

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 28, 2020

Findings Date: February 4, 2020

Project Analyst: Ena Lightbourne

Team Leader: Fatimah Wilson

Assistant Chief: Lisa Pittman

### COMPETITIVE REVIEW

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Project ID #: F-11755-19

Facility: Novant Health Matthews Medical Center

FID #: 945076

County: Mecklenburg

Applicant(s): Presbyterian Medical Care Corp.

Project: Acquire a second fixed MRI scanner pursuant to the need determination in the 2019 SMFP

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Project ID #: F-11760-19

Facility: Atrium Health Kenilworth Diagnostic Center #1

FID #: 190165

County: Mecklenburg

Applicant(s): Carolinas Physicians Network, Inc.

Project: Acquire one fixed MRI scanner pursuant to the need determination in the 2019 SMFP

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### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C – Both Applications

## **Need Determination**

The 2019 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 the 2019 SMFP identified a need for one additional fixed MRI scanner in Mecklenburg County service area. Two applications were submitted to the Certificate of Need Section (CON) proposing to acquire a total of two new fixed MRI scanners. However, pursuant to the need determination in the 2019 SMFP, only one fixed MRI scanner can be approved in this review. See the conclusion following the Comparative Analysis for the decision.

## **Policies**

There are two policies applicable to the review of the two applications submitted in response to the MRI need determination in the 2019 SMFP for the Mecklenburg County service area. *Policy GEN-3: Basic Principles*, and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, both on page 31.

*Policy GEN-3* states:

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

*Policy GEN-4* states:

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

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, 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. 131E184 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."*

### **Project ID# F-11755-19/ NHMMC/Acquire a Second Fixed MRI Scanner**

Presbyterian Medical Care Corp. proposes to acquire a second fixed MRI scanner to be installed in the Radiology Department of Novant Health Matthews Medical Center (NHMMC) in renovated space. NHMMC currently operates one fixed MRI scanner in their existing Radiology Department at NHMMC.

*Need Determination.* The applicant does not propose to acquire more fixed MRI scanners than are determined to be needed in the Mecklenburg County service area.

*Policy GEN-3.* In Section B, pages 15-18, the applicant explains why it believes its application is conforming to Policy GEN-3. On page 15, the applicant states:

*"At Novant Health, keeping patients safe and free from harm is our number one priority. Novant Health applies evidence-based best practice methods to prevent medical errors by building accountability for finding and fixing system problems."*

#### Promote Safety and Quality

The applicant describes how it believes its proposal would promote safety and quality in Section B.10, pages 15-18 and pages 23-24, Section N.2, pages 90-91, Section O.1, pages 94-97, and referenced Exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

#### Promote Equitable Access

The applicant describes how it believes its proposal would promote equitable access in Section B.10, pages 18-21 and pages 23-24, Section C.11, page 50, Section L, pages 81-86, Section

N.2, pages 91-93, and referenced Exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes its proposal would maximize health care value in Section B.10, pages 21-23 and pages 23-24, Section K.3, pages 78-79, Section N.2, pages 88-90, in the applicant's pro forma financial statements provided in Section Q, and referenced Exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

*Policy GEN-4.* The projected capital cost for the proposed project is greater than \$2 million but less than \$5 million. In Section B, page 25, the applicant explains why it believes its application is conforming to Policy GEN-4. On page 25, 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). The "written statement" reference in paragraph 1 of Policy GEN-4 in the 2019 SMFP is articulated in the broader framework of the 2019 SEMF."*

On page 25, the applicant also provides examples of energy efficient and water conservation features it will include for the proposed project.

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

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

- The applicant does not propose to acquire more fixed MRI scanners than are determined to be needed in Mecklenburg County.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3.

- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4.

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

Carolinas Physician Network, Inc. (CPN) proposes to acquire one fixed MRI scanner with cardiac capabilities to be located at Atrium Health Kenilworth Diagnostic Center #1, a previously approved but not yet operational diagnostic center.

*Need Determination.* The applicant does not propose to acquire more fixed MRI scanners than are determined to be needed in the Mecklenburg County service area.

*Policy GEN-3.* In Section B, page 22, the applicant explains why it believes the application is conforming to Policy GEN-3. The applicant states:

*“As discussed above, the proposed project incorporates the concepts of safety, quality, access, and maximum value for resources expended. As shown in Form C and the response to the Criteria and Standards for Magnetic Resonance Imaging Scanners, the projected utilization demonstrates the need for the proposed project.”*

#### Promote Safety and Quality

The applicant describes how it believes its proposal would promote safety and quality in Section B.10, page 20, Section N.2, pages 90-91, Section O.1, pages 93-94, and referenced Exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

#### Promote Equitable Access

The applicant describes how it believes its proposal would promote equitable access in Section B.10, pages 20-21, Section C.11, pages 46-48, Section L, pages 84-87, Section N.2, pages 91-92, and referenced Exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

#### Maximize Healthcare Value

The applicant describes how it believes its proposal would maximize health care value in Section B.10, page 21, Section K.3, pages 78-79, Section N.2, page 90, in the applicant's pro forma financial statements provided in Section Q and referenced Exhibits. The information

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

*Policy GEN-4.* The projected capital cost for the proposed project is greater than \$2 million but less than \$5 million. In Section B, pages 22-23, the applicant explains why it believes its application is conforming to Policy GEN-4. On page 23, the applicant states:

*“Atrium Health has demonstrated its commitment to a higher standard of excellence and will continue to do so relative to the proposed project. Atrium Health will work with experienced architects and engineers to develop this proposed project to ensure energy efficient systems are an inherent part of the proposed project to the degree appropriate with the proposed upfit.”*

On page 23, the applicant also provides examples of energy efficient and water conservation features it will include for the proposed project.

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

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

- The applicant does not propose to acquire more fixed MRI scanners than are determined to be needed in Mecklenburg County.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4.

(2) Repealed effective July 1, 1987.

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

C – Both Applications

**Project ID# F-11755-19/ NHMMC/Acquire a Second Fixed MRI Scanner**

Presbyterian Medical Care Corp. proposes to acquire a second fixed MRI scanner to be installed in the Radiology Department of NHMMC in renovated space. NHMMC currently operates one fixed MRI scanner in their existing Radiology Department at NHMMC.

In Section A, page 6, the applicant states that Novant Health, Inc. is the parent company of Presbyterian Medical Care Corp.

**Patient Origin**

On page 149, the 2019 SMFP defines the service area for a fixed MRI scanner as “a single county, except where there is no licensed acute care hospital located within the county.” The definition of the service area for a fixed MRI scanner then explains how a service area is determined when there is no licensed acute care hospital located within the county. For the purpose of this review, however, Mecklenburg County is the service area since it has multiple licensed acute care hospitals. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 28, the applicant provides the historical patient origin for NHMMC’s MRI service for January 1, 2018 through December 31, 2018. In Section C.3, page 29, the applicant provides the projected patient origin for the first three operating years of the proposed project. The following table illustrates current and projected patient origin:

County	NHMMC Historical MRI Patient Origin		NHMMC’s Projected MRI Patient Origin					
	1/1/2018-12/31/2018		1 <sup>st</sup> Full FY		2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY	
			7/1/2021-6/30/2022		7/1/2022-6/30/2023		7/1/2023-6/30/2024	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Mecklenburg	3,293	53.01%	4,284	53.01%	4,502	53.01%	4,731	53.01%
Union	2,253	36.27%	2,931	36.27%	3,080	36.27%	3,237	36.27%
Cabarrus	106	1.71%	138	1.71%	145	1.71%	153	1.71%
Stanly	99	1.59%	128	1.59%	135	1.59%	142	1.59%
Anson	49	0.79%	64	0.79%	67	0.79%	71	0.79%
Gaston	32	0.52%	42	0.52%	44	0.52%	46	0.52%
Iredell	11	0.18%	15	0.18%	15	0.18%	16	0.18%
Other NC Counties*	57	0.92%	74	0.92%	78	0.92%	82	0.92%
South Carolina	244	3.93%	318	3.93%	334	3.93%	351	3.93%
Other States	68	1.09%	88	1.09%	93	1.09%	97	1.09%
<b>Total</b>	<b>6,212</b>	<b>100.00%</b>	<b>8,081</b>	<b>100.00%</b>	<b>8,493</b>	<b>100.00%</b>	<b>8,926</b>	<b>100.00%</b>

Source: Section C, pages 28-29

\*Includes: Alexander, Brunswick, Carteret, Catawba, Cleveland, Cumberland, Davidson, Forsyth, Guilford, Harnett, Henderson, Hoke, Lee, Lincoln, Macon, Mitchell, Moore, Onslow, Pender, Randolph, Richmond, Robeson, Rowan, Rutherford, Scotland, Surry, Vance, Wake, Watauga, Wayne

In Section C.4, page 30, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states that the projected patient origin for MRI services for the first three years of the proposed project is based on the historical patient origin for MRI services at NHMMC. The applicant's assumptions are reasonable and adequately supported.

### **Analysis of Need**

In Section C, page 30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 30, the applicant states:

*“The proposed second fixed MRI unit will enable NHMMC to provide greater access to MRI services, ensure timely access to care, improve operational efficiencies, and decrease employee burnout due to overtime and on call hours.”*

In Section C, pages 30-39, the applicant describes the factors that support the need for the proposed services, as summarized below:

- The increase in MRI demand in Mecklenburg County as demonstrated by the 2019 SMFP need determination for one additional fixed MRI scanner in the county. [page 31]
- The significant growth in population in the service area, particularly the 65+ age cohort. The applicant used 2017 data from the North Carolina Office of State Budget and Management (NCOSBM) to illustrate the total service area projected population growth of 25.9 percent from 2019 to 2024 for the 65+ population. [page 32]
- High utilization of the existing fixed hospital-based MRI scanner at NHMMC and the Novant Health healthcare system in Mecklenburg County. The applicant states this is based on the larger population of the critically ill and vulnerable patients, including emergency patients that seek care in a hospital setting. [pages 32-35]
- Historical growth in other services at NHMMC that impact MRI utilization, such as neurology, heart and vascular, pediatrics, women's breast health and surgical. [pages 35-37]
- Growth in historical emergency department (ED) MRI scans at NHMMC as a result of daily outpatient MRIs from patients admitted through the ED resulting in significant delays and scheduling conflicts for non-ED patients. [pages 37-39]

The information is reasonable and adequately supported for the following reasons:

- 2019 SMFP need determination for one additional fixed MRI Scanner in Mecklenburg County;
- Population growth in Mecklenburg County, particularly for those 65+;
- Growth in other services that impact MRI utilization at NHMMC; and
- Historical utilization growth of MRI procedures at NHMMC.

