

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 26, 2018

Findings Date: October 26, 2018

Project Analyst: Gregory F. Yakaboski

Chief: Martha J. Frisone

Project ID #: G-11537-18

Facility: Davie Medical Center

FID #: 80175

County: Davie

Applicant(s): Davie Medical Center

North Carolina Baptist Hospital

Project: Acquire a fixed MRI scanner pursuant to Policy TE-3

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Davie Medical Center and North Carolina Baptist Hospital (NCBH), the applicants, propose to develop a fixed MRI at Davie Medical Center (DMC) through the acquisition of a fixed MRI scanner pursuant to Policy TE-3 in the 2018 State Medical Facilities Plan (SMFP). DMC currently contracts with Alliance Imaging for the use of a mobile MRI scanner at Davie Medical Center. Davie Medical Center is located at 329 NC Highway 801 N in Bermuda Run. NCBH owns the building and DMC leases the building from NCBH. [Davie Medical Center and NCBH are both acute care hospitals within the Wake Forest Baptist Medical Center (WFBMC). WFBMC is divided into an Academic Enterprise, a Commercial Enterprise and a Clinical Enterprise. The clinical enterprise is known as Wake Forest Baptist Health (WFBH). The academic enterprise is known as Wake Forest School of Medicine (WFSM). Davie Medical Center and NCBH are included in the clinical enterprise, WFBH. NCBH is the

primary Academic Medical Center Teaching Hospital for WFSM. MRI images taken at Davie Medical Center are read by WFSM radiologists with Davie Medical Center billing for the services. (See page 7 of the application.)]

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2018 SMFP. Therefore, there are no need determinations applicable to this review.

Policies

The following two policies are applicable to this review:

- Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners
- Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities

Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners (page 23 of the 2018 SMFP) states:

“Qualified applicants may apply for a fixed magnetic resonance imaging scanner (MRI).

To qualify, the health service facility proposing to acquire the fixed MRI scanner shall demonstrate in its certificate of need application that it is a licensed North Carolina acute care hospital with emergency care coverage 24 hours a day, seven days a week and that [sic] does not currently have an existing or approved fixed MRI scanner as reflected in the inventory in the applicable State Medical Facilities Plan.

The applicant shall demonstrate that the proposed fixed MRI scanner will perform at least 850 weighted MRI procedures during the third full operating year.

The performance standards in 10A NCAC 14C .2703 would not be applicable.

The fixed MRI scanner must be located on the hospital’s ‘main campus’ as defined in G.S. 131E-176(14n)a.”

Licensed North Carolina Acute Care Hospital with Emergency Care Coverage

Davie Medical Center is an existing licensed North Carolina acute care hospital and the applicants provide a copy of Davie Medical Center’s 2018 Hospital License in Exhibit O.2. Exhibit B.9, contains a copy of page 8 of Davie Medical Center’s 2018 License Renewal Application (LRA) which documents that Davie Medical Center provides emergency care 24 hours per day, seven days per week.

No Existing or Approved Fixed MRI Scanner as Reflected in the Applicable SMFP

The 2018 SMFP, Chapter 9, Table 9P *MRI Fixed and Mobile Procedures by MRI Service Area with Tiered Thresholds and Fixed Equivalents*, page 149, documents that there are no existing or approved fixed MRI scanners at Davie Medical Center in the inventory of MRI scanners for Davie County. Exhibit B.9 contains a copy of Table 9P, page 149, of the 2018 SMFP.

Performance Standards of at Least 850 Weighted MRI Procedures

In Section Q, page 87, the applicants state that the proposed fixed MRI scanner will perform 3,185 weighted procedures during the third full operating year (OY) which is fiscal year (FY) 2023 [7/1/22 to 6/30/23]. The assumptions and methodology used to project the weighted MRI procedures for OY3 are provided in Section Q, pages 88-93.

Located on Hospital's "Main Campus" as Defined in G.S. 131E-176(14n)(a)

In Section B.9, pages 19-20, the applicants state:

*"The development of the proposed fixed MRI scanner at DMC will occur on the main campus as defined in G.S. 131E-176(14n). Please reference the campus map of DMC located in **Exhibit B.9** which outlines the location of the proposed fixed MRI scanner within the hospital campus and the office of the President of DMC, who executes financial and administrative control of the facility."*

See Exhibit B.9.

