

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 28, 2020

Findings Date: May 5, 2020

Project Analyst: Gregory F. Yakaboski

Co-Signer: Lisa Pittman

COMPETITIVE REVIEW

Project ID #: J-11820-19
Facility: Raleigh Radiology Wake Forest
FID #: 090950
County: Wake
Applicant: Pinnacle Health Services of North Carolina, LLC
Project: Acquire one fixed MRI scanner pursuant to the need determination in the 2019 SMFP

Project ID #: J-11821-19
Facility: EmergeOrtho, P.A.
FID #: 190629
County: Wake
Applicant: EmergeOrtho, P.A.
Project: Acquire one fixed MRI scanner pursuant to the need determination in the 2019 SMFP for a total of one fixed MRI scanner and one mobile MRI scanner

Project ID #: J-11825-19
Facility: Raleigh Radiology Cary
FID #: 080405
County: Wake
Applicant: Raleigh Radiology, LLC
Project: Acquire one fixed MRI scanner pursuant to the need determination in the 2019 SMFP

Project ID #: J-11826-19
Facility: Raleigh Radiology Knightdale
FID #: 190281
County: Wake
Applicant: Raleigh Radiology, LLC
Project: Acquire one fixed MRI scanner pursuant to the need determination in the 2019 SMFP

Project ID #: J-11829-19
Facility: Duke Radiology Green Level
FID #: 190639
County: Wake
Applicant: Duke University Health System, Inc.
Project: Acquire one fixed MRI scanner pursuant to the need determination in the 2019 SMFP

Project ID #: J-11830-19
Facility: Wake Radiology Cary
FID #: 001330
County: Wake
Applicant(s): WR Imaging, LLC
Wake Radiology Diagnostic Imaging, Inc.
Project: Acquire one fixed MRI scanner pursuant to the need determination in the 2019 SMFP

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C All Applications

Need Determination

The 2019 State Medical Facilities Plan (SMFP) includes a need determination for one additional fixed magnetic resonance imaging (MRI) scanner in the Wake County MRI service area. Six applications were received by Agency for this review cycle.

Policies

There are two policies in the 2019 SMFP applicable to this review: *Policy GEN-3: Basic Principles*, and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-3 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 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. 131E184 is required to submit a plan for 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-11820-19/ Raleigh Radiology Wake Forest/ Develop one fixed MRI scanner

Pinnacle Health Services of North Carolina, LLC [PHSNC], the applicant, proposes to acquire one fixed MRI scanner to be located at Raleigh Radiology Wake Forest (RR-Wake Forest), an existing non-hospital licensed diagnostic center located at 839 Durham Road, Units A&B, Wake Forest, Wake County. PHSNC owns a mobile MRI that currently serves the existing diagnostic center at RR-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, pages 14-15, 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 15-16, the applicant describes the projects 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
- Remarks made at the public hearing
- 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.

J-11821-19/ EmergeOrtho, P.A./ Develop one fixed MRI scanner

EmergeOrtho, P.A. [EmergeOrtho] the applicant, proposes to acquire one fixed MRI scanner to be located at EmergeOrtho, P.A. (EmergeOrtho), an existing non-hospital licensed diagnostic center located at 3100 Duraleigh Road, Suite 100, Raleigh, Wake County. EmergeOrtho owns a mobile MRI scanner which provides MRI services at the existing

diagnostic center three days per week. The proposed fixed MRI scanner would replace the existing mobile MRI services.

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 20-23, 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
- Remarks made at the public hearing
- 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-11825-19/ Raleigh Radiology Cary/ Develop one fixed MRI scanner

Raleigh Radiology, LLC [Raleigh Radiology-Cary], the applicant, proposes to acquire one fixed MRI scanner to be located at Raleigh Radiology Cary (RR-Cary), an existing non-hospital licensed diagnostic center located at 150 Parkway Office Court, Suite 100, Cary, Wake County. Raleigh Radiology contracts with Alliance 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 26-28, the applicant explains why it believes its application is conforming to Policy GEN-3.

Policy GEN-4. The proposed capital expenditure is between \$2 million and \$5 million. In Section B.2, pages 29-30, 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
- Remarks made at the public hearing
- 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.

J-11826-19/Raleigh Radiology Knightdale/ Develop one fixed MRI scanner
Raleigh Radiology, LLC [Raleigh Radiology-Knightdale], the applicant, proposes to acquire one fixed MRI scanner to be located at Raleigh Radiology Knightdale (RR-Knightdale), an approved, but non-operational, non-hospital licensed diagnostic center located

at 1101 Great Falls Court, Knightdale, Wake County. RR-Knightdale does not currently offer MRI services.

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 26-27, the applicant explains why it believes its application is conforming to Policy GEN-3.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

J-11829-20/ Duke Radiology Green Level/ Develop one fixed MRI scanner
Duke University Health System [DUHS], the applicant, proposes to acquire one fixed MRI scanner to be located at Duke Radiology Green Level (Duke Green Level), creating a new non-

hospital licensed diagnostic center to be located within a medical office building currently being developed at 3208 Green Level W Road, Cary, Wake County. Duke Green Level does not currently offer MRI services.

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
- Remarks made at the public hearing
- 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.

J-11830-20/ Wake Radiology Cary/ Develop one fixed MRI scanner

WR Imaging, LLC and Wake Radiology Diagnostic Imaging, Inc. [Wake Radiology], collectively referred to as “Wake Radiology” or “the applicant” proposes to acquire one fixed MRI scanner to be located at Wake Radiology Cary (WR-Cary), an existing non-hospital licensed diagnostic center located at 300 Ashville Avenue, Cary, Wake County. Wake Radiology contracts with Alliance for 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 between \$2 million and \$5 million. In Section B.2, page 23, the applicant describes the projects 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
- Remarks made at the public hearing
- 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 six applicants are conforming to the need determination and to the applicable policies in the 2019 SMFP. The limit on the number of fixed MRI scanners that can be approved is one (1). Collectively, the applicants propose a total of six 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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C
PHSNC
EmergeOrtho
Raleigh Radiology-Cary
Raleigh Radiology-Knightdale
DUHS

NC
Wake Radiology

J-11820-19/ Raleigh Radiology Wake Forest/ Develop one fixed MRI scanner

PHSNC proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center. RR-Wake Forest, located at 839 Durham Road, Units A&B, Wake Forest.

Patient Origin

On page 149, the 2019 SMFP defines a fixed MRI scanner as “an MRI scanner that is not a mobile MRI scanner.” The 2019 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. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.” 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 projected patient origin.

County	Third Full FY of Operation following Project Completion (1/1/2023 – 12/31/2023)	
	Patients	% of Total
Wake	2,942	62.8%
Franklin	1,319	28.2%
Vance	158	3.4%
Nash	90	1.9%
Granville	54	1.2%
Warren	36	0.8%
Johnston	14	0.3%
Halifax	11	0.2%
Wilson	7	0.2%
Other*	54	1.2%
Total	4,685	100.0%

Source: Section C.3, page 23.

*Other includes <1% patient origin for the remaining counties in North Carolina.

Totals may not foot due to rounding.

In Section C, pages 23-24, 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 applicants historical MRI patient origin for the facility.

Analysis of Need

In Section C.4, pages 24-33, 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 2019 SMFP (page 24).
- Historical MRI Utilization in Wake County (page 25).
- Increasing use rate for MRI scanners in Wake County (pages 25-27).
- Wake County population growth and aging population (pages 27-29).
- Need for additional value-based fixed MRI scanner capacity in Wake County (page 29).
- Geographic need for a freestanding fixed MRI scanner in Wake Forest. (pages 30-33).

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

- The 2019 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.

Projected Utilization

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

Historical MRI Utilization at RRWF

	2015	2016	2017	2018	2019
# of MRI scanners	1	1	1	1	1
Unweighted Procedures	2,156	2,689	2,465	2,504	2,565
Weighted Procedures	2,234	2,953	2,941	2,704	2,778

Source: Table on page 102 of the application.

Projected MRI Utilization at RRWF

	Interim CY2020	OY1 CY2021	OY2 CY2022	OY3 CY2023
# of MRI scanners	1	1	1	1
Unweighted Procedures	2,565	3,680	4,172	4,685
Weighted Procedures	2,778	3,985	4,518	5,074

Source: Section Q, Form C.

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

- Step 1) Projected PHSNC Cedarhurst MRI Procedures (pages 98-99).
- Step 2) Projected PHSNC Wake Forest Mobile MRI Procedures (pages 99-100).
- 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 100-103).
- Step 4) Projected Shift of MRI procedures from Raleigh Radiology Cedarhurst (RRC) to Raleigh Radiology Wake Forest (RRWF) (pages 103-105).
- Step 5) Calculated Total Projected RRWF MRI Procedures (pages 105-106).
- Step 6) Calculate Total Projected RRC MRI Procedures (page 106).
- Step 7) Calculated Total Combined PHSNC Fixed MRI Procedures [RRC and RRWF] (pages 106-107).
- Step 8) Determine PHSNC Fixed MRI Market Share in Wake County, both Historic and Projected. (page 107)

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

- There was a need determination in the 2019 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 RR-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 RR-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 RRC to RRWF 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 107 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 (CY2023) of 10.14% is virtually identical to its Wake County market share in CY2018 of 10.44%.

Access

In Section C.11, page 38, the applicant states, “*PHSNC will continue to provide all services to all patients regardless of income, race/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.*”

In Section L, page 82, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Category	MRI Services as Percent of Total
Self-Pay	1.1%
Medicare*	23.1%
Medicaid*	3.4%
Insurance*	62.2%
Workers Compensation	6.9%
Other (government)	3.4%
Total	100.0%

Source: Table on page 82 of the application.

*Includes any managed care plans.

The projected payor mix is reasonable and adequately supported because it is based on the historical experience of the facility in providing MRI services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing

- 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 following reasons:

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

J-11821-19/ EmergeOrtho, P.A./ Develop one fixed MRI scanner

EmergeOrtho proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center, EmergeOrtho, located at 3100 Duraleigh Road, Suite 100, Raleigh.

Patient Origin

On page 149, the 2019 SMFP defines a fixed MRI scanner as “*an MRI scanner that is not a mobile MRI scanner.*” The 2019 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. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.*” 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 projected patient origin.

County	Third Full FY of Operation following Project Completion (1/1/2023 – 12/31/2023)	
	Patients	% of Total
Wake	3,840	75.6%
Johnston	308	6.1%
Franklin	163	3.2%
Harnett	133	2.6%
Durham	114	2.2%
Wayne	49	1.0%
Nash	43	0.8%
Halifax	37	0.7%
Cumberland	35	0.7%
Edgecombe	33	0.7%
Chatham	24	0.5%
Sampson	24	0.5%
Lee	24	0.5%
Granville	18	0.3%
Lenoir	18	0.3%
Orange	14	0.3%
Alamance	12	0.2%
Brunswick	10	0.2%
Vance	8	0.2%
Warren	8	0.2%
Forsyth	8	0.2%
Wilson	6	0.1%
Northampton	6	0.1%
Pitt	6	0.1%
Wilson	6	0.1%
Other NC Counties*	51	1.0%
VA	31	0.6%
Other States**	53	1.0%
Total	5,078	100.0%

Source: Section C.3, page 36.

*Other North Carolina Counties include Beaufort, Bertie, Camden, Carteret, Craven, Duplin, Gaston, Guilford, Hertford, Lincoln, Mecklenburg, Montgomery, Moore, Onslow, Pender, Randolph, Robeson, Union, Washington, and Watauga.

**Other States include Georgia, South Carolina, other.

Totals may not foot due to rounding.

In Section C, page 37, 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 patient origin for MRI services at the facility.

Analysis of Need

In Section C, pages 38-51, 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 2019 SMFP.
- Wake County population growth and aging population (pages 38-40).
- Scheduling backlogs because of the high utilization of the existing mobile MRI scanner owned by EmergeOrtho (pages 40-44).
- Limitation caused by using mobile MRI scanners (page 45).
- Ability to provide increased access and days of service at other EmergeOrtho locations due to freeing up of the EmergeOrtho mobile MRI scanner due to the acquisition of the fixed MRI scanner.
- Physician support for the proposed project and physician recruitment (pages 45-47).
- Utilization projections for the proposed fixed MRI scanner and the existing mobile MRI scanner are based on reasonable and supported assumptions and methodology (pages 47-51).

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

- The 2019 SMFP identifies the need for one additional fixed MRI scanner in Wake County.
- Population growth, particularly among the elderly is occurring in Wake County.
- High historic utilization of EmergeOrtho mobile MRI scanner at the proposed location
- The applicant provides information to support its projected utilizations including physician support.

Projected Utilization

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

Historical MRI Utilization at EmergeOrtho Duraleigh Facility

	Previous Yr	Quarter	Current Year	Interim Year
	10/1/2018 to 9/30/2019	10/1/2019 to 12/31/2019	1/1/2019 to 12/31/2019	1/1/2020 to 12/31/2020
# of MRI scanners	1	1	1	1
Type of MRI Scanner	Mobile	Mobile	Mobile	Mobile
Days per Week of Service	3	3	3	5
Unweighted Procedures	2,592	656	2,592	2,939
Weighted Procedures	2,704	685	2,704	3,067

Source: Table in Section Q and Section C, page 47.

Projected MRI Utilization

	OY1 CY2021	OY2 CY2022	OY3 CY2023
# of MRI scanners	1	1	1
Type of MRI Scanner	Fixed	Fixed	Fixed
Days per Week of Service	6	6	6
Unweighted Procedures	3,603	4,315	5,078
Weighted Procedures	3,759	4,502	5,298

Source: Table in Section Q.

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

- Step 1) Calculated the 4-year compound annual growth rate (CAGR) for unweighted MRI procedures in Wake County (4.30%) and North Carolina (2.65%). (page 113).
- Step 2) Projects Wake County MRI utilization (unweighted) for CY2019 – CY2023) based on a 4.0% growth rate [less than Wake County’s 4.3% CAGR] (page 113).
- Step 3) Calculate EmergeOrtho Duraleigh facility’s historic Wake County unweighted MRI market share for the years CY2017-CY2019 (page 114).
- Step 4) Calculate EmergeOrtho Duraleigh’s projected unweighted MRI scans through the third operating year (CY2023) based on a starting historic market share of 2.6% in 2019 and 2.8%, 3.3%, 3.8% and 4.3% respectively for the years CY2020 – CY2023. (page 114-115).
- Step 5 & Step 6) Calculate weighted MRI procedures (page 116).
- Step 7) Table showing Historic, Interim and Projected weighted and unweighted MRI scans at EmergeOrtho Duraleigh (page 117).

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

- There was a need determination in the 2019 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.
- Historically EmergeOrtho performed 2,704 weighted MRI scans at the Duraleigh location with a mobile MRI scanner only 3 days per week. If approved, the applicant plans to operate the fixed MRI scanner 6 days per week.

- The methodology and assumption utilized by the applicant were reasonable, conservative and well supported.
- In Exhibit C-4, the applicant provided estimated physician referral letters estimating 6,888 MRI referrals for the third operating year (CY2023). By Rule, the applicant only has to demonstrate that the proposed fixed MRI scanner would preform 4,805 by the end of the third year of operation (CY2023).

Access

In Section C.11, page 57, the applicant states, “*EmergeOrtho will not discriminate against anyone due to age, race, color, ethnicity, religion, gender, disability or ability to pay.*” In Section L, page 99, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Category	MRI Services as Percent of Total
Self-Pay	2.00%
Charity Care	0.15%
Medicare*	22.67%
Medicaid*	6.80%
Insurance*	56.80%
Workers Compensation	7.46%
Tricare	4.11%
Total	100.0%

Source: Table on page 99 of the application.

*Includes any managed care plans.

The projected payor mix is reasonable and adequately supported because it is based on the historical experience of the facility in providing MRI services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 following reasons:

- The applicant adequately identifies the population to be served.

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

J-11825-19/ Raleigh Radiology Cary/ Develop one fixed MRI scanner

Raleigh Radiology-Cary proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center, RR-Cary, located at 150 Parkway Office Court, Suite 100, Cary.

Patient Origin

On page 149, the 2019 SMFP defines a fixed MRI scanner as “an MRI scanner that is not a mobile MRI scanner.” The 2019 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. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.” 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 projected patient origin.

