#### **REQUIRED STATE AGENCY FINDINGS**

#### FINDINGS C = Conforming

CA = Conforming as Conditioned NC = Nonconforming NA = Not Applicable

Decision Date: Findings Date:	June 25, 2024 June 25, 2024
Project Analyst: Co-Signer:	Yolanda W. Jackson Michael J. McKillip
Project ID #:	G-12510-24
Facility:	Davie Medical Center
FID #:	080175
County:	Davie
Applicants:	Davie Medical Center
	North Carolina Baptist Hospital
Project:	Acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP need determination for a total of no more than two fixed MRI scanners upon project completion

#### **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.

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Davie Medical Center and North Carolina Baptist Hospital, herein after collectively referred to as "the applicant," propose to acquire no more than one fixed MRI scanner pursuant to the need determination in the 2024 State Medical Facilities Plan (SMFP) to be located at Davie Medical Center (DMC) in Davie County. Upon project completion, Davie Medical Center will operate two fixed MRI scanners.

#### Need Determination

The 2024 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

2024 SMFP identified a need for one fixed MRI scanner in Davie County. The application was submitted in response to the need determination in the 2024 SMFP for one fixed MRI scanner in Davie County. Therefore, the application is consistent with the need determination in the 2024 SMFP.

## **Policies**

Two policies in Chapter 4 of the 2024 SMFP are applicable to this application: Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

## **Policy GEN-3**

Policy GEN-3 on page 29 of the 2024 SMFP states:

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

In Section B, pages 25-26, the applicant explains why it believes its application is consistent with Policy GEN-3. The applicant states that DMC is dedicated to ensuring quality care and patient safety through compliance with all applicable federal, state, and local standards established regarding MR imaging and will maintain the highest standards and quality of care that DMC has sustained throughout its history of providing diagnostic imaging services. The proposed project will improve local access to MRI services for residents of Davie County and surrounding communities. DMC will continue to be accessible to all persons, including those in underserved groups. In Section N, page 98, the applicant states that the proposed MRI scanner will enable a higher volume of MRI procedures per day, thus containing the cost per procedure and as an existing MRI provider, DMC will leverage its existing MRI ancillary services for economies of scale in operating the additional fixed MRI scanner.

#### **Policy GEN-4**

Policy GEN-4 on page 30 of the 2024 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."

The proposed capital expenditure for this project is greater than \$5 million. In Section B, pages 26-27, the applicant describes the project's plan to improve energy efficiency and water conservation. The applicant states:

"Davie Medical Center will conform to the energy efficiency and water conservation rules, codes, and standards implemented by the Construction Section of the Division of Health Service Regulation and required by the North Carolina Building Code. During the design of this project, DMC will work with the project architects and engineers to assure that the latest technologies for enhanced building energy and water conservation are evaluated for the project and incorporated into the facility where most appropriate. The goal of this effort will be to maximize energy efficiency and water conservation, while creating the best possible care and healing environments for patients."

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant 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 based on the following:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of fixed MRI services in Davie County.

- The applicant adequately documents how the project will promote equitable access to fixed MRI services in Davie County.
- The applicant adequately documents how the project will maximize healthcare value for the resources expended.
- The applicant adequately documents that it has a plan in place to ensure water and energy conservation in the development of the proposed project.
- (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

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP need determination for a total of no more than two fixed MRI scanners upon project completion.

## Patient Origin

On page 335, the 2024 SMFP defines the fixed MRI service area as "... *the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1.*" Therefore, for the purpose of this review, the fixed MRI service area is Davie County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin for MRI services for DMC.

		DMC MRI Services			
County	-	torical 2023	Third Full FY of Operation following Project Completion CY 2028		
	Patients	% of Total	Patients	% of Total	
Forsyth	932	27.95%	1,234	27.95%	
Davie	907	27.20%	1,201	27.20%	
Iredell	261	7.83%	346	7.83%	
Yadkin	182	5.46%	241	5.46%	
Catawba	167	5.01%	221	5.01%	
Surry	86	2.58%	114	2.58%	
Wilkes	74	2.22%	98	2.22%	
Davidson	63	1.89%	83	1.89%	
Rowan	51	1.53%	68	1.53%	
Stokes	50	1.50%	66	1.50%	
Guilford	48	1.44%	64	1.44%	
Watauga	37	1.11%	49	1.11%	
Alexander	36	1.08%	48	1.08%	
Caldwell	33	0.99%	44	0.99%	
Other NC Counties**	253	7.59%	335	7.59%	
Other States	155	4.65%	205	4.65%	
Total	3,335	100.0%	4,416	100.0%	

Source: Section C, pages 32 and 34

\*\*Includes other North Carolina counties, each of which represents <1% of total patient origin. Note: Totals may not foot due to rounding.

