## **REQUIRED STATE AGENCY FINDINGS**

#### **FINDINGS**

## C = ConformingCA = Conforming as Conditioned NC = Nonconforming NA = Not Applicable

Decision D	ate:
Findings D	ate:

March 28, 2023 March 28, 2023

Project Analyst:	Tanya M. Saporito
Co-Signer:	Michael J. McKillip

**COMPETITIVE REVIEW** 

Project ID #:	F-12285-22		
Facility:	Novant Health Matthews Medical Center		
FID #:	945076		
County:	Mecklenburg		
Applicant(s):	Novant Health, Inc.		
	Presbyterian Medical Care Corporation		
Project:	Acquire no more than 1 fixed MRI scanner pursuant to the 2022 SMFP need		
-	determination for a total of no more than 2 fixed MRI scanners		
Project ID #:	F-12287-22		
Facility:	OrthoCarolina University		
FID #:	220734		
County:	Mecklenburg		
Applicant(s):	OrthoCarolina, P.A.		
Project:	Acquire no more than 1 fixed MRI scanner pursuant to the 2022 SMFP need		
2	determination		

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C .2700. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

## **REVIEW CRITERIA**

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

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

## **C-Both Applications**

## **Need Determination**

The 2022 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional fixed MRI scanners in North Carolina by service area. Application of the need methodology in the 2022 SMFP identified a need for one fixed MRI scanner in Mecklenburg County. Two applications were received by the Healthcare Planning and Certificate of Need Section (CON Section), each proposing to acquire one fixed MRI scanner, for a total of two MRI scanners. However, pursuant to the need determination, only one fixed MRI scanner may be approved in this review.

## **Policies**

One policy in Chapter 4 of the 2022 SMFP is applicable to both applications received in response to the need determination: *Policy GEN-3: Basic Principles*.

One Policy in Chapter 4 of the 2022 SMFP, *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities* is applicable only to the application submitted by Novant Health, Inc. and Presbyterian Medical Care Corporation.

# Policy GEN-3

Policy GEN-3 on page 30 of the 2022 SMFP states:

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

## **Policy GEN-4**

Policy GEN-4 on pages 30-31 of the 2022 SMFP states:

"Any person proposing a capital expenditure greater than \$4 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

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

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

# F-12285-22/ NH Matthews /Acquire one fixed MRI scanner

Novant Health Inc, and Presbyterian Medical Care Corporation, hereinafter collectively referred to as "the applicant", or Novant, propose to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at Novant Health Matthews Medical Center ("NH Matthews"). Upon project completion, NH Matthews will have two fixed MRI scanners.

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

*Policy GEN-3*. In Section B, pages 25-26, the applicant explains why it believes its application is conforming to Policy GEN-3.

*Policy GEN-4*. The proposed capital expenditure for this project is greater than \$4 million but less than \$5 million. In Section B, page 27, and Exhibit B.2, the applicant describes the project's plan to improve energy efficiency and conserve water. 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 develop more fixed MRI scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 for the following reasons:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in the service area;
  - The applicant adequately documents how the project will promote equitable access to MRI services in the service area; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
  - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

# F-12287-22/ OrthoCarolina/Acquire one fixed MRI scanner

OrthoCarolina, P.A., hereinafter referred to as "the applicant", or OrthoCarolina, proposes to acquire one fixed MRI scanner to be located at its outpatient medical clinic, OrthoCarolina University.

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

*Policy GEN-3*. In Section B, pages 25-26, the applicant explains why it believes its application is conforming to Policy GEN-3.

# **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 develop more fixed MRI scanners than are determined to be needed in the service area.

- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in the service area;
  - The applicant adequately documents how the project will promote equitable access to MRI services in the service area; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, persons with disabilities, the elderly, and other underserved groups are likely to have access to the services proposed.

С

**Both Applications** 

# F-12285-22/ NH Matthews /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at Novant Health Matthews Medical Center. Upon project completion, NH Matthews will operate two fixed MRI scanners.

# Patient Origin

The 2022 SMFP defines the service area for a fixed MRI scanner as "the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county." Therefore, for the purpose of this review, the fixed MRI service area is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

The following table, from pages 34 and 35 of the application, illustrates historical and projected patient origin for fixed MRI services at NH Matthews:

			3 <sup>RD</sup> FULL FY		
COUNTY	HISTORICAL CY 2021			2027 5-9/30/27)	
	PATIENTS % OF TOTAL		PATIENTS	% OF TOTAL	
Mecklenburg	4,198	60.4%	5,477	60.4%	
Union	1,193	28.7%	2,603	28.7%	
Other Counties and States*	761	10.9%	988	10.9%	
Total^	6,952	100.0%	9,069	100.0%	

Fixed MRI Services	Historical	and Projected	Patient Origin

\*The applicant state "Other Counties and States" includes 86 North Carolina counties. Percentages may not sum due to rounding.

In Section C, page 35, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on the applicant's historical MRI services patient origin.

## Analysis of Need

In Section C.4, pages 38-47, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Historical utilization of NH Matthews existing fixed MRI scanner, which has provided over 6,000 unweighted MRI scans, provides both inpatient and outpatient MRI scans, and operates 24 hours per day, seven days per week.
- Service area population growth and aging trends and projections, particularly in the over 65 age group, the group most likely to utilize MRI services.
- The life expectancy of Mecklenburg and Union County residents is increasing, thereby indicating an increasing need for MRI services.
- The six year compound annual growth rate (CAGR) for MRI services in both Mecklenburg and Union counties from FY 2015-FY 2021 was 2.32% and 2.65%, respectively.

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

- The 2022 SMFP identifies the need for one additional fixed MRI scanner in Mecklenburg County service area.
- The applicant provides information and data to support the assertions regarding service area population growth and aging, as well as an increasing need for additional MRI services due to increasing life expectancy in the service area.
- The applicant provides information and data to support the assertions regarding MRI utilization in the service area.

## Projected Utilization

In Section Q, Form C.2a and C.2b, the applicant provides interim and projected utilization, as illustrated in the following table:

	INTERIM FY	INTERIM FY 1 <sup>ST</sup> FULL FY		<b>3<sup>RD</sup> FULL FY</b>
	10/1/23-9/30/24	FY 2025	FY 2026	FY 2027
Number of Units	1	2	2	2
# Procedures (unweighted)	6,813	7,495	8,244	9,069
# Weighted Procedures	8,528	9,381	10,319	11,351

#### **NH Matthews Projected Utilization**

In Section Q, *Utilization Methodology and Assumptions*, the applicant provides the assumptions and methodology used to project utilization for the proposed MRI, as summarized below:

**Step 1:** Calculate the compound annual growth rate (CAGR) and the seven-year weighting average for Mecklenburg County MRI utilization for FY 2015-FY 2021 based on data in the SMFPs from 2017-2023. The applicant calculated a six-year CAGR of 2.32% in MRI scans from FY 2015-FY 2021, and a seven-year average weighting ratio of 1.196.

**Step 2:** Project Mecklenburg County total MRI utilization - Using the CAGR and the weighting average from Step 1, the applicant projected future Mecklenburg County MRI utilization from FY 2021-FY 2027. See the tables that illustrate these projections in Section Q.

**Step 3:** Historical Novant Health (NH) MRI scans, adjusted MRI scans and MRI scanners – The applicant calculated the CAGR and weighting ratio of its own MRI scanners, using the same data from the SMFPs as in the previous steps. The applicant adjusted its calculations to account for those scanners it currently owns and operates which were acquired after FY 2015.

**Step 4:** Historical NH MRI scans, adjusted MRI scans – The applicant totaled MRI utilization from Steps 1 and 2 and determined the NH six-year CAGR to be 6.09%, and the NH average weighting ratio to be 1.21.

**Step 5:** Project total NH MRI and adjusted MRI scans – Using the CAGR and weighting ratio calculated in the previous step, and accounting for actual time that each MRI scanner was in use, the applicant projects total NH MRI utilization of all scanners.

**Step 6:** Project total NH MRI and adjusted MRI scans – Using the CAGR and weighting ratio calculated in the previous step, and accounting for actual time that each MRI scanner was in use, the applicant projects total NH MRI utilization of its scanners by location in the service area.

**Step 7:** Project NH owned mobile MRI scans and adjusted scans – The applicant applied a 1.0% growth rate to project future utilization of each of its mobile MRI scanners. The applicant also calculated a weighting ratio for the mobile scanners, using FY 2021-FY 2022 data and applied that to projections through FY 2027.

**Step 8:** Project NH Matthews MRI and adjusted MRI scans – Using data from Step 6, and its internal FY 2021 data, the applicant projects the number of MRI scans to be performed at NH Matthews, adjusted for inpatient, outpatient, with contrast and without contrast.