County	Third Full FY of Operation following Project Completion (1/1/2023 – 12/31/2023)	
	Patients	% of Total
Wake	5,232	86.50%
Harnett	106	1.75%
Chatham	151	2.50%
Lee	109	1.80%
Johnston	73	1.2%
Durham	69	1.14%
Orange	62	1.03%
Nash	16	0.27%
Other NC Counties	162	2.68%
Other States	68	1.13%
Total	6,049	100.0%

Source: Section C.3, page 40.

Totals may not foot due to rounding.

In Section C, page 41, and Section Q, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately.

Analysis of Need

In Section C, pages 42-55, 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 the 2019 SMFP (pages 44-45).
- High demand for MRI services at RR-Cary (pages 42-43).
- Need to contain costs of offering MRI services ((pages 43-44).
- Wake County and core county population growth and aging (pages 45-46).
- MRI use rate increasing in Wake County and in North Carolina (page 47).
- Health status of the population of Wake county and other service area counties (pages 48-50).
- Need for accessible 3T MRI scanner in Wake County (pages 51-52)
- Need for low cost MRI services in Wake County (pages 52-53).
- Need for MRI outpatient facilities and weekend hours (page 53).
- Provider interest in referring to RR-Cary (pages 53-55).

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

- The 2019 SMFP identifies the need for one additional fixed MRI scanner in Wake County.
- Population growth, particularly among the elderly is occurring in Wake County.
- High historic utilization of the existing mobile MRI scanner at the proposed location
- The applicant provides reasonable and adequately supported information to support it projected utilizations including physician support.
- Increasing MRI use rate in Wake County.

Projected Utilization

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

Historical MRI Utilization at RR-Cary Facility

	Historical CY2019	Interim Year CY 2020
# of MRI scanners	1	1
Unweighted Procedures	6,424	6,554
Weighted Procedures	7,427	7,576

Source: Table in Section Q, page 152.

Projected MRI Utilization

	OY1 CY 2021	OY2 CY2022	OY3 CY2023
# of MRI scanners	1	1	1
Unweighted Procedures	6,684	6,815	6,946
Weighted Procedures	7,727	7,878	8,030

Source: Table in Section Q, page 146.

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

- Step 1. Identify the Service Area and Population to be Served (pages 131-133).
- Step 2. Determine MRI Use Rate and Need for MRI Procedures in Wake County (pages 133-134).
- Step 3. Determine the need for MRI Scanners in Wake County, FY2018-FY2024 (page 135).
- Step 4. Determine Population to be Served (Patient Origin) Using RR Cary History (pages 136-138).
- Step 5. Determine Weighted Average Population Increase Rate for Wake and Core Counties (page 139).
- Step 6. Forecast Future MRI Procedures Using Population Growth Rate (page 140)
- Step 7. Forecast Total MRI Procedures for Wake County and the Core Counties, FY2019-FY2024 (page 141).
- Step 8. Determine Market Share of Core Area Counties and Wake County (page 142).
- Step 9. Forecast RR Cary MRI Procedures by County and Out of Core Area (page 143).
- Step 10. Determine Adjusted MRI Procedure Distribution at RR Cary (page 144).
- Step 11. Forecast Adjusted MRI Procedures at RR Cary (page 145).
- Step 12. Determine Unadjusted and Adjusted MRI Procedures at Raleigh by Calendar Year (page 146).

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

- There was a need determination in the 2019 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 RR-Cary facility is already providing MRI services utilizing a leased mobile MRI scanner leased from Alliance which is classified as a “grandfathered fixed MRI” since the mobile scanner does not move to other locations. The proposed fixed MRI scanner would simply replace the leased mobile (“grandfathered fixed”) MRI scanner at the RR-Cary facility facilitating patient access and scheduling.
- In Exhibit I.2, the applicant provided estimated physician referral letters estimating between 5,886 and 7,482 MRI referrals for the first operating year (CY2021). By Rule, the applicant only has to demonstrate that the proposed fixed MRI scanner would preform 4,805 by the end of the third year of operation (CY2023).
- By Rule, the applicant must demonstrate that the proposed fixed MRI scanner would meet or exceed the performance standard of 4,805 weighted MRI scans by the end of

the third operating year. In 2019 the facility performed 7,427 weighted MRI scans, thus exceeding the performance standard by 2,622 weighted MRI scans.

Access

In Section C.11, page 61, the applicant states, “*Raleigh Radiology, LLC accepts all patients, regardless of gender, gender preference, race, ethnicity, age, income, or disability status.*” In Section L, page 114, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Category	MRI Services as Percent of Total
Self-Pay	2.79%
Charity Care	0.20%
Medicare*	25.95%
Medicaid*	3.37%
Insurance*	64.81%
Other (specify)	2.88%
Total	100.00%

Source: Table on page 114 of the application.

*Includes any managed care plans.

The projected payor mix is reasonable and adequately supported because it is based on the historical experience of the facility in providing MRI services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 following reasons:

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

J-11826-19/Raleigh Radiology Knightdale/ Develop one fixed MRI scanner

Raleigh Radiology-Knightdale proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center, RR-Knightdale, located at 1101 Great Falls Court, Knightdale.

Patient Origin

On page 149, the 2019 SMFP defines a fixed MRI scanner as “an MRI scanner that is not a mobile MRI scanner.” The 2019 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. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.” 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 projected patient origin.

County	Third Full FY of Operation following Project Completion (1/1/2023 – 12/31/2023)	
	Patients	% of Total
Wake	3,640	98.0%
Johnston	19	0.5%
Franklin	19	0.5%
Nash	19	0.5%
Out of Area	19	0.5%
Total	3,714	100.0%

Source: Section C.3, page 38.
 Totals may not foot due to rounding.

In Section C, page 39, and Section Q, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 40-53, 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 2019 SMFP (page 41).
- Availability of MRI scanners in Wake County (pages 42-45).
- Population growth and aging in the target area to be served (pages 45-48).
- MRI use rates (page 48).
- Access to MRI services (pages 48-50).

- Health status of the population in the Knightdale target area (pages 50-53).

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

- The 2019 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 utilizations including physician support.
- Increasing MRI use rate in Wake County.

Projected Utilization

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

Projected MRI Utilization

	2021	2022	2023
# of MRI scanners	1	1	1
Unweighted Procedures	2,071	3,154	4,269
Weighted Procedures	2,419	3,684	4,986

Source: Section Q, Form C, page 131 of the application.

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

- Step 1. Identify the Target Area and Population to be Served by MRI Equipment (pages 133-134).
- Step 2. Project MRI Scan Need for Population to be Served (page 135).
- Step 3. Determined Average State MRI Weighting Factor (page 136).
- Step 4. Determine Adjusted MRI Procedures for Target Area (page 136).
- Step 5. Determine Need for MRI Scanners in Target Area (page 137).
- Step 6. Determine Market Share and Unadjusted MRI Utilization (pages 138-139)
- Step 7. Determine In-migration from Outside Target Area for Raleigh Radiology Knightdale (page 140).
- Step 8. Calculate Adjusted MRI Procedures and Justify MRI Scanners for Raleigh Radiology Knightdale (pages 141-142).
- Step 9. Determine the Market Share of Wake County Represented by Target Area MRI Procedures (page 143).
- Step 10. Determine Target Area as Percent of Total Wake County Population (page 144).

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

- There was a need determination in the 2019 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.
- In Exhibit I.2, the applicant provided estimated physician referral letters estimating between 5,058 and 6,390 MRI referrals for the first operating year (CY2021). By Rule, the applicant only has to demonstrate that the proposed fixed MRI scanner would preform 4,805 by the end of the third year of operation (CY2023).
- The Knightdale area of Wake County is growing in population and there is no fixed MRI scanner in the Knightdale area.
- The applicant proposes to locate the fixed MRI scanner in an existing diagnostic center.

Access

In Section C.11, page 60, the applicant states, “*Raleigh Radiology, LLC accepts all patients, regardless of gender, gender preference, race, ethnicity, age, income, or disability status.*”

In Section L, page 114, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table

Payor Category	MRI Services as Percent of Total
Self-Pay	2.80%
Charity Care	1.45%
Medicare*	31.40%
Medicaid*	6.86%
Insurance*	55.52%
Other (specify)	1.97%
Total	100.00%

Source: Table on page 114 of the application.

*Includes any managed care plans.

The projected payor mix is reasonable and adequately supported because it is based on the historical experience of the applicant in providing MRI services from target zip codes and projecting that payor mix forward.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 following reasons:

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

J-11829-20/ Duke Radiology Green Level/ Develop one fixed MRI scanner

DUHS proposes to acquire one fixed MRI scanner creating a new non-hospital licensed diagnostic center, Duke Green Level, to be located within a medical office building currently being developed at 3208 Green Level W Road, Cary, Wake County.

Patient Origin

On page 149, the 2019 SMFP defines a fixed MRI scanner as “an MRI scanner that is not a mobile MRI scanner.” The 2019 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. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.” 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 projected patient origin.

County	Third Full FY of Operation following Project Completion (7/1/2024 – 6/30/2025)	
	Patients	% of Total
Wake	3,087	70.03%
Durham	451	10.23%
Chatham	257	5.83%
Orange	212	4.81%
Other NC	401	9.10%
Total	4,408	100.00%

Source: Section C.3, page 17.

Note: The applicant identified the patients by Zip Code and County. The project analyst totaled the patients by county.

Totals may not foot due to rounding.

In Section C, page 18, and Section Q, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 18-27, 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 2019 SMFP (pages 19-20).
- Growth in DUHS MRI volumes (pages 20-23).
- Enhanced access to non-hospital based services (page 23).
- Increased geographic access (pages 23-26).
- Coordination with other services at Duke Health at Green Level (pages 26-27).
- Growth in provider network (page 27).
- Benefits in discontinuing mobile MRI services (pages 27-28).

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

- The 2019 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

	2023	2024	2025
# of MRI scanners	1	1	1
Unweighted Procedures	1,927	3,121	4,408
Weighted Procedures	2,216	3,589	5,069

Source: Section Q, Form C.

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

- Step 1) Identify the Primary Service Area by Zip Code (Section Q, pages 1-2)
- Step 2) Calculate DUHS Share of Non-Emergent Outpatient MRI Volume for the Primary Service Area. (Section Q, page 3)
- Steps 3&4) Projected DUHS shift of cases from the primary service Zip Codes (page 3).
- Step 5) Project Incremental Growth (Section Q, page 4).
- Step 6) Project Shift in Cases from Outside the primary service area (Section Q, page 5)
- Step 7) Project In-migration (Section Q, page 5).
- Step 8) Apply a weighted average of 1.15/procedure (Section Q, page 5)

Projected MRI Utilization

		FY2023	FY2024	FY2025
a	Shifted Volume: from Primary Service Zip Codes	484	964	1,468
b	Incremental Volume: from Growth in Share from the Primary Service Zip Codes	1,214	1,819	2,484
c	Shifted Volume: from remainder of Wake County	54	54	54
d	Subtotal (a+b+c=d)	1,752	2,837	4,006
e	In-migration (10% of Row d)	175	284	401
	Unweighted Procedures	1,927	3,121	4,408
	Weighted Average	1.15	1.15	1.15
	Weighted Procedures	2,216	3,589	5,069
	Number of MRI Scanners	1	1	1

Source: Section Q, Form C.

Projected utilization is reasonable and adequately supported based on the following: (list your reasons or summarize your analysis)

- There was a need determination in the 2019 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.
- Projected in-migration of 10% is less than the approximately 17.5% in-migration experienced at DIHS Cary Parkway.
- The Weighted Average of 1.15 is less than the weighted average of outpatient MRI procedures performed at Cary Parkway at which DUHS provides MRI services utilizing a leased mobile MRI scanner.

Access

In Section C.11, page 32, the applicant states, “*There is no discrimination on the basis of race, ethnicity, age, gender, or disability. Policies to provide access to services by low income, medically indigent, uninsured, or underinsured patients are described and provided elsewhere in this application.*”

In Section L, page 69, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Category	MRI Services as Percent of Total
Self-Pay	1.6%
Charity Care	0.0%
Medicare*	37.8%
Medicaid*	3.9%
Insurance*	53.8%
Workers Compensation	0.3%
TRICARE	1.0%
Other (commercial, other government payors)	1.6%
Total	100.0%

Source: Table on page 69 of the application.

*Includes any managed care plans.

The projected payor mix is reasonable and adequately supported because it is based on “As a baseline for its payor mix for the non-emergent outpatient MRI procedures provided to patients from the identified zip codes in the primary service area in FY 19 (see Section Q). Based on input from DUHS Corporate Finance, the projections include an anticipated shift of 3.8% of private insurance patients to Medicare per year through FY 2022 to reflect the aging of the population and resulting utilization patterns of MRI services.”

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 following reasons:

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

J-11830-20/ Wake Radiology Cary/ Develop one fixed MRI scanner

Wake Radiology proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center, WR-Cary, located at 300 Ashville Avenue, Cary.

Patient Origin

On page 149, the 2019 SMFP defines a fixed MRI scanner as “an MRI scanner that is not a mobile MRI scanner.” The 2019 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. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.” 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 projected patient origin.

County	Third Full FY of Operation following Project Completion (1/1/2023 – 12/31/2023)	
	Patients	% of Total
Wake	3,937	89.0%
Harnett	94	2.1%
Chatham	61	1.4%
Lee	61	1.4%
Durham	59	1.3%
Other*	213	4.8%
Total	4,424	100.0%

Source: Section C.3, page 28.

*The counties and states included in the “Other” category are shown in the table on page 28 of the application.

Totals may not foot due to rounding.

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

Analysis of Need

In Section C, pages 29-42, 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 2019 SMFP (pages 29-32).
- The need for additional fixed MRI capacity within Wake Radiology (pages 32-37).
- The need for fixed MRI capacity at Wake Radiology Cary (pages 37-40).
- Wake County’s population growth and aging population (pages 40-42).

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

- The 2019 SMFP identifies the need for one additional fixed MRI scanner in Wake County.
- Population growth, particularly among the elderly is occurring in Wake County.
- Wake Radiology's historic MRI utilization.
- The applicant provides reasonable and adequately supported information to support its projected utilization including physician support.

Projected Utilization

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

Historical MRI Utilization

	CY2016	CY2017	2018	2019
# of MRI scanners	1	1	1	1
Unweighted Procedures	3,405	3,339	3,611	3,784
Weighted Procedures	3,884	3,794	4,064	4,367

Source: Section Q, Form C

Projected MRI Utilization

	Interim 2020	2021	2022	2023
# of MRI scanners	1	1	1	1
Unweighted Procedures	3,935	4,092	4,255	4,424
Weighted Procedures	4,541	4,722	4,910	5,106

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 three-year CAGR for weighted MRI scans based on its historical data for the WR-Cary facility as shown below:

	CY2016	CY2017	CY2018	CY2019*	CAGR
Unweighted Scan	3,405	3,339	3,611	3,784	
Weighted Scans	3,884	3,794	4,064	4,367	4.0%
Annual Growth**	na	-2.3%	7.1%	7.5%	

*CY2019 data based on March to August utilization annualized.

**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 (CY2019) of historical data for weighted MRI scans at the facility the applicant applied a 4.0% growth rate through the first three operating years (CY2021- CY2023) as shown in the table below:

	CY2019	CY2020	CY2021	CY2022	CY2023
Unweighted Scan	3,784	3,935	4,092	4,255	4,424
Weighted Scans	4,367	4,541	4,722	4,910	5,106
Annual Growth	na	4.0%	4.0%	4.0%	4.0%

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

In Form C Utilization- Assumptions and Methodology, page 1, the applicant states both that: #1) Wake Radiology entered into a joint venture with UNC REX Healthcare in late February 2019 and further state, in part, that *“As a result, fixed MRI utilization at Wake Radiology facilities, including Wake Radiology Cary, has increased since February 2019 and is expected to increase in the future.”*; and #2) that MRI scans for CY2019 are based on March to August utilization annualized.

Wake Radiology did not provide the actual historical number of MRI scans for two months; January 2019 and February 2019. Without the actual number of historical MRI scans for January 2019 and February 2019 the applicants annualized utilization for CY2019 is not reasonable. The Project Analyst notes that it is possible that the actual number of MRI scans at the WR-Cary facility was stagnant, exceptionally low or perhaps even non-existent. Furthermore, if the number of weighted MRI scans in CY2019 is questionable, the 4.0% CAGR growth calculation for CY2016 to CY2019 is also not reasonable.

The applicant projects 4,367 weighted MRI scans at the WR-Cary facility for CY 2019. The applicant also states that in CY2018 the WR-Cary facility performed 4,064 weighted MRI scans. From CY2018 to CY2019 the applicant has stated there was an increase of 303 weighted MRI scans [4367-4064 = 303 weighted MRI scans]. However, that also means if in January and February 2019, the months for which the applicant did not provide data for historic MRI scans, the facility, for any reason, performed just 303 less weighted MRI scans then there would have been no growth from CY2018 to CY2019.