#### *Projected Utilization*

In Section C, pages 39-46, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

#### *Step 1-Identify Novant Health Fixed and Mobile MRI Inventory in Mecklenburg County-Actual and Projected*

- Determine Novant Health's inventory of fixed and mobile MRI units serving Mecklenburg County based on the number of existing and approved but not yet implemented units.
- Identify specific changes effecting MRI capacity and mobile MRI unit inventory factored into utilization projections:
  - Pursuant to Exemption Record #2970, NHMMC was approved on June 18, 2019 to replace an existing fixed MRI scanner that was to be operational by December 2019 and discontinue mobile MRI service at NHMMC.
  - Due to a settlement agreement reached for Project ID# F-11184-16 (acquire a 2nd fixed MRI scanner) at Novant Health Huntersville Medical Center (NHHMC), a CON was issued for Project ID# F-008237-08 (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). A CON was not issued for Project ID# F-11184-16. In comments submitted to the Agency during the public comment period, it was stated that the applicant incorrectly represents in their historical utilization the number of fixed MRI units it has. Specifically, that NHHMC only had one fixed MRI unit instead of two. The comment asserts that this error resulted in inaccurate historical utilization. The Project Analyst notes that the Healthcare Planning staff recognized this error and issued a corrected Table 17E-1 in the proposed 2020 SMFP that reflects that NHHMC has two fixed MRI scanners. The second MRI scanner at NHHMC became operational August 2019. The applicant also adequately demonstrated its projected utilization based on NHHMC having two fixed MRI scanners.
  - Pursuant to a Declaratory Ruling issued on August 17, 2015, the 2<sup>nd</sup> MRI scanner approved for NHMMC for Project ID# F-008688-11 (acquire a 2<sup>nd</sup>

fixed MRI scanner) will be placed at Novant Health Mint Hill Medical Center (NHMHMC).

- Pursuant to Exemption Record #2983 approved on August 17, 2019, a grandfathered mobile MRI scanner will be replaced with a grandfathered fixed MRI scanner at Novant Health Presbyterian Medical Center (NHPMC).
- Pursuant to a Material Compliance determination approved on August 16, 2019, mobile MRI services at Novant Health Imaging University (NHI University) and Novant Health Imaging Steele Creek (NHI Steele Creek) will be discontinued effective August 15, 2019.
- The applicant states that the mobile schedule will not change during the first three years of the proposed project; however, based on the information above, there will be no mobile MRI services at NHMMC, NHI Steele Creek and NHI University during the first three years of the proposed project.

The following table provided by the applicant illustrates the historical, current, and projected inventory of MRI units operated by Novant Health and affiliates, including the proposed new fixed MRI scanner at NHMMC.

Number of MRI Units								
	FY 2017	FY 2018	FY 2019 Annualized	Interim FY 2020	Interim Q1-Q3 2021	Projected Years		
						FY2022 7/1/21-6/30/22	FY2023 7/1/22-6/30/23	FY2024 7/1/23-6/30/24
<b>NHPMC*</b>								
Fixed**	4	4	4.2	4.75	5	5	5	5
<b>NHHMC</b>								
Fixed	1	1	1	2	2	2	2	2
Mobile	0.10	0.23	0.46	-	-	-	-	-
<b>Total</b>	<b>1.10</b>	<b>1.23</b>	<b>1.46</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>
<b>NHMMC</b>								
Fixed	1	1	1	1	1	2	2	2
Mobile	0.02	0.13	0.18					
<b>Total</b>	<b>1.02</b>	<b>1.13</b>	<b>1.18</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>2</b>	<b>2</b>
<b>NHMHMC</b>								
Fixed	-	-	1	1	1	1	1	1
<b>Freestanding Mobile</b>								
NHI University	0.72	0.53	0.71	0.71	0.71	0.71	0.71	0.71
NHI Steele Creek	0.21	0.19	0.43	0.43	0.43	0.43	0.43	0.43
<b>Freestanding Fixed</b>								
NHI Ballantyne	1	1	1	1	1	1	1	1
NHI South Park	1	1	1	1	1	1	1	1

Source: Section C, Page 40

\* Includes Presbyterian Main, Charlotte Orthopedic Hospital and Novant Health Imaging Museum

\*\*FY2019 Annualized = number of fixed units + mobile fixed equivalent during the time period when the grandfathered mobile unit served Presbyterian-Main prior to exempt approval for conversion to a 5<sup>th</sup> fixed unit. Interim 2020 – Pursuant to a request for exemption submitted on July 8, 2019 and approved on July 17, 2019 (Record# 2983), Presbyterian Medical Center will convert an existing grandfathered mobile unit to a third fixed unit on its campus. The grandfathered mobile unit served Presbyterian prior to filing this

CON and conversion of the unit to a third fixed MRI. The fixed unit is planned to be operational as of late December 2019. Exhibit C-4.1 (Tab 3) pages 1 to 83.

Note: See bullets above table for other administrative determinations regarding the fixed and mobile MRI unit inventory for Novant Health in Mecklenburg County.

*Step 2: Review Historical Utilization Trends for all Novant Health Fixed and Mobile MRIs in Mecklenburg County*

The applicant used the historical Compound Annual Growth Rate (CAGR) for fixed and mobile units at Novant Health facilities in Mecklenburg County from FY 2017 (October 1, 2016 – September 30, 2017) to FY 2019 (October 21, 2018 – September 30, 2019) to project the number of MRI scans during the interim and the first three years of the project. The following table illustrates the 2-year CAGR based on the historical utilization.

Hospitals	FY 2017	FY 2018	FY 2019 Annualized	2-Year CAGR
<b>NHPMC**</b>				
Total	15,046	16,010	17,124	<b>6.7%</b>
<b>*NHHMC</b>				
Total	6,989	7,419	7,913	<b>6.4%</b>
<b>*NHMMC</b>				
Total	7,102	7,635	7,305	<b>1.4%</b>
<b>NHMHMC</b>				
Total	0	0	3,343	0
<b>Freestanding Mobile</b>				
NHI University	1,744	1,632	1,358	<b>-11.8%</b>
NHI Steele Creek	1,029	883	1,995	<b>39.2%</b>
<b>Freestanding Fixed</b>				
NHI Ballantyne	2,431	3,311	3,272	<b>16.0%</b>
NHI South Park	3,733	4,318	4,515	<b>10.0%</b>
<b>Novant Health Hospitals in Mecklenburg County**</b>	26,474	28,023	29,241	<b>5.1%</b>

Source: Section C, page 41

\*Includes fixed and mobile utilization

\*\* Does not include Novant Health Imaging Museum as it is not a hospital

Note: The applicant notes that NHHMC mobile MRI data was incorrectly published in the draft 2020 SMFP. The data in the table above is the correct volume. This discrepancy has been brought to the attention of Healthcare Planning.

*Step 3: Determine the Growth Rate Assumptions Used to Project the Utilization for Interim and project Years*

Using the 2-year CAGR determined in Step 2, the applicant determined the growth rate assumptions to project utilization for the interim and the first three years of the project. In comments submitted to the Agency during the public comment period, it states that NHMMC shows a decline in MRI procedures from FY2018 to FY2019 (annualized). However, there was also an increase in MRI procedures from FY2017 to FY2018. The applicant adequately demonstrated an overall increase in MRI procedures of 1.4% between FY2017 to FY2019

(annualized), despite a decline between FY2018 to FY2019 (annualized). The applicant projects the CAGR for the interim and the first three years of the project for NHPMC and NHHMC using the historical CAGR of 6.7% and 6.4%.

- For NHMMC, the historical 2-year CAGR of 1.4% was applied for the interim year, while the average CAGR of 5.1% for Novant Health hospitals in Mecklenburg County was applied for Project Year 1, 2, and 3. The applicant states that this assumption is conservative and reasonable, considering the annual growth rate of MRI utilization in the Novant Health system (2-year CAGR of 6.9%) and the annual growth rate of MRI utilization in Mecklenburg County (2-year CAGR of 4.7%) based on all units after correcting the identified data errors in 2019 and 2020 SMFP.
- The applicant states that the Novant Health Mint Hill Medical Center (NHMHMC) MRI utilization was not included in the calculation due to the fact that the facility just opened in October 2018. The Project Analyst notes that the 2019 license renewal application (LRA) time period is October 2017 through September 2018.
- For NHI University and NHI Steele Creek, the average CAGR of 5.1% for the Novant Health system in Mecklenburg County was used for Project Year 1, 2, and 3.
- The historical CAGR for NHI Ballantyne and South Park was applied to Project Year 1, 2, and 3.

*Step 4: Project the utilization for Interim Years and Projected Years 1, 2, and 3*

Based on the assumptions presented in Steps 1-3, the applicant projects utilization as follows:

Unweighted Number of MRI Scans						Projected Years		
	FY 2017	FY 2018	FY 2019 Annualized	Interim FY 2020	Interim Q1-Q3 2021	7/1/21-6/30/22	7/1/22-6/30/23	7/1/23-6/30/24
<b>Presbyterian Medical Center</b>								
Fixed	15,046	16,010	17,124	18,268	14,617	20,458	21,825	23,283
<b>Huntersville Medical Center</b>								
Fixed	6,530	6,328	6,672	8,939	7,134	9,965	10,604	11,283
Mobile	459	1,091	1,729					
<b>Total</b>	<b>6,989</b>	<b>7,419</b>	<b>8,401</b>	<b>8,939</b>	<b>7,134</b>	<b>9,965</b>	<b>10,604</b>	<b>11,283</b>
<b>Matthews Medical Center</b>								
Fixed	7,024	7,011	6,653	7,408	5,635	8,081	8,493	8,926
Mobile	78	624	652					
<b>Total</b>	<b>7,102</b>	<b>7,635</b>	<b>7,305</b>	<b>7,408</b>	<b>5,635</b>	<b>8,081</b>	<b>8,493</b>	<b>8,926</b>
<b>Mint Hill Medical Center</b>								
Fixed	-	-	3,343	3,514	2,769	3,833	4,028	4,233
<b>Freestanding Mobile</b>								
NHI University	1,744	1,632	1,358	1,765	1,721	1,925	2,023	2,126
NHI Steele Creek	1,029	883	1,995	2,097	1,653	2,287	2,404	2,526
<b>Freestanding Fixed</b>								
NHI Ballantyne	2,431	3,311	3,272	3,598	3,130	4,665	5,411	6,277
NHI South Park	3,733	4,318	4,515	4,965	4,096	5,867	6,453	7,099

Source: Section C, page 43

Note: See discussion regarding changes to Novant Health MRI unit inventory on pages 9-10 of these findings.

*Step 5: Calculate the Weighting Factor to Determine the Adjusted Total Scans*

To calculate the weighting factor to determine the adjusted total scans, the applicant used the weighted ratio (2020 Draft SMFP adjusted total/total MRI scans) for all MRI units for FY2018, assuming the weighted ratio will remain the same for the interim years and first three years of the project. The applicant used data from the proposed 2020 SMFP and the corrected 2019 LRAs submitted to Healthcare Planning, as documented in Exhibit C-4.2.

