

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 30, 2022

Findings Date: April 6, 2022

Project Analyst: Gregory F. Yakaboski

Co-Signer: Lisa Pittman

### COMPETITIVE REVIEW

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Project ID #: J-12141-21  
Facility: Raleigh Radiology Chapel Hill  
FID #: 210264  
County: Orange  
Applicant: RR WM Imaging Chapel Hill, LLC  
Project: Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP

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Project ID #: J-12145-21  
Facility: UNC Health Imaging Center  
FID #: 210831  
County: Orange  
Applicant: NC Imaging Centers, LLC  
Project: Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP

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Project ID #: J-12155-21  
Facility: Duke Coley Hall Imaging  
FID #: 200897  
County: Orange  
Applicant: Duke University Health System, Inc.  
Project: Change of scope for Project ID# J-012001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP

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

can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

## REVIEW CRITERIA

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

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

### C All Applications

#### Need Determination

The 2021 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional fixed Magnetic Resonance Imaging (MRI) scanners in North Carolina by service area. Application of the need methodology in the 2021 SMFP identified a need for one fixed MRI scanner in the Orange County service area. Three applications were received by the Healthcare Planning and Certificate of Need Section (CON Section) with each proposing to acquire one fixed MRI scanner. However, pursuant to the need determination, only one fixed MRI scanner may be approved in this review.

#### Policies

*Policy GEN-3: Basic Principles* of the 2021 SMFP is applicable to all three applications.

*Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities* of the 2021 SMFP is applicable to all three applications.

#### **Policy GEN-3**

Policy GEN-3 on page 29 of the 2021 SMFP states:

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

*volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

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

Policy GEN-4 on page 29 of the 2021 SMFP states:

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

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

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 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.”*

**J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP RR WM Imaging Chapel Hill, LLC, hereinafter referred to as “the applicant” or “RR-Imaging”, proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Raleigh Radiology Chapel Hill (RR-Chapel Hill). The proposed project would be a change of scope for Project ID# J-12062-21. RR-Chapel Hill is a non-hospital licensed diagnostic center to be located at 120 Banks Drive, Chapel Hill, Orange County. RR-Chapel Hill was issued a Certificate of Need effective October 29, 2021.**

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

*Policy GEN-3.* In Section B.2, pages 26-28, the applicant explains why it believes its application is conforming to Policy GEN-3.

*Policy GEN-4.* The proposed capital expenditure is between \$2 million and \$5 million. In Section B.2, pages 28-29, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

### **Conclusion**

The Agency reviewed the:

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

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

- The applicant does not propose to acquire 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 MRI services in Orange County;
  - The applicant adequately documents how the project will promote equitable access to MRI services in Orange County; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
  - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

### **J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

NC Imaging Centers, LLC, hereinafter referred to as “the applicant” or “NC Imaging”, proposes to develop a new diagnostic center, UNC Health Imaging Center (UNC Health Imaging), by acquiring one fixed MRI scanner. The proposed diagnostic center would be a non-hospital licensed diagnostic center to be located in leased space in a medical office building (MOB) located at 106 Carraway Crossing Drive, Chapel Hill, Orange County.

NC Imaging Centers, LLC is a wholly owned entity of the University of North Carolina Health System, formerly known as UNC Health Care, now known as UNC Health.

Currently, aside from UNC Health, only Wake Radiology (Chapel Hill Diagnostic Imaging, LLC) has a fixed MRI scanner in Orange County. On page 44, footnote 15, the applicant states *“Although UNC REX Hospital has a relationship with Wake Radiology, Wake Radiology Chapel Hill (a) does not share the same parent corporation or holding company with NC Imaging Centers, LLC; (b) is not a subsidiary of the same parent corporation or holding company as NC Imaging Centers, LLC; and (c) does not participate with NC Imaging Centers, LLC in a joint venture that provides the same type of health services proposed in this applications. As such, Wake Radiology Chapel Hill is not a related entity based on the definition of related entity as defined in 10A NCAC 14C .0202(10).”*

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

*Policy GEN-3.* In Section B.2, pages 27-32, the applicant explains why it believes its application is conforming to Policy GEN-3.

*Policy GEN-4.* The proposed capital expenditure exceeds \$5 million. In Section B.2, page 33, the applicant describes the project’s plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

## **Conclusion**

The Agency reviewed the:

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

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

- The applicant does not propose to acquire 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 MRI services in Orange County;
  - The applicant adequately documents how the project will promote equitable access to MRI services in Orange County; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

- The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

**J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**Duke University Health System, Inc., hereinafter referred to as “the applicant” or DUHS,** proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Duke Coley Hall Imaging. Duke Coley Hall Imaging, Project ID# J-12001-21, received a certificate of need with an effective date of March 25, 2022. The proposed project would be a change of scope for Project ID# J-12001-21. The proposed diagnostic center would be operated as an independent diagnostic testing facility (IDTF) located at 66 Vilcom Drive, Chapel Hill, Orange County.

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

*Policy GEN-3.* In Section B.2, page 25 and in Sections M, N and O, the applicant explains why it believes its application is conforming to Policy GEN-3.

*Policy GEN-4.* The proposed capital expenditure is between \$2 million and \$5 million. In Section B.2, pages 25-26, and in Section K, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

**Conclusion**

The Agency reviewed the:

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

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

- The applicant does not propose to acquire 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 MRI services in Orange County;
  - The applicant adequately documents how the project will promote equitable access to MRI services in Orange County; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
  - The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.
- (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**  
**All Applications**

**J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**RR-Imaging** proposes to add a fixed MRI scanner to an approved, under development diagnostic center, RR-Chapel Hill. RR-Chapel Hill will be non-hospital licensed and located at 120 Banks Drive, Chapel Hill, Orange County.

**Patient Origin**

The 2021 SMFP, page 344, defines the service area for a fixed MRI scanner 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, Orange County is the service area. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin.

**RR-Chapel Hill: MRI**

County	1 <sup>st</sup> Full FY		2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY	
	(CY2023)		(CY2024)		(CY2025)	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Orange	1,567	67%	2,352	67%	2,996	67%
Out of Area*	772	33%	1,158	33%	1,476	33%
Total	2,339	100%	3,510	100%	4,471	100%

Source: Table on page 37 of the application.

\*Out of Area includes all other NC counties and other states. Specific counties will vary from year to year.

In Section C, page 36, and in Section Q the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- The applicant based projected patient origin from Orange County on a 23% market share by the third operating year (CY2025) with a phased in ramp up of 50%, 75% and then 100% in the third operating years. (see pages 125-126)
- The applicant states that over 40% of reported Orange County residents currently go outside Orange County for MRI services with over 35% of those patients going to freestanding facilities.
- The applicant projected 33% in-migration. Wake Radiology, the only freestanding, non-hospital licensed MRI provider in Orange County, reported a range of 42% to 65% in-migration over the four-year period ending September 30, 2020.

### **Analysis of Need**

In Section C.4, pages 40-51, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below

- Need Determination: The need determination for one additional fixed MRI scanner in Orange County in the 2021 SMFP (page 40).
- Competition: Need for more competition in the Orange County MRI service area (page 41).
- Population: The population growth, aging and distribution in Orange County. (pages 42-46).
- Accommodate patients referred by local providers and Orange County health care specialists (pages 46-47).
- MRI use rates (page 48).
- Community access to MRI services in Orange County (pages 49-50).
- Social determinants of health (pages 50-51).

The information is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- The 2021 SMFP identifies the need for one additional fixed MRI scanner in Orange County.
- Population growth, particularly among the elderly is occurring in Orange County.
- Outmigration of Orange County residents for MRI services is high. The applicant states “an average of 43 percent of reported Orange County resident MRIs occurred at locations outside Orange County during the four years ending September 30, 2020.”
- MRI use rates have increased year over year from FY2014 – FY2019.



- The applicant uses clearly cited and reasonable historical and demographic data to identify the population to be served, its projected growth, and the need the identified population has for the proposed services.
- Letters from physicians/practices who have expressed support for the proposed project. See Exhibit C.4.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization, as illustrated in the following tables.

**RR-Chapel Hill: Projected MRI Utilization**

	<b>OY1 CY2023</b>	<b>OY2 CY2024</b>	<b>OY3 CY2025</b>
# of MRI scanners	1	1	1
Unweighted Procedures	2,339	3,510	4,471
Weighted Procedures	2,683	4,026	5,128

Source: Section Q, Form C.2b. See also page 129 of the application.

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

*Forecast Need*

- Step 1) *Determine RRCH MRI Service Area Population* (pages 119-120).
- Step 2) *Estimate Orange County Resident MRI Unadjusted Procedure Use Rate, 2021-2025* (pages 120-122).
- Step 3) *Determine Need for MRI Procedures by Orange County Residents* (page 122).
- Step 4) *Determine Average State MRI Weighting Factor* (page 123).
- Step 5) *Determine Adjusted MRI Procedure for Orange County* (page 124).

*Forecast Utilization*

- Step 6) *Determine Market Share and Unadjusted MRI Utilization* (pages 125-126).
- Step 7) *Determine In-migration from Outside Orange County to RRCH* (pages 126-127).
- Step 8) *Determine Adjusted MRI Procedures Using Weighting Factors* (page 128).
- Step 9) *Convert RRCH Adjusted MRI Procedures from Fiscal (Project) Years to Calendar Years* (page 129).

Projected utilization is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- There was a need determination in the 2021 SMFP for a fixed MRI scanner in the Orange County MRI service area and this proposed project will meet that need determination by developing a fixed MRI scanner in Orange County.
- Persons age 65+ are the primary users of imaging services. The 65+ age group of the population is growing in Orange County. There is a projected 3.3% (or 7,200 people) increase between 2019 to 2026 (see page 121).
- To project utilization the applicant utilizes an MRI use rate per 1,000 people of 85.50 in the third year which is conservative as it is below that State of NC MRI use rate.
- The methodology and assumptions utilized by the applicant were reasonable, conservative and well supported. The applicants projected total unadjusted Orange County MRI procedures combined with its projected market share of those MRI procedures combined with projected in-migration to the MRI services to be offered by the proposed facility is reasonable.
- MRI scans performed in a freestanding (non-hospital licensed) facility are generally less costly than MRI scans performed in a hospital licensed facility. There are ten fixed MRI scanners in Orange County, only one of which is in a freestanding facility. The applicant is proposing to develop a fixed MRI scanner in a freestanding diagnostic facility.
- The fixed MRI scanner is proposed to be in a diagnostic center with other diagnostic services (including mammography, x-ray, bone density and ultrasound services) and will benefit from this synergy.
- The proposed fixed MRI scanner is a “wide bore” which is more acceptable/workable for many patients, thus increasing desirability and access.
- The proposed fixed MRI scanner would be located in a new, freestanding facility (lower MRI costs as compared to hospital based fixed MRI scanners) located with easy access to major traffic corridors, ample parking, electric vehicle charging stations on site and with an adjacent covered bus stop facilitating public transportation access.
- The proposed fixed MRI scanner would be managed by an experienced management team with extensive experience and success managing facilities with MRI scanners in nearby Wake County, which like Orange County, has both medical facilities and specialists that draw-in patients from outside the County.
- Orange County also draws in a significant part of its workforce from outside the county per application exhibits. The convenience of a lower cost fixed MRI scanner in closer proximity to a patient’s workplace increases access.
- Outmigration of Orange County residents for MRI services is high. The applicant states “an average of 43 percent of reported Orange County resident MRIs occurred at locations outside Orange County during the four years ending September 30, 2020.”
- MRI use rates have increased year over year from FY2014 – FY2019.
- Letters of support with intent to refer in Exhibit I.2

### **Access to Medically Underserved Groups**

In Section C.6, page 57, the applicant states,

*“RRWMICH will adopt RRLLC policies at RRCH. As detailed in the non-discrimination policy in Exhibit C.6, RRLLC-managed facilities accept all patients regardless of gender, gender preference, race, ethnicity, age, income, religion, or disability status.”*

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

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	5.4%
Racial and ethnic minorities	23.1%
Women	52.3%
Persons with Disabilities	5.8%
Persons 65 and older	40.0%
Medicare beneficiaries	40.0%
Medicaid recipients	4.9%

Source: Table on page 59 of the application.

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 reasons:

- RR-Chapel Hill will be managed by RRLLC. RRLLC-managed facilities accept all patients regardless of gender, gender preference, race, ethnicity, age, income, religion, or disability status.
- The applicant will accept both Medicaid and Medicare and follow all applicable federal and state guidelines.
- The applicant will assure that the physicians providing service at RR-Chapel Hill maintain a Medicare and Medicaid provider number and serve beneficiaries of these government programs.
- The applicant's percentage projections for women, persons with disabilities and racial and ethnic minorities are matched to and based on Orange County US Census data.
- The applicant states that the proposal will be accessible to persons with disabilities as required by the American with Disabilities Act.

### **Conclusion**

The Agency reviewed the:

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

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

**J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

NC Imaging proposes to develop a new diagnostic center, UNC Health Imaging, by acquiring one fixed MRI scanner. The proposed diagnostic center would be a non-hospital licensed diagnostic center located at 106 Carraway Crossing Drive, Chapel Hill, Orange County.

**Patient Origin**

The 2021 SMFP, page 344, defines the service area for a fixed MRI scanner 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, Orange County is the service area. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin.