In summary, the applicants adequately demonstrate that Davie Medical Center is a licensed North Carolina acute care hospital providing emergency care coverage 24 hours per day, seven days per week; that there is no existing or approved fixed MRI scanner at Davie Medical Center as reflected in the 2018 SMFP; that the applicants reasonably project that the proposed fixed MRI will perform at least 850 weighted MRI procedures in its third operating year; and that the proposed MRI will be located on the hospital's "main campus" as defined in G.S. 131E-176(14n)(a). Therefore, the application is consistent with Policy TE-3.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities (page 33 of the 2018 SMFP) states:

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

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest

editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are 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 \$2 million and less than \$5 million; therefore, Policy GEN-4 is applicable to this review. In Section B.11, page 21, the applicants provide a written statement describing the project's plan to assure improved energy efficiency and water conservation which states:

"DMC and NCBH 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 State Building Code. During the design of this project the WFBMC Office of Facilities and Properties, in conjunction with the DMC Plan Operations, 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 our patients."

On page 21, the applicants state *"a plan for energy efficiency and water conservation will be developed during the design phase of the project."* The applicants adequately demonstrate 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 the review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates the proposal is consistent with Policy TE-3 in the 2018 SMFP.
- The applicant adequately demonstrates the proposal is consistent with Policy GEN-4.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicants propose to acquire a fixed MRI scanner pursuant to Policy TE-3 to be located at Davie Medical Center.

Patient Origin

On page 142, the 2018 SMFP defines the service area for fixed MRI scanners as “*a single county, except where there is no licensed acute care hospital located within the county.*” Thus, the service area consists of Davie County. Providers may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin for MRI services offered at Davie Medical Center.

County	Current Last Full FY (7/1/16 to 6/30/17)		Third Full FY of Operation following Project Completion (7/1/22 to 6/30/23)	
	Patients	% of Total	Patients	% of Total
Davie	448	29.8%	831	29.8%
Forsyth	375	24.9%	696	24.9%
Iredell	79	5.2%	146	5.2%
Catawba	65	4.3%	121	4.3%
Davidson	64	4.2%	119	4.2%
Yadkin	62	4.1%	114	4.1%
Guilford	40	2.7%	74	2.7%
Wilkes	39	2.6%	72	2.6%
Rowan	33	2.2%	61	2.2%
Caldwell	29	1.9%	53	1.9%
Surry	26	1.7%	49	1.7%
Burke	21	1.4%	38	1.4%
Alexander	19	1.3%	36	1.3%
Stokes	15	1.0%	28	1.0%
Watauga	14	0.9%	25	0.9%
Carroll, VA	10	0.7%	19	0.7%
Mercer, WV	10	0.7%	19	0.7%
Mecklenburg	8	0.5%	15	0.5%
Randolph	8	0.5%	15	0.5%
Patrick, VA	8	0.5%	15	0.5%
Lincoln	7	0.5%	13	0.5%
Alleghany	7	0.5%	13	0.5%
All Other	119	7.9%	220	7.9%
Total	1,505	100.0%	2,790	100.0%

In Section C, page 26, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, page 26-29, the applicants explain why they believe the population projected to utilize the proposed services needs the proposed services. On page 27, the applicants state the need for the proposed 3.0T fixed MRI scanner at Davie Medical Center is based on the following factors:

- Davie Medical Center growth (See page 27 of the application.)
- Expansion of Davie Medical Center to the provision of inpatient services in the spring of 2017 (See page 27 of the application.)
- Outmigration of MRI patients from Davie to Forsyth County (See pages 27-28 of the application.)
- Projected Davie County population growth, particularly for patients ages 65+ (See page 28 of the application.)
- Musculoskeletal Imaging Needs (See pages 28-29 of the application)
- Extension of Specialty Imaging into Davie County (See page 29 of the application)
- Expansion of Services offered at Davie Medical Center (See page 29 of the application.)

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

- The applicants rely on historical data that is clearly cited and reasonable demographical data to make the assumptions with regard to identifying the population to be served, and
- The applicants describe their methodologies and provide reasonable and adequately supported assumptions to demonstrate the need the population projected to be served has for the proposed services.

Projected Utilization

In Section Q, the applicants provide historical and projected utilization as illustrated in the following tables.

MRI Scanner	Historic FY2015	Historic FY2016	Historic FY2017	Interim FY2018	Interim FY2019	Partial* FY2020
# of Fixed Units	0	0	0	0	0	1
# of Procedures	657	1,159	1,505	1,971	2,113	2,265
# of Weighted Procedures	722	1,293	1,715	2,251	2,412	2,586

*Includes 3 months using mobile and 9 months with the proposed fixed MRI scanner.