Facility	Weighted Ratio
Presbyterian Medical Center*	1.26
Huntersville Medical Center	1.20
Huntersville Medical Center-Mobile	1.15
Matthews Medical Center	1.22
Matthews Medical Center-Mobile	1.17
Mint Hill Medical Center**	1.21
NHI University	1.06
NHI Steele Creek	1.07
NHI Ballantyne	1.13
NHI South Park	1.08

Source: Section C, page 44

\* Includes Presbyterian Main, Charlotte Orthopedic Hospital, and Novant Health Imaging Museum

\*\*Based on FY2019 internal data

*Step 6: Project the Adjusted Total MRI Scans by Location*

To project the adjusted total scans by location for interim years and project years 1, 2, and 3, the applicant used the weighted ratios presented in Step 5.

Adjusted Total MRI Scans*						Projected Years		
	FY 2017	FY 2018	FY 2019 Annualized	Interim FY 2020	Interim Q1-Q3 2021	7/1/21-6/30/22	7/1/22-6/30/23	7/1/23-6/30/24
<b>NHPMC</b>								
Fixed	18,918	20,180	21,584	23,026	18,423	25,786	27,509	29,347
<b>NHHMC</b>								
Fixed	7,728	7,617	8,031	10,760	8,587	11,995	12,764	13,581
Mobile	526	1,252	1,985					
<b>Total</b>	<b>8,254</b>	<b>8,869</b>	<b>10,015</b>	<b>10,760</b>	<b>8,587</b>	<b>11,995</b>	<b>12,764</b>	<b>13,581</b>
<b>NHMMC</b>								
Fixed	8,604	8,564	8,126	9,049	6,883	9,871	10,374	10,902
Mobile	87	732	765					
<b>Total</b>	<b>8,691</b>	<b>9,296</b>	<b>8,891</b>	<b>9,049</b>	<b>6,883</b>	<b>9,878</b>	<b>10,374</b>	<b>10,902</b>
<b>NHMHMC</b>								
Fixed	-	-	3,343	3,514	2,769	3,833	4,028	4,233
<b>Freestanding Mobile</b>								
NHI University	3,864	1,738	1,445	1,879	1,832	2,50	2,154	2,264
NHI Steele Creek	1,133	949	2,144	2,253	1,776	2,458	2,583	2,715
<b>Freestanding Fixed</b>								
NHI Ballantyne	2,691	3,743	3,698	4,067	3,539	5,274	6,117	7,096
NHI South Park	4,035	4,667	4,880	5,367	4,427	6,341	6,975	7,673

Source: Section C, page 44

\*Adjusted Total Scans = Total MRI Scans x Weighted Ratio

*Step 7: Determine the Projected Adjusted Total Scans per Unit*

To determine the projected adjusted total scans per unit, the applicant divided the adjusted total scans determined in Step 6, by the number of units projected in Step 1. For NHMMC, the applicant projected a total of 5,451 scans by Year 3 of the project, as illustrated below.

Adjusted Total MRI Scans Per Unit								
	FY 2017	FY 2018	FY 2019 Annualized	Interim FY 2020	Interim Q1-Q3 2021	Projected Years		
						7/1/21-6/30/22	7/1/22-6/30/23	7/1/23-6/30/24
<b>NHPMC</b>								
Fixed	4,730	5,045	5,374	4,848	4,913	5,157	5,502	5,869
<b>NHHMC</b>								
Fixed	7,728	7,617	8,031	5,380	5,725	5,998	6,382	6,791
Mobile	5,260	5,443	4,274	0	0	0	0	0
<b>Total</b>	<b>7,504</b>	<b>7,211</b>	<b>6,840</b>	<b>5,380</b>	<b>5,725</b>	<b>5,998</b>	<b>6,382</b>	<b>6,791</b>
<b>NHMMC</b>								
Fixed	8,604	8,564	8,126	9,049	9,177	4,935	5,187	5,451
Mobile	4,350	5,631	4,283	0	0	0	0	0
<b>Total</b>	<b>8,521</b>	<b>8,227</b>	<b>7,544</b>	<b>9,049</b>	<b>9,177</b>	<b>4,935</b>	<b>5,187</b>	<b>5,451</b>
<b>NHMHMC</b>								
Fixed	0	0	4,045	4,251	5,957	4,637	4,874	5,122
<b>Freestanding Mobile</b>								
NHI University	5,367	3,279	2,024	2,631	3,420	2,870	3,016	3,170
NHI Steele Creek	5,395	4,995	5,003	5,258	5,526	5,736	6,028	6,335
<b>Freestanding Fixed</b>								
NHI Ballantyne	2,691	3,743	3,698	4,067	4,718	5,274	6,117	7,096
NHI South Park	4,035	4,667	4,880	5,367	5,902	6,341	6,975	7,673

Source: Section C, page 44

In Section C, page 53, the applicant states that NHI University and NHI Steele Creek are grandfathered mobile units and therefore exempt from meeting the performance standards for MRI units. The Project Analyst notes that there is no language in the performance standards that indicates the exemption of grandfathered MRI units from the performance standards. Based on the tables above, the mobile units at NHI University and NHI Steele Creek do not have the historical or projected MRI utilization required to meet the performance standards in this review. However, due to the discontinuance of MRI services at these sites as previously discussed in these findings, the performance standard for mobile MRI services are not applicable to the review of this application.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates that its existing fixed MRI scanners in Mecklenburg County performed an average of 3,328 weighted MRI procedures in the most recent 12-month period for which it had data, as required in 10A NCAC 14C .2703(b)(1).
- The applicant adequately demonstrates that NHMMC's existing, approved, and proposed fixed MRI scanners are reasonably expected to perform more than 4,805

weighted MRI procedures in Mecklenburg County in the third year of operation following the completion of the proposed project, as required in 10A NCAC 14C .2703(b)(3).

- Projected population growth in Mecklenburg County.
- Historical growth in MRI volumes at Novant Health facilities in Mecklenburg County.

### Access

In Section C, page 50, the applicant states:

*“NHMMC and all Novant Health facilities in North Carolina continue to comply with the community service obligation, and there is no denial, restriction, or limitation of access to minorities or handicapped persons. NHMMC does not discriminate against any class of patient based on age sex, religion, race, handicap, ethnicity, or ability to pay. NHMMC actively participates in both the Medicaid and Medicare.”*

In Section L, page 83, 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>Novant Health Matthews Medical Center Projected Payor Mix Third FY 7/1/2023-6/30/24</b>		
<b>Payor Source</b>	<b>Entire Facility</b>	<b>MRI Services as Percent of Total</b>
Self-Pay/Charity Care	8.4%	3.7%
Medicare*	36.9%	42.8%
Medicaid*	9.8%	4.9%
Insurance*	42.7%	46.0%
Other (specify)**	2.3%	2.6%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

\*Including any managed care plans

\*\*Includes Behavioral Health, Institutional Accounts, Other Government, Workers Comp.

The projected payor mix is reasonable and adequately supported.

### 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 the following reasons:

- The applicant adequately identifies the population to be served.

- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

CPN proposes to acquire one fixed MRI scanner with cardiac capabilities to be located at Atrium Health Kenilworth Diagnostic Center #1, a previously approved but not yet operational diagnostic center.

In Section A, page 6, the applicant states that Carolinas Health Network, Inc. (CHN) is the sole member of CPN and that The Charlotte-Mecklenburg Hospital Authority (CMHA) is the sole member of CHN.

#### **Patient Origin**

On page 149, the 2019 SMFP defines the service area for a fixed MRI scanner as “*a single county, except where there is no licensed acute care hospital located within the county.*” The definition of the service area for a fixed MRI scanner then explains how a service area is determined when there is no licensed acute care hospital located within the county. For the purpose of this review, however, Mecklenburg County is the service area since it has multiple licensed acute care hospitals. Facilities may also serve residents of counties not included in their service area.

The applicant does not provide historical patient origin since the facility for the proposed project is not yet operational.

In Section C, page 30, the applicant states that Carolinas Medical Center and Carolina Medical Center- Mercy (CMC/CMC-Mercy) cardiac and non-cardiac MRI scans are expected to shift to the proposed location. Therefore, projected patient origin is based on CMC/CMC-Mercy’s CY 2018 historical patient origin for outpatient cardiac and non-cardiac MRI scans. The following table illustrates projected patient origin.

<b>Atrium Health Kenilworth Diagnostic Center #1 MRI Services Projected Patient Origin</b>						
<b>County</b>	<b>1<sup>st</sup> Full FY</b>		<b>2<sup>nd</sup> Full FY</b>		<b>3<sup>rd</sup> Full FY</b>	
	<b>1/1/2021-12/31/2021</b>		<b>1/1/2022-12/31/2022</b>		<b>1/1/2023-12/31/2023</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Mecklenburg	1,986	55.0%	2,091	55.0%	2,206	55.0%
Gaston	253	7.0%	267	7.0%	281	7.0%
York, SC	243	6.7%	256	6.7%	270	6.7%
Union	234	6.5%	246	6.5%	259	6.5%
Cabarrus	124	3.4%	130	3.4%	138	3.4%
Cleveland	98	2.7%	103	2.7%	109	2.7%
Lancaster, SC	77	2.1%	81	2.1%	85	2.1%
Lincoln	62	1.7%	66	1.7%	69	1.7%
Iredell	62	1.7%	65	1.7%	69	1.7%
Catawba	44	1.2%	46	1.2%	49	1.2%
Stanly	34	1.0%	36	1.0%	38	1.0%
Rowan	28	0.8%	29	0.8%	31	0.8%
Burke	22	0.6%	23	0.6%	25	0.6%
Rutherford	22	0.6%	23	0.6%	24	0.6%
Anson	19	0.5%	20	0.5%	21	0.5%
Other*	303	8.4%	319	8.4%	337	8.4%
<b>Total</b>	<b>3,612</b>	<b>100.0%</b>	<b>3,804</b>	<b>100.0%</b>	<b>4,011</b>	<b>100.0%</b>

Source: Section C, page 29

\*Includes: Alamance, Alexander, Ashe, Avery, Beaufort, Bladen, Brunswick, Buncombe, Caldwell, Carteret, Cherokee, Chowan, Chowan, Columbus Cumberland, Davidson, Davie, Duplin, Durham, Forsyth, Guilford, Harnett, Haywood, Henderson, Jackson, Macon, Madison, McDowell, Mitchell, Montgomery, Moore, New Hanover, Onslow, Orange, Pitt, Polk, Randolph, Richmond, Robeson, Scotland, Surry, Swain, Transylvania, Wake, Watauga, Wilkes, Yadkin, and Yancey County in North Carolina, as well as other states. None of the counties or states included in the Other category constitutes more than one percent of total projected patient origin.

