

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 5, 2021

Findings Date: January 5, 2021

Project Analyst: Julie M. Faenza

Team Leader: Fatimah Wilson

Project ID #: F-11946-20

Facility: Novant Health Imaging Southpark

FID #: 970309

County: Mecklenburg

Applicant(s): Mecklenburg Diagnostic Imaging, LLC

Novant Health, Inc.

Project: Acquire a second fixed MRI scanner pursuant to the need determination in the 2020 SMFP

### REVIEW CRITERIA

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

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

NC

Mecklenburg Diagnostic Imaging, LLC (MDI) and Novant Health, Inc. (Novant), referred to collectively hereinafter as “the applicant” or “Novant,” proposes to acquire a second fixed MRI scanner pursuant to the need determination in the 2020 SMFP at Novant Health Imaging Southpark (NHI Southpark), its existing diagnostic imaging center.

#### **Need Determination**

Chapter 17-E of the 2020 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional magnetic resonance imaging (MRI) scanners in North Carolina by service area. Application of the need methodology in Chapter 17-E of the 2020 SMFP identified a need for one additional fixed MRI scanner in the Mecklenburg County

service area as shown in Table 17E-3 on page 441 of the 2020 SMFP. Therefore, the applicant's proposal is consistent with the need determination in the 2020 SMFP.

### **Policies**

There are two policies in the 2020 SMFP applicable to this review.

Policy GEN-3: Basic Principles, on pages 30-31 of the 2020 SMFP, states:

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

In Section B, pages 15-20, the applicant explains why it believes its application is consistent with Policy GEN-3:

- The applicant describes its safety and quality record and the policies it has to ensure safety and quality in delivering care.
- The applicant states it will provide care to all patients and provides information on its Patient Non-Discrimination, Charity Care, Uninsured Discount, and Catastrophic Settlement policies.
- The applicant explains the ways it believes its proposed project will maximize healthcare value for resources expended, including by utilizing economies of scale and ability to negotiate equipment pricing to keep costs as low as possible for patients.

On page 20, the applicant states:

*“The addition of a second MRI scanner will allow NHI Southpark to handle additional MRI referrals more quickly and conveniently thereby enhance efficient, affordable, and effective care. Additionally, Novant Health Matthews Medical Center (“NH Matthews”) and Novant Health Presbyterian Medical Center (“NH Presbyterian”) are operating well above optimal capacity. NHI Southpark’s proximity to both hospitals allows for the IDTF to be a convenient, cost-effective alternative for patients seeking care at both hospitals thereby alleviating capacity constraints for all three facilities and improving patient access to care. Likewise, the radiologists and the Novant Health team members who work in the NHI Southpark MRI program will have a workplace that is more conducive to patient, employee, and radiologist safety. The renovated*

*space for the proposed new MRI scanner is proximate to the other existing MRI scanner which will also enhance MRI productivity and throughput. Since the proposed MRI scanner would be located in existing space that will be renovated for a second MRI scanner, the capital cost expenditures for this project will be less than the capital cost expenditures associated with construction of new square footage.”*

The applicant adequately documents how the project will promote safety and quality in the delivery of fixed MRI scanner services in Mecklenburg County and will promote equitable access to fixed MRI scanner services in Mecklenburg County.

However, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximizing healthcare value for resources expended. The applicant does not adequately demonstrate the need to add a second fixed MRI scanner to NHI Southpark in Mecklenburg County. The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference. An applicant cannot demonstrate how its projected volumes will maximize the value for healthcare resources expended in meeting the need identified in the 2020 SMFP and in addressing the needs of all residents in the service area when the applicant cannot demonstrate the need for the proposed project. Therefore, the application is not consistent with Policy GEN-3.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 31 of the 2020 SMFP, states:

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

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

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

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, page 21, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant states:

*"In all projects Novant Health considers energy efficiency and water conservation opportunities consistent with the Novant Health Sustainable Energy Management Plan (SEMP).*

...

*..., Novant Health and NHI Southpark will formulate a plan as part of the implementation of the proposed new MRI scanner, which will include methods to improve energy efficiency and water conservation. The plan will not adversely affect patient or resident health, safety, or infection control."*

The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion because it is not consistent with Policy GEN-3 based on the following:

- The applicant does not adequately demonstrate the need to add a second fixed MRI scanner to NHI Southpark. An applicant cannot demonstrate how its projected volumes will maximize the value for healthcare resources expended when the applicant cannot demonstrate the need for the proposed project.
- Therefore, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximizing healthcare value for resources expended as required in Policy GEN-3.

(2) Repealed effective July 1, 1987.

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

NC

The applicant proposes to acquire a second fixed MRI scanner at NHI Southpark pursuant to the need determination in the 2020 SMFP.

In Section C, page 22, the applicant states NHI Southpark is an existing independent diagnostic treatment facility (IDTF) that currently operates one fixed MRI scanner along with numerous other types of imaging equipment. The applicant proposes to acquire a second fixed MRI scanner at NHI Southpark.

There are a number of Novant facilities referenced throughout the discussion in these findings. For ease of understanding and reference, the Project Analyst created the table below to identify each facility that is referenced and the abbreviations for each facility that will be used throughout these findings.

<b>Novant Health Facilities in Mecklenburg County Discussed in This Review</b>		
<b>Name of Facility</b>	<b>Abbreviations Used</b>	<b>Type of Facility</b>
Novant Health Presbyterian Medical Center	NH Presbyterian, NH-PMC	Hospital
Novant Health Matthews Medical Center	NH Matthews, NH-MMC	Hospital
Novant Health Huntersville Medical Center	NH Huntersville, NH-HMC	Hospital
Novant Health Mint Hill Medical Center	NH Mint Hill, NH-MHMC	Hospital
Novant Health Imaging Southpark	NHI Southpark	Freestanding Imaging Center
Novant Health Imaging Museum	NHI Museum	Imaging Center licensed under NH-PMC
Novant Health Imaging University	NHI University	Freestanding Imaging Center
Novant Health Imaging Ballantyne	NHI Ballantyne	Freestanding Imaging Center
Novant Health Imaging Steele Creek	NHI Steele Creek	Freestanding Imaging Center

**Patient Origin**

Chapter 17-E of the 2020 SMFP defines the service area for fixed MRI scanners as “...*the same as an Acute Care Bed Service Area as defined in Chapter 5, and shown in Figure 5.1.*” Figure 5.1 on page 38 of the 2020 SMFP shows Mecklenburg County as its own Acute Care Bed Service Area. Thus, the service area for this review is Mecklenburg County. Facilities may also serve residents of counties not included in the service area.

The following table illustrates current and projected patient origin.

