
Mecklenburg	Mobile	F-007164-04	Novant Health Imaging University (Presbyterian Mobile Imaging, LLC)	0	0.04	216	153	63	0	0	241			

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-007164-04	Novant Health Imaging-Steele Creek (Presbyterian Mobile Imaging, LLC)	0	0.04	180	109	71	0	0	208			
Mecklenburg	Mobile	Grandfathered	Novant Health Matthews Medical Center (King's Medical Group)	0	0.13	624	353	271	0	0	732			
Mecklenburg	Mobile	Grandfathered	OrthoCarolina (Alliance Healthcare Services)	0	0.09	438	438	0	0	0	438			
Mecklenburg	Mobile	F-007987-07	OrthoCarolina - Huntersville (OrthoCarolina, P.A.)	0	0.33	1,575	1,374	201	0	0	1,655			
Mecklenburg	Mobile	F-007987-07	OrthoCarolina Matthews (OrthoCarolina, P.A.)	0	0.55	2,634	2,634	0	0	0	2,634			
Mecklenburg	Mobile	F-007987-07	OrthoCarolina Mobile Spine (OrthoCarolina, P.A.)	0	0.56	2,705	2,453	252	0	0	2,806			
Mecklenburg	Mobile	Grandfathered	OrthoCarolina, P.A. (Alliance Healthcare Services)	0	0.20	967	967	0	0	0	967			
Mecklenburg	Mobile	Grandfathered	OrthoCarolina-Spine Center (Alliance Healthcare Services)	0	0.17	820	713	107	0	0	863			
Mecklenburg			2019 SMFP Need Determination	1	1.00	0	0	0	0	0	0			
Mecklenburg				25	30.36	125,458					148,741	4,899	4,805	1
Mitchell	Hospital Fixed	D-006866-03	Blue Ridge Regional Hospital	1	1.00	1,360	921	377	28	34	1,549			
Mitchell				1	1.00	1,360					1,549	1,549	3,775	0
Montgomery	Mobile	J-007008-04	First Health Montgomery Memorial Hospital (Foundation Health Mobile Imaging LLC)	0	0.22	369	303	66	0	0	395			
Montgomery				0	0.22	369					395	395	1,716	0
Moore	Hospital Fixed	H-005602-97; H-006846-03; H-007097-04	FirstHealth Moore Regional Hospital	3	3.00	12,644	8,716	1,273	2,280	375	14,365			
Moore	Freestanding Fixed	H-006845-03	Pinehurst Surgical Clinic PA (Alliance Healthcare Services)	1	1.00	5,517	5,344	173	0	0	5,586			
Moore	Freestanding Fixed	H-008365-09	Southern Pines Diagnostic Imaging (Triad Imaging, LLC)	1	1.00	2,449	1,747	702	0	0	2,730			
Moore	Mobile	Grandfathered	Southern Pines Diagnostic Imaging (King's Medical Group)	0	0.00	0	0	0	0	0	0			
Moore				5	5.00	20,610					22,681	4,536	4,805	0
Nash	Hospital Fixed	L-005908-98	Nash General Hospital	2	2.00	4,741	2,790	1,035	716	200	5,601			
Nash	Mobile	Grandfathered	Boice- Willis Clinic (InSight Imaging)	0	0.05	214	113	101	0	0	254			
Nash	Mobile	Grandfathered	Boice-Willis Clinic (InSight Imaging)	0	0.03	112	48	64	0	0	138			
Nash	Mobile	Grandfathered	Carolina Regional Orthopaedics (Alliance Healthcare Services)	0	0.00	10	10	0	0	0	10			
Nash	Mobile	Grandfathered	Carolina Regional Orthopaedics (Alliance Healthcare Services)	0	0.05	241	241	0	0	0	241			
Nash				2	2.13	5,318					6,244	2,932	4,462	0
New Hanover	Hospital Fixed		New Hanover Regional Medical Center-Main Campus	2	2.00	7,384	1,295	1,220	3,057	1,812	10,544			
New Hanover	Hospital Fixed		New Hanover Regional Medical Center-Medical Mall	1	1.00	2,052	1,057	995	0	0	2,450			

