

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2016

Findings Date: September 29, 2016

Project Analyst: Gloria C. Hale

Team Leader: Fatimah Wilson

Assistant Chief: Martha J. Frisone

COMPETITIVE REVIEW

Project ID #: J-011167-16
Facility: Duke Radiology Holly Springs
FID #: 160156
County: Wake
Applicant: Duke University Health System, Inc.
Project: Acquire one fixed MRI scanner and develop a diagnostic center

Project ID #: J-11159-16
Facility: Raleigh Radiology Cary
FID #: 080405
County: Wake
Applicant: Raleigh Radiology, LLC
Project: Acquire one fixed MRI scanner

Project ID #: J-11172-16
Facility: Wake Radiology - Wake Forest MRI Office
FID #: 160160
County: Wake
Applicants: Wake Radiology Services LLC and Wake Radiology Diagnostic Imaging, Inc.
Project: Acquire one fixed MRI scanner and develop a diagnostic center

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C
DRHS
Raleigh Radiology

NC
Wake Radiology

Need Determination

The 2016 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional fixed MRI scanners by service area. Application of the need methodology in the 2016 SMFP did not identify a need for any additional fixed MRI scanners in the Wake County MRI Service Area. However, a need determination for one fixed MRI scanner was included based on a petition. Three applications were submitted to the Healthcare Planning and Certificate of Need Section, each proposing to acquire a fixed MRI scanner for Wake County.

Duke University Health System, Inc. (DUHS) d/b/a Duke Radiology Holly Springs (DRHS) - proposes to acquire one fixed MRI scanner to be installed in a new medical office building to be located at New Hill Road and NC Highway 55 Bypass in Holly Springs, Wake County. Primary care, urgent care, and specialty physician practices will be co-located in the building. DUHS owns and operates two fixed MRI scanners at Duke Raleigh Hospital. In addition, DUHS provides mobile MRI services, through a service agreement with Alliance Imaging, at both Duke Raleigh Hospital and Duke Imaging Services at Cary Parkway. DUHS does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2016 SMFP for Wake County. Therefore, the application is consistent with the need determination.

Raleigh Radiology, LLC d/b/a Raleigh Radiology Cary (Raleigh Radiology) – proposes to acquire one fixed MRI scanner to be installed at its Raleigh Radiology Cary (RR Cary) location at 150 Parkway Office Court, Suite 100, Cary, to replace an MRI scanner, which is owned and operated by Alliance Healthcare Services. In Section I.12, page 17, the applicant states that Raleigh Radiology operates two diagnostic centers, Raleigh Radiology Blue Ridge and Raleigh Radiology Cary, and one imaging center, Raleigh Radiology Breast Center, but does not own or operate the MRI scanners at Raleigh Radiology Blue Ridge or Raleigh Radiology Cary. Raleigh Radiology Breast Center does not offer MRI services. In Section II.8, page 30, the applicant states that neither it nor a related entity own a controlling interest in or operate fixed MRI scanners

or mobile MRI scanners in the proposed MRI service area. Raleigh Radiology does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2016 SMFP for Wake County. Therefore, the application is consistent with the need determination.

Wake Radiology Services, LLC and Wake Radiology Diagnostic Imaging, Inc. (Wake Radiology) – proposes to acquire one fixed MRI scanner to be installed at its Wake Radiology – Wake Forest MRI Office (WRWF). Wake Radiology owns and operates four fixed MRI scanners in Wake County: one at Wake Radiology-Garner, one at Wake Radiology Diagnostic Imaging in Cary, and two at Wake Radiology-Raleigh. In addition, Wake Radiology owns and operates a mobile MRI scanner at four locations in Wake County: North Raleigh, Fuquay-Varina, Wake Forest, and Cary. Wake Radiology does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2016 SMFP for Wake County. Therefore, the application is consistent with the need determination.

Policies

There are two policies in the 2016 SMFP that are applicable to this review, Policy GEN-3: Basic Principles, page 39, and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, pages 39-40.

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.”

DRHS

Promote Safety and Quality

The applicant describes how it believes its proposal would promote safety and quality in Section II.7, page 23, Section III.2, pages 81-82, , and Exhibit 5. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes its proposal would promote equitable access in Section II.1, pages 14-15, Section II.5, page 18, Section III.1, page 53, Section VI, pages 111-116, and Exhibits 7 and 8. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes its proposal would maximize health care value in Section III.2, page 80, and in the applicant's pro forma financial statements. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2016 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. The discussion regarding revenues and costs found in Criterion (5) is incorporated herein by reference. Therefore, the application is consistent with Policy GEN-3.

Raleigh Radiology

Promote Safety and Quality

The applicant describes how it believes its proposal would promote safety and quality in Section II.6, page 27, Section II.7, page 28, Section III.2, page 72, and Exhibits 9 and 10. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes its proposal would promote equitable access in Section III.1, pages 58-59, Section III.2, page 73, Section VI, pages 108-115, and Exhibits 18 and 19. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access based on the historical payor mix. However, see the discussion in Criterion (13c) regarding the reasonableness of the projected payor mix.

Maximize Healthcare Value

The applicant describes how it believes its proposal would maximize health care value in Section III.1, page 73, Section X.1, page 144, and in the applicant's pro forma financial

statements. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2016 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. The discussion regarding revenues and costs found in Criterion (5) is incorporated herein by reference. Therefore, the application is consistent with Policy GEN-3.

Wake Radiology

Promote Safety and Quality

The applicants describe how they believe their proposal would promote safety and quality in Section II.5, page 23, Section II.6, pages 23-24, Section II.7, pages 24-25, Section III.2, page 52, and Exhibits F and H. The information provided by the applicants is reasonable and adequately supports the determination that the applicants' proposal would promote safety and quality.

Promote Equitable Access

The applicants describe how they believe their proposal would promote equitable access in Section III.2, page 52, Section VI, pages 70-77, and Exhibit E. The information provided by the applicants is reasonable and adequately supports the determination that the applicants' proposal would promote equitable access.

Maximize Healthcare Value

The applicants describe how they believe their proposal would maximize health care value in Section III.2, page 52, Section X.1, page 94, and in the applicants' pro forma financial statements.

However, the applicants do not demonstrate how the projected volumes incorporate the concept of maximum value for resources expended. The applicants do not adequately demonstrate the need to acquire a fixed MRI scanner. Therefore, the applicants fail to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2016 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. The discussion regarding revenues and costs found in Criterion (5) is incorporated herein by reference. Therefore the application is not consistent with Policy GEN-3.

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. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

DRHS

The proposed capital expenditure for this project is greater than \$5 million. In Section III.2, page 79, Section XI.7, pages 155-156, the applicant describes how it will assure improved energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Raleigh Radiology

The proposed capital expenditure for this project is greater than \$2 million and less than \$5 million. In Section III.2, page 74, the applicant describes how it will assure improved energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Wake Radiology

The proposed capital expenditure for this project is less than \$2 million. Therefore, Policy GEN-4 is not applicable to the review of this application.

Conclusion

In summary, all three applications are conforming to the need determination in the 2016 SMFP for an additional MRI scanner in Wake County. However, the limit on the number of MRI scanners that may be approved in this review is one MRI scanner. Collectively, the three applicants propose a total of three MRI scanners. Therefore, even if all three applications were conforming to all statutory and regulatory review criteria, all three applications cannot be approved.

DRHS' and Raleigh Radiology's applications are conforming to Policy GEN-3. Wake Radiology's application is not conforming to Policy GEN-3.

DRHS' and Raleigh Radiology's applications are conforming to Policy GEN-4. Policy GEN-4 is not applicable to Wake Radiology's application.

Therefore, DRHS' and Raleigh Radiology's applications are conforming to this criterion and Wake Radiology's application is not conforming to this criterion.

See the Summary following the Comparative Analysis for the decision.

- (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
DRHS
Raleigh Radiology

NC
Wake Radiology

DRHS proposes to acquire one fixed MRI scanner to be installed in a new medical office building to be located in Holly Springs. Primary care, urgent care, and specialty physician practices will be co-located in the building. DUHS owns and operates two fixed MRI

scanners at Duke Raleigh Hospital. In addition, DUHS provides mobile MRI services, through a service agreement with Alliance Imaging, at both Duke Raleigh Hospital and Duke Imaging Services at Cary Parkway (Cary Parkway).

Population to be Served

On page 154, the 2016 SMFP defines the service area for a fixed MRI scanner as “*a single county, except where there is no licensed acute care hospital located within the county.*” The definition of the service area for a fixed MRI scanner then explains how a service area is determined when there is no licensed acute care hospital located within the county. For the purpose of this review, however, Wake County is the service area since it has multiple licensed acute care hospitals. Providers may serve residents of counties not included in their service area.

DRHS is not an existing facility, therefore there is no current patient origin. In Section III.5, page 90, the applicant provides the projected patient origin for DRHS for the first two operating years of the proposed project, as illustrated in the table below:

DRHS Projected Patient Origin

County	FY2019 Percent of Total	FY2020 Percent of Total
Wake	90.0%	88.0%
Other*	10.0%	12.0%
Total	100.0%	100.0%

*Other includes <1% patient origin from each of 33 North Carolina counties listed on page 90, and other states.

The applicant adequately identifies the population to be served.

Need Analysis

In Section III.1, pages 34-53, the applicant states that the need for the proposed fixed MRI scanner at the DRHS location is based on the following factors:

- Rapid population growth in Wake County and in the primary service area of Apex and Southwest Wake County. [see pages 35-39]
- Geographic access to MRI services in a sub-region where there is very limited access currently. [see pages 40-44]
- Stabilization of statewide and Wake County MRI utilization rates indicating an ongoing need for MRI services. [see pages 44-46]
- Growth in MRI utilization for DUHS in Wake County. [see pages 47-51]
- DUHS’ planned expansion of primary, specialty, and urgent care services in the service area. [see pages 51-53, Exhibits 16 and 17]

The information in the pages referenced above is reasonable and adequately supported for the following reasons:

- Population growth is occurring in Wake County and in the applicant's stated primary market,
- Access to MRI services in the proposed location is limited, and
- The applicant provides sufficient evidence of MRI services growth at its facilities.

Projected Utilization

Step 1:

In Section III.1, pages 54-57, the applicant discusses population growth in Wake County, providing a table of population data by zip code, on pages 55-56, and a table of population projections by zip code for its proposed service area, on page 57.

Step 2:

In Section III.1, pages 57-58, the applicant determines the statewide MRI utilization rate using North Carolina Office of State Budget and Management (OSBM) population data and the total number of MRI procedures reported in the annual SMFPs. The applicant states that the MRI use rate for the state has remained stable at a weighted average of 80.4 MRI procedures per 1,000 persons. The applicant projects that the statewide MRI use rate of 80.4 MRI procedures per 1,000 persons will remain stable based on population growth, aging, and the potential positive impact of the Affordable Care Act. Based on an analysis of this data, the Project Analyst finds this projected statewide MRI use rate to be reasonable.

Step 3:

The applicant projects the number of MRI procedures by zip codes in its primary market, Apex and Southwest Wake County, and for its secondary service area, the remainder of Wake County, by multiplying the population projections for these areas by the projected MRI use rate of 80.4 per 1,000 persons. A table depicting the results of these calculations is provided on page 59 of the application.

Step 4:

The applicant states, on page 60 of the application, that it has historically provided MRI services to patients in the proposed project's primary market at Duke Raleigh Hospital, Cary Parkway, and Duke University Hospital. Therefore, it anticipates that some of the MRI patient volume from these facilities from the proposed primary market will shift to DRHS. The applicant provides its assumptions for this shift on page 60.

Step 4a:

The applicant provides tables, on pages 61-62 of the application, depicting historical inpatient and outpatient MRI procedure volume for Duke Raleigh Hospital and Duke

University Hospital's fixed and mobile MRI scanners, and outpatient MRI procedure volume for Cary Parkway's mobile MRI scanner from the proposed project's primary market by zip code.

Step 4b:

The applicant projects MRI utilization before primary market patient volume shift to DRHS for Duke Raleigh Hospital, Cary Parkway, and Duke University Hospital, stating that increases in MRI utilization are expected at these facilities since increases in MRI utilization are expected throughout DUHS.

The applicant provides a table, on page 63 of the application, of projected MRI utilization for Duke Raleigh Hospital's fixed MRI scanners and states that projected inpatient MRI utilization is based on the inpatient CAGR of 1.7% for FY2013-FY2015. The applicant does not state if it uses the number of unweighted or weighted MRI procedures to calculate its CAGR. The Project Analyst calculates a CAGR of 1.7% using the number of unweighted MRI procedures, and determines that the application of this CAGR is reasonable.

In the same table, on page 63 of the application, the applicant provides projected outpatient MRI utilization of its fixed MRI scanners for Duke Raleigh Hospital, stating that it uses one-fourth of the outpatient CAGR of 22.8% for FY2013-FY2015 which is 5.7%. The applicant does not state if it uses the number of unweighted or weighted MRI procedures to calculate its CAGR. The Project Analyst calculated the CAGRs for both unweighted and weighted MRI procedures, resulting in the same CAGR for both of 20.6% which is slightly lower than the applicant's CAGR. The Project Analyst calculated one-fourth of the corrected CAGR of 20.6% at 5.2%. The Project Analyst determined that the applicant's projected utilization of outpatient MRI procedures is reasonable given the application of a growth factor that is much less than the CAGR.

The applicant provides a table, on page 63 of the application, of projected outpatient MRI utilization for the mobile MRI scanner at Duke Raleigh Hospital. The applicant states, on page 64, that it uses the same growth factor as it does for projecting its outpatient fixed MRI utilization of one-fourth of the outpatient fixed MRI CAGR of 22.8%, for FY2013-FY2015, which is 5.7%. The Project Analyst calculated a slightly lower CAGR of 20.6% and calculated one-fourth at 5.2%. However, based on MRI data reported in Duke Raleigh Hospital's License Renewal Applications (LRAs) for FY2013-FY2015, the CAGR for its unweighted outpatient mobile MRI procedures was -26%. However, the 2016 LRA reports 893 unweighted outpatient mobile MRI procedures, representing an increase of 262% from the previous year. In addition, Duke Raleigh Hospital's CAGR for unweighted MRI procedures for FY2013-FY2015 for all of three of its MRI scanners operated on campus, two fixed and one mobile, was 10.8%. Therefore, the Project Analyst concluded that the applicant's use of 5.7% to project utilization of the mobile MRI scanner is reasonable.

