

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 24, 2021

Findings Date: October 1, 2021

Project Analyst: Gregory F. Yakaboski

Co-Signer: Lisa Pittman

### COMPETITIVE REVIEW

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Project ID #: J-12063-21  
Facility: Cardinal Points Imaging of the Carolinas Wake Forest  
FID #: 090950  
County: Wake  
Applicants: Pinnacle Health Services of North Carolina, LLC  
Outpatient Imaging Affiliates, LLC  
Project: 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-12068-21  
Facility: Wake Radiology Garner  
FID #: 011023  
County: Wake  
Applicants: WR Imaging, LLC  
Wake Radiology Diagnostic Imaging, Inc.  
Project: Acquire a fixed MRI scanner pursuant to the need determination in 2021 SMFP

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Project ID #: J-12073-21  
Facility: Duke Imaging North Raleigh  
FID #: 210268  
County: Wake  
Applicant: Duke University Health System, Inc.  
Project: 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 Wake 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* is only applicable to the application Duke University Health System, Inc. (DUHS) [Project ID# J-12073-21].

#### **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-12063-21/ Cardinal Points Imaging of the Carolinas Wake Forest/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

**Pinnacle Health Services of North Carolina, LLC and Outpatient Imaging Affiliates, LLC, hereinafter collectively referred to as “the applicant” or “PHSNC”, proposes to develop a new diagnostic center by acquiring one fixed MRI scanner at its existing imaging center, Cardinal Points Imaging of the Carolinas Wake Forest (CPIC Wake Forest), located at 839 Durham Road, Unit A, Wake Forest, Wake County. PHSNC owns a mobile MRI that currently is used to offer MRI services CPIC Wake Forest three days per week. The proposed fixed MRI scanner would replace the existing mobile MRI service.)**

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

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

*Policy GEN-4.* The proposed capital expenditure is less than \$2 million. Therefore, Policy GEN-4 is not applicable to this application.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments [Note: The term “written comments” in this document includes the comments received by Raleigh Radiology, LLC.]
- 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 based on the following:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in Wake County;
  - The applicant adequately documents how the project will promote equitable access to MRI services in Wake County; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

**J-12068-21/ Wake Radiology Garner/ Acquire one fixed MRI scanner**  
**WR Imaging, LLC and Wake Radiology Diagnostic Imaging, Inc., hereinafter collectively referred to as “the applicant” or “Wake Radiology”,** proposes to acquire one fixed MRI scanner to be located at Wake Radiology Garner (WR-Garner), an existing non-hospital licensed diagnostic center located at 300 Health Park Drive, Suite 100, Garner, Wake County. Wake Radiology currently contracts with Alliance to offer MRI services at the existing diagnostic center. The lease with Alliance is for what is considered a fixed MRI scanner. The Alliance MRI scanner is a mobile MRI scanner that is termed a “grandfathered fixed MRI scanner” since it does not move to other locations. The proposed fixed MRI scanner would replace the existing Alliance leased “grandfathered fixed” MRI service.

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

*Policy GEN-3.* In Section B.2, pages 19-22, the applicant explains why it believes its application is conforming to Policy GEN-3.

*Policy GEN-4.* The proposed capital expenditure is less than \$2 million. Therefore, Policy GEN-4 is not applicable to this application.

### **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 based on the following:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in Wake County;
  - The applicant adequately documents how the project will promote equitable access to MRI services in Wake County; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

### **J-12073-21/ Duke Imaging North Raleigh/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

**Duke University Health System, Inc., hereinafter referred to as “the applicant” or DUHS,** proposes to develop a new diagnostic center, Duke Imaging North Raleigh, by acquiring one fixed MRI scanner. The proposed diagnostic center would be operated as an independent diagnostic testing facility (IDTF) located at Medical Office Building 9, 3300 Executive Dr, Raleigh, Wake County. The location is on the Duke Raleigh Hospital (DRAH) Campus

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

*Policy GEN-3.* In Section B.2, pages 12-13, 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 13-14, 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 Wake County;
  - The applicant adequately documents how the project will promote equitable access to MRI services in Wake 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.

### **Decision**

The applications submitted by each of the three applicants are conforming to the need determination and to the applicable policies in the 2021 SMFP. The limit on the number of fixed MRI scanners that can be approved is one (1). Collectively, the applicants propose a total of three fixed MRI scanners. Therefore, all the applications cannot be approved.

- (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**  
**PHSNC**  
**DUHS**

**NC**  
**Wake Radiology**

**J-12063-21/ Cardinal Points Imaging of the Carolinas Wake Forest/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

PHSNC proposes to develop a new diagnostic center by acquiring one fixed MRI scanner to be located at its existing imaging center, CPIC Wake Forest, located at 839 Durham Road, Unit A, Wake Forest, Wake County.

**Patient Origin**

The 2021 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.*” Therefore, for the purpose of this review, Wake County is the service area. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin for acute inpatient services at CPIC-Wake Forest.

County	Historical (Last CY2020)*		Third Full FY of Operation following Project Completion (CY2024)	
	# of Patients	% of Total	# of Patients	% of Total
Wake	1,158	58.3%	2,817	62.0%
Franklin	553	27.8%	1,232	27.1%
Vance	115	5.8%	208	4.6%
Nash	43	2.2%	78	1.7%
Granville	28	1.4%	51	1.1%
Warren	20	1.0%	36	0.8%
Johnston	11	0.6%	20	0.4%
Mecklenburg	9	0.5%	16	0.4%
Durham	7	0.4%	13	0.3%
Other Counties**	32	1.6%	53	1.2%
Other States	10	0.5%	23	0.5%
Total	1,986	100.0%	4,547	100.0%

Source: Tables on pages 29 and 31 of the application.

\*The dates of the last full fiscal year are the Calendar Year (CY) 1/1/2020 to 12/31/2020.

\*\*For "Historical" Other includes <0.2% patient origin for each of the remaining North Carolina counties. For "Projected" Other includes <0.1% patient origin for each of the remaining North Carolina counties.

Totals may not foot due to rounding.

In Section C, page 31, 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 following reasons:

- The applicant based projected patient origin on the historical MRI patient origin at the CPIC-Wake Forest site.
- The applicant adjusted historical patient origin to reflect the projected shift of some PHSNC patients from six Zip codes.

**Analysis of Need**

In Section C.4, pages 33-46, 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 the 2021 SMFP (pages 33-34).
- Historical and increasing MRI Utilization in Wake County (pages 34-36).
- Wake County population growth and aging population (pages 36-38).
- Need for additional value-based fixed MRI scanner capacity in Wake County (pages 38-40).
- Geographic need for a freestanding fixed MRI scanner in Wake Forest. (pages 41-45).
- Physician/provider support (pages 45-46).



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

- The 2021 SMFP identifies the need for one additional fixed MRI scanner in Wake County.
- Population growth, particularly among the elderly is occurring in Wake County.
- The Wake County MRI use rate is significantly higher than the North Carolina MRI use rate.
- 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, Form C, the applicant provides projected utilization, as illustrated in the following tables.

**CPIC Wake Forest: Projected MRI Utilization**

	<b>OY1 CY2022</b>	<b>OY2 CY2023</b>	<b>OY3 CY2024</b>
# of MRI scanners	1	1	1
Unweighted Procedures	3,641	4,087	4,547
Weighted Procedures	3,983	4,471	4,975

Source: Section Q, Form C.2b

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

- Step 1) Projected CPIC Midtown MRI Procedures (pages 115-116).
- Step 2) Projected CPIC Wake Forest Mobile MRI Procedures (pages 116-117).
- Step 3) Calculated PHSNC MRI Market Share for MRI Procedures performed in Wake County including growth based on both existing market share and incremental market share (pages 117-120).
- Step 4) Projected Shift of MRI procedures from CPIC Midtown to CPIC Wake Forest (pages 120-121).
- Step 5) Calculated Total Projected CPIC Wake Forest MRI Procedures (pages 121-122).
- Step 6) Calculate Total Projected CPIC Midtown MRI Procedures after Shift (page 122).
- Step 7) Calculated Total Combined PHSNC Fixed MRI Procedures [CPIC Midtown and CPIC Wake Forest] (page 122).
- Step 8) Determine PHSNC Fixed MRI Market Share in Wake County, both Historic and Projected. (page 123)

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

- There was a need determination in the 2021 SMFP for a fixed MRI scanner in the Wake County MRI service area and this proposed project will meet that need determination by developing a fixed MRI scanner in Wake County.
- The CPIC Wake Forest facility is already providing MRI services three days per week utilizing a mobile MRI scanner it currently owns. The proposed fixed MRI scanner would replace the mobile MRI scanner at the CPIC Wake Forest facility facilitating patient access and scheduling.
- The methodology and assumption utilized by the applicant were reasonable, conservative and well supported. The combination of historic utilization, historic growth rates, existing market share, incremental growth in market share and reasonable shifting of some MRI procedures from CPIC Midtown to CPIC Wake Forest was realistic and in some cases, conservative, especially considering that the applicant, if approved, would go from a part-time mobile MRI scanner to a fixed MRI scanner with increased hours and access.
- In Step 8 on page 1123 of the application the applicant further demonstrates the reasonableness of its projected MRI scans as its Wake County market share in the third operating year (CY2024) of 9.03% is only 1.27% more of Wake County market share in CY2019 (7.76%) with a fixed MRI scanner replacing a part-time (3 days per week) mobile MRI scanner at CPIC Wake Forest.

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

In Section C.6, page 51, the applicant states,

*“PHSNC does not discriminate based on income, race, ethnicity, creed, color, age, religion, national origin, gender, physical or mental handicap, sexual orientation, ability to pay or any other factor that would classify a patient as underserved.”*

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	8.0%
Racial and ethnic minorities	40.0%
Women	82.1%
Persons with Disabilities	5.8%
Persons 65 and older	27.3%
Medicare beneficiaries	25.0%
Medicaid recipients	3.9%

Source: Table on page 51 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:

- The applicant has historically provided access to services to underserved groups.

- The applicant provides underserved residents with access to medical imaging services through a collaboration with Project Access of Wake County.
- The applicant is a certified provider under Medicaid providing access to low-income persons.
- The applicant is a certified provider under Medicare providing imaging services to the elderly.
- 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-12068-21/ Wake Radiology Garner/ Acquire one fixed MRI scanner**

**Wake Radiology** proposes to acquire one fixed MRI scanner to be located at WR-Garner, an existing non-hospital licensed diagnostic center located at 300 Health Park Drive, Suite 100, Garner, Wake County.

### **Patient Origin**

The 2021 SMFP defines the service area for a fixed MRI scanner as *“the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.”* Therefore, for the purpose of this review, Wake County is the service area. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

County	Historical (CY2020)		Third Full FY of Operation following Project Completion (CY2025)	
	Patients	% of Total	Patients	% of Total
Wake	1,839	55.4%	2,462	55.4%
Johnston	959	28.9%	1,284	28.9%
Harnett	268	8.1%	359	8.1%
Sampson	50	1.5%	67	1.5%
Wayne	48	1.4%	64	1.4%
Other	158	4.8%	212	4.8%
Total	3,322	100.0%	4,447	100.0%

Source: Tables on pages 33 and 35 of the application.

\*\*Counties and other states included in the “Other” category are shown in the tables on pages 33 and 35 of the application.

In Section C.3, page 35, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based on the applicant’s historical CY2020 patient origin for MRI services at the facility.

**Analysis of Need**

In Section C.4, pages 37-54, 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 Wake County in the 2021 SMFP (pages 37-41).
- The need for additional fixed MRI capacity within Wake Radiology (pages 41-48).
- The need for fixed MRI capacity at WR-Garner (pages 48-53).
- Wake County’s population growth and aging population (pages 53-54).