**Step 9:** Perform a NH Matthews "*Reasonableness Check*" – Using data from Steps 2, 4 and 8, the applicant determined what percentage of total Mecklenburg County annual MRI scan growth NH Matthews would need to capture to meet the projections offered by the applicant. The applicant determined that it would need to capture an average of just under 25% of Mecklenburg County MRI utilization to meet its own growth projections. The applicant calculated that its projections capture between 22.4% and 25.9% of projected MRI utilization.

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

- There is a need determination in the 2022 SMFP for a fixed MRI scanner in the Mecklenburg County fixed MRI service area and this proposed project will meet that need.
- The applicant's projections of MRI scans to be performed are supported by the historical MRI volumes.
- The applicant's projections of MRI utilization utilize growth rates that are below the actual historical MRI growth rates.
- The applicant adequately demonstrates that its proposed fixed MRI scanner is reasonably expected to perform more than 3,364 adjusted MRI procedures in the third year of operation following the completion of the proposed project, as required by 10A NCAC 14C .2703(a)(7)(A).

# Access to Medically Underserved Groups

In Section C, page 53, the applicant states:

"Novant Health does not exclude from participation, deny benefits to, or otherwise discriminate against patients, students, or visitors on the basis of race; color; religion; national origin; culture; language; physical or mental disability; age; sex, including pregnancy, childbirth or related medical conditions; marital status; sexual orientation; gender identity or expression; socioeconomic status; source of payment; or any other protected status in admission to, participation in, or receipt of the services and benefits of any of its programs and activities, whether carried out by Novant Health directly or through a contractor other entity with whom Novant Health arranges to carry out its programs and activities."

On page 54, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

With Watchews Estimated Tereentages			
PAYOR GROUP	ESTIMATED PERCENTAGE		
	OF PATIENTS IN 3 <sup>RD</sup> FULL FY		
Low Income Persons*	8.2%		
Racial and Ethnic Minorities	28.3%		
Women	62.4%		
Persons with Disabilities^			
Persons 65 and Older	41.1%		
Medicare Beneficiaries	42.9%		
Medicaid Beneficiaries	5.2%		

#### **NH Matthews Estimated Percentages**

<sup>^</sup>The applicant states it is does not track this data.

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

- The applicant has historically provided access to services to underserved groups in its existing facilities and imaging centers.
- The applicant states that all patients will continue to receive equitable access to MRI services with the approval of the proposed fixed MRI.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Comments
- Response to comments

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

# F-12287-22/ OrthoCarolina / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at its existing outpatient medical clinic, OrthoCarolina University, in Charlotte. The applicant states on page 27 that it will install the proposed MRI scanner in a permanent modular structure next to the existing clinic.

Currently, OrthoCarolina provides MRI services on two fixed MRI scanners located at OrthoCarolina Ballantyne and OrthoCarolina Spine Center. The applicant also owns and operates a mobile MRI scanner in the service area that serves several host sites, and it leases one mobile MRI scanner that currently serves the University location.

## Patient Origin

The 2022 SMFP defines the service area for a fixed MRI scanner as "the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county." Therefore, for the purpose of this review, the fixed MRI service area is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

The following table, from pages 31 and 34 of the application, illustrates historical (CY 2021) patient origin for the mobile MRI scanner and projected patient origin for the proposed fixed MRI services at OrthoCarolina University:

COUNTY	HISTORICAL MOBILE MRI CY 2021		3 <sup>RD</sup> FULL FY CY 2026	
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL
Mecklenburg	947	71.74%	2,610	71.90%
Cabarrus	192	14.49%	648	17.90%
Iredell	22	1.66%	44	1.20%
Union	19	1.43%	38	1.00%
Gaston	18	1.36%	36	1.00%
Rowan	17	1.28%	34	0.90%
Stanly	15	1.13%	30	0.80%
Other NC Counties*	41	3.09%	81	2.20%
Other States	54	4.08%	107	3.00%
Total^	1,325	100.0%	3,627	100.0%

<b>Fixed MRI Services</b>	Historical a	and Proiected	Patient Origin

\*The applicant state "other" includes all other North Carolina counties. Percentages may not sum due to rounding.

In Section C, page 32 and in Section Q, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on OrthoCarolina's historical patient origin data for MRI services.

# Analysis of Need

In Section C, pages 36-55, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Need determination in the 2022 SMFP for one additional fixed MRI scanner in Mecklenburg County.
- Historical MRI utilization in Mecklenburg County. The historical MRI use rate is higher in Mecklenburg County than in the state as a whole, thus indicating need for additional fixed MRI capacity in the county.

- Limited access in Mecklenburg County for MRI services in a lower-cost, freestanding setting rather than hospital-based services. There is a need for enhanced access to MRI services at OrthoCarolina University, particularly for claustrophobic or obese patients.
- Mecklenburg County population growth rates, particularly in the over 65 age group. The over 65 age group in Mecklenburg County is projected to increase by a compound annual growth rate (CAGR) of 4.52% from 2022-2026, while overall population is projected to increase by a CAGR of 1.81% in the county as a whole.
- The need for improved geographic access to low-cost fixed MRI services in the University City area of Mecklenburg County, which is in the northeastern portion of the county. The applicant states most of the fixed MRI capacity is close to the central Charlotte area, and the University City area currently has only one freestanding MRI scanner. The other fixed MRI scanner in the area is a hospital-based scanner. Additionally, the University City area has a high minority population, thus indicating a need for increased access to lower cost MRI services.
- Support for the project is evidenced by letters of support provided in Exhibit I.2.

## Projected Utilization

OrthoCarolina owns and operates two fixed MRI scanners at its Spine Center and Ballantyne locations. The applicant also owns and operates one mobile MRI scanner and leases one mobile MRI scanner to serve its University location.

In Section Q, Form C.2b, the applicant provides projected utilization for the first three project years (CYs 2024-2026) for the proposed fixed MRI scanner at OrthoCarolina University, as illustrated in the following table:

	1 <sup>st</sup> Full FY CY 2024	3 <sup>rd</sup> Full FY CY 2026	
Number of MRI Scanners	1	1	1
# Unweighted Procedures	2,515	3,094	3,627
# Weighted Procedures	2,559	3,149	3,691

OrthoCarolina University	MRI Utilization
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Source: Application Section Q, Form C.2b, page 129

In Section Q, "*Form C.2b Assumptions and Methodology*", pages 134-144 the applicant provides the assumptions and methodology used to project utilization for the proposed MRI, as summarized below:

• The applicant examined historical MRI utilization from CY 2018-2022. The applicant calculated the following compound annual growth rate (CAGR) based on the historical utilization at each location: 4.39% at the Spine Center, 1.66% at the Ballantyne location, and 1.78% at the University location. The applicant also determined a ratio of weighted to unweighted MRI procedures based on historical utilization.

- The applicant projects future MRI utilization from CY 2022-CY 2026 based on onehalf of the CAGR for each location.
- The applicant determined the total MRI utilization in Mecklenburg County based on FY 2020-2021 utilization data. Relying on population data from the North Carolina Office of State Budget and Management (NCOSBM) regarding population growth projections in Mecklenburg County and the Mecklenburg County MRI use rate of 115.2, the applicant calculated its current market share of MRI services. The applicant's market share of MRI procedures in Mecklenburg County for 2020-2021 is illustrated in the following table from page 138:

ORTHOCAROLINA MARKET SHARE	2020	2021		
Combined Fixed MRI Procedures	13,315	15,593		
Combined Mobile MRI Procedures	6,716	7,731		
Mecklenburg County Procedures	127,152	134,298		
Market Share	15.75%	17.37%		

#### **OrthoCarolina MRI Market Share**

The applicant states the addition of a new fixed MRI scanner will increase its market share by 0.25%, 0.50% and 0.75% in each of the first three project years.