To project mobile MRI utilization for Cary Parkway, the applicant states, on page 64 of the application, that it uses a CAGR of 5.4% based on *“the average incremental increase of approximately 0.5 procedures per day per year.”* The applicant states that the CAGR is lower compared to the percentage growth rate from FY15 to FY16 annualized [34.3%] and is lower than the projected growth rate for Duke Raleigh Hospital’s outpatient MRI utilization of 5.7%. The CAGR for Cary Parkway for FY2014-FY2016 annualized was 165.9%. Therefore, the Project Analyst concluded that the applicant’s growth rate of 5.4% is reasonable. A table depicting Cary Parkway’s projected mobile MRI utilization is provided on page 64 of the application.

The applicant provides a table, on page 65 of the application, of projected MRI utilization for Duke University Hospital’s fixed and mobile MRI scanners. The applicant states that projected inpatient MRI utilization is based on the inpatient CAGR of 3.9% and projected outpatient MRI utilization is based on the outpatient CAGR of 3.2% for FY2013-FY2015. The applicant does not state if it is using weighted or unweighted MRI procedures in its calculations. Using unweighted MRI procedures, the Project Analyst calculated an inpatient CAGR of 2.0% and an outpatient CAGR of 20.7%. The Project Analyst also calculated the CAGR for total unweighted MRI procedures and weighted MRI procedures for FY2013-FY2015 at 16.8% and 16.0%, respectively. Therefore, the Project Analyst concluded that the applicant’s projections are reasonable.

Step 4c:

The applicant projects a gradual shift in outpatient MRI volume from DRHS’ primary market from Duke Raleigh Hospital, Cary Parkway, and Duke University Hospital to DRHS. The applicant provides its assumptions regarding the percentage of shift in MRI volume from the primary market, Apex and Southwest Wake County, on page 60 of the application. The applicant’s percentages of shift for each facility are provided in a table on page 66 of the application. The applicant’s percentages of gradual shift are reasonable given they represent only a portion of DUHS’ Wake County MRI service volume from the primary market. The applicant multiplies these percentages to its projected outpatient MRI utilization for Apex and Southwest Wake County for Duke Raleigh Hospital, Cary Parkway, and Duke University Hospital to obtain the projected MRI utilization based on shift of MRI volume for the first three operating years. The applicant provides these results in Exhibit 15, Attachment 2. A table summarizing the results from the three facilities combined is provided on page 67 of the application.

In addition, the applicant states, on page 67 of the application, that it expects a portion of DUHS’ projected MRI utilization to shift from the secondary market to DRHS, however, *“to remain conservative and for purposes of projecting utilization for the proposed project, DUHS projects volume to shift only from the primary service area [i.e., market].”*

Step 4d:

On page 68 of the application, the applicant states that it calculated DRHS' projected market share by dividing the projected MRI utilization based on shift of MRI volume by the total projected number of MRI procedures expected for the primary market. A table depicting percent market share is provided on page 68.

Step 5:

The applicant states that DRHS will gain additional, incremental market share based on several factors discussed on pages 68-72 of the application. A table is provided, on page 69, of DRHS' projected percentage of additional, incremental market share for the primary market by zip code. On page 72, the percentages of additional, incremental market share are multiplied by the projected number of MRI procedures by primary market zip codes in Step 3, resulting in the projected number of additional, incremental MRI procedures depicted in a table on page 72.

Step 6:

The applicant combines the percentages of market share by shift of MRI procedures in Step 4d and the percentages of additional, incremental MRI market share in Step 5, to reflect DRHS's total MRI market share, as depicted in a table on page 73 of the application. The Project Analyst calculated Duke Raleigh Hospital, Cary Parkway, and Duke University Hospital's outpatient MRI procedures market shares of the primary market for FY2016 annualized, the last year of historical data, using data reported by the applicant on pages 63-65 and from Exhibit 15, page 2, summarized as follows:

**Market Share for Primary Market, Outpatient MRI Procedures
FY2016 Annualized**

MRI facility	Duke Raleigh Hospital	Cary Parkway	Duke University Hospital
Market Share for Primary Market	4.5%	13.3%	2.7%

The average market share of outpatient MRI procedures in the primary market for DUHS' MRI services in Wake County in FY2016 was 6.8%. However, Cary Parkway's MRI market share for the primary market is likely to be more similar to that proposed for DRHS due to its relative proximity to the proposed fixed MRI site as compared to DUHS' other two MRI sites. The applicant projects that DRHS' total market share of the primary market will be 9.2%, 12.8%, and 17.4% in FY2019, FY2020, and FY2021, respectively. The proposed DRHS site is to be located within the applicant's primary market, therefore it is reasonable to assume that a larger proportion of MRI procedures from the primary market will be performed at DRHS. Therefore, the Project Analyst concludes that the applicant's total market share for the primary market for all three operating years is reasonable.

Step 7:

The applicant provides a table, on page 74 of the application, of the number of projected MRI procedures, by zip code, for DRHS. The number of projected MRI procedures is calculated by multiplying the total market share in Step 6 by the projected number of MRI procedures by primary market zip codes in Step 3.

Step 8:

The applicant states that in-migration of MRI patients will occur from outside Wake County to DRHS. The applicant states, on page 75 of the application, that in FY2015 approximately 29% of Duke Raleigh Hospital's MRI outpatients and approximately 31% of Cary Parkway's MRI outpatients were from counties outside Wake County. The Project Analyst determined that 26.2% of Duke Raleigh Hospital's patient origin for all MRI services, both inpatient and outpatient, were from outside Wake County in FY2015 according to Duke Raleigh Hospital's 2016 LRA. Therefore, the Project Analyst concluded that the applicant's percentages used for projecting in-migration are reasonable. Patient origin data was not available for Cary Parkway. The mobile MRI provider for Cary Parkway, Alliance Imaging Services, stated on its 2016 Registration and Inventory Form for Medical Equipment that it does not collect patient origin data. The applicant's projected percentages of in-migration for each of the three operating years are well below the percentages the applicant provides for FY2015 outpatient MRI procedures at Duke Raleigh Hospital and Cary Parkway. The applicant proposes 10%, 12%, and 15% in-migration for FY2019, FY2020, and FY2021, as stated on page 75 of the application.

The applicant adds its projected number of MRI patients from in-migration and provides its total unweighted MRI procedures in a table on page 76 of the application.

Step 9:

The applicant projects its weighted MRI procedures based on historical outpatient MRI utilization with contrast for Cary Parkway, its freestanding, off-campus MRI service in Wake County, in a table on page 76 of the application. As stated on page 76, based on FY2016 annualized data, approximately 42% of Cary Parkway's MRI procedures, or 711 [704] of 1,676 MRI procedures used contrast. Therefore, total weighted MRI procedures equaled 1,960 for a ratio of 1.17 (1,960 [1,958] weighted MRI procedures/1,676 unweighted procedures). The applicant applies the ratio of 1.17 to the total unweighted MRI procedures to project the total weighted MRI procedures for the first three operating years of the project. Since Cary Parkway's FY2016 data was not available to the Project Analyst, the FY2015 data from the Registration and Inventory of Medical Equipment form was reviewed. Cary Parkway performed 36.8% of its MRI procedures with contrast (498 with contrast/1,352 total). Therefore, total weighted MRI procedures equaled 1,551 for a ratio of 1.15 (1,551 weighted MRI procedures/1,352 unweighted procedures). Therefore, the Project Analyst concluded that the ratio used by the applicant to project its weighted MRI procedures for DRHS is reasonable.

As shown in the table on page 76, the applicant projects that its proposed fixed MRI scanner at DRHS will perform 5,193 weighted MRI procedures in FY2021, the third operating year of the proposed project.

Projected Utilization for Two Fixed MRI Scanners at Duke Raleigh Hospital

Step 1:

In Section III.4, page 63, and Section IV.1, page 99, the applicant provides historical and projected utilization for its two fixed MRI scanners at Duke Raleigh Hospital.

The applicant states, in Section III.4, page 63, and Section IV.1, page 99, that Duke Raleigh Hospital's projected inpatient fixed MRI utilization is based on the inpatient fixed MRI utilization CAGR of 1.7% for the period FY2013-FY2015. In addition, the applicant states that Duke Raleigh Hospital's projected outpatient MRI utilization is based on one-fourth of the outpatient CAGR of 5.7% (22.8% CAGR/4) for FY2013-FY2015. However, the Project Analyst calculated a slightly lower outpatient CAGR of 20.8%. One-fourth of 20.8% equals 5.2%. Therefore, the applicant's projected MRI utilization for Duke Raleigh Hospital for FY2017-FY2021 is slightly overstated.

Step 2:

The applicant states, in Section III.4, pages 65-66, and Section IV.1, page 100, that a portion of Duke Raleigh Hospital's outpatient fixed MRI utilization will shift to DRHS. The applicant provides its assumptions for this shift on page 60 of the application. The percentages of gradual shift, on page 66, are reasonable given they represent only a portion of Duke Raleigh Hospital's MRI service volume from the primary market. The applicant provides its projected volume of shift by zip code by DUHS facility in Exhibit 15, Attachment 2. The applicant provides a table, on page 100, of the number of MRI procedures projected at Duke Raleigh Hospital minus the number of MRI procedures shifted to DRHS.

Duke Raleigh Hospital's two fixed MRI scanners are projected to perform 14,413 weighted MRI procedures in the third operating year of the proposed project, FY2021. Each fixed MRI scanner will perform an average of 7,207 weighted MRI procedures (14,413/2).

Therefore the projected, combined weighted MRI utilization of the applicant's two fixed MRI scanners and its proposed fixed MRI scanner in the third year of operation following completion of the proposed project is illustrated as follows:

**DRHS
Projected Fixed MRI Procedures
Wake County
OY3**

Fixed MRI Scanners	# of Weighted MRI Procedures
Proposed MRI scanner at DRHS	5,193
Existing 2 MRI scanners at Duke Raleigh Hospital	14,413
Total	19,606
Average utilization per MRI scanner	6,535

The average annual utilization of the applicant's existing, approved and proposed fixed MRI scanners in the proposed MRI service area is projected to be 6,535 weighted MRI procedures in the third year of operation of the proposed project, thereby exceeding the performance standard of 4,805 weighted MRI procedures, as required by 10A NCAC 14C .2703(b)(3). Even with the slightly lower CAGR calculated by the Project Analyst, projected utilization exceeds 4,805 weighted MRI procedures per scanner.

Projected utilization is based on reasonable and adequately supported assumptions, summarized as follows:

- Population growth of the primary market,
- Historical MRI use rates,
- Historical market share,
- Lower than historical in-migration, and
- Historical weighting factor

Based on review of: 1) the information provided by the applicant in Section III, pages 54-76, Section IV, pages 99-100, including referenced exhibits; 2) comments received during the first 30 days of the review cycle; and 3) the applicant's response to the comments received at the public hearing, the applicant adequately documents the need for the project for the reasons discussed above.

Access

DRHS will be a new facility, therefore there is no historical payor mix for the diagnostic center. In Section VI, pages 111-116, the applicant describes its policies to ensure access to medically underserved persons, stating, on page 111, that DRHS will *"have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved."* In addition, in Section VI.15, page 124, the applicant projects that 32.6% of DRHS' MRI patients will be covered by Medicare (27.4%) and Medicaid (5.2%). The applicant projects the project's payor mix based on recent historical outpatient MRI

payor mix at Duke University Hospital, Duke Raleigh Hospital, and Cary Parkway in Section VI.14, pages 122-123.

Conclusion

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need the population to be served has for the proposed fixed MRI scanner. Furthermore, the applicant adequately demonstrates the extent to which all residents of the area, including medically underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

Raleigh Radiology

Raleigh Radiology proposes to acquire one fixed MRI scanner to be installed at its RR Cary location at 150 Parkway Office Court, Suite 100, Cary, to replace mobile MRI services provided by Alliance Healthcare Services.

Population to be Served

On page 154, the 2016 SMFP defines the service area for a fixed MRI scanner as “*a single county, except where there is no licensed acute care hospital located within the county.*” The definition of the service area for a fixed MRI scanner then explains how a service area is determined when there is no licensed acute care hospital located within the county. For the purpose of this review, however, Wake County is the service area since it has multiple licensed acute care hospitals. Providers may serve residents of counties not included in their service area.

In Section III.4, pages 80 and 83, the applicant provides its current and projected patient origin for MRI services at RR Cary, respectively, summarized as follows:

**RR Cary
Current and Projected MRI Services**

County	Current Patient Origin CY2015	Projected Patient Origin CY2018-CY2019
Wake	83.8%	84.3%
Harnett	4.1%	4.1%
Johnston	2.9%	2.9%
Chatham	2.5%	2.5%
Lee	1.3%	0.8%
Durham	1.0%	1.0%
All Others*	4.4%	4.4%
Total	100.0%	100.0%

*For a description of All Others, for current and projected patient origins, see pages 80 and 83, respectively.

The applicant states, in Section III.5, page 84, that it expects patient origin to change slightly based on where population growth is occurring. The applicant provides its assumptions for projected payor mix in Section III.5, pages 84-86. The applicant adequately identified the population proposed to be served.

Need Analysis

In Section III.1, pages 36-59, the applicant states that the need for the proposed fixed MRI scanner at RR Cary is based on the following factors:

- 2016 SMFP’s adjusted need determination for one, fixed MRI scanner in Wake County. [see pages 37-39]
- Higher projected growth of Wake County’s 45-64 and 65+ year old age groups than statewide growth for these respective age groups. [see pages 39-42]
- Higher projected growth in 4 of 5 counties RR Cary serves outside of Wake County as compared to statewide growth. [see pages 43-44]
- Limited access to MRI services as evidenced by lower ratio of MRI scanners per population in southern Wake County compared to northern Wake County. [see pages 44-47]
- Increasing demand for MRI services at RR Cary coupled with limited capacity. [see pages 48-50]
- Lack of access to 3T MRI scanner in Wake County. [see pages 51-52]
- Lack of access to low cost, full-service MRI services. [see pages 52-58]
- Need for MRI services operated at freestanding, lower cost outpatient facilities and that are operated on weekends. [see pages 58-59]

The information in the pages reference above is reasonable and adequately supported for the following reasons:

- Higher projected growth in older age groups in Wake County than statewide,
- Higher projected growth in applicant’s market outside Wake County than statewide,
- Historical growth of MRI procedures at proposed site, and
- Limited access to lower cost, outpatient MRI services.