Attachment 2

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
Outpatient/ No Contrast/ Sedation	1.0	0.0	0.0	30
Outpatient/ With Contrast/ Sedation	1.0	0.0	.4 (Add 12 minutes)	42
Inpatient/ No Contrast/ Sedation	1.0	.4 (Add 12 minutes)	0.0	42
Inpatient/ With Contrast/ Sedation	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.

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

Source: Section IV of the application.

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

Source: Section IV of the application.

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

Source: Section IV of the application.

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

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 4th 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
TOTALS		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)**

		Year 1	Year 2	Year 3
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-
TOTALS		3,820	4,389	4,632

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

		Year 1	Year 2	Year 3
# of Units*		6	6	6
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
TOTALS		30,020	30,770	31,539

* 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-
TOTALS		9,648	9,508	9,885

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-
TOTALS		5,482	5,453	5,460

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-
TOTALS		4,403	4,961	5,585

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-
TOTALS		4,185	4,809	5,075

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 4

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

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

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

COMPETITIVE REVIEW

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

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

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C – CIS
NC - Novant

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

10A NCAC 14C .2703 PERFORMANCE STANDARDS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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*

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(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 5

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

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

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

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
Total	6	11,649	7,970	4,526	1,698	32,200	5,367

*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		1,781					1,917

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		2,035			2,195

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
Average Weighted Scans	4,672	4,757	4,843

*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
Average Weighted Total	4,975	5,025	5,075