In Section C, page 30, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C, pages 30-41, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services as summarized below:

- 2019 SMFP’s need determination for one additional fixed MRI scanner in Mecklenburg County. [pages 30-32]
- The applicant states that Atrium Health and Carolina’s Imaging Services, LLC (CIS) facilities have been operating above the Mecklenburg County MRI planning threshold which warrants the need for an additional MRI scanner in Mecklenburg County. [pages 32-34]

- The applicant states that CMC/CMC-Mercy's historical growth in utilization is leading in the number of adjusted scans performed among providers in Mecklenburg County, which the applicant states warrants the need for additional MRI capacity at Atrium Health Kenilworth Diagnostic Center #1 [pages 36-39]. In comments submitted during the public comment period, it was stated that the applicant failed to present actual MRI utilization trends for Atrium Health's Mecklenburg County MRI units. The comments state that the applicant projects volumes based on adjusted scans, which is inconsistent with the declining unweighted MRI volume occurring across Atrium Health's Mecklenburg County MRI units. While the applicant does not use the term "unweighted" explicitly in its application, the applicant does state in one of the steps in its assumptions the weight factor that was used to arrive at its total adjusted MRI scans. For clarity purposes throughout this criterion, the Project Analyst has identified which tables of the applicant's use weighted and unweighted scans. The applicant adequately demonstrates the overall growth in historical MRI utilization at the facilities from which patients will be referred for MRI scans to the proposed facility. The Project Analyst also notes that the performance standard for MRI scans are based on weighted MRI procedures.
- Historical growth in MRI scans performed with cardiac capability [pages 39-40]. In comments submitted to the Agency during the public comment period, it is stated that the applicant's basis for the proposed scanner is the fact that they will provide a service with cardiac capability, however, their projections are heavily based on non-cardiac utilization. The applicant discusses within its application that the proposed scanner will be co-located on a campus with other CPN physicians that are responsible for both cardiac and non-cardiac scans. The applicant also adequately demonstrated a growth in cardiac MRI scans referred by CPN as demonstrated in Table #1 below. The applicant's projected MRI utilization is based on a combination of cardiac and non-cardiac MRI scans.
- The significant growth in 65+ population in the service area. The applicant used data from the North Carolina Office of State Budget and Management (NCOSBM) to illustrate the projected growth in the percentage of 65+ population in the service area from 2019-2023. [page 41]

The information is reasonable and adequately supported for the following reasons:

- 2019 SMFP need determination for one additional fixed MRI Scanner in Mecklenburg County;
- Population growth in Mecklenburg County, particularly for those 65+; and
- Growth in the historical utilization of adjusted MRI scans per unit in Mecklenburg County for Atrium Health and its affiliates.

#### *Projected Utilization*

In Section Q, Form C, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The project years are calendar years 2021, 2022, and 2023
- Projections are based on patients historically referred to and served by CMC/CMC-Mercy.
- The applicant presents the historical referrals of outpatient cardiac MRI scans at CMC. CMC-Mercy historically has not performed cardiac MRI procedures; therefore, they are not included in the table below. Between CY 2016 and CY 2019, the number of scans increased annually by 31.8%, as illustrated below:

**Table #1-Historical Unweighted**

<b>CMC outpatient Cardiac MRI Scans Referred by CPN</b>					
	<b>CY16</b>	<b>CY17</b>	<b>CY18</b>	<b>CY19*</b>	<b>CAGR</b>
Outpatient No Contrast	141	203	209	217	15.4%
Outpatient with Contrast	384	592	777	986	36.9%
<b>Total</b>	<b>525</b>	<b>795</b>	<b>986</b>	<b>1,203</b>	<b>31.8%</b>

Source: Section Q, Form C, page 1

\*CY 2019 annualized based on January to June data

- The applicant projects the number of outpatient cardiac MRI scans that will be referred by CPN using a conservative CAGR equal to a quarter of the CAGR for CY16-CY19 (31.8 percent / 4 = 8.0 percent), as illustrated below.

**Table#2-Projected Unweighted**

<b>Projected CMC Outpatient Cardiac MRI Scans Referred by CPN</b>						
	<b>CY19*</b>	<b>CY20</b>	<b>CY21</b>	<b>CY22</b>	<b>CY23</b>	<b>CAGR</b>
Outpatient No Contrast	217	234	253	273	294	8.0%
Outpatient with Contrast	986	1,065	1,150	1,241	1,340	8.0%
<b>Total</b>	<b>1,203</b>	<b>1,299</b>	<b>1,402</b>	<b>1,514</b>	<b>1,634</b>	<b>8.0%</b>

Source: Section Q, Form C, page 2

\*CY 2019 annualized based on January to June data

- The applicant assumes that 90% of the projected outpatient cardiac MRI scans will shift to the proposed MRI scanner at Atrium Health Kenilworth based on the following:
  - The scanner will be located near CPN cardiologists who are responsible for cardiac MRI referrals.
  - The proposed MRI scanner will be the only freestanding MRI scanner with cardiac capabilities in the service area.
- The applicant presents the historical referrals of outpatient non-cardiac MRI scans at CMC and CMC-Mercy. The data below includes scans performed at CMC's Morehead Medical

Plaza and not those performed at CMC’s radiology department at the main hospital. Scans performed at the medical plaza were assumed to be the most appropriate to be shifted to a freestanding facility. Between CY 2016 and CY 2019, the number of scans increased by a CAGR of 6.5%, as illustrated below:

**Table #3-Historical Unweighted**

<b>CMC/CMC-Mercy outpatient Non-Cardiac MRI Scans Referred by CPN</b>					
	<b>CY16</b>	<b>CY17</b>	<b>CY18</b>	<b>CY19*</b>	<b>CAGR</b>
<b>CMC</b>					
Outpatient No Contrast	1,009	1,033	1,061	1,277	8.2%
Outpatient with Contrast	2,556	2,750	2,628	2,804	3.1%
<b>CMC Subtotal</b>	<b>3,565</b>	<b>3,783</b>	<b>3,689</b>	<b>4,081</b>	<b>4.6%</b>
<b>CMC-Mercy</b>					
Outpatient No Contrast	1,072	1,365	1,660	1,851	20.0%
Outpatient with Contrast	848	634	613	694	-6.5%
<b>CMC-Mercy Subtotal</b>	<b>1,920</b>	<b>1,999</b>	<b>2,273</b>	<b>2,545</b>	<b>9.8%</b>
<b>CMC/ CMC-Mercy Total</b>	<b>5,485</b>	<b>5,782</b>	<b>5,962</b>	<b>6,626</b>	<b>6.5%</b>

Source: Section Q, Form C, page 3

\*CY 2019 annualized based on January to June data

Note: Despite any declines that are shown in historical MRI utilization over a specified time period, the applicant adequately demonstrates increases in overall MRI scans that supports the assumptions used for projected utilization.

- The applicant projects the number of outpatient non-cardiac MRI scans referred by CPN using a CAGR equal to a half of the CAGR for CY16-CY19. This is based on the historical growth of non-cardiac MRI scans and the growing demand for MRI services at Atrium Health, CIS and the region surrounding Mecklenburg County.

**Table #4-Projected Unweighted**

<b>Projected CMC/CMC-Mercy outpatient Non-Cardiac MRI Scans Referred by CPN</b>						
	<b>CY19*</b>	<b>CY20</b>	<b>CY21</b>	<b>CY22</b>	<b>CY23</b>	<b>CAGR</b>
<b>CMC</b>						
Outpatient No Contrast	1,277	1,329	1,383	1,440	1,499	4.1%
Outpatient with Contrast	2,804	2,847	2,892	2,937	2,983	1.6%
<b>CMC Subtotal</b>	<b>4,081</b>	<b>4,177</b>	<b>4,275</b>	<b>4,377</b>	<b>4,482</b>	
<b>CMC-Mercy</b>						
Outpatient No Contrast	1,851	2,036	2,239	2,463	2,709	10.0%
Outpatient with Contrast	694	649	607	568	531	-6.5%
<b>CMC-Mercy Subtotal</b>	<b>2,545</b>	<b>2,685</b>	<b>2,846</b>	<b>3,031</b>	<b>3,240</b>	
<b>CMC/ CMC-Mercy Total</b>	<b>6,626</b>	<b>6,862</b>	<b>7,122</b>	<b>7,408</b>	<b>7,722</b>	

Source: Section Q, Form C, page 4

\*CY 2019 annualized based on January to June data

- The applicant assumes that 35% of the projected CMC MRI scans and 30% of the projected CMC-Mercy MRI scans will shift to the proposed MRI scanner at Atrium Health Kenilworth based on the close proximity to CPN physicians that are responsible for non-cardiac referrals. The applicant projects that 2,541 non-cardiac MRI scans will shift to the proposed MRI scanner by Year 3 of the proposed project.

**Table #5-Projected Unweighted**

<b>Projected Outpatient Non-Cardiac MRI Scans to Shift to Proposed Scanner</b>			
	<b>CY21</b>	<b>CY22</b>	<b>CY23</b>
<b>CMC</b>			
Outpatient No Contrast	1,383	1,440	1,499
Outpatient with Contrast	2,892	2,937	2,983
<b>Assumed Shift</b>	<b>35%</b>	<b>35%</b>	<b>35%</b>
Outpatient No Contrast to shift	484	504	525
Outpatient with Contrast to shift	1,012	1,028	1,044
<b>CMC-Mercy</b>			
Outpatient No Contrast	2,239	2,463	2,709
Outpatient with Contrast	607	568	531
<b>Assumed Shift</b>	<b>30%</b>	<b>30%</b>	<b>30%</b>
Outpatient No Contrast to shift	672	739	813
Outpatient with Contrast to shift	182	170	159
<b>Total</b>			
<b>Total Outpatient no Contrast Scans to Shift</b>	<b>1,156</b>	<b>1,243</b>	<b>1,337</b>
<b>Total Outpatient with Contrast Scans to Shift</b>	<b>1,194</b>	<b>1,198</b>	<b>1,203</b>
<b>Total Non-Cardiac Scans to Shift</b>	<b>2,350</b>	<b>2,441</b>	<b>2,541</b>

Source: Section, Form C, page 5

Based on the assumptions and methodology summarized above, the applicant provides the projected utilization of the proposed MRI scanner based on the adjustment of 1.0 weight for outpatient no contrast and 1.4 weight for outpatient with contrast.