The information is not reasonable and not adequately supported based on the following:

- While the applicant does adequately demonstrate that the population needs MRI services, the proposed services in Wake Radiology’s application is for a fixed MRI scanner at WR-Garner. As discussed in Criterion 4 and in the Rules for the performance standards, the applicant owns two mobile MRI scanners which have historically had unused capacity. Therefore, with “proposed services” being defined as a fixed MRI scanner at WR-Garner, the need of the population for the proposed services of a fixed MRI scanner at WR-Garner has not been reasonably and adequately supported. The discussions found in Criterion (4) and in the Rules for the performance standards are incorporated herein by reference.
- Currently the grandfathered fixed MRI scanner at WR-Garner has unused capacity.

**Projected Utilization**

In Section Q, the applicant provides historical and projected utilization, as illustrated in the following tables.

Historical MRI Utilization

	Last Full FY CY2020	Last Full FY CY2020*	Interim CY2021	Interim CY2022
# of MRI scanners	1	1	1	1
Unweighted Procedures	3,322	3,510	3,680	3,858
Weighted Procedures	3,923	4,144	4,345	4,556

Source: Section Q, Form C

\*Adjusted to consider the impact of COVID.

Projected MRI Utilization

	OY1 CY2023	OY2 CY2024	OY3 CY2025
# of MRI scanners	1	1	1
Unweighted Procedures	4,046	4,242	4,447
Weighted Procedures	4,777	5,008	5,251

Source: Section Q, Form C.

In Section Q, Form C Utilization- Assumptions and Methodology, pages 1-2, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1) The applicant first calculated its four-year CAGR (CY2016 to CY2020) for weighted MRI scans based on its historical data for the WR-Garner facility as shown below:

	CY2016	CY2017	CY2018	CY2019	CY2020*	CAGR
# of fixed MRI scanners	1	1	1	1	1	
OP No Contrast	1,752	1,642	1,794	1,844	1,924	2.4%
OP With Contrast	793	848	1,038	1,296	1,586	18.9%
Total Scans	2,545	2,490	2,832	3,140	3,510	8.4%
Total Weighted Scans	2,862	2,829	3,247	3,658	4,144	9.7%
Weighted Scans Annual Growth**		-1.2%	14.8%	12.7%	13.3%	

\*CY2020 data normalized to adjust for the months of March, April and May when utilization was temporarily impacted by the COVID-19 pandemic.

\*\*Adjusted scans based on 1.0 weight for outpatient no contrast and 1.4 weight for outpatient with contrast.

Step 2) Starting with the last year (CY2020) of historical data for weighted MRI scans at the facility the applicant applied a 4.8% growth rate through the first three operating years (CY2023- CY2025) as shown in the table below:

	Last FY	Interim	Interim	OY1	OY2	OY3	CAGR
	CY2020	CY2021	CY2022	CY2023	CY2024	CY2025	
# of fixed MRI Scanners	1	1	1	1	1	1	
OP No Contrast	1,924	2,017	2,115	2,217	2,325	2,438	4.8%
OP With Contrast	1,586	1,663	1,744	1,828	1,917	2,010	4.8%
Total Scans	3,510	3,680	3,858	4,046	4,242	4,447	4.8%
Total Weighted Scans	4,144	4,345	4,556	4,777	5,008	5,251	4.8%*

\*The project analyst notes that the correct CAGR is 4.85%

However, projected utilization is not reasonable and adequately supported based on the following analysis:

Under “*Scope of the Project*”, in Section C.1, page 30, the applicant states,

*“...Wake Radiology intends to continue to contract with Alliance to support MRI service demand elsewhere in Wake County, the proposed fixed MRI unit will be used at Wake Radiology Garner in place of the existing contracted Alliance MRI unit.”*

In its application, the applicant neither discusses or addresses the impact of continuing to operate an additional mobile MRI scanner (leased from Alliance) in Wake County on the applicants projected utilization of its proposed new fixed MRI scanner at Wake Radiology Garner nor the impact on the applicants, or the applicant’s related entities, fixed and mobile MRI scanners in Wake County.

As set forth below, the applicant’s projected weighted MRI procedures for both its (and its related entities) fixed and mobile MRI scanners are very close to the minimum weighted MRI procedures required by Rule in the MRI performance standards.

In Section C, page 66, the applicant projects that in the third year (CY2025) following completion of the project its six fixed MRI scanners will perform 29,429 weighted MRI procedures for an average of 4,905 weighted MRI procedures  $[29,429 / 6 = 4,905]$  which is greater than the 4,805 weighted MRI procedures required by the MRI Performance Standards in 10A NCAC 14.C .2703 (b)(4).

The project analyst notes that the applicant only projects to exceed the required number of weighted MRI procedures by 601 (100 per MRI scanner x 6 fixed MRI scanners = 600. This would bring the average weighted MRI procedures per fixed MRI scanner (existing or proposed) down to 4,805 per MRI scanner from 4,905 per MRI scanner and one less MRI procedure would bring the average below the required 4,805 MRI procedures).

In Section C, page 67, Section Q, and Exhibit C.7-3, the applicant projects that each mobile MRI scanner is individually reasonably expected to perform more than 3,328 weighted MRI scans in the third year (CY2025) following completion of the proposed project. Mobile #1 is projected to perform 3,828 weighted MRI scans in CY2025 and Mobile #2 is projected to perform 3,347 weighted MRI scans in CY2025 which exceeds the requirement of 3,328 weighted MRI procedures per scanner in this performance standard.

For Mobile #2, the applicant is only projecting to exceed the requirement of 3,328 weighted MRI procedures by 20 weighted MRI procedures (19 less projected weighted MRI procedures would meet the required 3,328 weighted MRI procedures).

For Mobile #1, the applicant is projecting to exceed the requirement of 3,328 weighted MRI procedures by 500 weighted MRI procedures.

Historically, as noted below, the applicant's mobile MRI scanners have not met or exceeded the number of weighted MRI procedures required by Rule in the MRI performance standards for an applicant to meet as part of the application to develop a new fixed MRI scanner.

In Exhibit C.5, the applicant provides the historical number of MRI scans for both Mobile #1 and Mobile #2.

#### *Mobile #1*

The applicant states that for CY2020, adjusted to account for the impact of COVID-19 on utilization, Mobile #1 performed 3,194 weighted MRI procedures which is less than the required average of 3,328 weighted MRI procedures per scanner in this Rule.

#### *Mobile #2*

The applicant states that for CY2020, adjusted to account for the impact of COVID-19 on utilization, Mobile #2 performed 2,358 weighted MRI procedures which is less than the required average of 3,328 weighted MRI procedures per scanner in this Rule.

In addition, in Exhibit C.7-2, pages 2-3, the applicant provides the historical number of weighted MRI scans for both Mobile #1 and Mobile #2 for the four years running from CY2016 through CY2019. The project analyst notes that in no year from CY2016 to CY2019 did either of the two Mobile MRI scanners perform MRI procedures equal to or exceeding 3,328 weighted MRI procedures.

The projected weighted MRI procedures for the applicants (and related entities) for both the fixed and mobile MRI scanners are close to the minimum weighted MRI procedures required to meet the Rule's in the MRI performance standards.

The applicant did not address the impact of its stated intention of continuing to operate a mobile MRI scanner in Wake County, leased from Alliance, on the projected utilization of the both the fixed and mobile MRI scanners owned by the applicant and its related entities.

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

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

*“Wake Radiology ensures access to care for all patients regardless of income status, ability to pay, racial/ethnic origin, gender, age, physical or mental conditions, or any other characteristics that would classify a person as underserved or medically indigent.”*

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*	na
Racial and ethnic minorities*	na
Women	78.4%
Persons with Disabilities*	na
Persons 65 and older	37.6%
Medicare beneficiaries	38.1%
Medicaid recipients	2.3%

Source: Table on page 60 of the application.

\*Wake Radiology does not maintain data that includes the number of low-income persons, racial and ethnic minorities, 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 Wake Radiology’s historic CY2020 experience.
- The applicant complies with and intends to continue to comply with the American with Disabilities Act to ensure access to services and the facility for handicapped individuals.
- The applicant states it will continue to ensure services are rendered in compliance with Title VI of Civil Rights Act of 1963, Section 504 of Rehabilitation Act of 1973 and The Age Discrimination Act of 1975.

### **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 not conforming to this criterion because neither the need of the population projected to utilize the proposed services nor projected utilization is not reasonable and is not adequately supported.



**J-12073-21/ Duke Imaging North Raleigh/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

DUHS proposes to develop a new diagnostic center by acquiring one fixed MRI scanner. The proposed diagnostic center would be operated as an IDTF located at Medical Office Building 9, 3300 Executive Dr, Raleigh, Wake County. The location is on the DRAH Campus.

**Patient Origin**

The 2021 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.*” Therefore, for the purpose of this review, Wake 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 Imaging North Raleigh 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
Wake	2,843	66%	2,878	66%	2,913	66%
Franklin	201	5%	203	5%	205	5%
Johnston	198	5%	200	5%	203	5%
Cumberland	93	2%	94	2%	95	2%
Nash	77	2%	78	2%	78	2%
Harnett	74	2%	75	2%	76	2%
Wayne	51	1%	52	1%	52	1%
Other*	787	18%	796	18%	806	18%
<b>Total</b>	<b>4,323</b>	<b>100%</b>	<b>4,375</b>	<b>100%</b>	<b>4,428</b>	<b>100%</b>

Source: Section C, page 28.

\*Other includes those counties of origin for MRI patients at Duke Raleigh Hospital as reported in the 2021 license renewal application.

In Section C.3, page 28, 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 following:

- The applicant bases projected patient origin on the historic patient origin for MRI procedures performed at DRAH as the applicant anticipates a shift of MRI volume from DRAH to the proposed facility.

**Analysis of Need**

In Section C.4, pages 29-37, 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 Wake County in the 2021 SMFP (page 30).
- Population growth in Wake County and surrounding areas. (pages 30-31).
- Historical growth in patient volumes at DUHS facilities, including Duke Raleigh Hospital (pages 31-35).
- Coordination of care with other services and Duke Health strategic growth (pages 36-37).
- Costs advantages to patients and payors from an IDTF facility (page 36).
- Benefits in decreasing mobile MRI services at Duke Raleigh Hospital (page 37).

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

- The 2021 SMFP identifies the need for one additional fixed MRI scanner in Wake County.
- Population growth, particularly among the elderly is occurring in Wake County.
- 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	4,323	4,375	4,428
Weighted Procedures	4,971	5,031	5,092

Source: Section Q, 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) Projected MRI Utilization at DRAH from FY2021 to FY2026 (Section Q, pages 92-93).

Step 2) Projects MRI Utilization at DRAH after projected Shifts to Approved Imaging Centers in Holly Springs and Durham per assumptions in those respective applications. (Section Q, page 93).

Step 3) Projected shift of 40% of outpatient, non-emergent, non-sedation MRI volume from DRAH to the proposed IDTF (Duke Imaging North Raleigh) (Section Q, page 94)

*Duke Radiology Holly Springs (1 MRI Scanner)*

- Step 1) Identify service area by ZIP codes (Section Q, page 95-97).
- Step 2) Project shift from other DUHS MRI scanners (Section Q, pages 97-98).
- Step 3) Project shift from other DUHS MRI scanners in secondary service area. (Section Q, page 98).
- Step 4) Projected increase in share of total volume in the proximate zip codes (Section Q, pages 98-100).
- Step 5) Project in-migration (Section Q, page 101).

*Duke Raleigh Hospital (2 MRI Scanners)*

Project MRI volume at DRAH after shifts to other facilities (Section Q, page 102-103).

*Overall summary*

Average utilization factoring in all MRI scanners (Section Q, page 104).

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

- There was a need determination in the 2021 SMFP for a fixed MRI scanner in the Wake County MRI service area and this proposed project will meet that need determination by developing a fixed MRI scanner in Wake County.
- The methodology and assumptions utilized by the applicant were reasonable and adequately supported.
- The projected weighted average of 1.15 is less than the weighted average of outpatient MRI procedures performed currently at the applicant's IDTF in Cary and for outpatient scans performed currently at DRAH.
- The proposed fixed MRI scanner would be located in an IDTF on DRAH's campus and utilization is based on a 40% shift of outpatient MRI volumes from DRAH's projected overall MRI utilization.
- MRI scans performed at the IDTF on DRAH's campus would potentially be more cost-effective to both patient and payors.
- The proposed fixed MRI scanner would be co-located on DRAH's campus in a convenient geographic location.