In Section Q, page 114, 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 experience providing fixed MRI services to patients in the service area.

#### Analysis of Need

In Section C, pages 36-44, the applicant explains why it believes the population projected to utilize the proposed fixed MRI services needs the proposed services as summarized below:

• MRI Utilization Rate in Davie County – The applicant states that MRI utilization throughout North Carolina has trended upward over the most recent five-year reporting period; however, the MRI use rate in Davie County was consistently much lower for the same five-year reporting period than the comparable North Carolina MRI use rate. The applicant states that the lower rate is due to the lack of MRI capacity in Davie County and that during FFY2022, 3,393 of the 4,218 (80.41%) Davie County residents who were MRI patients received their MRI scans outside of Davie County. The applicant states that having a second fixed MRI scanner at DMC would benefit Davie county residents by providing more timely local access to MRI services, thus supporting the SMFP goals of providing geographic access to high quality healthcare services.

- **Population growth and aging in the service area** –The applicant states that the population in Davie County projects growth that is consistent with the overall projected North Carolina population growth according to the North Carolina Office of State Budget & Management (NCOSBM) data. The applicant states that on-going economic development in Davie County supports the projection of continued population growth in Davie County and that Davie County is home to a growing segment of residents age 65+ and that these factors will continue to create ongoing demand for diagnostic MR imaging capacity.
- **Population Health Characteristics** The applicant states that according to the North Carolina Institute of Medicine's Health Profile for Davie County, 21.7% of Davie County adults are obese, putting them at greater risk for orthopedic injuries The applicant states that due to the correlation of obesity and musculoskeletal damage, there is an existing and growing population in Davie County that will require MRI services for the evaluation of orthopedic injuries.
- **Referring Physician/Provider Support** The applicant states that Davie Medical Center has long-standing positive working relationships with the referring physician/provider community in Davie County and surrounding counties and anticipates that its network of referring physicians will continue to refer patients to Davie Medical Center for MR imaging services, just as they have been for many years.

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

- Davie County residents are having to travel outside the county to receive MR imaging due to a lack of MRI capacity in Davie County. The applicant states that during FFY2022, only 825 of 4,218 MRI scans performed on Davie County residents occurred in Davie County (page 38).
- The applicant states that according to NCOSBM data, Davie County population projected growth is consistent with the overall projected growth for North Carolina and that Davie County's growing population of residents aged 65+ will continue to create ongoing demand for diagnostic MR imaging capacity. (pages 38-39).
- The applicant states that health and prevention statistics from the North Carolina State Center for Health Statistics indicates that Davie County residents will continue to see the need for MRI scans because 21.7% of Davie County residents are obese which puts those residents at greater risk for orthopedic injuries (pages 41-42).

## Projected Utilization

In Section Q, Forms C.2a and C.2b, pages 109-110, the applicant provides historical and interim utilization for MRI services at DMC for calendar year (CY) 2023-2025 and projected utilization for MRI services through all three project years (CY 2026-2028), as illustrated in the following table:

Davie Medical Center	Historical and Interim Utilization			Pro	jected Utiliza	tion
	CY2023 CY2024 CY2025		CY2026	CY2027	CY2028	
# of Units (fixed MRI)	1	1	1	2	2	2
# of Procedures	4,170	4,437	4,687	4,950	5,228	5,522
# of Weighted Procedures	4,762	5,054	5,337	5,637	5,954	6,288

Source: Section Q, Forms C.2a and C.2b, pages 109-110

In Section Q, pages 112-114, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The applicant begins projections with the historical utilization of DMC's one fixed MRI scanner.