Projected Utilization – Raleigh Radiology’s Proposed Fixed MRI Scanner at RR Cary

Step 1:

In Section IV.1, page 99, the applicant provides the historical and projected utilization, as summarized below:

RR Cary Historical and Projected MRI Utilization							
	CY2014 Actual	CY2015 Actual	Interim CY2016	Interim CY2017*	Project Year 1 CY2018	Project Year 2 CY2019	Project Year 3 CY2020
Number of MRI Procedures	4,677	5,559	5,955	6,737	8,046	8,046	8,046
Number of Weighted MRI Procedures	4,943	5,871	6,288	7,114	8,496	8,496	8,496

*The fixed MRI scanner is projected to begin operating during CY 2017.

The applicant calculates the average MRI weighting factor for MRI procedures performed at RR Cary in 2013, 2014, and 2015, on page 94. The applicant applies a weighting factor of 1.2 to the number of MRI procedures performed with contrast to obtain the number of weighted MRI procedures performed. However, the weighting factor of 1.2 is incorrect. According to the 2016 SMFP, page 156, the weighting factor for outpatient MRI procedures with contrast is 1.4. The applicant divides the total number of weighted MRI procedures by the number of total unweighted MRI procedures to obtain the average weighting factor. The applicant calculates an average weighting factor of 1.06 for each year, 2013-2015. A table depicting RR Cary’s MRI utilization data for CY2013-CY2015, including its average weighting factor, is provided on page 94.

Step 2:

The applicant calculates the CAGR for RR Cary’s unweighted MRI procedures from CY2013-CY2015 on page 95. The CAGR is 20.5%. The applicant states, on page 96, that using the CAGR of 20.5% is reasonable given an even greater growth in its unweighted MRI procedures from 2010 to 2014 of 31.4%. A table is provided of RR Cary’s total unweighted MRI procedures and CAGR for CY2010-CY2014, on page 96. The applicant provides its assumptions for continued growth of MRI procedures at RR Cary, on pages 96-97, which include population growth in Wake County and in its secondary service areas of Harnett, Johnston, Chatham, Lee, and Durham counties, and an aging population.

Step 3:

The applicant calculates the capacity of the existing Alliance MRI scanner and the proposed, fixed MRI scanner for CY2017, on page 97, stating that the Alliance scanner will be operational for four months at an annual capacity of 5,955 MRI procedures, and the proposed fixed MRI scanner will be operational for eight months at an annual capacity of 8,046 MRI procedures. The total number of MRI procedures for CY2017 will be 7,349 $[5,955 \times (4/12) + 8,046 (8/12)]$. On page 97, the applicant provides its assumptions, stating,

“...the applicant assumes the procedure mix will remain constant, therefore the average scan times will remain constant and the average-weighting factor will remain constant. This is reasonable, as RRCary [sic] average weighting factors for RRCary have been relatively stable.”

Step 4:

The applicant projects, on page 97, the number of MRI procedures for CY2016 – CY2020 by applying the CAGR of 20.5%, stating that this results in the *‘total ‘possible’ MRI procedures at RR Cary, before considering its maximum capacity.’* The applicant reduces the number of MRI procedures for CY2017 by one month to account for downtime to remove the Alliance MRI scanner and install the proposed fixed MRI scanner. As stated in Step 3 above, the maximum capacity of the proposed fixed MRI scanner is 8,046 MRI procedures, therefore since the *‘possible’* projections for each of the first three operating years exceed 8,046 MRI procedures, the applicant keeps its projections level for the first three operating years at 8,046 MRI procedures. The applicant calculates the number of weighted MRI procedures for each year by multiplying the unweighted number of MRI procedures by the average weighting factor. The applicant provides a table summarizing its projected MRI utilization on page 99.

The applicant projects that the proposed fixed MRI scanner will perform 8,046 MRI procedures in operating years one, two, and three. Therefore, the applicant demonstrates that the average annual utilization of the proposed fixed MRI scanner which it or a related entity owns a controlling interest in and locates in Wake County is reasonably expected to perform at least 4,805 weighted MRI procedures in the third year of operation following completion of the proposed project.

Projected utilization is based on reasonable and adequately supported assumptions, summarized as follows:

- Historical growth rate of MRI procedures,
- Historical weighting factor, and
- Maintains level projections during all three project years.

Based on review of: 1) the information provided by the applicant in Section IV, pages 94-97, including referenced exhibits; 2) comments received during the first 30 days of the review cycle; and 3) the applicant's response to the comments received at the public hearing, the applicant adequately documents the need for the project for the reasons discussed above.

Access

In Section VI.2, page 108, the applicant states, that it "*accepts all patients, regardless of gender, race, ethnicity, age, income, or disability status.*" In addition, the applicant states that it provides a 100 percent discount for self-pay balances for families with incomes under 250 percent of the Federal Poverty Level. See Exhibit 18 for a copy of this policy. In addition, in Section VI.15, page 121, the applicant projects that 32.5% of RR Cary's MRI patients will be covered by Medicare (30.5%) and Medicaid (2.0%). The applicant provides its assumptions for its projections of payor mix in Section VI.15, pages 121-123. A discussion of the reasonableness of the applicant's assumptions is found in Criterion 13(c) of these Findings.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need the population to be served has for the proposed fixed MRI scanner and adequately demonstrates the extent to which all residents of the area, including medically underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

Wake Radiology

Wake Radiology proposes to acquire one fixed MRI scanner to be installed at its Wake Radiology – Wake Forest Office. Wake Radiology or a related entity owns a mobile MRI scanner that it operates at four locations in Wake County, including the Wake Forest site.

Population to be Served

On page 154, the 2016 SMFP defines the service area for a fixed MRI scanner as "*a single county, except where there is no licensed acute care hospital located within the county.*" The definition of the service area for a fixed MRI scanner then explains how a service area is determined when there is no licensed acute care hospital located within the county. For the purpose of this review, however, Wake County is the service area since it has multiple licensed acute care hospitals. Providers may serve residents of counties not included in their service area.

In Section III.4, page 55, the applicants provide their current patient origin for their mobile MRI services at WRWF, and state, in Section III.5, page 57, that their proposed

fixed MRI patient origin will be similar. Current patient origin for CY2015 is summarized as follows:

**WRWF
Patient Origin
Mobile MRI Service**

County	CY2015
Wake	65.5%
Franklin	26.7%
Other NC*	6.7%
Out of State	1.1%
Total	100.0%

*See page 55 for a listing of other NC counties

In Section III.5, page 57, the applicants provide their projected patient origin for fixed MRI services at WRWF for the first two operating years after project completion, summarized as follows:

**WRWF
Projected Patient Origin**

County	FY2018 (7/01/17 – 6/30/18)	FY2019 (7/01/18 – 6/30/19)
Wake	52.4%	58.1%
Franklin	41.6%	35.9%
Other NC*	5.0%	5.0%
Out of State	1.0%	1.0%
Total	100.0%	100.0%

*See page 57 of application for full listing of other NC counties

The applicants state, in Section III.5, page 57, that they project an increased percentage of Franklin County patients over historical levels due to the closure of the Novant Health Franklin Medical Center and its MRI service in October 2015. In addition, the applicants expect an increased percentage of Wake County patients and a decrease of Franklin County patients in operating year two due to the higher population growth of Wake County compared to Franklin County. The applicants provide their assumptions for projected payor mix in Section III.5, page 57. The applicants adequately identified the population proposed to be served.

Need Analysis

In Section III.1, pages 37-47, the applicants discuss the need for the proposed fixed MRI scanner at WRWF, summarized as follows:

- Need determination in the 2016 SMFP. [see page 37]
- Limitation of existing mobile MRI scanner at WRWF to perform breast scans due to absence of coil and to accommodate patients with claustrophobia or who are obese due to its narrow bore. [see page 37]
- Higher population growth rate of combined service area of Wake and Franklin counties as compared to statewide. [see page 38]
- Higher population growth rate of persons aged 65 and older for combined area of Wake and Franklin counties as compared to statewide. [see pages 38-39]
- Wake Forest is fastest growing area of the county, yet has no fixed MRI services. [see pages 39-44]
- Increase in number of mobile MRI scans at WRWF as a whole and, specifically, for Franklin County residents due to closure of the Novant Health Franklin Medical Center, that county's lone provider of MRI services. [see pages 44-46]
- Growth in the number of MRI patients served by Wake Radiology's four fixed and one mobile MRI scanners in Wake County. [see pages 48, 50-51]

The information in the pages referenced above is reasonable and adequately supported for the following reasons:

- Limitations of existing mobile MRI scanner in regard to technological capability and physical structure,
- Higher population growth rates of market than statewide,
- Limited access to MRI services in market area, and
- Historical growth in MRI procedures of applicants' MRI scanners in Wake County.

Historical Utilization of Wake Radiology's Four Fixed MRI Scanners

In Section II.8, page 28, the applicants provide historical MRI utilization for their four fixed MRI scanners located in Cary, Garner, and Raleigh, from 4/01/15 through 3/31/16, summarized as follows:

**Wake Radiology Historical Utilization, Fixed MRI Scanners
4/1/15 – 3/31/16**

Site	Number of Weighted MRI Procedures
Wake Radiology Raleigh MRI*	6,760
Wake Radiology Garner	2,783
Wake Radiology Cary	4,048
Total for all four fixed MRI scanners	13,592
Average per fixed MRI scanner	3,398

*There are two fixed MRI scanners at Wake Radiology Raleigh MRI

The applicants demonstrate that their existing fixed MRI scanners located in Wake County performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which they had data.

Projected Utilization of the proposed fixed MRI scanner at WRWF

Step 1:

In Section III.1, pages 48-49, the applicants project utilization of the proposed fixed MRI from 3/31/16 through 6/30/20. The applicants state that they used weighted mobile MRI procedures performed at WRWF from data published in the 2013 SMFP through the 2016 SMFP and annualized 2016 data to calculate a CAGR of 31.35%. The applicants provide a table, Exhibit 16, on page 45 of the application, of the historical, weighted mobile MRI procedures performed at WRWF. However, based on a review of MRI utilization data in the SMFPs, the Project Analyst concluded that Exhibit 16, on page 45 of the application, actually depicts data from FY2011 – FY2014 and annualized FY2016 data. MRI utilization data published in a SMFP is from two years prior. Therefore, MRI utilization data is missing from 10/1/14 through 3/31/15. In addition, the applicants' CAGR of 31.35% is not correct. The Project Analyst calculates a CAGR of only 21.02%.

Step 2:

In Section III.1, page 49, the applicants state that there has been a significant increase in MRI procedures at WRWF for patients from Franklin County and attribute this increase to the closure of Novant Health Franklin Medical Center (Franklin) in October 2015. They further state that WRWF is the closest MRI provider to many residents of Franklin County. The applicants project weighted MRI volume of the former Franklin facility for FY2014 – FY2020 using a CAGR of 0.93% based on historical population growth in Franklin County. The applicants project that WRWF will have a capture rate of 75% of the MRI volume that would have occurred at Franklin during FY2016, and that the capture rate will increase each year to a maximum of 90% in operating year two (FY2019) and remain at 90% in operating year three (FY2020). The applicants provide a table depicting these calculations in Exhibit 23, on page 49. The CAGR for historical population growth of Franklin County of 0.93% is slightly lower than the CAGR calculated by the Project Analyst for July 2010 - July 2014 of

0.973%¹, therefore it is reasonable. However, the applicants used different time periods than the time periods used in projecting WRWF's baseline weighted MRI volume in Step 1, therefore, for consistency, the Project Analyst recalculated the projected weighted MRI volume to be captured from Franklin County. Based on MRI utilization data reported in the SMFPs for FY2011 – FY2014, and Franklin's 2016 License Renewal Application, Franklin's MRI volume declined steadily, resulting in a CAGR of -13.89%. However, given the historical volume of MRI procedures performed at Franklin, an average of 1,040 MRI procedures from FY2011 – FY2015, a growing population in Franklin County, and the lack of access to MRI services due to Franklin's closure, the applicants provide sufficient evidence to support the projected MRI volume to be captured from Franklin County.

Step 3:

In Section III.1, page 50, the applicants provide a table, Exhibit 24, of the combined, projected weighted MRI volume for WRWF from the year ending 3/31/16 through the third operating year of the proposed project, FY2020 (7/01/19 – 6/30/20). The applicants project that the proposed fixed MRI scanner at WRWF will perform 4,505 "weighted" MRI procedures in the third operating year (FY2020).

However, in response to written comments, the applicants state the projections on page 50 are unweighted, not weighted. With regard to the first two operating years, that is clearly the case. However, with regard to the third operating year, there is a discrepancy between page 50 and other sections, including Section IV, page 62. Unweighted MRI procedures are reported to be 4,307, not 4,505. This calls into question the number of weighted MRI procedures for the third operating year as reported in Section IV, page 62.

Furthermore, regardless of whether the correct number of unweighted MRI procedures in the third operating year is 4,307 or 4,505, projected utilization is not based on reasonable and adequately supported assumptions regarding growth. See discussion in Step 1 above.

Projected Utilization for Wake Radiology's four existing fixed MRI scanners

Step 1:

In Section III.1, page 48, the applicants provide the historical, weighted number of MRI procedures reported in the 2014 SMFP through its most recent 12-month period, 4/1/15 – 3/31/2016, for their four existing fixed MRI scanners in Wake County. The applicants calculate a CAGR of 7.26% based on the total weighted MRI procedures for the two fixed MRI scanners at Wake Radiology Diagnostic Imaging (WRDI) Raleigh combined, one fixed MRI scanner at WRDI Cary, and one fixed MRI scanner at WRDI Garner. The applicants provide a table depicting this data in Exhibit 20, page 48. However, the applicants did not provide MRI data from 10/1/2014 – 3/31/2015, and therefore it is not utilized in the applicants' calculation of their CAGR. The data the applicants report for "YE 9/30/2015 SMFP 2016" is equivalent to the data reported in the 2016 SMFP, which is

¹ https://ncosbm.s3.amazonaws.com/s3fs-public/demog/countytotals_2010_2019.html

actually for FY2014, year ending 9/30/14, not FY2015. The data reported for “*YE 3/31/2016 Internal Data*” is for 4/1/2015 through 3/31/2016, as stated on page 48. Therefore, the CAGR calculated by the applicants is unreliable since it appears it was calculated with missing data.

The Project Analyst calculates the CAGR based on the total historical weighted MRI procedures of all four of the applicants’ fixed MRI scanners, from data reported in the SMFPs and data reported by the applicants in the 2016 Registration and Inventory Form for its fixed MRI scanners in Wake County, as follows:

**Wake Radiology
Historical, Weighted Fixed MRI Utilization***

	FY2013	FY2014	FY2015	FY2016	CAGR
Total Weighted MRI Procedures	12,124	13,655	13,200	13,400	3.39%

*Includes MRI utilization of four, fixed MRI scanners, WRDI Raleigh (2), WRDI Cary (1), and WRDI Garner (1)

As shown above, the Project Analyst calculates a CAGR of only 3.39% based on annual data reported to the Agency by the applicants. In addition, the CAGR of 7.26% is not correct because it is calculated without six months of data from 10/1/2014 through 3/31/2015.