<b>Atrium Health Kenilworth Diagnostic Center #1 Projected MRI utilization</b>			
	<b>CY2021</b>	<b>CY2022</b>	<b>CY2023</b>
<b>Cardiac MRI</b>			
Outpatient No Contrast to shift	227	245	265
Outpatient with Contrast to shift	1,035	1,117	1,206
<b>Total Cardiac MRI Scans to Shift</b>	<b>1,262</b>	<b>1,362</b>	<b>1,471</b>
<b>Non-Cardiac MRI</b>			
Outpatient No Contrast to shift	1,156	1,243	1,337
Outpatient with Contrast to shift	1,194	1,198	1,203
<b>Total Non-Cardiac MRI Scans to Shift</b>	<b>2,350</b>	<b>2,441</b>	<b>2,541</b>
<b>Proposed MRI Scanner Total</b>			
Outpatient No Contrast	1,383	1,488	1,602
Outpatient with Contrast	2,229	2,315	2,409
<b>Total MRI Scans</b>	<b>3,612</b>	<b>3,804</b>	<b>4,011</b>
<b>Adjusted Base No Contrast</b>	<b>1,383</b>	<b>1,488</b>	<b>1,602</b>
<b>Adjusted Base Contrast</b>	<b>3,121</b>	<b>3,241</b>	<b>3,373</b>
<b>Weight Adjustment</b>	<b>892</b>	<b>926</b>	<b>964</b>
<b>Total Adjusted MRI Scans*</b>	<b>4,504</b>	<b>4,730</b>	<b>4,975</b>

Source: Section Q, Form C, page 6

\*Adjusted scans based on 1.0 weight for outpatient no contrast and 1.4 weight for outpatient with contrast

Projected utilization is reasonable and adequately supported for the following reasons:

- Projections are based on historical growth in MRI utilization and the expected shift of patients from CMC/CMC-Mercy.
- The applicant uses a conservative growth rate to project future cardiac and non-cardiac MRI scans at the proposed facility that is lower than the historical growth rate.

**Access**

In Section C, pages 46-47, the applicant states:

*“Consistent with all CMHA facilities, CPN provides services to all persons in need of medical care, regardless of race, color, religion, nation origin, sex, age, disability, or source of payment.”*

In Section L, page 85, 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.

Atrium Health Kenilworth Diagnostic Center #1 Projected Payor Mix Third FY 01/01/2023-12/31/2023		
Payor Source	Facility	MRI Services
Self-Pay	4.5%	6.8%
Medicare *	43.8%	29.%
Medicaid *	7.6%	15.2%
Insurance *	43.1%	46.7%
Other (Specify)	1.0%	2.1%
Total	100.0%	100.0%

\* Includes any managed care plans  
 Source: Section L, page 85

The projected payor mix is reasonable and adequately supported.

**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 the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

#### NA-Both Applications

None of the applicants propose to reduce or eliminate or relocate a facility or service. Therefore, Criterion (3a) is not applicable to any applications in this review.

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

#### C – Both Applications

### **Project ID# F-11755-19/ NHMMC/Acquire a Second Fixed MRI Scanner**

Presbyterian Medical Care Corp. proposes to acquire a second fixed MRI scanner to be installed in the Radiology Department of NHMMC in renovated space. NHMMC currently operates one fixed MRI scanner in their existing Radiology Department at NHMMC.

In Section E, pages 61-62, 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 that maintaining the status quo would not be a viable solution due to the existing fixed MRI scanner at NHMMC reaching its peak capacity. The applicant states that it has reached its capacity due to referrals from ED patients and other referring physicians.

Add Additional Mobile MRI Days: The applicant states that adding mobile MRI days is not a feasible or sustainable alternative because of the current mobile MRI units are already operating at 124.8 percent of its capacity. In addition, the applicant has an approved exemption to convert one of the mobile units to a fixed unit which will further limit the mobile MRI resource.

Seek the State's Approval of NHMMC for a new Fixed MRI Unit: The applicant states that this is the most effective alternative because the current MRI unit at NHMMC is operating at full capacity. The new unit will allow patients to have timely access to MRI services in their service area, improve operational efficiencies, and decrease employee burnout. The applicant states this alternative is also the most effective because the unit will be located in the existing emergency department.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

## **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 the reasons stated above.

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

CPN proposes to acquire one fixed MRI scanner with cardiac capabilities to be located at Atrium Health Kenilworth Diagnostic Center #1, a previously approved but not yet operational diagnostic center.

In Section E, pages 61-62, 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 Status Quo-The applicant states that maintaining the status quo would not be an effective alternative because of the possible issues that may arise in accommodating future growth due to increasing demand of cardiac MRIs and the projected growth and aging of the population.

Develop MRI at Another Location-The applicant states that developing MRI at another location would not be an effective alternative due to need at the proposed location and the high volume of referrals from the other practices in close proximity.

Develop a Hospital-Based MRI-The applicant states that this would not be an effective alternative because a freestanding setting can serve patients in a more efficient manner as opposed to a hospital-based setting. The applicant states that is not a cost-effective alternative due to the cost in developing additional hospital-based capacity as compared to a freestanding setting.

Develop the Project as Proposed-The applicant states the proposed project is the most effective alternative because it will provide patients with convenient, high-quality, and cost-effective care. The additional MRI will shift patients from the highly utilized MRI scanners at CMC/CMC-Mercy.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

**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 the reasons stated above.

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

C – Both Applications

**Project ID# F-11755-19/ NHMMC/Acquire a Second Fixed MRI Scanner**

Presbyterian Medical Care Corp. proposes to acquire a second fixed MRI scanner to be installed in the Radiology Department of NHMMC in renovated space. NHMMC currently operates one fixed MRI scanner in their existing Radiology Department at NHMMC.

**Capital and Working Capital Costs**

In Section Q, page 104, the applicant projects the total capital cost of the project as shown in the table below.

Construction/Renovation (s)	\$1,623,777
Architect/Engineering Fees	\$165,625
Medical Equipment	\$1,687,539
Furniture	\$13,860
Consultant Fees	\$70,000
Information Technology	\$16,008
Low Voltage	\$8,000
Security	\$5,939
DHSR Review Costs	\$2,072
Special Inspections	\$120,000
Project Contingency	\$352,075
<b>Total</b>	<b>\$4,064,895</b>

In Section Q, page 105, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 65, the applicant projects there will be no start-up or initial operating expenses for the project because it currently staffs and operates the facility's existing MRI service.

**Availability of Funds**

In Section F, page 63, the applicant states that the capital cost will be funded as shown in the table below.

**Sources of Capital Cost Financing**

Type	Presbyterian Medical Care Corp d/b/a Novant Health Matthews Medical Center	Total
Loans	\$4,065,895	\$4,06 ,895
Accumulated reserves or OE *	\$0	\$0
Bonds	\$	\$
Other (Specify)	\$	\$
<b>Total Financing</b>	<b>\$4,065,895</b>	<b>\$4,065,895</b>

\* OE = Owner's Equity

Exhibit F-2.1 contains a letter from the Vice President of Operational Finance and Revenue Cycle for Novant Health, Inc., the parent company of Presbyterian Medical Corp d/b/a Novant Health Matthews Medical Center, dated July 29, 2019, committing to funding the capital cost of the proposed project. Exhibit F-2.2 contains financial statement for Novant Health, Inc. and affiliates for the years ending December 31, 2018 and 2017. As of December 31, 2018, Novant Health, Inc. had \$228,653,000 in cash and cash equivalents and \$4,038,900,000 in net assets to fund the proposed project.

**Financial Feasibility**

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

Novant Health Matthews Medical Center	1st Full FY 7/1/2021- 6/30/2022	2nd Full FY 7/1/2022- 6/30/2023	3rd Full FY 7/1/2023- 6/30/2024
Total MRI Procedures	8,081	8,493	8,926
Total Gross Revenues (Charges)	\$29,389,999	\$31,505,246	\$33,772,732
Total Net Revenue	\$6,697,981	\$6,864,993	\$7,021,351
Average Net Revenue per Procedure	\$828.85	\$808.31	\$786.61
Total Operating Expenses (Costs)	\$2,028,142	\$2,074,483	\$2,122,624
Average Operating Expense per Procedure	\$250.97	\$244.25	\$237.80
<b>Net Income</b>	<b>\$4,669,839</b>	<b>\$4,790,510</b>	<b>\$4,898,727</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application

for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) 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 for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- 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 costs and charges.

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

CPN proposes to acquire one fixed MRI scanner with cardiac capabilities to be located at Atrium Health Kenilworth Diagnostic Center #1, a previously approved but not yet operational diagnostic center.

### **Capital and Working Capital Costs**

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

Construction/Renovation Contract (s)	\$402,405
Architect/Engineering Fees	\$24,500
Medical Equipment	\$2,939,864
Non-Medical Equipment	\$144,058
Furniture	\$5,000
Consultant Fees	\$100,000
Other	\$204,900
<b>Total</b>	<b>\$3,820,727</b>

In Section Q, Form F, the applicant provides the assumptions used to project the capital cost. In Section F, page 66, the applicant projects that start-up costs will be \$121,115 and initial operating expenses will be \$181,672 for a total working capital of \$302,787. On page 66, the

applicant provides the assumptions and methodology used to project the working capital needs of the project.

**Availability of Funds**

In Section F, page 64, the applicant states that the capital cost will be funded as shown in the table below.

Type	Carolina Physicians Network, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$3,820,727	\$3,820,727
Bonds	\$0	\$0
Other (Specify)	\$ 0	\$0
<b>Total Financing</b>	<b>\$3,820,727</b>	<b>\$3,820,727</b>

\* OE = Owner's Equity

In Section F, page 67, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owne Equity	\$302,787
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	<b>Total *</b>	<b>\$302,787</b>

Exhibit F-2.1 contains a letter from the Executive Vice President and Chief Financial Officer of CPN, dated August 15, 2019, stating that CPN will commit the funds (capital and working capital) provided by CMHA to develop the proposed project. Exhibit F-2.2 contains financial statement for CMHA for the years ending December 31, 2018 and 2017. As of December 31, 2018, CMHA had \$82,900,000 in cash and cash equivalents and \$5,084,130,000 in net assets to fund the proposed project.

**Financial Feasibility**

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

<b>Atrium Health Kenilworth Diagnostic Center #1 with MRI</b>	<b>1st Full FY 1/1/2021- 12/31/2021</b>	<b>2nd Full FY 1/1/2022- 12/31/2022</b>	<b>3rd Full FY 1/1/2023- 12/31/2023</b>
Total MRI Procedures	4,504	4,730	4,975
Total Gross Revenues (Charges)	\$7,010,161	\$7,623,342	\$8,302,392
Total Net Revenue	\$1,507,788	\$1,639,675	\$1,785,730
Average Net Revenue per Procedure	\$334.76	\$346.65	\$358.94
Total Operating Expenses (Costs)	\$1,239,286	\$1,409,568	\$1,456,984
Average Operating Expense per Procedure	\$275.15	\$298.00	\$292.86
<b>Net Income</b>	<b>\$268, 503</b>	<b>\$230,107</b>	<b>\$328,746</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) 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 for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
  - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
  - 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 costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

**C – Both Applications**

On page 149, the 2019 SMFP defines the service area for a fixed MRI scanner as “*a single county, except where there is no licensed acute care hospital located within the county.*” The definition of the service area for a fixed MRI scanner then explains how a service area is determined when there is no licensed acute care hospital located within the county. For the purpose of this review, however, Mecklenburg County is the service area since it has multiple licensed acute care hospitals. Facilities may also serve residents of counties not included in their service area.