Davie Medical Center Historical MRI Utilization CY 2021 - 2024						
CY2021 CY2022 CY2023 CY2024 2-YR 3-YI Annualized CAGR CAG						
Unweighted Procedures	2,781*	3,618	4,170	4,437**	22.45%	16.85%

Source: Section Q, page 112

\*Note: This total includes 1,008 scans performed on a leased mobile scanner, and 1,773 scans performed on the newly installed fixed scanner that replaced the leased mobile MRI service.

\*\*Based on actual January/February 2024 utilization, annualized for CY2024.

Based on the estimated CY2024 annualized volume, the three-year (CY2021-CY2024) CAGR is 16.85%.

To project future utilization, DMC projects an increase in utilization from CY2025 through CY2028 based on one-third of the historical (CY2021-CY2024) compound annual growth rate (CAGR) of 16.85, or 5.62% (16.85/3), as shown in the following table:

Dave Medical Center						
Projected Fixed MRI Scanner Utilization (Unadjusted), CY2025 - CY2028						
CY2025 CY2026 CY2027 CY2028 4-YR CAGR						
Unweighted Procedures	4,687	4,950	5,228	5,522	5.62%	

Source: Section Q, page 112

The applicant summarizes the most recent adjusted (or weighted) historical utilization of the fixed scanner at DMC and the historical MRI procedures are categorized as either inpatient or outpatient, and either with or without contrast and/or sedation as shown in the following table:

Davie Medical Center Historical Adjusted MRI Procedures, CY2022 – CY2023						
Type of MRI Procedure	CY2022	CY2023 Unweighted	Weight Factor	CY2022 Weighted	CY2023 Weighted	Two-Year Combined Weighted
IP without contrast/sedation	93	105	1.82	169	191	360
IP with contrast/sedation	85	98	2.12	180	208	388
OP without contrast/sedation	1,939	2,101	1.00	1,939	2,101	4,040
OP with contrast/sedation	1,501	1,866	1.21	1,819	2,262	4,081
Total Weighted MRI Procedures	0	0	0.00	4,108	4,762	8,869
Total Unweighted MRI Procedures	3,618	4,170	0.00	3,618	4,170	7,788
Weighted Factor				1.135	1.142	1.139

Source: Section Q, page 113

\*Data reported for calendar years, which differs from federal fiscal year data shown in SMFPs.

To calculate the projected adjusted (or weighted) MRI procedures, DMC used the most recent two-year (CY2022-CY2023) combined average weighted MRI procedure ratio of 1.139, held the factor constant through CY2028, and multiplied it by the projected annual unadjusted DMC MRI procedures calculated above. This is shown in the following table.

Dave Medical Center Projected Fixed MRI Scanner Utilization (Adjusted), CY2025 – CY2028						
	CY2025	CY2026	CY2027	CY2028	3-YR CAGR	
Unweighted	4,687	4,950	5,228	5,522	5.62%	
Procedures						
Weighting Factor	1.139	1.139	1.139	1.139		
Weighted Procedures	5,337	5,637	5,954	6,288	5.62%	
Weighted Procedure	5,337	2,819	2,977	3,144		
per Scanner						
.2703 Performance				3,058		
Standard						

Source: Section Q, page 113

To project the MRI patients for CY2025-CY2028, DMC applied its CY2023 procedure/patient ratio of 1.25 (4,170/3,335) and held it constant through CY2028. Based on the 1.25 ratio, the table below portrays the projected MRI patients at DMC for CY2025-CY2028.

Dave Medical Center Projected MRI Patients, CY2025 – CY2028							
CY2025 CY2026 CY2027 CY2028 3-YR CAGR							
Unweighted Procedures	4,687	4,950	5,228	5,522	5.62%		
CY2023 Proc/Patient Ratio 1.25 1.25 1.25 1.25							
MRI Patients	3,748	3,959	4,181	4,416			

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

- The applicant relied on its historical MRI utilization as the starting point for projecting future utilization.
- The applicant relied on population growth projections from reliable sources to determine population growth in the service area.
- The applicant relied on specific demographic data to analyze the aging of the population in the service area, and the population in the service area most likely to utilize MRI services.

## Access to Medically Underserved Groups

In Section C, page 49, the applicant states that the Atrium Health Wake Forest Baptist (AHWFB) non-discrimination policy is used by DMC and is included as Exhibit C.6. The Notice of Non-Discrimination and Accessibility Services states,

"Wake Forest Baptist Health complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, religion, national origin, age, sex, sexual orientation, gender identity, gender expression, disability or source of payment. Wake Forest Baptist does not exclude people or treat them differently because of race, color, religion, national origin, age, sex, sexual orientation, gender identity, gender expression, disability or source of payment."

