

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: October 8, 2024

Findings Date: October 8, 2024

Project Analyst: Chalice L. Moore

Co-Signer: Mike McKillip

Project ID #: P-12522-24

Facility: UNC Lenoir Imaging

FID #: 240517

County: Lenoir

Applicant: UNC LCI, LLC

Project: Acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP need determination

REVIEW CRITERIA

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

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

C

UNC LCI, LLC, herein after referred to as “the applicant”, or “UNC Lenoir Imaging”, proposes to acquire no more than one fixed MRI scanner pursuant to the need determination in the 2024 State Medical Facilities Plan (SMFP) to be located at UNC Lenoir Imaging in Lenoir County. Upon project completion, UNC Lenoir Imaging will operate one fixed MRI scanner.

Need Determination

The 2024 SMFP includes a need methodology for determining the need for additional fixed MRI scanners in North Carolina by service area. Application of the need methodology in the 2024 SMFP identified a need for one fixed MRI scanner in Lenoir County. The application was submitted in response to the need determination in the 2024 SMFP for one fixed MRI

scanner in Lenoir County. Therefore, the application is consistent with the need determination in the 2024 SMFP.

Policies

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

Policy GEN-3

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

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

In Section B, pages 27-31, the applicant explains why it believes its application is consistent with Policy GEN-3. The applicant states:

“UNC LCI, LLC is dedicated to ensuring quality care and patient safety through compliance with all applicable federal, state, and local standards established regarding MR imaging and will maintain the highest standards and quality of care that UNC LCI, LLC has sustained throughout its history of providing diagnostic imaging services. The proposed project will improve local access to MRI services for residents of Lenoir County and surrounding communities. UNC LCI, LLC will continue to be accessible to all persons, including those in underserved groups. In Section N, page 103-104, The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to freestanding MRI services, which are unavailable in the service area. As discussed in Section C.4, the proposed MRI scanner at UNC Lenoir Imaging will be the first freestanding fixed MRI scanner in Lenoir County and will operate five days per week, providing a lower cost, convenient option for MRI services close to home.”

Policy GEN-4

Policy GEN-4 on page 30 of the 2024 SMFP states:

“Any person proposing a capital expenditure greater than \$4 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall

include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

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

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

The proposed capital expenditure for this project is greater than \$5 million. In Section B, pages 32-33, the applicant describes the project's plan to improve energy efficiency and water conservation. The applicant states:

"UNC Health's Energy Efficiency and Sustainability Plan, which will be utilized by UNC LCI, LLC for the development of the proposed project, addresses the following systems and features:

- Lighting Systems: Lighting systems will provide higher energy efficiency in accordance with energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The lighting systems shall not adversely affect patient or resident health, safety, or infection control.*
- Water Systems: Water systems, hand wash facilities, and toilets will provide higher energy efficiency in accordance with energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The water systems shall not adversely affect patient or resident health, safety, or infection control.*
- Heating, Ventilation, and Air-Conditioning (HVAC) Systems: HVAC systems will provide higher energy efficiency in accordance with energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The HVAC systems shall not adversely affect patient or resident health, safety, or infection control.*
- Minor equipment such as ice machines will be evaluated prior to purchase and implementation based on energy efficiency and water conservation. The minor equipment shall not adversely affect patient or resident health, safety, or infection control.*

• Other potential energy conservation measures for the project will be researched and evaluated by the project engineer and architect as well as UNC Health's administration.

As detailed above, the design of the proposed project will incorporate materials and equipment which enhance the containment of utilities and energy costs, as applicable to the proposed project."

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of fixed MRI services in Lenoir County.
The applicant adequately documents how the project will promote equitable access to fixed MRI services in Lenoir County.
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
 - The applicant adequately documents that it has a plan in place to ensure water and energy conservation in the development of the proposed project.

(2) Repealed effective July 1, 1987.

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

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP need determination. UNC Lenoir Imaging is wholly owned by UNC Health. UNC Health Lenoir, which is managed by UNC Health, currently operates one hospital-based fixed MRI scanner. UNC Lenoir Imaging proposes to locate the new fixed MRI scanner in a freestanding diagnostic center.

Patient Origin

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

The following table illustrates historical outpatient MRI patient origin at UNC Health Lenoir and projected patient origin for MRI services for UNC Lenoir Imaging.

County	UNC Health Lenoir		UNC Lenoir Imaging	
	Historical Outpatient MRI Patient Origin CY 2023		Third Full FY of Operation following Project Completion CY 2029	
	Patients	% of Total	Patients	% of Total
Lenoir County	1,619	70.0%	2,231	68.8%
Duplin County	166	7.2%	415	12.8%
Greene County	155	6.7%	199	6.1%
Pitt County	109	4.7%	149	4.6%
Wayne County	99	4.3%	98	3.0%
Craven County	74	3.2%	66	2.0%
Jones County	31	1.4%	28	0.9%
Onslow County	27	1.2%	24	0.8%
Other	34	1.5%	31	1.0%
Total	2,315	100.0%	3,241	100.0%

Source: Section C, pages 38 and 40

In Section Q, page 116, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based on the applicant’s experience providing fixed MRI services to outpatients at UNC Health Lenoir.