**Access to Medically Underserved Groups**

In Section C.6, page 42, 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	7.00%
Racial and ethnic minorities	32.10%
Women	51.40%
Persons with Disabilities*	na
Persons 65 and older	44.69%
Medicare beneficiaries	44.69%
Medicaid recipients	5.42%

Source: Table on page 42 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**  
**PHSNC**  
**DUHS**

**NC**  
**Wake Radiology**

**J-12063-21/ Cardinal Points Imaging of the Carolinas Wake Forest/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

PHSNC proposes to develop a new diagnostic center by acquiring one fixed MRI scanner at its existing imaging center, CPIC-Wake Forest, located at 839 Durham Road, Unit A, Wake Forest, Wake County.

In Section E, pages 63-65, 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 Wake County identified in the 2021 SMFP. Therefore, the applicant determined this was not the most effective alternative.
- *Develop the Proposed Diagnostic Center at Another Wake County Location*- As the CPIC-Wake Forest facility has been providing mobile MRI services three days per week, the needed ancillary and support services for a fixed MRI scanner are already in place with good geographic access near major transportation corridors. There are no other fixed MRI scanners in northern Wake County. Therefore, the applicant determined that a different geographic location would be a less effective alternative.
- *Acquire a 3.0T MRI scanner*- The applicant states that a 3.0T scanner costs more to both acquire and upfit as compared to a 1.5T scanner and a 1.5T scanners continue to be the clinical standard, providing reasonable scan times and quality images. Therefore, the applicant determined that this was a more costly alternative.

On page 65, the applicant states that its proposal is the most effective alternative because:

- The proposed project will increase access to freestanding MRI services in northern Wake County which does not currently have a freestanding fixed MRI scanner.
- The proposal would allow the applicant to beneficially redirect some MRI patients from its existing fixed MRI scanner in Raleigh at CPIC-Midtown.
- The proposed project will provide patients with convenient, cost-effective, high quality and continuous MRI imaging.

- Since CPIC-Wake Forest has already been providing mobile MRI services three days per week, the needed ancillary and support services for a fixed MRI scanner are already in place with good geographic access near major transportation corridors.

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 Wake County location was determined to be less effective because no other location was deemed geographically superior to the Wake Forest location.
- Maintaining the status quo of a mobile MRI scanner at Wake Forest would not address the need in the 2021 SMFP for an additional fixed MRI scanner in Wake 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-12068-21/ Wake Radiology Garner/ Acquire one fixed MRI scanner**

**Wake Radiology** proposes to acquire one fixed MRI scanner to be located at WR-Garner, an existing non-hospital licensed diagnostic center located at 300 Health Park Drive, Suite 100, Garner, Wake 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:

- *Maintain the Status Quo*-The applicant determined that this was not the most effective alternative as doing nothing would not meet the need for one additional fixed MRI scanner in Wake County identified in the 2021 SMFP. Furthermore, doing nothing would necessitate Wake Radiology continuing to contract with Alliance for the fixed MRI scanner which is an added cost and does not ensure long term access to fixed MRI services for its patients. Therefore, the applicant determined that this was neither the most effective nor the least costly alternative.

- *Develop the MRI at a Different Location-* Based on the current transportation infrastructure project in southern and western Wake County (the extension of I-540) and the projected commiserate residential and industrial development and approved health care facilities, the applicant believes the current location is best suited to provide these areas with lower-cost, local access to freestanding MRI services. Developing the proposed MRI in other areas of the County with smaller populations would not be as effective. Furthermore, the Garner area needs cost-effective healthcare options. Therefore, the applicant determined that a different geographic location would be a less effective alternative.

On page 77, the applicant states that its proposal is the most effective alternative because:

- The population of the Garner area is growing, and current transportation infrastructure projects are projected to increase that growth.
- The community will benefit from maintain adequate access to low cost freestanding MRI services.
- Wake Radiology Garner is an existing facility already providing MRI services.
- The proposed project will allow Wake Radiology to guarantee permanent access to a fixed MRI scanner at the WR-Garner facility rather than relying on a lease with Alliance for the grandfathered MRI currently being utilized at the facility.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant does not adequately demonstrate that need and projected utilization are based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- The applicant, did not evaluate and adequately demonstrate that utilizing the two mobile MRI scanners owned by the applicant [operated in the service area and with current unused capacity] at Wake Radiology Garner, is not the least costly or most effective alternative to replacing the current mobile scanner (identified as a grandfathered fixed MRI scanner because it is not required to service two or more sites and, instead, can remain full time at the Wake Radiology Garner) being leased from Alliance and utilized at the Wake Radiology Garner facility.
- The applicant does not adequately demonstrate compliance with the Performance Standards for MRI scanners promulgated in 10A NCAC 14C .2703. The discussion regarding 10A NCAC 14C .2703 is incorporated herein by reference.
- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

### **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 not conforming to this criterion for the reasons stated above.

**J-12073-21/ Duke Imaging North Raleigh/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

DUHS proposes to develop a new diagnostic center by acquiring one fixed MRI scanner. The proposed diagnostic center would be operated as an IDTF located at Medical Office Building 9, 3300 Executive Dr, Raleigh, Wake County. The location is on the Duke Raleigh Hospital Campus.

In Section E, page 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 Wake County identified in the 2021 SMFP. In addition, maintaining the status quo would not enable the applicant to accommodate utilization growth and address severe capacity constraints. Therefore, the applicant determined that this was not the most effective alternative.
- *Add another MRI at Duke Raleigh Hospital*-Developing another fixed MRI under the DRAH license would not allow the applicant to offer patients and payors a lower cost option that is available by developing the fixed MRI at an IDTF on the DRAH hospital campus. Therefore, the applicant determined that this would be a less effective alternative.
- *Develop Project at Alternative Location*- The applicant states that as it currently offers fixed MRI scanner service in southwest Wake County and mobile MRI services in Wake Forest and Cary and additional MRI capacity is needed in Raleigh at its DRAH campus. Therefore, the applicant determined that developing the fixed MRI at a different location would not be the most effective alternative.

On page 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 Wake County identified in the 2021 SMFP.
- The proposal would allow the applicant to address severe capacity constraints and accommodate utilization growth.
- The proposed project would permit the applicant to meet the needs of expanding capacity at DRAH while offering both payors and patients a potentially lower cost option for outpatient MRI services.
- The proposed project would reduce the applicant's reliance on mobile MRI services and free up existing MRI scanners for needed hospital services by decanting outpatient MRI volume to the fixed MRI scanner at the proposed IDTF on the DRAH 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 as an IDTF on the DRAH campus would allow the applicant to reduce reliance on mobile MRI services, decant outpatient volume and increase capacity needed for hospital services as well as offer 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 Wake 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**  
**PHSNC**  
**DUHS**

**NC**  
**Wake Radiology**

### **J-12063-21/ Cardinal Points Imaging of the Carolinas Wake Forest/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

PHSNC proposes to develop a new diagnostic center by acquiring one fixed MRI scanner at its existing imaging center, CPIC-Wake Forest, located at 839 Durham Road, Unit A, Wake Forest, Wake 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	\$389,000
Miscellaneous Costs	\$1,083,813
<b>Total</b>	<b>\$1,472,813</b>

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

- Medical equipment costs are based on quotes from vendors plus 7.25% sales tax.
- Furniture, IT and project contingency costs are based on PHSNC experience.
- Construction costs, including MRI electrical and shielding, are based on contractor estimates.
- Construction interest is based on estimated project length and financing costs are estimated at approximately 1.0%.

In Section F, page 68, the applicant state that there will be no start-up costs or initial operating expenses associated with this project.

**Availability of Funds**

In Section F, page 66, the applicant states that the capital cost will be funded, as shown in the table below.

Type	Pinnacle Health Services of North Carolina, LLC	Outpatient Imaging Affiliates, LLC	Total
Loans	\$1,380,821	\$0	\$ 1,380,821
Accumulated reserves or OE *	\$91,992	\$0	\$91,992
Bonds	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
<b>Total Financing</b>	<b>\$1,472,813</b>	<b>\$0</b>	<b>\$1,472,813</b>

\* OE = Owner's Equity

In Section F.1, page 66, the applicant states that it will use both a commercial loan and cash reserves to fund the capital costs. Exhibit F.2.2 contains a letter dated March 31, 2021 from Cannon King, who is both the managing member of PHSNC and the CEO of Outpatient Imaging Affiliates (OIA) which owns 100% interest in PHSNC, which commits up to \$250,000 to PHSNC and states that PHSNC will use those funds to cover a portion of the projected capital costs of the proposed project. Also included is a copy of a bank statement for OIA dated February 21, 2021, showing \$5.4 million. Exhibit F.2.1 contains a loan proposal from GE Healthcare Financial Services in the amount of \$1,380,821.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based 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 three full fiscal years following completion of the project, as shown in the table below.

**CPIC-Wake Forest: MRI Scanner**

	<b>1<sup>st</sup> Full Fiscal Year (CY2022)</b>	<b>2<sup>nd</sup> Full Fiscal Year (CY2023)</b>	<b>3<sup>rd</sup> Full Fiscal Year (CY2024)</b>
Total Procedures*	3,983	4,471	4,975
Total Gross Revenues (Charges)	\$6,677,530	\$7,495,211	\$8,340,144
Total Net Revenue	\$1,840,109	\$2,065,435	\$2,298,271
Average Net Revenue per Procedures	\$462	\$462	\$462
Total Operating Expenses (Costs)	\$1,243,824	\$1,456,387	\$1,576,415
Average Operating Expense per Procedures	\$312	\$326	\$317
Net Income	\$596,284	\$609,048	\$721,855

\*Note: Procedures equal weighted procedures.  
 Source: Form F.2b, page 129.

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 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 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-12068-21/ Wake Radiology Garner/ Acquire one fixed MRI scanner**

Wake Radiology proposes to acquire one fixed MRI scanner to be located at WR-Garner, an existing non-hospital licensed diagnostic center located at 300 Health Park Drive, Suite 100, Garner, Wake 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	\$295,350
Miscellaneous Costs	\$1,645,000
<b>Total</b>	<b>\$1,940,350</b>

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

- Medical equipment costs are based on quotes from vendors plus sales tax.
- Furniture costs are based on Wake Radiology experience and vendor estimates.
- Legal and consultant fees are based on Wake Radiology experience with similar projects.
- Construction costs are based on the contractor estimates.

In Section F, page 81, the applicant state that there will be no start-up costs or initial operating expenses associated with this project.

**Availability of Funds**

In Section F, page 79 , the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

Type	WR Imaging, LLC	Wake Radiology Diagnostic Imaging, Inc.	Total
Loans	\$1,940,350	\$0	\$1,940,350
Accumulated reserves or OE *	\$0	\$0	\$0
Bonds	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
<b>Total Financing</b>	<b>\$1,940,350</b>	<b>\$0</b>	<b>\$1,940,350</b>

\* OE = Owner's Equity

In Section F.2, pages 79-80, the applicant states that the capital costs of the proposed project will be funded by a loan. Exhibit F.2 contains a loan proposal, with terms, and dated March 24, 2021 from First Citizens Bank to WR Imaging LLC, with a loan amount of \$1,940,350. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based 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, 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 (CY2023)</b>	<b>2<sup>nd</sup> Full Fiscal Year (CY2024)</b>	<b>3<sup>rd</sup> Full Fiscal Year (CY2025)</b>
Total Procedures*	4,777	5,008	5,251
Total Gross Revenues (Charges)	\$10,145,300	\$10,956,238	\$11,831,997
Total Net Revenue	\$3,525,688	\$3,807,505	\$4,111,848
Average Net Revenue per Procedures	\$738	\$760	\$783
Total Operating Expenses (Costs)	\$2,447,751	\$2,732,992	\$2,879,377
Average Operating Expense per Procedures	\$512	\$547	\$548
Net Income	\$1,077,937	\$1,074,513	\$1,232,471

\*Note: Procedures equal weighted procedures.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. However, the applicant does not adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected utilization is not based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference. Therefore, projected revenues and operating expenses, which are based in part on projected utilization, are also questionable.

