

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 8, 2020

Findings Date: October 8, 2020

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: J-11913-20

Facility: Duke Health Arrington Radiology

FID #: 190274

County: Durham

Applicant: Duke University Health System, Inc.

Project: Acquire a fixed MRI scanner pursuant to the need determination in the 2020 SMFP which is a change of scope for Project ID#J-11718-19 (develop a new diagnostic center with one MRI scanner relocated from Page Road)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Duke University Health System, Inc. [DUHS], the applicant, proposes a change of scope (COS) for the approved, but undeveloped, Duke Health Arrington Radiology (Duke-Arrington) project (Project ID# J-11718-19), which authorized the development of a new diagnostic center with CT, mammography, ultrasound, X-ray and DEXA equipment and replacement and relocation of one existing Magnetic Resonance Imaging (MRI) scanner from Page Road. Duke-Arrington is currently under development and will be located at 5601 Arrington Park Drive, Morrisville, Durham County.

In the current application, the applicant proposes to add a second MRI scanner to the Duke-Arrington facility pursuant to a need determination in the 2020 State Medical Facilities Plan (SMFP) for one fixed MRI scanner in the Durham/Caswell multicounty MRI service area.

Upon completion, the Duke-Arrington facility will be an independent diagnostic testing facility (IDTF) and thus will not be billed as a hospital-based service.

### **Need Determination**

The 2020 SMFP includes a need methodology for determining need for additional MRI scanners in North Carolina by service area. Application of the need methodology in the 2020 SMFP identified a need determination for one additional fixed MRI scanner in the Durham/Caswell multicounty MRI service area. The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the Durham/Caswell multicounty MRI service area. Therefore, the applicant's proposal is consistent with the need determination in the 2020 SMFP.

### **Policy**

There are two policies in the 2020 SMFP applicable to this review: *Policy GEN-3: Basic Principles* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-3, on pages 30-31 of the 2020 SMFP, states:

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

**Promote Safety and Quality** - The applicant describes how it believes the proposed project would promote safety and quality in Section N, page 65; Section O, pages 67-68 and referenced exhibits. 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 the proposed project would promote equitable access in Section N, page 65; Section C, page 28; Section L, pages 58-63 and referenced exhibits. 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 the proposed project would maximize health care value in Section N, page 65; Section F, pages 40-44; Section K, pages 54-56; the applicant's pro forma financial statements in Section Q and referenced exhibits.

The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will maximize health care value and that the applicant's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2020 SMFP. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 31 of the 2020 SMFP, states:

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

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

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

The proposed capital expenditure for this project is greater than \$2.0 million and less than \$5.0 million. In Section B, pages 13-14, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

## **Conclusion**

The Agency reviewed the:

- Application

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

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

- The applicant does not propose to acquire more fixed MRI scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 based on the following:
  - The applicant adequately documents how the proposed project will promote safety and quality;
  - The applicant adequately documents how the proposed project will promote equitable access; and
  - The applicant adequately documents how the proposed project will maximize healthcare value for the resources expended.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because the applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

(2) Repealed effective July 1, 1987.

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

## C

DUHS proposes a COS for the approved, but undeveloped, Duke-Arrington project (Project I.D. #J-11718-19) which authorized the development of a new diagnostic center with CT, mammography, ultrasound, X-ray and DEXA equipment and replacement and relocation of one existing MRI scanner from Page Road. In the current COS application, DUHS proposes to add a second MRI scanner to the Duke-Arrington project pursuant to a need determination in the 2020 SMFP for one fixed MRI scanner in the Durham/Caswell multicounty MRI service area.

In the original application (Project I.D. #J-11718-19) the first operating year (OY) was Fiscal Year (FY) 2021 (7/1/2020 – 6/30/2021). However, in supplemental information, the applicant states that due to slight delays and the need to coordinate several projects currently under development within the same building and then significant delays due to the COVID-19 public health pandemic the first three operating years following completion of the proposed project were adjusted to the following dates:

OY1: FY2023 (7/1/2022 to 6/30/2023)  
 OY2: FY2024 (7/1/2023 to 6/30/2024)  
 OY3: FY2025 (7/1/2024 to 6/30/2025)

**Patient Origin**

On page 418, the 2020 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1.*” Thus, the service area for this facility consists of the multicounty service area of Durham/Caswell counties. Facilities may also serve residents of counties not included in their service area.

Duke-Arrington is an imaging center under development and thus there is no historical patient origin data. The following table illustrates projected patient origin.