*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 6

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

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

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

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 7

**Form F.4 Revenue & Expenses:
NHPMC MRI Dept.**

	Last Full Fiscal Year (FY) 12 Months From (01/01/2016) To (12/31/2016)	Interim Full FY 12 Months From (01/01/2017) To (12/31/2017)	Interim Full FY 12 Months From (01/01/2018) To (12/31/2018)	Interim Full FY 12 Months From (01/01/2019) To (12/31/2019)	Interim Partial FY From (01/01/2020) To (06/30/2020)	Project Year 1 First Full FY 12 Months From (07/01/2020) To (06/30/2021)	Project Year 2 Second Full FY 12 Months From (07/01/2021) To (06/30/2022)	Project Year 3 Third Full FY 12 Months From (06/01/2022) To (06/30/2023)
# of MRI Scans	9,670	10,001	10,301	10,610	5,464	11,206	11,688	12,190
REVENUE								
Gross Patient Revenue								
Self Pay/Indigent Care/Charity Care	\$ 1,462,997	\$ 1,492,257	\$ 1,522,102	\$ 1,552,544	\$ 791,798	\$ 1,971,945	\$ 2,097,899	\$ 2,231,764
Commercial Insurance/Managed Care	13,450,598	13,719,610	13,994,002	14,273,882	7,279,680	15,172,532	15,825,143	16,504,834
Medicare / Medicare Managed Care	13,193,227	13,457,092	13,726,233	14,000,758	7,140,387	4,481,788	4,768,053	5,072,298
Medicaid	3,832,220	3,908,864	3,987,042	4,066,783	2,074,059	17,540,366	18,660,720	19,851,443
Other (Other Government, Worker's Comp)	622,937	635,396	648,104	661,066	337,144	795,453	846,261	900,260
Total	\$ 32,561,979	\$ 33,213,219	\$ 33,877,483	\$ 34,555,033	\$ 17,623,067	\$ 39,962,084	\$ 42,198,076	\$ 44,560,598
Deductions from Gross Patient Revenue								
Self Pay/Indigent Care/Charity Care	\$ 1,458,169	\$ 1,487,332	\$ 1,517,079	\$ 1,547,421	\$ 789,185	\$ 1,965,438	\$ 2,090,976	\$ 2,224,399
Bad Debt	325,620	332,132	338,775	345,550	88,115	399,621	421,981	445,606
Medicare Contractual Adjustment	10,766,993	10,982,332	11,201,979	11,426,019	5,827,270	1,520,485	1,617,603	1,720,821
Medicaid Contractual Adjustment	3,321,768	3,388,204	3,455,968	3,525,087	1,797,794	16,943,391	18,025,615	19,175,813
Other Contractual Adjustments	6,591,702	6,723,536	6,838,006	6,995,166	3,567,535	6,214,099	6,294,509	6,366,058
Total Deductions from Patient Revenue	\$ 22,464,251	\$ 22,913,536	\$ 23,371,807	\$ 23,839,243	\$ 12,069,899	\$ 27,043,034	\$ 28,450,684	\$ 29,932,697
Net Patient Revenue	\$ 10,097,728	\$ 10,299,682	\$ 10,505,676	\$ 10,715,789	\$ 5,553,168	\$ 12,919,050	\$ 13,747,393	\$ 14,627,902
Other Revenue								
Total Revenue	\$ 10,097,728	\$ 10,299,682	\$ 10,505,676	\$ 10,715,789	\$ 5,553,168	\$ 12,919,050	\$ 13,747,393	\$ 14,627,902
EXPENSES								
Direct Expenses								
Salaries - Clinical Personnel	\$ 618,678	\$ 637,238	\$ 656,355	\$ 676,046	\$ 348,164	\$ 890,291	\$ 1,005,586	\$ 1,035,755
Salaries - Other Personnel								
Total Salaries	\$ 618,678	\$ 637,238	\$ 656,355	\$ 676,046	\$ 348,164	\$ 890,291	\$ 1,005,586	\$ 1,035,755
Payroll Taxes and Benefits	154,670	159,310	164,089	169,012	43,520	222,573	251,397	258,939
Medical Supplies	208,953	215,222	221,678	228,329	117,589	235,178	242,234	249,501
Other Supplies	4,115	4,238	4,366	4,497	2,316	4,631	4,770	4,914
Drugs	3,659	3,769	3,882	3,998	2,059	4,118	4,242	4,369
Other Direct Expenses (specify)								
Total Direct Expenses	990,075	1,019,777	1,050,370	1,081,881	513,648	1,356,792	1,508,228	1,027,297
Indirect Expenses								
Housekeeping/Laundry	12,600	13,104	13,628	10,630	5,528	14,598	15,182	11,055
Equipment Maintenance	19,654	20,440	21,258	16,581	8,622	22,771	23,682	17,244
Professional Fees	50,000	50,000	50,000	50,000	37,500	50,000	50,000	75,000
Rental Expense	0	0	0	0	0	0	0	0
Depreciation - Buildings	0	0	0	0	0	204,348	204,348	204,348
Depreciation - Equipment	412,334	416,457	420,622	424,828	212,414	382,788	382,788	424,828
Outside Services	21,143	21,989	22,868	23,554	12,367	24,734	25,724	24,734
Other Indirect/Corporate Overhead Expenses	428,000	451,503	476,297	502,453	265,022	530,044	559,151	589,857
Total Indirect Expenses	943,731	973,493	1,004,673	1,028,046	541,453	1,229,284	1,260,875	1,347,067
Total Expenses	\$ 1,933,806	\$ 1,993,270	\$ 2,055,043	\$ 2,109,927	\$ 1,055,101	\$ 2,586,076	\$ 2,769,104	\$ 2,374,363
Net Income	\$ 8,163,922	\$ 8,306,412	\$ 8,450,633	\$ 8,605,862	\$ 4,498,066	\$ 10,332,974	\$ 10,978,289	\$ 12,253,538