**UNC Health Imaging: MRI**

County	1 <sup>st</sup> Full FY		2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY	
	(7/1/2023 – 6/30/2024)		(7/1/2024 – 6/30/2025)		(7/1/2025 – 6/30/2026)	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Orange	562	27.9%	909	27.9%	1,308	27.9%
Alamance	419	20.8%	677	20.8%	974	20.8%
Durham	199	9.9%	322	9.9%	462	9.9%
Wake	156	7.8%	253	7.8%	364	7.8%
Chatham	59	2.9%	96	2.9%	138	2.9%
Guilford	59	2.9%	95	2.9%	137	2.9%
Other*	559	27.8%	905	27.8%	1,301	27.8%
Total	2,014	100%	3,258	100%	4,684	100%

Source: Table on page 39 of the application.

\*Other- Includes a list of other counties in North Carolina as well as other states as detailed on page 39 of the application.

In Section C.3, page 39, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- projected MRI utilization for the proposed facility is based on a shift of MRI patients from the UNC Hospitals Hillsborough Campus; and
- projected patient origin is based on the historical (CY2020) patient origin for outpatient MRI services at UNC Hospitals Hillsborough Campus.

**Analysis of Need**

In Section C.4, pages 41-54, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Population: The projected growth and aging of the population in the Orange County MRI service area (pages 42-43)
- Need Determination: The need determination for one additional fixed MRI scanner in Orange County in the 2021 SMFP (pages 43-46).
- The need for freestanding fixed MRI capacity in Orange County (pages 46-49).
- The need for freestanding fixed MRI capacity within UNC Health (pages 49-54).

The information is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- The 2021 SMFP identifies the need for one additional fixed MRI scanner in Orange County.
- Population growth, particularly among the elderly is occurring in Orange County.
- The proposed project is to develop the proposed fixed MRI scanner in a freestanding, non-hospital licensed facility which would provide significant economic benefits for both patients and payors alike. Outmigration of Orange County residents for MRI services is high. A freestanding, non-hospital licensed facility offering fixed MRI services would lower out-of-pocket expenses for patients.
- The applicant uses clearly cited and reasonable historical and demographic data to identify the population to be served, its projected growth, and the need the identified population has for the proposed services.
- Letters from physicians who have expressed support for the proposed project. See Exhibit I.2.

Projected Utilization

In Section Q, the applicant provides projected utilization, as illustrated in the following table.

**Projected MRI Utilization: UNC Health Imaging Center**

	<b>OY1 FFY2024</b>	<b>OY2 FFY2025</b>	<b>OY3 FFY2026</b>
# of MRI scanners	1	1	1
Unweighted Procedures	2,014	3,258	4,684
Weighted Procedures	2,488	4,025	5,788

Source: Section Q, Form C.2b- UNC Health Imaging Center

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

Background:

- The applicant’s fiscal year corresponds to the State Fiscal Year (SFY) July to June.
- The first three full fiscal years of the project are: SFY 2024, 2025 and 2026.

- The historical data presented is based on SFY's as opposed to the Federal Fiscal Year (FFY) included in License Renewal Applications (LRA's) and in the SMFP's.
- The applicant is a related entity to UNC Health. UNC Health has MRI's and MRI data from three locations: #1) UNC Medical Center; #2) UNC Hospitals Hillsborough Campus; and #3) UNC Imaging and Spine Center. UNC Health owns 9 fixed MRI scanners and utilizes lease mobile MRI scanners at both its UNC Hospitals Hillsborough Campus and the UNC Imaging and Spine Center.

Step #1) Analyze the historical MRI data from SFY2017 – SFY2021 for existing UNC Health MRI locations. (See Form C Utilization- Assumptions and Methodology, pages 1-3).

[Note- states on page 3- volume relatively flat while Hillsborough has compound annual growth MRI of 22.9%]

Step #2) Projects growth of Inpatient and Outpatient MRI demand at each existing facility at one-third of actual historical growth. (See Form C Utilization- Assumptions and Methodology, pages 4-5).

Step #3) Projects Shift from UNC Hospitals Hillsborough Campus . (See Form C Utilization- Assumptions and Methodology, pages 5-7).

Step #4) Projected UNC Hospitals Hillsborough Campus MRI Utilization after shift (both total and fixed) (See Form C Utilization- Assumptions and Methodology, pages 7-8).

Step #5) Summary of Projected fixed MRI utilization at all four facilities (3 existing and 1 proposed) (See Form C Utilization- Assumptions and Methodology, pages 9-10).

Step #6) Demonstrate CAGR for both Historical Total MRI scans and Projected Total MRI scans. (See Form C Utilization- Assumptions and Methodology, page 10).

Projected utilization is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- There was a need determination in the 2021 SMFP for a fixed MRI scanner in the Orange County MRI service area and this proposed project will meet that need determination by developing a fixed MRI scanner in Orange County.
- The methodology and assumptions utilized by the applicant were reasonable and adequately supported. The applicant used historic utilization as a baseline and conservatively based projected utilization on 50% of the CAGR for SFY2017- SFY2021.
- Currently, UNC Health only offers MRI services in Orange County at hospital-licensed facilities. The proposed facility will be a freestanding, non-hospital licensed facility which would provide outpatient MRI services at a lower cost.

- Weighted MRI scans for UNC Health for SFY2021 (fixed MRI scanners only) totaled 46,911. If approved, the applicant and its related entities (UNC Health) would have 10 fixed MRI scanners which, with no growth from SFY2021 through SFY2026, would average 4,691 weighted scans per fixed MRI scanner which is only 114 weighted scans per fixed MRI scanner (or 1,140 weighted scans in total) below the average of 4,805 weighted MRI scans per MRI scanner required in the Performance Standards.
- The methodology and assumptions utilized by the applicant were reasonable, conservative and well supported. The applicant’s projected total unadjusted Orange County MRI procedures combined with its projected market share of those MRI procedures combined with projected in-migration to the MRI services to be offered by the proposed facility is reasonable.

**Access to Medically Underserved Groups**

In Section C.6, page 60, the applicant states,

*“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.”*

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

Medically Underserved Groups	Percentage of Total Patients
Low income persons*	na
Racial and ethnic minorities	33.5%
Women	61.4%
Persons with Disabilities*	na
Persons 65 and older	30.6%
Medicare beneficiaries	36.9%
Medicaid recipients	8.0%

Source: Table on page 61 of the application.

\*UNC does not maintain data that includes the number of low-income or handicapped person it serves.

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 reasons:

- The projected estimates in the table above are based on historical percentages from UNC Hospitals Hillsborough Campus (CY2020).
- The construction related to the proposed project will be compliant with the latest Federal and State of North Carolina guidelines for handicapped accessibility and will be compliant with all applicable provisions of the American with Disabilities Act.
- The applicant will follow the document entitled *“Assuring Access to UNC HealthCare”* in Exhibit B.20-6 which states, in part *“as part of its mission, UNC Health Care provides care for residents of North Carolina who are uninsured or*

*underinsured and do not have the ability to pay for medically necessary healthcare services.”*

**Conclusion**

The Agency reviewed the:

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

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

**J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

DUHS proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Duke Coley Hall Imaging. The diagnostic center will be operated as an IDTF located at 66 Vilcom Drive, Chapel Hill, Orange County.

**Patient Origin**

The 2021 SMFP, page 344, defines the service area for a fixed MRI scanner 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, Orange County is the service area. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin.

County	Duke Coley Hall Imaging Projected Patient Origin, fixed MRI scanner					
	1 <sup>st</sup> Full FY		2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY	
	7/01/2023 to 6/30/2024		7/01/2024 to 6/30/2025		7/01/2025 to 6/30/2026	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Orange	1,668	63%	2,104	61%	2,581	60%
Alamance	587	22%	823	24%	1,083	25%
Other	398	15%	517	15%	647	15%
<b>Total</b>	<b>2,653</b>	<b>100%</b>	<b>3,445</b>	<b>100%</b>	<b>4,310</b>	<b>100%</b>

Source: Section C, page 29.

\*Other includes patients from in-migration, which includes all other North Carolina counties as well as other states.



In Section C.3, page 28, and in Section Q, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- The applicant bases projected patient origin, in part, on the historic and projected patient origin for MRI procedures DUHS outpatient MRI services for patients from Orange and Alamance counties from all MRI service locations and then projected a percentage shift of projected Orange and Alamance county outpatient MRI volume to the proposed facility.
- In addition, the applicant reasonably projects in-migration of 15% from outside Orange and Alamance counties.

### **Analysis of Need**

In Section C.4, pages 29-35, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below

- The need determination for one additional fixed MRI scanner in Orange County in the 2021 SMFP (page 31).
- Outmigration of Orange County patients to other counties for MRI services (pages 30-32).
- Population growth in Orange County and surrounding areas including Alamance County. (pages 32-33).
- Historical growth in patient volumes at DUHS facilities (pages 33-34).
- Coordination of care with other services and Duke Health strategic growth (pages 34-35).
- Costs advantages to patients and payors from an IDTF facility (page 34).

The information is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- The 2021 SMFP identifies the need for one additional fixed MRI scanner in Orange County.
- Population growth, particularly among the elderly is occurring in Orange and Alamance County.
- Historical growth in patient volumes at DUHS facilities.
- Outmigration of Orange County MRI patients to other counties for MRI services.
- The applicant provides reasonable and adequately supported information to support its projected utilization including physician support.

### **Projected Utilization**

In Section Q, the applicant provides projected utilization, as illustrated in the following table.

**Projected MRI Utilization**

	<b>OY1 FFY2024</b>	<b>OY2 FFY2025</b>	<b>OY3 FFY2025</b>
# of MRI scanners	1	1	1
Unweighted Procedures	2,653	3,445	4,310
Weighted Procedures	3,025	3,927	4,914

Source: Section Q, page 100, and Form C.2a.

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

*New Diagnostic Center (1 MRI Scanner)*

Step 1) Calculate Historical Orange and Alamance Volumes and Growth (Section Q, pages 95-97).

Step 2) Calculate future Orange/Alamance Outpatient Volumes Appropriate for New Facility (Section Q, pages 97-98).

Step 3) Project shift of Volumes to New Facility (Section Q, pages 98-99).

Step 4) Calculate in-migration (Section Q, page 99-100).

Step 5) Total Facility Volumes (Section Q, page 100)

Projected utilization is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- There was a need determination in the 2021 SMFP for a fixed MRI scanner in the Orange County MRI service area and this proposed project will meet that need determination by developing a fixed MRI scanner in Orange County.
- The methodology and assumptions utilized by the applicant were reasonable and adequately supported.
- The projected weighted average of 1.14 is the average weighting in FY2021 for all outpatient procedures performed at three of DUHS's off-campus MRI locations.
- Projected in-migration of 15% from counties outside of Orange and Alamance is conservative in that in-migration at Duke University Hospital's hospital licensed off-campus outpatient MRI at Duke Hospital Imaging Services at Southpoint in Durham County was 20% in each of FY2019-FY2021.
- The applicant conservatively projects a "shift" of current DUHS outpatient MRI patients from Orange and Alamance county patients (excluding emergency and cancer procedures and adjusted down 3% to exclude sedation procedures) to the proposed fixed MRI scanner located in an IDTF based on an initial "shift" of 40% for Orange County patients and 20% for Alamance County patients ramping up to 70% and 50% respectively for Orange and Alamance County patients by the third project year (FY2026).

- MRI scans performed at the IDTF would potentially be more cost-effective to both patient and payors.

### **Access to Medically Underserved Groups**

In Section C.6, page 40, the applicant states,

*“All individuals including low income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients and other underserved groups, will have access to the facility, as clinically appropriate.”*

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

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	9%
Racial and ethnic minorities	24%
Women	52%
Persons with Disabilities*	na
Persons 65 and older	39%
Medicare beneficiaries	39%
Medicaid recipients	5%

Source: Table on page 40 of the application.

\*DUHS does not retain data that includes the number of disabled persons it serves.

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:

- As stated in the proformas, a significant proportion of the facility’s proposed services will be provided to Medicaid, uninsured persons and Medicare recipients.
- As required by the Americans with Disabilities Act, the proposed new spaces will be accessible to persons with disabilities.
- DUHS has policies designed to ensure access to services, including financial assistance.

### **Conclusion**

The Agency reviewed the:

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

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

- (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 [persons with disabilities], and other underserved groups and the elderly to obtain needed health care.

**NA**  
**All Applications**

None of the applications in this review propose to reduce or eliminate a service, or to 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**  
**All Applications**

**J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**RR-Imaging** proposes to add a fixed MRI scanner to an approved, under development diagnostic center, RR-Chapel Hill. RR-Chapel Hill will be non-hospital licensed and located at 120 Banks Drive, Chapel Hill, Orange County.

In Section E, pages 70-72, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the Status Quo*- Doing nothing would not meet the need for one additional fixed MRI scanner in Orange County identified in the 2021 SMFP. Furthermore, maintaining the status quo would not address the growing need for services or for improved access to reasonably priced MRI services. Therefore, the applicant determined this was not the most effective alternative.
- *Develop the Proposed Diagnostic Center at Another Orange County Location*- The applicant states that all other sites were less effective in terms of geographic access, zoning, ability to utilize economies of scale with respect to shared office space with a larger physician office practice and transportation. Therefore, the applicant determined that a different geographic location would be a less effective and more costly alternative.
- *Acquire a 3.0T MRI scanner*- The applicant states that 1.5T scanners continue to be the clinical standard, providing reasonable scan times, quality images and is less costly than a 3.0T scanner. In addition, a 1.5T scanner can do a wider array of scans as compared to

a 3.0T scanner. Therefore, the applicant determined that this was a less effective and more costly alternative.

