

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 6, 2020

Findings Date: October 6, 2020

Project Analyst: Tanya M. Saporito

Assistant Chief: Lisa Pittman

Project ID #: H-11911-20

Facility: First Imaging of the Carolinas, LLC

FID #: 041040

County: Moore

Applicant(s): First Imaging of the Carolinas, LLC

Project: Acquire an existing MRI scanner from FirstHealth of the Carolinas, Inc.

### 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

First Imaging of the Carolinas, LLC, hereinafter referred to as “the applicant” or “First Imaging” proposes to acquire one fixed MRI scanner currently owned and operated by FirstHealth of the Carolinas, Inc. (FirstHealth) and located at Pinehurst Radiology Associates, PLLC in Pinehurst, Moore County. Pinehurst Radiology Associates owns the building, located at 30 Memorial Drive in Pinehurst, and leases space to First Imaging in which to operate a diagnostic center with a PET scanner, owned by First Imaging and an MRI, owned by First Health. First Imaging is co-owned by FirstHealth and Sandhills Diagnostic Imaging, LLC. FirstHealth is a not-for-profit organization that operates several acute care hospitals, urgent care centers and other health services in Moore, Richmond, Montgomery and Hoke Counties. Sandhills Diagnostic Imaging, LLC is a diagnostic center located in the same building. The applicant does not propose to relocate the MRI; it will continue to operate at the Pinehurst Radiology location. The application will simply result in a change of ownership from First Health to First Imaging.

The applicant proposes to acquire an existing MRI from FirstHealth to replace an existing MRI at First Imaging. The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP)
- acquire any medical equipment for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP)
- offer a new institutional health service for which there are any policies in the 2020 State Medical Facilities Plan (SMFP)

Therefore, Criterion (1) is not applicable to this review

- (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 applicant proposes to acquire an existing MRI located at First Imaging from FirstHealth and continue to operate that MRI at First Imaging.

On page 418, the 2020 SMFP defines the service area for a fixed MRI scanner as *the same as an Acute Care Bed service area*. Thus, the service area for this facility consists of Moore County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 27, the applicant provides a table to illustrate historical patient origin for fiscal year (FY) 2019 (10/1/2018-9/30/2019) for the MRI currently located at Pinehurst Radiology Associates, as shown below:

**First Imaging Historical Patient Origin, FY 2019**

COUNTY	LAST FULL FISCAL YEAR	
	# PATIENTS	% OF TOTAL
Moore	694	17.0%
Richmond	367	9.0%
Robeson	351	8.6%
Lee	322	7.9%
Hoke	297	7.3%
Scotland	297	7.3%
Montgomery	295	7.2%
<b>Service Area Subtotal</b>	<b>2,624</b>	<b>64.3%</b>
In-migration*	1,456	35.7%
<b>Total</b>	<b>4,080</b>	<b>100.0%</b>

\*On page 27, the applicant states “in-migration” includes 36 North Carolina counties and other states.

In Section C, page 28, the applicant provides a table to illustrate projected patient origin for the first three FYs of operation for the MRI to be located at First Imaging:

**First Imaging Projected Patient Origin**

COUNTY	1 <sup>ST</sup> FULL FY (1/1/2021-12/31/2021)		2 <sup>ND</sup> FULL FY (1/1/2022-12/31/2022)		3 <sup>RD</sup> FULL FY (1/1/2023-12/31/2023)	
	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL
Moore	846	17.0%	880	17.0%	914	17.0%
Richmond	448	9.0%	466	9.0%	484	9.0%
Robeson	428	8.6%	445	8.6%	463	8.6%
Lee	392	7.9%	407	7.9%	423	7.9%
Hoke	362	7.3%	376	7.3%	391	7.3%
Scotland	362	7.3%	376	7.3%	391	7.3%
Montgomery	359	7.2%	373	7.2%	388	7.2%
<b>Service Area Subtotal</b>	<b>3,196</b>	<b>64.3%</b>	<b>3,232</b>	<b>64.3%</b>	<b>3,455</b>	<b>64.3%</b>
In-migration*	1,775	35.7%	1,845	35.7%	1,918	35.7%
<b>Total</b>	<b>4,971</b>	<b>100.0%</b>	<b>5,168</b>	<b>100.0%</b>	<b>5,373</b>	<b>100.0%</b>

\*On page 27, the applicant states “in-migration” includes 36 North Carolina counties and other states.