Form F.4 Revenue & Expenses for NHPMC MRI Scanner– Assumptions

- In determining the financial projections for the addition of a third MRI scanner as part of the Certificate of Need application process, internal financial and operational information for NHPMC were relied upon. Operational projections were provided by Brooks Healthcare Consulting.
- Charges were estimated utilizing historical charge information for inpatient and outpatient MRI patients at NHPMC and adjusted for an average annual increase of approximately 2 percent and volume adjustments.
- Bad Debt and Charity Care was based on the historical experience of NHPMC. The other contractual percentages was based on the trend of contractual adjustments at NHPMC MRI scanners.
- Salary Expense assumes an annual increase of approximately 3 percent. In the Project Years, Salaries are determined per Form H. – Staffing
- Payroll Taxes & Benefits are estimated at approximately 25 percent of salaries.
- Medical & Other Supplies are based on historical experience and inflated 3 percent.
- Food, Housekeeping, & Laundry Costs are included in Outside Services and are assumed to increase approximately 3 percent annually.
- Equipment & Building Maintenance are based on experience and are inflated 3 percent.
- Utilities & Insurance are based on historical data and inflated 3 percent.
- Professional Fees are based on historical experience in the MRI department at NHPMC
- Rental Expense is based on actual and inflated 3 percent per year.
- Corporate Overhead and Other Indirect Expenses include, but are not limited to the following, inflated 3 to 4 percent annually: Cable Services, Community Outreach, Dues/Memberships, Education Fees, Employee Activities, Food Catering, Freight, Mileage, Mobile Phone Services, Pager Services, Postage, Seminars, infectious Waste Disposal, Licenses, Marketing, Telephone, Travel & Conference, and Miscellaneous/Other Expenses.
- Outside Services, included but are not limited to the following, inflated 3 to 4 percent annually: Ambulance Services, Armored Car Services, Banking Services, Billing Fees, Collection Fees, Consulting Fees, Courier Services, Contract Labor, Environmental Services, Extermination, Food Services, Infection Control, Lab Services, Mobile Services, Outside Record Storage, Patient Escort Services, Recruitment, Sterile Processing, Software Contract Agreement, Surgical & Diagnostic Services, Uniform Cleaning, Housekeeping, Miscellaneous and Other Expenses
- Corporate Overhead for NHPMC is based on the cost incurred by Novant Health for providing services and any additional costs required for: Human resources, Information Technology, Courier Services, Accounting and Finance Services, Facility Services, Materials Management, Patient Accounting, and Other Corporate Services.

Attachment 8

PRESBYTERIAN MATTHEWS HOSPITAL

FORM C SERVICE COMPONENT: (Summary Projected Results From Operations)

SECOND MRI

Projections Through Three Years After Completion

Specify Fiscal Year-->	Last		Interim		Interim		Project Year 1		Project Year 2		Project Year 3	
	Full Fiscal Year	12 Months	Full FY	12 Months	Full FY	12 Months	Full FY	12 Months	Full FY	12 Months	Full FY	12 Months
	1/1/2010	1/1/2011	1/1/2012	1/1/2013	1/1/2014	1/1/2015	10/1/2016	10/1/2017	10/1/2018	10/1/2019	10/1/2020	10/1/2021
	12/31/2010	12/31/2011	12/31/2012	9/30/2013	9/30/2014	9/30/2015	9/30/2016	9/30/2017	9/30/2018	9/30/2019	9/30/2020	9/30/2021
MRI SCANS	6,384	6,885	7,213	5,601	7,824	8,196	8,587					
Gross Revenue												
Private Pay	432,207	470,787	503,079	402,368	578,927	624,646	674,079					
Commercial Ins.	82,011	89,331	95,459	76,349	109,851	118,526	127,906					
Medicare	4,863,710	5,297,856	5,661,249	4,527,924	6,514,778	7,029,266	7,585,543					
Medicaid	626,824	682,776	729,609	583,549	839,610	905,916	977,608					
Other Government	184,125	200,560	214,317	171,413	246,629	266,106	287,165					
Blue Cross	2,769,418	3,016,622	3,223,540	2,578,220	3,709,544	4,002,495	4,319,242					
Worker Compensation	48,052	52,341	55,931	44,735	64,364	69,447	74,943					
County Assistance	0	0	0	0	0	0	0					
Managed Care	2,492,157	2,714,612	2,900,815	2,320,101	3,338,162	3,601,784	3,886,820					
Gross Patient MRI Revenue	11,498,504	12,524,886	13,384,000	10,704,658	15,401,865	16,618,187	17,933,306					
Deductions from Revenue												
Bad Debt	297,811	324,395	346,646	277,251	398,908	430,411	464,473					
Charity	656,565	715,171	764,226	611,236	879,446	948,898	1,023,992					
Contractuals	2,073,201	2,312,757	2,485,899	1,999,847	2,926,351	3,195,473	3,489,385					
Medicare	3,289,254	3,596,793	3,843,506	3,074,075	4,422,979	4,772,273	5,149,938					
Medicaid	501,729	525,259	561,288	448,924	645,912	696,921	752,073					
Net Patient MRI Net Revenue	4,679,945	5,050,512	5,382,436	4,293,326	6,128,268	6,574,211	7,053,446					
Other Revenue												
Net Operating Revenues	4,679,945	5,050,512	5,382,436	4,293,326	6,128,268	6,574,211	7,053,446					