<b>NHI Southpark Fixed MRI Scanner – Current &amp; Projected Patient Origin</b>								
<b>County</b>	<b>Current (FFY 2019)</b>		<b>Projected FY 1 (CY 2022)</b>		<b>Projected FY 2 (CY 2023)</b>		<b>Projected FY 3 (CY 2024)</b>	
	<b># Patients</b>	<b>% of Total</b>	<b># Patients</b>	<b>% of Total</b>	<b># Patients</b>	<b>% of Total</b>	<b># Patients</b>	<b>% of Total</b>
Mecklenburg	3,618	63.04%	4,524	63.04%	5,689	63.04%	6,960	63.04%
Union	923	16.08%	1,154	16.08%	1,451	16.08%	1,776	16.08%
Gaston	205	3.57%	256	3.57%	322	3.57%	394	3.57%
Cabarrus	98	1.71%	123	1.71%	154	1.71%	189	1.71%
Other NC Counties*	222	3.87%	278	3.87%	349	3.87%	427	3.87%
South Carolina	610	10.63%	763	10.63%	959	10.63%	1,174	10.63%
Other States	63	1.10%	79	1.10%	99	1.10%	121	1.10%
<b>Total</b>	<b>5,739</b>	<b>100.00%</b>	<b>7,176</b>	<b>100.00%</b>	<b>9,024</b>	<b>100.00%</b>	<b>11,041</b>	<b>100.00%</b>

**Sources:** Section C, pages 24-25

\*Other NC Counties includes Alamance, Anson, Ashe, Avery, Buncombe, Burke, Caldwell, Catawba, Clay, Cleveland, Cumberland, Davidson, Forsyth, Franklin, Guilford, Henderson, Iredell, Lincoln, Macon, Montgomery, New Hanover, Onslow, Orange, Robeson, Rowan, Rutherford, Scotland, Stanly, Surry, Wake, and Watauga counties

The Project Analyst notes that the projected number of patients for the first three full fiscal years following project completion is not consistent with the projected utilization on Form C in Section Q. However, the differences are minor and not significant enough to change any analysis under this criterion.

In Section C, page 25, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The projected patient origin is consistent with the historical patient origin.
- The applicant does not propose to develop any services or make any changes to its facility that could foreseeably impact the projected patient origin in more than minor ways.

**Analysis of Need**

In Section C, pages 30-36, the applicant explains why it believes the population projected to utilize the proposed service needs the proposed service. The applicant identifies multiple reasons to support the need for the proposed service, which are summarized below.

- Growth in total population and population age 65 and older: The applicant provides data from the North Carolina Office of State Budget and Management (NC OSBM) showing the population in Mecklenburg and Union counties is projected to increase at an annual rate of approximately 1.9 percent and 2.4 percent, respectively, between 2020 and 2025. The applicant cites data from NC OSBM showing the total population for all of North Carolina is projected to increase at approximately 1.1 percent annually between 2020 and 2025. The applicant further cites data from NC OSBM showing the population age 65 and older in Mecklenburg and Union counties is projected to increase at an annual rate of approximately 4.7 percent and 5.1 percent, respectively, between 2020 and 2025, compared with a projected annual increase of 3.1 percent for the statewide population age 65 and older during the same time period. The applicant states older populations use outpatient

diagnostic imaging services at higher rates as they age and provides a citation to a 2008 study supporting its statement. (page 30)

- Lower costs to patients for outpatient fixed MRI scanner services: The applicant states that freestanding (non-hospital based) outpatient fixed MRI scanner services provide patients with access to lower cost services than hospital-based fixed MRI scanner services. The applicant states Medicare and other third-party payors have begun to make changes in payment structures to incentivize patient use of lower-cost services. The applicant further states providing patient access to freestanding outpatient fixed MRI scanner services can mitigate potential capacity constraints for hospital-based fixed MRI scanner services. (pages 30-31)
- High utilization of existing fixed MRI scanner services: The applicant states there are approximately twice the number of hospital-based fixed MRI scanners than fixed MRI scanners located in freestanding outpatient settings in Mecklenburg County. The applicant states that, of the freestanding outpatient fixed MRI scanners, the two most highly utilized are located at OrthoCarolina facilities, which focus on orthopedic services, and that the existing fixed MRI scanner at NHI Southpark is the third most highly utilized fixed MRI scanner in freestanding outpatient settings, but the most highly utilized fixed MRI scanner that provides a full range of imaging services.

The applicant states that unavailability of fixed MRI scanner services at NH Mint Hill prior to its opening on October 1, 2018 contributed to high utilization of other Novant fixed MRI scanners. However, the applicant also notes that the Novant Health hospital system fixed MRI scanner utilization grew at a Compound Annual Growth Rate (CAGR) of 5.2 percent between FFY 2017 and FFY 2019 and utilization of all fixed MRI scanners in the Novant Health system grew at a CAGR of 10.2 percent between FFY 2017 and FFY 2019. (pages 31-35)

- Historical utilization at NHI Southpark: The applicant states NHI Southpark has seen the number of scans performed on its existing fixed MRI scanner grow at a CAGR of 7.9 percent between FFY 2015-2019 and was utilized at 105 percent of optimal capacity in FFY 2019. The applicant states NHI Southpark has already extended its operating hours during the week, including opening Monday through Friday from 5:00 p.m. to 9:00 p.m. and on Saturdays from 7:30 a.m. to 3:00 p.m. solely to offer MRI services, but that despite the increased hours of operation, NHI Southpark's fixed MRI scanner utilization continues to grow and is currently operating above optimal capacity. (page 35)
- Need for a 3T fixed MRI scanner at NHI Southpark: The applicant states its current fixed MRI scanner is a 1.5T unit, sufficient for routine MRI scans, but a 3T unit has technology to provide faster scans, increased clarity of images, and is ideal for abdominal and chest MRI scans. The applicant states it offers breast MRI imaging at NHI Southpark which is a service that would benefit from the expanded capabilities of a 3T unit. The applicant further states it works with two urology practices that typically refer their patients to NHI Southpark but cannot do so for patients needing 3T MRI imaging services, which increases travel time for patients. (page 36)

The information is reasonable and adequately supported based on the following:

- There is a need determination in the 2020 SMFP for one fixed MRI scanner in Mecklenburg County.
- The applicant relies on data from established and reliable sources and cites to the sources of any data used.
- The applicant relies on historical utilization to project future growth in utilization.

Projected Utilization

On Form C in Section Q, the applicant provides historical and projected utilization, as shown in the table below.

<b>NHI Southpark – Historical, Interim, and Projected Utilization – Fixed MRI Scanners</b>							
	Historical	Interim			Projected (FYs 1-3)		
	FFY 2019	FFY 2020	FFY 2021	10/2021 – 12/2021	CY 2022	CY 2023	CY 2024
# Units	1	1	1	1	2	2	2
# Procedures	4,646	4,150	5,406	1,119	7,164	9,000	11,033
# Weighted Procedures	5,030	4,493	5,853	1,212	7,757	9,745	11,946

In Section Q, pages 103-112, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant projects its first three full fiscal years following project completion will be CYs 2022-2024. The applicant, in clarifying information, confirmed CYs 2022-2024 as the first three full fiscal years following project completion, regardless of any tables or statements in the application with conflicting representations.
- The applicant calculated the FFY 2015-2019 CAGR for its existing and operational fixed MRI scanners along with the historical CAGR for mobile MRI scanners for all Novant facilities in Mecklenburg County. The applicant also calculated the combined FFY 2015-2019 CAGR for all Novant hospitals in Mecklenburg County and the combined FFY 2015-2019 CAGR for all Novant facilities that utilize mobile MRI scanners.