In Section C, page 28, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because it is based on First Imaging’s historical patient origin for MRI services.

**Analysis of Need**

In Section C, pages 29-32, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states that the services are needed based on the following factors:

- Service area population growth trends – Citing population growth statistics from the North Carolina Office of State Budget and Management (OSBM), the applicant states

that from 2015 to 2020, the Moore County population increased by 9.3%, and is projected to increase by 8.3% from 2020 to 2025. In addition, the over 65 age group, which represents 26.9% of Moore County’s total population, is projected to increase by 13.6% during that same time.

- Extended service area population growth trends – Citing the same data from the North Carolina OSBM, the applicant states that the total population of the extended service area (Hoke, Lee, Montgomery, Moore, Richmond, Robeson and Scotland counties) increased by 3.0% from 2015 to 2020 and is projected to increase by 3.0% from 2020 to 2025. Those seven counties, according to the applicant, comprise 64.3% of the projected MRI patients to be served at First Imaging. The applicants state that the 65+ age group comprises approximately 18.6% of the seven-county extended service area but is projected to comprise approximately 36.4% of the MRI patients to be served at First Imaging.
- Historical utilization of the existing MRI scanner – the applicant provides a table on page 32, reproduced below, that illustrates historical utilization of the existing MRI scanner located at First Imaging:

	FY 2017	FY 2018	FY 2019	FY 2020
MRI Scans	883	3,616	4,808	3,985
Weighted MRI Scans	947	3,859	5,146	4,272
Utilization Rate*	19.7%	80.3%	107.1%	88.9%

\*The applicant states on page 32 that the utilization rate is based on an adjusted threshold of 4,805 weighted MRI scans, 17.6% of which are with contrast.

- Outpatient MRI Services – the applicant states this application seeks to change ownership of the existing MRI scanner located at First Imaging, to respond to the continued demand for MRI services and offer its patients a lower-cost option for MRI services than a hospital-based scanner.

The information is reasonable and adequately supported because the applicant does not propose any change in the operation of the existing MRI scanner located at First Imaging. The applicant proposes only a change of ownership and relies on growth trends and historical utilization to support continued utilization.

#### *Projected Utilization*

In Section Q, Form C, the applicant provides historical and projected utilization, as illustrated in the following table:

	<b>PARTIAL FY 3/1/21- 9/30/21</b>	<b>1<sup>ST</sup> FULL FY 10/1/21- 9/30/22</b>	<b>2<sup>ND</sup> FULL FY 10/1/22- 9/30/23</b>	<b>3<sup>RD</sup> FULL FY 10/1/23- 9/30/24</b>
# MRI Scanners	1	1	1	1
# Procedures	2,391	4,971	5,168	5,373
# Weighted Procedures	2,559	5,321	5,532	5,751
# OP Scans w/ Contrast	421	875	910	946
# OP Scans w/o Contrast	1,970	4,096	4,258	4,427
OP Scans w/Contrast Weight	1.4	1.4	1.4	1.4
OP Scans w/o Contrast Weight	1.0	1.0	1.0	1.0
Weighted OP Scans w/Contrast	589	1,225	1,273	1,324
Weighted OP Scans w/o Contrast	1,970	4,096	4,258	4,427
<b>Total Weighted MRI Scans</b>	<b>2,559</b>	<b>5,321</b>	<b>5,532</b>	<b>5,751</b>

In Section Q and in clarifying information requested by the Agency, the applicant provides the assumptions and methodology used to project utilization, summarized below:

*Step 1: Calculate Annual Change from FY 2018 to FY 2020*

The applicant provides a table to illustrate historical and annualized MRI scans performed on the existing MRI scanner at First Imaging, as shown below:

**First Imaging Historical MRI Scans, FY 2017 – FY 2019**

	HISTORICAL			AVERAGE ANNUAL CHANGE	50% OF AVG. ANNUAL CHANGE
	FY 2018	FY 2019	FY 2020		
MRI Scanner	3,616	4,808	3,985	7.9%	4.0%
Annual Change*	--	33.0%	-17.7%		

The applicant calculated annual change by subtracting current year’s volume from previous year’s volume and dividing the result by the previous year’s volume.