Analysis of Need

In Section C, pages 42-50, the applicant explains why it believes the population projected to utilize the proposed fixed MRI services needs the proposed services as summarized below:

- **2024 State Medical Facilities Plan Need Determination**– The applicant states Because the MRI capacity within Lenoir County currently consists of one hospital-based fixed scanner at UNC Health Lenoir, the need determination in the 2024 SMFP for one additional fixed scanner to be located in Lenoir County is based on UNC Health Lenoir’s historical MRI utilization. Although UNC Health Lenoir is not the applicant, UNC Health Lenoir provided internal utilization data to UNC Lenoir Imaging for use in this application.
- **Barriers to MRI access in Lenoir County**–The applicant states although UNC Health Lenoir’s existing fixed MRI scanner has shown a historical trend of increasing utilization, Lenoir County residents still encounter barriers when accessing fixed MRI services. As demonstrated in the table below, Lenoir County residents receive MRI services within their home county at a rate of 42.6 scans per 1,000 population. When

compared to North Carolina overall, Lenoir County’s MRI use rate is low, indicating insufficient access.

- **The aging population residing in Lenoir in County and their overall health status:** According to data from the North Carolina Office of State Budget and Management (NC OSBM), Lenoir County’s population experienced a slight decline between 2014 and 2024. While Lenoir County’s overall population has slightly declined, the utilization of the existing fixed MRI at UNC Health Lenoir has grown significantly, as demonstrated previously. This is at least partly due to Lenoir County’s growing segment of residents over the age of 65. Lenoir County’s 65 and over cohort grew 15.5 percent over the last ten years. Lenoir County’s cohort of residents 65 and over now comprises 22 percent of the overall county population. As the population in Lenoir County continues to age, the demand for MRI services will also continue to grow as older residents utilize healthcare services at a higher rate than those who are younger.

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

- The applicant provides data demonstrating historical growth in utilization for the existing hospital-based MRI scanner at UNC Health Lenoir.
- The applicant provides data regarding the aging population residing in Lenoir County and their overall health status.
- The applicant provides information regarding MRI scanner use rates based on data from the NC OSBM and DHSR.

Projected Utilization

In Section Q, Form C.2b page 112, the applicant provides projected utilization for MRI services at UNC Lenoir Imaging the first three project years (SFY 2026-2029), as illustrated in the following table:

UNC Lenoir Imaging	Projected Utilization			
	Partial SFY2026	SFY2027	SFY2028	SFY2029
# of Units (fixed MRI)	1	1	1	1
# of Procedures	1,244	2,937	3,185	3,449
# of Adjusted Procedures	1,356	3,202	3,472	3,759

In Section Q, pages 115-127, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

On pages 115-116, the applicant provides the historical MRI utilization for UNC Health Lenoir. The applicant states that MRI scans performed at UNC Health Lenoir increased at an annual compound rate of 4.4 percent from FFY-to-FFY 2023, as demonstrated in the table below:

UNC Health Lenoir Historical MRI Utilization CY 2019-2023						
	CY2019	CY2020	CY2021	CY2022	2CY2023	2019-2023 CAGR[^]
Total Scans	2,261	2,670	2,822	3,126	3,133	4.4%

Source: Section Q, page 116

[^]Compound annual growth rate

The applicant uses this historical growth rate to project future MRI utilization at UNC Health Lenoir. The applicant states the ratio of scans by type (inpatient, outpatient, base, complex) is based on FFY 2023 ratios and is expected to remain constant. The table below illustrates the projected growth before any shifts of patient to the proposed MRI scanner at UNC Lenoir Imaging.

UNC Health Lenoir Projected MRI Utilization Before Shifts FFY								
	FFY2023	FFY2024	FFY2025	FFY2026	FFY2027	FFY2028	FF20Y29	CAGR
Total Scans	3,113	3, 250	3,393	3,542	3,697	3,860	4,029	4.4%
Total Outpatient Scans	2,484	2,593	2,707	2,826	2,950	3,080	3,215	
Base Outpatient	1,521	1,588	1,658	1,730	1,807	1,866	1,969	
Complex Outpatient	963	1,005	1,049	1,096	1,144	1,194	1,247	
Total Inpatient Scans	629	657	685	716	747	780	814	
Base Inpatient	449	469	489	511	533	557	581	
Complex Inpatient	180	188	196	205	214	223	233	

Source: Section Q, page 116

To align with the financial projections included in Section Q, the applicant converted these projections to correspond with the SFY with the following formula: Current SFY Procedures = Current FFY Procedures x 0.75 + Prior FFY Procedures x 0.25.as shown in the following table:

UNC Health Lenoir Projected MRI Utilization Before Shifts SFY							
	FFY2023	FFY2024	FFY2025	FFY2026	FFY2027	FFY2028	FFY2029
Total Scans	3,116	3,216	3,357	3,504	3,658	3,819	3,987
Total Outpatient Scans	2,482	2,566	2,679	2,796	2,919	3,048	3,181
Base Outpatient	1,520	1,571	1,640	1,712	1,788	1,866	1,948
Complex Outpatient	962	995	1,038	1,084	1,132	1,181	1,233
Total Inpatient Scans	635	650	678	708	739	772	806
Base Inpatient	397	464	484	505	528	551	575
Complex Inpatient	238	186	194	203	212	221	231

Source: Section Q, page 117

The applicant states that some outpatients may continue to need hospital-based MRI scans. The applicant assumes that 70 percent of outpatient scans at UNC Health Lenoir will shift to UNC Lenoir Imaging after the proposed fixed scanner begins operating in SFY 2026. This is shown in the following table.