<b>Novant Health Mecklenburg County MRI Providers</b>	
<b>Facility</b>	<b>FFY 2015-2019 CAGR</b>
<b>Freestanding Fixed MRI Providers</b>	
NHI Southpark	7.9%
NHI Ballantyne	8.1%
<b>Total</b>	<b>8.0%</b>
<b>Hospital-Based MRI Providers</b>	
NH Presbyterian*	4.4%
NH Matthews	3.9%
NH Huntersville	5.7%
NH Mint Hill**	--
<b>Total</b>	<b>7.1%</b>
<b>Freestanding Mobile MRI Providers</b>	
NHI University	-4.1%
NHI Steele Creek	7.5%
<b>Total</b>	<b>0.8%</b>
<b>Total All Novant MRI Providers</b>	<b>6.9%</b>
<b>Total NH Hospital-Based Units</b>	<b>4.2%</b>
<b>Total MRI Units Mecklenburg County***</b>	<b>5.2%</b>

Source: Section Q, Form C Assumptions, pages 104 & 106

\*Includes NHI Museum

\*\*NH Mint Hill did not open until October 1, 2018

\*\*\*Including other systems and providers

On pages 105-106, the applicant states it uses the FFY 2015-2019 CAGRs to project growth at each facility later in its assumptions and methodology, with the following exceptions:

- NH Matthews has the highest utilization of hospital-based fixed MRI scans of all Novant facilities in Mecklenburg County, and cannot maintain its historical growth rate due to capacity constraints; the applicant used roughly half of the FFY 2015-2019 CAGR for NH Matthews (1.9 percent instead of 3.9 percent) to project utilization.
- NH Mint Hill first opened on October 1, 2018 and has no meaningful historical CAGR; the applicant substituted the average FFY 2015-2019 CAGR for all Novant hospitals in Mecklenburg County.
- NHI University is now offering more days with mobile MRI scanners than it did historically; the applicant substituted the average FFY 2015-2019 CAGR for mobile MRI scans at Novant freestanding outpatient facilities.
- The applicant assumed it would shift patients eligible to receive fixed MRI scanner services at NHI Southpark away from hospital-based fixed MRI scanners at NH Presbyterian and NH Matthews. To project the shift in patients, the applicant determined which local ZIP codes were either closer to or at least equidistant from NHI Southpark and NH Presbyterian or NH Matthews. The applicant then analyzed the patients historically served at NH

Matthews and NH Presbyterian who were eligible to received fixed MRI scanner services at NHI Southpark and projected the following shifts in patients:

- Because of existing capacity constraints at NH Matthews, the applicant projected a shift of 80 percent of patients in ZIP codes that were closer to NHI Southpark, and a shift of 70 percent of patients in ZIP codes that were equidistant from both NHI Southpark and NH Matthews.
- The applicant states NH Presbyterian has had capacity constraints before and believes it will again soon; however, NH Presbyterian is also a tertiary care medical center. The applicant states that, despite potential capacity constraints, it projected a shift in only 35 percent of patients in ZIP codes closer to NHI Southpark and a shift of 25 percent of patients in ZIP codes equidistant from both NHI Southpark and NH Presbyterian, assuming that some of the patients eligible to shift from NH Presbyterian to NHI Southpark would be medically complex and benefit from receiving services from a hospital-based fixed MRI scanner.
- The applicant identified the number of NHI Southpark-eligible patients who lived in one of the applicable ZIP codes and who had been seen at either NH Presbyterian or NH Matthews during FFY 2019. The applicant then applied the projected growth rates it had calculated for each facility to the FFY 2019 patient numbers for each hospital. Finally, the applicant calculated the number of patients that would shift to NHI Southpark based on the assumptions about the percentage of patients that would shift from each ZIP code.
- The applicant states it assumed that FFY 2020 utilization is an outlier, due to the effects of the global pandemic, and projected a full recovery to pre-pandemic levels by FFY 2021; the applicant states it calculated utilization starting with FFY 2019 data to adjust for the effects of the pandemic in FFY 2020.
- The applicant calculated projected growth at all Novant facilities with fixed and/or mobile MRI scanners through CY 2024 by applying the CAGRs it calculated at the beginning of the assumptions and methodology.
- The applicant converted FFYs to CYs using the following formula:  $CY\ 2022 = [(FFY\ 2022 / 4) \times 3] + (FFY\ 2023 / 4)$ . The applicant does not explain how it made the conversion from FFYs to CYs; however, the Project Analyst was able to determine how the conversion was made based on publicly available information from previous Novant applications and verified by performing independent calculations.
- The applicant adjusted the totals at NH Presbyterian and NH Matthews to account for the projected shift in patients to NHI Southpark.
- As part of Project I.D. #F-11891-20, MRI-guided focused ultrasound services will be offered at NH Mint Hill. The applicant states these services have longer case times and it will offer mobile MRI services one day per week and 10 weekends per year to accommodate for the longer case times. The applicant assumed that the number of hours it

will offer the MRI-guided focused ultrasound services will equal the number of mobile MRI scans.

- The applicant calculated FFY 2019 ratio of total weighted MRI scans to actual MRI scans at all Novant facilities with fixed and/or mobile MRI scanners, assumed the FFY 2019 ratio would remain constant through the third full fiscal year following project completion, and applied that ratio to the number of projected MRI scans to calculate the number of weighted MRI scans at each facility.

The Project Analyst attempted to verify the applicant’s calculations based on the stated assumptions and methodology and was unable to do so. Based on the Project Analyst’s analysis, the applicant seemed to make mathematical errors in calculations or took steps in the final projections that were not clearly explained and that did not allow the Project Analyst to independently determine and verify the steps performed (as the Project Analyst was able to do with the conversion from FFYs to CYs). To determine the projected utilization during the first three full fiscal years following project completion, the Project Analyst calculated the projected utilization based on the applicant’s own assumptions and methodology. Please see the Working Papers for the full calculations performed by the Project Analyst. A summary of the calculations performed by the Project Analyst, which are based on the applicant’s stated assumptions and methodologies, are displayed in the table below.

<b>Novant MRI Scanners – Projected Utilization – FYs 1-3 (CYs 2022-2024)</b>								
Facility	CAGR	Total MRI Scans			Ratio	Weighted MRI Scans		
		CY 2022	CY 2023	CY 2024		CY 2022	CY 2023	CY 2024
<b>Facilities w/Freestanding Fixed MRI Scanners</b>								
NHI Southpark	7.9%	7,133	7,697	8,305	1.08	7,704	8,313	8,969
NHI Ballantyne Fixed	8.1%	4,214	4,547	4,907	1.12	4,720	5,093	5,495
NHI Ballantyne Mobile		425	458	494	1.00	425	458	494
<b>Hospitals</b>								
NH Presbyterian (Fixed only)	4.4%	19,305	20,154	21,041	1.26	24,324	25,394	26,511
NH Huntersville (Fixed only)	5.7%	7,726	8,166	8,631	1.20	9,271	9,799	10,358
<i>NH Matthews</i>								
Fixed	1.9%	6,408	6,529	6,653	1.23	7,881	8,031	8,184
Mobile		669	681	694	1.16	776	790	805
<i>NH Mint Hill</i>								
Fixed	4.2%	3,710	3,866	4,028	1.20	4,452	4,639	4,834
Mobile	--	496	496	496	1.16	575	575	575
<b>Facilities w/Mobile MRI Scanners Only</b>								
NHI University	0.8%	1,148	1,158	1,167	1.13	1,298	1,308	1,318
NHI Steele Creek	7.5%	1,352	1,453	1,562	1.11	1,500	1,613	1,734

Projected utilization is reasonable and adequately supported based on the following analysis:

- The applicant uses historical growth rates as the basis for projected utilization.

- The applicant adjusts projected growth rates for facilities facing capacity issues, facilities which have increased utilization more recently, and facilities without sufficient historical data to use a historical growth rate as the basis for projected growth.
- The applicant accounts for differences in the number of patients projected to shift to NHI Southpark based on patient location and where patients historically received services.
- The applicant accounts for the recent conversion of a mobile MRI scanner to a fixed MRI scanner at NH Huntersville.
- Even though the Project Analyst was unable to replicate exact calculations, the applicant provided the information necessary for the Project Analyst to determine projected utilization in a manner consistent with the applicant's assumptions and methodology.