- The applicant examined ZIP codes in and around the University location from which patients have historically come, and from which the applicant states additional patients will likely seek MRI services at the University location rather than either the Spine Center or Ballantyne location because of the proximity of the University location to those ZIP codes. The applicant projected that those patients who reside closer to the University location will shift their care to that location once the fixed MRI is in place.
- The applicant combined the projected number of procedures with its projected market share gain and the projected shift in patients from its other locations to University. The applicant applied its five-year average weighting ratio for the University location and held it constant through all three project years. The following table from page 142 summarizes these steps:

UNIVERSITY TOTAL AFTER SHIFT	2024	2025	2026
Unweighted Procedures	1,535	1,548	1,562
Shifted from Spine Center	429	569	671
Shifted from Ballantyne	2050	273	322
Market Share Gain	346	704	1,072
Total Unweighted Procedures	2,515	3,094	3,627
Weighted Procedures	2,559	3,149	3,691
Weighting Ratio	1.018	1.018	1.018

• The applicant projected utilization at its Spine Center and Ballantyne locations, accounting for the projected shift in patients who will seek MRI services at the University location. Additionally, the applicant projected the combined the total of all MRI procedures to be performed at each location, as well as on its owned and leased

mobile MRI scanners. Based on its historical market share and the calculations described above, the applicant projects its market share of MRI utilization will increase to 18.7% by the third project year, CY 2026. See the following tables that illustrate projected utilization of all fixed MRI scanners:

	1 <sup>st</sup> Full FY CY 2024	2 <sup>nd</sup> Full FY CY 2025	3 <sup>rd</sup> Full FY CY 2026
Number of MRI Scanners	1	1	1
# Unweighted Procedures	2,515	3,094	3,627
# Weighted Procedures	2,559	3,149	3,691

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Source: Application Section Q, Form C.2b, page 129

OrthoCarolina Spine Center MRI Utilization			
	1 <sup>st</sup> Full FY	2 <sup>nd</sup> Full FY	3 <sup>rd</sup> Full FY
	CY 2024	CY 2025	CY 2026
Number of MRI Scanners	1	1	1
# Unweighted Procedures	7,931	7,973	8,059
# Weighted Procedures	8,488	8,533	8,625

# OrtheCarolina Spine Conter MPI Utilization

Source: Application Section Q, Form C.2b, page 130

#### **OrthoCarolina Ballantyne MRI Utilization**

	1 <sup>st</sup> Full FY CY 2024	2 <sup>nd</sup> Full FY CY 2025	3 <sup>rd</sup> Full FY CY 2026
Number of MRI Scanners	1	1	1
# Unweighted Procedures	8,558	8,563	8,588
# Weighted Procedures	8,746	8,751	8,776

Source: Application Section Q, Form C.2b, page 131

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

- There is a need determination in the 2022 SMFP for a fixed MRI scanner in the ٠ Mecklenburg County fixed MRI service area and this proposed project will meet that need.
- The applicant's projections of MRI scans to be performed are supported by historical • volumes on its existing fixed MRI scanners, population data and its market share calculations.
- The applicant adequately demonstrates that its proposed fixed MRI scanner is • reasonably expected to perform more than 3,364 adjusted MRI procedures in the third year of operation following the completion of the proposed project, as required by 10A NCAC 14C .2703(a)(7)(A).

#### Access to Medically Underserved Groups

In Section C, page 60, the applicant states:

"... OrthoCarolina does not discriminate based on income, race, ethnicity, creed, color, gender, age, physical or mental handicap, religion, national origin, sexual orientation, or any other factor that would classify a patient as underserved. ... Low income persons will have access to MRI services at OrthoCarolina through Physicians Reach Out and Charlotte Community Health Clinic, and in other circumstances of need evaluated on a case-by-case basis."

On page 61, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

GROUP	ESTIMATED PERCENTAGE OF TOTAL PATIENTS DURING THE THIRD FULL FISCAL YEAR
Low income persons	11.0%
Racial and ethnic minorities	24.3%
Women	55.6%
Persons with disabilities	5.5%
Persons 65 and older	31.3%
Medicare beneficiaries	30.2%
Medicaid beneficiaries	4.0%

The applicant states on page 61 that it does not track data regarding income or disability status of its patients, but bases the estimates on U.S. Census Bureau data for Mecklenburg County.

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

- The applicant has historically provided access to MRI services to underserved groups and states it will continue to do so.
- The applicant states estimated percentages in the payor group classifications are based on the historical experience of patients served at OrthoCarolina as well as census data for Mecklenburg County.

# **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Comments
- Response to comments

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

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

#### NA Both Applications

Neither of the applications proposes to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA Both Applications

# F-12285-22/ NH Matthews /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at Novant Health Matthews Medical Center. Upon project completion, NH Matthews will operate two fixed MRI scanners.

In Section E, pages 68-69, 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 maintaining the status quo is not an option because the existing MRI scanner at NH Matthews is already operating above capacity, and those patients who are referred for an MRI scan must wait between 4 and 14 days. Therefore, maintaining the status quo would not only ignore the published need in the 2022 SMFP, but would also be detrimental to existing and projected patients.
- Add Additional Mobile MRI Days at NH Matthews The applicant states it considered adding additional mobile days at NH Matthews, but its mobile MRI scanners serve many other host sites across the state and thus there is limited availability. Additionally, providing additional mobile MRI days would not effectively serve non-ambulatory patients who need fixed MRI availability. Thus, providing additional mobile MRI days at NH Matthews is not an effective alternative.
- Locate the Proposed MRI Scanner at Another Novant Location The applicant considered locating the proposed MRI scanner at either NHI Ballantyne or NHI Southpark, but determined that NHI Ballantyne is the primary Novant Health location

for breast biopsies, which typically take much longer than a routine MRI scan. NHI Southpark was approved in 2021 for an additional fixed MRI scanner and thus is not an appropriate location for an additional fixed MRI scanner. Therefore, locating the proposed fixed MRI scanner in another Novant Health location is not an effective alternative.

The applicant adequately demonstrates that the alternative proposed in this application is its most effective alternative to meet the need based on the following:

- The applicant states locating the proposed fixed MRI scanner at NH Matthews will ensure timely access to fixed MRI services in the service area, increase quality of care and improve operational efficiencies.
- The applicant states the proposed fixed MRI scanner will be located in space in the patient tower when it is complete, thus providing cost-effective and efficient access to MRI services in the service area which will eliminate potential additional renovation and/or construction.
- The applicant provides reasonable and adequately supported information to explain why it believes the proposed project is the most effective alternative.

# **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments

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

# F-12287-22/ OrthoCarolina / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at its existing outpatient medical clinic, OrthoCarolina University, in Charlotte.

In Section E, pages 72-78, 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 maintaining the status quo would fail to address the need for an additional MRI scanner as identified in the 2022 SMFP. Additionally, the applicant states there is no fixed MRI provider in the northeastern region of Mecklenburg County, where the applicant proposes to locate its fixed MRI

scanner. Therefore, the applicant states that the status quo is not a reasonable alternative to address the need for MRI services in the area.

- Develop the project as proposed at a different location The applicant states the majority of existing fixed MRI scanners in Mecklenburg County are located in central Charlotte, with some of them in the northern and southern portions of the county. OrthoCarolina facility is located in the northeastern portion of the county, where there is currently no MRI provider and there is a large population of underserved groups. Locating the proposed fixed MRI scanner at this facility will provide needed MRI services to residents of this area and would be easily accessible via major highways. Thus, the applicant states that a different location will not be a reasonable alternative to serve area residents in need of MRI services.
- Acquire different MRI equipment The applicant states it considered a 3T MRI scanner rather than the proposed 1.5T scanner, but determined that the purchase and upfit costs would be too high, given that it could effectively serve the area population with a lower strength magnet and lower costs to its patients. Thus, the applicant determined a different strength MRI scanner would not be an effective alternative to the one proposed.

On page 78, the applicant states that its proposal is the most effective alternative because the proposed fixed MRI scanner at the proposed location will provide patients in the region with a cost effective alternative for outpatient MRI services.

The applicant adequately demonstrates that the alternative proposed in this application is its most effective alternative to meet the need based on the following:

- The applicant states that the proposal meets the need of patients in the service area by providing enhanced imaging in a cost-effective manner.
- The applicant provides reasonable and adequately supported information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

# **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Comments
- Response to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons *s*tated 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

# F-12285-22/ NH Matthews /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at Novant Health Matthews Medical Center. Upon project completion, NH Matthews will operate two fixed MRI scanners.

## **Capital Costs**

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

\$1,057,290		
\$1,933,313		
\$1,063,803		
\$4,054,406		

#### NH Matthews Capital Cost

In Exhibit F.1 the applicant provides information used to project the capital cost. In Section F, page 73, the applicant states that NH Matthews is an existing hospital and requires no start-up costs.

The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Facility upfit cost is based on an estimate from a licensed architect.
- Medical equipment cost is based on vendor quotations.

# Availability of Funds

In Section F, page 70, the applicant states that the capital cost will be funded as shown in the table below:

Түре	NOVANT HEALTH, INC.	
Loans	\$0	
Cash and Cash Equivalents, Accumulated reserves or OE *	\$4,054,406	
Bonds	\$0	
Other (Specify)	\$0	
Total Financing	\$4,054,406	

#### **Sources of Capital Cost Financing**

\* OE = Owner's Equity

In Exhibit F.2, the applicant provides a letter dated October 10, 2022, signed by the Senior Vice President of Operational Finance and Revenue Cycle confirming Novant Health's willingness to provide funding for the proposed capital needs of the project and the availability of those funds. Exhibit F.2 also contains the audited financial statements for years ending December 31, 2020 and December 31, 2021 for Novant Health, Inc. and Affiliates, the parent company to NH Matthews that documents the availability of sufficient funds for the project.