The following table provides the number of fixed MRI scanners, total weighted MRI procedures, and average weighted MRI procedures per MRI scanner for each of the fixed MRI scanners, summarized from Table 9P of 2019 SMFP.

<b>Fixed MRI Scanners in Mecklenburg County</b>			
<b>Provider</b>	<b># of Fixed MRI Scanners</b>	<b>Total MRI Scans</b>	<b>Adjusted Total</b>
Carolinas Healthcare System Pineville	2	8,321	10,162
Carolinas Healthcare System University	1	5,624	6,852
Carolina Medical Center-Main	5	18,789	25,597
Carolina Medical Center-Mercy	1	5,268	6,558
Novant Health Huntersville Medical Center**	2	6,530	7,728
Novant Health Matthews Medical Center	2	7,102	8,691
Novant Health Presbyterian Medical Center-Charlotte Orthopedic Hospital	1	2,931	3,311
Novant Health Presbyterian Medical Center-Main*	2	9,452	12,542
Novant Health Presbyterian Medical Center-Novant Health Imaging Museum	1	2,663	3,065
Carolinas Imaging Services-Ballantyne	1	4,068	4,540
Carolinas Imaging Services-Southpark	1	3,729	4,395
Carolina NeuroSurgery & Spine Associates Charlotte	1	4,304	4,603
OrthoCarolina Ballantyne	1	7,770	7,892
OrthoCarolina Spine Center	1	6,998	7,640
Novant Health Imaging Ballantyne	1	2,395	2,691
Novant Health Imaging Southpark	1	3,733	4,035
<b>Totals</b>			

Source: 2019 SMFP

\* Pursuant to Exemption Record #2983 approved on August 17, 2019, a grandfathered mobile MRI will be replaced with a grandfathered fixed MRI at NHPMC resulting in a total of five MRIs on that campus.

\*\*Due to a settlement agreement reached for Project ID# F-11184-16 (acquire a 2<sup>nd</sup> fixed MRI scanner), a CON was issued for Project ID# F-008237-08 (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 2<sup>nd</sup> unit became operational August 2019. A CON was not issued for Project ID# F-11184-16.

Note: Pursuant to a Declaratory Ruling issued on August 14, 2015, the 2<sup>nd</sup> MRI scanner approved for NHMMC for Project ID# F-008688-11 (acquire a 2<sup>nd</sup> fixed MRI scanner) will be placed at NHMMC.

### **Project ID# F-11755-19/ NHMMC/Acquire a Second Fixed MRI Scanner**

Presbyterian Medical Care Corp. proposes to acquire a second fixed MRI scanner to be installed in the Radiology Department of NHMMC in renovated space. NHMMC currently operates one fixed MRI scanner in their existing Radiology Department at NHMMC.

In Section G, page 70, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Mecklenburg County. The applicant states:

*“As previously established, the existing fixed MRI units in Mecklenburg are highly utilized, and the SMFP clearly acknowledges that there is a need for fixed MRI services. NHMMC’s fixed unit is currently running at well over optimal capacity.*

...  
*The ability to improve accessibility for patients served by NHMMC will not result in an unnecessary duplication of MRI services in the service area.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2019 SMFP for the proposed fixed MRI scanner.
- The applicant adequately demonstrates that the proposed fixed MRI is needed in addition to the existing or approved fixed MRI scanners in Mecklenburg County.

### **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 conforming to this criterion for the reasons stated above.

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

CPN proposes to acquire one fixed MRI scanner with cardiac capabilities to be located at Atrium Health Kenilworth Diagnostic Center #1, a previously approved but not yet operational diagnostic center.

In Section G, pages 71-72, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Mecklenburg County. The applicant states:

*“As discussed in Section C.4, Atrium Health/CIS scanners historically performed the highest volume of adjusted MRI scans in the county and the highest number in excess of the planning threshold indicating the greatest need for additional capacity. Additionally, Atrium/CIS scanners provide the broadest geographical access to patients seeking MRI scans in Mecklenburg County and have the highest complexity mix among all providers”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2019 SMFP for the proposed fixed MRI scanner.
- The applicant adequately demonstrates that the proposed fixed MRI is needed in addition to the existing or approved fixed MRI scanners in Mecklenburg County.

**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 conforming to this criterion for the reasons stated 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 – Both Applications

**Project ID# F-11755-19/NHMMC/Acquire a Second Fixed MRI Scanner**

In Section Q, page 107, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 6/30/2019	2nd Full Fiscal Year (71/2022-6/30/23)
Radiology Technologists (MRI)	6.00	12.00
MRI Manager	0.50	0.50
MRI Director	0.10	0.10
MRI Scheduler	0.75	1.00
<b>TOTAL</b>	<b>7.35</b>	<b>13.60</b>

The assumptions and methodology used to project staffing are provided in Section Q, page 108. 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.2 and H.3, page 71 and 72, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 75, the applicant identifies the current medical director. In Exhibit I-3.2, the applicant provides a letter

from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibit I-3.2, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide 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 for the reasons stated above.

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

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

Position	Projected FTE Staff
	2nd Full Fiscal Year 1/1/2022-12/31/2022
MRI Techs	4.0
<b>TOTAL</b>	<b>4.0</b>

The assumptions and methodology used to project staffing are provided in Section Q, Form H. 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.2, page 73, the applicant describes the methods used to recruit or fill new positions. Exhibit H.3 describes its existing training and continuing education programs. In Exhibit I.2-2, the applicant provides letters from physicians indicating their support for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide 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 for the reasons stated 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 – Both Applications

**Project ID# F-11755-19/ NHMMC/Acquire a Second Fixed MRI Scanner**

In Section I.1, page 73, the applicant states that the following ancillary and support services are necessary for the proposed services. The applicant provides a list of necessary ancillary and support services it will continue to have for its MRI services, including the proposed fixed MRI scanner. On pages 73-74, the applicant adequately explains how each ancillary and support services is available.

In Section I, page 74, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

**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.

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

In Section I.1, page 75, states that the MRI scanner is an ancillary service that will provide support to the CPN physicians practice located at Atrium Health Kenilworth.

In Section I.2, page 75, the applicant describes its existing relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2-1 and I-2-2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

## **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

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

### NA-Both applications

Neither applicant projects 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 applicants do 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-Both Applications

Neither applicant is 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- Both Applications

#### **Project ID# F-11755-19/ NHMMC/Acquire a Second Fixed MRI Scanner**

In Section K, page 78, the applicant states that the project involves renovating 2,287 square feet of existing space. Line drawings are provided in Exhibit K-2.

On page 78, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit K-3.1.

On page 78, 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 and provides supporting documentation in Exhibit K-3.1.

On page 79, 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.

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

In Section K, page 78, the applicant states that the project involves renovating 897 square feet of existing space. Line drawings are provided in Exhibit C.1-4.

On page 78, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit C.1-4.

On page 79, 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 and provides supporting documentation in Exhibit F.2-2.

On pages 79-80, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

**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.

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

C-Presbyterian Medical Corp.  
NA-Carolinas Physicians Network, Inc.

**Project ID# F-11755-19/ NHMMC/Acquire a Second Fixed MRI Scanner**

In Section L, page 82, the applicant provides the historical payor mix for NHMMC during CY 2018 for the proposed services, as shown in the table below.

<b>Payor Source</b>	<b>MRI Services as Percent of Total</b>
Self-Pay/Charity Care	3.5%
Medicare*	42.0%
Medicaid*	4.9%
Insurance*	46.8%
Other (specify)**	2.8%
<b>Total</b>	<b>100.0%</b>

Source: NHMMC Internal Data, NHMMC LRA

\*Including any managed care plans

\*\*Includes Behavioral Health, Institutional Accounts, Other Government, Workers Comp.

In Section L, page 81, the applicant provides the following comparison for NHMMC:

NHMMC	% of Total Patients Served by Last FY (1/1/18-12/31/18)	Percentage of the Population of the Service Area
Female	61.7%	51.6%
Male	38.3%	48.4%
Unknown	0.0%	0.0%
64 and Younger	60.6%	88.5%
65 and Older	39.4%	11.5%
American Indian	0.3%	0.5%
Asian	1.7%	5.4%
Black or African-American	17.0%	28.2%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	74.7%	56.4%
Other Race	5.2%	9.4%
Declined / Unavailable	1.1%	0.0%

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.

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

Neither the applicant nor any related entities owns, operates or manages a diagnostic center located in the service area. Therefore, Criterion (13a) is not applicable to this review.

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

C-Presbyterian Medical Corp.  
 NA-Carolinas Physicians Network, Inc.

**Project ID# F-11755-19/ NHMMC/Acquire a Second Fixed MRI Scanner**

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 82, the applicant states:

*“Further, Novant Health Hospitals fulfilled their Hill-Burton obligations long ago. NHMMC and all Novant Health facilities in North Carolina continue to comply with the community service obligation, and there is no denial, restriction, or limitation of access to minorities or handicapped persons. Novant Health’s acute care hospitals maintain a commitment to provide care to all persons, regardless of their ability to pay.”*

In Section L, page 83, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

Neither the applicant nor any related entities owns, operates or manages an existing diagnostic center located in the service area. Therefore, Criterion (13b) is not applicable to this review.

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

C-Both Applications

**Project ID# F-11755-19/ NHMMC/Acquire a Second Fixed MRI Scanner**

In Section L, page 83, 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>NHMMC Projected Payor Mix Third FY 7/1/2023-6/30/24</b>		
<b>Payor Source</b>	<b>Entire Facility</b>	<b>MRI Services as Percent of Total</b>
Self-Pay/Charity Care	8.4%	3.7%
Medicare*	36.9%	42.8%
Medicaid*	9.8%	4.9%
Insurance*	42.7%	46.0%
Other (specify)**	2.3%	2.6%
<b>Total</b>	<b>100.0</b>	<b>100.0%</b>

\*Including any managed care plans

\*\*Includes Behavioral Health, Institutional Accounts, Other Government, Workers Comp.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.7% of total services will be provided to self-pay and charity care patients, 42.3% to Medicare patients and 4.9% to Medicaid patients.

On page 83, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the because it is based on historical payor mix for its existing MRI services and the applicant does not expect payor mix for the proposed MRI services to change.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

In Exhibit F.2, the applicant projects a payor mix inconsistent with the projections in the following table. The projections in Section L are based on percentage of total gross revenue, while the projections in Exhibit F.2. are based on percentage of total patients. In Section L, page 85, 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>Atrium Health Kenilworth Diagnostic Center #1                      Projected Payor Mix                      Third FY 01/01/2023-12/31/2023</b>		
<b>Payor Source</b>	<b>Atrium Health Kenilworth Diagnostic Center #1</b>	<b>MRI Services as Percent of Total</b>
Self-Pay	4.5%	6.8%
Medicare *	43.8%	29.2%
Medicaid *	7.6%	15.2%
Insurance *	43.1%	46.7%
Other (Specify)	1.0%	2.1%
Total	100.0%	100.0%

\* Includes any managed care plans  
 Source: Section L, page 85

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 6.8% of total services will be provided to self-pay patients, 29.2% to Medicare patients and 15.2% to Medicaid patients.