However, the applicant does not adequately demonstrate the need to add a second fixed MRI scanner at NHI Southpark, as explained in the following discussion.

To demonstrate need for a proposed project, an applicant must be able to meet any applicable performance standards in regulatory rules duly promulgated by the Agency. Because this application proposes to acquire a fixed MRI scanner, the Criteria and Standards for Magnetic Resonance Imaging Scanner[s] apply to this application.

The Criteria and Standards for Magnetic Resonance Imaging Scanner[s] require the applicant to demonstrate the following in 10A NCAC 14C .2703(b)(2):

*“...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.]...” (emphasis added)*

As stated at the beginning of the discussion under Criterion (3), the MRI service area for this review is Mecklenburg County. In Section C, pages 45-46, the applicant states, in response to a question about this rule:

*“As a provider of both fixed and mobile MRI services, Novant Health and its affiliate, 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. However, other than temporary MRI scanners, there are no mobile MRI scanners in which NHI Southpark, or a related entity owns a controlling interest in and operates in the proposed MRI services area at the time of this filing.”*

However, that statement is not accurate. First, MDI (d/b/a NHI Southpark) is not the only applicant in this review; in Section A, page 6, Novant Health, Inc. (Novant) is specifically identified as an applicant. Second, MedQuest Associates (MedQuest) has more than just access to mobile MRI scanners – it owns multiple mobile MRI scanners, either directly or through subsidiaries. As stated above, MedQuest is an affiliate of Novant. In fact, it is more than an affiliate – it is a wholly-owned subsidiary of Novant. In Section C, page 27, the applicant states MedQuest was acquired by Novant in November 2007. Novant also owns other subsidiaries that provide mobile MRI scanner services in Mecklenburg County. In publicly available information, Novant has identified Presbyterian Medical Imaging, LLC (PMI) and Jacksonville Diagnostic Imaging, LLC (JDI), among others, as its subsidiaries.

JDI owns a mobile MRI scanner pursuant to Project I.D. #F-6626-02. In a material compliance request submitted to the Agency on April 13, 2018 (which was approved by the Agency on May 7, 2018), Novant and JDI identified the existing sites served by the mobile MRI scanner; those sites included NHI University and NHI Steele Creek. There are no further material compliance requests from Novant and/or JDI to indicate that they have ceased to serve those two locations. In fact, in the 2020 Registration and Inventory of Medical Equipment Form for Mobile Magnetic Resonance Imaging Scanners (“R&I Form”), which covers services provided during FFY 2019, NHI Steele Creek is listed as a location that was served by JDI during FFY 2019. It is unclear as to why NHI University is not listed on the 2020 R&I Form as there was no request from Novant or any of its affiliates to discontinue service to NHI University.

PMI owns a mobile MRI scanner pursuant to Project I.D. #F-7164-04. In an exemption request submitted to the Agency on July 8, 2019 (which was approved by the Agency on July 17, 2019), Novant and PMI notified the Agency of its plan to replace its existing mobile MRI scanner (see Record #2985). In that exemption request, Novant and PMI identified the existing sites served by the mobile MRI scanner; those sites included NHI Steele Creek and NHI University. In a material compliance request submitted to the Agency on August 12, 2019 (which was approved by the Agency on August 16, 2019), Novant and PMI sought Agency approval to discontinue service to NHI Steele Creek and NHI University. However, in a material compliance request submitted to the Agency on February 7, 2020 (which was approved by the Agency on February 12, 2020), Novant and PMI sought Agency approval to resume service to NHI Steele Creek and NHI University. The Agency has not received any material compliance requests since the one approved on February 12, 2020, that sought Agency approval to change or discontinue the sites served by Novant and PMI’s mobile MRI scanner.

Additionally, there appears to be at least one grandfathered mobile MRI scanner owned by Novant and MedQuest which serves sites in Mecklenburg County. On February 25, 2020, Novant and MedQuest submitted an exemption request to the Agency to bring in a mobile MRI scanner from out of state to temporarily replace a mobile MRI scanner it identified as “MQ 9” due to an immediate need for repairs to MQ 9. In that request (which was approved by the Agency on February 28, 2020), Novant and MedQuest represented to the Agency that MQ 9 was serving NHI Steele Creek and NHI University. Further, Novant and MedQuest represented to the Agency that MQ 9 would be brought back into service as soon as it was repaired, which Novant and MedQuest estimated would take several weeks. The Agency specifically identified the representation made by Novant that MQ 9 would be brought back into service as soon as it was repaired as one of the reasons for approving the exemption request (see Record #3230).

It is not clear which mobile MRI scanner is represented as MQ 9 – there are no such identifications on any 2019 or 2020 R&I Forms. Kings Medical Group submitted 2019 and 2020 R&I Forms identifying service to Novant facilities in Mecklenburg County; on those forms, Kings Medical Group identified MedQuest as the entity which gathered and submitted the data requested on the R&I Forms. The mobile MRI scanner identified as KINGS I on the 2020 R&I Form submitted by Kings Medical Group provided mobile MRI services to both NHI University and NHI Steele Creek during FFY 2019, but it is not clear if this is the mobile MRI scanner identified as MQ 9 by Novant and MedQuest.

While there is no reason to believe the MQ 9 scanner was not fully repaired and brought back into service to provide mobile MRI scanner services to NHI Steele Creek and NHI University, the Project Analyst notes grandfathered mobile MRI scanners do not need Agency approval or to provide notice to the Agency about changes in sites of service. Thus, it is possible that at the time the application was submitted, MQ 9 was not serving any sites in Mecklenburg County. However, based on the certificates of need for Project I.D. #F-6626-02 and Project I.D. #F-7164-04, the Agency does need to approve any changes to the sites of service for those particular mobile MRI scanners. Indeed, Novant is aware of this requirement, as it has submitted requests to change the sites served by those mobile MRI scanners several times in the last year. Thus, it is reasonable to believe mobile MRI scanners owned by Novant and which are not temporary mobile MRI scanners were serving sites in Mecklenburg County at the time of the submission of the application.

Even though the applicant has more recent data available than FFY 2019 data, as evidenced by the applicant annualizing FFY 2020 data in the assumptions and methodology found in Section Q, the Project Analyst could utilize publicly available information, if it existed, to determine whether the mobile MRI scanners operating pursuant to Project I.D. #F-6626-02 and Project I.D. #F-7164-04 each provided 3,328 weighted MRI scans during FFY 2019. While there is a 2020 R&I Form for the mobile MRI scanner operating pursuant to Project I.D. #F-6626-02, there is no 2020 R&I Form which identifies itself as being the mobile MRI scanner operating pursuant to Project I.D. #F-7164-04.

Further, the Criteria and Standards for Magnetic Resonance Imaging Scanner[s] require the applicant to demonstrate the following in 10A NCAC 14C .2703(b)(5):

*“...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.]...” (emphasis added)*

In Section C, page 47, in response to a question about this rule, the applicant provides the exact same answer as it did on page 46 in response to the question about historical utilization – that it does not own any mobile MRI scanners in the service area, other than temporary mobile MRI scanners.