# **Financial Feasibility**

In Section Q, the applicant provides pro forma financial statements for the first three full fiscal years (FY) of operation (October 1-September 30) following project completion. In Form F.2b, the applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years following completion of the project, as shown in the table below:

	1 <sup>st</sup> FULL FISCAL	2 <sup>ND</sup> FULL FISCAL	<b>3<sup>RD</sup> FULL FISCAL</b>
	YEAR	YEAR	YEAR
Total Procedures (unweighted)	7,495	8,244	9,069
Total Gross Revenues (Charges)	\$30,796,530	\$34,892,469	\$39,533,167
Total Net Revenue	\$8,081,009	\$9,155,784	\$10,373,503
Average Net Revenue per Procedure	\$1,078	\$1,111	\$1,144
Total Operating Expenses (Costs)	\$2,586,302	\$2,657,629	\$2,733,237
Average Operating Expense per Procedure	\$345	\$322	\$301
Net Income	\$5,494,707	\$6,498,155	\$7,640,266

**NH Matthews MRI Services** 

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q following Forms F.2 and F.3. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Payor category calculations are based on a calculation that includes the percentage for each category, the number of scans and the projected average charge based on the applicant's historical experience.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

# **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Comments
- Response to comments

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 for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the • proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

# F-12287-22/ OrthoCarolina / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at its existing outpatient medical clinic, OrthoCarolina University, in Charlotte.

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

OrthoCarolina Capital Cost			
Construction/Renovation Costs	\$168,468		
Medical Equipment	\$1,870,779		
Miscellaneous Costs	\$118,861		
Total	\$2,158,108		

OrthoCarolina	Capital	Cost

In Section Q Form F.1a, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Renovation costs are based on an estimate from a licensed architect.
- Medical equipment cost is based on vendor quotations plus 7.5% sales tax.
- Capital cost estimates are based on the applicant's experience with similar projects and its existing IT infrastructure.

In Section F, page 81, the applicant states there are no start-up costs nor initial operating expenses, since OrthoCarolina currently offers MRI services at the clinic.

## Availability of Funds

In Section F, page 79, the applicant states that the capital cost will be funded as shown in the table below:

ORTHOCAROLINA, P.A.
\$2,158,108
\$0
\$0
\$0
\$2,158,108

\* OE = Owner's Equity

In Exhibit F-2, the applicant provides a letter dated September 30, 2022 from Truist Bank, confirming the bank's willingness to provide financing for the proposed capital needs of the project up to \$2.3 million. The applicant adequately demonstrates the availability of adequate funds for the capital needs of the project.

## **Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years (FY) of operation, which the applicant states are calendar years (CY) 2024-2026, following project completion. In Form F.2b, the applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years following completion of the project, as shown in the table below:

OrthoCarolina			
	<b>1</b> <sup>st</sup> <b>FY</b>	2 <sup>ND</sup> FY	3 <sup>RD</sup> FY
	CY 2024	CY 2025	CY 2026
Total Procedures (unweighted)	2,515	3,094	3,627
Total Gross Revenues (Charges)	\$3,470,833	\$4,313,533	\$5,106,925
Total Net Revenue	\$1,290,669	\$1,604,036	\$1,899,068
Average Net Revenue per Procedure	\$513	\$518	\$524
Total Operating Expenses (Costs)	\$1,181,992	\$1,491,924	\$1,603,712
Average Operating Expense per Procedure	\$470	\$482	\$442
Net Income	\$108,677	\$112,112	\$295,356

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, in *"Form F.2/3 Assumptions."* The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Payor percentages, contractual allowances and bad debt are based on the applicant's historical data.
- Projected average charges are based on the applicant's experience and are inflated 1.0% annually.

- Salaries are based on the applicant's experience and are inflated 3.0% annually.
- Direct expenses for contrast and other medical supplies per MRI procedure are based on the applicant's historical experience.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

# **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Comments
- Response to comments

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

#### C Both Applications

The 2022 SMFP defines the service area for a fixed MRI scanner as "the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county." Therefore, for the purpose of this review, the fixed MRI service area is Mecklenburg. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in the Mecklenburg County service area, summarized from Table 17E-1, pages 353-354 of the 2022 SMFP:

Existing and Approved Fixed MRI Scanners in Mecklenburg County				
Provider	# OF FIXED	SERVICE TYPE	TOTAL MRI	ADJUSTED
	SCANNERS		SCANS	TOTAL
Atrium Health Pineville	2	Hospital Fixed	7,605	9,842
Atrium Health University City	1	Hospital Fixed	5,800	7,309
Carolinas Medical Center-Main	4	Hospital Fixed	16,816	23,426
Carolinas Medical Center-Mercy	1	Hospital Fixed	5,136	6,621
Novant Health Huntersville Medical Center	2	Hospital Fixed	7,735	9,384
Novant Health Matthews Medical Center	1	Hospital Fixed	6,151	7,619
Novant Health Mint Hill Medical Center	1	Hospital Fixed	2,990	3,550
NHPMC-Charlotte*	1	Hospital Fixed	2,818	3,261
NHPMC-Main	2	Hospital Fixed	11,372	15,299
NHPMC – Novant Health Imaging Museum	1	Hospital Fixed	2,472	2,837
Atrium Health Kenilworth Diagnostic Center^	1	Freestanding Fixed	0	0
Carolina Neurosurgery & Spine Associates-Charlotte	1	Freestanding Fixed	3,834	4,028
Carolinas Imaging Services-Ballantyne	1	Freestanding Fixed	4,230	4,842
Carolinas Imaging Services-Huntersville	1	Freestanding Fixed	3,737	4,245
Carolinas Imaging Services-Southpark	1	Freestanding Fixed	3,461	4,095
Novant Health Imaging Ballantyne	1	Freestanding Fixed	2,855	3,201
Novant Health Imaging Southpark**	1	Freestanding Fixed	0	0
Novant Health Imaging-Southpark	1	Freestanding Fixed	4,185	4,559
OrthoCarolina Ballantyne	1	Freestanding Fixed	7,863	8,081
OrthoCarolina Spine Center	1	Freestanding Fixed	5,716	6,123

#### Existing and Approved Fixed MRI Scanners in Mecklenburg County

\* Novant Health Presbyterian Medical Center

^ Not yet operational – See CON Project ID# F11760-19

\*\* Not yet operational-See CON Project ID# F-11946-20

# F-12285-22/ NH Matthews /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at Novant Health Matthews Medical Center. Upon project completion, NH Matthews will be operate two fixed MRI scanners.

In Section G, page 81, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in the proposed fixed MRI service area. The applicant states:

"Currently at NH Matthews, inpatient MRI scans are scheduled 4 to 6 days out and non-STAT outpatient MRI scans are scheduled 10 to 14 days out. ... When a scan is delayed, diagnosis and treatment are therefore delayed. To address delays, NH Matthews contracts for mobile MRI services but cannot increase the number of days the mobile MRI scanner is available because of a shortage of mobile MRI capacity across the state. As a result, patients have to wait days or weeks for an MRI scan. Otherwise, they must travel to another MRI site, which is costly, disruptive, and inconvenient for the patient and their family. ...

There will be no duplication of existing or approved resources as a result of this project."

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

- There is a need determination in the 2022 SMFP for the proposed fixed MRI scanner in the Mecklenburg County service area.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners in the service area.

# **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 all the reasons described above.

# F-12287-22/ OrthoCarolina / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at its existing outpatient medical clinic, OrthoCarolina University, in Charlotte.

In Section G, pages 88-90, 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:

"The proposed project will not result in unnecessary duplication of the existing or approved fixed MRI services in Mecklenburg County. OrthoCarolina does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2022 SMFP. ... OrthoCarolina's proposed project will improve local access for Mecklenburg County residents to high quality and cost-effective outpatient MR imaging in a low cost, geographically convenient, easily accessible freestanding diagnostic imaging setting."

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

- There is a need determination in the 2022 SMFP for the proposed fixed MRI scanner in Mecklenburg County.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners in the service area.

# **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 all the reasons described 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

# F-12285-22/ NH Matthews /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at Novant Health Matthews Medical Center. Upon project completion, NH Matthews will operate two fixed MRI scanners.

In Section Q Form H Staffing, the applicant provides the projected full-time equivalent (FTE) positions for the proposed fixed MRI service for the first three full fiscal years (FY) as summarized below:

NH Matthews Staffing			
	1 <sup>ST</sup> FULL FY 2 <sup>ND</sup> FULL FY 3RD FULL FY		
Position	10/1/24-9/30/25	10/1/25-9/30/26	10/1/26-9/30/27
MRI Technologists	11.72	11.72	11.72
Receptionist	2.70	2.70	2.70
Total	14.42	14.42	14.42

The assumptions and methodology used to project staffing are provided following Form H Staffing, Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 83-85, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

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

• The applicant adequately demonstrates its methods to recruit staff, which includes recruitment through NH's existing corporate and regional human resources departments.