On pages 85-86, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- Based on the CY 2018 patient origin of outpatient cardiac and non-cardiac MRI scans at CMC/CMC-Mercy.
- Based on the outpatient cardiac and non-cardiac MRI scans that are expected to shift from CMC/CMC-Mercy to the proposed facility.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C-Both Applications

**Project ID# F-11755-19/ NHMMC/Acquire a Second Fixed MRI Scanner**

In Section L, page 87, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

In Section L, pages 86-87, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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- Both Applications

**Project ID# F-11755-19/ NHMMC/Acquire a Second Fixed MRI Scanner**

In Section M, page 87, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

In Section M, page 88, the applicant describes the extent to which area health professional training programs have access to the facility for training purposes.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant did not adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is not conforming to this criterion.

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

### C-Both Applications

On page 149, the 2019 SMFP defines the service area for a fixed MRI scanner as “*a single county, except where there is no licensed acute care hospital located within the county.*” The definition of the service area for a fixed MRI scanner then explains how a service area is determined when there is no licensed acute care hospital located within the county. For the purpose of this review, however, Mecklenburg County is the service area since it has multiple licensed acute care hospitals. Facilities may also serve residents of counties not included in their service area.

The following table provides the number of fixed MRI scanners, total weighted MRI procedures, and average weighted MRI procedures per MRI scanner for each of the fixed MRI scanners, summarized from Table 9P of the 2019 SMFP.

<b>Fixed MRI Scanners in Mecklenburg County</b>			
<b>Provider</b>	<b># of Fixed MRI Scanners</b>	<b>Total MRI Scans</b>	<b>Adjusted Total</b>
Carolinas Healthcare System	2	8,321	10,162
Carolinas Healthcare System University	1	5,624	6,852
Carolina Medical Center-Main	5	18,789	25,597
Carolina Medical Center-Mercy	1	5,268	6,558
Novant Health Huntersville Medical Center	2	6,530	7,728
Novant Health Matthews Medical Center	2	7,102	8,691
Novant Health Presbyterian Medical Center-Charlotte Orthopedic Hospital	1	2,931	3,311
Novant Health Presbyterian Medical Center-Main	2	9,452	12,542
Novant Health Presbyterian Medical Center-Novant Health Imaging Museum	1	2,663	3,065
Carolinas Imaging Services-Ballantyne	1	4,068	4,540
Carolinas Imaging Services-Southpark	1	3,729	4,395
Carolina NeuroSurgery & Spine Associates Charlotte	1	4,304	4,603
OrthoCarolina Ballantyne	1	7,770	7,892
OrthoCarolina Spine Center	1	6,998	7,640
Novant Health Imaging Ballantyne	1	2,395	2,691
Novant Health Imaging Southpark	1	3,733	4,035

Source: 2019 SMFP

\* Pursuant to Exemption Record #2983 approved on August 17, 2019, a grandfathered mobile MRI will be replaced with a grandfathered fixed MRI at NHPMC resulting in a total of five MRIs on that campus.

\*\*Due to a settlement agreement reached for Project ID# F-11184-16 (acquire a 2<sup>nd</sup> fixed MRI scanner), a CON was issued for Project ID# F-008237-08 (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 2nd unit became operational August 2019. A CON was not issued for Project ID# F-11184-16.

**Project ID# F-11755-19/ NHMMC/Acquire a Second Fixed MRI Scanner**

In Section N, page 88, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 88, the applicant states:

*“Currently, NHMMC has one fixed MRI scanner, which is highly utilized. This utilization is driven solely by the significant and growing demand for diagnostic imaging services. Other Novant Health-affiliated hospitals that offer fixed MRI services in Mecklenburg County, namely NHPMC, are also highly utilized and are currently in the process of obtaining fixed MRI scanners. A fixed MRI scanner at NHMMC is part of Novant Health’s long-term strategic approach to ensuring patient access to MRI service.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections B, F, K, N and Q of the application and any exhibits)
- Quality services will be provided (see Section B, N and O of the application and any exhibits)
- Access will be provided to underserved groups (see Section C, L and N of the application and any exhibits)

### **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 conforming to this criterion for the reasons stated above.

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

In Section N, pages 90-92, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On pages 90-92, the applicant states:

*“As discussed in Section C.4, the proposed project will increase access to low-cost, freestanding fixed MRI services in Mecklenburg County while shifting patients from CMC/CMC-Mercy, which will in turn decompress the highly utilized MRI scanners at those hospitals.”*

...

*CPN and Atrium Health are dedicated to providing the highest quality care and are continually recognized locally and nationally for their commitment to delivering efficient, quality care.*

...

*The propose project will improve access to fixed MRI services in the service area. CPN and its parent organization, Atrium Health, have long-promoted economic access to their services as Atrium Health historically has provided services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay as demonstrated in Atrium Health’s Non-Discrimination policies provided in Exhibit C.11-1.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections B, F, K, N and Q of the application and any exhibits)
- Quality services will be provided (see Section B, N and O of the application and any exhibits)
- Access will be provided to underserved groups (see Section C, L and N of the application and any exhibits)

### **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 conforming to this criterion for 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-Both Applications

#### **Project ID# F-11755-19/ NHMMC/Acquire a Second Fixed MRI Scanner**

In Section Q, page 100, the applicant identifies the hospital located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 12 of this type of facility located in North Carolina.

In Section O, page 97, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care has not occurred in any of these facilities. According to the files in the Acute Care and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, three facilities have pending decisions regarding compliance. At the time of this review, these decisions are still pending. After reviewing and considering information provided by the applicant and by the Acute Care and Home Care Licensure and Certification Section and considering the quality of care provided at all 12 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

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

On page 94, the applicant states,

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

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

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

**C-Both Applications**

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

The specific criteria for both applications are discussed below.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- (6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- (c) *An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*
- (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure per hour times 40 hours per week times 52 weeks per year; and*
  - (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- NA-** Neither of the applicants propose the acquisition of a dedicated fixed breast MRI scanner. Therefore, this Rule is not applicable to this review.
- (d) *An applicant proposing to acquire a fixed extremity MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*
- (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(f)(7); and*
  - (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- NA-** Neither of the applicants propose the acquisition of a dedicated fixed extremity MRI scanner. Therefore, this Rule is not applicable to this review.
- (e) *An applicant proposing to acquire a fixed multi-position MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for a demonstration project shall:*
- (1) *demonstrate annual utilization of the proposed multi-position MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(g)(7); and*
  - (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- NA-** Neither of the applicants propose the acquisition of a dedicated fixed multi-position MRI scanner. Therefore, this Rule is not applicable to this review.

### COMPARATIVE ANALYSIS

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

Therefore, after considering all of the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

- Project ID# F-11755-19/**Novant Health Matthews Medical Center**/Acquire a second fixed MRI scanner pursuant to the need determination in the 2019 SMFP
- Project ID# f-11760-19/**Atrium Health Kenilworth Diagnostic Center #1**/ Acquire one fixed MRI scanner pursuant to the need determination in the 2019 SMFP

### **Conformity with Statutory and Regulatory Review Criteria**

Both applications are conforming to all applicable statutory and regulatory review criteria. Therefore, regarding the comparative factor both applications are equally effective alternatives.

### **Scope of Services**

With regard to scope of services, applications submitted by **Presbyterian Medical Care Corp. and CPN** are both in response to the 2019 State Medical Facilities Plan (SMFP) includes a need determination for one fixed MRI scanner. Novant Health Matthews Medical Center (NHMMC) is an existing acute care hospital that provides primarily inpatient services. **CPN's** approved facility, Atrium Health Kenilworth Diagnostic Center #1, is an approved but not yet operational diagnostic facility that only provides outpatient services. An inpatient acute care hospital is able to provide a much broader scope of services than an outpatient diagnostic facility. Therefore, with regard to scope of services, **Presbyterian Medical Care Corp.** is the more effective alternative.

### **Historical Utilization**

The following table illustrates the total MRI scans and the adjusted total of MRI scans performed by Novant Health Inc. and its affiliates and CMHA and its affiliates for all fixed MRIs in Mecklenburg County as published in Table 17E-1 of the 2020 SMFP.

<b>Facility</b>	<b>Total Fixed MRI Scans</b>	<b>Adjusted Total Fixed MRI Scans</b>
Novant Health	36,978	44,771
CMHA	43,666	55,944

Source: 2020 SMFP

**Novant Health** performed 36,978 total MRI scans and 44,771 adjusted MRI scans in Mecklenburg County and **CMHA** performed 43,666 total MRI scans and 55,944 adjusted MRI scans in Mecklenburg County. Based on the table above, **CMHA** has a higher historical MRI utilization in Mecklenburg County. Therefore, with regard to this factor, **CPN** is the more effective alternative.

**Geographical Accessibility (Location within the Service Area)**

The service area for the MRI scanner is Mecklenburg County.

The following table provides the location of the existing fixed MRI scanners in Mecklenburg County, summarized from Table 9P of 2019 SMFP and publicly available information.

Facility	Location	# of Scanners Per Facility	Population Estimate as of July 1, 2018	Population per Scanner
Atrium Health Pineville	Charlotte	2		
Atrium Health University	Charlotte	1		
CMC/CMC-Mercy	Charlotte	5		
Novant Health Presbyterian Medical Center**+	Charlotte	5		
CIS-Ballantyne	Charlotte	1		
CIS-SouthPark	Charlotte	1		
NHI Ballantyne	Charlotte	1		
NHI SouthPark	Charlotte	1		
<b>Total Charlotte</b>		<b>17</b>	<b>872,498</b>	<b>51,323</b>
CIS Huntersville	Huntersville	1		
Novant Health Huntersville Medical Center	Huntersville	2		
<b>Total Huntersville</b>		<b>3</b>	<b>57,098</b>	<b>19,033</b>
Novant Health Mint Hill	Mint Hill	1		
<b>Total Mint Hill</b>		<b>1</b>	<b>27,169</b>	<b>27,169</b>
Novant Health Matthews Medical Center	Matthews	1		
<b>Total Matthews</b>		<b>1</b>	<b>32,635</b>	<b>32,635</b>
<b>Total MRI Scanners</b>		<b>22</b>		

\*\*Pursuant to Exemption Record #2983 approved on August 17, 2019, a grandfathered mobile MRI will be replaced with a grandfathered fixed MRI at NHPMC resulting in a total of five MRIs on that campus.