## **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 not conforming to this criterion because the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

### **J-12073-21/ Duke Imaging North Raleigh/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

DUHS proposes to develop a new diagnostic center by acquiring one fixed MRI scanner. The proposed diagnostic center would be operated as an IDTF located at Medical Office Building 9, 3300 Executive Dr, Raleigh, Wake County. The location is on the Duke Raleigh Hospital Campus.

## **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	\$1,725,000
Miscellaneous Costs	\$3,220,000
<b>Total</b>	<b>\$4,945,000</b>

The applicant provides its assumptions and methodology for projecting capital cost in Section Q and Exhibits F-1(b) and K.3. 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 55, Section Q and referenced exhibits.

In Section F.3, page 57, the applicant projects that start-up costs will be \$81,213 and initial operating expenses will be \$464,061, for total working capital of \$545,274. 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 57-58, and Form F.3(b) of the application.

## **Availability of Funds**

In Section F, page 55, 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
Accumulated reserves or OE *	\$4,945,000	\$4,945,000
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$4,945,000</b>	<b>\$4,945,000</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	\$2,000,000
Lines of credit	\$0
Bonds	\$0
<b>Total *</b>	<b>\$2,000,000</b>

In Section F, pages 53 and 57-58, 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 58, the applicant states that CFO has documented at least \$2.0 million for this project beyond the projected capital cost. Exhibit F.2(a) contains a letter dated April 8, 2021 from the Chief Financial Officer for DUHS documenting that up to \$7.0 million funds will be made available for the capital costs and working capital costs of the project. Exhibit F.2(b) also contains the audited financial statements for DUHS for FY2020 which indicated the health system had \$157 million in cash and cash equivalents, \$7.36 billion in assets, and \$3.48 billion 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 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**	4,971	5,031	5,092
Total Gross Revenues (Charges)	\$4,924,476	\$5,083,385	\$5,247,866
Total Net Revenue	\$2,182,818	\$2,248,414	\$2,316,231
Average Net Revenue per Procedures	\$439	\$447	\$455
Total Operating Expenses (Costs)	\$1,570,354	\$1,648,082	\$1,690,587
Average Operating Expense per Procedures	\$316	\$328	\$332
Net Income	\$612,464	\$600,331	\$625,644

\* 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  
 PHSNC  
 DUHS**

**NC  
 Wake Radiology**

The 2021 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.*” Therefore, for the purpose of this review, Wake 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 Wake County.

Facility (Owner)	# of Fixed MRI Scanners	Total Weighted Procedures Performed during Federal Fiscal Year (FFY) 2019 *
Duke Radiology Holly Springs (Duke University Health System) **	1	0
Duke Raleigh Hospital (Duke University Health System)	2	13,935
Raleigh Neurology Associates (Raleigh Neurology Associates)	1	5,767
Raleigh Neurology Imaging, PLLC (Alliance)	1	6,176
Raleigh Radiology – Wake (Alliance)	1	6,335
Raleigh Radiology - Cary (Alliance) ^	1	7,253
Raleigh Radiology – Cedarhurst (Pinnacle)	1	7,532
Rex Hospital – Main (UNC Health System)	2	11,125
Rex Hospital – UNC Rex Health Care of Cary (UNC Health System)	1	0
The Bone and Joint Surgery Center (Bone & Joint)	1	1,745
Wake Radiology Diagnostic Imaging (Alliance)	1	4,287
Wake Radiology MRI (WR Imaging, LLC)	1	3,863
Wake Radiology MRI (WR Imaging, LLC)	1	3,862
Wake Radiology – Garner (Alliance)	1	3,540
WakeMed – New Bern Ave (WakeMed)	2	13,695
WakeMed Cary Hospital (WakeMed)	1	4,950
2021 Need Determination#	1	0
<b>Total</b>	<b>20</b>	

Source: 2021 SMFP, Table 17E-1, pages 361-362.

\* October 1, 2018 to September 30, 2019.

\*\* Under development as of the due date for data for the 2021 SMFP. This MRI scanner started to offer service in June 2020.

^ This MRI scanner is “permanently” installed. Pursuant to the need determination in the 2019 SMFP for one fixed MRI scanner in Wake County Raleigh Radiology, LLC applied for and was conditionally approved to develop a new fixed MRI scanner at Raleigh Radiology-Cary to replace the MRI scanner leased from Alliance. See Project ID# J-11825-19. This conditional approval is currently under appeal.

# Currently under review. There are three applications.

**J-12063-21/ Cardinal Points Imaging of the Carolinas Wake Forest/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

PHSNC proposes to develop a new diagnostic center by acquiring one fixed MRI scanner at its existing imaging center, CPIC-Wake Forest, located at 839 Durham Road, Unit A, Wake Forest, Wake County.

In Section G, page 76, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Wake County. The applicant states:

*“As evidenced by the need determination in the 2021 SMFP, the State Health Coordinating Council (SHCC) considers the existing and approved fixed MRI scanners inadequate to meet the need in the MRI service area. The SMFP ... determined a need for one additional fixed MRI scanner in Wake County.*

*PHSNC is an important freestanding outpatient diagnostic imaging provider that over many years has served thousands of Wake County residents. ... PHNSC's MRI service is needed by referring provider to aid them in diagnosing and treating their patient's illnesses or conditions. Please see Exhibit I.2 for letters of support from referring physicians and providers for this proposed CPIC Wake Forest fixed MRI scanner. ... PHSNC adequately demonstrates the need for a fixed MRI scanner at CPIC Wake Forest. See Section C and Section Q for discussion of need for the proposed project from qualitative and quantitative perspectives.”*

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 Wake 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-12068-21/ Wake Radiology Garner/ Acquire one fixed MRI scanner**

**Wake Radiology** proposes to acquire one fixed MRI scanner to be located at WR-Garner, an existing non-hospital licensed diagnostic center located at 300 Health Park Drive, Suite 100, Garner, Wake County.

In Section G, page 89, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI scanner services in Wake County. The applicant states:

*“The proposed project involves the development of a fixed MRI scanner at Wake Radiology Garner, which is in response to a need determination in the 2021 SMFP for an additional fixed MRI scanner to be located in Wake County. Thus, the 2021 SMFP has determined that additional MRI capacity is needed in Wake County.”*

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant does not adequately demonstrate that the proposed fixed MRI scanner is needed in addition to the applicants existing MRI scanner capacity in Wake County. Furthermore, the applicant does not adequately demonstrate that the proposed fixed MRI scanner at WR-Garner is the most effective alternative. See the discussion regarding projected utilization found in Criterion (3) and the discussion regarding alternatives found in Criterion (4), both discussions of which are incorporated herein by reference.

#### **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 not conforming to this criterion for the reason 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-12073-21/ Duke Imaging North Raleigh/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

DUHS proposes to develop a new diagnostic center by acquiring one fixed MRI scanner. The proposed diagnostic center would be operated as an IDTF located at Medical Office Building 9, 3300 Executive Dr, Raleigh, Wake County. The location is on the DRAH Campus.

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 Wake County. The applicant states:

*“As set forth in the 2021 SMFP, the County demonstrates a need for additional MRI capacity based on existing utilization. ... 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 Wake 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.

**J-12063-21/ Cardinal Points Imaging of the Carolinas Wake Forest/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

PHSNC proposes to develop a new diagnostic center by acquiring one fixed MRI scanner at its existing imaging center, CPIC-Wake Forest, located at 839 Durham Road, Unit A, Wake Forest, Wake 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 78-80, 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-12068-21/ Wake Radiology Garner/ Acquire one fixed MRI scanner**

Wake Radiology proposes to acquire one fixed MRI scanner to be located at WR-Garner, an existing non-hospital licensed diagnostic center located at 300 Health Park Drive, Suite 100, Garner, Wake 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 91-92, 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 91-92, 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-12073-21/ Duke Imaging North Raleigh/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

DUHS proposes to develop a new diagnostic center by acquiring one fixed MRI scanner. The proposed diagnostic center would be operated as an IDTF located at Medical Office Building 9, 3300 Executive Dr, Raleigh, Wake County. The location is on the DRAH Campus.

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 66-67, 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 66-67, 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-12063-21/ Cardinal Points Imaging of the Carolinas Wake Forest/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

PHSNC proposes to develop a new diagnostic center by acquiring one fixed MRI scanner at its existing imaging center, CPIC-Wake Forest, located at 839 Durham Road, Unit A, Wake Forest, Wake County.

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

In Section I.1, page 81, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 81-82, the applicant explains how each ancillary and support service is or will be made available, the applicant states,

*“PHSNC currently provides all ancillary and support services through its own staff or via contract with vendors...”*

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

#### **Coordination**

In Section I.2, pages 82-83, 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,

*“PHSNC currently offers a variety of medical diagnostic services (including mobile MRI) at CPIC Wake Forest, which opened for business in 2007. As an established local healthcare provider, PHSNC has long-standing positive working relationships with referring physicians/providers and the broader healthcare community in Wake and surrounding counties.”* [see page 82.]

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, pages 82-83, 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-12068-21/ Wake Radiology Garner/ Acquire one fixed MRI scanner**

**Wake Radiology** proposes to acquire one fixed MRI scanner to be located at WR-Garner, an existing non-hospital licensed diagnostic center located at 300 Health Park Drive, Suite 100, Garner, Wake County.

### **Ancillary and Support Services**

In Section I.1, page 93, the applicant identifies the necessary ancillary and support services for the proposed services. On page 93, the applicant explains how each ancillary and support service is or will be made available, the applicant states,

*“All necessary ancillary and support services required for Wake Radiology Garner ... are currently provided by either WRDI (image interpretation) or WRS, through the management services agreement, and will continue to be provided upon completion of the proposed project.”*

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

### **Coordination**

In Section I.2, page 94, 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,

*“For over 60 years, Wake Radiology has continually strived to strengthen its existing relationships with local providers and forge new ones.”*

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 94, 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-12073-21/ Duke Imaging North Raleigh/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

DUHS proposes to develop a new diagnostic center by acquiring one fixed MRI scanner. The proposed diagnostic center would be operated as an IDTF located at Medical Office Building 9, 3300 Executive Dr, Raleigh, Wake County. The location is on the DRAH Campus.

### **Ancillary and Support Services**

In Section I.1, page 68, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 68, the applicant explains how each ancillary and support service is or will be made available, the applicant states,

*“In addition to the staff positions assigned to the facility reflected in Form H, DUHS provides support services centrally ...”*

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

### **Coordination**

In Section I.2, page 69, 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 69, 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-12063-21/ Cardinal Points Imaging of the Carolinas Wake Forest/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

PHSNC proposes to develop a new diagnostic center by acquiring one fixed MRI scanner to be located at its existing imaging center, CPIC-Wake Forest, located at 839 Durham Road, Unit A, Wake Forest, Wake County.

In Section K, page 85, the applicant states that the project involves renovating 1,255 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 85, 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.
- The existing imaging center already includes all ancillary and support services necessary for the proposed fixed MRI scanner.
- The renovation is limited in scope, focusing on the spaces necessary to accommodate the proposed fixed MRI scanner.

On page 86, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following reasons:

- The fixed MRI scanner selected will be based on obtaining competitive market quotes from equipment vendors.
- Charges are either already negotiated with payors or largely set by the governments, thus the project will not increase charges to the public.
- The project leverages economies of scale taking into account the limited renovation needed and the existence of support spaces and ancillary services at CPIC Wake Forest.