• The applicant adequately demonstrates its methods to train and retain staff, as well as its existing and proposed methods to ensure continued staff certification based on NH's experience.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

# F-12287-22/ OrthoCarolina / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at its existing outpatient medical clinic, OrthoCarolina University, in Charlotte.

In Section Q Form H Staffing, the applicant provides the projected full-time equivalent (FTE) positions for the proposed fixed MRI service for the first three full fiscal years (FY), as summarized below:

OrthoCarolina Staffing			
	1 <sup>st</sup> FULL FY	2 <sup>ND</sup> FULL FY	3 <sup>RD</sup> FULL FY
POSITION	CY 2024	CY 2025	CY 2026
MRI Technologists	1.25	1.75	2.00
Administrator/CEO	0.25	0.25	0.25
Clerical (Scheduler)	1.00	1.25	1.25
Medical Director	1.00	1.00	1.00
Clinical Supervisor	0.25	0.25	0.25
MRI Tech Assistants	1.25	1.75	2.00
Total	5.00	6.25	6.75

The assumptions and methodology used to project staffing are provided in Section F, pages 91-92. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 91-93, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

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

• The applicant adequately demonstrates its methods to recruit staff, which includes recruitment through various social media platforms, job fairs, referral bonuses and its existing relationships with area college and high school programs.

• The applicant adequately demonstrates its methods to train and retain staff, as well as its methods to ensure continued staff competence and certification based on its experience at its existing facilities.

# **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C Both Applications

# F-12285-22/ NH Matthews /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at Novant Health Matthews Medical Center. Upon project completion, NH Matthews will operate two fixed MRI scanners.

# Ancillary and Support Services

In Section I, page 87, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 88-89, the applicant explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I-1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant provides a letter in Exhibit I.1 signed by the President and Chief Administrative Officer for NH Matthews that documents support for the necessary ancillary and support services.
- The applicant documents that its parent company, Novant Health, has experience in providing the ancillary and support services necessary for the project.

# **Coordination**

In Section H, page 89, the applicant describes its efforts to develop 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 based on the following:

- The applicant is part of Novant Health and has established relationships with existing local healthcare and social service providers.
- NH Matthews has established relationships with area physician practices, rural health clinics and county health departments, and provides documentation in Exhibit I.2.

# **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Comments
- Response to comments

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

# F-12287-22/ OrthoCarolina / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at its existing outpatient medical clinic, OrthoCarolina University, in Charlotte.

# Ancillary and Support Services

In Section I, page 95, the applicant identifies the necessary ancillary and support services for the proposed fixed MRI services. On pages 95-96, the applicant explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant documents that it has experience in providing the ancillary and support services necessary for the project.
- The applicant provides documentation from a board-certified radiologist that documents professional radiology services for interpretation of the MRI scans.

# **Coordination**

In Section I, pages 96-97, the applicant describes its existing 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, because the applicant currently has established relationships with

local healthcare and social service providers and commits to maintaining those relationships following project completion.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks at the public hearing
- Comments
- Response to comments

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

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

#### NA Both Applications

Neither of the applicants 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, neither of the applicants projects 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 of the applicants 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

# F-12285-22/ NH Matthews /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at Novant Health Matthews Medical Center. Upon project completion, NH Matthews will operate two fixed MRI scanners.

In Section K, page 92, the applicant states the project involves renovating 3,416 square feet of space in NH Matthews Medical Center. Line drawings are provided in Exhibit K.2.

On page 93, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states the proposed project involves renovation of existing space, which will be a cost-effective alternative for its patients.
- The applicant states the proposed renovation will comply with all applicable federal, state and local building codes.
- The applicant provides a letter from a licensed architect in Exhibit K.2 certifying the cost for renovation.

On page 93, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states the proposed project will not result in an increase in costs or charges to the public for the proposed services.
- The applicant relies on the expertise of the project architect in designing and renovating the existing space to be cost effective.

On page 93, the applicant identifies any applicable energy saving and water conservation features that will be incorporated into the construction plans.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Comments
- Response to comments

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

# F-12287-22/ OrthoCarolina / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at its existing outpatient medical clinic, OrthoCarolina University, in Charlotte.

In Section K, page 99 the applicant states the project involves renovating 1,764 square feet of existing space in the clinic and includes cost for a covered walkway to a modular building in which the proposed MRI will be installed. Line drawings are provided in Exhibit K-2.

On pages 99-100, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states the proposed project involves renovation of existing space, which is more cost-effective than new construction.
- The applicant provides a letter from a licensed architect in Exhibit K.3 certifying the cost for renovation and the covered walkway.

On page 100, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states the proposed project represents competitive equipment quotes to ensure the lowest acquisition cost possible.
- The applicant states the project will provide area residents an additional low cost option for MRI services in a freestanding facility.
- The applicant states the proposal represents improved access, convenience and efficiency for Mecklenburg County residents in need of MRI services.

On pages 100-101, the applicant identifies any applicable energy saving and water conservation features that will be incorporated into the construction plans.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Comments
- Response to comments

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

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

## C Both Applicants

# F-12285-22/ NH Matthews /Acquire one fixed MRI scanner

In Section L, page 96, the applicant provides the historical payor mix during calendar year 2021 for the proposed services, as shown in the table below:

PAYOR CATEGORY	MRI SERVICES AS PERCENT OF TOTAL
Self-Pay	1.8%
Charity Care	4.6%
Medicare	32.9%
Medicaid	9.1%
Insurance	48.5%
Other (Governmental)	3.2%
Total	100.0%

In Section L, page 97, the applicant provides the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	65.0%	51.7%
Male	34.9%	48.3%
Unknown	0.1%	0.0%
64 and Younger	67.6%	88.1%
65 and Older	32.4%	11.9%
American Indian	0.3%	0.9%
Asian	2.7%	6.5%
Black or African-American	20.2%	33.3%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	65.5%	56.6%
Other Race	8.1%	2.6%
Declined / Unavailable	3.0%	0.0%

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 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.

# F-12287-22/ OrthoCarolina / Acquire one fixed MRI scanner

In Section L, page 104 the applicant provides the historical payor mix at OrthoCarolina University during calendar year 2021 for its mobile MRI services, as shown in the table below:

PAYOR CATEGORY	MOBILE MRI SERVICES AS PERCENT OF TOTAL
Self-Pay	3.4%
Charity Care <sup>^</sup>	*
Medicare*	23.8%
Medicaid*	5.7%
Insurance*	62.0%
Workers Compensation	1.7%
TRICARE	2.3%
Other Government	1.1%
Total	100.0%

# ^The applicant states on page 104 that Charity Care is included in Self-Pay.\*Includes managed care plans

In Section L, page 105, the applicant provides the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	59.9%	51.7%
Male	40.1%	48.3%
Unknown	0.0%	0.0%
64 and Younger	75.0%	88.1%
65 and Older	25.0%	11.9%
American Indian	0.0%	0.9%
Asian	3.1%	6.5%
Black or African-American	39.2%	33.3%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	45.8%	45.7%
Other Race	0.0%	14.1%
Declined / Unavailable	11.9%	0.0%

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

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

C Both Applications

# F-12285-22/ NH Matthews /Acquire one fixed MRI scanner

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 98, the applicant states it is not under any obligation under any applicable federal regulations to provide such care.

In Section L, page 98, the applicant states that no patient civil rights access complaints have been filed against NH Matthews.

The Agency reviewed the:

- Application
- Exhibits to the application

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

# F-12287-22/ OrthoCarolina / Acquire one fixed MRI scanner

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 106, the applicant states that it has no obligation to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 106, the applicant states that no patient civil rights access complaints have been filed against OrthoCarolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

# C Both Applications

# F-12285-22/ NH Matthews /Acquire one fixed MRI scanner

In Section L, page 99, the applicant projects the following payor mix for the proposed MRI services during the third full fiscal year of operation following project completion, as shown in the table below:

PAYOR CATEGORY	PERCENTAGE OF TOTAL MRI	
	PATIENTS SERVED	
Self-Pay	3.0%	
Medicare*	42.9%	
Medicaid*	5.2%	
Insurance*	46.2%	
Other (Government)	2.7%	
Total	100.0%	

\*Including any managed care plans

On page 99, the applicant states charity care patients are in all payor categories.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.0% of total services will be provided to self-pay patients, 42.9% to Medicare patients and 5.2% to Medicaid patients.

On page 99, 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 because it is based on the historical payor mix for NH Matthews.