MRI Scanner	1st Full OY FY2021	2nd Full OY FY2022	3rd Full OY FY2023
# of Fixed Units	1	1	1
# of Procedures	2,428	2,603	2,790
# of Weighted Procedures	2,772	2,971	3,185

In Section Q, the applicants provide the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Determine Historic Utilization of the Mobile MRI scanner at Davie Medical Center (See pages 88-89 of the application)

#1: The applicants summarized the historical unweighted MRI procedures performed at Davie Medical Center, as show in the table below:

Davie Medical Center Historical Unweighted MRI Procedures

	IP w/o contrast or sedation	IP w/ contrast or sedation	OP w/o contrast or sedation	OP w/ contrast or sedation	Total # of MRI Procedures
FY2015	0	3	497	157	657
FY2016	0	1	826	332	1,159
FY2017	8	3	984	510	1,505
FY2018*	27	24	1,297	623	1,971

*Annualized based on actual data from 11 months (7/1/17 to 5/31/18)

#2: The applicants determined the percentage of MRI procedures that were IP, OP, with contrast or sedation or without contrast or sedation as illustrated in the table below.

Davie Medical Center Historical Unweighted MRI Procedures by Percent of Total MRI Procedures

	IP w/o contrast or sedation	IP w/ contrast or sedation	OP w/o contrast or sedation	OP w/ contrast or sedation	Total # of MRI Procedures
FY2018*-MRI Procedures	27	24	1,297	623	1,971
FY2018*- MRI Procedures as % of overall total	1.4%	1.2%	65.8%	31.6%	100.0%

*Annualized based on actual data from 11 months (7/1/17 to 5/31/18)

Source: Table C.10.2 on page 89 of the application.

Step 2: *Assess Historic Growth Rates and Projected Growth Trends to Determine an Appropriate Growth Rate for the Proposed Fixed MRI at Davie Medical Center (See pages 89-91 of the application)*

To determine a growth rate to apply to the historic mobile MRI utilization at Davie Medical Center to project future utilization, the applicants assessed historic and projected growth trends. Growth rates assessed are set forth below:

- Historic mobile MRI volume growth at Davie Medical Center.
- Historic emergency department volume growth at Davie Medical Center.
- Historic ambulatory clinic volume growth at Davie Medical Center.
- Historic combined operating and procedure room volume growth at Davie Medical Center.
- Projected Davie County population growth.

Step 3: *Determine the Most Reasonable and Conservative Growth Rate to Use to Project Future Fixed MRI Utilization at Davie Medical Center (See page 91 of the application)*

The growth rates assessed in Step 2 are summarized as illustrated in the table below:

Growth Rate Assessed	CAGR
Historic Mobile MRI Volume Growth, FY2015-FY2018	44.2%
Historic ED Volume Growth, FY2015 – FY2018	11.6%
Historic Ambulatory Clinic Volume Growth, Total FY2015 – FY2018	14.1%
Historic Ambulatory Clinic Volume Growth, Orthopedics	7.2%
Historic Combined OR and Procedure Room Volume Growth, Total	12.4%
Historic Combined OR and Procedure Volume Growth, Orthopedics	21.5%
Projected Population Growth, Total	1.2%
Projected Population Growth, 0-64	0.6%
Projected Population Growth, 65+	3.4%

Based on the assessments in Steps 2 and 3, the applicants selected the growth rate of 7.2% based on the “historic ambulatory clinic volume growth, orthopedics” from the table above to apply to historic mobile MRI data to project future utilization of the proposed fixed 3.0T MRI

scanner. The applicants choose the 7.2% growth rate because: 1) orthopedics are projected to be “a large, if not the largest” driver of MRI utilization; and 2) the growth rate of 7.2% is one of the more conservative of the various growth rates assessed and summarized in the table above.

Step 4: *Assess MRI Outmigration from Davie County to Forsyth County by Reviewing Patient Origin Data from the Annualized Hospital LRAs (See pages 91-92 of the application)*

On page 91 of the application, the applicants state that approximately 81% of residents of Davie County currently leave Davie County for hospital based MRI procedures. This analysis is based on patient origin data from the 2017 and 2018 LRAs for Novant Health Forsyth Medical Center and North Carolina Baptist Hospital.