The applicant states that DMC is fully committed to the health and well-being of all patients and will continue to provide hospital services (including MR imaging) to all persons in need of medical care.

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

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Medically Underserved Groups	Percentage of Total Patients
Low income persons*	11.4%
Racial and ethnic minorities**	19.5%
Women**	55.7%
Persons with Disabilities*	12.7%
Persons 65 or older**	31.8%
Medicare beneficiaries**	48.5%
Medicaid recipients**	6.6%

Source: Section C, page 50

\*Davie Medical Center does not track income demographics or disability status of its patients. Estimates are based on the most recent available U.S. Census Bureau demographics for Davie County. \*\*Based on the historical access to MRI services by these medically underserved groups at Davie Medical Center during CY2023.

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 states that it will provide access to all underserved groups.
- The applicant states the percentages of patients in each group listed above are based on recent facility experience.
- The applicant provides supporting documentation of the access it provides and programs to assist the underserved in Section L.

#### **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.

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

#### NA

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

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

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The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP need determination for a total of no more than two fixed MRI scanners upon project completion.

In Section E, pages 60-63, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain Status Quo The applicant states that one alternative was to do nothing; however, this was not the most effective alternative for several reasons. The 2024 SMFP identified a need for one fixed MRI scanner in Davie County. The applicant states that utilization of the fixed MRI scanner at DMC has grown steadily and most Davie County resident who need an MRI scan are either leaving the county or foregoing obtaining a scan. The applicant states that it is important from a health planning perspective to improve local access to MRI Services in Davie County to meet patients' MR imaging needs. Therefore, this is the less effective alternative.
- **Develop the Proposed Diagnostic Center in Another Davie County Location** The applicant states that DMC patients benefit from the convenient location of the hospital near their physician's offices, and timely access to diagnostic imaging services. The applicant states that the hospital location is within 20-25 minutes' drive for all Davie County residents, and within 15 minutes for most county residents. The applicant states that development of the fixed MRI scanner at a different location would entail either constructing or upfitting a different building to accommodate the scanner and would also involve developing additional ancillary and support spaces at the new location. Also, an MRI scanner located away from the hospital would only be able to serve outpatient and not inpatients or emergency patients. Therefore, this is not the most effective alternative.
- Acquire Different MRI Equipment The applicant considered acquiring a 1.5T scanner; however, the applicant plans to obtain a 3.0 Tesla (3T) fixed scanner because the applicant states that the 3T scanner offers the following advantages:
  - More scanning options for doctors that are not available in lower-power models of MRI scanners.
  - Higher resolution which produces more detailed images.
  - Higher detailed images in less time.
  - A lower risk of distorted images which lessens the need for repeated scans.
  - Patients with claustrophobia have more room and are less likely to request sedation and larger patients have an easier time getting a high-quality scan because they can fit into the MRI machine.

The applicant states that exam charges will be the same regardless of whether the exam is performed on a 1.5T or a 3.0T magnet, therefore the insurance plan cost will be the same for the higher level of technology.

The applicant also considered acquisition of a dedicated extremity scanner. The applicant states that the scanning duration is significantly longer for an extremity MRI and a standard MRI scanner provider superior image quality compared with extremity scanner. Therefore, an extremity scanner is a less effective alternative.

• Contract Access on a Leased Mobile MRI Scanner – The applicant considered contracting for supplemental mobile MRI scanner coverage. The applicant states that a mobile MRI scanner is not capable of addressing all of the needs of DMC's patient populations. Patients with additional medical equipment are not able to utilize mobile MRI units due to space constraints. Claustrophobic, pediatric, and obese patients are also limited in their ability to utilize mobile MRI units. Furthermore, the applicant states that mobile MRI scanner rentals are relatively expensive, which does not secure affordable long-term access. Therefore, contracting a mobile MRI scanner is a less effective alternative.