A review of publicly available information provided to the Agency by MedQuest and Novant shows there are no facilities in the state identifiable as Novant facilities which use any mobile MRI scanners other than ones owned and operated by MedQuest or another subsidiary of Novant. The potential exception is mobile MRI scanners owned and operated by Kings Medical Group; the affiliation between Kings Medical Group and MedQuest/Novant is not clear, but on a 2017 R&I Form MedQuest submitted to the Agency, it identified the serial number of the KINGS I mobile MRI unit as a MedQuest mobile MRI unit. In its projected utilization, the applicant includes mobile MRI scans it projects to provide at its facilities in Mecklenburg County through the third full fiscal year following project completion. As such, it is reasonable to believe that the mobile MRI scans projected by the applicant will be performed on at least one mobile MRI scanner owned by Novant and MedQuest. Those projections do not specify which mobile MRI scanners will be serving which facilities, nor do they include any information about such mobile MRI scans at other potential sites outside of Mecklenburg County; thus, it is impossible to determine if the mobile MRI scanners owned and operated by Novant in Mecklenburg County will reasonably project to perform 3,328 weighted MRI procedures in the third year of operation following project completion.

The applicant failed to respond as required to the Criteria and Standards for Magnetic Resonance Imaging Scanner[s] in the application as submitted. There is not enough existing publicly available information to determine that the application is conforming with the Criteria and Standards promulgated in 10A NCAC 14C .2703(b)(2) and (5). Because the applicant cannot demonstrate it conforms with the Criteria and Standards for Magnetic Resonance Imaging Scanner[s], the applicant did not demonstrate in its application as submitted the need to add a second fixed MRI scanner at NHI Southpark.

### Access

In Section C, page 41, the applicant states:

*“Services are available to all persons including: (a) low income persons, (b) racial and ethnic minorities, (c) women, (d) [persons with disabilities], (e) elderly, and (f) other underserved persons, including the medically indigent referred by their attending physicians.”*

In Section L, page 76, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>NHI Southpark Projected Payor Mix – FY 3 (CY 2024)</b>		
<b>Payor Source</b>	<b>Entire Facility</b>	<b>MRI</b>
Self-Pay	2.0%	1.4%
Charity Care	0.7%	1.1%
Medicare *	21.4%	18.3%
Medicaid *	1.9%	1.6%
Insurance *	55.9%	53.6%
Workers Compensation	16.9%	23.2%
TRICARE	0.8%	0.5%
Other (Specify)**	0.3%	0.4%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Source: NHI Southpark internal data

\* Including any managed care plans

\*\* Other Government and Institutional Payors

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides its projected payor mix, which includes underserved groups, and states its projected payor mix is based on its historical payor mix.
- The applicant provides written statements about its plans to offer access to all residents of the service area, including underserved groups.
- The applicant provides supporting documentation of its plan to offer access to all residents of the service area, including underserved groups, in Exhibits B-3.2 and B-3.3.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

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



NA

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

NC

The applicant proposes to acquire a second fixed MRI scanner at NHI Southpark pursuant to the need determination in the 2020 SMFP.

In Section E, pages 53-54, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo: the applicant states the existing fixed MRI scanner at NHI Southpark is at capacity, even with opening the facility during extended hours exclusively for MRI scans. The applicant further states its existing scanner is not appropriate for more detailed studies, which forces patients to go to other Novant facilities and which can be inconvenient for the patient and physician. Therefore, the applicant determined this was not an effective option.

Add Mobile MRI Scanner Services: the applicant states that the existing demand for mobile MRI scanners means there is limited capacity to add more host sites. The applicant further states that even if capacity were available or a third-party provider was contracted to provide service, NHI Southpark does not have the physical space to add a mobile MRI scanner pad to accommodate a mobile MRI scanner. Therefore, the applicant determined this was not an effective option.

Add a Fixed MRI Scanner at NHI Ballantyne: the applicant states the FFY 2015-2019 CAGR at NHI Ballantyne was 8.1 percent and utilization is growing rapidly. The applicant further states NHI Ballantyne is effectively at capacity due to the nature of the MRI-guided breast biopsies performed at NHI Ballantyne, which the applicant states are not accommodated in the SMFP methodology. The applicant also states NHI Ballantyne has the ability to utilize a mobile MRI scanner (and currently does so) and it is a less convenient location for patients to be redirected to based on its location related to NH Matthews and NH Presbyterian. Therefore, the applicant determined this was not an effective option.

On page 54, the applicant states its proposal is the most effective alternative because it will alleviate existing capacity constraints at NHI Southpark as well as NH Matthews, the physical space needed to accommodate the fixed MRI scanner already exists at NHI Southpark so it represents a cost-effective alternative, and it adds fixed MRI scanner services in an outpatient setting, which offers lower costs for patients.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need based on the following analysis:

- The applicant did not demonstrate in the application as submitted that it was conforming with the Criteria and Standards for Magnetic Resonance Imaging Scanner[s] promulgated in 10A NCAC 14C .2703(b)(2) and (5), and there is not enough publicly available information to determine that the application is conforming with the applicable Criteria and Standards notwithstanding the applicant's failure to include the necessary information in its application. The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference. A proposal that cannot meet required performance standards cannot be the most effective alternative.
- Because the applicant failed to provide the necessary information to demonstrate it was conforming with the applicable Criteria and Standards, and there was not enough publicly available information to determine the application was conforming to the applicable Criteria and Standards, the applicant did not demonstrate the need it has for the proposed project. The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference. A proposal that is not determined to be necessary cannot be the most effective alternative.
- Because the applicant did not demonstrate the need to develop the proposed project, the applicant cannot demonstrate that it needs the proposed fixed MRI scanner in addition to the existing and approved fixed MRI scanners in Mecklenburg County. The discussion regarding unnecessary duplication found in Criterion (6) is incorporated herein by reference. A project that is unnecessarily duplicative cannot be the most effective alternative.
- Because the applicant did not demonstrate the need for the second fixed MRI scanner, it cannot demonstrate that any enhanced competition in the service area includes a positive impact on the cost-effectiveness of the proposed services. An applicant that did not demonstrate the need for a proposed project cannot demonstrate the cost-effectiveness of the proposed project. The discussion regarding demonstrating the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, found in Criterion (18a) is incorporated herein by reference. A project that cannot show a positive impact on the cost-effectiveness of the proposed services as the result of any enhanced competition cannot be the most effective alternative.
- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons stated above. Therefore, the application is denied.

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

C

The applicant proposes to acquire a second fixed MRI scanner at NHI Southpark pursuant to the need determination in the 2020 SMFP.

**Capital and Working Capital Costs**

On Form F.1a in Section Q, the applicant projects the total capital cost of the project, as shown in the table below.

<b>NHI Southpark Projected Capital Expenditure</b>	
Construction/Renovation Contract	\$467,500
Architect/Engineering Fees	\$42,000
Medical Equipment	\$1,781,134
Consultant Fees	\$50,000
Construction Contingency/Architect Site Visits	\$42,500
<b>Total</b>	<b>\$2,383,134</b>

The applicant provides its assumptions and methodology for projecting capital cost in Section Q and Exhibits F-1 and K-3.1. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibit F-1, the applicant provides a vendor quote for the fixed MRI scanner the applicant proposes to acquire.
- In Exhibit K-3.1, the applicant provides documentation from an architect of the construction plans and costs which are included in the projected capital cost.

In Section F, page 58, the applicant states there will be no start-up costs or initial operating expenses because NHI Southpark is an existing facility which already offers fixed MRI scanner services.

**Availability of Funds**

In Section F, page 57, the applicant states the capital cost will be funded via accumulated reserves from Novant Health, Inc.