See Table on page 92 of the application.

Step 5: *Project Fixed MRI Utilization at Davie Medical Center (See page 92 of the application)*

	Historic (FY2018)*	Interim (FY2019)	Partial** (FY2020)	OY1 (FY2021)	OY2 (FY2022)	OY3 (FY2023)
# of MRI Procedures	1,971	2,113	2,265	2,428	2,603	2,790
Projected Growth Rate		7.2%	7.2%	7.2%	7.2%	7.2%

*Annualized based on actual data from 11 months (7/1/17 to 5/31/18)

**Includes 3 months using mobile and 9 months with the proposed fixed MRI scanner.

Step 6: *Convert Total Fixed MRI Procedures to Weighted Procedures (See pages 92-93 of the application)*

1st: Used the percentages calculated in Step 1, to determine the number of IP, OP, with contrast or sedation and without contrast or sedation procedures, as illustrated in the table below:

Davie Medical Center Projected Unweighted MRI Procedures

	IP w/o contrast or sedation (1.4% of total)	IP w/ contrast or sedation (1.2% of total)	OP w/o contrast or sedation (65.8% of total)	OP w/ contrast or sedation (31.6% of total)	Total # of MRI Procedures
FY2019	30	25	1,390	668	2,113
FY2020	32	27	1,490	716	2,265
OY1(FY2021)	34	29	1,598	767	2,428
OY2 (FY2022)	36	31	1,713	823	2,603
OY3 (FY2023)	39	33	1,836	882	2,790

2nd: Apply the percentages

Davie Medical Center Projected Weighted MRI Procedures

	IP w/o contrast or sedation (x 1.4)	IP w/ contrast or sedation (x 1.8)	OP w/o contrast or sedation (x 1.0)	OP w/ contrast or sedation (x 1.4)	Total # of MRI Procedures
FY2019	42	45	1,390	935	2,412
FY2020	45	49	1,490	1,002	2,586
OY1(FY2021)	48	52	1,598	1,074	2,772
OY2 (FY2022)	50	56	1,713	1,152	2,971
OY3 (FY2023)	55	59	1,836	1,235	3,185

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

- As shown in the tables above, the applicants project to perform 3,185 weighted MRI procedures in the third full fiscal year of operation, which is more than the 850 weighted procedures, as required by Policy TE-3.
- In FY2018, 1,971 weighted MRI procedures on Alliance Imaging’s mobile MRI scanner.
- The applicant applies reasonable growth assumptions bases on historical data.

Access

In Section C, page 33, the applicant states “*Services are available to all persons including low income persons, racial and ethnic minorities, women handicapped persons, the elderly, and other underserved persons including the medically indigent, the uninsured and the underinsured.*” In Section L, page 74, the applicants project the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Category	Entire Facility Services as Percent of Total	MRI Services as Percent of Total
Medicaid	9.9%	7.3%
Medicare	40.8%	44.0%
Self Pay	7.6%	2.7%
Managed Care	36.6%	43.0%
All Other*	5.1%	3.1%
Total	100.0%	100.0%

Source: Table on page 73 of the application.

*Other includes liability, other government programs, Workers Com, and TRICARE

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

NA

The applicants do not propose to reduce, eliminate or relocate a facility of 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

Davie Medical Center and NCBH propose to acquire a fixed MRI scanner pursuant to Policy TE-3 to be located at Davie Medical Center.

In Section E, pages 48-49, the applicants describe the alternatives they considered and explain 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:

- Continue to provide mobile MRI services through the existing contract with Alliance Imaging: Currently Davie Medical Center offers MRI services by contracting with Alliance Imaging for the use of a mobile MRI scanner. However, the applicants determined that a mobile MRI scanner was not the least costly or most effective alternative because: a fixed 3.0T MRI is required to support musculoskeletal imaging; a fixed 3.0T MRI will provide more reliability in comparison to a mobile MRI; and a fixed 3.0T MRI will permit for the extension of specialty imaging into Davie County and for the expansion of services to be offered at Davie Medical Center.

- Purchase a 1.5T fixed MRI scanner for DMC through Policy TE-3: The applicants considered purchasing a 1.5T fixed MRI scanner, however, the applicants determined that this was not the most effective alternative because a fixed 3.0T MRI will permit for the extension of specialty imaging into Davie County and for the expansion of services to be offered at Davie Medical Center and a fixed 3.0T MRI is required to support musculoskeletal imaging.