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

- The 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. Therefore, the application can be approved.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

1. Davie Medical Center and North Carolina Baptist Hospital (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.

- 2. The certificate holder shall acquire no more than one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at Davie Medical Center.
- **3.** Upon completion of the project, Davie Medical Center shall have no more than two fixed MRI scanners.
- 4. The certificate holder shall 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.
- 5. Progress Reports:
  - a. Pursuant to G.S. 131E-189(a), the certificate holders 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:. https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.
  - 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 January 1, 2025.
- 6. 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.
- 7. 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.
- (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.

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The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP need determination for a total of no more than two fixed MRI scanners upon project completion.

## **Capital and Working Capital Costs**

In Section Q, Form F.1a, page 115, the applicant projects the total capital cost of the project as shown in the table below.

Davie Medical Center Projected Capital Costs				
Construction/Renovation Contract(s)	\$1,048,581			
Architect/Engineering Fees	\$190,000			
Medical Equipment	\$3,680,000			
Non-Medical Equipment	\$26,000			
Furniture	\$2,000			
Consultant Fees	\$65,507			
Other (IT, contingency, misc. taxes & fees)	\$573,714			
Total	\$5,585,802			

In Section Q, page 115, 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:

- The applicant projects construction cost based on the contractor's estimate.
- The cost of medical equipment is based on vendor quotation.
- Architect/Engineering fees, Furniture and other costs are based on Atrium Health Wake Forest Baptist (AHWFB) experience.

In Section F.3, page 66, the applicant states there will be no working capital costs because DMC is an existing and operational acute care hospital currently offering MRI services.

## Availability of Funds

In Section F, page 65, the applicant states the capital cost will be funded through the accumulated reserves of DMC.

Exhibit F.2 contains a letter signed by the Senior Vice President and Chief Financial Officer for AHWFB which commits to funding the capital cost from accumulated reserves of AHWFB which includes Davie Medical Center. North Carolina Baptist Hospital is the parent company of Davie Medical Center. Wake Forest University Baptist Medical Center is the parent company of North Carolina Baptist Hospital. Exhibit F.2 also contains the most recent AHWFB audited financial statements documenting the availability of the necessary funds.

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

- The applicant provides documentation of AHWFB's commitment to use the necessary funding toward development of the proposed project.
- The applicant documents the availability of sufficient financial resources to fund the proposed capital cost.

## **Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F.2b, page 117, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years (FY) following project completion, as shown in the table below:

MRI Services	1 <sup>st</sup> Full FY CY 2026	2 <sup>nd</sup> Full FY CY 2027	3 <sup>rd</sup> Full FY CY 2028
# of Scans (Weighted)	5,637	5,954	6,288
Total Gross Revenues (Charges)	\$20,057,277	\$22,031,398	\$24,199,821
Total Net Revenue	\$3,998,042	\$4,391,546	\$4,823,781
Average Net Revenue per Weighted MRI Scan	\$709	\$738	\$767
Total Operating Expenses (Costs)	\$2,484,971	\$2,674,641	\$2,596,884
Average Operating Costs per Weighted MRI Scan	\$441	\$449	\$413
Net Income	\$1,513,071	\$1,716,905	\$2,226,897

Source: Section Q, Form F.2b, Page 117

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section F, page 68 and 70. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant's projected MRI operating expenses and revenue are based on its own experience offering MRI services and revenue and expense data provided by DMC and AHWFB staff.
- Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of 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.

С

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP need determination for a total of no more than two fixed MRI scanners upon project completion.

On page 335, the 2024 SMFP defines the fixed MRI scanner service area as "... *the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1*". Therefore, for the purpose of this review, the fixed MRI scanner service area is Davie County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the one existing and approved fixed MRI scanner located in the Davie County service area, summarized from Table 15E-1, page 342 of the 2024 SMFP:

Location	Fixed MRI Scanners	Total MRI Scans	Average # of Scans/Unit
Davie Medical Center	1.0	3373	3373
Total Davie County MRI	1.0	3373	3373
Scanners			

Source: Table 15E-1, page 342, 2024 SMFP

In Section G, pages 72-73, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed MRI services in Davie County. The applicant states:

"As evidenced by the need determination in the 2024 SMFP, the State Health Coordinating Council (SHCC) considers the existing fixed MRI scanner inadequate to meet the need in the MRI service area. In this application Davie Medical Center has documented that thousands of MRI scans performed on Davie County residents occur in other counties. There is not any other MRI scanner providing service within Davie County. As described throughout this application, particularly in Sections C and N, Davie Medical Center's proposed project will improve local access for Davie County residents to high quality and cost-effective outpatient MR imaging in a convenient, easily assessable diagnostic imaging setting. ... Therefore, this project creates improved access for patients in Davie County, with no unnecessary duplication of existing resources."