On page 72, the applicant states that its proposal is the most effective alternative because:

- The proposed project will increase access to competitively price freestanding MRI services in Orange County.
- The proposal location is expandable and has good transportation access to the entire county.
- The proposed 1.5T MRI scanner would enable the applicant to meet the needs for MRI services in Orange County and other patients who need access to the proposed equipment.

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

- Developing the proposed fixed MRI scanner in another Orange County location was determined to be less effective because no other location was deemed superior to the proposed location.
- Maintaining the status quo would not address the need in the 2021 SMFP for an additional fixed MRI scanner in Orange County.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 reasons stated above.

### **J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

NC Imaging proposes to develop a new diagnostic center, UNC Health Imaging, by acquiring one fixed MRI scanner. The proposed diagnostic center would be a non-hospital licensed diagnostic center located at 106 Carraway Crossing Drive, Chapel Hill, Orange County.

In Section E, pages 76-77, 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:

- *Develop the Freestanding Fixed MRI scanner as Hospital-Based-* The applicant determined that developing the proposed fixed MRI scanner as hospital-based might result in negatively impacting patients with possible temporary closures and workflow interruptions during upfitting and renovations withing a UNC Hospital facility. In addition, this would not improve access for patients to lower cost MRI services in an outpatient setting nor alleviate capacity constraints at the Hillsborough Campus. Therefore, the applicant determined that this was neither the most effective nor the least costly alternative.
- *Develop the Freestanding MRI at a Different Location-* The applicant determined that geographically, because the proposed site was very close to a major transportation corridor and situated between UNC Hospitals Hillsborough Campus and UNC Medical Center the proposed site best provided for a fluid continuum of care at a lower cost. In addition, locating the proposed facility in a MOB was less costly as a third-party developer of the MOB will bear the construction costs of the building. The applicant will only be responsible for the upfit (renovation) costs of the space to be leased for the proposed diagnostic center. The upfit will occur contemporaneously with the development of the MOB which will be more cost-effective than upfitting a building which was not originally designed for the intended use. The applicant will only be responsible for the lease of the space needed. Therefore, the applicant determined that a different location would be a less effective alternative and more costly alternative.

On pages 76-77, the applicant states that its proposal is the most effective alternative because:

- Developing the proposed facility in a to be constructed MOB situated between UNC Hospitals Medical Center and UNC Hospitals Hillsborough Campus near I-40 provides both cost savings and convenient transportation access to lower cost outpatient MRI services.
- Developing the proposed fixed MRI scanner in a freestanding non-hospital licensed facility provides patients with access to lower cost outpatient MRI services and alleviate capacity constraints on the fixed MRI scanners currently located at the UNC Hospitals Hillsborough Campus.

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

- Developing the proposed fixed MRI scanner at a freestanding, non-hospital licensed facility offers both patient and payors a lower cost option for outpatient MRI services and lessens capacity constraints at UNC Hospitals Hillsborough Campus by utilizing an easily accessible alternative location.
- Maintaining the status quo would not address the need in the 2021 SMFP for an additional fixed MRI scanner in Orange County.

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 reasons stated above.

### **J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

DUHS proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Duke Coley Hall Imaging. The diagnostic center will be operated as an IDTF located at 66 Vilcom Drive, Chapel Hill, Orange County.

In Section E, pages 52-53, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the Status Quo*-The applicant determined that doing nothing would not meet the need for one additional fixed MRI scanner in Orange County identified in the 2021 SMFP. In addition, maintaining the status quo would continue to force Orange County residents seeking services from Duke to travel outside the county. Therefore, the applicant determined that this was not the most effective alternative.
- *Develop Project at Alternative Location*- The applicant states that this is the most effective location in Orange County, approximately one mile from I-40, offering convenient access to both patients from Orange County and patients traveling from other nearby counties. Furthermore, the applicant is already developing imaging facilities at the proposed location which are co-located with specialty and primary services, physical and occupational therapy and ambulatory surgery. Therefore, the applicant determined that developing the fixed MRI at a different location would not be the most effective alternative.
- *Acquire Different MRI Equipment*- The applicant states that it selected an MRI vendor with the goals of maximizing healthcare value for the resources expended while promoting safety and quality. The MRI equipment selected, among other things, allowed for a reduction in exam-time, simple interaction between the patient and the scanner, large

bore size which provides benefits for claustrophobic patients, and the 1.5T size provides optimum images for an outpatient setting. Therefore, the applicant determined that acquiring different MRI equipment this was not the most effective alternative or least costly alternative.

- *Contract with a Mobile Provider-* The applicant states that contracting for a mobile MRI scanner would increase costs in terms of lease payments which would continue for as long as the applicant utilized the MRI scanner and the applicant would be subject to the terms and conditions of the contract and thus would lose flexibility to expand hours of service. Therefore, the applicant determined that this was not the most effective alternative or least costly alternative.

On pages 52-53, the applicant states that its proposal is the most effective alternative because:

- The proposed project would meet the need for one additional fixed MRI scanner in Orange County identified in the 2021 SMFP.
- The proposal would allow Orange County residents seeking Duke outpatient MRI services to stay in the county for MRI services and at a lower cost.
- The locating the proposed MRI scanner with other imaging services and near other Duke health services provides better access to health care for patients.
- The applicant determined that the MRI equipment most readily achieved the applicant's goals in the least costly manner.

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

- Developing the proposed fixed MRI scanner as an IDTF offers both patient and payors a lower cost option for outpatient MRI services.
- Maintaining the status quo would not address the need in the 2021 SMFP for an additional fixed MRI scanner in Orange County.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 reasons stated above.



- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

**C**  
**All Applications**

**J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**RR-Imaging** proposes to add a fixed MRI scanner to an approved, under development diagnostic center, RR-Chapel Hill. RR-Chapel Hill will be non-hospital licensed and located at 120 Banks Drive, Chapel Hill, Orange County.

**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>Original Costs (Project ID # J-12062-21)*</b>	<b>Current Application (Develop Fixed MRI)</b>	<b>Total</b>
Site Costs	\$0	\$0	\$0
Construction Costs	\$273,180	\$504,300	\$777,480
Miscellaneous Costs	\$1,095,935	\$2,980,104	\$4,076,039
<b>Total</b>	<b>\$1,369,115</b>	<b>\$3,484,404</b>	<b>\$4,853,519</b>

\*Source: Findings for Project J-12062-21.

The applicant provides its assumptions and methodology for projecting capital cost in Section Q and Exhibit F.1. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based the information provided in Section F.1, page 73, Section Q and referenced exhibits.

In Section F.3, page 75, the applicant projects that start-up costs will be \$27,730 and initial operating expenses will be \$209,291, for total working capital of \$237,021. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the information provided in Section F.3, page 75, and Form F.3(b) [MRI Services], of the application.

**Availability of Funds**

In Section F, page 73, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

Type	RRWMICH	Total
Loans	\$3,484,404	\$3,484,404
Cash and Cash Equivalents, Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$3,484,404</b>	<b>\$3,484,404</b>

\* OE = Owner's Equity

In Section F, page 76, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Sources of Financing for Working Capital	Amount
Loans	\$237,022
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$0
Lines of credit	\$0
Bonds	\$0
<b>Total *</b>	<b>\$237,022</b>

In Section F, pages 73 and 76, the applicant states that the capital costs and working capital costs for the project will be funded by loans. In Section F, page 76, the applicant states that BB&T Bank (now Truist Bank) has agreed to provide the necessary funds for the proposed project. Exhibit F.2 contains a letter dated August 25, 2021 from John Lane, Truist Commercial Banking, documenting that \$4.25 million will be available to fund the proposed project (equipment, construction, start-up) for the capital costs and working capital costs of the project. Exhibit F.2 also contains a letter from the Chief Operating Officer of Raleigh Radiology, dated August 28, 2021, confirming that the Truist funds will be committed to the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the information provided in Section F and Exhibit F.2 of the application.

**Financial Feasibility**

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

	<b>1<sup>st</sup> Full Fiscal Year (CY2023)</b>	<b>2<sup>nd</sup> Full Fiscal Year (CY2024)</b>	<b>3<sup>rd</sup> Full Fiscal Year (CY2025)</b>
Total Procedures*	2,683	4,026	5,128
Total Gross Revenues (Charges)	\$4,417,060	\$6,628,388	\$8,443,087
Total Net Revenue	\$1,163,957	\$1,694,587	\$2,096,210
Average Net Revenue per Procedures	\$434	\$421	\$409
Total Operating Expenses (Costs)	\$1,401,281	\$1,676,561	\$1,842,566
Average Operating Expense per Procedures	\$522	\$416	\$359
Net Income	(\$237,324)	\$18,026	\$253,643

\*Note: Procedures equal weighted procedures.

Source: Section Q, Form F.2b [MRI], page 134.

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

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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

**J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

NC Imaging proposes to develop a new diagnostic center, UNC Health Imaging, by acquiring one fixed MRI scanner. The proposed diagnostic center would be a non-hospital licensed diagnostic center located at 106 Carraway Crossing Drive, Chapel Hill, Orange County.

**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.

Site Costs	\$0
Construction Costs	\$2,654,408
Miscellaneous Costs	\$3,097,767
<b>Total</b>	<b>\$5,752,175</b>

The applicant provides its assumptions and methodology for projecting capital cost in Section Q and Exhibits C.1-3, C.1-4 and F-1. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based the information provided in Section F.1, page 78, Section Q and referenced exhibits.

In Section F.3, pages 80-81, the applicant projects that start-up costs will be \$97,479 and initial operating expenses will be \$486,782, for total working capital of \$584,261. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the information provided in Section F.3, pages 80-81, and Form F.3(b), of the application.

**Availability of Funds**

In Section F, page 78, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

Type	NC Imaging Centers, LLC	Total
Loans	\$0	\$0
Cash and Cash Equivalents, Accumulated reserves or OE *	\$5,752,175	\$5,752,175
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$5,752,175</b>	<b>\$5,752,175</b>

\* OE = Owner's Equity

In Section F, pages 80-81, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Sources of Financing for Working Capital	Amount
Loans	\$0
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$584,261
Lines of credit	\$0
Bonds	\$0
<b>Total *</b>	<b>\$584,261</b>

In Section F, pages 78-79 and 80-81, the applicant states that the capital costs and working capital costs for the project will be funded by accumulated reserves of UNC Health. In Section F, pages 79 and 82, the applicant states that the CFO of UNC Health has documented the availability of accumulated reserves of UNC Health to fund the capital and working capital costs of the proposed project.

Exhibit F.2-1 contains a letter dated October 15, 2021 from the Associate Chief Financial Officer for UNC Health documenting that up to \$6.752 million funds will be made available for the capital costs and working capital costs of the project. Exhibit F.2-2 contains the audited financial statements for UNC Health for SFY2020 which indicated the health system had \$431.6 million in cash and cash equivalents, \$3.09 billion in assets, and \$481.4 million in net assets, as of June 30, 2020.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the information provided in Section F and Exhibits F.2-1 and F.2-2 of the application.

**Financial Feasibility**

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

	1 <sup>st</sup> Full Fiscal Year (FY2024)*	2 <sup>nd</sup> Full Fiscal Year (FY2025)	3 <sup>rd</sup> Full Fiscal Year (FY2026)
Total Procedures**	2,488	4,025	5,788
Total Gross Revenues (Charges)***	\$8,492,806	\$14,150,801	\$20,958,410
Total Net Revenue***	\$1,240,358	\$2,066,697	\$3,060,935
Average Net Revenue per Procedures	\$499	\$513	\$529
Total Operating Expenses (Costs)	\$1,597,999	\$2,428,780	\$2,645,982
Average Operating Expense per Procedures	\$642	\$603	\$457
Net Income	(\$357,641)	(\$362,083)	\$414,953

\* FY starts on 7/1/\_\_\_ and ends on 6/30/\_\_\_.

\*\*Note: Procedures equal weighted procedures.

\*\*\*Form F.2 Assumptions (a) states, in part, "Patient Services Gross Revenue is based on projected payor mix and average charge for the service based on UNC's FY2021 experience with outpatient MRIs at the UNC Hospitals Hillsborough Campus." (b) states, in part, "Contractual adjustments by payor are based on FY2021 experience for outpatient MRI procedures at the

*UNC Hospitals Hillsborough Campus, and adjusted to account for the lower reimbursement structure associated with a Freestanding IDTF location.”*

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

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.

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

### **J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

DUHS proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Duke Coley Hall Imaging. The diagnostic center will be operated as an IDTF located at 66 Vilcom Drive, Chapel Hill, Orange County.

### **Capital and Working Capital Costs**

In Section Q, Form F.1b, the applicant provides the previously approved capital costs for Project J-12001-20 in addition the projected additional capital costs associated with the proposed project, as shown in the table below.

	<b>Original Costs (Project ID # J-12001-20)</b>	<b>Current Application (Develop Fixed MRI)</b>	<b>Total</b>
Site Costs	\$0	\$0	\$0
Construction Costs	\$630,000	\$784,750	\$1,414,750
Miscellaneous Costs	\$1,090,000	\$2,865,250	\$3,955,250
<b>Total</b>	<b>\$1,720,000</b>	<b>\$3,650,000</b>	<b>\$5,370,000</b>

The applicant provides its assumptions and methodology for projecting capital cost in Section Q and Exhibits F-1(a), F-1(b) and K.2. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based the information provided in Section F.1, page 54, Section Q and referenced exhibits.