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

- The applicants demonstrate that mobile MRI services on a full-time basis is more costly,
- The applicants demonstrate that a fixed MRI scanner improves quality of the images,
- The applicants demonstrate that a fixed 3.0T MRI scanner is more effective than a fixed 1.5T MRI scanner in that it allows more advanced MRI images, the potential to expand specialty services at Davie Medical Center, and to support musculoskeletal imaging needed by a substantial portion of the patients served by Davie Medical Center,
- The data cited is reasonable and supports the assumptions made with regard to the least costly or most effective alternative for development of the proposed project.

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 shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Davie Medical Center and North Carolina Baptist Hospital shall materially comply with the last made representation.**
- 2. Davie Medical Center and North Carolina Baptist Hospital shall acquire no more than one fixed MRI scanner to be located at Davie Medical Center as part of this project.**
- 3. Davie Medical Center and North Carolina Baptist Hospital 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.**

4. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Davie Medical Center and North Carolina Baptist Hospital 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.**

 5. **Davie Medical Center and North Carolina Baptist Hospital 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.

C

The applicants propose to acquire a fixed MRI scanner pursuant to Policy TE-3 to be located at Davie Medical Center.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 94, the applicants project the total capital cost of the project as shown in the table below.

Site Costs	\$0.00
Construction Costs	\$1,170,000
Architect/Engineering Fees	\$102,000
Medical Equipment	\$2,761,000
Furniture	\$4,000
Miscellaneous Costs (Other)	\$33,000
Total	\$4,070,000

In Section Q, Exhibit C.1 and Exhibit K.4, the applicants provide the assumptions used to project the capital cost.

In Section F, page 52, the applicants project that there will be no start-up costs or initial operating expenses as the proposed project is an expansion of an existing service.

Availability of Funds

In supplemental information requested by the Agency, the applicants state that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing	
Type	DMC
Loans	\$0
Accumulated reserves or OE *	\$4,070,000
Bonds	\$ 0
Other (Specify)	\$ 0
Total Financing	\$4,070,000

* OE = Owner's Equity

On page 50, the applicants state that the financing of the proposed project will come from the accumulated reserves of DMC. Wake Forest Baptist Medical Center is the sole member of DMC. In Exhibit F.2, the applicants provide a letter dated June 13, 2018 from the Associate Vice President, Treasury for Wake Forest Baptist Medical Center, which states:

“Wake Forest Baptist Medical Center agrees to make available from its accumulated reserves a total of \$4,070,000 for ... the aforementioned project. ... Please reference our audited financial statements.”

In Exhibit F.2, the applicants provide a copy of Wake Forest Baptist Medical Center's and other related entities audited combined financial statements ending June 30, 2017 and June 30, 2016. On page 48, the balance sheet for DMC shows that it had \$13.0 million in net assets as of June 30, 2017.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.4, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1st Full OY	2nd Full OY	3rd Full OY
Total Cases	2,112	2,265	2,427
Total Gross Revenues (Charges)	\$11,665,023	\$13,135,578	\$14,778,831
Total Net Revenue	\$2,507,599	\$2,787,428	\$3,095,976
Average Net Revenue per Case	\$1,187.31	\$1,230.65	\$1,275.64
Total Operating Expenses (Costs)	\$959,715	\$993,653	\$1,030,488
Average Operating Expense per Case	\$454.41	\$438.70	\$424.59
Net Income	\$1,547,883	\$1,793,775	\$2,065,488

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

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

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

C

The applicants propose to acquire a fixed MRI scanner pursuant to Policy TE-3 to be located at Davie Medical Center.

On page 142, the 2018 SMFP defines the service area for fixed MRI scanners as *“a single county, except where there is no licensed acute care hospital located within the county.”* Thus, the service area consists of Davie County. Facilities may also serve residents of counties not included in their service area.

Per the 2018 SMFP, there are no fixed MRI scanners and one mobile MRI scanner serving Davie County. Davie Medical Center obtains the mobile MRI services from Alliance Imaging. The following table identifies the provider, fixed MRI magnet equivalent, and utilization of each of the mobile MRI scanners, summarized from Table 9P of the 2018 SMFP.

MRI Scanner Inventory and Utilization – Davie County FY 2016		
Location	Fixed Equiv.	Weighted Scans
Davie Medical Center	0.69	1,526

In Section G.3, pages 57-58, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in the Davie County service area. The applicant states:

“As there is no fixed MRI in Davie County, the project will not and cannot result in unnecessary duplication of MRI services in Davie County.”