The applicant states FY 2020 scans are based on 10 months of data; therefore, the applicant annualized the FY 2020 data to project a FY 2021 base utilization of 4,782 [3,985 / 10 = 389.5. 389.5 x 12 = 4,782 MRI scans].

*Step 2: Determine MRI operator for FY 2021*

The applicant states the in the first half of FY 2021, FirstHealth will continue to operate the existing MRI scanner. In the second half of FY 2021, First Imaging will assume operation of the existing MRI scanner, because it will own the MRI. See the following table provided by the applicant:

**Projected MRI Scans, FY 2021**

	FIRSTHEALTH MOORE REGIONAL HOSPITAL		FIRST IMAGING
	FY 2020	PARTIAL FY 2021	PARTIAL FY 2021
# MRI Scans	3,985	2,391	2,391

*Step 3: Project Future Utilization Based on 4.0% growth*

The applicant projects future MRI utilization based on 50% of the average annual change of 7.9% calculated from FY 2018 to FY 2020. The applicant states it adjusted the growth rate to account for the impact of COVID-19 on MRI utilization during FY 2020. See the following table provided by the applicant:

	HISTORICAL			INTERIM	PROJECTED		
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
# MRI Scans	3,616	4,808	3,985	4,782	4,971	5,168	5,373

Utilization based on 4% growth.  
 Calculations may not foot due to rounding.

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

- The applicant’s utilization projections are supported by the historical utilization of the MRI scanner sought to be purchased with this application.
- The applicant provided adequate support for the increase in incremental projections.
- The applicant provided adequate support for the projected population growth in Moore County.
- The application meets the Performance Standards in 10A NCAC 14C 2700.

**Access**

In Section C, page 38, the applicant states:

*“First Imaging is a not-for-profit organization that does not discriminate against any class of patient based on ability to pay, race, ethnicity, handicap or age. First Imaging actively participates in both the Medicaid and Medicare programs. In FY 2019, Medicare patients accounted for 71.6 percent of First Imaging’s PET cases, while Medicaid patients accounted for 5.0 percent.”*

In Section L, page 74, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

PAYOR CATEGORY	MRI SERVICES AS A % OF TOTAL
Self-Pay	8.2%
Charity Care	0.0%
Medicare*	41.9%
Medicaid*	12.9%
Insurance*	25.6%
TRICARE	11.0%
Other (specify)	0.4%
<b>Total</b>	<b>100.0%</b>

\*Includes any managed care plans.

The projected payor mix is reasonable and adequately supported because the projected payor mix is based on current actual payor mix of MRI patients at First Imaging and the applicant does not expect payor mix for the proposed MRI services to change.

The Agency reviewed the:

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

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

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

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

NA

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.

C

The applicant proposes to acquire an existing MRI scanner located at First Imaging from FirstHealth of the Carolinas, Inc. and continue to operate that MRI at First Imaging.

In Section E, page 54, the applicant states it did not consider any alternatives to this application, as this application proposes only to change ownership of an existing MRI. There will be no change to services being offered or patients projected to be served.

## **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. First Imaging of the Carolinas, LLC shall materially comply with all representations made in the certificate of need application.**
  - 2. First Imaging of the Carolinas, LLC shall acquire the existing fixed Hitachi Oasis High-Field Open MRI scanner located at 30 Memorial Drive in Pinehurst from FirstHealth of the Carolinas and continue to operate the MRI scanner at the existing location.**
  - 3. First Imaging of the Carolinas, LLC 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 fiscal years of operation following initiation of the services authorized by this certificate of need, First Imaging of the Carolinas, LLC 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. First Imaging of the Carolinas, LLC 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 applicant proposes to acquire an existing MRI scanner located at First Imaging from FirstHealth of the Carolinas, Inc. and continue to operate that MRI at First Imaging.

**Capital and Working Capital Costs**

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

<b>FIRST IMAGING CAPITAL COSTS</b>	
Construction/Renovation Contract(s)	\$0
Landscaping	\$0
Architect/Engineering Fees	\$0
Medical Equipment	\$1,127,000
Consultant Fees	\$40,000
<b>Total</b>	<b>\$1,167,000</b>

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

In Section F, page 57, the applicant states there are no start-up costs or initial operating expenses associated with this project.