The annualized MRI scans for CY2019 are based on data from March 2019 thru August 2019, however, it is not reasonable to apply this data retroactively to January 2019 and February 2019 as the applicant itself has stated that since the inception of the joint venture with UNC REX Healthcare, utilization of the MRI scanner in general has increased. That joint venture, and any benefits of that joint venture resulting in increased MRI scans would not reasonably apply to January 2019 and February 2019, a period of time when that joint venture was not in existence.

Further, outpatient with contrast scans are weighted at 1.4 in the calculation of adjusted scans as opposed to outpatient without contrast scans which are weighted at 1.0. The project analyst notes that at the WR-Cary facility outpatient with contrast scans had been declining each year

from CY2016 to CY2018: 1,198, 1,138, 1,132 respectively. However, in CY2019 the outpatient with contrast MRI scans increased by 326 scans from CY2018 or 456.4 adjusted scans [$326 \times 1.4 = 456.4$]. If the annualized MRI scans for CY2019 overstate the actual outpatient with contrast MRI scans for January 2019 and February 2019 that would have an impact based on a 1.4 weighted adjustment. This further calls into question as to why the applicant did not provide the actual historical MRI scan data for January 2019 and February 2019.

The project analyst notes that just an increase of 217 outpatient with contrast scans was needed to account for the 303 weighted MRI scan increase from CY2018 to CY2019 [$217 \times 1.4 = 303.8$].

In Step #2, the applicant simply applies 4.0% CAGR for weighted MRI scans that it calculated in Step #1 for CY2016 to CY2019. However, as stated above, it is not reasonable to project MRI scan data for January 2019 and February 2019 utilizing annualized MRI scan data based on MRI scans from March 2019 through August 2019 both because the actual, historic MRI scan data was available to be used and there was a change in circumstances starting March 2019 (the joint venture), which the applicant states has led to an increase in the number of MRI scans, which was not in existence for January 2019 and February 2019. Therefore, the correct CAGR for CY2016 through CY2019 cannot be ascertained and thus the projected utilization for the proposed fixed MRI scanner at WR-Cary cannot be determined based on the data provided as well as the lack of data provided.

Pursuant to The Criteria and Standards for Magnetic Resonance Imaging Scanners Rule 10A NCAC 14C .2703(b) the applicant is required to:

#1) demonstrate that the existing fixed MRI scanners which the applicant or a related entity (in this case UNC REX Healthcare) owns a controlling interest in the service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [10A NCAC 14C .2703(b)(1)]: the applicant did not provide this data. The project analyst notes that the applicant filed a Registration and Inventory of Medical Equipment Form which covered the time period of 10/1/2018 to 9/30/2019 for each of its existing fixed MRI scanners.

#2) demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in the service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [10A NCAC 14C .2703(b)(2)]: the applicant did not provide the historical data for MRI procedures performed on the applicants two existing mobile MRI scanners for January 2019 and February 2019 but rather relied on annualized data from March 2019 through August 2019.

The project analyst notes that the applicant filed a Registration and Inventory of Medical Equipment Form (R&I Form) which covered the time period of 10/1/2018 to 9/30/2019 for each of its existing mobile MRI scanners. The R&I Form covering 10/1/2018 to 9/30/2019 documented that one of the mobile MRI scanners performed 2,649.8 weighted MRI procedures and the other mobile MRI scanner performed 1,196 weighted MRI procedures for that 12-

month period. Therefore, for the 12-month period ending 9/30/2019 neither of the mobile MRI scanners in the service area performed an average of 3,328 weighted MRI procedures as required by 10A NCAC 14C .2703(b)(2).

Furthermore, in the applicant's Exhibit C.12-3 the applicant provided historic data for its two mobile MRI scanners documenting that one of the mobile MRI scanners performed 2,383 and 2,844 weighted MRI procedures for CY2018 and CY2019 respectively while the second mobile MRI scanner performed 1,803 and 2,033 weighted MRI procedures for CY2018 and CY2019 respectively. Thus, the applicant acknowledges that neither of the two mobile MRI scanners performed an average of 3,328 weighted MRI procedures in the most recent 12-month period for which the applicant has data and therefore the application is not in compliance with 10A NCAC 14C .2703(b)(2).

#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 the service area performed an average of 4,805 weighted MRI procedures in the third year of operation following completion of the proposed project[10A NCAC 14C .2703(b)(3)]: The applicant did not utilize the actual historical data for January 2019 and February 2019 in calculating the number of MRI procedures for CY2019 thus the number of MRI procedures for CY 2019 cited by the applicant for each of its existing fixed MRI scanners covered by this Rule is not reasonable and is not adequately supported. The applicant then relied on its stated number of MRI procedures for CY2019 to project utilization for each of its fixed MRI scanners for the third year of operation (CY2023) following completion of the proposed project. Since the projected utilization for all fixed MRI scanners for CY2023 relied on the data from CY2019 which was not reasonable and not adequately supported the projected utilization for all the fixed MRI scanners covered by this Rule is also not reasonable and not adequately supported.

In Section C, page 52 the applicant projects that in the third year (CY2023) following completion of the project its six fixed MRI scanners will perform 28,940 weighted MRI procedures for an average of 4,823 weighted MRI procedures $[28,940 / 6 = 4,823]$ which is greater than the 4,805 per MRI scanner average of weighted MRI procedures required by the Rule.

However, the minimum total weighted MRI procedures the 6 MRI scanners can perform in CY2023 and still be in compliance with this Rule is 28,830 $[4805 \times 6 = 28,830]$. The applicant projects that the 6 MRI scanners will perform 28,940 weighted scans in CY2023. That is only 110 weighted MRI scans [or 79 outpatient scans with contrast $[79 \times 1.4 = 110.6]$ weighted MRI scans] more than the minimum necessary to comply with this rule. Said differently, if the applicant's fixed MRI scanners performed, in total, just 78 less outpatient scans with contrast, the applicant would not conform to this Rule.

#4) demonstrate that the projected annual utilization of the proposed fixed MRI scanner is reasonably projected to perform 4,805 weighted MRI procedures in the third year of operation (CY2023) following completion of the proposed fixed MRI scanner will be located at a different site than the applicants other existing fixed MRI scanners [10A NCAC 14C

.2703(b)(4)]: the applicant’s projected adjusted MRI scans for the proposed fixed MRI scanner at WR-Cary are not reasonable and are not adequately supported. See the analysis above.

#5) demonstrate that the average annual utilization of the existing, approved and proposed mobile MRI scanners which the applicant or a related entity owns a controlling interest in the service area performed an average of 4,805 weighted MRI procedures in the third year of operation following completion of the proposed project[10A NCAC 14C .2703(b)(5)]: Again, the applicant did not utilize the actual historical data for January 2019 and February 2019 in calculating the number of MRI procedures for CY2019 thus the number of MRI procedures for CY 2019 cited by the applicant for each of its existing mobile MRI scanners covered by this Rule is not reasonable and is not adequately supported. The applicant then relied on its stated number of MRI procedures for CY2019 to project utilization for each of its mobile MRI scanners for the third year of operation (CY2023) following completion of the proposed project. Since the projected utilization for all mobile MRI scanners for CY2023 relied on the data from CY2019 which was not reasonable and not adequately supported the projected utilization for all the mobile MRI scanners covered by this Rule is also not reasonable and not adequately supported.

Access

In Section C.11, page 47, 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.*”

In Section L, page 81, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table

Payor Category	MRI Services as Percent of Total
Self-Pay	0.2%
Medicare*	43.3%
Medicaid*	1.2%
Insurance*	53.4%
Other (specify)	1.9%
Total	100.0%

Source: Table on page 81 of the application.

*Includes any managed care plans

The projected payor mix is reasonable and adequately supported because it is based on the historical experience of the facility in providing MRI services.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 projected utilization is not reasonable and is not adequately supported.

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

NA

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

EmergeOrtho

Raleigh Radiology-Cary

DUHS

NC

Raleigh Radiology-Knightdale

Wake Radiology

J-11820-19/ Raleigh Radiology Wake Forest/ Develop one fixed MRI scanner

PHSNC proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center. RR-Wake Forest, located at 839 Durham Road, Units A&B, Wake Forest.

In Section E, pages 53-55, 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 of a mobile MRI service at Wake Forest

- Develop the proposed fixed MRI scanner in another Wake County location
- Acquire a 1.5T MRI scanner

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- Maintaining the status quo of a mobile MRI scanner at Wake Forest would not address the need in the 2019 SMFP for an additional fixed MRI scanner in Wake County nor address the need for 3T MRI scans.
- 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.
- Acquiring a 1.5T MRI scanner is less effective because 3T MRI scans are charged the same as 1.5T MRI scans and produce higher resolution images, allow for more sophisticated imaging procedures and require shorter examination times.
- The proposed 3T MRI scanner at the Wake Forest location meets the stated need in the 2019 SMFP for an additional fixed MRI scanner in Wake County while meeting patient's needs for a high quality, cost-effective and conveniently located freestanding fixed 3T MRI scanner.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 for the reasons stated above.

J-11821-19/ EmergeOrtho, P.A./ Develop one fixed MRI scanner

EmergeOrtho proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center, EmergeOrtho, located at 3100 Duraleigh Road, Suite 100, Raleigh.

In Section E, pages 72-73, 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 of a mobile MRI service at the Duraleigh location
- Develop the proposed fixed MRI scanner in another EmergeOrtho Wake County location
- Acquire a 3.0T MRI scanner

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- Maintaining the status quo of a mobile MRI scanner at the Duraleigh location would not address the address the limitations of a mobile MRI scanner in terms of patient access, higher maintenance costs, and decreased productivity due to capacity constraints.
- Developing the proposed fixed MRI scanner in another EmergeOrtho Wake County location was determined to be less effective because no other location had the facility space and historical MRI utilization as the Duraleigh location.
- Acquiring a 3.0T MRI scanner was determined to less effective because of the higher cost for a 3.0T MRI scanner, the need for extensive construction and shielding which would add to the cost of the project and potential issues with artifacts, heat and noise in comparison to the 1.5T MRI scanner.
- The proposed 1.5T MRI scanner at the EmergeOrtho Duraleigh location meets the stated need in the 2019 SMFP for an additional fixed MRI scanner in Wake County, features a larger bore for increased patient access and comfort, has extensive support from referring physicians and allows for staffing and scheduling resulting in higher productivity.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 for the reasons stated above.

J-11825-19/ Raleigh Radiology Cary/ Develop one fixed MRI scanner

Raleigh Radiology-Cary proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center, RR-Cary, located at 150 Parkway Office Court, Suite 100, Cary.

In Section E, pages 78-82, 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
- Purchase a 1.5T MRI scanner
- Replace MRI scanner at Raleigh Radiology Blue Ridge
- Develop the project in a different area of Wake County
- Purchase the Alliance Scanner

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- Maintaining the status quo of a mobile MRI scanner at the RR-Cary facility would not address the need in the 2019 SMFP for an additional fixed MRI scanner in Wake County. Furthermore, it does not address the higher operating costs and less flexibility associated with leasing the mobile MRI scanner.
- Replacing the MRI scanner at Raleigh Radiology Blue Ridge is less effective because while the applicant would also like to replace the leased MRI scanner at Raleigh Radiology Blue Ridge there is a need determination for only one fixed MRI scanner in Wake County and the Raleigh Radiology Cary location is the more highly utilized location.
- Developing the proposed fixed MRI scanner in a different area of Wake County is less effective than the proposed project as the Raleigh Radiology Cary location is projected to be more highly utilized than any other Wake County location.
- Purchasing the mobile MRI scanner currently being leased from Alliance and utilized at the RR-Cary facility is not an effective alternative as Alliance will only sell all 28 of the MRI CON rights it owns in North Carolina in a single transaction.
- Purchasing a 1.5T MRI scanner is less effective because 3T MRI scans are charged the same as 1.5T MRI scans and produce higher resolution images, allow for more sophisticated imaging procedures and require shorter examination times.

- The proposed replacement of the leased 1.5T MRI scanner with a new owned 3.0T MRI scanner at the Raleigh Radiology Cary location is the most effective and least costly alternative in that the proposed project meets the stated need in the 2019 SMFP for an additional fixed MRI scanner in Wake County while meeting patient's needs for a high quality, cost-effective and conveniently located freestanding fixed 3.0T MRI scanner.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 for the reasons stated above.

J-11826-19/Raleigh Radiology Knightdale/ Develop one fixed MRI scanner

Raleigh Radiology-Knightdale proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center, RR-Knightdale, located at 1101 Great Falls Court, Knightdale.

In Section E, pages 78-80, 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
- Replace the MRI scanner at a current Raleigh Radiology location
- Develop the project in a different area of Wake County
- Purchase a 3.0 Tesla MRI scanner

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need because in Section E, page 79, the applicant states that the proposal to develop a fixed MRI scanner at RR-Knightdale is not the most effective and least costly alternative but rather the second least costly and most effective alternative. On page 79 the applicant states "*Raleigh Radiology decided that replacing the MRI at Cary is a less costly and more effective alternative. ... Should the Agency reject the Raleigh Radiology Care application, Raleigh Radiology determined that a new "fixed" MRI at Raleigh Radiology Knightdale is the next least costly and most effective alternative.*"

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11829-20/ Duke Radiology Green Level/ Develop one fixed MRI scanner

DUHS proposes to acquire one fixed MRI scanner to be located at the proposed new non-hospital licensed diagnostic center, Duke Green Level, to be located within a medical office building currently being developed at 3208 Green Level W Road, Cary, Wake County.

In Section E, page 43, 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
- Develop the project in a different area of Wake County
- Contract with a mobile provider

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- Maintaining the status quo would not address the growing need for DUHS imaging services.
- Developing the proposed fixed MRI scanner in a different area of Wake County is less effective because no other location is superior to the proposed location.
- Contracting with a mobile provider is a less effective alternative because contracting for mobile MRI services is not the most cost-effective or efficient method for providing full-time MRI services.
- The proposed purchase of a 1.5T MRI scanner is the most effective and least costly alternative in that the proposed project meets the stated need in the 2019 SMFP for an additional fixed MRI scanner in Wake County while meeting patient needs for a high quality, cost-effective and conveniently located freestanding fixed MRI scanner.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 for the reasons stated above.

J-11830-20/ Wake Radiology Cary/ Develop one fixed MRI scanner

Wake Radiology proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center, WR-Cary, located at 300 Ashville Avenue, Cary.

In Section E, pages 60-61, 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
- Develop the project in a different area of Wake County

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 projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- 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 the most effective alternative.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Remarks made at the public hearing
- 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.

- (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
EmergeOrtho
Raleigh Radiology Cary
Raleigh Radiology Knightdale
DUHS

NC
Wake Radiology

J-11820-19/ Raleigh Radiology Wake Forest/ Develop one fixed MRI scanner

PHSNC proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center. RR-Wake Forest, located at 839 Durham Road, Units A&B, Wake Forest.

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	\$0.00
Construction Costs	\$495,988
Miscellaneous Costs	\$1,678,810
Total	\$2,174,798

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

In Section F, pages 58-59, the applicant projects there will be no start-up or initial operating expenses for the project because it currently staffs and operates the facility’s existing mobile MRI service.

Availability of Funds

In Section F, page 57, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing		
Type	PHSNC	Total
Loans	\$2,027,998	\$2,027,998
Accumulated reserves or OE *	\$146,800	\$146,800
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$2,174,798	\$2,174,798

* OE = Owner's Equity

In Section F, page 58, the applicant states that it will use both a commercial loan and cash reserves to fund the capital costs. Exhibit 7 contains a letter dated October 31, 2019 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 October 31, 2019 showing \$5.1 million. Exhibit 7 also includes a loan proposal from GE Healthcare Equipment Finance in the amount of \$2,027,998. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

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

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Procedures*	3,680	4,172	4,685
Total Gross Revenues (Charges)	\$6,773,965	\$7,679,676	\$8,624,545
Total Net Revenue	\$1,803,374	\$2,044,493	\$2,296,037
Average Net Revenue per Procedure*	\$490	\$490	\$490
Total Operating Expenses (Costs)	\$1,354,908	\$1,579,933	\$1,749,875
Average Operating Expense per Procedure*	\$368	\$379	\$374
Net Income	\$448,465	\$464,560	\$546,163

Source: Section Q, Form F.2 for MRI Service Component.