PRESBYTERIAN MATTHEWS HOSPITAL

FORM C SERVICE COMPONENT: (Summary Projected Results From Operations)

SECOND MRI

Projections Through Three Years After Completion

	Last		Interim		Interim		Project Year 1		Project Year 2		Project Year 3	
	Full Fiscal Year		Full FY		Part Year		Full FY		Full FY		Full FY	
	12 Months	1/1/2010	12 Months	1/1/2011	9 Months	1/1/2013	12 Months	10/1/2013	12 Months	10/1/2014	12 Months	10/1/2015
Specify Fiscal Year>>	12/31/2010	12/31/2011	12 Months	12/31/2012	9 Months	9/30/2013	12 Months	9/30/2014	12 Months	9/30/2015	12 Months	9/30/2016
EXPENSES												
Direct Expenses												
Salaries - Clinical Personnel	318,033	327,574	337,401	281,244	648,886	668,353	688,403					
Salaries - Other Personnel	11,625	11,973	12,333	9,486	13,027	13,418	13,820					
Total Salaries	329,658	339,547	349,734	290,730	661,913	681,771	702,224					
Payroll Taxes and Benefits	82,414	84,887	87,433	72,682	165,478	170,443	175,556					
Medical Supplies	85,140	95,494	104,046	83,217	120,895	131,708	143,511					
Other Supplies	10,000	11,216	12,221	9,774	14,200	15,470	16,856					
Raw Food	12,768	14,321	15,603	12,480	18,130	19,752	21,522					
Other Direct Expenses (specify)												
Total Direct Expenses	519,980	545,466	569,036	468,882	980,615	1,019,143	1,059,668					
Indirect Expenses												
Housekeeping/Laundry												
Equipment Maintenance	51,000	52,785	54,632	55,862	115,634	119,681	123,870					
Building & Grounds Maintenance												
Utilities												
Insurance												
Professional Fees (Physics Support)	20,000	20,600	21,218	21,695	43,391	44,693	46,033					
Rental Expense												
Property and other Taxes (except Income)												
Depreciation - Buildings					79,109	79,109	79,109					
Depreciation - Equipment	182,951	182,669	179,556	45,165	282,577	282,577	282,181					
Outside Services												

PRESBYTERIAN MATTHEWS HOSPITAL

FORM C SERVICE COMPONENT: (Summary Projected Results From Operations)