**Availability of Funds**

First Imaging is co-owned by FirstHealth of the Carolinas, Inc. and Sandhills Diagnostic Imaging, LLC (Sandhills). In Section F, page 56, the applicant states that the capital cost will be funded as shown in the table below:

<b>Sources of Capital Cost Financing</b>			
TYPE	FIRSTHEALTH	SANDHILLS	TOTAL
Loans	\$	\$0	\$0
Accumulated reserves or OE *	\$	\$0	\$0
Bonds	\$	\$0	\$0
Other (Cash Reserves)	\$583,500	\$583,500	\$1,167,000
<b>Total Financing</b>	<b>\$583,500</b>	<b>\$583,500</b>	<b>\$1,167,000</b>

\* OE = Owner's Equity

Exhibit F.2 contains a July 10, 2020 letter from the Chief Financial Officer of FirstHealth committing \$583,500 toward the capital cost of the proposed project. Exhibit F.2 also contains a July 10, 2020 letter from Sandhills committing \$583,500 toward the capital cost of the proposed project. The exhibit contains a July 10, 2020 letter from the Chief Financial Officer of First Imaging, committing the total of \$1,167,000 to purchase the MRI as proposed in this application. Exhibit F.2 also contains audited financial statements for FirstHealth for the years ending December 31, 2019 and 2018. As of December 31, 2019, FirstHealth had \$33,617,000 in cash and cash equivalents and \$917,698,000 in net assets to fund the proposed project.

**Financial Feasibility**

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

MRI	1 <sup>ST</sup> FFY FY 2022	2 <sup>ND</sup> FFY FY 2023	3 <sup>RD</sup> FFY FY 2024
Total MRI Scans (weighted)	5,321	5,532	5,751
Total Gross Revenues (Charges)	\$13,887,831	\$15,448,878	\$17,186,009
Total Net Revenue	\$2,360,931	\$2,626,309	\$2,921,622
Average Net Revenue per Procedure	\$443.70	\$474.75	\$508.02
Total Operating Expenses (Costs)	\$691,683	\$701,494	\$711,637
Average Operating Expense per Procedure	\$130.00	\$126.81	\$123.74
<b>Net Income</b>	<b>\$1,669,248</b>	<b>\$1,924,815</b>	<b>\$2,209,985</b>

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The applicant proposes to acquire an existing MRI scanner located at First Imaging from FirstHealth of the Carolinas, Inc. and continue to operate that MRI at First Imaging.

On page 418, the 2020 SMFP defines the service area for a fixed MRI scanner as *the same as an Acute Care Bed service area*. Thus, the service area for this facility consists of Moore County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 61, the applicant provides a table, reproduced below to illustrate the existing MRI scanners in Moore County:

FACILITY	# MRI SCANNERS	# MRI SCANS
FirstHealth Moore Regional Hospital	3	14,365
Pinehurst Surgical Clinic	1	5,586
Southern Pines Diagnostic Imaging	1	2,730

In Section G, page 61, the applicant explains why it believes its proposal would not result in the unnecessary duplication of approved MRI services in Moore County. The applicant states:

*“First Imaging will acquire an existing MRI scanner in Moore County. This transfer will not result in an increase in the number of MRI scanners in the MRI Service Area inventory.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant proposes to acquire an existing MRI from FirstHealth. The MRI will not change location and the project will not result in a change in services to be offered or the population to be served.

### **Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion based on 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, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

**First Imaging Number of FTE Positions, First Three Project Years**

<b>STAFF POSITION</b>	<b>1<sup>ST</sup> FY (FY 2022)</b>	<b>2<sup>ND</sup> FY (FY 2023)</b>	<b>3<sup>RD</sup> FY (FY 2024)</b>
MRI Technologist	2.25	2.25	2.25
Assistant	0.50	0.50	0.50
Supervisor	0.10	0.10	0.10
Clerical	0.90	0.90	0.90
<b>Total</b>	<b>3.75</b>	<b>3.75</b>	<b>3.75</b>

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.3, which is found in Section Q. In Section H.2 and H.3, page 63, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Exhibit H.3, the applicant provides supporting documentation.