In Section F.3, page 56, the applicant projects that start-up costs will be \$97,312 and initial operating expenses will be \$1,140,714, for total working capital of \$1,238,026. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the information provided in Section F.3, pages 56-57, and Form F.3(b) [MRI Services], of the application.

**Availability of Funds**

In Section F, page 54, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

Type	DUHS, Inc.	Total
Loans	\$0	\$0
Cash and Cash Equivalents, Accumulated reserves or OE *	\$3,650,000	\$3,650,000
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$3,650,000</b>	<b>\$3,650,000</b>

\* OE = Owner's Equity

In Section F, pages 58-59, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Sources of Financing for Working Capital	Amount
Loans	\$0
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$1,238,026
Lines of credit	\$0
Bonds	\$0
<b>Total *</b>	<b>\$1,238,026</b>

In Section F, pages 54-5 and 58-59, the applicant states that the capital costs and working capital costs for the project will be funded by accumulated reserves of DUHS. In Section F, page 59, the applicant states that the CFO has documented at least \$1.35 million for this project beyond the projected capital cost. Exhibit F.2(a) contains a letter dated October 4, 2021 from the Chief Financial Officer for DUHS documenting that up to \$5.0 million funds will be made available for the capital costs and working capital costs of this proposed project. Exhibit F.2(b) also contains the audited financial statements for DUHS for FY2021 which indicated the health system had \$98.5 million in cash and cash equivalents, \$9.07 billion in assets, and \$5.67 billion in net assets, as of June 30, 2021.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the information provided in Section F and Exhibits F.2(a) and F.2(b) of the application.

**Financial Feasibility**

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

	<b>1<sup>st</sup> Full Fiscal Year (FY2024)*</b>	<b>2<sup>nd</sup> Full Fiscal Year (FY2025)</b>	<b>3<sup>rd</sup> Full Fiscal Year (FY2026)</b>
Total Procedures**	3,025	3,927	4,914
Total Gross Revenues (Charges)	\$2,785,997	\$3,690,055	\$4,708,917
Total Net Revenue	\$1,444,613	\$1,909,985	\$2,433,066
Average Net Revenue per Procedures	\$478	\$486	\$495
Total Operating Expenses (Costs)	\$1,028,977	\$1,140,238	\$1,428,780
Average Operating Expense per Procedures	\$340	\$290	\$291
Net Income	\$415,636	\$769,747	\$1,004,286

\* FY starts on 7/1/\_\_\_\_ and ends on 6/30/\_\_\_\_.

\*\*Note: Procedures equal weighted procedures.

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

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

**Conclusion**



The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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

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

**C**  
**All Applications**

The 2021 SMFP, page 344, defines the service area for a fixed MRI scanner 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, Orange County is the service area. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in Orange County.

**Orange County: Fixed MRI**

Facility (Owner)	# of Fixed MRI Scanners	Total Weighted Procedures Performed during Federal Fiscal Year (FFY) 2019
University of North Carolina Hospitals-Hillsborough	1	8,039
University of North Carolina Hospitals-Medical Center	6	31,268
University of North Carolina Hospitals-Imaging Center	2	9,958
Wake Radiology (Chapel Hill Diagnostic Imaging, LLC)	1	1,646
<b>Total</b>	<b>10</b>	<b>50,911</b>

Source: 2021 SMFP, Table 17E-1, page 359.

**J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**RR-Imaging** proposes to add a fixed MRI scanner to an approved, under development diagnostic center, RR-Chapel Hill. RR-Chapel Hill will be non-hospital licensed and located at 120 Banks Drive, Chapel Hill, Orange County.

In Section G, page 82-84, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Orange County. The applicant states:

*“The proposal will not result in unnecessary duplication of existing MRI services in the service area. First, the proposed project responds to the need determination of one fixed MRI scanner in the Orange County service area as calculated by the 2021 SMFP standard methodology. The plan indicates use exceeded its threshold in FY2019.*

...

*.... [P]opulation growth and increased median age in the county, combined with health status and increasing demand for outpatient healthcare services, will sustain need for the proposed additional capacity. Growth in the size and age of the service area population ... will only increase the need for MRI services in the county.”*

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 2021 SMFP for the proposed fixed MRI scanner.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners in Orange County.

**Conclusion**

The Agency reviewed the:

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

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

**J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

NC Imaging proposes to develop a new diagnostic center, UNC Health Imaging, by acquiring one fixed MRI scanner. The proposed diagnostic center would be a non-hospital licensed diagnostic center located at 106 Carraway Crossing Drive, Chapel Hill, Orange County.

In Section G, pages 87-88, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI scanner services in Orange County. The applicant states:

*“The proposed project is in response to a need determination for one additional fixed MRI scanner in the 2021 SMFP for Orange County. ... Currently, nine of the ten fixed MRI scanners in Orange County are hospital-based at UNC locations. ... it is imperative that lower-cost free standing MRI services be made available. ... The proposed project represents the first UNC Health owned freestanding fixed MRI scanner in Orange County.”*

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 2021 SMFP for the proposed fixed MRI scanner.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners in Orange County.

**Conclusion**

The Agency reviewed the:

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

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

**J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

DUHS proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Duke Coley Hall Imaging. The diagnostic center will be operated as an IDTF located at 66 Vilcom Drive, Chapel Hill, Orange County.

In Section G, page 65, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed MRI services in Orange County. The applicant states:

*“As set forth in the 2021 SMFP, Orange County utilization demonstrates a need for additional MRI capacity based on existing procedures performed in the county. The anticipated population growth in the county described in Section C will only exacerbate the need for additional capacity. Therefore, any expanded capacity will not unnecessarily duplicate existing or approved health service facilities but instead is necessary to meet the growing demand for services in the county.”*

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 2021 SMFP for the proposed fixed MRI scanner.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners in Orange County.

### **Conclusion**

The Agency reviewed the:

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

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

## **C All Applications**

### **J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**RR-Imaging** proposes to add a fixed MRI scanner to an approved, under development diagnostic center, RR-Chapel Hill. RR-Chapel Hill will be non-hospital licensed and located at 120 Banks Drive, Chapel Hill, Orange County.

In Section Q, Form H, the applicant provides projected staffing for the proposed services through the first three operating years of the project.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Sections H.2 and H.3, pages 87-88, 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 information provided in Section H, pages 78-80, and in Section Q, Form H, as described above.

### **Conclusion**

The Agency reviewed the:

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

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

### **J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

NC Imaging proposes to develop a new diagnostic center, UNC Health Imaging, by acquiring one fixed MRI scanner. The proposed diagnostic center would be a non-hospital licensed diagnostic center located at 106 Carraway Crossing Drive, Chapel Hill, Orange County.

In Section Q, Form H, the applicant provides projected staffing for the proposed services through the first three operating years of the project.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Sections H.2 and H.3, pages 89-90, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit B.20-4 the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the information provided in Section H, pages 89-90, Exhibit B.20-4 and in Section Q, as described above.

### **Conclusion**

The Agency reviewed the:

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

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

### **J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

DUHS proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Duke Coley Hall Imaging. The diagnostic center will be operated as an IDTF located at 66 Wilcom Drive, Chapel Hill, Orange County.

In Section Q, Form H, the applicant provides projected staffing for the proposed services through the first three operating years of the project.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Sections H.2 and H.3, pages 68-69, the applicant describes the methods used to recruit or fill new positions and its existing 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 based on the information provided in Section H, pages 68-69, Exhibit H.3 and in Section Q, Form H, as described above.

### **Conclusion**

The Agency reviewed the:

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

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

- (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 All Applications

### **J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**RR-Imaging** proposes to add a fixed MRI scanner to an approved, under development diagnostic center, RR-Chapel Hill. RR-Chapel Hill will be non-hospital licensed and located at 120 Banks Drive, Chapel Hill, Orange County.

#### **Ancillary and Support Services**

In Section I.1, page 89, the applicant identifies the necessary ancillary and support services for the proposed services. On page 89, the applicant explains how each ancillary and support service is or will be made available, the applicant states,

*“RRWMICH will provide all listed ancillary services, except billing, through its staff and via an external contract. ... Change Healthcare provides billing for all Raleigh Radiology site[sic] and will serve RRCH as well.”*

The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

#### **Coordination**

In Section I.2, page 90, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant states,

*“RRWMICH’s proposed management services company, RRLLC, is an established provider with relationships with the local healthcare and social service providers. ...*

*RRA, the affiliated radiology practice that will provide radiologist staffing for the diagnostic center has also become the primary radiology group for WakeMed Health & Hospitals and WakeMed Key Community Care, the largest ACO in North Carolina.”*

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2, page 90, and Exhibit I.2, as described above.

### **Conclusion**

The Agency reviewed the:

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

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

### **J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

NC Imaging proposes to develop a new diagnostic center, UNC Health Imaging, by acquiring one fixed MRI scanner. The proposed diagnostic center would be a non-hospital licensed diagnostic center located at 106 Carraway Crossing Drive, Chapel Hill, Orange County.

### **Ancillary and Support Services**

In Section I.1, pages 91-92, the applicant identifies the necessary ancillary and support services for the proposed services and provides supporting documentation in Exhibit I.1. On page 91, the applicant explains how each ancillary and support service is or will be made available, the applicant states,

*“NC Imaging will enter into a professional services agreement with UNC Health and as such, will benefit from the existing ancillary and support services at UNC Hospitals. UNC Hospitals has all ancillary and support services in place to support operations, including the proposed freestanding fixed MRI services at UNC Health Imaging Center.”*

The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

### **Coordination**

In Section I.2, page 92, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant states,



*“NC Imaging will benefit from the existing longstanding relationships established by UNC Health, the sole member of NC Imaging. UNC Health’s relationships ... will continue following completion of the proposed project.”*

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2, page 92, and Exhibit I.2, as described above.

### **Conclusion**

The Agency reviewed the:

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

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

### **J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

DUHS proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Duke Coley Hall Imaging. The diagnostic center will be operated as an IDTF located at 66 Vilcom Drive, Chapel Hill, Orange County.

#### **Ancillary and Support Services**

In Section I.1, page 71, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 71-72, the applicant explains how each ancillary and support service is or will be made available, the applicant states,

*“The diagnostic center will include certain dedicated staff positions reflected in Form H. Housekeeping will be provided pursuant to a third party contract ... For the remaining corporate/support services and clinical engineering/equipment maintenance ... DUHS provides such services centrally...”*

The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

### **Coordination**

In Section I.2, page 72, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant states,

*“This facility will be part of the Duke University Health System, which includes inpatient acute care, outpatient surgery, psychiatric, and rehabilitation services, primary care, home health and hospice services. ... Through specialty program affiliations ... Duke Network Services links community-based specialty programs at hospitals throughout the region with Duke Centers of Excellence.”*

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2, page 72, as described above.

### **Conclusion**

The Agency reviewed the:

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

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

- (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 All Applications**

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**  
**All Applications**

None of the applicants is an HMO. Therefore, Criterion (10) is not applicable to this review.

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

**C**  
**All Applications**

**J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**RR-Imaging** proposes to add a fixed MRI scanner to an approved, under development diagnostic center, RR-Chapel Hill. RR-Chapel Hill will be non-hospital licensed and located at 120 Banks Drive, Chapel Hill, Orange County.

In Section K, page 93, the applicant states that the project involves renovating 831 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 94, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following reasons:

- The renovation and upfit will be planned and designed by a professional general contractor including compliance with all applicable standards and codes.
- Delay and raw site costs will be reduced by the fact that the facility has adequate access to water, sewer and power and is appropriately zoned.
- The applicant will only be responsible for the upfit (renovation) costs of the space to be leased for the proposed diagnostic center. The upfit will occur contemporaneously with the development of the MOB which will be more cost-effective than upfitting a building which was not originally designed for the intended use.

On pages 94-95, 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 reasons:

- The proposed project will provide patients an option to receive high-quality MRI imaging at costs much lower than local hospital-based alternatives.
- The applicant states that projected, conservative service area market share and in-migration estimates support sufficient utilization volume of MRI procedures to keep unit costs low.
- The facility will be managed by RRLLC which has experience in efficiently operating facilities to keep costs low.

On page 95 and in Section B, page 28, 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
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

### **J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**NC Imaging** proposes to develop a new diagnostic center, UNC Health Imaging, by acquiring one fixed MRI scanner. The proposed diagnostic center would be a non-hospital licensed diagnostic center located at 106 Carraway Crossing Drive, Chapel Hill, Orange County.

In Section K.2, page 95, the applicant states that the project involves renovating 4,230 square feet of existing space. Line drawings are provided in Exhibit C.1-2.

On page 96, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following reasons:

- NC Imaging is proposed to be in a MOB which would be built by a third-party developer.
- The third-party developer of the MOB will bear the construction costs of the building.
- The applicant will only be responsible for the upfit (renovation) costs of the space to be leased for the proposed diagnostic center. The upfit will occur contemporaneously with

the development of the MOB which will be more cost-effective than upfitting a building which was not originally designed for the intended use.

- The applicant will only be responsible for the lease of the space needed.