*Unweighted procedures

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application

for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

J-11821-19/ EmergeOrtho, P.A./ Develop one fixed MRI scanner

EmergeOrtho proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center, EmergeOrtho, located at 3100 Duraleigh Road, Suite 100, Raleigh.

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	\$0.00
Construction Costs	\$620,865
Miscellaneous Costs	\$1,352,232
Total	\$1,973,097

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

In Section F, pages 76-77, the applicant projects there will be no start-up or initial operating expenses for the project because it currently staffs and operates the facility's existing mobile MRI service.

Availability of Funds

In Section F, page 75, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing		
Type	EmergeOrtho, PA	Total
Loans	\$1,973,097	\$1,973,097
Accumulated reserves or OE *		
Bonds		
Other (Specify)		
Total Financing	\$1,973,097	\$1,973,097

* OE = Owner's Equity

In Section F, page 76, the applicant states that the capital needs of the MRI project will be funded by a loan. Exhibit F.2 contains a loan proposal, with terms, and dated November 6, 2019 from the Senior Vice President of First Citizens Bank in the amount of \$1,973,097. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposed project.

Financial Feasibility

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

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Procedures*	3,603	4,315	5,078
Total Gross Revenues (Charges)	\$4,323,600	\$5,178,000	\$6,093,600
Total Net Revenue	\$1,936,973	\$2,319,744	\$2,729,933
Average Net Revenue per Procedure*	\$538	\$538	\$538
Total Operating Expenses (Costs)	\$1,044,681	\$1,227,459	\$1,305,239
Average Operating Expense per Procedure*	\$290	\$285	\$257
Net Income	\$892,292	\$1,092,285	\$1,424,694

*Unweighted procedures

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

J-11825-19/ Raleigh Radiology Cary/ Develop one fixed MRI scanner

Raleigh Radiology-Cary proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center, RR-Cary, located at 150 Parkway Office Court, Suite 100, Cary.

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	\$0.00
Construction Costs	\$415,541
Miscellaneous Costs	\$2,488,611
Total	\$2,904,152

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

In Section F, page 87, the applicant projects there will be no start-up or initial operating expenses for the project because it currently staffs and operates the facility’s existing mobile MRI service.

Availability of Funds

In Section F, page 84, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Raleigh Radiology, LLC	Total
Loans	\$2,905,000	\$2,905,000
Accumulated reserves or OE *		
Bonds		
Other (Specify)		
Total Financing	\$2,905,000	\$2,905,000

* OE = Owner's Equity

In Section F, pages 84-85, 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 October 25, 2019 from Branch Banking and Trust Company with the loan amount being not to exceed \$3.0 million. Exhibit F.2 also includes a letter dated November 15, 2019 from the Chief Operating Officer of Raleigh Radiology, LLC committing up to \$3.0 million in funds from the loan from Branch Banking and Trust Company for the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposed project.

Financial Feasibility

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

	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
Total Procedures*	6,684	6,815	6,946
Total Gross Revenues (Charges)	\$10,381,190	\$10,584,462	\$10,788,293
Total Net Revenue	\$3,045,344	\$2,993,012	\$2,935,153
Average Net Revenue per Procedure*	\$456	\$439	\$423
Total Operating Expenses (Costs)	\$1,878,831	\$2,032,935	\$2,021,044
Average Operating Expense per Procedure*	\$281	\$298	\$291
Net Income	\$1,166,513	\$960,077	\$914,109

*Unweighted procedures

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

J-11826-19/Raleigh Radiology Knightdale/ Develop one fixed MRI scanner proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center, RR-Knightdale, located at 1101 Great Falls Court, Knightdale.

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	\$0.00
Construction Costs	\$452,879
Miscellaneous Costs	\$2,117,076
Total	\$2,569,955

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

In Section F, page 84, the applicant projects that start-up costs will be \$95,977, and initial operating expenses will be \$204,181, for a total working capital cost of \$300,157. In Section Q, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, page 82, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Raleigh Radiology, LLC	Total
Loans	\$2,569,955	\$2,569,955
Accumulated reserves or OE *		
Bonds		
Other (Specify)		
Total Financing	\$2,569,955	\$2,569,955

* OE = Owner's Equity

In Section F, page 85, 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
(a)	Loans	\$300,157
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	Total	\$300,157

In Section F, pages 82 and 85, the applicant states that the capital costs and working capital needs of the proposed project will be funded by a loan.

Exhibit F.2 contains a loan proposal, with terms, and dated November 8, 2019 from Branch Banking and Trust Company with the loan amount not to exceed \$3.0 million to cover the capital and working capital costs of the proposed project. Exhibit F.2 also includes a letter dated November 15, 2019 from the Chief Operating Officer of Raleigh Radiology, LLC committing up to \$2.0 million in funds from the loan from Branch Banking and Trust Company for the proposed project and \$500,000 from Raleigh Radiology for working capital from ongoing operations. The Project Analyst notes that the letter from the Chief Operating Officer committing funds from the \$3.0 million loan only references committing up to \$2.0 million of the loan funds. The Project Analyst notes that this is most likely a typo and, if this application had been approvable this issue could have been conditioned.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposed project.

Financial Feasibility

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

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Procedures*	2,071	3,154	4,269
Total Gross Revenues (Charges)	\$3,164,451	\$4,818,735	\$6,522,524
Total Net Revenue	\$880,638	\$1,312,196	\$1,737,496
Average Net Revenue per Procedure*	\$425	\$416	\$407
Total Operating Expenses (Costs)	\$937,089	\$1,307,227	\$1,482,189
Average Operating Expense per Procedure*	\$453	\$415	\$347
Net Income	(\$56,451)	\$4,969	\$255,306

*Unweighted procedures

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

J-11829-20/ Duke Radiology Green Level/ Develop one fixed MRI scanner

DUHS proposes to acquire one fixed MRI scanner to be located at the proposed new non-hospital licensed diagnostic center, Duke Green Level, to be located within a medical office building currently being developed at 3208 Green Level W Road, Cary, 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	\$0.00
Construction Costs	\$1,234,618
Miscellaneous Costs	\$2,461,482
Total	\$3,696,100

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

In Section F, pages 45-47 the applicant projects there will be no start-up or initial operating expenses for the project because the facility will be operated as part of the Duke University Health System and will not have separate financial statements. [On page 47 the applicant notes for informational purposes that operating expenses for the first six months of the first project year would be \$447,076 and “start-up costs” would be \$50,000 for a total of \$497,076 in working capital.]

Availability of Funds

In Section F, page 44, the applicant states that the capital cost will be funded, as shown in the table below.

Type	DUHS	Total
Loans		
Accumulated reserves or OE *	\$3,696,100	\$3,696,100
Bonds		
Other (Specify)		
Total Financing	\$3,696,100	\$3,696,100

* OE = Owner’s Equity

In Section F, pages 44-45, the applicant states that the capital costs for the project will be funded by accumulated reserves of DUHS. In Section F, pages 46-47, the applicant states that CFO has documented at least \$2.0 million for this project beyond the projected capital cost. Exhibit F.2 contains a letter dated November 11, 2019 from the Chief Financial Officer for DUHS documenting that the funds will be made available for the capital costs of the project. Exhibit F.2 also contains the audited financial statements for DUHS which indicated the health system had \$251 million in cash and cash equivalents, \$6.6 billion in assets, and \$3.78 billion in net assets, as of June 30, 2019.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposed project.

Financial Feasibility

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

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Procedures*	1,927	3,121	4,048
Total Gross Revenues (Charges)	\$2,890,138	\$4,773,322	\$6,874,811
Total Net Revenue	\$1,208,111	\$1,992,899	\$2,866,862
Average Net Revenue per Procedure*	\$627	\$639	\$708
Total Operating Expenses (Costs)	\$895,369	\$1,157,064	\$1,495,477
Average Operating Expense per Procedure*	\$465	\$371	\$369
Net Income	\$312,742	\$835,836	\$1,371,385

*Unweighted procedures

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

J-11830-20/ Wake Radiology Cary/ Develop one fixed MRI scanner

Wake Radiology proposes to acquire one fixed MRI Scanner to be located at the existing non-hospital licensed diagnostic center, WR-Cary, located at 300 Ashville Avenue, Cary.

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	\$277,650
Miscellaneous Costs	\$2,204,798
Total	\$2,482,448

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

In Section F, pages 63-64, the applicant projects there will be no start-up or initial operating expenses for the project because it currently staffs and operates the facility’s existing mobile MRI service.

Availability of Funds

In Section F, page 62, 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	Total
Loans	\$2,482,448	\$2,482,448
Accumulated reserves or OE *		
Bonds		
Other (Specify)		
Total Financing	\$2,482,448	\$2,482,448

* OE = Owner’s Equity

In Section F, page 62, 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 November 6, 2019 from First Citizens Bank to WR Imaging, with a loan amount of \$2,482,448.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposed project.

Financial Feasibility

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

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Procedures*	4,092	4,255	4,424
Total Gross Revenues (Charges)	\$6,782,024	\$7,263,797	\$7,779,794
Total Net Revenue	\$2,603,526	\$2,788,472	\$2,986,556
Average Net Revenue per Procedure*	\$636	\$655	\$675
Total Operating Expenses (Costs)	\$1,420,628	\$1,585,361	\$1,610,476
Average Operating Expense per Procedure*	\$347	\$373	\$364
Net Income	\$1,182,897	\$1,203,111	\$1,376,080

*Unweighted procedures

However, the assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable and adequately supported because projected utilization is questionable. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, since projected revenues and expenses are based at least in part on projected utilization, projected revenues and expenses 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.

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

C
 All Applications

Table 9R, page 172 of the 2019 SMFP, provides the projected need determination for one additional fixed MRI scanner in Wake County, based on the standard methodology used to determine need for fixed MRI scanners in the 2019 SMFP, pages 151-152.

On page 149, the 2019 SMFP defines a fixed MRI scanner as “an MRI scanner that is not a mobile MRI scanner.” The 2019 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. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.” 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 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) 2018 *
Duke Radiology Holly Springs (Duke University Health System) **	1	0
Duke Raleigh Hospital (Duke University Health System)	2	13,892
Raleigh Neurology Associates (Raleigh Neurology Associates)	1	5,634
Raleigh Neurology Imaging (Alliance)	1	5,988
Raleigh Radiology – Blue Ridge (Alliance)	1	6,004
Raleigh Radiology – Cary (Alliance) ^	1	7,511
Raleigh Radiology – Cedarhurst (Pinnacle)	1	8,111
Rex Hospital – Main (UNC Health System)	2	11,525
Rex Hospital – UNC Rex Health Care of Cary (UNC Health System)	1	532
The Bone and Joint Surgery Center (Bone & Joint) ^^	1	106
Wake Radiology – Garner (Alliance)	1	3,300
Wake Radiology (Wake Radiology)	1	3,445
Wake Radiology Diagnostic Imaging (Alliance)	1	4,123
Wake Radiology Raleigh MRI Center (Wake Radiology)	1	3,445
WakeMed (WakeMed)	2	12,949
WakeMed Cary Hospital (WakeMed)	1	4,855
2019 Need Determination #	1	0
Total	20	91,420

Source: Table 17E-1 in the Proposed 2020 SMFP.

* October 1, 2017 to September 30, 2018.

** Under development.

^ In the version of Table 17E-1 posted on the Agency’s website on or about July 1, 2019, this site was incorrectly classified as a mobile site. This MRI scanner is “permanently” installed.

^^ The first replacement MRI scanner was damaged beyond repair in January 2018. Thus, it was only in operation approximately 3 months during FFY 2018 (October through December).

Currently under review. There are six applications.

The 19 existing and approved fixed MRI scanners are owned by the following entities:

- Alliance (5 scanners)
- Duke University Health System (3 scanners)
- UNC Health System (3 scanners)
- WakeMed (3 scanners)
- Wake Radiology (2 scanners)

- Bone & Joint (1 scanner)
- Raleigh Neurology Associates (1 scanner)
- Pinnacle (1 scanner)

J-11820-19/ Raleigh Radiology Wake Forest/ Develop one fixed MRI scanner

PHSNC proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center, RR-Wake Forest, located at 839 Durham Road, Units A&B, Wake Forest.

In Section G, pages 65-66, 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 2019 SMFP, the State ... has determined a need for one additional fixed MRI scanner in Wake County.

PHSNC is an important freestanding outpatient diagnostic imaging provider in Wake County. ... PHSNC's MRI service is needed by referring providers to aid them in diagnosing and treating their patients' illnesses or conditions. Please see Exhibit I.2 for letters of support from referring physicians for this proposed Wake Forest fixed MRI scanner.”

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 2019 SMFP for one additional fixed MRI scanner in Wake County.
- 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
- Remarks made at the public hearing
- 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-11821-19/ EmergeOrtho, P.A./ Develop one fixed MRI scanner

EmergeOrtho proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center, EmergeOrtho, located at 3100 Duraleigh Road, Suite 100, Raleigh.

In Section G, pages 84-85, 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:

“The 2019 State Medical Facilities Plan includes a methodology for determining the need for additional fixed MRI Scanners by service area. Application of the need methodology identifies the need for one additional fixed MRI Scanner in the Wake County MRI Service Area...”

The 2019 SMFP takes into consideration all MRI utilization performed on the existing MRI scanners and includes the pending MRI need determinations that were included in the 2016 SMFP.”

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 2019 SMFP for one additional fixed MRI scanner in Wake County.
- 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
- Remarks made at the public hearing
- 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-11825-19/ Raleigh Radiology Cary/ Develop one fixed MRI scanner

Raleigh Radiology-Cary proposes to acquire one fixed MRI Scanner to be located at the existing non-hospital licensed diagnostic center, RR-Cary, located at 150 Parkway Office Court, Suite 100, Cary.

In Section G, pages 91-95, 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:

“...the applicant intends to have only one MRI scanner at RR Cary. When the proposed new MRI scanner becomes operational, Raleigh Radiology, LLC will discontinue any MRI lease for this site, hence all RRCary MRI service will transfer immediately to new MRI equipment.”

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 2019 SMFP for one additional fixed MRI scanner in Wake County.
- 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
- Remarks made at the public hearing
- 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-11826-19/Raleigh Radiology Knightdale/ Develop one fixed MRI scanner

Raleigh Radiology-Knightdale proposes to acquire one fixed MRI Scanner to be located at the approved but not operational non-hospital licensed diagnostic center, RR-Knightdale, located at 1101 Great Falls Court, Knightdale.

In Section G, pages 90-94, 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:

“The project is a response to Need Determination in the 2019 SMFP for one new fixed MRI in Wake County. This proposal will not result in unnecessary duplication of existing MRI services in the service area.”

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 2019 SMFP for one additional fixed MRI scanner in Wake County.
- 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
- Remarks made at the public hearing
- 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-11829-20/ Duke Radiology Green Level/ Develop one fixed MRI scanner

DUHS proposes to acquire one fixed MRI scanner creating a new non-hospital licensed diagnostic center, Duke Green Level, to be located within a medical office building currently being developed at 3208 Green Level W Road, Cary, Wake County.

In Section G, page 51, 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:

“The state planning process embodied in the 2019 SMFP determined that the service area needs an incremental fixed MRI scanner, supporting the conclusion that the incremental MRI scanner will not unnecessarily duplicate any existing or approved facilities.”

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 2019 SMFP for one additional fixed MRI scanner in Wake County.
- 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
- Remarks made at the public hearing
- 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-11830-20/ Wake Radiology Cary/ Develop one fixed MRI scanner

Wake Radiology proposes to acquire one fixed MRI Scanner to be located at the existing non-hospital licensed diagnostic center, WR-Cary, located at 300 Ashville Avenue, Cary.

In Section G, page 68-69, 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:

“The proposed project involves the development of a fixed MRI scanner at Wake Radiology Cary, which is in response to a need determination in the 2019 SMFP for an additional fixed MRI scanner to be located in Wake County. Thus, the 2019 SFMP has determined that additional MRI capacity is needed in Wake 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 2019 SMFP for one additional fixed MRI scanner in Wake County.
- 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
- Remarks made at the public hearing
- 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.

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

C
All Applications

J-11820-19/ Raleigh Radiology Wake Forest/ Develop one fixed MRI scanner

In Section Q, Form H, the applicant provides current and 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 costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 68-69, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I.3, page 72, the applicant identifies the current medical director. In Exhibit H.1, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 for the reasons stated above.