On page 86, 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-12068-21/ Wake Radiology Garner/ Acquire one fixed MRI scanner**

**Wake Radiology** proposes to acquire one fixed MRI scanner to be located at WR-Garner, an existing non-hospital licensed diagnostic center located at 300 Health Park Drive, Suite 100, Garner, Wake County.

In Section K.97, the applicant states that the project involves renovating 1,241 square feet of existing space). Line drawings are provided in Exhibit C.1-1.

On pages 97-98, 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:

- Minimal renovation is required as the proposed fixed MRI scanner will be installed in the same space currently occupied by a leased grandfathered fixed MRI scanner utilized by WR-Garner.
- Minimally renovating existing space as opposed to constructing new space permits the proposed project to be operationalized in a much more cost-effective manner.

On page 98, 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 necessary support and ancillary services are already in place at WR-Garner.
- The proposed project will provide increased access to low-cost non-hospital licensed MRI service.
- The proposed fixed MRI scanner will replace a leased fixed MRI scanner, which will allow Wake Radiology to guarantee long term accessibility to MRI services at WR-Garner as well as eliminating the expense of leasing the current fixed MRI scanner.

On page 98, 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-12073-21/ Duke Imaging North Raleigh/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

DUHS proposes to develop a new diagnostic center by acquiring one fixed MRI scanner. The proposed diagnostic center would be operated as an IDTF located at Medical Office Building 9, 3300 Executive Dr, Raleigh, Wake County. The location is on the DRAH Campus.

In Section K, page 72, the applicant states that the project involves renovating 3,217 square feet of existing space. Line drawings are provided in Exhibit K.2.

On pages 72-73, 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 73, 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 73, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.3.

### **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;

**C**  
**PHSNC**  
**Wake Radiology**

**NA**  
**DUHS**

### **J-12063-21/ Cardinal Points Imaging of the Carolinas Wake Forest/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

In Section L, page 89, the applicant provides the historical payor mix during CY2020 for CPIC-Wake Forest, as shown in the table below.

<b>Payor Category</b>	<b>Percent of Total Patients Served</b>
Self-Pay	2.1%
Charity Care	1.1%
Medicare*	19.5%
Medicaid*	3.0%
Insurance*	68.8%
Workers Compensation	3.4%
TRICARE	2.1%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 89 of the application.

\*Note: Including any managed care plans.

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

	<b>Percentage of Total Patients Served by the Facility or Campus during the Last Full FY</b>	<b>Percentage of the Population of the Service Area</b>
Female	82.1%	51.4%
Male	17.9%	48.6%
Unknown	0.0%	0.0%
64 and Younger	72.7%	88.0%
65 and Older	27.3%	12.0%
American Indian	**	0.8%
Asian	**	7.7%
Black or African American	**	21.0%
Native Hawaiian or Pacific Islander	**	0.1%
White or Caucasian	**	60.0%
Other Race	**	10.4%
Declined / Unavailable	**	0.0%

\*\* PHSNC does not capture and track ethnic/racial data.

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 applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's

service area which is medically underserved. Therefore, the application is conforming to this criterion.

**J-12068-21/ Wake Radiology Garner/ Acquire one fixed MRI scanner**

In Section L, page 101, the applicant provides the historical payor mix during CY2020 for WR-Garner services, as shown in the table below.

Payor Category	Percent of Total Patients Served
Self-Pay	1.1%
Medicare*	38.1%
Medicaid*	2.3%
Insurance*	55.8%
Other (specify)	2.7%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 101 of the application.

\*Including any managed care plans.

In Section L, page 102, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	78.4%	51.4%
Male	21.6%	48.6%
Unknown	NA	
64 and Younger	62.4%	88.0%
65 and Older	37.6%	12.0%
American Indian	NA	0.8%
Asian	NA	7.7%
Black or African American	NA	21.0%
Native Hawaiian or Pacific Islander	NA	0.1%
White or Caucasian	NA	67.9%
Other Race	NA	2.6%
Declined / Unavailable	NA	0/0%

Note: Wake Radiology does not track patient race/ethnicity internally.

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

**J-12073-21/ Duke Imaging North Raleigh/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

Duke Imaging North Raleigh 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;

**C  
All Applications**

**J-12063-21/ Cardinal Points Imaging of the Carolinas Wake Forest/  
Develop a new diagnostic center by acquiring one fixed MRI scanner**

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 91, the applicant states,

*“PHSNC has no obligation under federal regulations to provide uncompensated care or community service, or access by minorities and handicapped persons.”*

In Section L, page 92, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- 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-12068-21/ Wake Radiology Garner/ Acquire one fixed MRI scanner**

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 103, the applicant states,

*“The facility is not obligated or under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.”*

In Section L, page 104, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- 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-12073-21/ Duke Imaging North Raleigh/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 78, the applicant states,

*“Duke University Health System hospitals have satisfied the requirements of applicable federal regulations to provide, on annual basis, a certain amount of uncompensated care in return for Hill Burton funds previously received. ... DUHS has no special obligation under applicable Federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons ....*

In Section L, page 79, the applicant states that during the 18 months immediately preceding the application deadline two civil rights access complaints have been filed against DUHS, both alleging lack of accessibility of interpreter. DUHS has responded detailing the interpreter services that were provided to each patient and both complaints are still pending.

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.

- (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-12063-21/ Cardinal Points Imaging of the Carolinas Wake Forest/  
Develop a new diagnostic center by acquiring one fixed MRI scanner**

In Section L, page 92, 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.

**CPIC Wake Forest: Entire Facility**

<b>Payor Category</b>	<b>Percent of Total Patients Served</b>
Self-Pay	2.1%
Charity Care	1.1%
Medicare*	19.5%
Medicaid*	3.0%
Insurance*	68.8%
Workers Compensation	3.4%
TRICARE	2.1%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 92 of the application.

\*Note: Including any managed care plans.

**CPIC Wake Forest: Fixed MRI Scanner**

<b>Payor Category</b>	<b>Percent of Total Patients Served</b>
Self-Pay	1.5%
Charity Care	1.4%
Medicare*	25.0%
Medicaid*	3.9%
Insurance*	57.3%
Workers Compensation	8.0%
TRICARE	2.9%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 92 of the application.

\*Note: Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.5% of fixed MRI services will be provided to self-pay patients, 1.4% to charity care patients, 25.0% to Medicare patients and 3.9% to Medicaid patients.

On pages 92-93, 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 historical CY2020 payor mix for MRI service at CPIC Wake Forest.
- The applicant's assumption that existing referring physicians/providers will continue to be the source of referrals to CPIC Wake Forest.

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-12068-21/ Wake Radiology Garner/ Acquire one fixed MRI scanner**

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.

**Wake Radiology: Entire Facility**

<b>Payor Category</b>	<b>Percent of Total Patients Served</b>
Self-Pay	1.1%
Medicare*	38.1%
Medicaid*	2.3%
Insurance*	55.8%
Other (specify)	2.7%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 104 of the application.

\*Including any managed care plans.

**Wake Radiology: Fixed MRI**

<b>Payor Category</b>	<b>Percent of Total Patients Served</b>
Self-Pay	0.6%
Medicare*	42.0%
Medicaid*	3.2%
Insurance*	55.8%
Other (specify)	1.5%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 104 of the application.

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.6% of fixed MRI services will be provided to self-pay patients, 42.0% to Medicare patients and 3.2% to Medicaid patients.

In Section Q, Form F.2 MRI Assumptions, 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 historical (CY2020) payor mix for Wake Radiology Garner MRI.

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-12073-21/ Duke Imaging North Raleigh/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

In Section L, page 80, 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.

<b>Payor Category</b>	<b>Percent of Total Patient Served</b>
Self-Pay	0.43%
Charity Care	1.56%
Medicare*	44.69%
Medicaid*	5.42%
Insurance*	43.65%
Workers Compensation	0.40%
TRICARE	1.81%
Other	2.04%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 80 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 0.43% of total services will be provided to self-pay patients, 1.56% to charity care patients, 44.69% to Medicare patients and 5.42% to Medicaid patients.

On page 80, 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 projections are based on historical payor mix as the proposed project assumes that a percentage of existing Duke Raleigh Hospital outpatient MRI volume will shift to the new facility.
- The historic payor mix was adjusted based on the assumption that 3.1% 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.

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-12063-21/ Cardinal Points Imaging of the Carolinas Wake Forest/  
Develop a new diagnostic center by acquiring one fixed MRI scanner**

In Section L, page 94, 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-12068-21/ Wake Radiology Garner/ Acquire one fixed MRI scanner**

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-12073-21/ Duke Imaging North Raleigh/ Develop a new diagnostic  
center by acquiring one fixed MRI scanner**

In Section L, page 82, 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 defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.*” Therefore, for the purpose of this review, Wake 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 Wake County.

Facility (Owner)	# of Fixed MRI Scanners	Total Weighted Procedures Performed during Federal Fiscal Year (FFY) 2019 *
Duke Radiology Holly Springs (Duke University Health System) **	1	0
Duke Raleigh Hospital (Duke University Health System)	2	13,935
Raleigh Neurology Associates (Raleigh Neurology Associates)	1	5,767
Raleigh Neurology Imaging, PLLC (Alliance)	1	6,176
Raleigh Radiology – Wake (Alliance)	1	6,335
Raleigh Radiology - Cary (Alliance) ^	1	7,253
Raleigh Radiology – Cedarhurst (Pinnacle)	1	7,532
Rex Hospital – Main (UNC Health System)	2	11,125
Rex Hospital – UNC Rex Health Care of Cary (UNC Health System)	1	0
The Bone and Joint Surgery Center (Bone & Joint)	1	1,745
Wake Radiology Diagnostic Imaging (Alliance)	1	4,287
Wake Radiology MRI (WR Imaging, LLC)	1	3,863
Wake Radiology MRI (WR Imaging, LLC)	1	3,862
Wake Radiology – Garner (Alliance)	1	3,540
WakeMed – New Bern Ave (WakeMed)	2	13,695
WakeMed Cary Hospital (WakeMed)	1	4,950
2021 Need Determination#	1	0
<b>Total</b>	<b>20</b>	

Source: 2021 SMFP, Table 17E-1, pages 361-362.

\* October 1, 2018 to September 30, 2019.

\*\* Under development as of the due date for data for the 2021 SMFP. This MRI scanner started to offer service in June 2020.

^ This MRI scanner is “permanently” installed. Pursuant to the need determination in the 2019 SMFP for one fixed MRI scanner in Wake County Raleigh Radiology, LLC applied for and was conditionally approved to develop a new fixed MRI scanner at Raleigh Radiology-Cary to replace the MRI scanner leased from Alliance. See Project ID# J-11825-19. This conditional approval is currently under appeal.