The Agency reviewed the:

- Application
- Exhibits to the application

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

# F-12287-22/ OrthoCarolina / Acquire one fixed MRI scanner

In Section L, page 108, the applicant projects the following payor mix for the proposed MRI services at OrthoCarolina University during the third full fiscal year of operation following project completion, as shown in the table below:

PAYOR CATEGORY	PERCENTAGE OF TOTAL MRI PATIENTS SERVED
Self-Pay^	3.16%
Medicare*	24.82%
Medicaid*	5.04%
Insurance*	62.37%
Workers Compensation	1.51%
TRICARE	2.05%
Other Government	1.06%
Total	100.0%

ORTHOCAROLINA		
PROJECTED PAYOR MIX, FY 2026		

\*Including any managed care plans

^The applicant states Charity Care is included in Self Pay.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.16% of total services will be provided to self-pay patients which includes charity care, 24.82% to Medicare patients and 5.04% to Medicaid patients.

On page 106, 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 because it is based on the applicant's historical payor mix for MRI services at the existing 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 based on the reasons stated above.

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

#### C Both Applications

# F-12285-22/ NH Matthews /Acquire one fixed MRI scanner

In Section L, page 100, the applicant adequately describes the range of means by which patients will have access to the proposed MRI 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.

# F-12287-22/ OrthoCarolina / Acquire one fixed MRI scanner

In Section L, page 111, 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

**Both Applications.** In Section M, the applicants describe the extent to which health professional training programs in the area have or will have access to the facility for training purposes and provide supporting documentation in the referenced exhibits.

The Agency reviewed the:

- Applications
- Exhibits to the applications

Based on that review, the Agency concludes that all of the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, all of the applications are 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.

## С

## Both Applications

The 2022 SMFP defines the service area for a fixed MRI scanner as "the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county." Therefore, for the purpose of this review, the fixed MRI service area is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in the Mecklenburg County service area, summarized from Table 17E-1, pages 353-354 of the 2022 SMFP:

Existing and Approved Fixed MRI Scanners in Mecklenburg County					
Provider	# OF FIXED	SERVICE TYPE	TOTAL MRI	ADJUSTED	
	SCANNERS		SCANS	TOTAL	
Atrium Health Pineville	2	Hospital Fixed	7,605	9,842	
Atrium Health University City	1	Hospital Fixed	5,800	7,309	
Carolinas Medical Center-Main	4	Hospital Fixed	16,816	23,426	
Carolinas Medical Center-Mercy	1	Hospital Fixed	5,136	6,621	
Novant Health Huntersville Medical Center	2	Hospital Fixed	7,735	9,384	
Novant Health Matthews Medical Center	1	Hospital Fixed	6,151	7,619	
Novant Health Mint Hill Medical Center	1	Hospital Fixed	2,990	3,550	
NHPMC-Charlotte*	1	Hospital Fixed	2,818	3,261	
NHPMC-Main	2	Hospital Fixed	11,372	15,299	
NHPMC – Novant Health Imaging Museum	1	Hospital Fixed	2,472	2,837	
Atrium Health Kenilworth Diagnostic Center^	1	Freestanding Fixed	0	0	
Carolina Neurosurgery & Spine Associates-Charlotte	1	Freestanding Fixed	3,834	4,028	
Carolinas Imaging Services-Ballantyne	1	Freestanding Fixed	4,230	4,842	
Carolinas Imaging Services-Huntersville	1	Freestanding Fixed	3,737	4,245	
Carolinas Imaging Services-Southpark	1	Freestanding Fixed	3,461	4,095	
Novant Health Imaging Ballantyne	1	Freestanding Fixed	2,855	3,201	
Novant Health Imaging Southpark**	1	Freestanding Fixed	0	0	
Novant Health Imaging-Southpark	1	Freestanding Fixed	4,185	4,559	
OrthoCarolina Ballantyne	1	Freestanding Fixed	7,863	8,081	
OrthoCarolina Spine Center	1	Freestanding Fixed	5,716	6,123	

#### Existing and Approved Fixed MRI Scanners in Mecklenburg County

\* Novant Health Presbyterian Medical Center

^ Not yet operational – See CON Project ID# F11760-19

\*\* Not yet operational-See CON Project ID# F-11946-20

# F-12285-22/ NH Matthews /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at Novant Health Matthews Medical Center. Upon project completion, NH Matthews will operate two fixed MRI scanners.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 104, the applicant states:

"NH Matthews expects the acquisition of a new MRI scanner to have a positive effect on competition in the service area because it will increase the current capacity of MRI scanner services in the service area. The current existing fixed MRI scanner at NH Matthews is stretched beyond the practical limits of its capacity. This creates delays in receiving scans or causes patients and physicians to seek MRI scans at other locations the GE SIGNA Hero 3T MRI scanner will allow more complex MRI scans to be performed in the south Mecklenburg County community."

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 104-105, the applicant states:

"Novant Health is delivering value and quality in outcomes through its Population Health Management programs. This approach encourages wellness and preventive care and managing existing conditions to slow or reverse the progression of disease, all while lowering the overall cost of care."

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

Regarding the impact of the proposal on quality, in Section N, pages 106-107, the applicant states:

"The Novant Health Utilization Review Plan is used at NH Matthews. Utilization Review consists of interdisciplinary professionals and supporting team members providing a wide range of functions for patients and the organization. ...

The Novant Health Risk Management Plan is used at NH Matthews. ... Risk Management identifies and presents risk exposures and assures pro-active risk assessments are conducted. ...

... NH Matthews strives to meet Novant Health's high level of quality when it operates the fixed MRI scanner."

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 107, the applicant states:

"NH Matthews provides services to all persons regardless of race, sex, age, religion, creed, disability, national origin, or ability to pay. ... Novant Health facilities and programs do not discriminate against the listed persons, or other medically underserved persons, regardless of their ability to pay. The Novant Health Charity Care Policy allows a patient with household income up to 300% of the Federal Poverty Level to seek Charity Care by completing a simple one-page form...."

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adetely demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services.

3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

## **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 based on all the reasons described above.

# F-12287-22/ OrthoCarolina / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at its existing outpatient medical clinic, OrthoCarolina University, in Charlotte.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 112, the applicant states:

"With this project to acquire one fixed MRI scanner, OrthoCarolina, as an experienced diagnostic imaging provider, is expecting to enhance competition in the service area by augmenting the medical diagnostic imaging services it currently offers in Mecklenburg County, and promoting improved patient access to quality, cost-effective, and accessible diagnostic imaging."

Regarding the impact of the proposal on cost effectiveness, in Section N, page 114, the applicant states:

"As a dedicated outpatient center, OrthoCarolina offers affordable prices on imaging exams, and for most patients the simplicity of one bill with no additional facility or radiology fee.

The proposed 1.5T wide-bore MRI scanner is modern technology and offers ease of operation, excellent imaging quality, patient comfort, along with high throughput and dependability, cost-effective capital and operating costs, and energy efficiency capabilities."

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

Regarding the impact of the proposal on quality, in Section N, page 115, the applicant states:

"OrthoCarolina is an experienced local provider of healthcare and diagnostic imaging services, and is dedicated to ensuring quality and patient safety through compliance with all applicable regulatory standards established regarding diagnostic imaging."

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 116, the applicant states:

"OrthoCarolina will continue to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or any other factor that would classify a patient as underserved."

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

# **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 based on all the reasons described 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 Applicants

# F-12285-22/ NH Matthews /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at Novant Health Matthews Medical Center. Upon project completion, NH Matthews will operate two fixed MRI scanners.

In Section Q, Form O, the applicant identifies the types of facilities owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 36 facilities owned, operated or managed by the applicant or a related entity.

In Section O.5, page 113, the applicant states that, during the 18 months immediately preceding the submittal of the application, one incident related to quality of care was identified on June 24, 2022 in one facility, Novant Health New Hanover Regional Medical Center. The applicant states it received documentation from CMS dated August 22, 2022 that confirms the facility is back in compliance. After reviewing and considering information provided by the applicant, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

# F-12287-22/ OrthoCarolina / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at its existing outpatient medical clinic, OrthoCarolina University, in Charlotte.

In Section Q, Form O, the applicant identifies the types of facilities owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 3 facilities owned, operated or managed by the applicant or a related entity.