On pages 96-97, 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 reasons:

- The proposed project, as a member of the UNC Health system, will benefit from significant cost saving measures from large economies of scale and the consolidation of multiple services.
- The proposed project will provide increased access to low-cost non-hospital licensed MRI service. If approved, the project would be UNC Health's first free-standing fixed MRI scanner in Orange County. It will provide a cost-effective and convenient alternative to the highly utilized hospital-based fixed MRI scanners at UNC Hospitals.
- Locating the proposed fixed MRI scanner in a free-standing, non-hospital licensed facility will allow those patients who can utilize a lower-intensity out-patient setting to receive fixed MRI services at a lower cost.

In Section B.21, page 33, 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
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

### **J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

DUHS proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Duke Coley Hall Imaging. The diagnostic center will be operated as an IDTF located at 66 Vilcom Drive, Chapel Hill, Orange County.

In Section K, page 75, the applicant states that the project involves renovating 1,515 square feet of existing space. Line drawings are provided in Exhibit K.2.

On pages 75-76, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following reasons:

- The applicant relied on the professional advice of experienced architects and project managers including the architect's cost estimates in Exhibit F.1.
- The architect based the projected renovation and design cost on a review of the actual costs of similar projects, the architect's design experience and published construction costing data.
- The project was designed to meet both the current and anticipated clinical needs and patient satisfaction in a cost-effective manner.

On page 76, 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 reasons:

- The proposed project, based on careful consideration of the type of services offered, equipment selection, construction scope, design, location and staffing model, will not unduly increase the cost to deliver service or require increased charges to consumers.
- The costs incurred to both develop and operate the project have been determined to be necessary and appropriate to enhance acute care access for patients.
- Projected reimbursement and charges will not be increased as they are established by existing private payor contracts and/or Medicaid and Medicare.

On page 76, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit F.1 and K.2.

### **Conclusion**

The Agency reviewed the:

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

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

- (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;

**NA**  
**All Applications**

**J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**RR-Imaging** proposes to add a fixed MRI scanner to an approved, under development diagnostic center, RR-Chapel Hill. RR-Chapel Hill will be non-hospital licensed and located at 120 Banks Drive, Chapel Hill, Orange County.

RR-Chapel Hill is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

**J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**NC Imaging** proposes to develop a new diagnostic center, UNC Health Imaging, by acquiring one fixed MRI scanner. The proposed diagnostic center would **be** a non-hospital licensed diagnostic center located at 106 Carraway Crossing Drive, Chapel Hill, Orange County.

UNC Health Imaging Center is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

**J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**DUHS** proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Duke Coley Hall Imaging. The diagnostic center will be operated as an IDTF located at 66 Vilcom Drive, Chapel Hill, Orange County.

Duke Coley Hall Imaging is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

- (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;

NA  
All Applications

**J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**RR-Imaging** proposes to add a fixed MRI scanner to an approved, under development diagnostic center, RR-Chapel Hill. RR-Chapel Hill will be non-hospital licensed and located at 120 Banks Drive, Chapel Hill, Orange County.

RR-Chapel Hill is not an existing facility. Therefore, Criterion (13b) is not applicable to this review.

**J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**NC Imaging** proposes to develop a new diagnostic center, UNC Health Imaging, by acquiring one fixed MRI scanner. The proposed diagnostic center would be a non-hospital licensed diagnostic center located at 106 Carraway Crossing Drive, Chapel Hill, Orange County.

UNC Health Imaging Center is not an existing facility. Therefore, Criterion (13b) is not applicable to this review.

**J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**DUHS** proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Duke Coley Hall Imaging. The diagnostic center will be operated as an IDTF located at 66 Vilcom Drive, Chapel Hill, Orange County.

Duke Coley Hall Imaging is not an existing facility. Therefore, Criterion (13b) is not applicable to this review.

- (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**  
**All Applications**

**J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**RR-Imaging** proposes to add a fixed MRI scanner to an approved, under development diagnostic center, RR-Chapel Hill. RR-Chapel Hill will be non-hospital licensed and located at 120 Banks Drive, Chapel Hill, Orange County.

In Section L, page 102, 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.

**RR-Chapel Hill: MRI (CY2025)**

<b>Payor Category</b>	<b>Percent of Total Patients Served</b>
Self-Pay	1.4%
Charity Care*	na
Medicare**	40.0%
Medicaid**	4.9%
Insurance**	47.3%
Other (Champus, Tricare, MedSolutions, Workers Comp)	6.3%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 102 of the application.

\*Charity Care is 0.5% of gross patient revenue.

\*\*Note: Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.4% of fixed MRI services will be provided to self-pay patients, 40.0% to Medicare patients and 4.9% to Medicaid patients.

In Section Q, Form F.2b [MRI] the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following reasons:

- The applicant's relied on historical data for imaging modality for Raleigh Radiology, LLC in Wake County.
- The applicant adjusted the historical data to account for the higher percentage of persons below poverty level in Orange County (up 2.0% for Medicaid and down 2.0% for insurance)
- The applicant adjusted Medicare projections to reflect the increase in the age of the population. Increases in Medicare are offset by decreases in insurance.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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.

**J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

NC Imaging proposes to develop a new diagnostic center, UNC Health Imaging, by acquiring one fixed MRI scanner. The proposed diagnostic center would be a non-hospital licensed diagnostic center located at 106 Carraway Crossing Drive, Chapel Hill, Orange County.

In Section L, page 104, 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.

Payor Category	Percent of Total Patients Served
Self-Pay	10.3%
Charity Care*	na
Medicare**	36.9%
Medicaid**	8.0%
Insurance**	38.1%
Other (Other Govt, Worker Comp and TRICARE)	6.7%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 104 of the application.

\*Charity Care is not tracked as a payor source by UNC Health. See Form F.2 for charity care projections. Patients in any payor category can and do receive charity care. Form F.2 (c) states, in part, "Charity Care is the difference between gross and net revenue for self pay."

\*\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 10.3% of fixed MRI services will be provided to self-pay patients, 36.9% to Medicare patients and 8.0% to Medicaid patients.

On page 104 and in Section Q, Form C Assumptions and Methodology, the applicant provides the assumptions and methodology used to project payor mix during the third

full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- Projected utilization is based on a shift of MRI patients from UNC Hospitals Hillsborough Campus.
- The applicant based projected payor mix on historical payor mix from State Fiscal Year (SFY 2021) outpatient MRI services at UNC Hospitals Hillsborough Campus.
- The applicant made no adjustments to the historical payor mix relied upon.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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.

**J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

DUHS proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Duke Coley Hall Imaging. The diagnostic center will be operated as an IDTF located at 66 Vilcom Drive, Chapel Hill, Orange County.

In Section L, page 83, 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.

Payor Category	Percent of Total Patient Served
Self-Pay	1.6%
Charity Care	0.7%
Medicare*	38.8%
Medicaid*	5.5%
Insurance*	52.0%
Workers Compensation	0.4%
TRICARE	0.6%
Other	0.3%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 83 of the application.

\*Includes any managed care plans.

As shown in the table above, during third full fiscal year of operation, the applicant projects that 1.6% of total services will be provided to self-pay patients, 0.7% to charity care patients, 38.8% to Medicare patients and 5.5% to Medicaid patients.

On page 83, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The MRI projections are based on historical payor mix for non-emergent, non-cancer outpatient MRI scans performed in FY2021 on patients from Orange and Alamance Counties as the baseline for projected payor mix.
- The historic payor mix was adjusted based on the assumption that 3.8% of current managed care/insurance patient population will shift to Medicare for each of 2022 and 2023 to reflect an anticipated aging of DUHS's existing patient population. The payor mix is then held constant from FY2023 through the third project year.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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.

- (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 All Applications

### **J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**RR-Imaging** proposes to add a fixed MRI scanner to an approved, under development diagnostic center, RR-Chapel Hill. RR-Chapel Hill will be non-hospital licensed and located at 120 Banks Drive, Chapel Hill, Orange County.

In Section L, page 104, 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
- Written comments
- Responses to comments
- 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.

**J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

NC Imaging proposes to develop a new diagnostic center, UNC Health Imaging, by acquiring one fixed MRI scanner. The proposed diagnostic center would be a non-hospital licensed diagnostic center located at 106 Carraway Crossing Drive, Chapel Hill, Orange County.

In Section L, page 106, 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
- Written comments
- Responses to comments
- 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.

**J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

DUHS proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Duke Coley Hall Imaging. The diagnostic center will be operated as an IDTF located at 66 Vilcom Drive, Chapel Hill, Orange County.

In Section L, page 85, 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
- Written comments
- Responses to comments
- 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.

- (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 All Applications**

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

The Agency reviewed the:

- Applications
- Exhibits to the applications

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

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

demonstrate that its application is for a service on which competition will not have a favorable impact.

**C  
 All Applications**

The 2021 SMFP, page 344, defines the service area for a fixed MRI scanner 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, Orange County is the service area. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in Orange County.

**Orange County: Fixed MRI**

Facility (Owner)	# of Fixed MRI Scanners	Total Weighted Procedures Performed during Federal Fiscal Year (FFY) 2019
University of North Carolina Hospitals-Hillsborough	1	8,039
University of North Carolina Hospitals-Medical Center	6	31,268
University of North Carolina Hospitals-Imaging Center	2	9,958
Wake Radiology (Chapel Hill Diagnostic Imaging, LLC)	1	1,646
<b>Total</b>	<b>10</b>	<b>50,911</b>

Source: 2021 SMFP, Table 17E-1, page 359.

**J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**RR-Imaging** proposes to add a fixed MRI scanner to an approved, under development diagnostic center, RR-Chapel Hill. RR-Chapel Hill will be non-hospital licensed and located at 120 Banks Drive, Chapel Hill, Orange County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 106, the applicant states:

*“The proposed fixed MRI scanner will offer a significant competitive alternative with regard to access. Consumers and payors will pay less for the MRI scans at the proposed new MRI than at other MRIs in the service area. The proposed MRI scanner [sic] be one of only two freestanding outpatient MRI scanners in Orange County. ... As a freestanding ACR Accredited location that bills for MRI globally, RRWMCH will provide a significant competitive impact in the proposed service area...*

...

*Even among the freestanding MRI providers, Blue Cross price comparisons in Exhibit C.4, page 6 show that MRI charges at sites which receive management services from RRLLC are lower than at sites operated by Orange County's only freestanding provider, Wake Radiology.*

...

*To attract and retain patients, it will have to offer not only price, but convenience of parking, scheduling and services that are more attractive to patients and referring providers. Like any new competitor, it will provide a new benchmark against which customers will evaluate existing providers."*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 107, the applicant states:

*"The design of the facility supports a low-charge, low-reimbursement structure.*

*RRCH MRI will contain administrative costs by sharing overhead with RRLLC and with the rest of the RRCH diagnostic center*

.

...

*The proposed lower fee structure will advance cost effective care throughout the community."*

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

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

*"The applicant will pursue American College of Radiology accreditation for the proposed MRI scanner. This third party, peer reviewed oversight will provide transparency to the proposed project's technical quality. ...*

*All technical staff and physicians who read/interpret the studies will be required to maintain appropriate and current licensure and continuing education. ...*

*The MRI scanner will function as a component of a physician office that has a National Provider Identification Number with CMS for payment providing yet more third-party oversight."*

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

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

*"The facility will accept referred patients without regard to source of payment and has plans to provide charity for medical necessity. It will accept most third party commercial payors,*



*including the State Employees Medical plan, Tricare for military veterans, Medicaid and Medicare.”*

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant 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
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

### **J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

NC Imaging proposes to develop a new diagnostic center, UNC Health Imaging, by acquiring one fixed MRI scanner. The proposed diagnostic center would be a non-hospital licensed diagnostic center located at 106 Carraway Crossing Drive, Chapel Hill, Orange County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 110 , the applicant states:

*“NC Imaging ... believes that the proposed project will foster competition in the proposed service area. ... the proposed project will enhance competition by expanding the capacity of freestanding MRI services in Orange County ... the proposed project will offer UNC Health’s*

*first freestanding MRI services in Orange County, thus increasing patient choice and fostering competition within the service area.”*

Regarding the impact of the proposal on cost effectiveness, in Section B.20, pages 30-31, the applicant states:

*“The proposed project will result in UNC Health’s first freestanding fixed MRI scanner in Orange County... In a freestanding diagnostic center, there are no other hospital-based expenses related allocate to MRI services; the only expenses are those generated directly by services provided by the freestanding diagnostic center. As a result, patients and payors do not incur the charges associated with hospital-based care. ...*

*Moreover, as a wholly owned entity of the larger UNC Health system, NC Imaging benefits from significant cost saving measures through the consolidation of multiple services and large economies of scale. [See pages 30-31]*

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

Regarding the impact of the proposal on quality, in Section B, page 27-29, and in Section N, pages 110-111, the applicant states:

*“NC Imaging Centers, LLC (NC Imaging) believes that the proposed project will promote the provision of high quality freestanding MRI services... UNC Health, the sole member of NC Imaging, is know for providing the utmost in quality care for the patients it serves and expects the proposed project to bolster its high-quality reputation...As a wholly owned entity of UNC Health, NC Imaging’s commitment to providing quality care will be guided by the policies already in use at other UNC Health facilities. ... Further, as a complement to the services provided at UNC Hospitals, UNC Health Imaging center will maintain the importance of continuous quality monitoring ... see Exhibit B.20-4 for UNC Hospitals’ Competency Assessment Policy, which will be used to guide practices at UNC Health Imaging Center upon completion of the proposed project to ensure that the right person is performing the right job in the right way to deliver patient care. [See pages 28-29]*