# Currently under review. There are three applications.

**J-12063-21/ Cardinal Points Imaging of the Carolinas Wake Forest/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

PHSNC proposes to develop a new diagnostic center by acquiring one fixed MRI scanner to be located at its existing imaging center, CPIC-Wake Forest, located at 839 Durham Road, Unit A, Wake Forest, Wake County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 96, the applicant states:

*“With acquisition of a fixed MRI scanner at CPIC Wake Forest, PHSNC will have a positive effect on competition in the service area. The proposed fixed MRI scanner will promote cost effective, high quality medical diagnostic imaging services that will be even more accessible by local residents. ...”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 97, the applicant states:

*“Patients will benefit directly because of the PHSNC focus on lower costs, and patients will also benefit indirectly through lower costs to the payors, resulting in lower costs to the healthcare system... Outpatient diagnostic imaging services at CPIC Wake Forest contribute to cost-effective patient care because the services have a charge structure less costly than hospital-based diagnostic services.”*

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 97-98, the applicant states:

*“PHSNC is an experienced local provider of imaging services and is dedicated to ensuring quality and patient safety through compliance with all applicable licensure and certification standards established regarding diagnostic imaging. ... PHSNC maintains accreditation for all fixed and mobile MR, CT, ultrasound, and mammography equipment at all locations. ... PHSNC will utilize its existing quality-related policies and procedures, which serve well in operating existing PHSNC MRI services. These quality management programs emphasize a customer-oriented perspective that is used to determine the needs of patients, physicians, and others who utilize medical diagnostic services.”*

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 99, the applicant states:

*“PHSNC has historically provided care and services to medically underserved populations. PHSNC does not discriminate based on income, race, ethnicity, creed, color, age, religion, national origin, gender, physical or mental handicap, sexual orientation, ability to pay or any other factor that would classify a patient as underserved. PHSNC will continue to have a policy to provide all services to all patients ... PHSNC is a participating Medicare and*

*Medicaid provider serving the elderly and medically indigent populations in Wake County and surrounding communities. ... PHSNC is committed to caring for the local community, one patient at a time, and will continue to serve the medically indigent with charitable care. ... PHSNC offers self-pay discounts on all procedures for uninsured patients and has annual pledge agreements with Project Access of Wake County to provide no-charge imaging.”*

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-12068-21/ Wake Radiology Garner/ Acquire one fixed MRI scanner**

**Wake Radiology** proposes to acquire one fixed MRI scanner to be located at WR-Garner, an existing non-hospital licensed diagnostic center located at 300 Health Park Drive, Suite 100, Garner, Wake County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 108 , the applicant states:

*“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to fixed MRI services ...”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 108 , the applicant states:

*“The proposed project represents a low-cost alternative for the provision of MRI services. The proposed project will be developed in existing space at Wake Radiology Garner, an existing freestanding outpatient diagnostic imaging center. As an existing MRI service provider, Wake Radiology has all necessary ancillary and support services in place; thus, the cost of the project is significantly lower than if Wake Radiology were to develop additional fixed MRI capacity in new construction to house the proposed equipment.”*

*...The proposed project will increase access to low-cost, freestanding fixed MRI services in Wake County while shifting patients that are appropriate for a freestanding setting from the highly utilized hospital-based MRI scanners in the county through the Wake Radiology and UNC Rex joint venture.”*

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 109-110 , the applicant states:

*“All Wake Radiology facilities are accredited by the ACR (American College of Radiology). ... In addition, Wake Radiology has internal policies, processes, and procedures to maintain high quality of care.”*

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 110 , the applicant states:

*“Wake Radiology prohibits the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability, or the patient’s ability to pay. ... In 2020, Wake Radiology provided over \$678,000 in charity care through Project Access, Alliance Medical Ministry, the Open Door Clinic, and contributions through its association with UNC Rex.”*

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-12073-21/ Duke Imaging North Raleigh/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

DUHS proposes to develop a new diagnostic center by acquiring one fixed MRI scanner. The proposed diagnostic center would be operated as an IDTF located at Medical Office Building 9, 3300 Executive Dr, Raleigh, Wake County. The location is on the DRAH Campus.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 84, the applicant states:

*“The project will promote cost-effectiveness, quality, and access to services and therefore will promote competition in Wake County because it will allow DUHS to create a new point of access for imaging services with an alternative reimbursement structure to hospital-based services, to better meet the needs of its existing patient population and to ensure the timely provision of services. By ensuring sufficient capacity to meet patient demand, this project enhances patient choice.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 84 , the applicant states:

*“As an IDTF, the proposed facility will have a different reimbursement structure than the existing hospital MRI scanners on the same campus. For many patients and payors, this may be a more cost-effective option for appropriate outpatient procedures. This project will also allow DUHS to reduce the need for mobile MRI services contracts, which are a significant operating expenditure each year.”*

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 84-85, 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 sub-specialty, 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 85, 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 bringing hospital services closer to a growing population, 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-12063-21/ Cardinal Points Imaging of the Carolinas Wake Forest/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

PHSNC proposes to develop a new diagnostic center by acquiring one fixed MRI scanner to be located at its existing imaging center, CPIC-Wake Forest, located at 839 Durham Road, Unit A, Wake Forest, Wake 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 six of this type of facility located in North Carolina.

In Section O.3 and O.4, pages 103-104, the applicant states,

*“PHSNC provides care for Medicare and Medicaid patients and is currently certified by CMS (see Exhibit O.3.2).*

*PHSNC has always obtained ACR accreditation for its MR imaging equipment. PHSNC will obtain accreditation for the proposed fixed MRI scanner at CPIC Wake Forest.*

...

*... Neither PHSNC nor its management company OIA has ever had its Medicare or Medicaid provider agreement terminated. All PHSNC and OIA's operational diagnostic centers in North Carolina ... have provided quality care and operated in compliance with Medicare Conditions of Participation during the 18 months immediately preceding submission of this application.”*

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

**J-12068-21/ Wake Radiology Garner/ Acquire one fixed MRI scanner**

Wake Radiology proposes to acquire one fixed MRI scanner to be located at WR-Garner, an existing non-hospital licensed diagnostic center located at 300 Health Park Drive, Suite 100, Garner, Wake County.

Wake Radiology

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 fourteen of this type of facility located in North Carolina.

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

*“Each of the facilities identified in Form O have provided quality care during the 18 months preceding the submission of this application (18-month look-back period).*

*Each of the facilities identified in Form O Facilities has continually maintained all relevant certification and accreditation for the 18 months preceding the submission of this application.”*

After reviewing and considering information provided by the applicant regarding the quality of care provided at the three facilities, the applicant provided sufficient evidence that quality care has been provided in the past.

UNC Hospitals

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 hospitals in the UNC Hospital System. 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 the hospitals in the UNC Hospital System, the applicant provided sufficient evidence that quality care has been provided in the past.

Therefore, the application is conforming to this criterion.

**J-12073-21/ Duke Imaging North Raleigh/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

**DUHS** proposes to develop a new diagnostic center by acquiring one fixed MRI scanner. The proposed diagnostic center would be operated as an IDTF located at Medical Office Building 9, 3300 Executive Dr, Raleigh, Wake County. The location is on the DRAH Campus.

In Section Q, Form O, the applicant identifies the diagnostic centers and hospitals with fixed MRI scanners located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of five of these type of facilities (four existing and one approved/under development) located in North Carolina.

In Section O.4, page 88, 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 hospitals. 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**  
**PHSNC**  
**DUHS**

**NC**  
**Wake Radiology**

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;*

**-C- PHSNC.** The MRI service area is Wake County. In Section C, page 53, the applicant states that it owns and operates one fixed MRI scanner in Wake County, at its CPIC Midtown diagnostic center. During the most recent 12-month period for which PHSNC has data (CY2020) PHSNC performed 5,450 weighted MRI procedures which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.

**-C- Wake Radiology.** On page 64, the applicant states, in summary, that this Rule is not applicable given the public health emergency and because “*the Agency has expressed its belief that this rule is unnecessary*”.

The applicant is incorrect. This Rule is applicable.

The MRI service area is Wake County. In Section C, page 64, the applicant states that there are two applicants: WR Imaging and WRDI and one related entity, Rex Hospital, Inc (UNC REX). Combined, the applicants and the related entity own five fixed MRI scanners (WR Imaging owns two; UNC REX owns three; and WRDI does not own any). The Project Analyst notes that the applicants also operate two additional grandfathered fixed MRI scanners at Wake Radiology Cary and Wake Radiology Garner, however, neither the applicants nor an entity related to the applicants own a controlling interest in either of those grandfathered fixed MRI scanners.

In Exhibit C.7-1, pages 3 and 5, the applicant states that during the most recent 12-month period (CY2020) for which Wake Radiology provided data, the applicants and UNC REX performed 19,645 [9,603 at Wake Radiology Raleigh + 10,042 at UNC REX = 19,645] weighted MRI procedures (adjusted to account for the impact of COVID-19) for an average of 3,929 weighted MRI procedures per fixed MRI scanner (19,645/ 5 fixed MRI scanners = 3,929) which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.

- C- **DUHS.** The MRI service area is Wake County. In Section C, pages 45, the applicant states that it owns and operates three fixed MRI scanners in Wake County, two at Duke Raleigh Hospital and one in Holly Springs. The applicant notes that the fixed MRI scanner in Holly Springs began service on June 16, 2020 and therefore, was not in operation for 12 months as of the date this application was filed. During the most recent 12-month period for which DUHS has data (FY2020) DUHS performed 12,927.8 weighted MRI procedures on the two fixed MRI scanners at Duke Raleigh Hospital. Even if no MRI procedures performed in FY2020 on the fixed MRI scanner in Holly Springs are included but the Holly Springs fixed MRI scanner is included in the equation, this still equates to an average of 4,309 weighted MRI procedures per scanner ( $12,927.8 / 3 = 4,309$ ) which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.
- (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.];*
- C- **PHSNC.** The MRI service area is Wake County. In Section C, page 54, and Section Q, the applicant states that it owns and operates one mobile MRI scanner in Wake County. The mobile MRI scanner serves three sites in Wake and Johnston counties. During the most recent 12-month period for which PHSNC has data (CY2020) PHSNC states the mobile MRI scanner performed 6,203 weighted MRI procedures which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.
- NC- **Wake Radiology.** On pages 64-65, the applicant states, in summary, that this Rule is not applicable given the public health emergency and because “*the Agency has expressed its belief that this rule is unnecessary*”.

The applicant is incorrect. This Rule is applicable.

The MRI service area is Wake County. In Section C, page 64, the applicant states that there are two applicants: WR Imaging and WRDI and one related entity, Rex Hospital, Inc (UNC REX). WR Imaging owns two mobile MRI scanners. Neither WRDI nor UNC REX own a mobile MRI scanner in Wake County.

In Section C, page 67, and Exhibit C.7-3, the applicant states projected utilization for the two mobile MRI scanners owned by WR Imaging. In Exhibit C.7-3, the applicant identifies the mobile MRI scanner approved by Project ID#J-7012-04 as WR Imaging Mobile #1 (Mobile #1) and the mobile MRI scanner approved by Project ID#J-11291-17 as WR Imaging Mobile #2 (Mobile #2).

In Exhibit C.5, the applicant provides the historical number of MRI scans for both Mobile #1 and Mobile #2.

*Mobile #1*

The applicant states that for CY2020, adjusted to account for the impact of COVID-19 on utilization, Mobile #1 performed 3,194 weighted MRI procedures which is less than the required average of 3,328 weighted MRI procedures per scanner in this Rule.

*Mobile #2*

The applicant states the for CY2020, adjusted to account for the impact of COVID-19 on utilization, Mobile #2 performed 2,358 weighted MRI procedures which is less than the required average of 3,328 weighted MRI procedures per scanner in this Rule.

In addition, in Exhibit C.7-2, pages 2-3, the applicant provides the historical number of weighted MRI scans for both Mobile #1 and Mobile #2 for the four years running from CY2016 through CY2019. The project analyst notes that in no year from CY2016 to CY2019 did either of the two Mobile MRI scanners perform MRI procedures equal to or exceeding 3,328 weighted MRI procedures.

Therefore, the application is not conforming with this Rule.

-NA- **DUHS.** The MRI service area is Wake County. The applicant states that neither the applicant nor a related entity owns a controlling interest in an existing mobile MRI scanner in the Wake 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- **PHSNC.** The MRI service area is Wake County. The 2021 SMFP shows more than four fixed MRI scanners in Wake County. In Section C, page 54, and in Section Q the applicant states that it projects to perform 10,885 weighted MRI procedures on its existing (1) and proposed (1) MRI scanners during the third year (CY2024) of the proposed project for an average of 5,442 weighted MRI scans per scanner [ $10,885 / 2 = 5,442$ ] 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.