Step 2:

In Section III.1, page 48, the applicants use the historical growth rate, reported in Exhibit 20, page 48, to project utilization from 4/1/2015 - 3/31/2016 through OY3, 7/1/2019 – 6/30/2020, as depicted in Exhibit 21, page 48. However, the applicants end their historical total of weighted MRI procedures, at 14,445, for the year ending 3/31/16, yet begin their calculations for their projections at 11,526, also for the year ending 3/31/16. The applicants do not provide an explanation for this discrepancy.

For all the reasons described above, the applicants did not adequately demonstrate that projected utilization for its four fixed MRI scanners is reasonable and adequately supported.

Historical Utilization of Wake Radiology’s mobile MRI scanner

In Section II.1, page 29, the applicants provide the historical utilization of their one mobile MRI scanner for each site it served in Wake County from 4/1/15 through 3/31/16, summarized as follows:

**Wake Radiology Mobile MRI Utilization
4/01/15 – 3/31/16**

Site	Total Weighted MRI Procedures
Wake Radiology Wake Forest	1,346
Wake Radiology Fuquay-Varina	329
Wake Radiology Cary	449
Total	2,124

The applicants' mobile MRI scanner performed only 2,124 weighted MRI procedures in the applicants' most recent 12-month period, 4/01/15 - 3/31/16, therefore it did not perform 3,328 weighted MRI scans as required by 10A NCAC 14C .2703(b)(2). In their response to comments, the applicants argue that this Rule should be void as not reasonably necessary for the Agency to determine whether the applicants demonstrate a need for the proposed fixed MRI scanner. However, the Rule is necessary as it would not be consistent with the premise of the CON Law to approve an applicant to acquire an additional MRI scanner (fixed or mobile) when the applicant has access to an existing mobile MRI scanner which has the capacity to serve more patients than it is currently serving.

Projected Utilization of Wake Radiology's mobile MRI scanner

Step 1:

In Section III.1, page 50, in Exhibit 25, the applicants provide the historical weighted MRI utilization of their mobile MRI scanner by facility location, with the exception of the WRWF location, for FY2011-FY2015, and for the 12-month period ending 3/31/16. Locations include WRDI Cary, WRDI Fuquay-Varina, and WRDI Raleigh. The applicants state, on page 50, Exhibit 25, that the CAGR for the mobile MRI scanner, from FY2011 through the 12-month period ending 3/31/16, was 33.1%. However, the data reported by the applicants is actually for FY2010 – FY2014, as reported in the 2012 – 2016 SMFPs. Since FY2014 ends 9/30/14, and the next data period reported by the applicants begins 4/1/15, it is unclear whether the applicants are reporting data for 10/01/2014 – 3/31/15. In addition, the CAGR is not correct.

The Project Analyst calculated the CAGR based on weighted MRI procedures reported in the 2012 – 2016 SMFPs and the weighted MRI procedures calculated from the applicants' 2016 Registration and Inventory for Medical Equipment Form for its mobile MRI scanner. This results in a CAGR of only 27.26%.

Step 2:

In Section III.1, page 50, the applicants state that utilization of their mobile MRI scanner is projected using a CAGR of 33.3%, however, Exhibit 25 on page 50, and Exhibit 26 on page 51, use a CAGR of 31.1%. In addition, the applicants state, in Section II, page 32, that when the fixed MRI scanner becomes operational at WRWF, the mobile MRI scanner used at WRWF will be used for additional days of service at other existing Wake Radiology

locations and will be used to cover scanner downtime at existing sites. The applicants project an additional 30% increase in MRI volume due to the increased availability and use of the mobile MRI scanner during each of the three initial operating years of the proposed project. The applicants provide the projected utilization of their mobile MRI scanner in Exhibit 26 in Section III.1, page 51. The applicants project that their mobile MRI scanner will perform 3,532 weighted MRI procedures in operating year three.

However, the Project Analyst calculated the projected utilization of the mobile MRI scanner using the corrected CAGR of 27.26%, which results in only 3,164 weighted MRI procedures in operating year three, summarized as follows:

**Wake Radiology
Projected Utilization of Mobile MRI Scanner**

	FY2015	FY2016	Interim 10/1/16- 6/30/17	OY1 7/1/17- 6/30/18	OY2 7/1/18- 6/30/19	OY3 7/1/19- 6/30/20
Number of Weighted MRI Procedures	771	981	1,181	1,503	1,913	2,434
Additional Weighted MRI Procedures (30%)	0	0	0	451	574	730
Total Weighted MRI Procedures	771	981	1,182	1,954	2,486	3,164

As illustrated in the table above, the Project Analyst concludes that the applicants' mobile MRI scanner is projected to perform only 3,164 weighted MRI procedures in operating year three. Therefore, the applicants do not adequately demonstrate that their existing mobile MRI scanner is reasonably expected to perform 3,328 weighted MRI procedures in the third operating year of the proposed project as required by 10A NCAC 14C .2703(b)(5).

In summary, the applicants adequately demonstrate that their existing fixed MRI scanners which they or a related entity owns a controlling interest in and locate in the proposed service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data.

However, the applicants do not adequately demonstrate that:

- 1) 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 is reasonably expected to perform 4,805 weighted MRI procedures in the third year of operation following completion of the proposed project, as required in 10A NCAC 14C .2703(b)(3); and

- 2) Each existing mobile MRI scanner owned by a related entity and operating at host sites in the proposed service area performed at least 3,328 weighted MRI scans in the most recent 12 month period for which the applicant has data, as required in 10A NCAC .2703(b)(2); and
- 3) The 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, as required in 10A NCAC 14C .2703(b)(5).

Based on review of: 1) the information provided by the applicant in Section II, pages 28-29, Section III, pages 48-51, including reference exhibits; 2) comments received during the first 30 days of the review cycle; and 3) the applicants' response to the comments received at the public hearing, the applicant did not adequately document the need for the project for the reasons discussed above.

Access

In Section VI.2, page 70, the applicants state, "*Wake Radiology ensures access to all health agencies [sic] 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 medical [sic] indigent.*" In addition, the applicants state that they will provide \$100,000 in free MRI services to Franklin County residents in need once the proposed project becomes operational. In addition, in Section VI.15, page 76, the applicants project that 38.2% of their MRI services patients will be Medicare or Medicare Managed Care recipients and that 6.3% will be Medicaid recipients. The applicants adequately demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicants adequately identify the population to be served and the extent to which all residents of the area, including medically underserved groups, are likely to have access to the proposed services. However, the applicants do not adequately demonstrate the need the population to be served has for the proposed fixed MRI scanner. Consequently, the application is not conforming to this criterion.

- (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

- (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
DRHS

NC
Raleigh Radiology
Wake Radiology

DRHS. In Section III.3, pages 82-84, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – the applicant determined that this is not an effective alternative because it does not address the growth in DUHS' Wake County MRI services, particularly for the two fixed MRI scanners at Duke Raleigh Hospital. The applicant states that with an annualized 2016 average 85% utilization rate for these two fixed MRI scanners, scheduling becomes problematic and patient satisfaction is negatively impacted.
- 2) Locate the proposed fixed MRI scanner at Duke Raleigh Hospital – the applicant states that locating the proposed fixed MRI scanner at Duke Raleigh Hospital's main campus would not be a viable option due to space limitations and would not provide patients with a freestanding outpatient charge structure. Furthermore, it would not address patients' desires to obtain MRI services at an outpatient facility.
- 3) Locate the proposed fixed MRI scanner at Cary Parkway – the applicant states that locating the proposed fixed MRI scanner at its Cary facility would also not be the most effective alternative due to the space limitations of the building, and because the Cary area has sufficient access to MRI services as described in Section III.1, pages 40-41.

The applicant concluded that developing a fixed MRI scanner at DRHS would be the most effective alternative because it would greatly improve geographic access to fixed MRI services in Wake County. Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and therefore, is approvable. An application that cannot be approved cannot be an effective alternative. Specifically, the applicants do not adequately demonstrate the need for their proposal for the following reasons:

- 1) 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 is reasonably expected to perform 4,805 weighted MRI procedures in the third year of operation following completion of the proposed project, as required in 10A NCAC 14C .2703(b)(3); and
- 2) Each existing mobile MRI scanner owned by a related entity and operating at host sites in the proposed service area performed at least 3,328 weighted MRI scans in the most recent 12 month period for which the applicant has data, as required in 10A NCAC .2703(b)(2); and
- 3) The 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, as required in 10A NCAC 14C .2703(b)(5).

In summary, the applicant adequately demonstrates that its proposal is its least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion.

Raleigh Radiology. In Section III.3, pages 76-78, the applicant discusses seven alternatives it considered, summarized as follows:

- 1) Maintain the status quo – the applicant states that this is not an acceptable option for several reasons. The applicant projects that the Alliance MRI scanner will not have the capacity to keep up with growth projected for its MRI services since there is no flexibility to adjust operating hours to increase capacity. In addition, the applicant states that it cannot reduce costs further under its agreement with Alliance. Furthermore, the applicant states that there is no guarantee that the Alliance contract for MRI services will continue. Therefore, this is not an effective alternative.
- 2) Purchase a 1.5T MRI scanner – the applicant states that while the 1.5T MRI scanner meets the standards of the physicians at RR Cary, it does not allow for additional types of MRI scans. In addition, the 3T MRI scanner would improve image quality, scan times, and patient comfort in some instances. Moreover, the applicant states that while the cost for the 3T MRI scanner is higher than the 1.5T MRI scanner, the *“benefits outweigh the difference in price.”* Therefore, the applicant concludes that purchasing a 1.5T MRI scanner is not the most effective alternative.
- 3) Replace the MRI scanner at its Blue Ridge location – the applicant states that adding MRI capacity in the northern part of the county would not address the need for additional

MRI capacity in the southern part of the county where the population is growing faster than any other area of the county. Therefore, this is not the most effective alternative.

- 4) Construct a new facility for the proposed fixed MRI scanner – the applicant states that this alternative would be much more costly due to new construction that must meet the standards for an MRI scanner and new operating costs for administrative support. Therefore, this is not the most effective alternative.
- 5) Pursue a joint venture with another organization – the applicant states that a new facility constructed under a joint venture would be much more costly than providing the MRI service in an existing facility. In addition, the applicant states that a joint venture with RR Cary would add complexity and that RR Cary can already provide the experience, expertise, and financial investment needed. Therefore, this is not the most effective alternative.
- 6) Purchase the Alliance MRI scanner – the applicant states it had approached Alliance with this idea, however there was not much interest and the cost was much higher than what the applicant could support. Therefore, this was not a viable alternative.
- 7) Wait for another Wake County need determination for a fixed MRI scanner in the SMFP – the applicant states that this is not the most effective alternative since the state has already recognized the need for one fixed MRI scanner in the county for 2016 and waiting for an additional need would not address current need for the service. Therefore, this is not the most effective alternative.

The applicant concluded that acquiring a fixed MRI scanner at RR Cary would be the least costly and most effective alternative, stating, on page 78, that its proposal would improve image quality, provide better access in regard to cost, and serve a growing area of the county in its present location, southern Wake County.

However, the application is not conforming to all other applicable statutory and regulatory review criteria, and therefore, is not approvable. An application that cannot be approved cannot be an effective alternative. Specifically, the applicant does not adequately demonstrate that its projected payor mix is based on reasonable and adequately supported assumptions.

In summary, the applicant does not adequately demonstrate that its proposal is its least costly or most effective alternative to meet the need. Therefore, the application is not conforming to this criterion.

Wake Radiology. In Section III.3, pages 52-53, the applicants discuss alternatives they considered to the proposed project, summarized as follows:

- 1) Maintain the Status Quo – the applicants state that the four days of mobile MRI services currently available at WRWF are insufficient to meet the growing demand for services, especially for Franklin County residents seeking MRI services since the closure of Novant Health Franklin Medical Center. In addition, the applicants state that this alternative would not enable them to provide MRI services on the proposed Aera technology which has greater imaging capabilities. Therefore, this is not the most effective alternative.
- 2) Add Additional Days of Mobile MRI Service – the applicants state that adding additional days of service would not create enough additional capacity to meet the growing demand for MRI services at WRWF and that the mobile MRI service has access limitations for patients and for physicians and emergency personnel. In addition, it would not address the need for “*cutting edge technology in the service area.*” Therefore, the applicants conclude that this is not an effective alternative to the proposed project.

The applicants concluded that acquiring a fixed MRI scanner at WRWF would be the most effective alternative to meet the needs of residents in the service area, stating, on page 53, that their proposal would allow them to expand their imaging service to offer a greater range of diagnostic MRI services and meet the growth in demand.

However, the application is not conforming to all other applicable statutory and regulatory review criteria, and therefore, is not approvable. An application that cannot be approved cannot be an effective alternative. Specifically, the applicants do not adequately demonstrate the need for their proposal because the applicants do not adequately demonstrate that:

- 1) 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 is reasonably expected to perform 4,805 weighted MRI procedures in the third year of operation following completion of the proposed project, as required in 10A NCAC 14C .2703(b)(3); and
- 2) Each existing mobile MRI scanner owned by a related entity and operating at host sites in the proposed service area performed at least 3,328 weighted MRI scans in the most recent 12 month period for which the applicant has data, as required in 10A NCAC .2703(b)(2); and
- 3) The 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, as required in 10A NCAC 14C .2703(b)(5).

In summary, the applicants do not adequately demonstrate that their proposal is their least costly or most effective alternative to meet the need. Therefore, the application is not conforming to this criterion.

- (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
DRHS
Raleigh Radiology

NC
Wake Radiology

DRHS

Capital and Working Capital Costs

In Section VIII.1, page 133, the applicant states the capital cost for the project will be \$5,965,000, comprised as follows:

Site Costs	\$1,004,500
Construction Contract	\$1,876,915
Equipment/Miscellaneous	\$3,083,585
Total Capital Cost	\$5,965,000

In Section IX.1, page 142, the applicant states there will be \$30,000 in start-up expenses and \$50,000 in initial operating expenses for the project.

Availability of Funds

In Section VIII.3, page 136, the applicant states that the project will be funded with accumulated reserves of DUHS. In Section IX.2, page 142, the applicant states that the working capital will be funded by the unrestricted cash of DUHS. Exhibit 13 contains a letter dated April 8, 2016 from the Senior Vice President, Chief Financial Officer and Treasurer of DUHS, documenting the applicant's intention to fund the capital and working capital costs for the proposed project.