Exhibit F-2.1 contains a letter dated August 18, 2020 from the Senior Vice President of Operational Finance for Novant Health, Inc., committing to funding the capital cost of the proposed project. Exhibit F-2.2 contains the Consolidated Financial Statements and Supplemental Information for Novant Health, Inc. and Affiliates for the years ending December 31, 2019 and 2018. As of December 31, 2019, Novant had adequate cash and assets available to fund the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from an appropriate individual confirming the availability of the type of funding proposed for the capital needs of the project and the commitment to using that funding for the capital needs of the project.
- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital and working capital needs of the project.

**Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. On Form F.2 in Section Q, the applicant projects revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

<b>NHI Southpark Projected Revenue &amp; Expenses – FYs 1-3 (CYs 2022-2024)</b>			
	<b>FY 1 (CY 2022)</b>	<b>FY 2 (CY 2023)</b>	<b>FY 3 (CY 2024)</b>
# of MRI procedures (unweighted)	7,164	9,000	11,033
Gross Revenue	\$18,036,478	\$22,658,785	\$27,777,120
Net Revenue	\$3,148,310	\$3,955,145	\$4,848,562
Average Net Revenue per Procedure	\$439	\$439	\$439
Operating Costs	\$1,890,972	\$2,276,915	\$2,596,680
Average Operating Costs per Procedure	\$264	\$253	\$235
<b>Profit/(Loss)</b>	<b>\$1,257,338</b>	<b>\$1,678,230</b>	<b>\$2,251,883</b>

Because the Project Analyst recalculated the number of projected MRI procedures due to apparent issues with calculations in the application, the Project Analyst also recalculated the financial feasibility of the proposal with the adjusted number of projected MRI procedures to determine if the changes would impact the financial feasibility of the proposal. Please see the Working Papers for the Project Analyst’s recalculations of financial feasibility. The recalculated financial feasibility analysis did not change the determination of financial feasibility under this criterion.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant accounts for projected operating expenses, such as salaries, consistent with projections elsewhere in the application.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

NC

The applicant proposes to acquire a second fixed MRI scanner at NHI Southpark pursuant to the need determination in the 2020 SMFP.

Chapter 17-E of the 2020 SMFP defines the service area for fixed MRI scanners as “...*the same as an Acute Care Bed Service Area as defined in Chapter 5, and shown in Figure 5.1.*” Figure 5.1 on page 38 of the 2020 SMFP shows Mecklenburg County as its own Acute Care Bed Service Area. Thus, the service area for this review is Mecklenburg County. Facilities may also serve residents of counties not included in the service area.

The following table summarizes the facility location and historical utilization of all fixed MRI scanners in Mecklenburg County during FFY 2019.

<b>Mecklenburg County Fixed MRI Scanners and Utilization – FFY 2019</b>			
<b>Provider</b>	<b># MRI Scanners</b>	<b># Procedures</b>	<b># Weighted Procedures</b>
<b>Novant Health Facilities</b>			
NH Huntersville*	2	6,450	7,759
NH Matthews	1	6,647	8,179
NH Mint Hill	1	3,245	3,894
NH-PMC – Charlotte Orthopedic Hospital	1	3,113	3,544
NH-PMC – Main**	2	11,073	14,644
NHI Ballantyne	1	4,603	5,141
NHI Museum***	1	3,084	3,569
NHI Southpark	1	5,739	6,204
<b>Atrium Health Facilities</b>			
Atrium Health Pineville	2	8,131	10,374
Atrium Health University City	1	6,084	7,539
Carolinas Medical Center – Main	4	18,146	25,072
Carolinas Medical Center – Mercy	1	5,606	7,091
Atrium Health Kenilworth Diagnostic Center #1****	1	0	0
Carolinas Imaging Services – Ballantyne	1	3,858	4,414
Carolinas Imaging Services – Huntersville	1	3,455	3,929
Carolinas Imaging Services – Southpark	1	3,168	3,764
<b>Other Facilities</b>			
Carolina Neurosurgery & Spine Associates	1	4,271	4,505
OrthoCarolina Ballantyne	1	8,252	8,494
OrthoCarolina Spine Center	1	6,819	7,333

**Sources:** Section G, page 62; Agency records

\* Due to a settlement agreement reached for Project I.D. # F-11184-16 (acquire a 2<sup>nd</sup> fixed MRI scanner), a CON was re-issued for Project I.D. # F-8237-08 (acquire a mobile MRI scanner which may be replaced with no more than one fixed MRI scanner to be located on the campus of NHHMC). The second unit became operational in August 2019. A CON was not issued for Project I.D. # F-11184-16.

\*\*Pursuant to Exemption Record #2983 approved on August 17, 2019, a grandfathered mobile MRI was replaced with a grandfathered fixed MRI at NHPMC, for a total of 3 fixed MRIs on NHPMC’s main campus and 5 fixed MRIs in total on the NHPMC license. The grandfathered fixed MRI became operational in May 2020, after the FFY 2019 reporting period.

\*\*\*NHI Museum is licensed as part of NHPMC.

\*\*\*\*The fixed MRI scanner for this facility is approved but has not been developed at the time of this decision.

In Section G, page 63, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing and approved fixed MRI scanner services in Mecklenburg County. The applicant states:

*“The existing MRI unit at NHI Southpark [performed] 5,030 weighted procedures in FFY 2019 which indicates a need for more than one MRI. ... the proposed project will provide much-needed capacity, allowing NHI Southpark to better serve patients throughout the Novant Health system in Mecklenburg County in a low-cost environment. Further, NHI Southpark proposes a 3T unit which will add imaging capability that does not currently exist at NHI Southpark. The ability to improve accessibility for patients served by Novant Health will not result in an unnecessary duplication of MRI services in the service area.”*

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area, based on the following analysis:

- The applicant did not demonstrate in the application as submitted that it was conforming with the Criteria and Standards for Magnetic Resonance Imaging Scanner[s] promulgated in 10A NCAC 14C .2703(b)(2) and (5), and there is not enough publicly available information to determine that the application is conforming with the applicable Criteria and Standards notwithstanding the applicant's failure to include the necessary information in its application. The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference.
- Because the applicant failed to provide the necessary information to demonstrate it was conforming with the applicable Criteria and Standards, and there was not enough publicly available information to determine the application was conforming to the applicable Criteria and Standards, the applicant cannot demonstrate the need it has for the proposed project. The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference.
- Because the applicant did not demonstrate the need to develop a second fixed MRI scanner at NHI Southpark, it cannot demonstrate that the second fixed MRI scanner is needed in addition to the existing and approved fixed MRI scanners in Mecklenburg County.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion based on the analysis above.

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

C

On Form H in Section Q, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as summarized in the table below.

<b>NHI Southpark Fixed MRI Current and Projected Staff</b>				
<b>Position</b>	<b>Current (12/31/19)</b>	<b>FY 1 (CY 2022)</b>	<b>FY 2 (CY 2023)</b>	<b>FY 3 (CY 2024)</b>
Clerical Staff	0.40	0.40	0.40	0.40
Radiology Technologists	1.35	2.35	2.35	2.35
<b>Total</b>	<b>1.75</b>	<b>2.75</b>	<b>2.75</b>	<b>2.75</b>

The assumptions and methodology used to project staffing costs are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 64-66, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs and provides supporting documentation in Exhibits H-3.1 and H-3.2.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately documents the number of additional FTEs it needs to offer the proposed services.
- The applicant accounts for projected salaries and other costs of employment in its projected operating expenses found on Form F.3 in Section Q.
- The applicant provides adequate documentation of its existing recruitment, training, and continuing education programs.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

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

C

**Ancillary and Support Services**

In Section I, page 67, the applicant identifies the necessary ancillary and support services for the proposed services. On page 67, the applicant explains how each ancillary and support



service is or will be made available and provides supporting documentation in Exhibit I-1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant specifically identifies the existing providers of the ancillary and support services.
- The applicant states the existing providers will continue to provide the necessary ancillary and support services through each of the first three full fiscal years following project completion.