J-11821-19/ EmergeOrtho, P.A./ Develop one fixed MRI scanner

In Section Q, Form H, the applicant provides current and 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 costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 86-87, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I.3, page 90, the applicant identifies the current medical director. In Exhibit I.3, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 for the reasons stated above.

J-11825-19/ Raleigh Radiology Cary/ Develop one fixed MRI scanner

In Section Q, Form H, the applicant provides current and 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 costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 98-99, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I.3, page 103, the applicant identifies the current medical director. In Exhibit I.2, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 for the reasons stated above.

J-11826-19/Raleigh Radiology Knightdale/ Develop one fixed MRI scanner

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 costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 96-97, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I.3, page 101, the applicant identifies the current medical director. In Exhibit I.2, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 for the reasons stated above.

J-11829-20/ Duke Radiology Green Level/ Develop one fixed MRI scanner

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 costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 53-54, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Exhibit I.3, the applicant provides a letter from Dr. Ted Boyse indicating an interest in serving as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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 for the reasons stated above.

J-11830-20/ Wake Radiology Cary/ Develop one fixed MRI scanner

In Section Q, Form H, the applicant provides current and 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 costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 70-71, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I.3, page 73, the applicant identifies the current medical director. In Exhibit I.3, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Remarks made at the public hearing
- 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 for the reasons stated above.

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

C

All Applications

J-11820-19/ Raleigh Radiology Wake Forest/ Develop one fixed MRI scanner

In Section I, page 70, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Patient Scheduling
- Human resources/payroll
- Housekeeping/linens
- Accounting and billing
- Medical records
- Staff education
- Infection control
- Quality and performance improvement
- Information technology
- Equipment maintenance

On page 70, the applicant adequately explains how each ancillary and support service is or will be made available.

In Section I.2, page 70, 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 adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11821-19/ EmergeOrtho, P.A./ Develop one fixed MRI scanner

In Section I, page 88, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Business office
- Management
- Accounting
- Information systems
- Human resources
- Medical director
- Radiologist interpretation
- Scheduling and pre-procedure registration
- Medical waste disposal
- Housekeeping
- Facility maintenance
- Transporter
- MRI technologist

On page 88, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1.

In Section I.2, page 89, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit C.4.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11825-19/ Raleigh Radiology Cary/ Develop one fixed MRI scanner

In Section I, page 100, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Medical records
- Scheduling
- Administration
- Patient billing and financial services
- Pharmacy
- IT services
- Physician and physicist services
- General maintenance
- Housekeeping
- Reception/front desk
- MRI maintenance

On pages 101-102, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits F.1, I.1 and I.2.

In Section I, page 102, 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 adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing

- 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-11826-19/Raleigh Radiology Knightdale/ Develop one fixed MRI scanner

In Section I, page 98, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Medical records
- Scheduling
- Administration
- Patient billing and financial services
- Pharmacy
- IT services
- Physician and physicist services
- General maintenance
- Housekeeping
- Reception/front desk
- MRI maintenance

On pages 99-100, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits F.1, I.1 and I.2.

In Section I, page 100, 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 adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11829-20/ Duke Radiology Green Level/ Develop one fixed MRI scanner

In Section I, page 55, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Quality control
- Medical records
- Clinical engineering
- Administration
- Business office/registration
- Laundry/housekeeping
- Materials management

On page 55, the applicant adequately explains how each ancillary and support service is or will be made available.

In Section I, page 56, the applicant describes its efforts to develop relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11830-20/ Wake Radiology Cary/ Develop one fixed MRI scanner

In Section I, page 72, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Image interpretation
- Human resources
- Marketing
- Quality improvement
- Billing and collections

- Contract negotiations
- Management

On page 72, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1.

In Section I.2, page 72, 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 adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

- (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

None of the applicants 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, none of the applicants 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-11820-19/ Raleigh Radiology Wake Forest/ Develop one fixed MRI scanner

In Section K, page 75, the applicant states that the project involves renovating 1,255 square feet of existing space. Line drawings are provided in Exhibit K.1.

In Section K.3(a), page 75, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

In Section K.3(b), pages 75-76, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

In Section K.3(c), page 76, 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
- Remarks made at the public hearing
- 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-11821-19/ EmergeOrtho, P.A./ Develop one fixed MRI scanner

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

In Section K.3(a), pages 93-94, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

In Section K.3(b), page 94, 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.

In Section K.3(b), page 94, 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
- Remarks made at the public hearing
- 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-11825-19/ Raleigh Radiology Cary/ Develop one fixed MRI scanner

In Section K, page 106, the applicant states that the project involves renovating 1,058 square feet of existing space. Line drawings are provided in Exhibit K.2.

In Section K.3(a), page 107, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibits F.1 and I.2.

In Section K.3(b), page 108, 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 and provides supporting documentation in Exhibits F.3 and C.4.

In Section B.11, pages 29-30, and Section K.3(c), page 108, 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
- Remarks made at the public hearing
- 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-11826-19/Raleigh Radiology Knightdale/ Develop one fixed MRI scanner

In Section K, page 104, the applicant states that the project involves renovating 1,061 square feet of approved, non-operational space. Line drawings are provided in Exhibit K.2.

In Section K.3(a), pages 105-106, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibits I.2 and K.2.

In Section K.3(b), page 106, 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.

In Section B.11, pages 28-29, and Section K.3(c), page 106, 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
- Remarks made at the public hearing
- 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-11829-20/ Duke Radiology Green Level/ Develop one fixed MRI scanner

In Section K, page 59, the applicant states that the project involves renovating 3,295 square feet of existing space. Line drawings are provided in Exhibit K.2.

In Section K.3(a), pages 59-60, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibits F.1(a).

In Section K.3(b), page 60, 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.

In Section K.3(c), pages 60-61, 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
- Remarks made at the public hearing
- 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-11830-20/ Wake Radiology Cary/ Develop one fixed MRI scanner

In Section K, page 75, the applicant states that the project involves renovating 734 square feet of existing space. Line drawings are provided in Exhibit C.1-1.

In Section K.3(a), page 75 the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

In Section K.3(b), page 76, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

In Section K.3(c), page 76, 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
- Remarks made at the public hearing
- 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.

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

C
PHSNC
EmergeOrtho
Raleigh Radiology-Cary
Wake Radiology

NA
Raleigh Radiology-Knightdale
DUHS

J-11820-19/ Raleigh Radiology Wake Forest/ Develop one fixed MRI scanner

In Section L, page 81, the applicant provides the historical payor mix during CY2018 for the existing mobile MRI services at the existing RR-Wake Forest facility, as shown in the table below.

Payor Category	Mobile MRI Services as Percent of Total
Self-Pay/Charity Care	1.1%
Medicare*	23.1%
Medicaid*	3.4%
Insurance*	62.2%
Workers Compensation	6.9%
Other (government)	3.4%
Total	100.0%

Source: Table on page 81 of the application.

*Includes any managed care plans.

In Section L, page 80, 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	80.2%	51.3%
Male	19.7%	48.7%
Unknown	0.1%	0.00%
64 and Younger	73.7%	88.4%
65 and Older	26.3%	11.6%
American Indian	*	0.8%
Asian	*	7.5%
Black or African-American	*	21.0%
Native Hawaiian or Pacific Islander	*	0.1%
White or Caucasian	*	60.3%
Other Race	*	10.3%
Declined / Unavailable	*	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11821-19/ EmergeOrtho, P.A./ Develop one fixed MRI scanner

In Section L, page 98, the applicant provides the historical payor mix during CY2018 for the existing Duraleigh mobile MRI services at the existing facility, as shown in the table below.

Payor Category	Duraleigh Mobile MRI Services as Percent of Total
Self-Pay	2.00%
Charity Care	0.15%
Medicare*	22.67%
Medicaid*	6.80%
Insurance*	56.80%
Workers Compensation	7.46%
Tricare	4.11%
Total	100.00%

Source: Table on page 98 of the application.

*Includes any managed care plans.

In Section L, page 97, 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	54.0%	51.3%
Male	46.0%	48.7%
Unknown	0.0%	0.0%
64 and Younger	78.0%	88.8%
65 and Older	22.0%	11.2%
American Indian	0.2%	0.8%
Asian	1.0%	7.2%
Black or African-American	14.0%	21.1%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	72.0%	68.4%
Other Race	12.7%	12.7%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Remarks made at the public hearing
- 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-11825-19/ Raleigh Radiology Cary/ Develop one fixed MRI scanner

In Section L, page 112, the applicant provides the historical payor mix during CY2018 for the MRI services at the existing facility, as shown in the table below.

Payor Category	MRI Services as Percent of Total
Self-Pay	2.73%
Charity Care	0.74%
Medicare*	23.51%
Medicaid*	1.77%
Insurance*	67.56%
Other (specify)	3.68%
Total	100.00%

Source: Table on page 112 of the application.

*Includes any managed care plans.

In Section L, page 111, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during 10/1/2018-9/30/2019	Percentage of the Population of the Service Area
Female	na	51.3%
Male	na	48.7%
Unknown	na	na
64 and Younger	74.9%	88.4%
65 and Older	25.1%	11.6%
American Indian	na	0.8%
Asian	na	7.5%
Black or African-American	na	21.0%
Native Hawaiian or Pacific Islander	na	0.10%
White or Caucasian	na	68.1%
Other Race	na	3.3%
Declined / Unavailable	na	na

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11826-19/Raleigh Radiology Knightdale/ Develop one fixed MRI scanner

Raleigh Radiology-Knightdale is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

J-11829-20/ Duke Radiology Green Level/ Develop one fixed MRI scanner

Duke Green Level is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

J-11830-20/ Wake Radiology Cary/ Develop one fixed MRI scanner

In Section L, page 80, the applicant provides the historical payor mix during CY2018 for the MRI services at the existing facility, as shown in the table below.

Payor Category	MRI Services as Percent of Total
Self-Pay	0.2%
Medicare*	37.5%
Medicaid*	1.4%
Insurance*	59.0%
Other (specify)	1.9%
Total	100.0%

Source: Table on page 80 of the application.

*Includes any managed care plans.

In Section L, page 79, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during Last Full Fiscal Year	Percentage of the Population of the Service Area
Female	81.6%	51.3%
Male	18.4%	48.7%
Unknown		
64 and Younger	66.3%	88.4%
65 and Older	33.7%	11.6%
American Indian		0.8%
Asian		7.5%
Black or African-American		21.0%
Native Hawaiian or Pacific Islander		0.1%
White or Caucasian		68.1%
Other Race		2.5%
Declined / Unavailable		0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

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

C
 All Applications

J-11820-19/ Raleigh Radiology Wake Forest/ Develop 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 81, the applicant states that it has no obligations for uncompensated care or community services, or access by minorities and handicapped persons. On page 81 the applicant states, "*PHSNC is committed to caring for the local community. ... PHSNC offers self-pay discounts on all procedures for uninsured patients, and has annual pledge agreements with Project Access of Wake County to provide free imaging. ... PHSNC does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay.*"

In Section L, page 82, 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
- Remarks made at the public hearing
- 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-11821-19/ EmergeOrtho, P.A./ Develop 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 98, the applicant states that it has no obligations for uncompensated care or community services, or access by minorities and handicapped persons. On page 100 the applicant states, "*EmergeOrtho will not discriminate against anyone due to age, race, color, ethnicity, religion, gender, disability, or ability to pay.*"

In Section L, page 98, 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
- Remarks made at the public hearing
- 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-11825-19/ Raleigh Radiology Cary/ Develop 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 113, the applicant states that it has no obligations for uncompensated care or community services, or access by minorities and handicapped persons. On page 117, the applicant states, "*Raleigh Radiology has also committed to provide MRI services to patients referred to its location by Project Access. ... Raleigh Radiology determines need for transportation. It has made arrangements with Community Care of North Carolina to provide transportation to qualified persons who need assistance through CCPN.*"

In Section L, page 113, 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
- Remarks made at the public hearing
- 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-11826-19/Raleigh Radiology Knightdale/ Develop 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 113, the applicant states that it has no obligations for uncompensated care or community services, or access by minorities and handicapped persons. On page 118, the applicant states, "*Raleigh Radiology has also committed to provide MRI services to patients referred to its location by Project Access of Wake County.*"

In Section L, page 113, the applicant states that during the last five years no patient civil rights access complaints have been filed against Raleigh Radiology, LLC or any other parties related to this entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11829-20/ Duke Radiology Green Level/ Develop one fixed MRI scanner

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 67-68, the applicant states that it has no obligations for uncompensated care or community services, or access by minorities and handicapped persons but that DUHS provides services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor.

In Section L.2, pages 68-69, the applicant states that during the last five years four patient civil rights access complaints have been filed against DUHS. The applicant reports that three have been closed without further investigation and one complaint is pending.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11830-20/ Wake Radiology Cary/ Develop 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 80, the applicant states that it has no obligations for uncompensated care or community services, or access by minorities and handicapped persons. On page 82, the applicant states, "*Wake*

Radiology does not deny care to any individual based on his or her ability to pay or services, nor does it require financial payment prior to rendering services.”

In Section L, page 81, 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
- Remarks made at the public hearing
- 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-11820-19/ Raleigh Radiology Wake Forest/ Develop one fixed MRI scanner

In Section L, page 82, the applicant projects the following payor mix for the proposed services during the third full fiscal year (CY2023) of operation following completion of the project, as shown in the table below.

Payor Category	MRI Services as Percent of Total
Self-Pay	1.1%
Medicare*	23.1%
Medicaid*	3.4%
Insurance*	62.2%
Workers Compensation	6.9%
Other (government)	3.4%
Total	100.0%

Source: Table on page 82 of the application.

*Includes any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.1% of total services will be provided to self-pay patients, 23.1% to Medicare patients and 3.4% to Medicaid patients.

On page 82, 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 because it is based on the historical experience of the facility in providing MRI services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11821-19/ EmergeOrtho, P.A./ Develop one fixed MRI scanner

In Section L, page 99, the applicant projects the following payor mix for the proposed services during the third full fiscal year (CY2023) of operation following completion of the project, as shown in the table below.

Payor Category	MRI Services as Percent of Total
Self-Pay	2.00%
Charity Care	0.15%
Medicare*	22.67%
Medicaid*	6.80%
Insurance*	56.80%
Workers Compensation	7.46%
Tricare	4.11%
Total	100.00%

Source: Table on page 99 of the application.

*Includes any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.0% of total services will be provided to self-pay patients, 0.15% to charity care patients, 22.67% to Medicare patients and 6.8% to Medicaid patients.

On page 99, 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 because it is based on the historical experience of the facility in providing MRI services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11825-19/ Raleigh Radiology Cary/ Develop one fixed MRI scanner

In Section L, page 114, the applicant projects the following payor mix for the proposed services during the third full fiscal year (CY2023) of operation following completion of the project, as shown in the table below.

Payor Category	MRI Services as Percent of Total
Self-Pay	2.79%
Charity Care	0.20%
Medicare*	25.95%
Medicaid*	3.37%
Insurance*	64.81%
Other (specify)	2.88%
Total	100.00%

Source: Table on page 114 of the application.

*Includes any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.79% of total services will be provided to self-pay patients, 0.20% to charity care patients, 25.95% to Medicare patients and 3.37% to Medicaid patients.

On page 114-116, 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 because it is based on the historical experience of the facility in providing MRI services.

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Remarks made at the public hearing
- 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-11826-19/Raleigh Radiology Knightdale/ Develop one fixed MRI scanner

In Section L, page 114, the applicant projects the following payor mix for the proposed services during the third full fiscal year (CY2023) of operation following completion of the project, as shown in the table below.

Payor Category	MRI Services as Percent of Total
Self-Pay	2.80%
Charity Care	1.45%
Medicare*	31.40%
Medicaid*	6.86%
Insurance*	55.52%
Other (specify)	1.97%
Total	100.00%

Source: Table on page 114 of the application.

*Includes any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.80% of MRI services will be provided to self-pay patients, 1.45% to charity care patients, 31.40% to Medicare patients and 6.86% to Medicaid patients.

On pages 115-117, 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 because it is based on the historical experience of the applicant in providing MRI services from target zip codes and projecting that payor mix forward.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11829-20/ Duke Radiology Green Level/ Develop one fixed MRI scanner

In Section L, page 69, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	MRI Services as Percent of Total
Self-Pay	1.6%
Charity Care	0.0%
Medicare*	37.8%
Medicaid*	3.9%
Insurance*	53.8%
Workers Compensation	0.3%
TRICARE	1.0%
Other (commercial, other government payors)	1.6%
Total	100.0%

Source: Table on page 69 of the application.