Exhibit 14 contains audited financial statements for DUHS for the years ending June 30, 2015 and June 30, 2014. As of June 30, 2015, DUHS had \$434,336,000 in cash and cash equivalents, total assets of \$5,039,776,000 and total liabilities of \$1,856,894,000. Net assets were equal to \$3,182,882,000 (total assets less total liabilities). The applicant

adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first three years of the project in Section XIII, pages 160-168. In Form C, page 163, the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below:

DRHS Fixed MRI Services			
DRHS Fixed MRI Scanner	Project Year 1 7/01/2018- 6/30/2019	Project Year 2 7/01/2019- 6/30/2020	Project Year 3 7/01/2020- 6/30/2021
Projected # of Unweighted Procedures	2,098	3,013	4,440
Projected Average Charge (Gross Patient Revenue/Projected # of Unweighted Procedures)	\$1,053	\$1,053	\$1,053
Gross Patient Revenue	\$2,208,720	\$3,171,511	\$4,673,085
Deductions from Gross Patient Revenue	\$1,088,125	\$1,562,443	\$2,302,193
Net Patient Revenue	\$1,120,595	\$1,609,067	\$2,370,891
Total Expenses	\$1,161,432	\$1,461,868	\$1,774,551
Net Income	(\$40,837)	\$147,199	\$596,340

As shown in the table above, the applicant projects a negative net income in the first operating year of the project and positive net income in operating years two and three. The applicant also projects a positive net income for DUHS in each of the first three operating years of the project. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. The discussion of projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. The application is conforming to this criterion.

Raleigh Radiology

Capital and Working Capital Costs

In Section VIII.2, page 136-137, the applicant states the capital cost for the project will be \$2,922,552, comprised as follows:

Raleigh Radiology Fixed MRI Scanner Capital Cost	
Construction Contract	\$93,442
Equipment/Miscellaneous	\$2,829,110
Total Capital Cost	\$2,922,552

In Section IX.1, page 142, the applicant states there will be \$31,723 in start-up expenses for one month of staff training and no initial operating expenses for the project.

However, the applicant's capital costs are questionable, particularly for Fixed Equipment. The applicant states, in Section VIII, page 137, that its fixed equipment cost will be \$2,499,043. However, Exhibit 5 contains vendor quotes for the MRI System, Optional Equipment, including a breast coil, and warranties. The vendor costs are summarized as follows:

Fixed Equipment Line	Vendor Quote
MRI System	\$2,073,079
Optional equipment, including breast coil	\$365,025
Injector	\$30,939
Warranty on MRI Scanner	\$159,981
Warranty on Chiller	\$6,500
Total	\$2,635,524

Therefore, there is a discrepancy of \$136,481 between the applicant's stated capital costs of \$2,499,043 for fixed equipment and the vendor quotes it obtained for fixed equipment of \$2,635,524. In addition, the applicant's costs for fixed and moveable equipment do not include state taxes which would be incurred for equipment purchased by a proprietary, in-state corporation. See Section I.10, page 13, for applicant ownership information.

Availability of Funds

In Section VIII.3, page 138, the applicant states that the project will be funded through a conventional loan. In Section IX.2, page 143, the applicant states that the working capital will be funded by the operating income of RR Cary. Exhibit 32 contains a letter dated March 22, 2016 from the Vice President, Wells Fargo Equipment Finance, documenting Wells Fargo's willingness to finance the capital cost of the proposed project up to \$3,500,000. Although it appears in the letter that the dollar amount Wells Fargo would be willing to finance may have been altered, it is not possible for the Agency to determine if, in fact, it had been altered, and if so, by whom. The loan amount is sufficient to cover the applicant's stated capital cost, or the potentially higher capital cost, including any applicable taxes, and the working capital.

Exhibit 33 contains an unaudited financial statement for Raleigh Radiology, LLC for the year ending December 31, 2015. As of December 31, 2015, Raleigh Radiology, LLC had total revenues of \$21,277,923, total operating expenses of \$16,994,396, and depreciation expense of \$348,176. Net income was equal to \$3,935,352 (total revenue less total operating expenses and depreciation expense). The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first three years of the project in Section XIII, pages 159-170. In Form C, page 161, the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below:

RR Cary Fixed MRI Services

RR Cary Fixed MRI Scanner	Project Year 1 CY2018	Project Year 2 CY2019	Project Year 3 CY2020
Projected # of Unweighted Procedures	8,046	8,046	8,046
Projected Average Charge (Gross Patient Revenue/Projected # of Unweighted Procedures)	\$1,250	\$1,213	\$1,177
Gross Patient Revenue	\$10,060,940	\$9,759,111	\$9,466,338
Deductions from Gross Patient Revenue	\$6,921,559	\$6,754,919	\$6,464,763
Net Patient Revenue	\$3,139,380	\$3,004,192	\$3,001,575
Total Expenses	\$1,799,424	\$1,839,136	\$1,827,592
Net Income	\$1,339,956	\$1,165,056	\$1,173,984

As shown in the table above, the applicant projects a positive net income for RR Cary MRI services in all three operating years. The applicant also projects a positive net income for the entire facility of RR Cary in each of the first three operating years of the project.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. The discussion of projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. The application is conforming to this criterion.

Wake Radiology

Capital and Working Capital Costs

In Section VIII.2, page 89, the applicants state the capital cost for the project will be \$1,779,992, comprised as follows:

**Wake Radiology
Fixed MRI Scanner Capital Cost**

Construction Contract	\$356,700
Equipment/Miscellaneous	\$1,423,292
Total Capital Cost	\$1,779,992

In Section IX.1, page 93, the applicants state that *“Wake Radiology will expense all initial operating costs for the proposed fixed MRI.”* However, the applicant does not include sales tax in its calculation of capital costs. Wake Radiology is a proprietary, in-state corporation. See Section I.10, page 8, for applicant ownership information.

Availability of Funds

In Section VIII.3, page 90, the applicants state that the project will be funded through a conventional loan. Attachment P contains a letter dated March 28, 2016 from the Senior Vice President, Commercial Banking, documenting Wells Fargo’s willingness to finance up to \$2 million for the capital cost of the proposed project. Therefore, the loan amount is sufficient to cover the applicant’s stated capital cost with any applicable taxes.

Attachment R, pages 389-391, contains an unaudited financial statement for Wake Radiology Services for the year ending December 15, 2015. As of December 15, 2015, Wake Radiology Services had total revenues of \$41,820,653, total operating expenses of \$32,794,308. Net income was equal to \$9,026,345 (total revenue less total operating expenses). The applicants adequately demonstrate the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

The applicants provide pro forma financial statements for the first three years of the project on pages 103-110. In Form C, page 105, the applicants project that revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below:

Wake Radiology Fixed MRI Services

Wake Radiology Fixed MRI Scanner	OY1 7/1/17 – 6/30/18	OY2 7/1/18 – 6/30/19	OY3 7/1/19 – 6/30/20
Projected # of Unweighted Procedures	3,083	3,743	4,307
Projected Average Charge (Gross Patient Revenue/Projected # of Unweighted Procedures)	\$2,184	\$2,184	\$2,184
Gross Patient Revenue	\$6,734,800	\$8,176,567	\$9,408,622
Deductions from Gross Patient Revenue	\$4,118,522	\$5,000,204	\$5,753,641
Net Patient Revenue	\$2,616,277	\$3,176,363	\$3,654,981
Total Expenses	\$2,128,236	\$2,366,012	\$2,569,287
Net Income	\$488,041	\$810,350	\$1,085,695

As shown in the table above, the applicant projects a positive net income in all three operating years. The applicant also projects a positive net income for Wake Radiology Services, LLC in each of the first three operating years of the project.

However, the applicants did not adequately demonstrate that the projected number of unweighted MRI procedures are reasonable and adequately supported. The discussion of

projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, revenues and expenses based on that projected utilization are not reliable. Consequently, the applicants do not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges and the application is not conforming to this criterion.

- (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
DRHS
Raleigh Radiology

NC
Wake Radiology

On page 154, the 2016 SMFP defines the service area for a fixed MRI scanner as “*a single county, except where there is no licensed acute care hospital located within the county.*” The definition of the service area for a fixed MRI scanner then explains how a service area is determined when there is no licensed acute care hospital located within the county. For the purpose of this review, however, Wake County is the service area since it has multiple licensed acute care hospitals. Providers may serve residents of counties not included in their service area.

The 2016 SMFP identifies a need determination for one fixed MRI scanner in Wake County. There are 16 existing fixed MRI scanners in Wake County according to the 2016 SMFP. The following table provides the number of fixed MRI scanners, total weighted MRI procedures, and average weighted MRI procedures per MRI scanner for each of the fixed MRI scanners, summarized from Table 9P of the 2016 SMFP.

Fixed MRI Scanners in Wake County

Facility	# of Fixed MRI Scanners	Total Weighted MRI Procedures	Average Weighted MRI Procedures per MRI Scanner*
Duke Raleigh Hospital	2	8,987	4,494
Rex Hospital	3	8,896	2,965
WakeMed	2	12,028	6,014
WakeMed Cary	1	4,290	4,290
Raleigh Neurology Associates (Alliance Healthcare Services)	1	5,133	5,133
Raleigh Neurology Associates	1	5,665	5,665
Raleigh Radiology (Alliance Healthcare Services)	1	4,545	4,545
Raleigh Radiology Cedarhurst (Pinnacle Health Services of NC, LLC)	1	7,392	7,392
Wake Radiology Diagnostic Imaging (Alliance Healthcare Services)	1	3,681	3,681
Wake Radiology Garner (Alliance Healthcare Services)	1	2,767	2,767
Wake Radiology Raleigh MRI Center (Wake Radiology Diagnostic Imaging)	1	3,850	3,850
Wake Radiology Raleigh MRI Center (Wake Radiology Diagnostic Imaging)	1	2,902	2,902

*Average weighted MRI procedures are rounded to nearest whole number.

DRHS proposes to acquire one fixed MRI scanner to be located at a newly constructed medical office building in Holly Springs. DRHS does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2016 SMFP for Wake County. The applicant adequately demonstrates that the proposed fixed MRI scanner it proposes to develop in Wake County is needed in addition to the existing and approved fixed MRI scanners in Wake County. The applicant adequately demonstrates that its 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 adequately demonstrates that the proposal would not result in unnecessary duplication of existing or approved fixed MRI scanner services in Wake County. Therefore, the application is conforming to this criterion.

Raleigh Radiology proposes to acquire one fixed MRI scanner to be located at its existing RR Cary facility at 150 Parkway Office Court, Suite 100, Cary, to replace mobile MRI services. Raleigh Radiology does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2016 SMFP for Wake County. The applicant adequately demonstrates that the proposed fixed MRI scanner it proposes to develop in Wake County is needed in addition to the existing and approved fixed MRI scanners in Wake County. The applicant adequately demonstrates that its 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 adequately demonstrates that the proposal would not result in unnecessary duplication of existing or approved fixed MRI scanner services in Wake County. Therefore, the application is conforming to this criterion.

Wake Radiology proposes to acquire one fixed MRI scanner to be located at its existing WRWF facility at 3150 Rogers Road, Suite 105, Wake Forest. Wake Radiology does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2016 SMFP for Wake County. However, the applicants do not adequately demonstrate that the proposed fixed MRI scanner it proposes to develop in Wake County is needed in addition to the fixed and mobile MRI scanners owned by Wake Radiology or a related entity and operated in Wake County. The applicants do not adequately demonstrate that their 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 applicants do not adequately demonstrate that the proposal would not result in unnecessary duplication of existing or approved fixed MRI scanner services in Wake County. Therefore, the application is not conforming to this criterion.

- (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
DRHS
Raleigh Radiology
Wake Radiology

DRHS. In Section VII.1(b), page 126, the applicant provides the projected staffing for the proposed fixed MRI scanner. The applicant projects to employ 1.62 full-time

equivalent (FTE) MRI Technologists, 1.62 FTE Clinical Nurse IIs, 0.25 FTE Imaging Manager, and 2.24 FTE Financial Care Counselors in the second operating year of the proposed project. In Section VII.6(a), pages 128-129, the applicant describes its methods for recruiting and retaining staff. Exhibit 3 contains a letter from Mustafa Bashir, M.D., indicating his intent to serve as Medical Director for the proposed service. The applicant adequately demonstrates the availability of health manpower and management personnel for the provision of the proposed service. Therefore, the application is conforming to this criterion.

Raleigh Radiology. In Section VII.1(b), page 124, the applicant provides the projected staffing for the proposed fixed MRI scanner. The applicant projects staffing will consist of 2.60 FTE MRI Technologists, 1.42 FTE MRI Tech Assistants, and 1.09 MRI Technologist/Supervisor in project year two, CY2019. In Section VII.3, page 126, and Section VII.6, page 130, the applicant discusses its methods pertaining to recruitment and retention of staff. In Exhibit 27, the applicant provides a letter from Dr. Donald G. Detweiler documenting his intent to continue to serve as Medical Director for RR Cary. The applicant adequately demonstrates the availability of health manpower and management personnel for the provision of the proposed services. Therefore, the application is conforming to this criterion.

Wake Radiology. In Section VII.1(b), page 80, the applicants provide the projected staffing for the proposed fixed MRI scanner. The applicants project staffing will consist of 4.0 FTE MRI Technologists, 2.0 Clerical, and 1.0 Manager in project year two, 7/1/18 – 6/30/19. In Section VII.3, page 84, and Section VII.6, page 85, the applicants discuss their methods pertaining to recruitment and retention of staff. In Section V.3, page 67, the applicants state that William Way, M.D. will be the Medical Director of WRWF. Dr. Way's resume is included in Attachment L. The applicants adequately demonstrate the availability of health manpower and management personnel for the provision of the proposed services. Therefore, the application is conforming to this criterion.

- (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
DRHS
Raleigh Radiology
Wake Radiology

DRHS. In Section II.2, page 16, the applicant provides a listing of necessary ancillary and support services it will have for the proposed MRI service. In addition, Exhibit 7 contains DUHS policies related to patient referral and transfer to an acute care hospital. Exhibit 16 contains letters of support from physicians.

The applicant adequately demonstrates the availability of the necessary ancillary and support services and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

Raleigh Radiology. In Section II.2, page 25, the applicant provides a listing of all necessary ancillary and support services that will be available for the proposed MRI service. Exhibit 5 contains a proposal from Siemens to provide MRI maintenance via a contract. In addition, Exhibits 6 and 7 contain copies of letters indicating availability of necessary ancillary and support services.