+Includes Charlotte Orthopedic Hospital and Imaging Museum

**Presbyterian Medical Care Corp.** proposes to locate the additional fixed MRI scanner in Matthews, Mecklenburg County. **CPN** proposes to locate the additional fixed MRI scanner in Charlotte, Mecklenburg County. Based on the Mecklenburg County population estimates as of July 1, 2018, 51,323 people are using the MRI scanners located in Charlotte on a per capita basis as opposed to only 32,635 people using the MRI scanner in Matthews on a per capita basis, as illustrated in the table above. Based on this analysis, the geographic location of the MRI scanner in Charlotte is a better

option for MRI services in Mecklenburg County for the reasons stated above. Neither applicant is proposing to locate the additional scanner in Huntersville or Mint Hill. Thus, with respect to geographic accessibility, the proposal submitted by **CPN** is the more effective alternative.

**Access by Service Area Residents**

On page 149, the 2019 SMFP defines the service area for a fixed MRI scanner as “a single county, except where there is no licensed acute care hospital located within the county.” Thus, the service area for this review is Mecklenburg County. Facilities may also serve residents of counties not included in their service area. Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative since the need determination is for a fixed MRI scanner to be located in Mecklenburg County.

The following table illustrates the projected number of service area residents and the projected number of MRI fixed scanners for both applicants, during the third full fiscal year following project completion.

<b>Application</b>	<b>Service Area Residents</b>	<b>Percentage of Service Areas Residents</b>	<b># of Fixed MRI scanners</b>	<b># of patients per scanner</b>
Presbyterian Medical Care Corp.	4,731	53.01%	2	2,365
Carolinas Physicians Network, Inc. (CPN)	2,206	55.0%	1	2,206

As shown in the table above, **Presbyterian Medical Care Corp.** projects to serve 2,365 service area residents per scanner. **CPN** projects to serve 2,206 service area residents per scan. There is very little difference in the number of residents to be served by each applicant per scanner. Thus, with regard to geographic access by service area residents, the proposals submitted by **Presbyterian Medical Care Corp.** and **CPN** are equally effective.

**Access by Underserved Groups**

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

*“Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority.”*

For access by underserved groups, applications are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

The Agency may use one or more of the following metrics to compare the applications:

- Total charity care, Medicare or Medicaid patients
- Charity care, Medicare or Medicaid patients as a percentage of total patients
- Charity care, Medicare or Medicaid patients per fixed MRI scanner
- Total charity care, Medicare or Medicaid dollars
- Charity care, Medicare or Medicaid dollars as a percentage of total net revenues
- Charity care, Medicare or Medicaid dollars per fixed MRI scanner

Whether or not the Agency used all the metrics listed above in this review was determined by whether or not every application included in this review included data that could be compared for each metric.

***Projected Charity Care***

The following table compares projected charity care in the third full fiscal year following project completion for each facility using the following metrics.

<b>Charity Care-OY 3</b>		
<b>Projected Charity Care</b>	<b>Projected Total Charity Care</b>	<b>% of Total Net Revenue</b>
Presbyterian Medical Care Corp.	\$1,013,182	0.14%
CPN	\$1,411,631	0.17%

As shown in the table above, **Presbyterian Medical Care Corp.** projects its charity care based on the entire hospital experience and not per procedure, which is subtracted from the gross revenue. **CPN** projects its charity care based the difference between gross and net revenue by payor. Due to the different methodology used to project charity care, the differences in the type of facility and services offered by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

***Projected Medicaid***

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for each facility using the following metrics.

<b>Medicaid-OY 3</b>	
<b>Projected Medicaid</b>	<b>Percent of Services</b>
Presbyterian Medical Care Corp.	4.9%
CPN	15.2%

As shown in the table above, during the third full fiscal year following project completion, **Presbyterian Medical Care Corp.** projects to provide 4.9 percent of services to Medicaid patients and **CPN** projects to provide 15.2 percent of services to Medicaid patients. However, differences in the type of facility and the services offered by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

***Projected Medicare***

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for each facility using the following metrics.

<b>Medicare-OY 3</b>	
<b>Projected Medicare</b>	<b>Percent of Services</b>
Presbyterian Medical Care Corp.	42.8%
CPN	29.2%

As shown in the table above, during the third full fiscal year following project completion, **Presbyterian Medical Care Corp.** projects to provided 42.8 percent of services to Medicare patients, including patients with Medicare managed care plans. **CPN** projects to provide 29.2 percent of services to Medicare patients, including patients with Medicare managed plans. However, differences in the type of facility and the services offered by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

**Competition (Access to a new or Alternative provider)**

The following table illustrates the existing and approved providers located in the service area for each of the applicant's health systems.

Fixed MRI Scanners in Mecklenburg County		
Provider	# of Fixed MRI Scanners	Location
Atrium Health Pineville	2	Charlotte
Atrium Health University City	1	Charlotte
CMC/CMC-Mercy	5	Charlotte
CIS-Ballantyne	1	Charlotte
CIS-SouthPark	1	Charlotte
CIS-Huntersville	1	Huntersville
<b>Total</b>	<b>11</b>	
Novant Health Huntersville Medical Center	2	Huntersville
Novant Health Matthews Medical Center	1	Matthews
Novant Health Presbyterian Medical Center*+	5	Charlotte
Novant Health Mint Hill	1	Mint Hill
NHI Ballantyne	1	Charlotte
NHI SouthPark	1	Charlotte
<b>Total</b>	<b>11</b>	

\*Includes Charlotte Orthopedic Hospital and Imaging Museum

+ Pursuant to Exemption Record #2983 approved on August 17, 2019, a grandfathered mobile MRI will be replaced with a grandfathered fixed MRI at NHPMC resulting in a total of five MRIs on that campus.

Source: Figure 9 on page 53 of the Presbyterian Medical Care Corp. application and Table 2, page 51 of the CPN application.

As shown in the table above, there are 22 existing fixed MRI scanners in Mecklenburg County between the two health systems. **Novant Health Inc.** owns 11 of the facilities listed in the table above and is the parent company of Presbyterian Medical Care Corp. **CMHA** owns 11 of the providers listed in the table above and is the parent company to **Carolinas Physicians Network, Inc.** Each applicant proposes to add an additional fixed MRI scanner in Mecklenburg County. Therefore, regarding the comparative factor both applications are equally effective alternatives.

**Projected Average Net Revenue per MRI procedure**

The following table compares projected average net revenue per procedure in the third full fiscal year following project completion for each facility. Generally, the application proposing the lowest average net revenue per procedure is the more effective alternative with regard to this comparative factor to the extent the average could ultimately result in a lower cost to the patient or third-party payor.

Average Net Revenue per Procedure 3 <sup>rd</sup> Full FY			
Applicant	Total # of Procedures	Net Revenue	Average Net Revenue per Procedure
Presbyterian Medical Care Corp.	8,926	\$7,021,351	\$786.61
CPN	4,975	\$1,785,730	\$358.94

Source: Section Q of both applications

As shown in the table above, **Presbyterian Medical Care Corp.** projects the lowest average net revenue per procedure in the third full fiscal year following project completion. However, the scope of service is different for inpatient and outpatient. Inpatient services will generate a higher net revenue per procedure due to the larger scope of services. However, differences in the type of facility and the services offered by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

**Projected Average Operating Expense per MRI Procedure**

The following table compares projected average operating expense per procedure in the third full fiscal year following project completion for each facility. Generally, regarding this factor, the application proposing the lowest average operating expense per procedure is the more effective since a lower average may indicate a lower cost to the patient or third-party payor or more cost-effective service.

<b>Average Operating Expense per Procedure 3<sup>rd</sup> Full FY</b>			
<b>Applicant</b>	<b>Total # of Procedures</b>	<b>Operating Expenses</b>	<b>Average Net Revenue per Procedure</b>
Presbyterian Medical Care Corp.	8,926	\$2,122,624	\$237.80
CPN	4,975	1,456,984	\$292.86

Source: Section Q of both applications

As shown in the table above, **Presbyterian Medical Care Corp.** projects the lowest average operating expense per procedure in the third full fiscal year following project completion. Inpatient services will generate a higher operating expense per procedure due to the larger scope of services. However, differences in the type of facility and the services offered by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

**SUMMARY**

The following table lists the comparative factors and indicates whether each application was more effective, less effective or equally effective for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

<b>Comparative Factor</b>	<b>Presbyterian Medical Care Corp.</b>	<b>CPN</b>
Conformity with Statutory and Regulatory Review Criteria	Equally Effective	Equally Effective
Scope of Services	More Effective	Less Effective
Historical Utilization	Less Effective	More Effective
Geographic Accessibility (Location within the Service Area)	Less Effective	More Effective
Access by Service Area Residents	Equally Effective	Equally Effective
Access by Charity Care Patients	Inconclusive	Inconclusive
Access by Medicaid Patients	Inconclusive	Inconclusive
Access by Medicare Patients	Inconclusive	Inconclusive
Competition (Access to a New or Alternative Provider)	Equally Effective	Equally Effective
Projected Average Net Revenue per Patient Day, Surgical Case or Procedure	Inconclusive	Inconclusive
Projected Average Operating Expense per Patient Day, Surgical Case or Procedure	Inconclusive	Inconclusive

Both applications are conforming to all applicable statutory and regulatory review criteria, and thus both applications are approvable standing alone. However, collectively they propose a total of one MRI scanner but the need determination is for only one MRI scanner. Therefore, only one MRI scanner can be approved.

As shown in the table above, **CPN** was determined to be a more effective alternative for the following factor:

- **CMHA** has a higher historical MRI utilization in Mecklenburg County.

As shown in the table above, **CPN** was determined to be a more effective alternative for the following factor:

- Based on the Mecklenburg County population estimate as of July 1, 2018, more people are using the MRI scanners located in Charlotte as opposed to Matthews, on a per capita basis.

## **DECISION**

Based upon the independent review of each application and the Comparative Analysis, the Agency determined that the application submitted by **CPN** is the most effective alternative proposed in this review for the development of one additional MRI scanner.

While the other application, **Presbyterian Medical Care Corp.** is approvable standing alone, the approval of the either of them would result in the approval of more MRI scanners than are determined to be needed, and therefore, the applications submitted by **Presbyterian Medical Care Corp.** is denied.

CPN proposes to acquire one fixed MRI scanner with cardiac capabilities to be locate at Atrium Health Kenilworth Diagnostic Center #1, a previously approved but not yet operational diagnostic center.

- 1. Carolina Physicians Network, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Carolina Physicians Network, Inc. shall acquire no more than one fixed MRI scanner for a total of no more than one MRI scanner to be locate at Atrium Health Kenilworth Diagnostic Center #1.**
- 3. Upon completion of the project, Atrium Health Kenilworth Diagnostic Center #1 shall be licensed for no more than one MRI scanner.**
- 4. Carolina Physicians Network, Inc. shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 5. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, Presbyterian Medical Care Corp. shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
  - a. Payor mix for the services authorized in this certificate of need.**
  - b. Utilization of the services authorized in this certificate of need.**
  - c. Revenues and operating costs for the services authorized in this certificate of need.**
  - d. Average gross revenue per unit of service.**
  - e. Average net revenue per unit of service.**
  - f. Average operating cost per unit of service.**

- 6. Carolina Physicians Network, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**