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

- The applicants adequately demonstrate in the application that the proposal conforms with Policy TE-3, and
- The applicants adequately demonstrate that the fixed MRI scanner is needed to serve Davie Medical Center patients seeking MRI services in Davie County.

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.

- (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

In Section Q, Form H., page 109, the applicants provide current and projected staffing for the proposed services, as illustrated in the following table.

Position	Current	Projected		
	As of 6/11/2018	1 st Full Fiscal Year 7/1/20 – 6/30/21	2 nd Full Fiscal Year 7/1/21 – 6/30/22	3 rd Full Fiscal Year 7/1/22 – 6/30/23
Technologists	0.0	2.4	2.4	2.4
TOTAL	0.0	2.4	2.4	2.4

Source: Form H in Section Q of the application.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H., pages 60-62, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H.4, page 62, the applicant identifies the current medical director. In supplemental information requested by the Agency, the applicants provide a letter from the current medical director supporting the proposal. In Section H, pages 62-63, the applicant describes its physician recruitment plans.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

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

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

C

In Section I, page 64, the applicants state that the following ancillary and support services are necessary for the proposed services:

- Clinical Services: Pharmacy, Lab and Emergency Services.
- Professional Services: Emergency Medicine, Pathology and Radiology
- Corporate Services: Human Resources, Interpreter Services, Legal, Supply Chain, Media and Marketing, Information Technology, Billing/Revenue, Environmental Services/Housekeeping, Accounting, Finance, Security, Compliance and Internal Audit, Risk Management and Strategic Planning

On page 64, the applicants adequately explain how each ancillary and support service is or will be made available.

In Section I, pages 64-65, the applicants describe the existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2. The applicants adequately demonstrate that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

The applicants 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 applicants do not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (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

Neither of the applicants are an HMO. Therefore, Criterion (10) is not applicable to this review.

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

C

In Section K, page 68, the applicants state that the project involves upfitting 1,127 square feet of existing space. Line drawings are provided in Exhibit K-2.

On pages 68-69, the applicants adequately explain how the cost, design and means of construction represent the most reasonable alternative for the proposal and provide supporting documentation in Exhibit K.4.

On page 69, the applicants adequately explain why the proposal will not unduly increase the costs to the applicants of providing the proposed services or the costs and charges to the public for the proposed services and provide supporting documentation in Exhibit K.4.

On pages 21-22, the applicants identify any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 73, the applicants provide the historical payor mix during 7/1/2016 to 6/30/2017 for the proposed services, as shown in the table below.

Payor Category	Entire Facility Services as Percent of Total	Mobile MRI Services as Percent of Total
Medicaid	9.9%	7.6%
Medicare	40.8%	43.0%
Self Pay	7.6%	2.7%
Managed Care	36.6%	43.3%
All Other*	5.1%	3.5%
Total	100.0%	100.0%

Source: Table on page 73 of the application.

*Other includes liability, other government programs, Workers Com, and TRICARE

In Section L.1, page 73, the applicants provide the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY2017	Percentage of the Population of the Service Area
Female	55.5%	51.1%
Male	44.5%	48.9%
Unknown	0.0%	0.0%
64 and Younger	60.8%	79.5%
65 and Older	39.2%	20.5%
American Indian	0.4%	0.4%
Asian	0.6%	0.8%
Black or African-American	9.6%	6.3%
Native Hawaiian or Pacific Islander	0.1%	0.0%
White or Caucasian	85.8%	86.6%
Other Race	3.6%	5.9%
Declined / Unavailable	0.1%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicants adequately document the extent to which medically underserved populations currently use the applicants existing services in comparison to the percentage of the population in the applicants 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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 73, the applicants state:

“The Patient Protection and Affordable Care Act, requires tax exempt hospitals exempt under ICR Section 501(c)(3) to have a written financial assistance policy and emergency medical care policy that provides discounts for emergent and other medically necessary care provided to eligible financial assistance patients.”

Exhibit C.11 contains a copy of DMC’s Financial Assistance Policy. A copy of DMC’s Emergency Medical Treatment Policy is included in Exhibit L.2.