- NC- **Wake Radiology.** The MRI service area is Wake County. The 2021 SMFP shows more than four fixed MRI scanners in Wake County. WR Imaging and UNC Rex have a total of six fixed MRI scanners under this Rule (five existing and one proposed) in Wake County. In Section C, page 66, the applicant projects that in the third year (CY2025) following completion of the project its six fixed MRI scanners will perform 29,429 weighted MRI procedures for an average of 4,905 weighted MRI procedures  $[29,429 / 6 = 4,905]$  which is greater than the 4,805 weighted MRI procedures required by the Rule. However, the applicant does not adequately demonstrate that projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming with this Rule.
- C- **DUHS.** The MRI service area is Wake County. The 2021 SMFP shows more than four fixed MRI scanners in Wake County. In Section Q and Form C, the applicant identifies a total of four fixed MRI scanners in Wake County (2 existing at Duke Raleigh Hospital, one at Holly Springs and the MRI scanner proposed in this application). In Section Q, DUHS projects weighted MRI volume of 20,440 scans in the third year of operation (FY2026) or 5,110 MRI scans per MRI scanner  $[20,440/4 = 5,110]$  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;*
- C- **PHSNC.** The MRI service area is Wake County. The 2021 SMFP shows more than four fixed MRI scanners in Wake County. 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 CY2024. In Section C, page 55 and in Section Q, the applicant projects that the proposed MRI

scanner will perform 4,975 weighted MRI procedures in the third year of operation (CY2024), which is greater than the 4,805 weighted MRI procedures required by the Rule.

- NC- **Wake Radiology.** 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 CY2025. In Section C, page 66, Section Q, and Exhibit C.7-1 the applicant projects that the proposed MRI scanner will perform 5,251 weighted MRI procedures in the third year of operation (CY2025), which is greater than the 4,805 weighted MRI procedures required by the Rule. However, the applicant does not adequately demonstrate that projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming with this Rule.
  
- C- **DUHS.** 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 (7/1/2025 to 6/30/2026). In Section C, page 46, and in Section Q, the applicant projects that the proposed MRI scanner will perform 5,092 weighted MRI procedures in the third year of operation (FY2026), which is greater than the 4,805 weighted MRI procedures required by the Rule.
  - (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*
  
- C- **PHSNC.** The applicant and its related entities own a controlling interest in one mobile MRI scanner. In Section C, page 55, and in Section Q, the applicant projects that the mobile MRI scanner is reasonably expected to perform 5,712 weighted MRI scans in the third year (CY2024) following completion of the proposed project which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.
  
- NC- **Wake Radiology.** The applicant and its related entities own a controlling interest in two mobile MRI scanners. In Section C, page 67, Section Q, and Exhibit C.7-3, the applicant projects that each mobile MRI scanner is reasonably expected to perform more than 3,328 weighted MRI scans in the third year (CY2025) following completion of the proposed project. Mobile #1 is projected to perform 3,828 weighted MRI scans in CY2025 and Mobile #2 is projected to perform 3,347 weighted MRI scans in CY2025 which exceeds the required 3,328 weighted MRI procedures per scanner in this performance standard. However, the applicant does not adequately demonstrate that projected utilization is reasonable and adequately supported. The

discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming with this Rule.

- NA- **DUHS.** 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 Wake County.
  - (6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- C- **PHSNC.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q.
- NC- **Wake Radiology.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section C, Section Q and Exhibits C.5, C.7-1, C.7-2 and C.7-3. However, the applicant does not adequately demonstrate that projected utilization is reasonable and adequately supported. The discussions regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming with this Rule.
- 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 Wake County in this review. Because the three applications in this review collectively propose to develop three additional fixed MRI scanners to be located in Wake 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-12063-21/ Cardinal Points Imaging of the Carolinas Wake Forest/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

**PHSNC** proposes to develop a new diagnostic center by acquiring one fixed MRI scanner to be located at its existing imaging center, CPIC Wake Forest, located at 839 Durham Road, Unit A, Wake Forest, Wake County. The applicant proposes to perform 4,975 total weighted MRI procedures on the proposed fixed MRI scanner from January 1 – December 31, 2024, the third full year of operation following completion of the project.

### **J-12068-21/ Wake Radiology Garner/ Acquire one fixed MRI scanner**

**Wake Radiology** proposes to acquire one fixed MRI scanner to be located at WR-Garner, an existing non-hospital licensed diagnostic center located at 300 Health Park Drive, Suite 100, Garner, Wake County. The applicant proposes to perform 5,251 total weighted MRI procedures on the proposed fixed MRI scanner from January 1 – December 31, 2025, the third full year of operation following completion of the project.

### **J-12073-21/ Duke Imaging North Raleigh/ Develop a new diagnostic center by acquiring one fixed MRI scanner**

**DUHS** proposes to develop a new diagnostic center by acquiring one fixed MRI scanner. The proposed diagnostic center would be operated as an IDTF located at Medical Office Building 9, 3300 Executive Dr, Raleigh, Wake County. The location is on the DRAH Campus. The applicant proposes to perform 5,192 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**

The applications submitted by PHSNC and DUHS are conforming with all applicable statutory and regulatory review criteria.

However, the application submitted by Wake Radiology is not conforming with all applicable statutory and regulatory review criteria. An application that is not conforming to all applicable statutory and regulatory review criteria cannot be approved. Therefore, regarding this comparative factor, the

applications submitted by **PHSNC** and **DUHS** are equally effective alternatives and more effective than the application submitted by Wake Radiology

**Scope of Services**

<b>Applicant</b>	<b>Type of Fixed MRI Scanner</b>	<b>Hospital Based or Freestanding*</b>
PHSNC	1.5T	Freestanding
Wake Radiology	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. However, Wake Radiology does not comply with all applicable statutory and regulatory criteria and therefore Wake Radiology is not approvable. Therefore, regarding this comparative factor, the applications the applications submitted by **PHSNC** and **DUHS** are equally effective alternatives and more effective than the application submitted by Wake Radiology.

**Historical Utilization**

The following table illustrates historical utilization of each applicant as provided in the **2021** SMFP representing FY2019 reported utilization.

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

<b>Facility (Owner)</b>	<b># of Fixed MRI Scanners</b>	<b>Total Weighted Procedures Performed during Federal Fiscal Year (FFY) 2019</b>	<b>Weighted Procedures per Scanner</b>
<b>PHSNC*</b>			
Cardinal Points Imaging of the Carolinas Midtown f/k/a Raleigh Radiology – Cedarhurst	1	7,532	7,532
<b>Wake Radiology &amp; Related Entities</b>			
Rex Hospital – Main (UNC Health System)	2	11,125	5,562.5
Rex Hospital – UNC Rex Health Care of Cary (UNC Health System)	1	0	0
Wake Radiology MRI (WR Imaging, LLC)	1	3,863	3,863
Wake Radiology MRI (WR Imaging, LLC)	1	3,862	3,862
Wake Radiology Diagnostic Imaging (Alliance)	1	4,287	4,287
Wake Radiology – Garner (Alliance)	1	3,540	3,540
<b>DUHS*</b>			
Duke Radiology Holly Springs (Duke University Health System)	1	0	0
Duke Raleigh Hospital (Duke University Health System)	2	13,935	6,967.5

Source: 2021 SMFP, Table 17E-1, pages 361-362.

\*PHSNC and DUHS do not have any related entities that own a controlling interest in a fixed MRI scanner in Wake County.

Two of the applications, PHSNC and DUHS, both propose to provide MRI services at new facilities and thus have no historical utilization with a fixed MRI scanner. Thus, the result of this analysis is inconclusive.

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

The 2021 SMFP identifies the need for one fixed MRI scanner in Wake County. The following table identifies the location of the existing and approved fixed MRI scanners in Wake County.

Facility (Owner)	# of Fixed MRI Scanners	Hospital Based or Freestanding	Location
Raleigh Radiology – Cary (Alliance)^	1	Freestanding	Cary
Wake Radiology Diagnostic Imaging (Alliance)	1	Freestanding	Cary
WakeMed Cary Hospital (WakeMed)	1	Hospital	Cary
<b>TOTAL FOR CARY*</b>	<b>3</b>		
Wake Radiology – Garner (Alliance)	1	Freestanding	Garner
<b>TOTAL FOR GARNER</b>	<b>1</b>		
Duke Radiology Holly Springs (Duke University Health System)	1	Freestanding	Holly Springs
Rex Hospital – UNC Rex Health Care of Cary (UNC Health System)*	1	Hospital	Holly Springs
<b>TOTAL FOR HOLLY SPRINGS***</b>	<b>2</b>		
Duke Raleigh Hospital (Duke University Health System)	2	Hospital	Raleigh
Rex Hospital – Main (UNC Health System)	2	Hospital	Raleigh
WakeMed (WakeMed)	2	Hospital	Raleigh
Raleigh Neurology Associates (Raleigh Neurology Associates)	1	Freestanding	Raleigh
Raleigh Neurology Imaging (Alliance)	1	Freestanding	Raleigh
Raleigh Radiology – Blue Ridge (Alliance)	1	Freestanding	Raleigh
Raleigh Radiology – Cedarhurst	1	Freestanding	Raleigh
The Bone and Joint Surgery Center (Bone & Joint)	1	Freestanding	Raleigh
Wake Radiology (Wake Radiology)	1	Freestanding	Raleigh
Wake Radiology Raleigh MRI Center (Wake Radiology)	1	Freestanding	Raleigh
<b>TOTAL FOR RALEIGH</b>	<b>13</b>		

Source: 2021 SMFP, Table 17E-1, pages 361-362.

^ This MRI scanner is “permanently” installed. Pursuant to the need determination in the 2019 SMFP for one fixed MRI scanner in Wake County Raleigh Radiology, LLC applied for and was conditionally approved to develop a new fixed MRI scanner at Raleigh Radiology-Cary to replace the MRI scanner leased from Alliance. See Project ID# J-11825-19. This conditional approval is currently under appeal.

\*Per Wake Radiology which formed a joint venture with UNC Rex HealthCare in late February 2019 the fixed MRI scanner at UNC Rex Healthcare of Cary is being relocated to the UNC REX Holly Springs Hospital upon completion of UNC REX Holly Springs Hospital in 2021. See Wake Radiology Application Section C.12, page 52 and Exhibit C.12-1, page 4.

**Current Fixed MRI Scanners in Wake County**

Area	Population	Total Fixed MRI Scanners	Total Freestanding (Fixed) MRI Scanners	Average Population per Total Fixed Scanner	Average Population per Total Freestanding (Fixed) MRI Scanners
Wake Forest	37,469	0	0	37,469	37,469
Garner*	32,213	1	1	32,213	32,213
Raleigh	470,396	13	7	36,184	67,199

Source: North Carolina Office of State Management and Budget. Population estimates from July 1, 2019.

\*The single freestanding (fixed) MRI scanner shown to be located in Garner is the grandfathered fixed MRI scanner located at WR-Garner.

As shown in the table above, based on the Wake County population estimates as of July 1, 2019 for each freestanding (fixed) MRI scanner Raleigh has 67,199 residents and Garner has 32,213 residents. Wake Forest has 37,469 residents but no freestanding (fixed) MRI scanner

PHSNC is proposing to develop a new freestanding (fixed) MRI scanner in Wake Forest. Wake Radiology is proposing to replace the existing freestanding grandfathered fixed MRI scanner (owned by Alliance and leased to Wake Radiology and located at the WR-Garner facility) in Garner with a freestanding fixed MRI scanner owned by Wake Radiology. Thus, if Wake Radiology’s application is approved, upon project completion there would still be only one (1) freestanding (fixed) MRI scanner in Garner. DUHS is proposing to develop a new freestanding (fixed) MRI scanner in Raleigh.

**Fixed MRI Scanners in Wake County (if each application was approved)**

Area	Population	Total Fixed MRI Scanners	Total Freestanding (Fixed) MRI Scanners	Average Population per Total Fixed Scanner	Average Population per Total Freestanding (Fixed) MRI Scanners
Wake Forest	37,469	0	1	37,469	37,469
Garner	32,213	1	1	32,213	32,213
Raleigh	470,396	13	8	36,184	58,799

Source: North Carolina Office of State Management and Budget. Population estimates from July 1, 2019.

\*The single freestanding (fixed) MRI scanner shown to be located in Garner is the grandfathered fixed MRI scanner located at WR-Garner.