SECOND MRI

Projections Through Three Years After Completion

Specify Fiscal Year<>>	Last		Interim		Interim		Project Year 1		Project Year 2		Project Year 3	
	Full Fiscal Year	12 Months	Full FY	12 Months	Part Year	9 Months	Full FY	12 Months	Full FY	12 Months	Full FY	12 Months
	1/1/2010	1/1/2011	1/1/2011	1/1/2012	1/1/2013	1/1/2013	10/1/2013	10/1/2014	10/1/2014	10/1/2015	10/1/2015	10/1/2016
Other Indirect Expenses (specify)	350,313	362,574	375,264	281,448	388,398	401,992	416,062					
Total Indirect Expenses	604,264	618,628	630,671	404,170	909,108	928,051	947,255					
Total Expenses	1,124,244	1,164,093	1,199,707	873,052	1,889,724	1,947,194	2,006,923					
Net Income	3,555,701	3,886,419	4,182,729	3,420,273	4,238,544	4,627,016	5,046,523					

Federal & State Income Taxes (NONE)

PRESBYTERIAN MATTHEWS HOSPITAL

ASSUMPTIONS

In determining the financial projections for the additional Presbyterian Matthews Hospital MRI as part of the Certificate of Need Application process, the following information was relied upon: financial and operational information derived from the current data of the existing MRI department at Presbyterian Matthews Hospital

FORM B - ENTIRE HOSPITAL - PRESBYTERIAN MATTHEWS HOSPITAL

Reflects the projected revenue and expense for both inpatients and outpatients at the Presbyterian Matthews Hospital based on actual data inflated for price and volume increases thru the year ending September 30, 2016

<u>Gross Revenue Payor Mix</u>	Project Year 1	Project Year 2	Project Year 3
	10/1/2013	10/1/2014	10/1/2015
	9/30/2014	9/30/2015	9/30/2016
	12 Months	13 Months	14 Months
Private Pay	8.00%	8.00%	8.00%
Commercial Ins.	0.82%	0.82%	0.82%
Medicare	38.80%	38.80%	38.80%
Medicaid	9.17%	9.17%	9.17%
Other Government	1.84%	1.84%	1.84%
Blue Cross	22.20%	22.20%	22.20%
Worker Compensation	0.55%	0.55%	0.55%
County Assistance	0.00%	0.00%	0.00%
Managed Care	<u>18.61%</u>	<u>18.61%</u>	<u>18.61%</u>
	<u>100.00%</u>	<u>100.00%</u>	<u>100.00%</u>

All patients will be accepted regardless of payer or the ability to pay.

<u>Patient Payor Mix</u>	Project Year 1	Project Year 2	Project Year 3
	10/1/2013	10/1/2014	10/1/2015
	9/30/2014	9/30/2015	9/30/2016
	12 Months	12 Months	12 Months
Private Pay	11.50%	11.50%	11.50%
Commercial Ins.	1.06%	1.06%	1.06%
Medicare	27.68%	27.68%	27.68%
Medicaid	11.73%	11.73%	11.73%
Other Government	2.31%	2.31%	2.31%
Blue Cross	23.74%	23.74%	23.74%
Worker Compensation	0.84%	0.84%	0.84%
County Assistance	0.00%	0.00%	0.00%
Managed Care	<u>21.15%</u>	<u>21.15%</u>	<u>21.15%</u>
	<u>100.00%</u>	<u>100.00%</u>	<u>100.00%</u>

NOTE: Based on actual payor mix for the entire hospital for the calendar year 2010

FORM C - MRI DEPARTMENT

Reflects the projected revenue and expense for the MRI department at the Presbyterian Matthews Hospital from the year 2010 thru the three project years ending September 30, 2016.

Gross MRI revenue was determined by multiplying the number of MRI scans by the average gross revenue per scan. The estimated MRI charges were increased 3.0% annually.

To obtain the net revenue, the gross revenue was adjusted for bad debt, charity care, and other contractual percentages based on actual data in the MRI department.

Salaries were determined by using the current hourly rate for each job classification and then inflating salaries by 3% per year based on job classification. The FTEs were determined based on projected MRI volumes.

See staffing table in Section VII of the CON.

The benefits cost were assumed to be 25.0% of salaries for all project years.