### **Coordination**

NHI Southpark is an existing facility. In Section I, pages 68-69, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-3. On page 68, the applicant states that NHI Southpark is part of the Novant Health system and is thus part of that system's coordination to provide community medical care. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because the applicant provides documentation that it has existing relationships with other local health care and social service providers.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

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

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

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

C

In Section K, page 71, the applicant states the project involves renovating 737 square feet of existing space. Line drawings are provided in Exhibit K-2.

On page 71, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant explains why the cost, design, and means of construction chosen are more cost-effective than other alternatives.
- In Exhibit K-3.1, the applicant provides supporting documentation of the proposed costs that are consistent with projections elsewhere in the application.

On page 71, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states it will locate the second fixed MRI scanner in space contiguous to existing support spaces which will facilitate efficient delivery of care.
- The applicant states it is using existing space without developing any new square footage, which the applicant states will keep the capital cost to develop the project lower than it would be if it constructed additional space.

On page 72, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K-3.2.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

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

C

In Section L, page 75, the applicant provides the historical payor mix during FFY 2019 for the proposed services, as shown in the table below.

<b>NHI Southpark Historical Payor Mix – FFY 2019</b>		
<b>Payor Source</b>	<b>Entire Facility</b>	<b>MRI</b>
Self-Pay	2.0%	1.4%
Charity Care	0.7%	1.1%
Medicare *	21.4%	18.3%
Medicaid *	1.9%	1.6%
Insurance *	55.9%	53.6%
Workers Compensation	16.9%	23.2%
TRICARE	0.8%	0.5%
Other (Specify)**	0.3%	0.4%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Source: NHI Southpark internal data

\* Including any managed care plans

\*\* Other Government and Institutional Payors

In Section L, page 74, the applicant provides the following comparison.

	<b>Percentage of Total Patients Served by NHI Southpark during FFY 2019</b>	<b>Percentage of the Population of Mecklenburg County</b>
Female	64.6%	51.6%
Male	35.4%	48.4%
Unknown	0.0%	0.0%
64 and Younger	75.7%	88.5%
65 and Older	24.3%	11.5%
American Indian	0.3%	0.5%
Asian	2.6%	5.4%
Black or African-American	22.5%	28.2%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	56.4%	56.4%
Other Race	18.0%	9.4%
Declined / Unavailable	0.1%	0.0%

Sources: NHI Southpark internal data; Spotlight

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities

and ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 75, the applicant states it has no such obligation.

In Section L, page 75, the applicant states that during the last five years no patient civil rights access complaints have been filed against Novant Health facilities and programs located in North Carolina.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L, page 76, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

<b>NHI Southpark Projected Payor Mix – FY 3 (CY 2024)</b>		
<b>Payor Source</b>	<b>Entire Facility</b>	<b>MRI</b>
Self-Pay	2.0%	1.4%
Charity Care	0.7%	1.1%
Medicare *	21.4%	18.3%
Medicaid *	1.9%	1.6%
Insurance *	55.9%	53.6%
Workers Compensation	16.9%	23.2%
TRICARE	0.8%	0.5%
Other (Specify)**	0.3%	0.4%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Source: NHI Southpark internal data

\* Including any managed care plans

\*\* Other Government and Institutional Payors

On page 76, the applicant states charity care is provided to patients across payor categories, but it isolated all charity care adjustments and adjusted gross revenue categories as needed for purposes of providing the information in the table above.

As shown in the table above, during the third full fiscal year of operation, the applicant projects 2.0 percent and 1.4 percent of total facility services and MRI services, respectively, will be provided to self-pay patients; 0.7 percent and 1.1 percent of total facility services and MRI services, respectively, will be provided to charity care patients; 21.4 percent and 18.3 percent of total facility services and MRI services, respectively, will be provided to Medicare patients; and 1.9 percent and 1.6 percent of total facility services and MRI services, respectively, will be provided to Medicaid patients.

On page 76, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The projected patient payor mix is consistent with the historical patient payor mix.
- The applicant does not propose to develop any services or make any changes to its facility that could foreseeably impact the projected patient payor mix in more than minor ways.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

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

C

In Section L, pages 78-79, the applicant adequately describes the range of means by which patients will have access to the proposed services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

### C

In Section M, page 80, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant provides documentation of existing health professional training programs in the area for which it already provides access at NHI Southpark and other Novant facilities.
- The applicant states it will continue to provide access to NHI Southpark as it has in the past.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

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

NC

The applicant proposes to acquire a second fixed MRI scanner at NHI Southpark pursuant to the need determination in the 2020 SMFP.

Chapter 17-E of the 2020 SMFP defines the service area for fixed MRI scanners as “...the same as an Acute Care Bed Service Area as defined in Chapter 5, and shown in Figure 5.1.” Figure 5.1 on page 38 of the 2020 SMFP shows Mecklenburg County as its own Acute Care Bed Service Area. Thus, the service area for this review is Mecklenburg County. Facilities may also serve residents of counties not included in the service area.

The following table summarizes the facility location and historical utilization of all fixed MRI scanners in Mecklenburg County during FFY 2019.

<b>Mecklenburg County Fixed MRI Scanners and Utilization – FFY 2019</b>			
<b>Provider</b>	<b># MRI Scanners</b>	<b># Procedures</b>	<b># Weighted Procedures</b>
<b>Novant Health Facilities</b>			
NH Huntersville*	2	6,450	7,759
NH Matthews	1	6,647	8,179
NH Mint Hill	1	3,245	3,894
NH-PMC – Charlotte Orthopedic Hospital	1	3,113	3,544
NH-PMC – Main**	2	11,073	14,644
NHI Ballantyne	1	4,603	5,141
NHI Museum***	1	3,084	3,569
NHI Southpark	1	5,739	6,204
<b>Atrium Health Facilities</b>			
Atrium Health Pineville	2	8,131	10,374
Atrium Health University City	1	6,084	7,539
Carolinas Medical Center – Main	4	18,146	25,072
Carolinas Medical Center – Mercy	1	5,606	7,091
Atrium Health Kenilworth Diagnostic Center #1****	1	0	0
Carolinas Imaging Services – Ballantyne	1	3,858	4,414
Carolinas Imaging Services – Huntersville	1	3,455	3,929
Carolinas Imaging Services – Southpark	1	3,168	3,764
<b>Other Facilities</b>			
Carolina Neurosurgery & Spine Associates	1	4,271	4,505
OrthoCarolina Ballantyne	1	8,252	8,494
OrthoCarolina Spine Center	1	6,819	7,333

**Sources:** Section G, page 62; Agency records

\* Due to a settlement agreement reached for Project I.D. # F-11184-16 (acquire a 2<sup>nd</sup> fixed MRI scanner), a CON was re-issued for Project I.D. # F-8237-08 (acquire a mobile MRI scanner which may be replaced with no more than one fixed MRI scanner to be located on the campus of NHHMC). The second unit became operational in August 2019. A CON was not issued for Project I.D. # F-11184-16.