In Section O.4, page 121, the applicant states that diagnostic centers are not required by the Division of Health Service Regulation to be licensed and therefore there are no licensing requirements. The applicant states that it has never had its Medicare or Medicaid provider agreement terminated, and that each of the facilities listed on Form O has provided quality care and has operated in compliance with the Medicare Conditions of Participation for the18 months preceding application submission. After reviewing and considering information provided by the applicant regarding its three facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183(b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any

facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

## **C-Both Applications**

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

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

## 10A NCAC 14C .2703 PERFORMANCE STANDARDS

- (a) An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:
  - (1) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;
- -C- **NH Matthews.** In Section C, page 57, the applicant identifies 11 existing fixed MRI scanners owned or operated by the applicant or a related entity located in the Mecklenburg County fixed MRI service area.
- -C- **OrthoCarolina.** In Section C, page 63 the applicant states OrthoCarolina owns and operates two fixed MRI scanners located in the Mecklenburg County fixed MRI scanner service area.
  - (2) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;
- -C- **NH Matthews.** In Section C, page 57, the applicant identifies one approved fixed MRI scanner owned or operated by the applicant or a related entity that will be located at Novant Health Imaging Southpark, in Mecklenburg County.
- -NA- **OrthoCarolina.** Neither the applicant nor any related entity has been approved to own or operate a fixed MRI scanner in the proposed fixed MRI scanner service area.
  - (3) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service area during the 12 months before the application deadline for the review period;
- -C- **NH Matthews.** In Section C, page 57, the applicant identifies two mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites in Mecklenburg County, the proposed fixed MRI scanner service area and has operated the scanners during the 12 months before the application deadline for this review.

- -C- **OrthoCarolina.** In Section C, page 63 the applicant states OrthoCarolina owns and operates one mobile MRI scanner that provides mobile MRI services at host sites in Mecklenburg County, the proposed fixed MRI scanner service area, and has operated the scanner during the 12 months before the application deadline for this review.
  - (4) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area;
- -NA- **NH Matthews.** Neither the applicant nor any related entity has been approved to own or operate an additional mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.
- -NA- **OrthoCarolina.** Neither the applicant nor any related entity has been approved to own or operate a mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.
  - (5) provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed MRI scanner during each of the first three full fiscal years of operation following completion of the project;
- -C- **NH Matthews.** In Section Q, "*Utilization Methodology and Assumptions*", the applicant provides projected utilization for all of its existing, approved and proposed fixed and mobile MRI scanners during each of the first three full fiscal years of operation following project completion.
- -C- **OrthoCarolina.** In Section Q, Form C.2b, the applicant provides projected utilization for its existing fixed and mobile MRI scanners, and the proposed fixed MRI scanner during each of the first three full fiscal years of operation following project completion.
  - (6) provide the assumptions and methodology used to project the utilization required by Subparagraph (5) of this Paragraph;
- -C- **NH Matthews.** In Section Q, "*Utilization Methodology and Assumptions*", the applicant provides assumptions and methodology for all of its existing, approved and proposed fixed and mobile MRI scanners during each of the first three full fiscal years of operation following project completion.
- -C- **OrthoCarolina.** In Section Q, *"Form C.2.b Assumptions and Methodology"*, the applicant provides the assumptions and methodology used to project utilization for all of its existing and proposed fixed and mobile MRI scanners during each of the first three full fiscal years of operation following project completion.
  - (7) project that the fixed MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed MRI scanner shall perform during the third full fiscal year of operation following completion of the project as follows:

- (A) 3,364 or more adjusted MRI procedures per fixed MRI scanner if there are four or more fixed MRI scanners in the fixed MRI scanner service area;
- (B) 3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI scanners in the fixed MRI scanner service area;
- (C) 2,883 or more adjusted MRI procedures per fixed MRI scanner if there are two fixed MRI scanners in the fixed MRI scanner service area;
- (D) 2,643 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or
- (E) 1,201 or more adjusted MRI procedures per fixed MRI scanner if there are no existing fixed MRI scanners in the fixed MRI scanner service area.

There are currently 27 existing fixed MRI scanners in the fixed MRI scanner service area; thus, Subparagraph (A) applies to this review.

- -C- **NH Matthews.** In Section C, page 58, the applicant projects to provide in excess of 3,364 adjusted MRI procedures per MRI scanner during the third full fiscal year of operation following project completion on each of its existing and proposed fixed MRI scanners. The full methodology and assumptions are provided in Section Q. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- -C- **OrthoCarolina.** In Section Q, Forms C.2.b for each MRI scanner, the applicant projects to provide in excess of 3,364 adjusted MRI procedures per MRI scanner during the third full fiscal year of operation following project completion. The full methodology and assumptions are provided in Section Q. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
  - (8) project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform 3,328 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal year of operations following completion of the project.
- -C- **NH Matthews.** In Section C, page 59, the applicant projects to provide 3,328 or more adjusted MRI procedures during the third full fiscal year of operation following project completion on each of its mobile MRI scanners. The full methodology and assumptions are provided in Section Q. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- -NA- **OrthoCarolina.** In Section Q, the applicant projects to provide 3,328 or more adjusted MRI procedures during the third full fiscal year of operation following project completion on its mobile MRI scanner. The full methodology and assumptions are provided in Section Q. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (b) An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;
- (2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;
- (3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;
- (4) *identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that will be located in the proposed mobile MRI scanner service area;*
- (5) identify the existing and proposed host sites for each mobile MRI scanner identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile MRI scanner;
- (6) provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed mobile MRI scanner during each of the first three full fiscal years of operation following completion of the project;
- (7) provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;
- (8) project that the mobile MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile MRI scanner shall perform 3,328 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operations following completion of the project; and
- (9) project that the fixed MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform during the third full fiscal year of operations following completion of the project:
  - (A) 3,364 or more adjusted MRI procedures per fixed MRI scanner if there are four or more fixed MRI scanners in the fixed MRI scanner service area;
  - (B) 3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI scanners in the fixed MRI scanner service area;
  - (C) 2,883 or more adjusted MRI procedures per MRI scanner if there are two fixed MRI scanners in the fixed MRI scanner service area;
  - (D) 2,643 or more adjusted MRI procedures per MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or
  - (E) 1,202 or more adjusted MRI procedures per MRI scanner if there are no fixed MRI scanners in the fixed MRI scanner service area.
- -NA- **NH Matthews.** The applicant does not propose to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period.

-NA- **OrthoCarolina.** The applicant does not propose to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period.

## **COMPARATIVE ANALYSIS**

Pursuant to G.S. 131E-183(a)(1) and the 2022 State Medical Facilities Plan, no more than one fixed MRI scanner may be approved for the Mecklenburg County fixed MRI service area in this review. Because the two applications in this review collectively propose to develop two additional fixed MRI scanners to be located in Mecklenburg County, both of the applications cannot be approved. Therefore, after considering all 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.

Below is a brief description of each project included in this review:

## • F-12285-22/ NH Matthews /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at Novant Health Matthews Medical Center. Upon project completion, NH Matthews will operate two fixed MRI scanners.

## • F-12287-22/ OrthoCarolina / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at its existing outpatient medical clinic, OrthoCarolina University, in Charlotte.

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

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved. Both applications are conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, both applications are equally effective alternatives.

## **Geographic Accessibility (Location within the Service Area)**

The 2022 SMFP identifies the need for one fixed MRI scanner in the Mecklenburg County fixed MRI service area.

According to the 2022 SMFP, there are currently 27 fixed MRI scanners in Mecklenburg County, located primarily in Charlotte and Matthews, with others in other areas of the county to the north, east and south of Charlotte. The application submitted by **NH Matthews** proposes to locate the proposed fixed MRI scanner at the hospital in Matthews. The application submitted by **OrthoCarolina** proposes to locate the proposed fixed MRI scanner in Charlotte. Each of the applicants proposes to locate its proposed fixed MRI scanner in a community that currently has fixed MRI services; therefore, regarding this comparative factor, both applications are equally effective.

## **Competition**

Generally, the application proposing to increase competition in the service area is the more effective alternative with regard to this comparative factor. The introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer fixed MRI scanners than another provider would also potentially encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

The following table identifies the number of existing and approved fixed MRI scanners for each applicant as a percent of the total existing and approved Mecklenburg County fixed MRI scanners, based on Table 17E1 of the 2022 SMFP. The table shows a total of 26 existing and approved fixed MRI scanners in Mecklenburg County, excluding the need determination for one fixed MRI scanner in the 2021 SMFP:

LOCATION / PROVIDER		APPLICANTS' FIXED MRI SCANNERS AS A PERCENT OF TOTAL SERVICE AREA
	NUMBER OF FIXED MAGNETS	MAGNETS
Novant Health Matthews Medical Center	1	
Novant Health Mint Hill Medical Center	1	
NHPMC-Charlotte*	1	
NHPMC-Main	2	
NHPMC – Novant Health Imaging Museum	1	
Novant Health Imaging Ballantyne	1	
Novant Health Imaging Southpark**	1	
Novant Health Imaging-Southpark	1	
Novant Health System	9	33.3%
OrthoCarolina Ballantyne	1	
OrthoCarolina Spine Center	1	
OrthoCarolina	2	7.4%

Applicants' Existing and Approved Mecklenburg County Fixed MRI Scanners as a Percent of Total

\* Novant Health Presbyterian Medical Center

\*\* Not yet operational-See CON Project ID# F-11946-20

As shown in the table above, the Novant Health System controls 33.3 percent of the existing and approved fixed MRI scanners in Mecklenburg County, and OrthoCarolina controls 7.4 percent of the existing and approved fixed MRI scanners in Mecklenburg County. Therefore, with regard to increasing competition for fixed MRI services in the Mecklenburg County fixed MRI service area, the application submitted by **OrthoCarolina** represents a more effective alternative.