Projected Shift from UNC Health Lenoir to UNC Lenoir Imaging						
	SFY2024	SFY2025	SFY2026	SFY2027	SFY2028	SFY2029
Total Inpatient Scans	650	678	708	739	772	806
Total Outpatient Scans before Shift	2,566	2,679	2,796	2,919	3,048	3,181
Total Scans Before Shift	3,216	3,357	3,504	3,658	3,819	3,987
70% Outpatient Shift to Proposed MRI	0	0	-979	-2,043	-2,133	-2,227
Total Scans after Shift	3,216	3,357	2,526	1,615	1,686	1,760

*To account for the third quarter start date, the applicant adjusted the shift projected in SFY 2026 based on the number of months UNC Lenoir Imaging will be performing procedures during the year [979 = 1,957 *(6 ÷ 12)].

UNC Health Lenoir’s projected adjusted MRI utilization – after accounting for the outpatient shift to UNC Lenoir Imaging. This is shown in the table below.

UNC Health Lenoir Projected MRI Utilization After Shift							
	FFY2023	FFY2024	FFY2025	FFY2026	FFY2027	FFY2028	FFY2029
Total Scans	3,116	3,216	3,357	2,526	1,615	1,686	1,760
Total Outpatient Scans	2,482	2,566	2,679	1,818	876	914	954
Base Outpatient	1,520	1,571	1,640	1,113	536	560	584
Complex Outpatient	962	995	1,038	705	340	354	370
Total Inpatient Scans	635	650	678	708	739	772	806
Base Inpatient	397	464	484	505	528	551	575
Complex Inpatient	238	186	194	203	212	221	231
Total Adjusted Scans*	3,912	4,015	4,191	3,316	2,356	2,459	2,568

*Adjusted scans are based on the assumptions outlined in the 2024 SMFP. Outpatient adjusted scans are the sum of [Complex Scans x (40/33)] + Base Scans. Inpatient adjusted scans are the sum of [Complex Scans x (70/33)] + [Base Scans x (60/33)]. Total adjusted scans are the sum of outpatient adjusted scans and inpatient adjusted scans.

The projected shift of adjusted outpatient MRI scans from UNC Health Lenoir to UNC Lenoir Imaging is shown in the table below.

Adjusted Outpatient MRI Scans Projected to Shift from UNC Health Lenoir to UNC Lenoir Imaging				
	SFY2026	SFY2027	SFY2028	SFY2029
Total Outpatient Scans	979	2,43	2,133	2,227
Base Outpatient	599	1,251	1,306	1,364
Complex Outpatient	379	792	827	863
Total Outpatient Adjusted Scans to Shift	1,059	2,212	2,309	2,410

*Total outpatient adjusted scans are the sum of [Complex Scans x (40/33)] + Base Scans.

In addition to the shifted outpatient scans from UNC Health Lenoir, the applicant also expects to draw Lenoir County residents receiving MRI services at freestanding facilities in Pitt County.

Historical Lenoir County Residents Receiving Freestanding MRI services in Pitt County, FFY 2022	FFY 2022
Lenoir County residents receiving MRI services at a freestanding imaging facility in Pitt County	775

Source: 2023 Patient Origin Reports as compiled by NC DHSR.

The applicant projects that the subset of MRI patients from Lenoir County will grow at UNC Health Lenoir’s historical MRI scan growth rate of 4.4 percent through FFY 2029, consistent with the historical growth of MRI scans in Lenoir County, as shown in the table below

Projected Lenoir County Residents Receiving Freestanding MRI Services in Pitt County (FFY)									
	FFY2022	FFY2023	FFY2024	FFY2025	FFY2026	FFY2027	FFY2028	FFY2029	CAGR
Lenoir County residents receiving MRI services at a Freestanding facility in Pitt County	775	809	845	882	920	961	1,003	1,047	4.4%

The applicant converted these projections to correspond with the SFY using the same formula previously discussed. This is shown in the table below.

Projected Lenoir County Residents Receiving Freestanding MRI Services in Pitt County (SFY)							
	SFY2023	SFY2024	SFY2025	SFY2026	SFY2027	FFY2028	SFY2029
Lenoir County residents receiving MRI services at a Freestanding facility in Pitt County	809	845	882	920	961	1,003	1,047

The number of Lenoir County residents projected to repatriate from freestanding MRI services in Pitt County to UNC Lenoir Imaging after accounting for the ramp up. This is shown in the table below.