\*\*Pursuant to Exemption Record #2983 approved on August 17, 2019, a grandfathered mobile MRI was replaced with a grandfathered fixed MRI at NHPMC, for a total of 3 fixed MRIs on NHPMC’s main campus and 5 fixed MRIs in total on the NHPMC license. The grandfathered fixed MRI became operational in May 2020, after the FFY 2019 reporting period.

\*\*\*NHI Museum is licensed as part of NHPMC.

\*\*\*\*The fixed MRI scanner for this facility is approved but has not been developed at the time of this decision.



Regarding the expected effects of the proposal on competition in the service area, in Section N, page 81, the applicant states:

*“The proposed project will promote cost-effective approaches, expand health care services to the medically underserved, and encourage quality health care services by improving access to MRI services for the patient population served by NHI Southpark...”*

...

*.... NHI Southpark not only delivers MRI services but also promotes coordinated, high-quality, financially accessible care for its patients. Thus, approval of the proposed project will have a positive impact on competition.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 81-82, the applicant states:

*“Novant Health is delivering value and quality in outcomes through its Population Health Management programs. This approach encourages wellness and preventive care and managing existing conditions to slow or reverse the progression of disease, all while lowering the overall cost of care. .... Ultimately this type of care provides value-safe, more affordable care with better outcomes-and is centered on our patients’ unique needs. .... Novant Health is collaborating with payors and partners to identify payment models that match Novant Health’s value-based care delivery. Getting the right care in the right setting at the right price is the future of healthcare. It is what makes healthcare affordable and more sustainable. It is Novant Health’s new approach to delivering remarkable healthcare, so that people can get better and stay healthy. The approval of the proposed project will create access to enhanced 3T MR imaging in a low-cost setting.”*

See also Sections B, C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, pages 83-84, the applicant states:

*“NHI Southpark is committed to providing exceptional quality of care for service area residents. The American College of Radiology (ACR) provides a rigorous accreditation process that mandates each facility offer outstanding quality in order to bear its seal.*

*In addition to maintaining its ACR accreditation status, NHI Southpark adheres to all applicable Novant Health quality and safety policies.*

...

*Additionally, Novant Health has twice received the prestigious Ernest A. Codman award for improving systemwide the quality and safety of care provided to patients.*

...

*...NHI Southpark will continue to strive to meet Novant Health's high level of quality when it implements the new fixed MRI scanner on its campus."*

See also Sections B, C, and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 85-86, the applicant states:

*"NHI Southpark will provide services to all persons regardless of race, sex, age, religion, creed, disability, national origin or ability to pay. ...*

...

*Services are available to all persons including: (a) low income persons, (b) racial and ethnic minorities, (c) women, (d) handicapped persons, (e) elderly, and (f) other underserved persons, including the medically indigent referred by their attending physicians. ...*

...

*All these policies and processes are fully described in Novant Health's Charity Care and related policies .... These policies illustrate that Novant Health also has processes and policies that facilitate access to Charity Care, including the medically indigent, the uninsured, and the underinsured."*

See also Sections B, C, and L of the application and any exhibits.

However, the applicant does not adequately demonstrate how any enhanced competition in the service area will have a positive impact on the cost-effectiveness of the proposed services. The applicant did not adequately demonstrate the need to add a second fixed MRI scanner at NHI Southpark and that the project is the least costly or most effective alternative. The discussions regarding analysis of need, including projected utilization, and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference. A project that cannot demonstrate the need for the services proposed and a project that cannot demonstrate it is the least costly or most effective alternative cannot demonstrate how any enhanced competition will have a positive impact on the cost-effectiveness of the proposal.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons stated above.

- (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

On Form A in Section Q, the applicant identifies the diagnostic imaging facilities which offer MRI scanner services (either fixed, mobile, or both) located in North Carolina and which are owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 23 diagnostic imaging facilities located in North Carolina.

In Section O, page 89, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 23 diagnostic imaging 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.

G.S. 131E-183 (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 Criteria and Standards for Magnetic Resonance Imaging Scanner[s], promulgated in 10A NCAC 14C .2700, are applicable to this review. The application is not conforming with all Criteria and Standards. Each of the applicable Criteria and Standards 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- The applicant does not 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 MRI service area is Mecklenburg County. In Section C, page 45, the applicant states that, during FFY 2019, the 10 fixed MRI scanners applicable to this Rule performed an average of 5,028 weighted MRI procedures, which exceeds the required average of 3,328 weighted MRI procedures per scanner as required in this Rule. Therefore, the application is conforming with this Rule.

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

-NC- The MRI service area is Mecklenburg County. In Section C, pages 45-46, the applicant states that neither the applicant or a related entity owns a controlling interest in an existing mobile MRI scanner in Mecklenburg County; however, that information is not accurate. Novant Health, Inc., one of the applicants in this review, is the owner of MedQuest Associates and other subsidiaries, at least one of which owned and operated at least one mobile MRI scanner in Mecklenburg County as of the date this application

was submitted. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant did not provide enough information in the application as submitted to determine the application was conforming with this Rule and there was not enough publicly available information to determine the application was conforming with this Rule; therefore, the application is not conforming with 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;*

-C- The 2020 SMFP shows that there are more than four fixed MRI scanners located in the MRI service area of Mecklenburg County. Therefore, the 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 following completion of the proposed project. In Section C, page 46, the applicant states it projects to perform an average of 5,674 weighted MRI procedures on its 12 existing and proposed MRI scanners in the third operating year following completion of the proposed project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant reasonably projects to perform in excess of an average of 4,805 weighted MRI procedures in Mecklenburg County during the third operating year following project completion. Therefore, the application is conforming with 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- The proposed fixed MRI scanner will be located at NHI Southpark where there is an existing fixed MRI scanner owned by the applicant. Therefore, this Rule is not applicable to 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*

-NC- The MRI service area is Mecklenburg County. In Section C, page 47, the applicant states that neither the applicant or a related entity owns a controlling interest in an existing mobile MRI scanner in Mecklenburg County; however, that information is not accurate. Novant Health, Inc., one of the applicants in this review, is the owner of MedQuest Associates and other subsidiaries, at least one of which owned and operated at least one mobile MRI scanner in Mecklenburg County as of the date this application was submitted. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Further, the applicant projects to offer mobile MRI scanner services at several sites owned by Novant Health, Inc. during the first three full operating years following project completion, and it is reasonable to believe that at least one of the sites offering mobile MRI scanner services will be serviced by a mobile MRI scanner owned by MedQuest or another of Novant's subsidiaries.

The applicant did not provide enough information in the application as submitted to determine the application was conforming with this Rule and there was not enough publicly available information to determine the application was conforming with this Rule; therefore, the application is not conforming with this Rule.

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

-NC- The applicant's assumptions and data supporting the methodology used for the projection required under subsection (3) of this Rule can be found in Section Q of the application. However, the applicant does not provide any assumptions or methodology to conform with the projection required under subsection (5) of this Rule. Therefore, the application is not conforming with this Rule.

- (c) *An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*
- (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure per hour times 40 hours per week times 52 weeks per year; and*
  - (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- NA- The applicant does not 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- The applicant does not propose the acquisition of a dedicated fixed extremity MRI scanner. Therefore, this Rule is not applicable to this review.
- (e) *An applicant proposing to acquire a fixed multi-position MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for a demonstration project shall:*
- (1) *demonstrate annual utilization of the proposed multi-position MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(g)(7); and*
  - (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- NA- The applicant does not propose the acquisition of a dedicated fixed multi-position MRI scanner. Therefore, this Rule is not applicable to this review.