Medical Supplies based on actual cost per scan inflated 4% annually.

Other Supplies - books, subscriptions, office supplies, printing & forms based on cost per scan inflated 4% annually.

Raw Food - Water, juices, soft drinks, coffee, tea, and snacks after MRI scan.

Equipment Maintenance based on history at Presbyterian Matthews Hospital MRI department inflated 3.5 % annually, adjusted for second MRI.

Equipment Depreciation - New MRI based on 8 year life. Current MRI department equipment will be fully depreciated during the first project year

Building Upfit - Based on 8 Year life

Indirect Expenses include but are not limited to the following expenses inflated 2.5% to 4% annually.

- | | | | |
|--------------|---------------|-------------------|---------------------|
| Housekeeping | Accounting | Seminars | Licenses |
| Laundry | Billings | Education Fees | Travel & Conference |
| Utilities | Collections | Facility Overhead | |
| Insurance | Pager Service | Other | |

<u>Gross Revenue Payer Mix</u>	Project Year 1	Project Year 2	Project Year 3
<u>MRI DEPARTMENT</u>	10/1/2013	10/1/2014	10/1/2015
	9/30/2014	9/30/2015	9/30/2016
	12 Months	13 Months	14 Months
Private Pay	3.76%	3.76%	3.76%
Commercial Ins.	0.71%	0.71%	0.71%
Medicare	42.30%	42.30%	42.30%
Medicaid	5.45%	5.45%	5.45%
Other Government	1.60%	1.60%	1.60%
Blue Cross	24.09%	24.09%	24.09%
Worker Compensation	0.42%	0.42%	0.42%
County Assistance	0.00%	0.00%	0.00%
Managed Care	<u>21.67%</u>	<u>21.67%</u>	<u>21.67%</u>
	<u>100.00%</u>	<u>100.00%</u>	<u>100.00%</u>

All patients will be accepted regardless of payer or the ability to pay.

<u>Patient Payor Mix</u>	Project Year 1	Project Year 2	Project Year 3
<u>MRI DEPARTMENT</u>	10/1/2013	10/1/2014	10/1/2015
	9/30/2014	9/30/2015	9/30/2016
	<u>12 Months</u>	<u>12 Months</u>	<u>12 Months</u>
Private Pay	3.96%	3.76%	3.76%
Commercial Ins.	0.68%	0.71%	0.71%
Medicare	40.29%	42.30%	42.30%
Medicaid	5.26%	5.45%	5.45%
Other Government	1.61%	1.60%	1.60%
Blue Cross	24.97%	24.09%	24.09%
Worker Compensation	0.54%	0.42%	0.42%
County Assistance	0.00%	0.00%	0.00%
Managed Care	<u>22.69%</u>	<u>21.67%</u>	<u>21.67%</u>
	<u>100.00%</u>	<u>100.00%</u>	<u>100.00%</u>

NOTE: Based on actual payor mix for the MRI department

	Project Year 1	Project Year 2	Project Year 3
<u>VOLUMES</u>	10/1/2013	10/1/2014	10/1/2015
<u>MRI SCANS</u>	9/30/2014	9/30/2015	9/30/2016
	<u>12 Months</u>	<u>12 Months</u>	<u>12 Months</u>
MRI SCANS	<u>7,824</u>	<u>8,196</u>	<u>8,587</u>

Revenue reported on **Form D - MRI** is the projected gross revenue for the patients having a MRI.

Reported on **Form E - MRI** is the projected net revenue for the patients having a MRI.

BALANCE SHEET - FORM A

Balance Sheet is for Novant Health, Inc. and Affiliates

Balance Sheet on calendar basis (January - December)

Patient Receivables increase based on revenue forecasted

Inventories are inflated at 3% per year

Building and equipment for this project is included in on the balance sheet assets beginning in year 2013 and ongoing thru 2016.

Accounts Payable based on projected level of debt

Salary accruals are inflated at 3% each year