The applicant states, in Section V.3, page 104, that as an established provider it has strong ties to area physicians and receives referrals for MRI services from hundreds of individual practitioners. Exhibit 22 contains letters of support from many of its primary referral sources.

The applicant adequately demonstrates the availability of the necessary ancillary and support services and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

Wake Radiology. In Section II.2, page 21, the applicants state that all of the necessary ancillary and support services needed to provide the MRI service will be provided by staff at the existing WRWF site, including, but not limited to, management, billing, quality improvement, and staff education.

The applicants state, in Section V.3, page 67, that there is significant support from local physicians for the proposed project and that these physicians currently refer patients to WRWF for mobile MRI services. Attachment J contains letters of support for the project from various types of health care providers.

The applicants adequately demonstrate the availability of the necessary ancillary and support services and that the proposed services will be coordinated with the existing health care system. Therefore, 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

- (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

- (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
DRHS
Raleigh Radiology
Wake Radiology

DRHS. In Section XI.4, page 152, the applicant states that the square footage for the MRI service will consist of 3,650 square feet of new construction, exclusive of the remainder of the medical office building.

In Section XI.4(f), page 153, the applicant projects the following cost per square foot for the MRI services space, as illustrated in the following table:

DRHS			
	Estimated Square Feet	Construction Cost Per Square Foot*	Total Cost** per Square Foot
Total	3,650	$\$1,876,915 / 3,650 =$ \$514	$\$5,965,000 / 3,650 =$ \$1,634

*Construction cost does not include site preparation costs. See page 133.

**Total cost is the total capital cost of the project.

Exhibit 12 contains a letter from an architect that estimates the construction cost only for the MRI services portion of the medical office building at \$1,876,915. This cost is consistent with the projected construction cost provided by the applicant in Section

VIII.1, page 133, of the application. In Section XI.7, pages 155-156, the applicant describes the methods that will be used to maintain energy efficiency and to obtain the most cost effective utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design, and means of construction represent the most reasonable alternative and that the construction cost would not unduly increase costs and charges of providing MRI services. Therefore, the application is conforming to this criterion.

Raleigh Radiology. In Section XI.4, page 152, the applicant states that the square footage for its facility will not change and that it will be 21,924 square feet. The applicant states that only the MRI suite, consisting of 1,059 square feet, will be renovated and that the square footage will remain unchanged.

In Section XI.4(f), page 153, the applicant projects the following cost per square foot for the MRI services space, illustrated below:

RR Cary			
	Estimated Square Feet	Construction Cost Per Square Foot	Total Cost per Square Foot*
Total	1,059	$\$93,442/1,059 =$ \$88	$\$2,922,552/1,059 =$ \$2,760

*Total cost is the total capital cost of the project.

Exhibit 34 contains a letter from a licensed architect from Studio Forty estimating the construction cost for the project at \$93,442. This cost is consistent with the projected construction cost provided by the applicant in Section VIII.2, page 136, of the application.

In Section III.2, page 74, the applicant discusses its plans for energy efficiency and water conservation. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design, and means of construction represent the most reasonable alternative and that the construction cost would not unduly increase costs and charges of providing MRI services. Therefore, the application is conforming to this criterion.

Wake Radiology. In Section XI.4, page 98, the applicants state that the square footage for its facility will not change and that it will be 2,666 square feet. The facility will be renovated, however there will be no added space.

In Section XI.4(g), page 99, the applicants project the following cost per square foot for the renovation of WRWF to accommodate an MRI Suite, illustrated below:

Wake Radiology

	Estimated Square Feet	Construction Cost Per Square Foot	Total Cost per Square Foot*
Total	2,666	$\$356,700/2,666 =$ \$133.80	$\$1,779,992/2,666 =$ \$667.66

*Total cost is the total capital cost of the project.

Attachment C contains a letter from DK Design, PLLC, an architectural firm, describing the scope of the renovation for the proposed MRI Suite and an attached proposal from R.L. Pullen & Associates, Inc., a contractor, estimating the construction cost for the project at \$356,700. This cost is consistent with the projected construction cost provided by the applicant in Section VIII.2, page 89, of the application.

The applicants state, in Section XI.7, page 100, that they will lease the WRWF space and that the facility has already been designed to be in compliance with all North Carolina building codes for energy efficiency and to contain the cost of utilities. In addition, the applicants state, on page 100, that they use energy-efficient appliances in their radiology offices and will work with the lessor in that regard. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicants adequately demonstrate that the cost, design, and means of construction represent the most reasonable alternative and that the construction cost would not unduly increase costs and charges of providing MRI services. Therefore, 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
DRHS
Raleigh Radiology
Wake Radiology

DRHS. In Section VI.13, pages 122-123, the applicant provides the payor mix for its existing outpatient MRI services at Duke University Hospital (DUH) for FY2016, and Duke Raleigh Hospital (DRH) and Cary Parkway for FY2015, illustrated in the table below:

**MRI Services
Current Patient Days/ Procedures
as Percent of Total Utilization***

	DUH FY2016	DRH FY2015	Cary Parkway FY2015
Self Pay/Indigent/Charity	1.9%	1.6%	2.0%
Medicare/Medicare Managed Care	28.0%	39.5%	23.6%
Medicaid	8.7%	5.4%	3.1%
Commercial Insurance	1.3%	46.9%	61.2%
Managed Care	50.2%	1.2%	1.1%
Other	9.9%	5.4%	8.9%
Total	100.0%	100.0%	100.0%

*Totals may not foot due to rounding.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Wake	10%	51%	39%	12%	5%	14%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table_2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

Raleigh Radiology. In Section VI.13, page 119, the applicant provides the payor mix for mobile MRI services for CY2015, as illustrated in the table below:

**MRI Services
CY2015
Current Patient Days/ Procedures
as Percent of Total Utilization**

Self Pay/Indigent/Charity	1.0%
Medicare/Medicare Managed Care	23.0%
Medicaid	1.0%
Commercial Insurance	3.0%
Managed Care	64.0%
Worker’s Comp and TriCare	8.0%
Total	100.0%

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Wake	10%	51%	39%	12%	5%	14%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table_2014_Estimate_as_of_December_22_2015.

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicant adequately demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

Wake Radiology. The applicants do not provide the payor mix for the existing, mobile MRI services that are provided at WRWF. The applicants state, in Section VI.12, page 75, that WRWF does not provide fixed MRI services. However, the applicants provide mobile MRI services at the WRWF location using a mobile

MRI scanner owned by the applicants or a related entity. In Section VI.15, page 76, the applicants state that the projected payor mix is based on the historical payor mix at WRWF. The projected payor mix is illustrated in the following table.

**MRI Services
7/01/2018 – 6/30/2019
Projected Patient Days/ Procedures
as Percent of Total Utilization***

Self Pay/Indigent/Charity	1.9%
Medicare/Medicare Managed Care	38.2%
Medicaid	6.3%
Commercial Insurance	0.2%
Managed Care	51.4%
Other	1.5%
Total	100.0%

*Totals may not foot due to rounding.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Wake	10%	51%	39%	12%	5%	14%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table_2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicants’ projected payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicants adequately demonstrate that they currently provide adequate access to medically underserved populations based on the assumption that the current payor mix is similar to the projected payor mix. 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;

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Raleigh Radiology
Wake Radiology

DRHS. The applicant states, in Section VI.11, page 120, that it has no obligations under federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. However, the applicant states that it provides access to care to the medically underserved and does not discriminate on the basis of sex, age, religion, national origin, handicap, or ability to pay. In addition, services are provided to the community, including charity care. Furthermore, the applicant states, on page 120, that it is *“not aware of any court actions filed alleging equal access violations in the past five years.”*

The application is conforming to this criterion.

Raleigh Radiology. The applicant states, in Section VI.11, page 117, that it has no obligations under federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities. In Section VI.2, page 108, the applicant states that it provides access to care for all patients, regardless of gender, race, ethnicity, age, income, or disability status. In addition, the applicant states, in Section VI.2, page 108, that it has a generous charity care policy and provides discounts to uninsured patients who do not meet the charity care requirements. Moreover, for underinsured patients, such as those with high deductible health plans, Raleigh Radiology, LLC works with insurers to obtain low negotiated costs to reduce out-of-pocket expense for patients. Lastly, the applicant states, on page 117, that it has not had any civil rights equal access claims filed against it.

The application is conforming to this criterion.

Wake Radiology. In Section VI.11, page 74, the applicants state that although they have no obligation under federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities, they will continue to provide radiology services to low income persons, racial and ethnic minorities, women, handicapped persons, elderly, and other underserved persons, including the medically indigent, the uninsured and the underinsured. In addition, in Section VI.6, page 72, the applicants list several charitable organizations they

support that expand access to their radiology services for the underserved population of Wake and Franklin counties. Moreover, the applicants state, on page 72, that they provide charitable care to patients of WakeMed Health and Hospitals and Maria Parham Medical Center. Lastly, the applicants state, in Section VI.10, page 74, that no civil rights access complaints have been filed against them or any facilities or services owned, managed, or operated by them in the last five years.

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

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Raleigh Radiology

DRHS. In Section VI.14, page 121, the applicant provides the projected payor mix for the second operating year following completion of the project (FY 2020), as illustrated in the table below:

DRHS Fixed MRI Scanner Projected Payor Mix FY 2020	
Self-Pay	1.9%
Medicare	27.4%
Medicaid	5.2%
Commercial Insurance	1.2%
Managed Care	57.6%
Other	6.7%
Total	100.0%

In Section VI.14, pages 122-123, the applicant provides its assumptions and methodology for projecting payor mix for DRHS in the second operating year. The applicant adequately demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

Raleigh Radiology. In Section VI.15, page 121, the applicant provides the projected payor mix for the proposed fixed MRI scanner during the second

operating year following completion of the project (CY 2019), as illustrated in the table below:

RR Cary Projected Payor Mix CY 2019	
Payor	% of Total Procedures
Self Pay / Indigent / Charity	5.8%
Medicare / Medicare Managed Care	30.5%
Medicaid	2.0%
Commercial Insurance	3.0%
Managed Care	50.6%
Workers Comp. and TriCare	8.0%
Total	100.0%

In Sections III.1, pages 39-44, and Section VI.15(b), pages 121-123, the applicant provides its assumptions and methodology for its payor mix projections. In Section VI.13, page 119, the applicant states that its Medicare percentage was 23% in CY2015. In Section VI.15(b), page 121, the applicant projects 30.5% Medicare, or a 7.5% increase, for CY2019.

However, the applicant does not adequately demonstrate that the projected Medicare percentage is reasonable and adequately supported. In Section III.1, page 41, the applicant uses 2011 data from a *Regents Health Study* and population data for Wake County from the North Carolina Office of State Budget and Management (OSBM), to calculate the percentage of new MRI procedures for persons aged 65+ in Wake County. However, the MRI use rates the applicant uses from the *Regents Health Study*, are derived from the South Atlantic Region, which includes nine states. The MRI use rate used in the applicant's calculations is 181.64 per 1,000 persons aged 65+. The MRI use rate for the state of North Carolina for 2011 is only 80.4 per 1,000 persons and for Wake County it is only 82.4%. The number of MRI procedures is not broken down by age group in the SMFP, however persons aged 65+ are more likely to be higher users of MRI scanners, therefore it is reasonable to assume that a large portion of the statewide and Wake County MRI use rate represents this age group. The applicant does not adequately demonstrate that the MRI use rate it uses in its calculations is reasonable and adequately supported. In addition, the applicant states that 41% of the number of additional MRI procedures it projects for all of Wake County in 2019, will be performed at RR Cary. Considering there are 15 other fixed MRI scanners and several mobile MRI sites operating in Wake County, it is not reasonable to project that over 40% of additional MRI scans for Medicare

recipients would be performed at RR Cary. The applicant provides no support for this assumption.

Moreover, the applicant does not adequately explain, in the application as submitted, the changes in the percentages for the other payor categories. See table below.

**RR Cary
Historical and Projected Payor Mix**

Payor	% of Total Procedures CY2015	% of Total Procedures CY2019	Difference (CY2019- CY2015)
Self Pay / Indigent / Charity	1.0%	5.8%	4.8
Medicare / Medicare Managed Care	23.0%	30.5%	7.5
Medicaid	1.0%	2.0%	1.0
Commercial Insurance	3.0%	3.0%	0.0
Managed Care	64.0%	50.6%	(13.4)
Workers Comp. and TriCare	8.0%	8.0%	0.0
Total	100.0%	100.0%	

Therefore, because the applicant’s projected payor mix is questionable, the applicant does not adequately demonstrate that medically underserved groups will have adequate access to the proposed fixed MRI scanner. Therefore, the application is not conforming to this criterion.

Wake Radiology. In Section VI.15, page 76, the applicants provide the projected payor mix for the proposed fixed MRI scanner during the second operating year following completion of the project (7/01/18 – 6/30/19), as illustrated in the table below:

Wake Radiology Projected Payor Mix 7/01/18 – 6/30/19	
Payor	% of Total Procedures
Self Pay / Indigent / Charity	1.9%
Medicare / Medicare Managed Care	38.2%
Medicaid	6.3%
Commercial Insurance	0.2%
Managed Care	51.4%
Other	1.5%
Total	100.0%

In Section VI.15(b), page 77, the applicants state that their projected payor mix is based on the existing mobile MRI services it owns and operates at WRWF in addition to the “\$100,000 of free care to financially needy patients from Franklin County.” The applicants adequately demonstrate that medically underserved groups will have adequate access to the proposed fixed MRI scanner. Therefore, the application is conforming to this criterion.

- (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.

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Raleigh Radiology
Wake Radiology

DRHS. In Section VI.9(a), page 118, the applicant states that access to the proposed MRI services is by physician referral. In Section V.7, page 108, that applicant states that it will “accept referrals from all physicians as well, regardless of their affiliation with other physician groups or hospitals.” In addition, in Section VI.6, page 115, the applicant states that it will work with area physicians or other agencies and providers to help ensure clinical access to the MRI service for those who do not have access to physicians. The applicant adequately demonstrates the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

Raleigh Radiology. In Section VI.9(a), page 115, the applicant states that access to the proposed fixed MRI services is available by physician referral or by an authorized order from a provider for an MRI. In Section V.2, page 103, the applicant states it will accept referrals from Rex Hospital where Raleigh Radiology Associates physician members provide interpretation services, and will also accept referrals from physicians practicing at other hospitals. The applicant states that RR Cary’s MRI service received over 1,000 referrals from practitioners representing a broad cross section of the medical and surgical community in 2015. A listing of RR Cary’s top ten referring practices is provided in Section VI, on page 116.