Projected Lenoir County Residents Receiving Freestanding MRI Services in Pitt County (SFY)							
	SFY2023	SFY2024	SFY2025	SFY2026	SFY2027	FFY2028	SFY2029
Lenoir County residents receiving MRI services at a Freestanding facility in Pitt County	801	836	872	911	951	993	1,036
Capture Percentage				75%	75%	75%	75%
Ramp-up Factor				0.25*	0.80	0.90	1.0
Net Repatriation Percentage				19%	60%	68%	75%
Total Repatriated MRI patients				171	570	670	777

*Reflects a 50 percent ramp-up adjusted for partial year (third quarter start date).

The applicant calculated the ratio of adjusted MRI scans to patients at UNC Health Lenoir in SFY 2023. This is shown in the table below.

UNC Health Lenoir Ratio of Adjusted MRI Scans to MRI Patients	
	SFY 2023
Total Outpatient MRI Patients^	2,296
Adjusted Outpatient MRI Scans^^	775
Ratio of Adjusted Outpatient MRI Scans to Outpatients	1.16

The applicant calculated the projected volume of repatriated MRI patients by using the ratio of adjusted MRI scans to patients. As shown in the table below.

Lenoir County Adjusted Scans Projected to Repatriate from Freestanding MRI Facilities in Pitt County to UNC Lenoir Imaging				
	SFY2026	SFY2027	SFY2028	SFY2029
Total Repatriated MRI Patients	171	570	670	777
Ratio of Adjusted MRI Scans to MRI Patients	1.16	1.16	1.16	1.16
Total Repatriated Adjusted MRI Scans	198	662	777	902

In addition to the shifted outpatient scans from UNC Health Lenoir, the applicant also expects to draw Greene and Wayne County residents receiving MRI services at freestanding facilities in Pitt County.

Wayne and Greene County Residents Receiving Freestanding MRI Services in Pitt County, FFY 2022	
Green County	412
Wayne County	165
Total	577

Source: 2023 Patient Origin Reports as compiled by NC DHSR

The applicant projects that this subset of MRI patients will grow at Wayne County’s historical average annual change rate, or 4.4 percent, as calculated in Table 15E-2 of the 2024 SMFP. (Greene County does not have an existing MRI scanner and thus does not have any historical MRI utilization data reported in the 2024 SMFP.) The projected data is shown in the table below.

Projected Lenoir County Residents Receiving Freestanding MRI Services in Pitt County (FFY)									
	FFY2022	FFY2023	FFY2024	FFY2025	FFY2026	FFY2027	FFY2028	FFY2029	CAGR
Wayne County residents receiving MRI services at a freestanding facility in Pitt County	165	172	180	188	196	205	214	223	4.4%
Greene County residents receiving MRI services at a freestanding facility in Pitt County	412	430	449	469	489	511	533	557	4.4%
Total	577	602	629	656	685	715	747	779	

The applicant converted the above projections to correspond with the SFY. The projections are shown in table below.

Projected Wayne and Greene County Residents Receiving Freestanding MRI Services in Pitt County (SFY)							
	SFY2023	SFY2024	SFY2025	SFY2026	SFY2027	SFY2028	SFY2029
Total Wayne and Greene County residents receiving MRI services at a freestanding facility in Pitt County	596	622	649	678	708	739	771

The number of residents originating from Wayne and Greene counties projected to shift from freestanding MRI services in Pitt County to UNC Lenoir is shown in the table below.

Wayne and Greene County Residents Projected to Shift from Freestanding MRI Facilities in Pitt County to UNC Lenoir Imaging				
	SFY2026	SFY2027	FFY2028	SFY2029
Total Wayne and Greene County residents receiving MRI services at a freestanding facility in Pitt County	678	708	739	71
Capture Percentage	50%	50%	50%	50%
Ramp-up Factor	0.25*	0.80	0.90	1.0
Net Capture Percentage	13%	40%	45%	50%
Total Wayne and Greene Residents Captured at UNC Lenoir Imaging	85	283	332	386

*Reflects a 50 percent ramp-up adjusted for partial year (third quarter start date).

On page, 123, the applicant provides the number of Wayne and Greene County residents adjusted scans projected to shift from freestanding MRI services in Pitt County to UNC Lenoir Imaging to account for SFY is shown in the table below.

Wayne and Greene County Residents Projected to Shift from Freestanding MRI Facilities in Pitt County to UNC Lenoir Imaging				
	SFY2026	SFY2027	SFY2028	SFY2029
Total Wayne and Greene County residents Shifted to UNC Lenoir Imaging	85	283	332	386
Ratio of Adjusted MRI Scans to Patients	1.16	1.16	1.16	1.16
Total Wayne and Greene County Adjusted Scans Shifted to UNC Lenoir Imaging	98	328	386	447

On page 123, the applicant provides the projected volume of adjusted scans to be served by the proposed fixed MRI scanner at UNC Lenoir imaging in the first three full fiscal years of the proposed project. The projection data is summarized in the table below.