In Section L.2, page 74, the applicants state that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicants or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 74, the applicants project the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	Entire Facility Services as Percent of Total	Mobile MRI Services as Percent of Total
Medicaid	9.9%	7.3%
Medicare	40.8%	44.0%
Self Pay	7.6%	2.7%
Managed Care	36.6%	43.0%
All Other*	5.1%	3.1%
Total	100.0%	100.0%

Source: Table on page 73 of the application.

*Other includes liability, other government programs, Workers Com, and TRICARE

As shown in the table above, during the second full fiscal year of operation, the applicants project that 7.6% of total services will be provided to self-pay patients, 40.8% to Medicare patients and 9.9% to Medicaid patients.

On page 74, the applicants provide the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it was based on historical payor mix.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.5, page 76, the applicants adequately describe the range of means by which a person 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

In Section M.1, page 77, the applicants describe 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 Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

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

C

The applicants propose to acquire a fixed MRI scanner pursuant to Policy TE-3 to be located at Davie Medical Center.

On page 142, the 2018 SMFP defines the service area for fixed MRI scanners as “a single county, except where there is no licensed acute care hospital located within the county.” Thus, the service area consists of Davie County. Facilities may also serve residents of counties not included in their service area.

Per the 2018 SMFP, there are no fixed MRI scanners and one mobile MRI scanner serving Davie County. Davie Medical Center obtains the mobile MRI services from Alliance Imaging. The following table identifies the provider, fixed MRI magnet equivalent, and utilization of each of the mobile MRI scanners, summarized from Table 9P of the 2018 SMFP.

MRI Scanner Inventory and Utilization – Davie County FY 2016		
Location	Fixed Equiv.	Weighted Scans
Davie Medical Center	0.69	1,526

In Section N, pages 78-80, the applicants describe the expected effects of the proposed services on competition in the service area and discuss how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On pages 78-79, the applicants state:

“Mobile MRI services are more costly and less efficient than offering the service with a fixed MRI. ... A dedicated fixed MRI will improve quality for several reasons, as outlined below: ... Dedicated MRI Technologists allow for more familiarity with the machine and its associated imaging protocols. Knowing how to execute the protocol appropriately is invaluable to ensuring high quality imaging. ... Claustrophobia is a common issue with MRI exams in general and having that scanner in a very narrow tractor trailer only increases the frequency of this. When patients are claustrophobic, they are more likely to move or terminate the exam, both of which can negatively impact the quality of the examination. ... Fixed units have improved image quality due to the stability of the magnetic field. ... Over 80% of patients leave Davie County for hospital-based MRI services. ... Medically underserved groups generally have less resources available to them, such as transportation, which can impact their overall health. The development of a fixed MRI in Davie County will improve

access to the medically underserved individuals residing in Davie County as this service will be provided closer to their homes than what is currently available.”

The applicants adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrate:

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

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.

- (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

Davie Medical Center and North Carolina Baptist Hospital propose to develop a fixed MRI at Davie Medical Center. Davie Medical Center currently contracts with Alliance Imaging for the use of a mobile MRI scanner at Davie Medical Center. WFBMC owns, operates, or manages: North Carolina Baptist Hospital, Lexington Medical Center and Wilkes Regional Medical Center.

In Section O.3, pages 82-84, the applicant states that both Davie Medical Center and North Carolina Baptist Hospital are accredited by the Joint Commission. On page 83 of the application the applicant states

“In February 2018, NCBH was deemed noncompliant with conditions of participation by CMS. This was due to deficiencies in pathology related to cancer misdiagnoses involving an individual who is no longer with the Medical Center. Following an extensive on-site review of NCBH processes and remediation plan, on April 9, 2018 CMS rescinded notice of termination for NCBH. CMS Surveyors returned on June 11, 2018 to review the implementation of the NCBH corrective action plan and NCBH is currently awaiting a response from CMS as to the outcome of that visit.”

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, Davie Medical Center, Lexington Medical Center and Wilkes Regional Medical Center are all currently in compliance with all CMS Conditions of Participation. No incidents occurred within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on Davie Medical Center, Lexington Medical Center or Wilkes Regional Medical Center. North Carolina Baptist Hospital is currently out of compliance with one or more CLIA requirements but is back in compliance with all Medicare Conditions of Participation. The applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming with this criterion.

(21) Repealed effective July 1, 1987.

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

NA

The applicants propose to develop a fixed MRI scanner at Davie Medical Center pursuant to Policy TE-3 in the 2018 State SMFP. Per Policy TE-3, *“The performance standards in 10A NCAC 14C .2703 would not be applicable.”*