Based on this analysis, the geographic location of the freestanding fixed MRI scanner in Raleigh is a better option for MRI services in Wake County. If each application was approved, Raleigh would still have the lowest ratio of freestanding (fixed) MRI scanners per person, but the ratio would improve.

Thus, with respect to geographic accessibility, the proposal submitted by **DUHS** is the more effective alternative.

**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 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. Wake County has more than one licensed acute care hospital. Therefore, for the purpose of this review, Wake County is the service area because it has multiple licensed acute care hospitals. Facilities may also serve residents of counties not included in their service area.

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

<b>Applicant</b>	<b>Wake County Residents Served</b>	<b>Wake County Residents per Scanner</b>	<b>Projected Total Patients</b>	<b>Wake County Residents Served as a % of Total Patients</b>
PHSNC	2,817	2,817	4,547	61.95%
Wake Radiology	2,462	2,462	4,447	55.36%
DUHS	2,913	2,913	4,428	65.79%

As shown in the table above, DUHS 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. Therefore, regarding both the highest total number of service area residents and projected service to percentage of service area residents as compared to total patients served **DUHS** 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 all the applicants as a percentage of gross revenue, and per MRI scan, as shown below.

Applicant	Gross Revenue	MRI Scans	Charity Care	Charity Care as a % of Gross Revenue	Charity Care / MRI Scan
PHSNC	\$8,340,144	4975	\$119,994	1.44%	\$24.12
Wake Radiology	\$11,831,997	5,251	\$18,533	0.16%	\$3.53
DUHS	\$5,247,866	5,195	\$81,876	1.56%	\$15.76

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

PHSNC proposes both the highest dollar amount of charity percentage of charity care and the highest amount of charity care per MRI scan while DUHS proposes the higher amount of charity care as a percent of gross revenue. Therefore, with respect to charity care, **PHSNC** is the more effective alternative.

However, two of the applicants, PHSNC and Wake Radiology, bill globally and include “professional fees” which cover professional interpretation of MRI studies by radiologists as an expense line in their pro formas. DUHS does not bill for “professional fees” nor does DUHS include an expense line in its pro formas for professional fees. These differences in billing, which impact revenue (both gross and net) and expenses, does not allow for a comparison between the applications. Thus, the result of this analysis is inconclusive.

*Projected Medicare*

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for all the applicants in the review using gross Medicare dollars as a percentage of gross revenue.

The total number of Medicare patients was not provided by the applicants in this review; therefore, total Medicare patients and Medicare patients as a percentage of total patients cannot be compared. Thus, in this review, Medicare is compared as a percentage of gross revenue only.

Applicant	Gross Revenue	MRI Scans	Medicare	Medicare as a % of Gross Revenue	Medicare/MRI Scan
PHSNC	\$8,340,144	4,975	\$2,082,498	24.97%	\$419
Wake Radiology	\$11,831,997	5,251	\$5,043,210	42.62%	\$960
DUHS	\$5,247,866	5,195	\$2,345,173	44.69%	\$451

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

Wake Radiology proposes both the highest dollar amount of Medicare and the highest amount of Medicare care per MRI scan while DUHS proposes the higher amount of Medicare as a percent of gross revenue and the next highest dollar amount of Medicare and the highest amount of Medicare care per MRI scan. However, Wake Radiology does not comply with all applicable statutory and regulatory criteria and therefore Wake Radiology is not approvable. Therefore, with respect to charity care, **DUHS** is the more effective alternative.

However, two of the applicants, PHSNC and Wake Radiology, bill globally and include “professional fees” which cover professional interpretation of MRI studies by radiologists as an expense line in their pro formas. DUHS does not bill for “professional fees” nor does DUHS include an expense line in its pro formas for professional fees. These differences in billing, which impact revenue (both gross and net) and expenses, does not allow for a comparison between the applications. Thus, the result of this analysis is inconclusive.

*Projected Medicaid*

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for all the applicants using gross Medicaid dollars as a percentage of gross revenue.

Applicant	Gross Revenue	MRI Scans	Medicaid	Medicaid as a % of Gross Revenue	Medicaid/MRI Scan
PHSNC	\$8,340,144	4,975	\$329,310	3.95%	\$66
Wake Radiology	\$11,831,997	5,251	\$358,892	3.03%	\$68
DUHS	\$5,247,866	5,195	\$284,617	5.42%	\$55

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

Wake Radiology proposes both the highest dollar amount of Medicaid and the highest amount of Medicaid per MRI scan while PHSNC proposes the higher amount of Medicaid as a percent of gross revenue and the second highest dollar amount of Medicaid and the second highest amount of Medicaid per MRI scan. However, Wake Radiology does not comply with all applicable statutory and regulatory criteria and therefore Wake Radiology is not approvable. Therefore, with respect to Medicaid, **PHSNC** is the more effective alternative.

However, two of the applicants, PHSNC and Wake Radiology, bill globally and include “professional fees” which cover professional interpretation of MRI studies by radiologists as an expense line in their pro formas. DUHS does not bill for “professional fees” nor does DUHS include an expense line in its pro formas for professional fees. These differences in billing, which impact revenue (both gross and net) and expenses, does not allow for a comparison between the applications. Thus, the result of this analysis is inconclusive.

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

All the applicants and/or related entities provide MRI services in the service area of Wake County; therefore, none of the applicants would qualify as a new or alternative provider in the service area. However, the application submitted by Wake Radiology is not conforming with all applicable statutory and regulatory review criteria. An application that is not conforming to all applicable statutory and regulatory review criteria cannot be approved. Therefore, regarding this comparative factor, the applications submitted by PHSNC and DUHS are equally effective alternatives and more effective than the application submitted by Wake Radiology

**Projected Average Net Revenue per MRI Procedure**

The following table compares the projected average net revenue per unweighted 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
PHSNC	\$2,298,271	4,975	\$462
Wake Radiology	\$4,111,848	5,251	\$783
DUHS	\$2,316,231	5,192	\$446

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

As shown in the table above, DUHS 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 DUHS, which proposes the lowest average net revenue per weighted MRI procedure in the third full year following project completion, is the more effective alternative.

However, two of the applicants, PHSNC and Wake Radiology, bill globally and include “professional fees” which cover professional interpretation of MRI studies by radiologists as an expense line in their pro formas. DUHS does not bill for “professional fees” nor does DUHS include an expense line in its pro formas for professional fees. These differences in billing, which impact revenue (both gross and net) and expenses, does not allow for a comparison between the applications. Thus, the result of this analysis is inconclusive.

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



The following table compares the projected average operating expense per unweighted 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.

<b>Applicant</b>	<b>Operating Expense</b>	<b># of MRI Procedures</b>	<b>Average Operating Expense per Procedure</b>
PHSNC	\$1,576,415	4,975	\$317
Wake Radiology (MRI)	\$2,879,377	5,251	\$548
DUHS	\$1,690,587	5,192	\$326

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

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

However, two of the applicants, PHSNC and Wake Radiology, bill globally and include “professional fees” which cover professional interpretation of MRI studies by radiologists as an expense line in their pro formas. DUHS does not bill for “professional fees” nor does DUHS include an expense line in its pro formas for professional fees. These differences in billing, which impact revenue (both gross and net) and expenses, does not allow for a comparison between the applications. Thus, the result of this analysis is inconclusive.

**Adding Fixed MRI scanner to Wake County Fixed MRI scanner Inventory**

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. Under the need methodology fixed MRI scanners are comprised of fixed MRI scanners and grandfathered fixed MRI scanners. Grandfathered fixed MRI scanners are mobile MRI scanners that are not required to be moved between two or more sites. Application of the need methodology in the 2021 SMFP identified a need for one fixed MRI scanner in the Wake 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.

PHSNC is proposing to develop a new freestanding (fixed) MRI scanner in Wake Forest, which, if approved, would increase the number of fixed MRI scanners in Wake County.

DUHS is proposing to develop a new freestanding (fixed) MRI scanner in Wake Forest, which, if approved, would increase the number of fixed MRI scanners in Wake County.

Wake Radiology is proposing to replace the existing freestanding, grandfathered fixed MRI scanner (owned by Alliance and leased to Wake Radiology) located at the WR-Garner facility in Garner with a freestanding fixed MRI scanner owned by Wake Radiology. Wake Radiology’s application to

replace the grandfathered fixed MRI rather than develop a new fixed MRI scanner which would add to the inventory of fixed MRI scanner’s in Wake County, is permitted as set forth below,

*“Chapter 17: Technology and Equipment E. Magnetic Resonance Imaging Scanners, of the 2021 SMFP, page 345, states,*

...

*“8. A facility that offers MRI services on a full-time basis pursuant to a service agreement with an MRI provider is not precluded from applying for a need determination to replace the existing contracted service with a fixed MRI scanner under the applicant’s ownership and control. It is consistent with the purposes of the Certificate of Need law and the SMFP for a facility to acquire and operate an MRI scanner to replace such a contracted service, if the acquisition and operation of the facility’s own MRI scanner will allow the facility to reduce the cost of providing the MRI service at that facility.”*

Wake Radiology’s proposed project, if approved, would not increase the number of fixed MRI scanners in Wake County as it would be replacing a grandfathered fixed MRI scanner as defined above.

Therefore, since the proposals, if approved, of both PHSNC and DUHS would increase the number of fixed MRI scanners in Wake County regarding this comparative factor, the applications submitted by **PHSNC** and **DUHS** are equally effective alternatives and more effective than the applications submitted by Wake Radiology

### 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	PHSNC	Wake Radiology	DUHS
Conformity with Statutory and Regulatory Review Criteria	<b>Yes</b>	<b>No</b>	<b>Yes</b>
Scope of Services	<b>Equally Effective</b>	Not Approvable	<b>Equally Effective</b>
Historical Utilization of the Facility	Inconclusive	Not Approvable	Inconclusive
Geographic Accessibility	Less Effective	Not Approvable	<b>More Effective</b>
Access by Service Area Residents	Less Effective	Not Approvable	<b>More Effective</b>
Access by Charity Care Patients	Inconclusive	Not Approvable	Inconclusive
Access by Medicare Patients	Inconclusive	Not Approvable	Inconclusive
Access by Medicaid Patients	Inconclusive	Not Approvable	Inconclusive
Competition (Access to New or Alternative Provider)	<b>Equally Effective</b>	Not Approvable	<b>Equally Effective</b>
Projected Average Net Revenue per MRI procedure	Inconclusive	Not Approvable	Inconclusive
Projected Average Operating Expense per MRI procedure	Inconclusive	Not Approvable	Inconclusive
Would Add to the Inventory	<b>Equally Effective</b>	Not Approvable	<b>Equally Effective</b>

As shown in the table above, the **Wake Radiology** application is not an effective alternative with respect to Conformity with Review Criteria; therefore, the Wake Radiology application is not approvable and will not be further discussed in the comparative evaluation below:

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

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

- Geographic Accessibility
- Access by Service Area Residents

## **CONCLUSION**

All the applications are conforming to the need determination in the 2021 SMFP for one fixed MRI scanner in Wake County. N.C.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 Agency.

However, the application submitted by Wake Radiology is not approvable and therefore cannot be considered an effective alternative. Consequently, the application submitted by Wake Radiology, Project I.D.#J-12068-21 is denied.

The Agency determined that the application submitted by **DUHS** is the more effective alternative proposed in this review for one additional fixed MRI scanner for Wake County and is approved. The approval of any of the other applications would result in the approval of MRI scanners in excess of the need determination in the 2021 SMFP and therefore, the application submitted by Pinnacle Health Services of North Carolina, LLC (Project ID # J-12063-21) is denied.

The application submitted by **Duke University Health System, Inc. (Project ID #J-12073-21)** is approved subject to the following conditions:

1. **Duke University Health System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall develop a new diagnostic center by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.**
3. **Upon completion of the project, Duke Imaging North Raleigh 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: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**

- b. The certificate holder shall complete all sections of the Progress Report form.**
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
  - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on January 1, 2022. The second progress report shall be due on April 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.**