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 2024 SMFP for the proposed fixed MRI scanner.
- There is only one MRI scanner in Davie County which is located at Davie Medical Center.
- The applicant adequately demonstrates the need for the proposed fixed MRI scanner at Davie Medical Center in addition to the existing MRI scanner in the service area.

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.

(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.

С

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP need determination for a total of no more than two fixed MRI scanners upon project completion.

In Section Q, Form H, page 121, the applicant provides current and projected full-time equivalent (FTE) staffing for its MRI services, as illustrated in the following table:

Staffing	Current FTE Staff As of 01/01/24	1 <sup>st</sup> Full FY CY2026	2 <sup>nd</sup> Full FY CY2027	3 <sup>rd</sup> Full FY CY2028
Radiology Technologists (MRI)	2.50	4.50	4.75	5.00
Administrator/CEO	0.25	0.25	0.25	0.25
Business Office	0.25	0.50	0.50	0.50
Clerical (Scheduler/Receptionist)	0.25	0.50	0.50	0.50
Other (MRI Tech Assistant)	0.90	1.80	2.00	2.00
Total	4.15	7.55	8.00	8.25

The assumptions and methodology used to project staffing are provided in Section H, page 74. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3(b). In Section H, pages 74-77, the applicant describes the methods used to recruit or fill new positions and its existing 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 states that the project will be staffed by Davie Medical Center MRI technologists and support staff. DMC has existing management, registration, business office and clinical staff.
- The applicant states that it anticipates that the labor force will continue to supply employees for the hospital, including the MRI service.

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.

С

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP need determination for a total of no more than two fixed MRI scanners upon project completion.

## Ancillary and Support Services

In Section I, page 79, the applicant identifies the necessary ancillary and support services for the proposed fixed MRI services. In Section I, pages 79-80 the applicant explains how each ancillary and support service is and will be available and supporting documentation is provided in Exhibit I.1.1 and I.1.2. The applicant adequately demonstrates that the necessary ancillary and support services are and will be made available because these services are currently provided for patients of Davie Medical Center and will continue to be after the proposed project is developed.

## **Coordination**

In Section I, pages 80-83, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because the applicant currently coordinates its services with the existing health care system and will continue to do so following the acquisition of the proposed fixed MRI scanner.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

## NA

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

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

## NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction

project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

С

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP need determination for a total of no more than two fixed MRI scanners upon project completion.

In Section K, page 85, the applicant states that the project involves constructing 1,056 square feet of new space. Line drawings are provided in Exhibit K.1.

In Section K, page 85-86, 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 that the project to accommodate the additional fixed MRI scanner will be planned and directed by experienced architects and construction professionals.
- The applicant states that the scanner will be located in a new space to be part of the Radiology Department, and thus leverage the existing infrastructure and support services.

In Section K, page 86, 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 that Davie Medical Center will obtain competitive market quotes from equipment vendors and will negotiate the acquisition cost of the fixed MRI scanner.
- The fixed MRI scanner will increase productivity due to economies of scale associated with operating two fixed MRI scanners rather than one.
- The applicant states that the proposed additional fixed MRI scanner can achieve higher productivity and cost savings with advanced technology and improved scheduling.
- The applicant states that the project will not increase MRI charges to the public because the charges are set by the government or already negotiated with payors.

In Section K, page 86, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the 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;

In Section L, page 89, the applicant provides the historical payor mix during FY 2023 for its existing fixed MRI services at Davie Medical Center, as shown in the table below:

Davie Medical Center Historical Payor Mix, CY2023				
Payor Source	MRI Services as Percent of Total			
Self-Pay	1.5%			
Charity Care (including self-pay)	0.0%			
Medicare*	48.5%			
Medicaid*	6.6%			
Insurance*	38.1%			
Workers Compensation	0.3%			
TRICARE	0.5%			
Other (other government)	4.5%			
Total	100.0%			

Source: Section L, page 89

\* Includes any managed care plans.