*See previously referenced Exhibits B.20-1 through B.20-3 for a copy of UNC Hospitals quality policies, including its Performance Improvement Program, Utilization Management Plan, and Risk Management Program policies. ... Upon completion of the proposed project, NC Imaging, as part of UNC Health, will use UNC Hospitals’ policies as the framework for such policies at UNC Health Imaging Center. [See page 110-111]”*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section B, pages 29-30, and in Section N, page 111 , the applicant states:

*“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 Hospitals’*

*commitment to treating all patients regardless of their ability to pay is evidenced by its payor mix. ... As noted in its Financial Assistance policy, Exhibit B.20-6, 'as part of its mission, UNC Health Care provides care for residents of North Carolina who are uninsured or underinsured and do not have the ability to pay for medically necessary healthcare services...' [See pages 29-30]*

*See previously referenced Exhibits B.20-5 and B.20-6 for copies of UNC Hospitals' access and financial policies. Upon completion of the proposed project, NC Imaging, as part of UNC Health, will use UNC Hospitals' policies as the framework for such policies at UNC Health Imaging Center. [See page 111]"*

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant 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
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

**J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**DUHS** proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Duke Coley Hall Imaging. The diagnostic center will be operated as an IDTF located at 66 Vilcom Drive, Chapel Hill, Orange County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 87, the applicant states:

*“The project will promote cost-effectiveness, quality, and access to services and therefore will promote competition in Orange County, primarily because DUHS will be a new, highly regarded provider of MRI services in Orange County.”*

*All MRI services in Orange County are currently offered either by UNC or a UNC affiliate (Wake Radiology UNC Healthcare). In 2019, UNC Hospitals and Wake Radiology formally entered into a joint venture to combined outpatient imaging services...”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 87, the applicant states:

*“All but one of the UNC-affiliated sites in Orange County ... are operated as hospital-based clinics. DUHS’s project will provide an alternative billing and reimbursement structure as an IDTF. For many patients and payors, this may be a more cost-effective option for appropriate outpatient procedures.”*

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

Regarding the impact of the proposal on quality, in Section N, page 88, the applicant states:

*“DUHS is committed to delivering high-quality care at all of its facilities and will continue to maintain the highest standards and quality of care, consistent with the standards that DUHS has sustained throughout its illustrious history of providing patient care. ... The scans generated at this facility will be read by Duke Health’s radiologists in the appropriate subspecialty, just as they are at Duke Raleigh Hospital.”*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 88, the applicant states:

*“...DUHS will continue to have a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental condition, age, ability to pay or any other factor that would classify a patient as underserved. Duke’s financial assistance policy will apply to these services. By brining imagining services closer to a new convenient location, it also makes them more accessible for patients with transportation challenges.”*

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant 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
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

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

### **C All Applications**

#### **J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**RR-Imaging** proposes to add a fixed MRI scanner to an approved, under development diagnostic center, RR-Chapel Hill. RR-Chapel Hill will be non-hospital licensed and located at 120 Banks Drive, Chapel Hill, Orange County.

In Section Q, Form O, the applicant identifies the diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of eight of this type of facility located in North Carolina.

In Section O.4, page 114, the applicant states,

*“North Carolina does not license diagnostic centers. However, these facilities meet the requirements of several external quality entities for its imaging sites.*

...

*Practices served by RRLLC are registered with CMS; all RRA physicians are in good standing with CMS and with the North Carolina Medical Board.*

...

*Raleigh Radiology has been deemed a Breast Cancer of Excellence by ACR for all of its facilities, effective September 2021. This involves a rigorous review of policies, procedures, image quality, and interpretations. It extends to breast MRIs provided at locations served by RRLLC. RRCH will enjoy this umbrella designation.”*

See also Exhibit O.1 for a list of existing Raleigh Radiology locations which currently maintain MRI American College of Radiology (ACR) accreditation. On page 109 the applicant states,

*“ACR accreditation involves peer review of quality, safety, procedures, and personal requirements/qualifications. ACR also conducts regular reviews of images done for patients and of physics reports on the equipment to judge the quality of both the interpretation and the images themselves.”*

After reviewing and considering information provided by the applicant regarding the quality of care provided, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

NC Imaging proposes to develop a new diagnostic center, UNC Health Imaging, by acquiring one fixed MRI scanner. The proposed diagnostic center would be a non-hospital licensed diagnostic center located at 106 Carraway Crossing Drive, Chapel Hill, Orange County.

In Section Q, Form O, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of fourteen of this type of facility located in North Carolina.

In Section O.4, page 113, the applicant states that, during the 18 months immediately preceding the submittal of the application, “Each of the facilities identified in Form O has continually maintained all relevant licensure, certification, and accreditation...”. 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, incidents related to quality of care occurred in none of the 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 five facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

DUHS proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Duke Coley Hall Imaging. The diagnostic center will be operated as an IDTF located at 66 Vilcom Drive, Chapel Hill, Orange County.

In Section Q, Form O, the applicant identifies the diagnostic centers and hospitals offering MRI services located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of eight of these type of facilities (either existing or approved) located in North Carolina.

In Section O.4, page 91, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in none of these facilities. 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, incidents related to quality of care occurred in none of the 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 five 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**  
**All Applications**

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

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

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

- (a) *An applicant proposing to acquire a 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- All Applications-** None of the applicants 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;*

**-NA- RR-Imaging.** The MRI service area is Orange County. In Section C, page 61, the applicant states that neither it, nor any related entities, own a controlling interest in a fixed MRI scanner in Orange County.

**-C- NC Imaging.** The MRI service area is Orange County. The applicant does not own a fixed MRI scanner. However, in Section C, pages 65, the applicant states that UNC Health, a related entity to NC Imaging, owns and operates nine fixed MRI scanners in Orange County [six at UNC Medical Center, one at UNC Hospitals Hillsborough Camps and two at the Imaging and Spine Center]. During the most recent 12-month period for which UNC Health has data (July 2020 through June 2021) the nine fixed MRI scanners performed 46,911 weighted MRI procedures. This equates to an average of 5,212 weighted MRI procedures per scanner



(46,911/ 9 = 5,212) which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.

UNC Health has a controlling interest in nine of the ten fixed MRI scanners in Orange County. There is a tenth fixed MRI scanner in Orange County identified as “Grandfathered”, the service site is listed as “Wake Radiology” and the provider/owner is listed as “Chapel Hill Diagnostic Imaging, LLC” [See Table 17E-1, page 359, of the 2021 SMFP]. This will be referred to as the “Chapel Hill Diagnostic Imaging fixed MRI”. Comments were raised that this is a “related entity” to the applicant, NC Imaging. The project analyst notes that NC Imaging only must account for existing fixed MRI scanners in the service area that either NC Imaging or a related entity “owns a controlling interest in.” There is no indication Chapel Hill Diagnostic Imaging, LLC is a related entity to either NC Imaging or UNC Health. Furthermore, there is no indication that either NC Imaging or UNC Health own a controlling interest in the Chapel Hill Diagnostic Imaging fixed MRI.

The project analyst notes that if NC Imaging did have to account for the Chapel Hill Diagnostic Imaging fixed MRI NC Imaging would still be conforming pursuant to the Rule even without attributing any historic utilization to the Chapel Hill Diagnostic Imaging fixed MRI scanner [46,911/10 fixed MRI scanners = 4,691 average weighted MRI scans per fixed MRI scanner.]

-NA- **DUHS.** The MRI service area is Orange County. In Section C, page 43, the applicant states that neither it, nor any related entities, own a controlling interest in a fixed MRI scanner in Orange County.

(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- **RR-Imaging.** The MRI service area is Orange County. In Section C, page 61, the applicant states that neither it, nor any related entities, owns a controlling interest in a mobile MRI scanner in Orange County.

-NA- **NC Imaging.** The MRI service area is Orange County. In Section C, page 65, the applicant states that neither it, nor any related entities, owns a controlling interest in a mobile MRI scanner in Orange County.

-NA- **DUHS.** The MRI service area is Orange County. The applicant states that neither the applicant nor a related entity owns a controlling interest in an existing mobile MRI scanner in the Orange County.

(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;*

-C- **RR-Imaging.** The MRI service area is Orange County. The 2021 SMFP shows more than four fixed MRI scanners in Orange County. In Section C, page 62, and in Section Q, page 129, the applicant states that it projects to perform 5,128 weighted MRI procedures on its proposed fixed MRI scanner in the third year of operation following completion of the proposed project which exceeds the required average of 4,805 weighted MRI procedures per scanner in this performance standard. The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.

-C- **NC Imaging.** The MRI service area is Orange County. The 2021 SMFP shows more than four fixed MRI scanners in Orange County. UNC Health, a related entity to NC Imaging, owns and operates nine fixed MRI scanners in Orange County [six at UNC Medical Center, one at UNC Hospitals Hillsborough Camps and two at the Imaging and Spine Center].

NC Imaging and its related entity have a total of ten fixed MRI scanners under this Rule (nine existing and one proposed) in Orange County. In Section C, page 66, and in Section Q, the applicant projects that in the third year of operating (FY2026) following completion of the proposed project the 10 fixed MRI scanners will perform 54,159 weighted MRI procedures for an average of 5,416 weighted MRI procedures [ $54,159 / 10 = 5,416$ ] which is greater than the 4,805 weighted MRI procedures required by the Rule. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is conforming with this Rule.

UNC Health has a controlling interest in nine of the ten fixed MRI scanners in Orange County. There is a tenth fixed MRI scanner in Orange County identified as “Grandfathered”, the service site is listed as “Wake Radiology” and the provider/owner is listed as “Chapel Hill Diagnostic Imaging, LLC” [See Table 17E-1, page 359, of the 2021 SMFP]. This will be referred to as the “Chapel Hill Diagnostic Imaging fixed MRI”. Comments were raised that this is a “related entity” to the applicant, NC Imaging. The project analyst notes that NC Imaging only must account for existing fixed MRI scanners in the service area that either NC Imaging or a related entity “owns a controlling interest in.” There is no indication Chapel Hill Diagnostic Imaging, LLC is a related entity to either NC Imaging or UNC Health. Furthermore, there is no indication that either NC Imaging or UNC Health own a controlling interest in the Chapel Hill Diagnostic Imaging fixed MRI.

The project analyst notes that if NC Imaging did have to account for the Chapel Hill Diagnostic Imaging fixed MRI NC Imaging would still be conforming pursuant to the Rule even without attributing any projected utilization to the Chapel Hill Diagnostic Imaging fixed MRI scanner [54,159/11 fixed MRI scanners = 4,923.5 average weighted MRI scans per fixed MRI scanner].

-C- **DUHS.** The MRI service area is Orange County. The 2021 SMFP shows more than four fixed MRI scanners in Orange County. The third OY is FY2026 (7/1/2025 to 6/30/2026). In Section Q, the applicant projects that the proposed MRI scanner will perform 4,914 weighted MRI procedures in the third year of operation following completion of the proposed project, which is greater than the 4,805 weighted MRI procedures required by the which exceeds the required average of 4,805 weighted MRI procedures per scanner in this performance standard. The discussion regarding projected utilization in Criterion (3) 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- **RR-Imaging.** Neither the applicant, nor any related entities, owns a controlling interest in any MRI scanners in Orange County aside from the proposed fixed MRI scanner.

-C- **NC Imaging.** 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 related entity. Therefore, pursuant to the rule, the applicant must demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform 4,805 weighted MRI procedures in the third year following completion of the proposed project. The third OY is FY2026. In Section C, pages 66-67, and in Section Q - Form C Assumptions and Methodology the applicant projects that the proposed MRI scanner will perform 5,788 weighted MRI procedures in the third year of operation (FY2026), which is greater than the 4,805 weighted MRI procedures required by the Rule. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is conforming with this Rule.

-NA- **DUHS.** Neither the applicant, nor any related entities, owns a controlling interest in any MRI scanners in Orange County aside from the proposed fixed MRI scanner.

- (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- **RR-Imaging.** The MRI service area is Orange County. In Section C, page 63, the applicant states that neither it, nor any related entities, own an existing, approved or proposed mobile MRI scanner in Orange County.
- NA- **NC Imaging.** The MRI service area is Orange County. In Section C, page 67, the applicant states that neither it, nor any related entities, owns a controlling interest in an existing, approved or proposed mobile MRI scanner in Orange County.
- NA- **DUHS.** The MRI service area is Orange County. In Section C, page 44, 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 Orange County.
- (6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- C- **RR-Imaging.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q.
- C- **NC Imaging.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q.
- C- **DUHS.** 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- **All Applications-** None of the applicants 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- All Applications-** None of the applicants 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- All Applications-** None of the applicants propose the acquisition of a dedicated fixed multi-position MRI scanner. Therefore, this rule is not applicable to this review.

## COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2019 State Medical Facilities Plan, no more than one fixed MRI scanner may be approved for Orange County in this review. Because the three applications in this review collectively propose to develop three additional fixed MRI scanners to be located in Orange County, all the applications cannot be approved for the total number of fixed MRI scanners proposed. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

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

**J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**RR-Imaging** proposes to add a fixed MRI scanner to an approved, under development diagnostic center, RR-Chapel Hill. RR-Chapel Hill will be non-hospital licensed and located at 120 Banks Drive, Chapel Hill, Orange County. RR-Chapel Hill was issued a Certificate of Need effective October 29, 2021 (see Project ID# J-12062-21). The applicant proposes to perform 5,128 total weighted MRI procedures on the proposed fixed MRI scanner from January 1, 2025–December 31, 2025, the third full year of operation following completion of the project.

**J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**NC Imaging** proposes to develop a new diagnostic center, UNC Health Imaging, by acquiring one fixed MRI scanner. The proposed diagnostic center would be a non-hospital licensed diagnostic center located at 106 Carraway Crossing Drive, Chapel Hill, Orange County. The applicant proposes to perform 5,788 total weighted MRI procedures on the proposed fixed MRI scanner from July 1, 2025–June 30, 2026, the third full year of operation following completion of the project.

**J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

**DUHS** proposes to add a fixed MRI scanner to an approved, undeveloped diagnostic center, Duke Coley Hall Imaging. The diagnostic center will be operated as an IDTF located at 66 Vilcom Drive, Chapel Hill, Orange County. Duke Coley Hall Imaging was issued a Certificate of Need effective March 25, 2022 (see Project ID#J-12001-20). The proposed project would be a change of scope for Project ID# J-12001-21. The applicant proposes to perform 4,914 total weighted MRI procedures on the proposed fixed MRI scanner from July 1, 2025–June 30, 2026, the third full year of operation following completion of the project.

**Conformity with Statutory and Regulatory Review Criteria**

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved.

All three applications are conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, the applications submitted by **RR-Imaging**, **NC Imaging** and **DUHS** are equally effective alternatives.

**Scope of Services**

The following table compares the scope of services proposed to be offered. Generally, the application offering the greater scope of services is the more effective alternative for this comparative factor.

<b>Applicant</b>	<b>Type of Fixed MRI Scanner</b>	<b>Hospital Based or Freestanding*</b>
RR-Imaging	1.5T	Freestanding
NC Imaging	1.5T	Freestanding
DUHS	1.5T	Freestanding

\*Freestanding means not operating under a hospital license.

All the applicants propose to acquire and operate a fixed MRI scanner in a freestanding outpatient setting. Therefore, regarding this comparative factor, the applications submitted by **RR-Imaging**, **NC Imaging** and **DUHS** are equally effective alternatives.

**Historical Utilization**

The following table illustrates historical utilization of each applicant as provided in the **2021** SMFP representing FY2019 reported utilization. Generally, regarding this comparative factor, an existing provider with higher historical utilization rates is the more effective alternative based on an assumption that that provider has a greater need for the proposed fixed MRI scanner in order to serve its projected patients.

**Fixed MRI Scanners in Orange County Owned by the Applicants: 2021 SMFP Based on FY2019 Data**

Facility (Owner)	# of Fixed MRI Scanners	Total Weighted Procedures Performed during Federal Fiscal Year (FFY) 2019	Total Weighted Procedures per Scanner
University of North Carolina Hospitals-Hillsborough	1	8,039	
University of North Carolina Hospitals-Medical Center	6	31,268	
University of North Carolina Hospitals-Imaging Center	2	9,958	
<b>Total UNC Health MRI Scanners</b>	<b>9</b>	<b>49,265</b>	<b>5,473</b>
Wake Radiology (Chapel Hill Diagnostic Imaging, LLC)	1	1,646	1,646
<b>Total</b>	<b>10</b>	<b>50,911</b>	<b>5,091</b>
<b>Total with all 10 fixed MRI scanners but with no MRI procedure from the Chapel Hill Diagnostic Imaging, LLC MRI Scanner</b>	<b>10</b>	<b>49,265</b>	<b>4,926</b>

Source: 2021 SMFP, Table 17E-1, page 359.

Note: There are no approved, but undeveloped, fixed MRI scanners in Orange County.

All three of the applications propose to provide MRI services at new facilities and thus have no historical utilization with a fixed MRI scanner at those proposed facilities. However, NC Imaging is wholly owned by UNC Health which owns nine of the 10 existing fixed MRI scanners in Orange County. Furthermore, the project analyst notes that according to the 2021 SMFP the only mobile MRI scanners operated in Orange County are utilized by UNC Health facilities. The UNC Health MRI scanners are the sole driver of the need determination in the 2021 SMFP for one fixed MRI scanner in the Orange County fixed MRI scanner service area. As shown in the table above, even backing out all of the MRI procedures performed using the Chapel Hill Diagnostic Imaging, LLC fixed MRI scanner but still counting the Chapel Hill Diagnostic Imaging, LLC fixed MRI scanner the MRI utilization on the UNC Health fixed MRI scanners was 4,926.5 [ $49,265 / 10 = 4,926.5$ ] which exceeds the average of 4,805 weighted MRI procedures per scanner as required by the MRI performance standards. Therefore, regarding this comparative factor, the application submitted by **NC Imaging** is the more effective alternative.

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

The 2021 SMFP identifies the need for one fixed MRI scanner in the Orange County fixed MRI service area.

The following table illustrates where in the service area each applicant proposes to develop its proposal.



	<b>Proposed Locations</b>
RR-Imaging	120 Banks Dr., Chapel Hill
NC Imaging	106 Carraway Crossing, Chapel Hill
DUHS	66 Vilcom Center Drive, Chapel Hill

All three applications are proposing to locate the fixed MRI scanner in Chapel Hill. Per Google Maps the three locations are less than two miles apart (7 min drive).

Thus, with respect to geographic accessibility, the **RR-Imaging**, **NC Imaging** and **DUHS** are equally effective alternatives.

**Access by Service Area Residents**

On page 344, the 2021 SMFP defines a fixed MRI scanner as “an MRI scanner that is not a mobile MRI scanner.” The 2021 SMFP, page 344, defines the service area for a fixed MRI scanner as “the same as an Acute Care Bed Service area as defined in Chapter 5 and shown in Figure 5.1.” Based on that definition, the fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county. Orange County has a licensed acute care hospital. Therefore, for the purpose of this review, Orange County is the service area because it has an acute care hospital. Facilities may also serve residents of counties not included in their service area. Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for additional fixed MRI services in the service area where they live.

The following table illustrates access by service area residents during the third full fiscal year following project completion.

<b>Applicant</b>	<b>Orange County Residents Served</b>	<b>Orange County Residents per Scanner</b>	<b>Projected Total Patients</b>	<b>Orange County Residents Served as a % of Total Patients</b>
RR-Imaging	2,996	2,996	4,471	67.0%
NC Imaging	1,308	1,308	4,684	27.9%
DUHS	2,581	2,581	4,310	59.9%

As shown in the table above, **RR-Imaging** projects to serve both the highest total number of service area residents and the highest percentage of service area residents and compared to overall total patients. There is a documented high out-migration from Orange County with respect to MRI services of Orange County residents leaving Orange County for MRI services. In addition, it is reasonable to state that both the overall number of Orange County residents receiving MRI services and the out-migration of Orange County residents receiving MRI services outside of Orange County are both undercounted based on the fact that there are a significant number of Alliance MRI scanners in Orange, Durham, Alamance and Wake counties for which the patient county of origin is not reported. Therefore, while it is recognized that the UNC Health MRI scanners (9 fixed) pull in a large number of out-of-county residents to Orange County for MRI services and that this has been a major factor in

generating a need for another fixed MRI scanner in Orange County the large out-migration of Orange County residents seeking MRI services combined with the cost benefit (which is a form of economic access) of a freestanding fixed MRI demonstrates the need and value in Orange County for a freestanding fixed MRI to serve Orange County residents. Thus, this comparative factor is pertinent to this review.

Therefore, regarding this comparative factor, the application submitted by **RR-Imaging** is the more effective alternative.

**Access by Underserved Groups**

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

*“Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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 access by underserved groups, applications are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

The Agency may use one or more of the following metrics to compare the applications:

- Total charity care, Medicare or Medicaid patients
- Charity care, Medicare or Medicaid patients as a percentage of total patients
- Charity care, Medicare or Medicaid patients per MRI procedure
- Total charity care, Medicare or Medicaid dollars
- Charity care, Medicare or Medicaid dollars as a percentage of total gross or net revenues
- Charity care, Medicare or Medicaid dollars per MRI procedure

Which of the above metrics the Agency uses is determined by whether or not the applications included in the review provide data that can be compared as presented above and whether or not such a comparison would be of value in evaluating the alternative factors.

*Projected Charity Care*

The following table compares projected charity care in the third full fiscal year following project completion for each facility using the following metrics: Charity Care dollars; Charity Care dollars as a percentage of total gross revenues; and Charity Care dollars per MRI procedure.

<b>Applicant</b>	<b>Gross Revenue</b>	<b>MRI Scans*</b>	<b>Charity Care</b>	<b>Charity Care as a % of Gross Revenue</b>	<b>Charity Care / MRI Scan</b>
RR-Imaging	\$8,443,087	5,128	\$42,215	0.50%	\$8.23
NC Imaging	\$20,958,410	5,788	\$2,118,674	10.10%	\$366.05
DUHS	\$4,708,917	4,914	\$35,111	0.75%	\$7.15

Source: Section Q Form C and Form F.2b of the respective applications

\*MRI Scans are weighted scans. This is to be in sync with the MRI performance rules which exclusively look to weighted scans. Weighted scans account for differences in MRI scans which can result in a particular MRI scan taking more time and resources than a different MRI scan, such as one requiring the use of contrast.

NC Imaging proposes the highest amount of charity care dollars, the highest amount of charity care dollars as a percent of total gross revenues, and the highest amount of charity care dollars per MRI scan. Therefore, with respect to charity care, **NC Imaging** is the more effective alternative.

However, one of the applicants, RR-Imaging, bills globally. This means that RR-Imaging includes “professional fees”, which cover professional interpretation of MRI studies by radiologists, in its bills to payors. Two of the applicants, NC Imaging and DUHS, do not bill globally. Billing to payors, whether global billing or non-global billing, is how gross revenue is derived. Since the applicants bill differently and thus generate gross revenue differently a comparison based on gross revenue is inconclusive. In addition, NC Imaging based its billing on MRI hospital rates as opposed to MRI freestanding (non-hospital) rates. NC Imaging is proposing to develop a fixed MRI scanner in a freestanding diagnostic center. MRI hospital rates are generally higher than MRI free-standing rates. Therefore, NC Imaging’s stated gross revenue cannot be compared to the gross revenue of either RR-Imaging or DUHS, both of which derived gross revenue based on MRI freestanding rates. The charity care analysis above is based on gross revenue. As gross revenue between the applications cannot be compared the charity care comparison is unreliable. The project analyst notes that a comment was received suggesting that while the gross revenues could not be compared the Agency could use the percentage of gross revenue to compare charity care as the stated percentage would not be impacted by the actual gross revenue. However, this is incorrect. The project analyst does not know, and cannot determine, the impact on RR-Imaging’s percentage of gross revenue for charity care if the professional fees were not included as a part of gross revenue. On the other side, the project analyst does not know, and cannot determine, the impact on NC Imaging or DUHS’s percentage of gross revenue for charity care if either of those applicants switched from non-global billing to global billing (including professional fees). In either case, the charity care percentage of gross revenue could go up, down, or stay the same. Thus, for the reasons stated above, the result of the analysis of this comparative factor is inconclusive.

*Projected Medicare*

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for each facility using the following metrics: Medicare dollars; Medicare dollars as a percentage of total gross revenues; and Medicare dollars per MRI procedure.

<b>Applicant</b>	<b>Gross Revenue</b>	<b>MRI Scans*</b>	<b>Medicare</b>	<b>Medicare as a % of Gross Revenue</b>	<b>Medicare/MRI Scan</b>
RR-Imaging	\$8,443,087	5,128	\$3,382,607	40.10%	\$659.63
NC Imaging	\$20,958,410	5,788	\$7,737,592	37.02%	\$1,336.83
DUHS	\$4,708,917	4,914	\$1,828,383	38.83%	\$372.07

Source: Section Q Form F.2b of the respective applications

\*MRI Scans are weighted scans. This is to be in sync with the MRI performance rules which exclusively look to weighted scans. Weighted scans account for differences in MRI scans which can result in a particular MRI scan taking more time and resources than a different MRI scan, such as one requiring the use of contrast.

NC Imaging proposes both the highest amount of Medicare dollars and the highest amount of Medicare dollars per MRI scan while RR-Imaging proposes the higher amount of Medicare dollars as a percent of gross revenue and the next highest amount of Medicare dollars and the highest amount of Medicare dollars per MRI scan. Therefore, with respect to Medicare, **NC Imaging** is the more effective alternative.