UNC Lenoir Imaging Projected Adjusted MRI Utilization				
	SFY2026	SFY2027	SFY2028	SFY2029
Total Adjusted MRI Scans Shifted from UNC Health Lenoir	1,059	2,212	2,309	2,410
Total Adjusted MRI Scans Repatriated from Pitt County	198	662	777	902
Total Adjusted MRI Scans Shifted from Wayne and Green County	98	328	386	447
Total UNC Lenoir Imaging Outpatient Adjusted Scans	1,356	3,202	3,472	3,759

On page 125, the applicant projected adjusted MRI scans at UNC Lenoir Imaging and UNC Health Lenoir through the first three full fiscal years of the project as illustrated in the table below:

Projected Adjusted MRI Utilization UNC Lenoir Imaging and UNC Health Lenoir				
	SFY2026	Projected Year SFY2027	Projected Year SFY2028	Projected Year SFY2029
UNC Lenoir Imaging	1,356	3,202	3,472	3,759
UNC Health Lenoir	3,316	2,356	2,459	2,568
Total Adjusted MRI Scans	4,672	5,558	5,931	6,327
Number of MRI Units	2	2	2	2
Total Adjusted Scans per Unit	2,336	2,779	2,996	3,163

As shown in the table above, the applicant projects the two fixed MRI scanners at UNC Lenoir Imaging and UNC Health Lenoir will perform 3,163 adjusted MRI procedures per fixed MRI scanner in the third full fiscal year of operating following completion of the project, which exceeds the utilization threshold required in 10A NCAC 14c.2703 (a)(7)(b).

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

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

Access to Medically Underserved Groups

In Section C, page 57, the applicant states:

“As noted previously, UNC LCI, LLC is a wholly owned entity of UNC Health. As North Carolina’s only state-owned, comprehensive, full-service hospital system,

UNC Health has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status, or lack of medical insurance. UNC Health is guided by Diversity, Equity, and Inclusion as three of its core principles, while also recognizing that its efforts are ongoing as it continues to look for ways to improve.”

As outlined in its “Assuring Access at UNC Health Care”¹⁸ document, Exhibit B.20-5, UNC Health strives to provide adequate financial assistance and expand its overall capacity in order to meet the healthcare needs of all North Carolinians.

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

Medically Underserved Groups	Percentage of Total Patients during the Third Full Fiscal Year
Low income persons	NA*
Racial and ethnic minorities	40.5%
Women	57.8%
Persons with Disabilities	NA*
Persons 65 or older	49.9%
Medicare beneficiaries	64.3%
Medicaid recipients	12.1%

Source: Section C, page 50

*The applicant states it does not maintain data on low-income persons or persons with disabilities.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

CA

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP.

In Section E, pages 70-71, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- **Forgo applying given the reporting error in the 2024 SMFP-** As discussed in Section C.4, during the process of building this application, the applicant discovered that, if not for the reporting error in UNC Health Lenoir's 2023 HLRA, the 2024 SMFP MRI need methodology would not have generated a need determination for an additional fixed MRI scanner in Lenoir County. However, irrespective of the reporting error, there is in fact a need determination in the 2024 SMFP for which applicants can apply. As discussed throughout this application, the applicant states that there is a clear need for additional fixed MRI capacity in Lenoir County, particularly freestanding fixed MRI capacity, and that this need can best be met through the development of UNC Lenoir Imaging.
- **Develop the proposed MRI in another location-** The applicant considered developing the proposed MRI scanner at a different location to meet the need for additional fixed MRI capacity in Lenoir County. However, the applicant states a central location, like the proposed site, is best for the county's first freestanding fixed MRI scanner to maximize patient access. Additionally, developing the proposed MRI scanner in an existing building as proposed will minimize construction costs. For these reasons, the applicant determined that developing the proposed fixed MRI scanner at a different site would be a more costly and less effective alternative.
- **Develop the proposed MRI as a hospital-based service-** The MRI capacity within Lenoir County currently consists of one hospital-based fixed scanner at UNC Health Lenoir. In FFY 2023, almost 80 percent of the MRI volume at UNC Health Lenoir was classified as outpatient. However, there are no freestanding fixed MRI scanners

in the county. The proposed MRI scanner at UNC Lenoir Imaging will not only introduce lower cost, freestanding fixed MRI services to Lenoir County, but it will also create additional capacity that, in turn, will enhance timely access to the existing hospital-based MRI services provided at UNC Health Lenoir. Thus, a freestanding option will increase access and improve convenience and patient satisfaction for all those seeking MRI services in Lenoir County. It will also offer significant cost savings to patients via lower co-payments and coinsurance charges. For these reasons as well as others discussed elsewhere in the application, developing the proposed project as a freestanding diagnostic center was determined to be a more effective alternative than developing additional hospital-based capacity.

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

- The applicant provides reasonable and adequately supported information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. UNC LCI, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall acquire no more than one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at UNC Lenoir Imaging.**
- 3. Upon completion of the project, UNC Lenoir Imaging shall have no more than one fixed MRI scanner.**
- 4. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 5. Progress Reports:**

- a. Pursuant to G.S. 131E-189(a), the certificate holders shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
 - b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on March 1, 2025.
6. The certificate holder shall not acquire as part of this project any equipment that is not included in the project’s proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 128, the applicant projects the total capital cost of the project as shown in the table below.