In Section L, page 90, the applicant provides the following comparison:

Davie Medical Center Last Full FY before Submission of the Application			
	Percentage of Total Patients Served	Percentage of the Population of the Service Area*	
Female	55.66%	50.8%	
Male	44.34%	49.2%	
Unknown	0.0%	0.0%	
64 and Younger	68.19%	77.7%	
65 and Older	31.81%	22.3%	
American Indian	0.48%	0.7%	
Asian	0.88%	0.9%	
Black or African American	12.09%	6.6%	
Native Hawaiian or Pacific Islander	0.06%	0.0%	
White or Caucasian	80.49%	83.1%	
Other Race	5.66%	8.7%	
Declined / Unavailable	0.34%	0.0%	

Source: Section L, page 90

\* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <u>https://www.census.gov/quickfacts/fact/table/US/PST045218</u>. Just enter the name of the county.

Sources: Davie Medical Center, and United States Census Bureau QuickFacts for Davie County, July 1, 2023 estimate.

#### **Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the 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;

С

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 91, the applicant states it has no such obligation.

In Section L, page 92, the applicant states that neither DMC nor NCBH is aware of any patient civil rights equal access complaint filed against either facility in the last 18 months. AHWFB is aware of one patient civil rights equal access complaint filed against one of its facilities (High Point Medical Center) during the last 18 months. The applicant states that the Office of Civil Rights (OCR) provided technical assistance to the facility in the form of educational materials and closed the case without finding a violation.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

(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

## С

In Section L, pages 92-93, the applicant projects the following payor mix for DMC as a whole and DMC MRI services during the third full fiscal year of operation following completion of the project, as shown in the tables below:

Davie Medical Center Projected Payor Mix, FY 2028				
Payor Source	Entire Facility as Percent of Total			
Self-Pay	2.52%			
Charity Care (including self-pay)	0.00%			
Medicare*	48.66%			
Medicaid*	6.16%			
Insurance*	37.09%			
Workers Compensation	0.97%			
TRICARE	0.52%			
Other (other government)	4.08%			
Total	100.00%			

Source: Section L, page 92

\* Including any managed care plans.

Davie Medical Center Projected Payor Mix, CY2028			
Payor Source	MRI Services as Percent of Total		
Self-Pay	1.50%		
Charity Care (including self-pay)	0.0%		
Medicare*	48.50%		
Medicaid*	6.60%		
Insurance*	38.10%		
Workers Compensation	0.30%		
TRICARE	0.50%		
Other (other government)	4.50%		
Total	100.0%		

Source: Section L, page 93

\* Including any managed care plans.

As shown in the tables above, during the third full fiscal year of operation, the applicant projects that 2.52% of total services provided by DMC will be provided to self-pay patients, and 48.66% and 6.16% of total services will be provided to Medicare and Medicaid patients, respectively.

Additionally, during the third full fiscal year of operation, the applicant projects that 1.50% of MRI services provided by DMC will be provided to self-pay patients, and 48.50% and 6.60% of total MRI services will be provided to Medicare and Medicaid patients, respectively.

In Section L, page 92, the applicant provides the assumptions 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 DMC's most recent CY2023 historical payor mix for MRI services.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

In Section L, page 94, the describes the means by which a person will have access to the proposed additional fixed MRI services at DMC.

## **Conclusion**

The Agency reviewed the:

- o 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.

С

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP need determination for a total of no more than two fixed MRI scanners upon project completion.

In Section M, page 95, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have and will continue to have access to the facility for training purposes based on the following:

- DMC has partnered with community college and university healthcare programs to provide firsthand learning experiences for students.
- DMC accepts students for clinical rotations who are enrolled in a variety of allied health academic programs.
- DMC maintains clinical training affiliations agreements with many colleges and universities.
- DMC has relationships with area health professional training programs and the proposed additional fixed MRI scanner will offer expanded opportunity for training area health professionals.

# **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

С

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP need determination for a total of no more than two fixed MRI scanners upon project completion.