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 65, the applicant states that support services needed to support the proposed MRI service include, but are not limited to: Billing, accounts payable and general accounting, facility management, information management, legal services, materials management, quality management and infection control and scheduling.

On page 65, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1.

In Section I, page 66, the applicant states that it has established 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.

**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 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.

NA

The applicant proposes to acquire an existing MRI scanner located at First Imaging from FirstHealth of the Carolinas, Inc. and continue to operate that MRI at First Imaging. The applicant proposes only to change ownership of the existing MRI scanner; the project involves no relocation, construction of new space or renovation of existing space. Therefore, this Criterion is not applicable to this review.

- (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 applicant provides the historical payor mix during FY 2019 for the proposed services, as shown in the table below:

**Historical Payor Mix MRI Scanner at 30 Memorial Drive**

PAYOR CATEGORY	MRI SERVICES AS A % OF TOTAL
Self-Pay	8.2%
Charity Care	0.0%
Medicare	41.9%
Medicaid	12.9%
Insurance	25.6%
TRICARE	11.0%
Other (specify)	0.4%
<b>Total</b>	<b>100.0%</b>

\*Includes any managed care plans.

In Section L, page 72, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	57.6%	51.8%
Male	42.4%	48.2%
Unknown	0.0%	0.0%
64 and Younger	31.0%	76.1%
65 and Older	69.0%	23.9%
American Indian	2.7%	0.9%
Asian	0.3%	1.6%
Black or African-American	20.3%	12.2%
Native Hawaiian or Pacific Islander	0.1%	0.2%
White or Caucasian	74.3%	77.3%
Other Race	2.1%	7.8%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 applicant states:

*“Neither First Imaging nor its parent companies are obligated under any applicable federal regulations to provide uncompensated care, community service or access by minorities and handicapped persons.”*

In Section L, page 73, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below:

**Projected Payor Mix MRI Scanner at 30 Memorial Drive**

PAYOR CATEGORY	MRI SERVICES AS A % OF TOTAL
Self-Pay	8.2%
Charity Care	0.0%
Medicare*	41.9%
Medicaid*	12.9%
Insurance*	25.6%
TRICARE	11.0%
Other (specify)	0.4%
<b>Total</b>	<b>100.0%</b>

\*Includes any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 8.2% of total services will be provided to self-pay patients, 41.9% to Medicare patients and 12.9% to Medicaid patients.

On page 74, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on current actual payor mix of MRI patients at First Imaging and the applicant does not expect payor mix for the proposed MRI services to change.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 75, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 78, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 applicant proposes to acquire an existing MRI scanner located at First Imaging from FirstHealth of the Carolinas, Inc. and continue to operate that MRI at First Imaging.

On page 418, the 2020 SMFP defines the service area for a fixed MRI scanner as *the same as an Acute Care Bed service area*. Thus, the service area for this facility consists of Moore County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 61, the applicant provides a table, reproduced below to illustrate the existing MRI scanners in Moore County:

FACILITY	# MRI SCANNERS	# MRI SCANS
FirstHealth Moore Regional Hospital	3	14,365
Pinehurst Surgical Clinic	1	5,586
Southern Pines Diagnostic Imaging	1	2,730

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 80, the applicant states it will be able to provide the same MRI services that existing patients are receiving at a lower cost, since the MRI scanner will provide outpatient scans on a scanner owned by First Imaging rather than the hospital.

Regarding the impact of the proposal on cost effectiveness, in Section N, page 80, the applicant states:

*“The cost associated with the acquisition of the MRI scanner is minimal based on asset valuation, but patients and insurers will benefit from the decreased charges offered by the freestanding MRI services as compared to hospital-based MRI services.”*

Regarding the impact of the proposal on quality, in Section N, page 80, the applicant states:

*“First Imaging, through FirstHealth of the Carolinas, is committed to developing and carrying out a performance improvement plan to ensure safety and quality. The objective is to make certain an objective is in place, which will ensure the occurrence of an ongoing evaluation of various aspects of the operation of the project. The plan provides a methodology to monitor, analyze and improve performance.”*

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 81, the applicant states:

*“The First Imaging MRI scanner will continue to be readily accessible to any resident of Moore County with access to the Moore County transportation service.*

...