UNC Lenoir Imaging Projected Capital Costs	
Construction/Renovation Contract(s)	\$2,480,427
Architect/Engineering Fees	\$233,780
Medical Equipment	\$2,194,248
Non-Medical Equipment	\$602,744
Furniture	\$83,342
Consultant Fees	\$87,011
Other (Contingencies, Escalation. Application fees & Permit fees)	\$409,801
Total	\$6,091,353

In Section Q, page 123, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant projects construction cost based on the contractor's estimate.
- The cost of medical equipment is based on vendor for proposed MRI scanner quotation.
- Costs to cover contingencies, escalation fees, application fees, and permit fees, and are based on the experience of UNC Health with similar projects.

In Section F.3b, page 74-75, the applicant states there will be start-up cost in the amount of \$28,124. This amount includes the cost of paying for mortgage, hiring staff, utilities, purchasing supplies and equipment, as well as training staff. In Section F.3c, page 75, the applicant states that there will be initial operating costs in the amount of \$112,496, for a total working capital cost of \$140,620.

The applicant adequately demonstrates the working capital needs of the project based on the following:

- The applicant projects the start-up cost based on one month of supplies, utilities, staffing, and all other non-depreciation expenses.
- The applicant projects the initial operating period cost number of months during which cash outflow (operating costs) for the entire facility exceeds cash inflow (revenues) for the entire facility; that period ends for UNC Lenoir Imaging after four months.
- The applicant projects include all non-depreciation expenses, calculated as the difference between the total cash outflow (operating costs) during the initial operating period for the entire facility and total cash inflow (revenues) during the initial operating period for the entire facility.

Availability of Funds

In Section F, page 72, the applicant states the capital cost will be funded through the accumulated reserves of UNC Health. Exhibit F.2-1 contains a letter signed Will Bryant, Chief Financial Officer (CFO) of UNC Health, documenting the availability of accumulated reserves to fund the proposed project. Exhibit F.2-2 the applicant provides a copy of the most recent audited financials for UNC Hospitals, an affiliated enterprise of UNC Health.

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

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

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F.2b, page 130, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years (FY) following project completion, as shown in the table below:

MRI Services	1st Full FY SFY 2027	2nd Full FY SFY 2028	3rd Full FY SFY 2029
# of Scans Adjusted	\$3,202	\$3,472	\$3,756
Total Gross Revenues (Charges)	\$4,929,931	\$5,505,878	\$6,140,589
Total Net Revenue	\$1,078,410	\$1,204,397	\$1,343,239
Average Net Revenue per Weighted MRI Scan	\$337	\$347	\$358
Total Operating Expenses (Costs)	\$1,190,071	\$1,268,400	\$1,297,748
Average Operating Costs per Weighted MRI Scan	\$372	\$365	\$346
Net Income	(\$111,661)	(\$64,003)	\$45,491

Source: Section Q, Form F.2b, Page 130

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section F, page 77 and 79. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant's projected patient services gross revenue is based on projected payor mix and average charge for the service based on UNC Health Lenoir's FY 2023 experience for outpatient MRI, adjusted downward to reflect freestanding reimbursement.
- Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP.

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

The following table identifies the one existing fixed MRI scanner located in the Lenoir County service area, summarized from Table 15E-1, page 346 of the 2024 SMFP:

Location	Fixed MRI Scanners	Total MRI Scans	Average # of Scans/Unit
UNC Lenoir Health Care	1.0	3,126	3,126

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

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

“The proposed MRI scanner at UNC Lenoir Imaging will be the first freestanding fixed MRI scanner in Lenoir County and will operate five days per week, providing a lower cost, convenient option for MRI services close to home. Further, as discussed in Section C.4, UNC Health Lenoir’s existing scanner is well utilized, and MRI volume continues to grow. By shifting appropriate outpatients— those who are clinically appropriate, geographically proximate, or prefer a freestanding alternative regardless of their geographic origin—to UNC Lenoir Imaging, UNC Health Lenoir will be able to focus its capacity on quality, timely care for higher acuity patients. Thus, the proposed project will not result in any unnecessary duplication.”

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

- There is a need determination in the 2024 SMFP for the proposed fixed MRI scanner.
- There is only one MRI scanner in Lenoir County which is located at UNC Lenoir Health Care.

- The applicant adequately demonstrates the need for the proposed fixed MRI scanner at UNC Lenoir Imaging in addition to the existing MRI scanner in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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

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

In Section Q, Form H, page 134, the applicant provides current and projected full-time equivalent (FTE) staffing for its MRI services, as illustrated in the following table:

Staffing	1st Full FY SFY2027	2nd Full FY SFY2028	3rd Full FY SFY2029
MRI Technologists	2.0	2.0	2.0
Administrative Support Staff	2.0	2.0	2.0
Total	4.0	4.0	4.0

The assumptions and methodology used to project staffing are provided in Section H, page 84. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3(b). In Section H, pages 84-85, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant states that the project will be all staff will be employed and trained by UNC Health and leased to the applicant to staff UNC Lenoir Imaging.
- The applicant states that UNC Health’s employment offices use a variety of venues to recruit new staff and hire the best applicant considering job fit and organization fit.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP.