*Includes any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.6% of MRI services will be provided to self-pay patients, 37.8% to Medicare patients and 3.9% to Medicaid patients.

On pages 69-70, 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 because it is based on *“As a baseline for its payor mix for the non-emergent outpatient MRI procedures provided to patients from the identified zip codes in the primary service area in FY 19 (see Section Q). Based on input from DUHS Corporate Finance, the projections include an anticipated shift of 3.8% of private insurance patients to Medicare per year through FY 2022 to reflect the aging of the population and resulting utilization patterns of MRI services.”*

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Remarks made at the public hearing
- 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-11830-20/ Wake Radiology Cary/ Develop one fixed MRI scanner

In Section L, page 81, the applicant projects the following payor mix for the proposed services during the third full fiscal year (CY2023) of operation following completion of the project, as shown in the table below.

Payor Category	MRI Services as Percent of Total
Self-Pay	0.2%
Medicare*	43.3%
Medicaid*	1.2%
Insurance*	53.4%
Other (specify)	1.9%
Total	100.0%

Source: Table on page 81 of the application.

*Includes any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.2% of total services will be provided to self-pay patients, 43.3% to Medicare patients and 1.2% to Medicaid patients.

On page 81, 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 because it is based on the historical experience of the facility in providing MRI services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11820-19/ Raleigh Radiology Wake Forest/ Develop one fixed MRI scanner

In Section L.5, page 84, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-11821-19/ EmergeOrtho, P.A./ Develop one fixed MRI scanner

In Section L.5, pages 99-100, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-11825-19/ Raleigh Radiology Cary/ Develop one fixed MRI scanner

In Section L.5, page 117, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-11826-19/Raleigh Radiology Knightdale/ Develop one fixed MRI scanner

In Section L.5, page 118, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-11829-20/ Duke Radiology Green Level/ Develop one fixed MRI scanner

In Section L.5, page 70, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-11830-20/ Wake Radiology Cary/ Develop one fixed MRI scanner

In Section L.5, 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

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.

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

Table 9R, page 172 of the 2019 SMFP, provides the projected need determination for one additional fixed MRI scanner in Wake County, based on the standard methodology used to determine need for fixed MRI scanners in the 2019 SMFP, pages 151-152.

On page 149, the 2019 SMFP defines a fixed MRI scanner as “*an MRI scanner that is not a mobile MRI scanner.*” The 2019 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. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.*” 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 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) 2018 *
Duke Radiology Holly Springs (Duke University Health System) **	1	0
Duke Raleigh Hospital (Duke University Health System)	2	13,892
Raleigh Neurology Associates (Raleigh Neurology Associates)	1	5,634
Raleigh Neurology Imaging (Alliance)	1	5,988
Raleigh Radiology – Blue Ridge (Alliance)	1	6,004
Raleigh Radiology – Cary (Alliance) ^	1	7,511
Raleigh Radiology – Cedarhurst (Pinnacle)	1	8,111
Rex Hospital – Main (UNC Health System)	2	11,525
Rex Hospital – UNC Rex Health Care of Cary (UNC Health System)	1	532
The Bone and Joint Surgery Center (Bone & Joint) ^^	1	106
Wake Radiology – Garner (Alliance)	1	3,300
Wake Radiology (Wake Radiology)	1	3,445
Wake Radiology Diagnostic Imaging (Alliance)	1	4,123
Wake Radiology Raleigh MRI Center (Wake Radiology)	1	3,445
WakeMed (WakeMed)	2	12,949
WakeMed Cary Hospital (WakeMed)	1	4,855
2019 Need Determination #	1	0
Total	20	91,420

Source: Table 17E-1 in the Proposed 2020 SMFP.

* October 1, 2017 to September 30, 2018.

** Under development.

^ In the version of Table 17E-1 posted on the Agency’s website on or about July 1, 2019, this site was incorrectly classified as a mobile site. This MRI scanner is “permanently” installed.

^^ The first replacement MRI scanner was damaged beyond repair in January 2018. Thus, it was only in operation approximately 3 months during FFY 2018 (October through December).

Currently under review. There are six applications.

The 19 existing and approved fixed MRI scanners are owned by the following entities:

- Alliance (5 scanners)
- Duke University Health System (3 scanners)
- UNC Health System (3 scanners)
- WakeMed (3 scanners)
- Wake Radiology (2 scanners)
- Bone & Joint (1 scanner)
- Raleigh Neurology Associates (1 scanner)
- Pinnacle (1 scanner)

J-11820-19/ Raleigh Radiology Wake Forest/ Develop one fixed MRI scanner

PHSNC proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center. RR-Wake Forest, located at 839 Durham Road, Units A&B, Wake Forest.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 86, the applicant states:

“With acquisition of a fixed MRI scanner, PHSNC will continue to 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 87, the applicant states:

“The outpatient diagnostic imaging services in Wake Forest contribute to cost-effective patient care because the services have a charge structure different from hospital-based diagnostic services, typically less costly.”

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

“PHSNC’s proposal to obtain a 3T fixed scanner in Wake Forest will be of great benefit to the local community from a quality perspective, offering several advantages, including:

- Higher resolution which produces more detailed images, which are beneficial when diagnosing pathological conditions involving the brain, spine, and musculoskeletal system.*
- Lower risk of distorted images, thus eliminating the need for repeated scans. ...*
- More sophisticated imaging procedures with more accurate diagnosis.*
- Shorter examination times due to the efficiency of the 3T magnet....”*

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 90, the applicant states:

“PHSNC is committed to caring for local communities. One way PHSNC demonstrates this commitment is providing access to underserved persons regardless of their ability to pay. PHSNC offers self-pay discounts on all procedures for uninsured patients and has annual agreements with Project Access of Wake County to provide free imaging. 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.”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11821-19/ EmergeOrtho, P.A./ Develop one fixed MRI scanner

EmergeOrtho proposes to acquire one fixed MRI scanner to be located at the existing non-hospital licensed diagnostic center, EmergeOrtho, located at 3100 Duraleigh Road, Suite 100, Raleigh.

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

“Obtaining the proposed fixed MRI scanner will enable EmergeOrtho to more effectively compete in terms of enhancing patient convenience, expanding access to cost effective MRI service with lower out-of-pocket costs and increasing access to advanced diagnostic imaging capabilities for patients with special needs.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 102, the applicant states:

“Developing the fixed MRI provides for greater cost effectiveness because the investment in the fixed MRI equipment can improve MRI scheduling and increase productivity with faster image acquisition.”

Regarding the impact of the proposal on quality, in Section N, page 103, the applicant states:

“Patient safety and quality will be incorporated into all aspects of the project including equipment selection, facility design, licensure and certification, credentialing, staff education, patient selection, patient scheduling and continuous quality measures and patient satisfaction surveys.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 104, the applicant states:

“EmergeOrtho will expand access for the medically underserved by providing MRI procedures to patients who are indigent, lack health insurances or are otherwise medically underserved.”

... EmergeOrtho will continue to provide no charge MRI scans to patients referred through Project Access.”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11825-19/ Raleigh Radiology Cary/ Develop one fixed MRI scanner

Raleigh Radiology-Cary proposes to acquire one fixed MRI Scanner to be located at the existing non-hospital licensed diagnostic center, RR-Cary, located at 150 Parkway Office Court, Suite 100, Cary.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 120, the applicant states:

“When it directly owns the equipment and employs the staff, Raleigh Radiology will have better capacity to foster market competition by keeping out of pocket costs to patients low.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 120, the applicant states:

“The project will enable Raleigh Radiology to replace high payments for a leased older scanner with lower operating costs for a new one that has more capabilities.”

Regarding the impact of the proposal on quality, in Section N, page 121, the applicant states:

“RRCary MRI is accredited by the American College of Radiology ... Moreover, all of Raleigh Radiology LLC’s member radiologists are board certified in Radiology...”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 122, the applicant states:

“The facility will accept patients without regard to source of payment and has plans to provide charity for medical necessity. ...

The location, ADA complaint building design, and willingness to accept Medicare, Medicaid, hardship patients, and uninsured will all increase access for patients...”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11826-19/Raleigh Radiology Knightdale/ Develop one fixed MRI scanner

Raleigh Radiology-Knightdale proposes to acquire one fixed MRI Scanner to be located at the approved, non-operational, non-hospital licensed diagnostic center, RR-Knightdale, to be located at 1101 Great Falls Court, Knightdale.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 121, the applicant states:

“As a new freestanding competitor in eastern Wake County, Raleigh Radiology will provide market competition that will help keep prices low. The competitive option for consumers and

others for whom price is a concern should also work to contain prices for outpatients at local hospitals.””

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 121-122, the applicant states:

“Construction will take advantage of existing infrastructure. Thus, minimizing capital costs.

The center will contain administrative costs by sharing overhead with other Raleigh Radiology, LLC locations.”

Regarding the impact of the proposal on quality, in Section N, page 122, the applicant states:

“The proposed MRI will pursue American College of Radiology accreditation. ...

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

Raleigh Radiology maintains a Continuous Quality Improvement (CQI) program focusing on improving specific clinical and patient experience outcomes such as telephone hold times, contrast reactions and overall patient satisfaction.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 123, the applicant states:

“The facility will accept patients without regard to source of payment and has plans to provide charity for medical necessity. ...

The location, ADA compliant building design, and willingness to accept Medicare, Medicaid, hardship patients, and uninsured will all increase access for patients...”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Remarks made at the public hearing
- 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-11829-20/ Duke Radiology Green Level/ Develop one fixed MRI scanner

DUHS proposes to acquire one fixed MRI scanner to be located at the proposed new non-hospital licensed diagnostic center, Duke Green Level, to be located within a medical office building currently being developed at 3208 Green Level W Road, Cary, Wake County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 73, the applicant states:

“This project will benefit competition by creating a new outpatient/non-hospital based MRI service in Apex. This new center will expand provider choice for patients, particularly those in Apex, Cary, and surrounding areas.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 73, the applicant states:

“This project creates a new, non-hospital based imaging site. The proposed IDTF structure typically has lower reimbursement than hospital facilities and is more cost effective for many payors and patients depending on their plan terms. This project will also enable Duke Health to reduce its costs incurred in mobile MRI agreements already in place.”

Regarding the impact of the proposal on quality, in Section N, page 73, the applicant states:

“Patients will have access to all of the highly specialized radiology services for which Duke is known; with the PACS system, images can be accessed by radiologists throughout the system, and therefore patients will have access to high-quality state-of-the-art services in a new location and with a different reimbursement structure. This will also improve coordination of care for patients seeking other services within the Duke Health system.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 74, 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.”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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-11830-20/ Wake Radiology Cary/ Develop one fixed MRI scanner

Wake Radiology proposes to acquire one fixed MRI Scanner to be located at the existing non-hospital licensed diagnostic center, WR-Cary, located at 300 Ashville Avenue, Cary.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 84, 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 84, 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 Cary, an existing freestanding outpatient diagnostic imaging center. As an existing MRI service provider, Wake Radiology has all necessary ancillary and support services in place...”

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.”

Regarding the impact of the proposal on quality, in Section N, pages 85-86, 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.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 86, 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 patients ability to pay.”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

- (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-11820-19/ Raleigh Radiology Wake Forest/ Develop one fixed MRI scanner

In Form A, the applicant identifies six diagnostic centers that are owned, operated, or managed by the applicant or a related entity, including Raleigh Radiology Cedarhurst, Raleigh Radiology Wake Forest, Raleigh Radiology Clayton, Raleigh Radiology Brier Creek, Wake Forest Baptist Imaging-Winston-Salem and Wake Forest Baptist Imaging-Kernersville.

In Section O.2 and O.3, page 94, the applicant states, “*PHSNC provides care for and is currently certified for Medicare and Medicaid patients. PHSNC obtains ACR accreditation for its imaging equipment. PHSNC will obtain accreditation for the proposed fixed MRI scanner at RRWF. ... 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-11821-19/ EmergeOrtho, P.A./ Develop one fixed MRI scanner

In Form A, the applicant identifies six MRI scanners (2 mobile and 4 fixed) that are owned, operated, or managed by the applicant or a related entity.

In Section O.3, page 109, the applicant states, “*EmergeOrtho confirms that all of the MRI scanners have provided quality care during the 18 months immediately preceding the application. ... EmergeOrtho confirms that none of the EmergeOrtho MRI scanners that are identified in Form A were found to have any incidents resulting in a finding of immediate jeopardy. EmergeOrtho has had no penalties or licensure limitations imposed in the last 18 months.*” After reviewing and considering information provided by the applicant regarding the quality of care provided at the other facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

J-11825-19/ Raleigh Radiology Cary/ Develop one fixed MRI scanner

In Form A, the applicant identifies three diagnostic centers that are owned, operated, or managed by the applicant or a related entity, including Raleigh Radiology Blue Ridge, Raleigh Radiology Cary, and Raleigh Radiology Knightdale.

On page 123, the applicant states, “*As a part of Raleigh Radiology, LLC, the MRI will be subject to an established and continually improving quality management program.*” In Section O.3, page 124, the applicant states, “*Raleigh Radiology maintains American College of Radiology accreditation for all of its facilities. ... Raleigh Radiology practices are registered with the Centers for Medicare and Medicaid Service and all Raleigh Radiology physicians are in good standing with CMS. ... No Raleigh Radiology location was found by DHSR or CMS to have had any incidents resulting in a finding of immediate jeopardy during the 18-month look-back period.*” 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. Therefore, the application is conforming to this criterion.

J-11826-19/Raleigh Radiology Knightdale/ Develop one fixed MRI scanner

In Form A, the applicant identifies three diagnostic centers that are owned, operated, or managed by the applicant or a related entity, including Raleigh Radiology Blue Ridge, Raleigh Radiology Cary, and Raleigh Radiology Knightdale (not yet operational).

In Section O.3, page 126, the applicant states, “*Raleigh Radiology maintains American College of Radiology MRI accreditation for all of its facilities. ... Raleigh Radiology practices are registered with the Centers for Medicare and Medicaid Service and all Raleigh Radiology physicians are in good standing with CMS. ... No Raleigh Radiology location was found by DHSR or CMS to have had any incidents resulting in a finding of immediate jeopardy during the 18-month look-back period.*” 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. Therefore, the application is conforming to this criterion.

J-11829-20/ Duke Radiology Green Level/ Develop one fixed MRI scanner

DUHS owns or manages three hospitals, Duke University Hospital, Duke Regional Hospital, and Duke Raleigh Hospital and one ambulatory surgery center, the James E. Davis Ambulatory Surgery Center. In Section Q, Form A, DUHS identifies four diagnostic centers (2 existing and 2 approved) that it owns or manages.

In Section O.3, page 76, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred at the facilities identified in Form A. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in either the three hospitals or the ambulatory surgery center owned or managed by DUHS. 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 DUHS facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

J-11830-20/ Wake Radiology Cary/ Develop one fixed MRI scanner

In Form A, the applicant identifies fifteen diagnostic centers that are owned, operated, or managed by the applicant or a related entity.

In Section O.3, page 89, the applicant states, “*Each of the facilities identified in response to Section A, Question 7, Form A Facilities has continually maintained all relevant licensure, certification, and accreditation ... for the 18 months preceding the submission of this application. ... None of the facilities identified in response to Section A, Question 7, Form A Facilities was found by the Division of Health Service Regulation or CMS to have had any incidents resulting in a finding of immediate jeopardy during the 18 month look-back period.*” 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. Therefore, the application is conforming to this criterion.

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

C
PHSNC
EmergeOrtho
Raleigh Radiology-Cary
Raleigh Radiology-Knightdale
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, pages 42-43, the applicant states that it owns and operates one fixed MRI scanner in Wake County, at its Cedarhurst diagnostic center. During the most recent 12-month period for which PHSNC has data (September 2018 – August 2019) PHSNC performed 7,303 weighted MRI procedures which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.

-NA- EmergeOrtho. The MRI service area is Wake County. Neither the applicant or a related entity owns a controlling interest in an existing fixed MRI scanner in the Wake County.

-NA- Raleigh Radiology-Cary. The MRI service area is Wake County. Neither the applicant or a related entity owns a controlling interest in an existing fixed MRI scanner in the Wake County.

-NA- Raleigh Radiology-Knightdale. The MRI service area is Wake County. Neither the applicant or a related entity owns a controlling interest in an existing fixed MRI scanner in the Wake County.