## 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 ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority."

For access by underserved groups, applications are compared with respect to two underserved groups: Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

## **Projected Medicare**

The following tables show each applicant's percentage of gross revenue (charges) projected to be provided to Medicare patients, and the projected number of MRI procedures to be provided to Medicare patients, in the applicant's third full fiscal year of operation following completion of their projects, based on the information provided in the applicant's pro forma financial statements in Section Q. Generally, the application proposing to provide a higher percentage to services and higher number of MRI procedures to Medicare patients is the more effective alternative with regard to this comparative factor.

Total Services to Medical e Patients - Project Teal S					
	Medicare Gross Total Gross Medicare % of Total				
Applicant	Revenue	Revenue	Gross Revenue		
NH Matthews	\$16,959,729	\$39,533,167	42.9%		
OrthoCarolina	\$1,267,412	\$5,106,925	24.8%		

**Total Services to Medicare Patients - Project Year 3** 

Source: Form F.2 for each applicant.

Applicant	Total MRI Procedures (Unweighted)	Total MRI Procedures for Medicare Patients	Total MRI Procedures for Medicare Patients per MRI Scanner*
NH Matthews	9,069	3,890	1,945
OrthoCarolina	3,627	900	900

#### Number of Scans Provided to Medicare Patients - Project Year 3

Source: Form C.2.b and Form F.2 for each applicant.

\*NH Matthews would operate two fixed MRI scanners upon project completion.

As shown in the tables above, the application submitted by **NH Matthews** projects that 42.9% of its MRI services will be provided to Medicare patients, and that it will provide a total of 3,890 MRI procedures to Medicare patients, or 1,945 MRI procedures per MRI scanner, in the third year of the project. The application submitted by **OrthoCarolina** projects that 24.8% of its MRI services will be provided to Medicare patients, and that it will provide a total of 900 MRI procedures to Medicare patients, in the third year of the project. Therefore, with regard to service to Medicare patients, the application submitted by **NH Matthews** is the more effective alternative.

## **Projected Medicaid**

The following tables show each applicant's percentage of gross revenue (charges) projected to be provided to Medicaid patients, and the projected number of MRI procedures to be provided to Medicaid

patients, in the applicant's third full fiscal year of operation following completion of their projects, based on the information provided in the applicant's pro forma financial statements in Section Q. Generally, the application proposing to provide a higher percentage to services and higher number of MRI procedures to Medicaid patients is the more effective alternative with regard to this comparative factor.

Services to Medicaid Patients - Project Year 3				
Medicaid Gross Total Gross Medicaid % of Tot   Revenue Revenue Gross Revenue				
Novant Health Matthews Medical Center	\$2,055,725	\$39,533,167	5.2%	
OrthoCarolina University	\$257,513	\$5,106,925	5.0%	

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Source: Form F.2 for each applicant.

Number of Scans Provided to Medicald Patients - Project Year 3			
Applicant			Total MRI
	Total MRI Procedures (Unweighted)	Total MRI Procedures for Medicaid Patients	Procedures for Medicaid Patients per MRI Scanner*
NH Matthews	9,069	472	236
OrthoCarolina	3,627	183	183

# Number of Coope Drovided to Medicaid Datients - Droject Veer 2

Source: Form C.2.b and Form F.2 for each applicant.

\*NH Matthews would operate two fixed MRI scanners upon project completion.

As shown in the tables above, the application submitted by NH Matthews projects that 5.2% of its MRI services will be provided to Medicaid patients, and that it will provide a total of 472 MRI procedures to Medicaid patients, or 236 MRI procedures per MRI scanner, in the third year of the project. The application submitted by OrthoCarolina projects that 5.0% of its MRI services will be provided to Medicaid patients and that it will provide a total of 183 MRI procedures to Medicaid patients in the third year of the project. Therefore, with regard to service to Medicaid patients, the application submitted by NH Matthews is the more effective alternative.

## **Projected Average Net Revenue per Weighted MRI Procedure**

The following table compares the projected average net revenue per weighted MRI procedure for the third year of operation following project completion for all the applicants, based on the information provided in the applicants' pro forma financial statements (Section Q). Generally, the application proposing the lowest average net revenue per MRI procedure is the more effective alternative with regard to this comparative factor.

	Net Revenue	# of Weighted MRI Procedures	Average Net Revenue/Weighted MRI Procedure
Novant Health Matthews Medical Center	\$10,373,503	11,351	\$914
OrthoCarolina University	\$1,899,068	3,691	\$515

#### Net Revenue per Weighted MRI Procedure - Project Year 3.

Source: Form F.2 for each application. Weighted procedures from Form C.2b of the applications.

As shown in the table above, the application submitted by **OrthoCarolina** projects the lowest net revenue per weighted MRI procedure in the third operating year. Therefore, the application submitted

by **OrthoCarolina** is the most effective application with respect to average net revenue per weighted MRI procedure.

## Projected Average Operating Expense per Weighted MRI Procedure

The following table compares the projected average operating expense per weighted MRI procedure in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements (Form F.2). Generally, the application proposing the lowest average operating expense per MRI procedure is the more effective alternative with regard to this comparative factor.

## Projected Operating Expense per Weighted MRI Procedure - Project Year 3

	Operating Expenses*	# of Weighted MRI Procedures	Average Operating Expenses/Weighted MRI Procedure
Novant Health Matthews Medical Center	\$2,733,237	11,351	\$241
OrthoCarolina University	\$1,439,340	3,691	\$390

Source: Form F.2 for each application. Weighted procedures from Form C.2b of the applications.

\*NH Matthews did not include professional fees in its projected operating expenses. Therefore, professional fees were deducted from the projected operating expenses for OrthoCarolina for this comparison.

As shown in the table above, the application submitted by **NH Matthews** projects the lowest average operating expense per weighted MRI procedure in the third operating year. Therefore, the application submitted by **NH Matthews** is the most effective application with respect to operating expense per weighted MRI procedure.

## <u>Summary</u>

The following table lists the comparative factors and indicates whether each application was more effective or less 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.

Comparative Factor	NH Matthews	OrthoCarolina
Conformity with Review Criteria	Yes	Yes
Geographic Accessibility	Equally Effective	
Competition (Access to new or alternate provider)	Less effective	More effective
Access by Medicare Patients	More effective	Less effective
Access by Medicaid Patients	More Effective	Less effective
Average Net Revenue per MRI Procedure	Less effective	More Effective
Average Operating Expense per MRI Procedure	More Effective	Less effective

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 two fixed MRI scanners in the Mecklenburg County fixed MRI service area, and the need determination in the 2022 SMFP is for only one fixed MRI scanner. Therefore, only one fixed MRI scanner in the service area can be approved.

As shown in the table above, **NH Matthews** was determined to be a more effective alternative for the following three factors:

- Access by Medicare patients
- Access by Medicaid patients
- Projected average operating expense per weighted MRI procedure

As shown in the table above, **OrthoCarolina** was determined to be a more effective alternative for the following two factors:

- Competition
- Projected average net revenue per weighted MRI procedure

# DECISION

Each application is individually conforming to the need determination in the 2022 SMFP for one fixed MRI scanner in the Mecklenburg County fixed MRI service area, as well as individually conforming to all statutory and regulatory review criteria. However, G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed MRI scanners that can be approved by the Healthcare Planning and Certificate of Need Section.

Based upon the independent review of each application and the Comparative Analysis, the following application is approved:

• Project I.D. # F-12285-22 / Novant Health, Inc. and Presbyterian Medical Care Corporation / Acquire one fixed MRI scanner pursuant to the 2022 SMFP need determination

And the following application is denied:

• Project I.D. # F-12287-22 / OrthoCarolina, P.A. / Acquire one fixed MRI scanner pursuant to the 2022 SMFP need determination

Project I.D. # F-12285-22 / Novant Health, Inc. and Presbyterian Medical Care Corporation is approved subject to the following conditions:

- 1. Novant Health Inc. and Presbyterian Medical Care Corporation (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
- 2. The certificate holder shall acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP to be located in the Novant Health Matthews Medical Center, for a total of two fixed MRI scanners at Novant Health Matthews Medical Center.

- 3. Progress Reports:
  - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <u>https://info.ncdhhs.gov/dhsr/coneed/progressreport.html</u>.
  - b. The certificate holder shall complete all sections of the Progress Report form.
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
  - d. The first progress report shall be due on September 1, 2023.
- 4. The certificate holder 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, the certificate holder 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. The certificate holder 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.