However, one of the applicants, RR-Imaging, bills globally. This means that RR-Imaging includes “professional fees”, which cover professional interpretation of MRI studies by radiologists, in its bills to payors. Two of the applicants, NC Imaging and DUHS, do not bill globally. Billing to payors, whether global billing or non-global billing, is how gross revenue is derived. Since the applicants bill differently and thus generate gross revenue differently a comparison based on gross revenue is inconclusive. In addition, NC Imaging based its billing on MRI hospital rates as opposed to MRI free-standing (non-hospital) rates. NC Imaging is proposing to develop a fixed MRI scanner in a freestanding diagnostic center. MRI hospital rates are generally higher than MRI free-standing rates. Therefore, NC Imaging’s stated gross revenue cannot be compared to the gross revenue of either RR-Imaging or DUHS, both of which derived gross revenue based on MRI freestanding rates. The Medicare analysis above is based on gross revenue. As gross revenue between the applications cannot be compared the Medicare comparison is unreliable. The project analyst notes that a comment was received suggesting that while the gross revenues could not be compared the Agency could use just the percentage of gross revenue to compare Medicare as the stated percentage would not be impacted by the actual gross revenue. However, this is incorrect. The project analyst does not know, and cannot determine, the impact on RR-Imaging’s percentage of gross revenue for Medicare if the professional fees were not included as a part of gross revenue. On the other side, the project analyst does not know, and cannot determine, the impact on NC Imaging or DUHS’s percentage of gross revenue for Medicare if either of those applicants switched from non-global billing to global billing (including professional fees). In either case, the Medicare percentage of gross revenue could go up, down, or stay the same. Thus, for the reasons stated above, the result of the analysis of this comparative factor is inconclusive.

*Projected Medicaid*

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for each facility using the following metrics: Medicaid dollars; Medicaid dollars as a percentage of total gross revenues; and Medicaid dollars per MRI procedure.

<b>Applicant</b>	<b>Gross Revenue</b>	<b>MRI Scans*</b>	<b>Medicaid</b>	<b>Medicaid as a % of Gross Revenue</b>	<b>Medicaid/ MRI Scan</b>
RR-Imaging	\$8,443,087	5,128	\$415,215	4.92%	\$80.97
NC Imaging	\$20,958,410	5,788	\$1,667,614	8.01%	\$288.12
DUHS	\$4,708,917	4,914	\$258,820	5.51%	\$52.67

Source: Section Q Form F.2b of the respective applications

\*MRI Scans are weighted scans. This is to be in sync with the MRI performance rules which exclusively look to weighted scans. Weighted scans account for differences in MRI scans which can result in a particular MRI scan taking more time and resources than a different MRI scan, such as one requiring the use of contrast.

NC Imaging proposes the highest amount of Medicaid dollars, the highest amount of Medicaid dollars as a percent of gross revenue and the highest amount of Medicaid dollars per MRI scan. Therefore, with respect to Medicaid, **NC Imaging** is the more effective alternative.

However, one of the applicants, RR-Imaging, bills globally. This means that RR-Imaging includes “professional fees”, which cover professional interpretation of MRI studies by radiologists, in its bills to payors. Two of the applicants, NC Imaging and DUHS, do not bill globally. Billing to payors, whether global billing or non-global billing, is how gross revenue is derived. Since the applicants bill differently and thus generate gross revenue differently a comparison based on gross revenue is inconclusive. In addition, NC Imaging based its billing on MRI hospital rates as opposed to MRI freestanding (non-hospital) rates. NC Imaging is proposing to develop a fixed MRI scanner in a freestanding diagnostic center. MRI hospital rates are generally higher than MRI freestanding rates. Therefore, NC Imaging’s stated gross revenue cannot be compared to the gross revenue of either RR-Imaging or DUHS, both of which derived gross revenue based on MRI freestanding rates. The Medicaid analysis above is based on gross revenue. As gross revenue between the applications cannot be compared the Medicaid comparison is unreliable. The project analyst notes that a comment was received suggesting that while the gross revenues could not be compared the Agency could use just the percentage of gross revenue to compare Medicaid as the stated percentage would not be impacted by the actual gross revenue. However, this is incorrect. The project analyst does not know, and cannot determine, the impact on RR-Imaging’s percentage of gross revenue for Medicaid if the professional fees were not included as a part of gross revenue. On the other side, the project analyst does not know, and cannot determine, the impact on NC Imaging or DUHS’s percentage of gross revenue for Medicaid if either of those applicants switched from non-global billing to global billing (including professional fees). In either case, the Medicaid percentage of gross revenue could go up, down, or stay the same. Thus, for the reasons stated above, the result of the analysis of this comparative factor is inconclusive.

### **Competition (Access to a New or Alternative Provider in the Service Area)**

Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer fixed MRI scanners than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

On page 344, the 2021 SMFP defines a fixed MRI scanner as “*an MRI scanner that is not a mobile MRI scanner.*” The 2021 SMFP, page 344, defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service area as defined in Chapter 5 and shown in Figure 5.1.*” Based on that definition, the fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county. Orange County has a licensed acute care hospital. Therefore, for the purpose of this review, Orange County is the service area.

NC Imaging is wholly owned by UNC Health. UNC Health currently provides fixed MRI scanner services in the service area of Orange County. Neither RR-Imaging nor DUHS currently provide fixed MRI scanner services in the service area of Orange County. Therefore, both RR-Imaging and DUSH would qualify as a new or alternative provider in the service area. Therefore, regarding this comparative factor, the applications submitted by **RR-Imaging** and **DUHS** are both more effective alternatives and NC Imaging is the least effective alternative.

**Projected Average Net Revenue per MRI Procedure**

The following table compares the projected average net revenue per weighted MRI procedure for the third year of operation following project completion for all the applicants, based on the information provided in the applicants’ pro forma financial statements (Section Q). Generally regarding this factor, the application proposing the lowest average net revenue per MRI procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor.

Applicant	Net Revenue	# of MRI Procedures*	Average Net Revenue per MRI Procedure
RR-Imaging	\$2,096,210	5,128	\$409
NC Imaging	\$3,060,935	5,788	\$529
DUHS	\$2,433,066	4,914	\$495

Source: Section Q Form C and Form F.2 of the respective applications

\*MRI Scans are weighted scans. This is to be in sync with the MRI performance rules which exclusively look to weighted scans. Weighted scans account for differences in MRI scans which can result in a particular MRI scan taking more time and resources than a different MRI scan, such as one requiring the use of contrast.

As shown in the table above, RR-Imaging proposes the lower average net revenue per weighted MRI procedure in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the proposal by **RR-Imaging** is the more effective alternative.

However, one of the applicants, RR-Imaging, bills globally. This means that RR-Imaging includes “professional fees”, which cover professional interpretation of MRI studies by radiologists, in its bills to payors. Two of the applicants, NC Imaging and DUHS, do not bill globally. Billing to payors, whether global billing or non-global billing, is how gross revenue is derived. Since the applicants bill differently and thus generate gross revenue differently a comparison based on gross revenue is inconclusive. In addition, NC Imaging based its billing on MRI hospital rates as opposed to MRI free-standing (non-hospital) rates. NC Imaging is proposing to develop a fixed MRI scanner in a freestanding diagnostic center. MRI hospital rates are generally higher than MRI free-standing rates. Therefore, NC Imaging’s stated gross revenue cannot be compared to the gross revenue of either RR-Imaging or DUHS, both of which derived gross revenue based on MRI free-standing rates. Net revenue is derived from gross revenue. As gross revenue between the applications cannot be compared the net revenue comparison is unreliable. Thus, for this comparative factor, the result of the analysis is inconclusive.

**Projected Average Total Operating Cost per MRI Procedure**

The following table compares the projected average operating expense per weighted MRI procedure for the third year of operation following project completion for all the applicants, based on the

information provided in the applicants’ pro forma financial statements (Section Q). Generally regarding this factor, the application proposing the lowest average operating expense per MRI procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

Applicant	Operating Expense	# of MRI Procedures	Average Operating Expense per Procedure
RR-Imaging	\$1,842,566	5,128	\$359
NC Imaging	\$2,645,982	5,788	\$457
DUHS	\$1,428,780	4,914	\$291

Source: Section Q Form C and Form F.2 of the respective applications

As shown in the table above, DUHS proposes a lower average operating expense per weighted MRI procedure. Therefore, regarding average operating expense per MRI procedure, the proposal by **DUHS** is the more effective alternative.

However, one of the applicants, RR-Imaging, bills globally. This means that RR-Imaging includes “professional fees”, which cover professional interpretation of MRI studies by radiologists, in its bills to payors. Two of the applicants, NC Imaging and DUHS, do not bill globally. Billing to payors, whether global billing or non-global billing, is how gross revenue is derived. Since the applicants bill differently and thus generate gross revenue differently a comparison based on gross revenue is inconclusive. In addition, NC Imaging based its billing on MRI hospital rates as opposed to MRI free-standing (non-hospital) rates. NC Imaging is proposing to develop a fixed MRI scanner in a freestanding diagnostic. Net revenue is derived from gross revenue. As gross revenue between the applications cannot be compared the net revenue comparison is unreliable. RR-Imaging derives its professional fees expense, which is included as part of its operating expenses, based on a formula which includes net revenue (see page 142 of the RR-Imaging application). Therefore, in the case of RR-Imaging, the expense line of professional fees is impossible for the Project Analyst to simply “break out” from the overall expenses with the degree of certainty needed to be fair to both RR-Imaging and the other applicants.

Furthermore, each of the applications proposes to add a single fixed MRI scanner. The project analyst notes that DUHS provided projected FTE’s for its entire proposed facility, which includes equipment and services beyond just the MRI scanner, in contrast to NC Imaging which provided projected FTE’s for just the proposed MRI service. In addition to the issues raised by global billing/ non-global billing, while each application proposed to develop just one fixed MRI scanner, significant differences in the number of projected FTE’s, FTE salaries, taxes and benefits, cost of leased space (including projected square footage for the MRI scanner) and other differences in expenses further preclude the ability of the Project Analyst from making an “apples to apples” comparison of operating expenses per weighted MRI scan.

The project analyst also further notes that it is uncertain with respect to RR-Imaging if there are other expenses listed in its Form 3.b that are directly associated with RR-Imaging’s global billing including any administrative fees such as processing and collection, which further render it unreasonable for the project analyst to try and simply “back out” professional fees from RR-Imaging’s operating expenses.

Thus, for this comparative factor, the result of the analysis is inconclusive.

## SUMMARY

The following table lists the comparative factors and indicates whether each application was more effective, less effective or equally effective for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

Comparative Factor	RR-Imaging	NC Imaging	DUHS
Conformity with Statutory and Regulatory Review Criteria	Yes	Yes	Yes
Scope of Services	<b>Equally Effective</b>	<b>Equally Effective</b>	<b>Equally Effective</b>
Historical Utilization	Less Effective	<b>More Effective</b>	Less Effective
Geographic Accessibility	<b>Equally Effective</b>	<b>Equally Effective</b>	<b>Equally Effective</b>
Access by Service Area Residents	<b>More Effective</b>	Less Effective	Less Effective
Access by Charity Care Patients	Inconclusive	Inconclusive	Inconclusive
Access by Medicare Patients	Inconclusive	Inconclusive	Inconclusive
Access by Medicaid Patients	Inconclusive	Inconclusive	Inconclusive
Competition (Access to New or Alternative Provider)	<b>More Effective</b>	Less Effective	<b>More Effective</b>
Projected Average Net Revenue per MRI procedure	Inconclusive	Inconclusive	Inconclusive
Projected Average Operating Expense per MRI procedure	Inconclusive	Inconclusive	Inconclusive

The RR-Imaging, NC Imaging and DUHS applications are conforming to all applicable statutory and regulatory review criteria, and thus all three applications are approvable standing alone. However, collectively they propose a total of three fixed MRI scanners in Orange County, but the need determination is for only one fixed MRI scanner in Orange County. Therefore, only one fixed MRI scanner can be approved.

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

- Access by Service Area Residents
- Competition (Access to New or Alternative Provider)

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

- Historical Utilization

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

- Competition (Access to New or Alternative Provider)

As shown in the table above, **RR-Imaging, NC Imaging and DUHS** were determined to be equally effective for the following factors:

- Scope of Services
- Geographic Accessibility



## DECISION

Each application is individually conforming to the need determination in the 2021 SMFP for one additional fixed MRI scanner in Orange County fixed MRI scanner service area as well as individually conforming to all review criteria. However, G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed MRI scanners that can be approved by the Healthcare Planning and Certificate of Need Section.

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

- **Project ID #J-12141-21/ Raleigh Radiology Chapel Hill /Change of scope for Project ID#J-12062-21 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

And the following two applications are denied:

- **Project I.D. #J-12145-21/ UNC Health Imaging Center/ Develop a new diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**
- **Project ID# J-12155-21/ Duke Coley Hall Imaging/ Change of scope for Project ID# J-12001-20 (develop a new diagnostic center) by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP**

The application submitted by **RR WM Imaging Chapel Hill, LLC (Project ID #J-12141-21)** is approved subject to the following conditions:

1. **RR WM Imaging Chapel Hill, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall add a fixed MRI scanner to the approved, under development, Raleigh Radiology Chapel Hill diagnostic center (Project ID#J-12062-21), which is change of scope, by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.**
3. **Upon completion of this project, Raleigh Radiology Chapel Hill shall be licensed for no more than one fixed MRI scanner.**
4. **Progress Reports:**
  - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: .**

- 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. Progress reports shall be due on the first day of every third month. The first progress report shall be due on July 1, 2022. The second progress report shall be due on October 1, 2022 and so forth.**
- 5. 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.**
- 6. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
  - a. Payor mix for the services authorized in this certificate of need.**
  - b. Utilization of the services authorized in this certificate of need.**
  - c. Revenues and operating costs for the services authorized in this certificate of need.**
  - d. Average gross revenue per unit of service.**
  - e. Average net revenue per unit of service.**
  - f. Average operating cost per unit of service.**
- 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.**