-C- DUHS. The MRI service area is Wake County. In Section C, pages 34, the applicant states that it owns and operates two fixed MRI scanner in Wake County, at Duke Raleigh Hospital. During the most recent 12-month period for which DUHS has data (FY2019) DUHS performed 13,834.8 weighted MRI procedures for an average of 6,917.4 ($13,834.8 / 2 = 6,917.4$) which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.

-NC- Wake Radiology. The MRI service area is Wake County. In Section C, pages 50-51, the applicant states that there are two applicants: WR Imaging and WRDI and one related entity, Rex Hospital, Inc (UNC Rex).

WR Imaging: In Section C, page 50, the applicant states that WR Imaging acquired ownership of two fixed MRI scanners located at Wake Radiology Raleigh in Wake County in February 2019. The applicant further states that based on that fact that WR Imaging has not owned fixed MRI scanners in the service area for a 12-month period this rule does not apply to WR Imaging.

WR Imaging is incorrect in its assertion that this Rule does not apply to it since WR Imaging has not owned fixed MRI scanners in the service area for a 12-month period. For the Rule to apply: #1) the applicant, WR Imaging, must be proposing to “*acquire a fixed magnetic resonance imaging (MRI) scanner*”. WR Imaging is proposing to acquire a fixed MRI scanner; and #2) own a fixed MRI scanner in the service area. WR Imaging states that it owns two fixed MRI scanners in Wake County. Therefore, WR Imaging meets all the criteria for this Rule to apply.

Next, to comply with this Rule, WR Imaging is required to demonstrate that the two MRI scanners it owns in Wake County performed an average of 3,328 weighted MRI procedures in the most recent 12-month period for which the applicant has data. WR Imaging did not provide any data for the two fixed MRI scanners for “*the most recent 12 month period for which the applicant has data*”. Furthermore, WR Imaging does not demonstrate that it does not have access to or does not know the historical data for a 12-month period for the two fixed MRI scanners it owns. Thus, WR Imaging did not demonstrate that the two fixed MRI scanners it owns in Wake County performed an average of 3,328 weighted MRI procedures for the most recent 12 month period for which WR Imaging has such historical data nor did WR Imaging demonstrate that it could not provide historical data for the 2 fixed MRI scanners it owns in Wake County for a 12 month period. Therefore, the application is non-conforming to this Rule.

WRDI: In Section C, page 51, the applicant states that WRDI does not own any fixed MRI scanners in Wake County.

UNC Rex: In Section C, pages 51, the applicant states that UNC Rex owns and operates three fixed MRI scanner in Wake County, two at UNC Rex Hospital and one at UNC Rex Cary Outpatient Imaging. During the most recent 12-month period, September 2018 to August 2019, UNC Rex’s three fixed MRI scanners performed 11,305 weighted MRI procedures for an average of 3,768 scans per MRI scanner ($11,305 / 3 = 3,768$) which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.

The applicant further states that no other related entities own fixed MRI scanners in Wake County.

The applicant and its related entities own five fixed MRI scanners and only documented that three of the five fixed MRI scanners met or exceeded the required average of 3,328 weighted MRI procedures for the most recent 12-month period for which the applicant or its related entities had data. Therefore, the application is non-conforming to this Rule.

- (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 43, 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 (September 2018 – August 2019) PHSNC states the mobile MRI scanner performed 7,789 weighted MRI procedures which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.
- C- **EmergeOrtho.** The MRI service area is Wake County. In Section C, page 62, the applicant states that it owns and operates one mobile MRI scanner in Wake County. During the most recent 12-month period for which EmergeOrtho has data (10/1/18 – 9/30/19) the applicant states the mobile MRI scanner performed 4,882 weighted MRI procedures which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.
- NA- **Raleigh Radiology-Cary.** The MRI service area is Wake County. The applicant states that neither the applicant or a related entity owns a controlling interest in an existing mobile MRI scanner in the Wake County.
- NA- **Raleigh Radiology-Knightdale.** The MRI service area is Wake County. The applicant states that neither the applicant or a related entity owns a controlling interest in an existing mobile MRI scanner in the Wake County.
- NA- **DUHS.** The MRI service area is Wake County. The applicant states that neither the applicant or a related entity owns a controlling interest in an existing mobile MRI scanner in the Wake County.
- NC- **Wake Radiology.** The MRI service area is Wake County. In Section C, pages 50-51, the applicant states that there are two applicants: WR Imaging and WRDI and one related entity, Rex Hospital, Inc (UNC Rex).

WR Imaging: In Section C, page 51, the applicant states that in February 2019 WR Imaging acquired ownership of two mobile MRI scanners operating in Wake County. The applicant further states that since WR Imaging has not owned the mobile MRI scanners in the service area for a 12-month period this rule does not apply to WR Imaging.

WRDI: In Section C, page 51, the applicant states that WRDI does not own any mobile MRI scanners in Wake County.

In Section C, page 51, the applicant states that no related entities own mobile MRI scanners in Wake County.

WR Imaging is incorrect in its assertion that this Rule does not apply to it based on the fact that WR Imaging has not owned the two mobile MRI scanners in the service area for a 12-

month period. For the Rule to apply: #1) the applicant, WR Imaging, must be proposing to “*acquire a fixed magnetic resonance imaging (MRI) scanner*”. WR Imaging is proposing to acquire a fixed MRI scanner; and #2) own a mobile MRI scanner in the service area. WR Imaging states that it owns two mobile MRI scanners in Wake County. Therefore, WR Imaging meets all the criteria for this Rule to apply.

Next, to comply with this Rule, WR Imaging is required to demonstrate that the two mobile MRI scanners it owns in Wake County performed an average of 3,328 weighted MRI procedures in the most recent 12-month period for which the applicant has data. WR Imaging did not provide any data for the two mobile MRI scanners for “*the most recent 12 month period for which the applicant has data*”. Furthermore, WR Imaging does not demonstrate that it does not have access to or does not know the historical data for a 12-month period for the two mobile MRI scanners it owns. Thus, WR Imaging did not demonstrate that the two mobile MRI scanners it owns in Wake County performed an average of 3,328 weighted MRI procedures for the most recent 12 month period for which WR Imaging has such historical data nor did WR Imaging demonstrate that it could not provide historical data for the 2 mobile MRI scanners it owns in Wake County for a 12 month period.

The project analyst notes that the applicant filed a Registration and Inventory of Medical Equipment Form (R&I Form) which covered the time period of 10/1/2018 to 9/30/2019 for each of its existing mobile MRI scanners. The R&I Form covering 10/1/2018 to 9/30/2019 documented that one of the mobile MRI scanners performed 2,649.8 weighted MRI procedures and the other mobile MRI scanner performed 1,196 weighted MRI procedures for that 12-month period. Therefore, for the 12-month period ending 9/30/2019 neither of the mobile MRI scanners in the service area performed an average of 3,328 weighted MRI procedures as required by 10A NCAC 14C .2703(b)(2).

Furthermore, in the applicant’s Exhibit C.12-3 the applicant provided historic data for its two mobile MRI scanners documenting that one of the mobile MRI scanners performed 2,383 and 2,844 weighted MRI procedures for CY2018 and CY2019 respectively while the second mobile MRI scanner performed 1,803 and 2,033 weighted MRI procedures for CY2018 and CY2019 respectively. Thus, the applicant acknowledges that neither of the two mobile MRI scanners performed an average of 3,328 weighted MRI procedures in the most recent 12-month period for which the applicant has data and therefore the application is not in compliance with 10A NCAC 14C .2703(b)(2).

Therefore, the application is non-conforming to this Rule.

- (3) *demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*
 - (A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*

- (B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
- (C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
- (D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*
- (E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

The 2019 SMFP shows that there are more than four (4) fixed MRI scanners located in the fixed MRI service area of Wake County. Therefore, each applicant must demonstrate that the average annual utilization for the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns and locates in Wake County will be at least 4,805 weighted MRI procedures in the third operating year.

- C- **PHSNC.** In Section Q the applicant states that it projects to perform 11,584 weighted MRI procedures on its existing (1) and proposed (1) MRI scanners during the third year (CY2023) of the proposed project for an average of 5,792 weighted MRI scans per scanner [$11,584 / 2 = 5,792$] 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.
- NA- **EmergeOrtho.** Neither the applicant or a related entity owns a controlling interest in an existing fixed MRI scanner in Wake County.
- NA- **Raleigh Radiology-Cary.** Neither the applicant or a related entity owns a controlling interest in an existing fixed MRI scanner in Wake County.
- NA- **Raleigh Radiology-Knightdale.** Neither the applicant or a related entity owns a controlling interest in an existing fixed MRI scanner in Wake County.
- C- **DUHS.** 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 23,451 scans in the third year of operation (FY2025) or 5,862.7 MRI scans per MRI scanner [$23,451/4 = 5,862.7$] 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.** 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 52 the applicant project that in the third year (CY2023) following completion of the project its six fixed MRI scanners will perform 28,940 weighted MRI procedures for an average of 4,823 weighted MRI procedures [$28,940 / 6 = 4,823$] 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 discussions regarding projected

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

- (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 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 CY2023. In Section C.12, page 44 and in Section Q, the applicant projects that the proposed MRI scanner will perform 5,074 weighted MRI procedures in the third year of operation (CY2023), which is greater than the 4,805 weighted MRI procedures required by the Rule.
- NA- **EmergeOrtho.** Neither the applicant or a related entity owns a controlling interest in an existing fixed MRI scanner in Wake County.
- NA- **Raleigh Radiology-Cary.** Neither the applicant or a related entity owns a controlling interest in an existing fixed MRI scanner in Wake County.
- NA- **Raleigh Radiology-Knightdale.** Neither the applicant or a related entity owns a controlling interest in an existing fixed MRI scanner in Wake County.
- 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 FY2025 (7/1/2024 to 6/30/2025). In Section C.12, page 35, and in Section Q, the applicant projects that the proposed MRI scanner will perform 5,068 weighted MRI procedures in the third year of operation (CY2023), 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 CY2023. In Section C.12, pages 52-53, and in Section Q, the applicant projects that the proposed MRI scanner will perform 5,106 weighted MRI procedures in the third year of operation (CY2023), 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 discussions regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming with this 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.12, page 44, and in Section Q, the applicant projects that the mobile MRI scanner is reasonably expected to perform 5,284 weighted MRI scans in the third year (CY2023) following completion of the proposed project which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.
- C- EmergeOrtho.** The applicant and its related entities own a controlling interest in one mobile MRI scanner. In Section C.12, page 44, and in Section Q, the applicant projects that the mobile MRI scanner is reasonably expected to perform 5,298 weighted MRI scans in the third year (CY2023) following completion of the proposed project which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.
- NA- Raleigh Radiology-Cary.** The applicant states that neither the applicant or a related entity owns a controlling interest in an existing, approved or proposed mobile MRI scanner in Wake County.
- NA- Raleigh Radiology-Knightdale.** The applicant states that neither the applicant or a related entity owns a controlling interest in an existing, approved or proposed mobile MRI scanner in Wake County.
- NA- DUHS.** The applicant states that neither the applicant or a related entity owns a controlling interest in an existing, approved or proposed mobile MRI scanner in Wake County.
- NC- Wake Radiology.** The applicant and its related entities own a controlling interest in two mobile MRI scanners. In Section C.12, page 53, and in Section Q, the applicant projects that each mobile MRI scanner is reasonably expected to perform more than 3,328 weighted MRI scans

in the third year (CY2023) following completion of the proposed project. WR Imaging Mobile MRI #1 is projected to perform 3,500 weighted MRI scans in CY2023 and WR Imaging Mobile MR #2 is projected to perform 3,971 weighted MRI scans in CY2023. 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.

(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.
- C- **EmergeOrtho.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q.
- C- **Raleigh Radiology-Cary.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q.
- C- **Raleigh Radiology-Knightdale.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q.
- C- **DUHS.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q.
- NC- **Wake Radiology.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q and Exhibits C.12-1 to C.12-3. However, the applicant does not adequately demonstrate that projected utilization is reasonable and adequately supported. The discussions regarding analysis of projected utilization found in Criterion (3) are incorporated herein by reference. Therefore, the application is not conforming with this Rule.
- (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 six applications in this review collectively propose to develop six 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.

- **Project ID #J-11820-19/ Raleigh Radiology Wake Forest/ (PHSNC)** Acquire one fixed MRI Scanner to be located at RR-Wake Forest, an existing non-hospital licensed diagnostic center located at 839 Durham Road, Units A&B, Wake Forest, Wake County. The applicant proposes to perform 5,074 total weighted MRI procedures on the proposed fixed MRI scanner from January 1, 2023–December 31, 2023, the third full year of operation following completion of the project.
- **Project ID #J-11821-19/ EmergeOrtho, P.A./ (EmergeOrtho)** Acquire one fixed MRI Scanner to be located at EmergeOrtho, an existing non-hospital licensed diagnostic center located at 3100 Duraleigh Road, Suite 100, Raleigh, Wake County. The applicant proposes to perform 5,298 total weighted MRI procedures on the proposed fixed MRI scanner from January 1, 2023–December 31, 2023, the third full year of operation following completion of the project.
- **Project ID #J-11825-19/ Raleigh Radiology Cary/ (Raleigh Radiology-Cary)** Acquire one fixed MRI Scanner to be located at RR-Cary, an existing non-hospital licensed diagnostic center located at 150 Parkway Office Court, Suite 100, Cary, Wake County. The applicant proposes to perform 8,030 total weighted MRI procedures on the proposed fixed MRI scanner from January 1, 2023–December 31, 2023, the third full year of operation following completion of the project.
- **Project ID #J-11826-19/ Raleigh Radiology Knightdale/ (Raleigh Radiology-Knightdale)** Acquire one fixed MRI Scanner to be located at RR-Knightdale, an approved, non-operational, non-hospital licensed diagnostic center to be located at 1101 Great Falls Court, Knightdale, Wake County. The applicant proposes to perform 4,986 total weighted MRI procedures on the proposed fixed MRI scanner from January 1, 2023–December 31, 2023, the third full year of operation following completion of the project.
- **Project ID #J-11829-19/ Duke Radiology Green Level/ (DUHS)** Acquire one fixed MRI Scanner to be located at Duke Green Level, a proposed new non-hospital licensed diagnostic center to be located within a medical office building currently being developed at 3208 Green Level W Road, Cary, Wake County. The applicant proposes to perform 5,069 total weighted

MRI procedures on the proposed fixed MRI scanner from July 1, 2024–June 30, 2025, the third full year of operation following completion of the project.

- **Project ID #J-11830-19/ Wake Radiology Cary/ (Wake Radiology)** Acquire one fixed MRI Scanner to be located at WR-Cary, an existing non-hospital licensed diagnostic center located at 300 Ashville Avenue, Cary, Wake County. The applicant proposes to perform 5,106 total weighted MRI procedures on the proposed fixed MRI scanner from January 1, 2023–December 31, 2023, the third full year of operation following completion of the project.

Conformity with Statutory and Regulatory Review Criteria

The applications submitted by PHSNC, EmergeOrtho, Raleigh Radiology-Cary, and DUHS are conforming with all applicable statutory and regulatory review criteria.

However, the applications submitted by Raleigh Radiology-Knightdale and Wake Radiology are 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, EmergeOrtho, Raleigh Radiology-Cary** and **DUHS** are equally effective alternatives and more effective than the applications submitted by Raleigh Radiology-Knightdale and Wake Radiology

Scope of Services

Applicant	Type of Fixed MRI Scanner	Hospital Based or Freestanding*
PHSNC	3T	Freestanding
EmergeOrtho	1.5T	Freestanding
Raleigh Radiology-Cary	3T	Freestanding
Raleigh Radiology-Knightdale	1.5T	Freestanding
DUHS	1.5T	Freestanding
Wake Radiology	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, neither Raleigh Radiology-Knightdale nor Wake Radiology comply with all applicable statutory and regulatory criteria and therefore neither Raleigh Radiology-Knightdale nor Wake Radiology are approvable. Therefore, regarding this comparative factor, the applications the applications submitted by **PHSNC, EmergeOrtho, Raleigh Radiology-Cary** and **DUHS** are equally effective alternatives and more effective than the applications submitted by Raleigh Radiology-Knightdale and Wake Radiology.

Historical Utilization

The following table illustrates historical utilization of each applicant as provided in the **2020 SMFP** representing FY2018 reported utilization.