On page 335, the 2024 SMFP defines the fixed MRI scanner service area as "... *the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1*". Therefore, for the purpose of this review, the fixed MRI scanner service area is Davie 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 Davie County service area, summarized from Table 17E-1, page 350 of the 2023 SMFP:

Location	Fixed MRI Scanners	Mobile MRI Scanner Host Site (Fixed Equivalent Scanner)
Davie Medical Center	1.0	0.0
<b>Total Davie County MRI Scanners</b>	1.0	0.0

Source: Table 15E-1, page 342, 2024 SMFP

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 97, the applicant states:

"The proposed project is to develop additional fixed MRI scanner capacity at DMC, yet the project will certainly enhance competition because it will expand local access to high quality MRI services for residents of Davie County. Davie County currently hosts just one fixed MRI scanner, located at Davie Medical Center."

Regarding the expected effects of the proposal on cost effectiveness, in Section N, page 98, the applicant states that the proposed fixed MRI scanner will enable a higher volume of MRI procedures per day, thus containing the cost per procedure and as an existing MRI provider, DMC

will leverage its existing MRI ancillary and support services for economies of scale in operating the additional fixed MRI scanner.

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

Regarding the expected effects of the proposal on quality in the service area, in Section N, page 99, the applicant states:

"Patient safety and quality will be incorporated into all aspects of the project, including equipment selection and installation, facility construction, staff credentialing and education, patient selection and scheduling, and continuous quality measures and patient satisfaction surveys."

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

Regarding the expected effects of the proposal on access by medically underserved groups in the service area, in Section N, page 100, the applicant states that DMC has historically provided care and services to all medically underserved populations and with the approval of the fixed MRI scanner project, DMC will have increased opportunity to offer its services to the uninsured and underserved populations in Davie County and surrounding communities.

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 and the applicant's record of providing quality care in the past.
- 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

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

С

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP need determination for a total of no more than two fixed MRI scanners upon project completion.

In Section Q, Form O, page 122, the applicant identifies the health service facilities located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 40 hospitals and diagnostic centers located in North Carolina.

In Section O, page 104, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities. The applicant states that all the problems have been corrected. After reviewing and considering information provided by the applicant and the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 40 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.

#### С

# 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- According to the 2024 SMFP, Table 15E-1, page 342, the applicant owns and operates one fixed MRI scanner at Davie Medical Center, located in the Davie 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;
- -NA- There are no approved fixed MRI scanners owned or operated by the applicant or a related entity located in the Davie County fixed MRI 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;
- -NA- According to the 2024 SMFP, Table 15E-1, page 342, there are no mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the Davie County proposed fixed MRI scanner service area 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- Neither the applicant nor a 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.
  - (5) provide projected utilization of the MRI scanners identified in Subparagraphs (a)(1) through (a)(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- In Section Q, pages 112-114, the applicant provides projected utilization for all of its existing and proposed fixed MRI scanners 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 (a)(5) of this Paragraph;
- -C- In Section Q, *pages 112-114*, the applicant provides assumptions and methodology for all of its existing and proposed fixed 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 (a)(1) and (a)(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:
  - (a) 3,494 or more adjusted MRI procedures per fixed MRI scanner if there are two or more fixed MRI scanner in the fixed MRI scanner service area;
  - (b) 3,058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or
  - (c) 1,310 or more adjusted MRI procedures per MRI scanner if there are no existing fixed MRI scanners in the fixed MRI scanner service area;

There is currently one existing fixed MRI scanner in the fixed MRI scanner service area; thus, Subparagraph (b) applies to this review.

- -C- In Section Q, pages 113, the applicant projects to provide 3,144 adjusted (or weighted) 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. This exceeds 3,058 adjusted MRI procedures per fixed MRI scanner in the fixed MRI scanner service area. The full methodology and assumptions are provided in Sections 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 3,120 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal year of operations following completion of the project.
- -NA- According to the 2024 SMFP, Table 15E-1, page 342, there are no mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites in the Davie County proposed fixed MRI scanner service area during the 12 months before the application deadline for this review.
- (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 (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner;
- (6) provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(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 (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner shall perform 3,120 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 (b)(3) and (b)(4) of this Paragraph shall perform during the third full fiscal year of operations following completion of the project:
  - (a) 3,494 or more adjusted MRI procedures per fixed MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area;
  - (b) 3,058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area;
  - (c) 1,310 or more adjusted MRI procedures per fixed MRI scanner if there are no fixed MRI scanners in the fixed MRI scanner service area.
- -NA- 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.