Ancillary and Support Services

In Section I, page 86, the applicant identifies the necessary ancillary and support services for the proposed fixed MRI services. In Section I, pages 86-87 the applicant explains how each ancillary and support service is and will be available and supporting documentation is provided in Exhibit I.1.1. The applicant adequately demonstrates that the necessary ancillary and support services are and will be made available.

Coordination

In Section I, pages 87, the applicant describes that although the facility will be new, UNC Lenoir Imaging will benefit from existing relationships with UNC Health's relationships with local health care and social service providers. The applicant provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

- (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

- (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

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP.

In Section K, page 90, the applicant states that the project involves constructing 3,218 square feet of renovated space. Line drawings are provided in Exhibit C.1-2.

In Section K, page 90, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal because the design and means of the proposed renovation, were developed to minimize the cost of the project by renovating existing space rather than constructing new space.

In Section K, page 91, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states that the proposed costs are necessary to ensure the proposed project can be developed, which in turn will increase access to convenient, lower cost MRI services in the service area.
- The applicant states the proposed fixed MRI scanner at UNC Lenoir Imaging will have lower fixed expenses than the existing hospital-based MRI service at UNC Health Lenoir.
- The applicant states that outpatient MRI procedures performed at a freestanding facility also have a lower reimbursement level than those performed at a hospital, resulting in lower costs to patients and insurers.

In Section B.21, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved.

In Section L, page 94, the applicant states that they are not an existing facility, therefore historical payor sources do not exist. The applicant, however, does provide the historical payor mix during for UNC Lenoir Health for its existing fixed MRI services, as shown in the table below:

UNC Lenoir Health Historical Payor Mix, CY2023	
Payor Source	MRI Services as Percent of Total
Self-Pay	2.5%
Medicare*	64.3%
Medicaid*	10.8%
Insurance*	11.7%
Other^	10.7%
Total	100.0%

Source: Section L, page 89

*Including any managed care plans.

^Workers Compensation, TRICARE, and other payors.

In Section L, page 94, the applicant states that UNC Lenoir Imaging is not an existing facility and therefore historical patient data does not exist. The applicant however provides UNC Lenoir Health demographics, as the assumption is they will serve similar demographic populations, see the table below:

UNC Lenoir Health Last Full FY before Submission of the Application		
	Percentage of Total Patients Served	Percentage of the Population of the Service Area*
Female	57.8%	52.3%
Male	42.2%	47.7%
Unknown	0.0%	0.0%
64 and Younger	50.1%	78.3%
65 and Older	49.9%	21.7%
American Indian	0.1%	0.7%
Asian	0.0%	0.8%
Black or African American	37.2%	41.3%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	59.0%	54.8%
Other Race	3.2%	2.2%
Declined / Unavailable	0.5%	0.0%

Source: Section L, page 96

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

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's

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

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 98, the applicant states it has no such obligation.

In Section L, page 98, the applicant states that the facility identified in Section A.4, UNC Lenoir Imaging, is not an existing facility and there have been no patient civil rights equal access complaints filed.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, pages 98-99, the applicant projects the following payor mix for MRI services at UNC Lenoir Imaging for the third full fiscal year of operation (SFY2029), as shown in the table below:

UNC Lenoir Imaging MRI Services Projected Payor Mix SFY2029	
Payor Source	Entire Facility as Percent of Total
Self-Pay	1.3%
Medicare*	64.3%
Medicaid*	12.1%
Insurance*	11.7%
Other^	10.7%
Total	100%

Source: Section L, page 98

* Including any managed care plans.

^Workers Compensation, TRICARE, and other payors.

In Section L, page 92, the applicant provides the assumptions used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the UNC Lenoir Health most recent historical payor mix for outpatient MRI services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 100, the applicant describes the means by which a person will have access to the proposed fixed MRI services at UNC Lenoir Imaging.

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.

- (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

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP.

In Section M, page 102, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have and will continue to have access to the facility for training purposes based on the following:

- The applicant states the proposed freestanding fixed MRI services at UNC Lenoir Imaging will be accessible to the existing professional training programs affiliated with UNC Health.
- UNC Health Lenoir will be the primary clinical training site for students in the new Computed Tomography and Magnetic Resonance Imaging Program at Lenoir Community College.
- UNC Health Lenoir has a long history of supporting health professional training programs in the community at large.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP.

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

The following table identifies the one existing and approved fixed MRI scanner located in the Lenoir County service area, summarized from Table 15E-1, page 346 of the 2024 SMFP:

Location	Fixed MRI Scanners	Total MRI Scans	Average # of Scans/Unit
UNC Lenoir Health Care	1.0	3,126	3,126

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

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 102, the applicant states

“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to freestanding MRI services, which are unavailable in the service area. As discussed in Section C.4, the proposed MRI scanner at UNC Lenoir Imaging will be the first freestanding fixed MRI scanner in Lenoir County and will operate five days per week, providing a lower cost, convenient option for MRI services close to home. The proposed MRI scanner will not only introduce lower cost, freestanding fixed MRI services to Lenoir County, but it will also create additional capacity that, in turn, will enhance timely access to the existing hospital-based MRI services provided at UNC Health Lenoir. Thus, a freestanding option will increase access and improve convenience and patient satisfaction for all those seeking MRI services in Lenoir County. It will also offer significant cost savings to patients via lower copayments and coinsurance charges. Ultimately, the proposed fixed MRI scanner at UNC Lenoir Imaging will promote competitive access to lower cost, freestanding MRI services not currently available in Lenoir County and for which hundreds of resident’s travels outside the county each year.”