Fixed MRI Scanners in Wake County
 2020 SMFP Based on FY2018 Data

Facility	# of Fixed MRI Scanners*	Weighted Procedures	Weighted MRI Procedures per Scanner
Duke Raleigh Hospital	2	13,892	6,946
Rex Hospital	2	11,525	5,762.5
Rex Hospital-UNC Rex Health Care of Cary	1	532	532
WakeMed Cary Hospital	1	4,855	4,855
WakeMed-New Bern Ave	2	12,949	6,474.5
Duke Radiology Holly Springs	1	0	0
Raleigh Neurology Associates, P.A. (Raleigh Neurology Associates)	1	5,634	5,634
Raleigh Neurology Imaging	1	5,988	5,988
Raleigh Radiology Blue Ridge (Alliance Healthcare Services)	1	6,004	6,004
Raleigh Radiology Cary (Alliance Healthcare Services)	1	7,511	7,511
Raleigh Radiology Cedarhurst (Pinnacle Health Services of NC, LLC)	1	8,111	8,111
The Bone & Joint Surgery Clinic	1	106	106
Wake Radiology Diagnostic Imaging (Alliance Healthcare Services)	1	3,445	3,445
Wake Radiology Diagnostic Imaging Cary (Alliance Healthcare Services)	1	4,123	4,123
Wake Radiology Raleigh MRI Center (Wake Radiology)	1	3,445	3,445
Wake Radiology Garner (Alliance Healthcare Services)	1	3,300	3,300
Totals	19		

Source: 2020 SMFP, pages 436-437

Two of the applications, Raleigh Radiology-Knightdale and DUHS, both propose to provide MRI services at new facilities and thus have no historical utilization. Thus, the result of this analysis is inconclusive.

Geographic Accessibility (Location within the Service Area)

The 2019 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
TOTAL FOR CARY***	3		
Wake Radiology – Garner (Alliance)	1	Freestanding	Garner
TOTAL FOR GARNER	1		
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
TOTAL FOR HOLLY SPRINGS***	2		
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 (Pinnacle)	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
TOTAL FOR RALEIGH	13		
2019 Need Determination			
Proposed: PHSNC	1	Freestanding	Wake Forest
Proposed: EmergeOrtho	1	Freestanding	Raleigh
Proposed: Raleigh Radiology-Cary	1	Freestanding	Cary
Proposed: Raleigh Radiology-Knightdale	1	Freestanding	Knightdale
Proposed: DUHS	1	Freestanding	Cary
Proposed: Wake Radiology	1	Freestanding	Cary

Source: Table 17E-1 in the Proposed 2020 SMFP.

* October 1, 2017 to September 30, 2018.

** Under development.

*** 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.

^ In the version of Table 17E-1 posted on the Agency’s website on or about July 1, 2019, this site was incorrectly classified as a mobile site. This MRI scanner is “permanently” installed.

^^ The first replacement MRI scanner was damaged beyond repair in January 2018. Thus, it was only in operation approximately 3 months during FFY 2018 (October through December).

Currently under review. There are six applications.

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
Raleigh	464,451	13	7	35,727	66,350
Cary	162,321	3	2	54,107	81,160
Wake Forest	37,279	0	0	37,279	37,279
Knightdale	15,305	0	0	15,305	15,305
Holly Springs	34,068	2	1	17,034	34,068
Garner	30,783	1	1	30,783	30,781

Source: North Carolina Office of State Management and Budget. Population estimates from July 1, 2018.

Based on the Wake County population estimates as of July 1, 2018, 81,160 people are using the freestanding fixed MRI scanner located in Cary on a per capital basis as opposed to only 66,350 in Raleigh. While there are no fixed MRI scanners located in either Wake Forest or Knightdale their populations are only 37,279 and 15,305 respectively. There are no applications proposing to locate a fixed MRI scanner in either Holly Springs or Garner. Based on this analysis, the geographic location of the MRI scanner in Cary is a better option for MRI services in Wake County for the reasons stated above.

PHSNC proposes to locate the additional fixed MRI scanner in Wake Forest, Wake County. EmergeOrtho proposes to locate the additional fixed MRI scanner in Raleigh, Wake County. Raleigh Radiology-Knightdale proposes to locate the additional fixed MRI scanner in Knightdale, Wake County. Raleigh Radiology-Cary, DUHS and Wake Radiology all propose to locate the additional fixed MRI scanner in Cary, Wake County. However, Wake Radiology does not comply with all applicable statutory and regulatory criteria and therefore Wake Radiology is not approvable. Thus, with respect to geographic accessibility, the proposals submitted by **Raleigh Radiology-Cary and DUSH** are equally effective and both are more effective than the proposals submitted by PHSNC and EmergeOrtho.

Access by Service Area Residents

On page 149, the 2019 SMFP defines a fixed MRI scanner as “an MRI scanner that is not a mobile MRI scanner.” The 2019 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. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.” 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.

Applicant	Wake County Residents Served	Wake County Residents per Scanner	Wake County Residents Served as a % of Total
PHSNC	2,942	2,942	62.79%
EmergeOrtho	3,840	3,840	75.62%
Raleigh Radiology-Cary	5,232	5,232	86.49%
Raleigh Radiology-Knightdale	3,640	3,640	98.00%
DUHS	3,086	3,086	70.00%
Wake Radiology	3,937	3,937	88.99%

As shown in the table above, Raleigh Radiology-Cary projects to serve the highest total number of service area residents. Therefore, regarding projected service to number of residents of the service area, the application submitted by **Raleigh Radiology-Cary** is the more effective alternative.

As also shown in the table above, Raleigh Radiology-Knightdale projects to serve the highest percentage of service area residents and Wake Radiology projects to serve the next highest percentage of service area residents. However, neither Raleigh Radiology-Knightdale nor Wake Radiology comply with all applicable statutory and regulatory criteria and therefore neither Raleigh Radiology-Knightdale nor Wake Radiology are approvable. Therefore, regarding projected service to percentage of service area residents as compared to total patients served **Raleigh Radiology-Cary** 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 and net revenue, and per MRI scan, as shown below.

Applicant	Gross Revenue	Net Revenue	MRI Scans (Unweighted)	Charity Care	Charity Care as a % of Gross Revenue	Charity Care as a % of Net Revenue	Charity Care / MRI Scan
PHSNC	\$8,624,545	\$2,296,037	4,685	\$86,245	1.00%	3.76%	\$18.41
EmergeOrtho	\$6,093,600	\$2,729,933	5,078	\$6,896	0.11%	0.25%	\$1.36
Raleigh Radiology-Cary	\$10,788,293	\$2,935,153	6,946	\$21,902	0.20%	0.75%	\$3.15
Raleigh Radiology-Knightdale	\$6,522,524	\$1,737,496	4,269	\$94,698	1.45%	5.45%	\$22.18
DUHS	\$6,874,811	\$2,866,862	4,408	\$86,525	1.26%	3.02%	\$19.63
Wake Radiology	\$11,113,991	\$4,266,508	4,424	\$0.00	0.00%	0.00%	\$0.00

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

As a percent of net revenue, Raleigh Radiology-Knightdale proposes the highest percentage of charity care as a percent of net revenue. In addition, Raleigh Radiology-Knightdale also provides a higher dollar amount of charity care per MRI scan than any of the other applicants. However, Raleigh Radiology-Knightdale does not comply with all applicable statutory and regulatory criteria and therefore Raleigh Radiology-Knightdale is not approvable. Therefore, regarding the highest percentage of charity care as a percent of net revenue **PHSNC** is the more effective alternative and regarding the dollar amount of charity care per MRI scan **DUHS** is the more effective alternative.

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	Medicare	Medicare as a % of Gross Revenue
PHSNC	\$8,624,545	\$1,990,520	23.08%
EmergeOrtho	\$6,093,600	\$1,043,524	17.13%
Raleigh Radiology-Cary	\$10,788,293	\$2,799,418	25.95%
Raleigh Radiology-Knightdale	\$6,522,524	\$2,047,980	31.40%
DUHS	\$6,874,811	\$2,598,303	37.80%
Wake Radiology	\$11,113,991	\$4,916,033	44.23%

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

Wake Radiology proposes both the highest dollar amount of Medicare and the highest percentage of Medicare as a percent of gross revenue. Raleigh Radiology-Cary proposes the second highest dollar amount of Medicare and Raleigh Radiology-Knightdale proposes the second highest percentage of Medicare as a percent of gross revenue. However, neither Raleigh Radiology-Knightdale nor Wake Radiology comply with all applicable statutory and regulatory criteria and therefore neither Raleigh Radiology-Knightdale nor Wake Radiology are approvable.

Therefore, regarding access by Medicare patients in terms of the highest dollar amount of Medicare **Raleigh Radiology-Cary** is the more effective alternative and **DUHS** is the more effective alternative with respect to percentage of Medicare as a percent of gross revenue.

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	Medicaid	Medicaid as a % of Gross Revenue
PHSNC	\$8,624,545	\$292,585	3.39%
EmergeOrtho	\$6,093,600	\$313,011	5.14%
Raleigh Radiology-Cary	\$10,788,293	\$363,279	3.37%
Raleigh Radiology-Knightdale	\$6,522,524	\$447,595	6.86%
DUHS	\$6,874,811	\$270,050	3.93%
Wake Radiology	\$11,113,991	\$129,138	1.16%

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

Raleigh Radiology-Knightdale proposes both the highest dollar amount of Medicaid and the highest Medicaid as a percentage of Gross Revenue. However, Raleigh Radiology-Knightdale does not comply with all applicable statutory and regulatory criteria and therefore Raleigh Radiology-Knightdale is not approvable. Raleigh Radiology-Cary proposes the second highest dollar amount of Medicaid and EmergeOrtho proposes the second highest Medicaid as a percent of Gross Revenue.

Therefore, regarding access to Medicaid patients, **Raleigh Radiology-Cary** is the more effective alternative with respect to proposing the highest dollar amount of Medicaid and **EmergeOrtho** is the more effective alternative with respect to proposing the highest Medicaid as a percent of Gross Revenue.

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 applications submitted by Raleigh Radiology-Knightdale and Wake Radiology are 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, EmergeOrtho, Raleigh Radiology-Cary** and **DUHS** are equally effective alternatives and more effective than the applications submitted by Raleigh Radiology-Knightdale and 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 Unweighted MRI Procedures	Average Net Revenue per MRI Procedure
PHSNC	\$2,296,037	4,685	\$490
EmergeOrtho	\$2,729,933	5,078	\$538
Raleigh Radiology-Cary	\$2,935,153	6,946	\$423
Raleigh Radiology-Knightdale	\$1,737,496	4,269	\$407
DUHS	\$2,866,862	4,408	\$650
Wake Radiology	\$4,266,508	4,424	\$964

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

As shown in the table above, Raleigh Radiology-Knightdale proposes the lower average net revenue per unweighted MRI procedure in the third full fiscal year following project completion. However, Raleigh Radiology-Knightdale does not comply with all applicable statutory and regulatory criteria and therefore Raleigh Radiology-Knightdale is not approvable. Therefore, regarding this comparative factor, the proposal by **Raleigh Radiology-Cary**, which proposes the second lowest average net revenue per unweighted MRI procedure in the third full year following project completion, is the more effective alternative.

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.

Applicant	Operating Expense	# of Unweighted MRI Procedures	Average Operating Expense per Procedure
PHSNC	\$1,749,875	4,685	\$374
EmergeOrtho	\$1,305,239	5,078	\$257
Raleigh Radiology-Cary	\$2,021,044	6,946	\$291
Raleigh Radiology-Knightdale	\$1,482,189	4,269	\$347
DUHS	\$1,495,477	4,408	\$339
Wake Radiology	\$2,890,428	4,424	\$653

Source: Section Q Form C, Form F.2, and Form F.3 of the respective applications

As shown in the table above, EmergeOrtho proposes a lower average operating expense per unweighted MRI procedure. Therefore, regarding average operating expense per MRI procedure, the proposal by **EmergeOrtho** appears more effective.

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	EmergeOrtho	Raleigh Radiology-Cary	Raleigh Radiology-Knightdale	DUHS	Wake Radiology
Conformity with Statutory and Regulatory Review Criteria	Yes	Yes	Yes	No	Yes	No
Scope of Services	Equally Effective	Equally Effective	Equally Effective	Not Approvable	Equally Effective	Not Approvable
Historical Utilization	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Geographic Accessibility	Less Effective	Less Effective	Equally Effective	Not Approvable	Equally Effective	Not Approvable
Access by Service Area Residents: Number of Residents	Less Effective	Less Effective	More Effective	Not Approvable	Less Effective	Not Approvable
Access by Service Area Residents: Percentage of Residents	Less Effective	Less Effective	More Effective	Not Approvable	Less Effective	Not Approvable
Access by Charity Care as a percent of net revenue	More Effective	Less Effective	Less Effective	Not Approvable	Less Effective	Not Approvable
Charity Care per MRI Scan	Less Effective	Less Effective	Less Effective	Not Approvable	More Effective	Not Approvable
Access by Medicare highest dollar amount	Less Effective	Less Effective	More Effective	Not Approvable	Less Effective	Not Approvable
Access by Medicare as a % of Gross Revenue	Less Effective	Less Effective	Less Effective	Not Approvable	More Effective	Not Approvable
Access by Medicaid highest dollar amount	Less Effective	Less Effective	More Effective	Not Approvable	Less Effective	Not Approvable
Access by Medicaid as a % of Gross Revenue	Less Effective	More Effective	Less Effective	Not Approvable	Less Effective	Not Approvable
Competition (Access to New or Alternative Provider)	Equally Effective	Equally Effective	Equally Effective	Not Approvable	Equally Effective	Not Approvable
Projected Average Net Revenue per MRI procedure	Less Effective	Less Effective	More Effective	Not Approvable	Less Effective	Not Approvable
Projected Average Operating Expense per MRI procedure	Less Effective	More Effective	Less Effective	Not Approvable	Less Effective	Not Approvable

As shown in the table above, neither the **Raleigh Radiology-Knightdale** application or the **Wake Radiology** application is an effective alternative with respect to Conformity with Review Criteria; therefore, neither are approvable and neither will be further discussed in the comparative evaluation below:

The **PHSNC**, **EmergeOrtho**, **Raleigh-Radiology-Cary** and **DUHS** applications are conforming to all applicable statutory and regulatory review criteria, and thus these four applications are approvable standing alone. However, collectively they propose a total of four 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, **PHSNC** was determined to be a more effective alternative for the following one factor:

- Access by Charity Care as a percent of net revenue

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

- Access by Medicaid as a % of Gross Revenue
- Projected Average Operating Expense per MRI procedure

As shown in the table above, **Raleigh Radiology-Cary** was determined to be a more effective alternative for the following five factors:

- Access by Service Area Residents: Number of Residents
- Access by Service Area Residents: Percentage of Residents
- Access by Medicare highest dollar amount
- Access by Medicaid highest dollar amount
- Projected Average Net Revenue per MRI procedure

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

- Charity Care per MRI Scan
- Access by Medicare as a % of Gross Revenue

As shown in the table above, **Raleigh Radiology-Cary** and **DUHS** were determined to be equally effective alternatives for the following factor:

- Geographic Accessibility

As shown in the table above, **PHSNC**, **EmergeOrtho**, **Raleigh Radiology-Cary** and **DUHS** were determined to be equally effective alternatives for the following two factors:

- Scope of Services
- Competition (Access to New or Alternative Provider)

CONCLUSION

All the applications are conforming to the need determination in the 2019 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 applications submitted by Raleigh Radiology-Knightdale and Wake Radiology are not approvable and therefore cannot be considered an effective alternative. Consequently, the application submitted by Raleigh Radiology-Knightdale, Project I.D.# J-11826-19 is denied and the application submitted by Wake Radiology, Project I.D.#J-11830-19 is denied.

The Agency determined that the application submitted by Raleigh Radiology, LLC, **Project ID # J-11825-19 (Raleigh Radiology-Cary)** 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 2019 SMFP and therefore, the applications submitted by Pinnacle Health Services of North Carolina, LLC, Project ID # J-11820-19; EmergeOrtho, P.A., Project ID #J-11821-19; and Duke University Health System, Inc., Project ID #J-11829-19; are denied.

The application submitted by Raleigh Radiology, LLC., **Project ID #J-11825-19**, is approved subject to the following conditions:

- 1. Raleigh Radiology, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Raleigh Radiology, LLC shall acquire no more than one fixed MRI scanner pursuant to the need determination in the 2019 SMFP to be located at Raleigh Radiology Cary.**
- 3. Upon completion of the project, Raleigh Radiology Cary shall be licensed for no more than one fixed MRI scanner.**
- 4. Raleigh Radiology, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 5. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Raleigh Radiology, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**

- d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**
- 6. Raleigh Radiology, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**