The applicant adequately demonstrates it will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

Wake Radiology. In Section VI.5, page 71, and Section II.3, page 21, the applicants state that the majority of their radiology services are provided by

physician referral through a written order. In addition, in Section V.2, page 66, the applicants state that their physicians have privileges at WakeMed Health and Hospitals and Maria Parham Medical Center and that WRWF will accept referrals from these hospitals in the future. Lastly, Attachment J includes letters of support from physicians who refer and are willing to continue to refer patients to WRWF.

The applicants adequately demonstrate they will offer a range of means by which patients will have access to the proposed services. Therefore, 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.

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Raleigh Radiology
Wake Radiology

DRHS. In Section V.1, page 102, the applicant provides a listing of DUHS sites used for health professional training programs. In addition, on page 103, the applicant states that DRHS will be included in the existing DUHS training agreements. Moreover, the applicant states that DRHS will be made available as a training site for radiology programs at Duke University School of Medicine and Duke's Department of Radiology. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

Raleigh Radiology. In Section V.1(a), page 102, the applicant states that it has existing training agreements with Pitt Community College, Johnston Community College, and Wake Technical Community College for their radiology students. Exhibit 23 contains copies of the applicant's affiliation agreements with these educational institutions. The information provided is reasonable and supports a finding of conformity with this criterion.

Wake Radiology. In Section V.1(a), page 65, the applicants state that they offer clinical training programs at two of their radiology sites: North Hills and Raleigh MRI Center. The applicants provide copies of clinical training agreements with Edgecombe Community College and Wake Technical Community College in Attachment K. The applicants further state, on page 65, that while they have no immediate plans to offer clinical training at WRWF, they are "*committed to exploring new relationships with schools in the area.*" The information provided is reasonable and supports a finding of conformity with 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.

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Raleigh Radiology
Wake Radiology

On page 154, the 2016 SMFP defines the service area for a fixed MRI scanner as “*a single county, except where there is no licensed acute care hospital located within the county.*” The definition of the service area for a fixed MRI scanner then explains how a service area is determined when there is no licensed acute care hospital located within the county. For the purpose of this review, however, Wake County is the service area since it has multiple licensed acute care hospitals. Providers may also serve residents of counties not in their service area.

The 2016 SMFP identifies a need determination for one fixed MRI scanner in Wake County. There are 16 existing fixed MRI scanners in Wake County according to the 2016 SMFP. The following table provides the number of fixed MRI scanners, the number of total weighted MRI procedures, and the average weighted MRI procedures per MRI scanner, summarized from Table 9P of the 2016 SMFP.

Fixed MRI Scanners in Wake County

Facility	# of Fixed MRI Scanners	Total Weighted MRI Procedures	Average Weighted MRI Procedures per MRI Scanner*
Duke Raleigh Hospital	2	8,987	4,494
Rex Hospital	3	8,896	2,965
WakeMed	2	12,028	6,014
WakeMed Cary	1	4,290	4,290
Raleigh Neurology Associates (Alliance Healthcare Services)	1	5,133	5,133
Raleigh Neurology Associates	1	5,665	5,665
Raleigh Radiology (Alliance Healthcare Services)	1	4,545	4,545
Raleigh Radiology Cedarhurst (Pinnacle Health Services of NC, LLC)	1	7,392	7,392
Wake Radiology Diagnostic Imaging (Alliance Healthcare Services)	1	3,681	3,681
Wake Radiology Garner (Alliance Healthcare Services)	1	2,767	2,767
Wake Radiology Raleigh MRI Center (Wake Radiology Diagnostic Imaging)	1	3,850	3,850
Wake Radiology Raleigh MRI Center (Wake Radiology Diagnostic Imaging)	1	2,902	2,902

*Average weighted MRI procedures are rounded to nearest whole number.

DRHS proposes to acquire one fixed MRI scanner to be located at a newly constructed medical office building in Holly Springs, Wake County. In Sections II.5, pages 17-22, II.7, page 23, V.7, pages 108-110, VI.2, pages 111-112, X.1, pages 144-145, and Exhibit 5, the applicant discusses how the proposed project will enhance competition in the service area, including how it will have a positive impact on the cost effectiveness, quality and access to MRI services in Wake County. The applicant states, in Section V.7, pages 108-109, that the proposed project will offer patients “*a potentially lower cost alternative...will be available to all patients...*” In addition, the applicant states, on page

109, that the proposed MRI service will utilize established DUHS methods to insure and maintain quality of care.

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- ◆ The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- ◆ The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- ◆ The applicant adequately demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1), (3) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

Raleigh Radiology proposes to acquire one fixed MRI scanner to be located at its existing RR Cary facility at 150 Parkway Office Court, Suite 100, Cary, to replace a fixed, leased MRI scanner. In Sections II.5, page 27, II.6, page 27, II.7, page 28, V.7, pages 106-107, VI.2, pages 108-110, X.1, page 144, and Exhibits 9, 10, 19, and 30, the applicant discusses how the proposed project will enhance competition in the service area, including how it will have a positive impact on the cost effectiveness, quality and access to MRI services in Wake County. The applicant states, in Section V.7, page 106, that the proposed project will *“materially foster competition by offering if not the lowest, one of the lowest cost, highest quality full service MRI scanner accessible available in Wake County and by improving access by expanding capacity to all payers and committing to additional uninsured referrals from Project Access.”*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The applicant adequately demonstrates:

- ◆ the need for the project. The discussion regarding the analysis of need found in Criteria (3) is incorporated herein by reference.
- ◆ it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.

However, the applicant does not adequately demonstrate that it is a cost effective alternative. The discussion regarding alternatives found in Criteria (4) is incorporated herein by reference.

In addition, the applicant does not adequately demonstrate that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13c) is incorporated herein by reference. This determination is based on the information in the application and the following analysis:

- ◆ The applicant does not adequately demonstrate that the projected payor mix for Medicare patients is based on reasonable and adequately supported assumptions which are provided in Sections III.1, pages 39-44, and VI.15(b), pages 121-122.

Therefore, the application is not conforming to this criterion.

Wake Radiology proposes to acquire one fixed MRI scanner to be located at its existing WRWF facility at 3150 Rogers Road, Suite 105, Wake Forest. The fixed MRI scanner will replace the use of the applicants' mobile MRI scanner at WRWF. In Sections II.5, pages 22-23, II.6, pages 23-24, II.7, pages 24-25, III.2, page 52, V.7, page 68, VI.2, page 70, X.1, page 94, and Attachments F and H, the applicants discuss how the proposed project will enhance competition in the service area, including how it will have a positive impact on the cost effectiveness, quality and access to MRI services in Wake County.

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The applicants adequately demonstrate:

- ◆ that they will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- ◆ that they will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1), (3) and (13) is incorporated herein by reference.

However, the applicants do not adequately demonstrate any enhanced competition will have a positive impact on the cost-effectiveness of the proposed services. This determination is based on the information in the application and the following analysis:

- ◆ The applicants do not adequately demonstrate that projected utilization for their existing or proposed fixed MRI scanners in the proposed service area is based on reasonable and adequately supported assumptions.

- ◆ The applicants do not adequately demonstrate that the average annual utilization of their existing, approved and proposed fixed MRI scanners is reasonably expected to perform 4,805 weighted MRI procedures in the third year of operation following completion of the proposed project.
- ◆ The applicants do not adequately demonstrate that the mobile MRI scanner owned by one of the applicants or a related entity and operated at host sites in the service area performed at least 3,328 weighted MRI scans in the most recent 12-month period for which the applicants have data.
- ◆ The applicants do not adequately demonstrate that the projected utilization of their mobile MRI scanner operating at host sites in the service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project.
- ◆ The discussion regarding historical and projected utilization found in Criterion (3) is incorporated herein by reference.

Therefore, the application is not conforming to this criterion.

- (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.

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Raleigh Radiology
Wake Radiology

DRHS. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, one of DUHS three hospitals that it owns or operates in the State of North Carolina was out of compliance with the Medicare Conditions of Participation within the eighteen months immediately preceding submission of the application through the date of this decision. The facility is now back in compliance. The applicant states, in Section II.7, page 23, that it will assure quality of care through its system-wide quality improvement program, patient satisfaction research and accreditation of the proposed services. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all DUHS hospitals, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Raleigh Radiology. In Section II.5, page 27, the applicant discusses how the proposed 3T fixed MRI scanner will improve quality of care. In Section II.6, page 27, the applicant states that its MRI services at RR Cary are accredited by the American College of Radiology. See Exhibit 8 for documentation of ACR accreditation. In Section II.7, page 28, and Exhibit 9, the applicant discusses its quality of care processes. In Section III.2, page 72, the applicant discusses additional methods it uses to ensure quality. After reviewing and considering information provided by the applicant, and considering the quality of care provided at all of its offices, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Wake Radiology. In Sections II.5, II.6, and II.7, pages 23-24, the applicants state that all of its offices are accredited by the American College of Radiology (ACR), including the mobile MRI service at WRWF, and that the proposed, fixed MRI services will also adhere to these standards. In addition, as stated on page 24, Wake Radiology has internal quality of care processes and procedures in place to assure quality of care, including its Wake Radiology Peer Review process. See Attachment F for documentation of accreditation and Attachment H for documentation of the applicants' Peer Review process and policies. After reviewing and considering information provided by the applicants and considering the quality of care provided, the applicants provide 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.

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Wake Radiology

DRHS proposes to acquire a new fixed MRI scanner pursuant to a need determination in the 2016 SMFP for one fixed MRI scanner in Wake County. Therefore, the Criteria and Standards for Magnetic Resonance Imaging Scanner in 10A NCAC 14C .2700 are applicable to this review. The application is conforming to all applicable Criteria and Standards for Magnetic Resonance Imaging Scanner.

Raleigh Radiology proposes to acquire a new fixed MRI scanner pursuant to a need determination in the 2016 SMFP for one fixed MRI scanner in Wake County. Therefore, the Criteria and Standards for Magnetic Resonance Imaging Scanner in 10A NCAC 14C .2700 are applicable to this review. The application is conforming to all applicable Criteria and Standards for Magnetic Resonance Imaging Scanner.

Wake Radiology proposes to acquire a new fixed MRI scanner pursuant to a need determination in the 2016 SMFP for one fixed MRI scanner in Wake County. Therefore, the Criteria and Standards for Magnetic Resonance Imaging Scanner in 10A NCAC 14C .2700 are applicable to this review. The application is not conforming to all applicable Criteria and Standards for Magnetic Resonance Imaging Scanner.

The specific criteria for all three applications are discussed below.

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- None of the applications propose the acquisition of a mobile MRI scanner.

(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- **DRHS.** In Section II, page 28, the applicant states that its two fixed MRI scanners at Duke Raleigh Hospital performed a total of 10,391 weighted MRI procedures from February 2015 – January 2016, for an average of 5,196 weighted MRI procedures per scanner.

-NA- **Raleigh Radiology.** Neither the applicant nor a related entity owns or has a controlling interest in any fixed MRI scanners located in Wake County.

-C- **Wake Radiology.** In Section III.1, page 48, the applicants state that their four fixed MRI scanners performed 14,455 weighted MRI procedures from 4/01/15 – 3/31/16, for an average of 3,611 weighted MRI procedures per scanner.

- (2) demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This*

is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];

- NA- **DRHS.** Neither the applicant nor a related entity owns or has a controlling interest in any mobile MRI scanners operated in Wake County.
- NA- **Raleigh Radiology.** Neither the applicant nor a related entity owns or has a controlling interest in any mobile MRI scanners operated in Wake County.
- NC- **Wake Radiology.** In Section III.1, page 45, the applicants state that their mobile MRI scanner performed 1,402 weighted MRI procedures at the WRWF location from 4/01/15 – 3/31/16. In Section III.1, page 50, the applicants state that their mobile MRI scanner performed 791 weighted MRI procedures at WRDI Cary, Fuquay-Varina and North Raleigh sites from 4/01/15 – 3/31/16, for a combined total of 2,193 weighted MRI procedures. Therefore, the applicants do not adequately demonstrate that their mobile MRI scanner performed at least 3,328 weighted MRI procedures in the most recent 12 month period for which they had data. The application is not conforming to this Rule.

In their response to comments, the applicants argue that this Rule should be void as not reasonably necessary for the Agency to determine whether the applicants demonstrate a need for the proposed fixed MRI scanner. However, the Rule is necessary as it would not be consistent with the premise of the CON Law to approve an applicant to acquire an additional MRI scanner (fixed or mobile) when the applicant has access to an existing mobile MRI scanner which has the capacity to serve more patients than it is currently serving.

(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 2016 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 is reasonably expected to perform 4,805 weighted MRI procedures in the third operating year.

- C- **DRHS.** The applicant owns and operates two existing fixed MRI scanners and proposes to acquire one additional fixed MRI scanner in Wake County, for a total of three fixed MRI scanners. In Section III.1, page 76, the applicant projects that its proposed fixed MRI scanner will perform 5,193 weighted MRI procedures in the third operating year. In Section IV.1, page 100, the applicant projects that its two existing fixed MRI scanners will perform a total of 14,413 weighted MRI procedures in the third operating year, for an average of 7,207, rounded up.

The application is conforming to this Rule.

- C- **Raleigh Radiology.** In Section IV.1, page 99, the applicant projects that its proposed fixed MRI scanner will perform 8,496 weighted MRI procedures in the third year of operation following project completion.

The application is conforming to this Rule.

- NC- **Wake Radiology.** In Section II, page 30, the applicants state that the average number of weighted MRI procedures for its proposed fixed MRI scanner and its four existing fixed MRI scanners will be 4,860. However, the applicants do not adequately demonstrate that projected utilization of the proposed, fixed MRI scanner or their four existing fixed MRI scanners are based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is not conforming to 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- **DRHS.** The proposed fixed MRI scanner would be located at a different site from the applicant's two existing fixed MRI scanners. In Section III.1, page 76, the applicant projects that it's proposed fixed MRI scanner to be located in Holly Springs will perform 5,193 weighted MRI procedures in the third operating year.

-NA- **Raleigh Radiology.** The applicant does not own or operate any fixed MRI scanners in Wake County.