Regarding the expected effects of the proposal on cost effectiveness, in Section B, page 27 and Section N, page 103, the applicant states that UNC Lenoir Imaging commitment to maximizing the healthcare value for resources expanded in the delivery of MRI services and the positive impact that the proposed project will have on the cost-effectiveness of the proposed services.

Regarding the expected effects of the proposal on quality in the service area, in Section N, page 103, the applicant states Section B, and Section N page 103

“UNC LCI, LLC’s commitment to promoting safety and quality in the delivery of MRI services and the positive impact that the proposed project will have on the quality of the proposed services.”

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

Regarding the expected effects of the proposal on access by medically underserved groups in the service area, in Section N, page 104, the applicant states that UNC commitment to promoting equitable access in the provision of MRI services and the positive impact the proposed project will have on access by medically underserved groups to the proposed services.

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

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP.

In Section Q, Form O, page 136, the applicant identifies the health service facilities located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 15 hospitals and diagnostic centers located in North Carolina.

In Section O, page 105, 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.. After reviewing and considering information provided by the applicant and the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 15 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

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

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(a) *An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

(1) *identify the existing fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;*

-C- In Section C, page 59, the applicant states UNC Health Lenoir owns and operates one fixed MRI scanner.

(2) *identify the approved fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;*

-NA- In Section C, page 60, the applicant states there are no approved fixed MRI scanners owned or operated by the applicant, or a related entity located in the Lenoir County fixed MRI service area.

- (3) *identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service area during the 12 months before the application deadline for the review period;*
- NA- In Section C, page 60, the applicant states, there are no mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the Lenoir County proposed fixed MRI scanner service area during the 12 months before the application deadline for this review.
- (4) *identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area;*
- NA- In Section C, page 60 the applicant states that neither the applicant nor a related entity has been approved to own or operate an additional mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.
- (5) *provide projected utilization of the MRI scanners identified in Subparagraphs (a)(1) through (a)(4) of this Paragraph and the proposed fixed MRI scanner during each of the first three full fiscal years of operation following completion of the project;*
- C- In Section Q, pages 111-127, the applicant provides projected utilization for both its existing and proposed fixed MRI scanners during each of the first three full fiscal years of operation following project completion.
- (6) *provide the assumptions and methodology used to project the utilization required by Subparagraph (a)(5) of this Paragraph;*
- C- In Section Q, pages 115-127, the applicant provides assumptions and methodology for both of its existing and proposed fixed MRI scanners during each of the first three full fiscal years of operation following project completion.
- (7) *project that the fixed MRI scanners identified in Subparagraphs (a)(1) and (a)(2) of this Paragraph and the proposed fixed MRI scanner shall perform during the third full fiscal year of operation following completion of the project:*
- (a) *3,494 or more adjusted MRI procedures per fixed MRI scanner if there are two or more fixed MRI scanner in the fixed MRI scanner service area;*
 - (b) *3,058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or*
 - (c) *1,310 or more adjusted MRI procedures per MRI scanner if there are no existing fixed MRI scanners in the fixed MRI scanner service area;*

There is currently one existing fixed MRI scanner in Lenoir County at UNC Health Lenoir; thus, Subparagraph (b) applies to this review.

-C- In Section Q, pages 125, the applicant projects to provide 3,163 adjusted MRI procedures per MRI scanner during the third full fiscal year of operation following project completion on each of its existing and proposed fixed MRI scanners. This exceeds 3,058 adjusted MRI procedures per fixed MRI scanner in the fixed MRI scanner service area. The full methodology and assumptions are provided in Sections Q. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(8) *project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform 3,120 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal year of operations following completion of the project.*

-NA- In Section C, page 61, the applicant states, there are no mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites in the Lenoir County proposed fixed MRI scanner service area during the 12 months before the application deadline for this review.

(b) *An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

- (1) *identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;*
- (2) *identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;*
- (3) *identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;*
- (4) *identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that will be located in the proposed mobile MRI scanner service area;*
- (5) *identify the existing and proposed host sites for each mobile MRI scanner identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner;*
- (6) *provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph and the proposed mobile MRI scanner during each of the first three full fiscal years of operation following completion of the project;*
- (7) *provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;*
- (8) *project that the mobile MRI scanners identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner shall perform 3,120 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operations following completion of the project; and*
- (9) *project that the fixed MRI scanners identified in Subparagraphs (b)(3) and (b)(4) of this Paragraph shall perform during the third full fiscal year of operations following completion of the project:*

- (a) *3,494 or more adjusted MRI procedures per fixed MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area;*
- (b) *3,058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area;*
- (c) *1,310 or more adjusted MRI procedures per fixed MRI scanner if there are no fixed MRI scanners in the fixed MRI scanner service area.*

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