*First Imaging, through FirstHealth of the Carolinas, attempts to address the barriers to access in its daily operation. First Imaging does not discriminate against any class of patient based on age, sex, religion, race, handicap, ethnicity, or ability to pay.*

*First Imaging, through FirstHealth of the Carolinas, actively participates in both the Medicaid and Medicare programs....”*

Considering all the information in the application, 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 (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L and N 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 based on 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

In Section Q, Form A, the applicant identifies the facilities that operate MRI scanners located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 3 of this type of facility located in North Carolina.

In Section O, page 87, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. In Exhibit O.3, the applicant provides a July 10, 2020 letter signed by the Chief Executive Officer of FirstHealth of the Carolinas, Inc. that states all three related facilities identified in Form A have operated in compliance with the Medicare Conditions of Participation. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all three facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion

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

## C

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

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

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

- (a) *An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner shall:*
- (1) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the mobile MRI region in which the proposed equipment will be located, except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; with the exception that in the event an existing mobile MRI scanner has been in operation less than 12 months at the time the application is filed, the applicant shall demonstrate that this mobile MRI scanner performed an average of at least 277 weighted MRI procedures per month for the period in which it has been in operation;*

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

-NA- The applicant does not propose to acquire a mobile MRI scanner. Therefore, this rule is not applicable to this review.

- (b) *An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:*
  - (1) *demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;*

-C- The applicant states the acquisition of the existing MRI scanner will not increase the inventory of MRI scanners in the Moore County service area. The applicant provides a table to illustrate the utilization of the three existing MRI scanners owned by FirstHealth of the Carolinas that are reported on the FirstHealth Moore Regional Hospital (FMRH) License Renewal Application and in the 2021 SMFP. See the following table, from page 42:

**FirstHealth MRI Utilization**

	# MRI SCANNERS	TOTAL SCANS	OUT PT./ NO CONTRAST	OP / WITH CONTRAST	IP / No CONTRAST	OP / WITH CONTRAST	ADJUSTED TOTAL	AVG. WEIGHTED MRI SCANS
FMRH	3	13,944	10,110	1,512	2,042	280	15,590	5,197

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

-NA- Neither the applicant or a related entity owns a controlling interest in an existing mobile MRI scanner in the Moore County MRI service area.

- (3) *demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*

- (A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,
- (B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,
- (C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,
- (D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or
- (E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;

The 2020 SMFP shows that there are three fixed MRI scanners located in the Moore County MRI service area which the applicant or a related owns a controlling in. Therefore, the applicant must demonstrate that the average annual utilization for the existing, approved and proposed fixed MRI scanners at First Imaging will be at least 4,462 weighted MRI procedures in the third operating year.

-C- In Section Q, Form C the applicant states that it projects to perform 5,751 weighted MRI procedures on the MRI scanner located at First Imaging in the third year of the proposed project. This exceeds the required 4,462 weighted MRI in this performance standard. The discussion regarding projected utilization in Criterion (3) and in Section Q is incorporated herein by reference.

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

-NA- The MRI scanner to be acquired will not be in a different location.

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

- NA- The applicant states that neither the applicant nor a related entity owns a controlling interest in an existing, approved or proposed mobile MRI scanner in Moore County.
- (6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- C- The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q.
- (c) *An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*
- (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure per hour times 40 hours per week times 52 weeks per year; and*
- (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- NA- The applicant does not propose the acquisition of a dedicated fixed breast MRI scanner. Therefore, this Rule is not applicable to this review.
- (d) *An applicant proposing to acquire a fixed extremity MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*
- (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(f)(7); and*
- (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- NA- The applicant does not propose the acquisition of a dedicated fixed extremity MRI scanner. Therefore, this Rule is not applicable to this review.
- (e) *An applicant proposing to acquire a fixed multi-position MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for a demonstration project shall:*
- (1) *demonstrate annual utilization of the proposed multi-position MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(g)(7); and*
- (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- NA- The applicant does not propose the acquisition of a dedicated fixed multi-position MRI scanner. Therefore, this Rule is not applicable to this review.