-NC- **Wake Radiology.** The applicants' proposed fixed MRI scanner will be located at the Wake Forest site where the applicants do not currently have a fixed MRI scanner. In Section IV, page 62, the applicants project to perform 4,835 weighted MRI procedures on the proposed fixed MRI scanner in the third operating year. However, the applicants do not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions regarding growth. The discussion regarding projected utilization of the proposed fixed MRI scanner found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming to 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*

- NA- **DRHS.** The applicant does not own any mobile MRI scanners in Wake County.
- NA- **Raleigh Radiology.** The applicant does not own any mobile MRI scanners in Wake County.
- NC- **Wake Radiology.** In Section III.1, page 51, the applicants project that their mobile MRI scanner will perform 3,532 weighted MRI procedures in operating year three. However, the applicants do not adequately demonstrate that the projected utilization of their mobile MRI scanner is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization of their mobile MRI scanner found in Criterion (3) is incorporated herein by reference. The application is not conforming to this Rule.
 - (6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- C- **DRHS.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section III, pages 54-76, and Section IV, pages 99-100.
- C- **Raleigh Radiology.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section IV.1, pages 94-101.
- C- **Wake Radiology.** The applicants' assumptions and data supporting the methodology used for each projection required by this Rule are described in Section II.8, pages 31-32, and Section III.1, pages 44-51.
 - (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- None of the applications propose the acquisition of a dedicated fixed breast MRI scanner.

- (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- None of the applications propose the acquisition of a fixed extremity MRI scanner.

- (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- None of the applications propose the acquisition of a fixed multi-position MRI scanner.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2016 State Medical Facilities Plan, no more than one additional fixed MRI scanner may be approved in this review for Wake County. Because the three applications in this review collectively propose to acquire three additional fixed MRI scanners, only one of the applications can be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved. For the reasons set forth below and in the rest of the findings, the application submitted by Duke University Health System, Inc., Project I.D. #J-11167-16, is approved and the other applications, submitted by Raleigh Radiology, LLC, and Wake Radiology Services, LLC and Wake Radiology Diagnostic Imaging, Inc., are denied.

Geographic Distribution

The 2016 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	City/Town	# of Existing and Approved Fixed MRI Units
Duke Raleigh Hospital	Raleigh	2
Rex Hospital	Raleigh	3
WakeMed	Raleigh	2
WakeMed Cary	Cary	1
Raleigh Neurology Associates (Alliance Healthcare Services)	Raleigh	1
Raleigh Neurology Associates	Raleigh	1
Raleigh Radiology (Alliance Healthcare Services)	Cary	1
Raleigh Radiology Cedarhurst (Pinnacle Health Services of NC, LLC)	Raleigh	1
Wake Radiology Diagnostic Imaging (Alliance Healthcare Services)	Cary	1
Wake Radiology Garner (Alliance Healthcare Services)	Garner	1
Wake Radiology Raleigh MRI Center (Wake Radiology Diagnostic Imaging)	Raleigh	1
Wake Radiology Raleigh MRI Center (Wake Radiology Diagnostic Imaging)	Raleigh	1
Total		16

As shown in the table above, there are 16 existing and approved fixed MRI scanners located in Wake County. Twelve are located in Raleigh, three are located in Cary, and one is located in Garner. There are no fixed MRI scanners located in other Wake County cities.

DRHS proposes to locate an additional fixed MRI scanner in Holly Springs in the southwestern part of Wake County. Raleigh Radiology proposes to locate a fixed MRI scanner in Cary in the western part of Wake County. Wake Radiology proposes to locate a fixed MRI scanner in Wake Forest in the northern part of Wake County. Thus, with respect to geographic distribution, the proposals submitted by DRHS and Wake Radiology are more effective alternatives since there are no fixed MRI scanners in Holly Springs or Wake Forest, respectively. However, the proposal submitted by Wake Radiology is not approvable. Therefore, the proposal submitted by DRHS is the most effective alternative with respect to geographic distribution.

Demonstration of Need

DRHS and Raleigh Radiology adequately demonstrated that projected utilization of the proposed fixed MRI scanner was reasonable, adequately documented their assumptions and methodologies, and demonstrated the need the population they project to serve has for the proposed fixed MRI scanner. However, the proposal submitted by Raleigh Radiology is not approvable. Wake Radiology did not adequately demonstrate the need the population they propose to serve has for the proposed fixed MRI scanner. The discussion regarding demonstration of need found in Criterion (3)

is incorporated herein by reference. Therefore, the application submitted by DRHS is the most effective alternative with regard to demonstration of need.

Access by Underserved Groups

The following table illustrates the percentage of total MRI procedures projected to be provided to Medicaid and Medicare recipients in Project Year 2, as stated in Section VI.15(b) of DRHS and Wake Radiology’s respective applications, and in Section VI.15(a) of Raleigh Radiology’s application.

Application	Percentage of Total Procedures to be Provided to Medicaid Recipients	Percentage of Total Procedures to be Provided to Medicare Recipients
DRHS	5.2%	27.4%
Raleigh Radiology	2.0%	30.5%
Wake Radiology	6.3%	38.2%

As shown in the table above, Wake Radiology proposes to serve the highest percentage of both Medicaid and Medicare recipients. However, the proposal submitted by Wake Radiology is not approvable. Raleigh Radiology’s Medicare percentage is not reliable because the applicant does not adequately demonstrate that its payor mix is reasonable and adequately supported. DRHS proposed to serve the next highest percentage of both Medicaid and Medicare recipients. Therefore, DRHS is the more effective alternative with regard to access by Medicaid and Medicare recipients.

Ownership of Fixed MRI Scanners in Wake County

There are 16 existing fixed MRI scanners in Wake County. The following table identifies the provider, number, and average utilization of each of the fixed MRI scanners, summarized from Table 9P of the 2016 SMFP.

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Facility	# of Existing Fixed MRI Scanners	Total Weighted MRI Scans	Average Weighted MRI Scans Per Scanner*
Duke Raleigh Hospital	2	8,987	4,494
Rex Hospital	3	8,896	2,965
WakeMed	2	12,028	6,014
WakeMed Cary	1	4,290	4,290
Raleigh Neurology Associates (Alliance Healthcare Services)	1	5,133	5,133
Raleigh Neurology Associates	1	5,665	5,665
Raleigh Radiology (Alliance Healthcare Services)	1	4,545	4,545
Raleigh Radiology Cedarhurst (Pinnacle Health Services of NC, LLC)	1	7,392	7,392
Wake Radiology Diagnostic Imaging (Alliance Healthcare Services)	1	3,681	3,681
Wake Radiology Garner (Alliance Healthcare Services)	1	2,767	2,767
Wake Radiology Raleigh MRI Center (Wake Radiology Diagnostic Imaging)	1	3,850	3,850
Wake Radiology Raleigh MRI Center (Wake Radiology Diagnostic Imaging)	1	2,902	2,902

*Average weighted MRI scans per scanner are rounded to the nearest whole number.

As shown in the table above, two of the 16 existing fixed MRI scanners are operated at Duke Raleigh Hospital which is owned by Duke University Health System, Inc. (DUHS), the applicant of the DRHS application. Wake Radiology Services, LLC and Wake Radiology Diagnostic Imaging, Inc. own four fixed MRI scanners in Wake County, listed in the above table as Wake Radiology Raleigh MRI Center, Wake Radiology Diagnostic Imaging, and Wake Radiology Garner.

DUHS does not own a mobile MRI scanner that it operates in Wake County. Wake Radiology owns one mobile MRI scanner that is operated at several host sites in Wake County. Both applicants contract with an unrelated provider, Alliance Healthcare Services, for mobile MRI services at host sites in Wake County.

DRHS owns two fixed MRI scanners and Wake Radiology owns four fixed MRI scanners that each operates in Wake County. Raleigh Radiology does not own any fixed MRI scanners in Wake County. However, the application submitted by Raleigh Radiology is not approvable. Therefore, DRHS is the more effective alternative with regard to the number of fixed MRI scanners owned and operated in Wake County.

Projected Average Gross Revenue per MRI Procedure

The following table shows the projected average gross revenue per MRI procedure for the second year of operation for DRHS (FY2020) and the third year of operation for Raleigh Radiology

(CY2020) and Wake Radiology (FY2020), based on the information provided in the applicants' pro forma financial statements (Form C). DRHS does not include professional fees (i.e., charges for interpretation of the images by a radiologist) in its pro formas. Wake Radiology does include professional fees in its pro formas. The Project Analyst cannot determine if Raleigh Radiology includes professional fees in its pro formas because there is no line item for them in Form C and no discussion regarding professional fees in the applicant's assumptions for the pro formas. All of the applicants deduct bad debt from gross revenue.

Application	Gross Revenue	Deduct Professional Fees	Gross Revenue less Professional Fees	# of Unweighted MRI Procedures	Ave. Gross Revenue Per Procedure
DRHS (OY2: 7/1/19 - 6/30/20)	\$3,171,511	N/A	\$3,171,511	3,013	\$1,053
Raleigh Radiology (OY3: 1/1/20 – 12/31/20)	\$9,466,338	*	\$9,466,338	8,046	\$1,177
Wake Radiology (OY3: 7/1/19 – 6/30/20)	\$9,408,622	(\$1,439,519)	\$7,969,103	4,307	\$1,850

*The Project Analyst cannot determine if professional fees were included in the applicant's pro formas, Form C.

As shown in the table above, DRHS projects the lowest average gross revenue per MRI procedure. Therefore, with regard to projected average gross revenue per MRI procedure, the proposal submitted by DRHS is the most effective alternative.

Projected Average Net Revenue per MRI Procedure

The following table shows the projected net revenue per MRI procedure for the second year of operation for DRHS (FY2020) and the third year of operation for Raleigh Radiology (CY2020) and Wake Radiology (FY2020), based on the information provided in the applicants' pro forma financial statements (Form C).

Application	Net Revenue	Deduct Professional Fees	Net Revenue Less Professional Fees	# of Unweighted MRI Procedures	Average Net Revenue Per Procedure
DRHS (OY2: 7/1/19-6/30/20)	\$1,609,067	N/A	\$1,609,067	3,013	\$534
Raleigh Radiology (OY3: 1/1/20 – 12/31/20)	\$3,001,575	*	\$3,001,575	8,046	\$373
Wake Radiology (OY3: 7/1/19 – 6/30/20)	\$3,654,981	(\$1,439,519)	\$2,215,462	4,307	\$514

*The Project Analyst cannot determine if professional fees were included in the applicant's pro formas, Form C.

As shown in the table above, Raleigh Radiology projects the lowest average net revenue per MRI procedure. However, the proposal submitted by Raleigh Radiology is not approvable. Wake

Radiology projects the next lowest average net revenue per MRI procedure. However, Wake Radiology did not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. Consequently, projected revenues are not reliable. The discussion regarding demonstration of need found in Criterion (3) is incorporated herein by reference. Therefore, with regard to projected average net revenue per procedure, the proposal submitted by DRHS is the most effective alternative.

Projected Average Operating Expense per MRI Procedure

The following table shows the projected average operating expense per MRI procedure for the second year of operation for DRHS (FY2020) and the third year of operation for Raleigh Radiology (CY2020) and Wake Radiology (FY2020), based on the information provided in the applicants’ pro forma financial statements (Form C).

Application	Total Operating Expenses	Deduct Professional Fees	Operating Expenses Less Professional Fees	Unweighted MRI Procedures	Average Operating Expense Per Procedure
DRHS (OY2: 7/1/19-6/30/20)	\$1,461,868	N/A	\$1,461,868	3,013	\$485
Raleigh Radiology (OY3: 1/1/20 – 12/31/20)	\$1,827,592	*	\$1,827,592	8,046	\$227
Wake Radiology (OY3: 7/1/19 – 6/30/20)	\$2,569,287	(\$1,439,519)	\$1,129,768	4,307	\$262

* The Project Analyst cannot determine if professional fees were included in applicant’s pro formas, Form C.

As shown in the table above, Raleigh Radiology projects the lowest average operating expense per MRI procedure. However, the proposal submitted by Raleigh Radiology is not approvable. Wake Radiology projects the next lowest average operating expense per MRI procedure. However, Wake Radiology did not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding demonstration of need in Criterion (3) is incorporated herein by reference. Therefore, with regard to projected average operating expense per procedure, the proposal submitted by DRHS is the most effective alternative.

SUMMARY

The following is a summary of the reasons the proposal submitted by DRHS is determined to be the most effective alternative in this review:

- DRHS proposes to locate the proposed fixed MRI scanner in a geographic area of Wake County that does not have any fixed MRI scanners.
- DRHS projects the lowest average gross revenue per MRI procedure.

- The application submitted by DRHS was determined to be conforming to all applicable statutory and regulatory review criteria.

The following is a summary of the reasons the proposal submitted by Raleigh Radiology is determined to be a less effective alternative in this review than the approved applicant:

- Raleigh Radiology proposed to locate the proposed fixed MRI scanner in a geographic area of Wake County that already has three fixed MRI scanners.
- Raleigh Radiology did not demonstrate that underserved groups would have adequate access to the proposed services. The discussion regarding access found in Criterion (13c) is incorporated herein by reference.
- Raleigh Radiology projected the lowest combined percentage of MRI procedures for Medicaid and Medicare recipients.
- The application submitted by Raleigh Radiology was determined to be nonconforming to Criteria (4), (13c), and (18a).

The following is a summary of the reasons the proposal submitted by Wake Radiology is determined to be a less effective alternative in this review than the approved applicant:

- Wake Radiology did not demonstrate the need for the proposed project in Wake County. The discussion regarding need found in Criterion (3) is incorporated herein by reference.
- The application submitted by Wake Radiology was determined to be nonconforming to Criteria (1), (3), (4), (5), (6), (18a) and 10A NCAC 14C .2703(b)(2), (3), (4) and (5).

CONCLUSION

All of the applications are conforming to the need determination in the 2016 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. The Agency determined that the application submitted by DRHS is the most effective alternative proposed in this review for one additional fixed MRI scanner for Wake County and is approved. The approval of any other application would result in the approval of MRI scanners in excess of the need determination in the 2016 SMFP and therefore, the applications submitted by Raleigh Radiology and Wake Radiology are denied.

The application submitted by DRHS is approved subject to the following conditions:

- 1. Duke University Health System, Inc. shall materially comply with all representations made in the certificate of need application.**

- 2. Duke University Health System, Inc. shall acquire no more than one fixed MRI scanner which results in the development of a new diagnostic center.**
- 3. Duke University Health System, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**
- 4. Duke University Health System, Inc. shall obtain accreditation from The Joint Commission, the American College of Radiology, or a comparable accreditation authority as determined by the Agency, for magnetic resonance imaging within two years following operation of the proposed MRI scanner.**
- 5. Duke University Health System, Inc. 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.**