**Projected Patient Origin- MRI**

County	1st Full FY of Operation (7/1/2022 – 6/30/2023)		2nd Full FY of Operation (7/1/2023 – 6/30/2024)		3rd Full FY of Operation (7/1/2024 – 6/30/2025)	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Durham	1,698	44.0%	2,745	43.0%	3,832	42.0%
Wake	264	7.0%	459	7.0%	660	7.0%
Orange	1,716	45.0%	2,929	46.0%	4,192	46.0%
Other NC	175	5.0%	292	5.0%	413	5.0%
Total	3,853	100.0%	6,425	100.0%	9,097	100.0%

Source: Section C.3, page 17.

In Section C, pages 17-18, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the methodology used to project utilization for the proposed MRI services and DUHS’s experience at other imaging sites.

**Analysis of Need**

In Section C.4, pages 18-24, and supplemental information, the applicant explains why it believes the population projected to utilize the MRI scanner services included in the COS application needs the proposed services, including:

- The need determination in the 2020 SMFP for a fixed MRI scanner in the Durham/Caswell multicounty MRI service area (page 18).
- The need for increased MRI capacity in Durham County (pages 18-20).
- Growth in DUHS MRI volumes (pages 20-22).
- The increased demand for access to non-hospital based MRI services (page 22).
- The benefits of increased coordination of care and access with other services at Duke-Arrington, including improved geographic access (pages 22-23).
- The growth in DUHS’s provider network (pages 23-24).

The information provided by the applicant in the pages referenced above is reasonable and adequately supported based on the following reasons:

- There is a need determination in the 2020 SMFP for a fixed MRI scanner in the Durham/Caswell multicounty MRI service area and this proposed project will meet that need determination by developing a fixed MRI scanner in Durham County.
- The applicant’s assumptions for projected utilization are based on its historical experience operating MRI services.
- The applicant provides information regarding the current and projected population by county for its proposed service area from Stratasan.
- There is a growing demand for outpatient services at non-hospital based facilities and DUHS does not currently offer non-hospital based MRI services in Durham County.

*Projected Utilization*

In Section Q, Form C, and supplemental information, the applicant provides projected utilization, as illustrated in the following table.

	Interim Year (7/1/2020- 6/30/2021)	Interim Year (7/1/2021- 6/30/2022)	OY1 (7/1/2022- 6/30/2023)	OY2 (7/1/2023 – 6/30/2024)	OY3 (7/1/2024 - 6/30/2025)
# of MRI Scanners	1	2	2	2	2
# of Scans	623	3,529	6,204	8,864	9,086
# of Weighted Scans	716	4,057	7,135	10,189	10,445
# of Weighted Scans per MRI Scanner	716	2,028.5	3,567.5	5,094.5	5,222.5

Source: Form C.

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

Step 1. Projected Overall Service Area Outpatient MRI Volume: The applicant projected overall outpatient MRI utilization by first identifying projected population of the primary service area based on ZIP Codes within a 30-minute drive and multiplying that by the NC statewide MRI use rate of 85.5 procedures per 1,000 population based on the 2020 SMFP data.

Step 2. The applicant calculated its historic outpatient MRI (non-emergent) volumes from July 2019 through February 2020 (8 months) and annualized that to establish its MRI outpatient volumes from the primary service area for FY2020 (7/1/2019 to 6/30/2020). The applicant did not use data from March 2020 through June 2020 due to the impact of the COVID-19 pandemic.

Step 3. Market share. The applicant calculated its market share of the projected service area of non-emergent outpatient MRI volume from all locations. The FY2020 market share was 21.0%.

Steps 4. Shift from Page Road facility: The applicant projects that all the volume on the existing MRI scanner located at Page Road will shift to the new Duke-Arrington facility and grow by the same rate as the projected population growth in the identified ZIP codes. In Project ID# J-11718-19 DUHS was approved to replace and relocate the existing MRI scanner at Page Road to the Duke-Arrington Diagnostic Center. The Page Road facility and the approved Duke-Arrington facility are in close proximity.

Step 5. Shift from non-Page Road DUHS facilities: The applicant also projects a shift of the projected MRI outpatient volumes of patients originating from the identified service area for other (non-Page Road) DUHS facilities to Duke-Arrington. The percentage of the shift of volumes varies by ZIP code. In addition, the shift is subject to a ramp-up period.

Step 6. The applicant calculates the total volume of the anticipated shift from all non-Page Road DUHS facilities.

Step 7. The applicant totals the volumes of the anticipated shift from both the Page Road facility and from all non-Page Road facilities.

Step 8. Increased market share (incremental growth) from the primary service area: The applicant also projects that the proposed Duke-Arrington facility will attract and serve new, additional, market share of the overall projected MRI outpatient volume for each of the ZIP Codes in the identified service area. This is based on several factors including: increased geographic access and patient convenience; historic growth of DUHS services, provider recruitment, increase in population and overall service area utilization and cost benefits of Duke-Arrington being a non-hospital based facility. This increase market share also varies by ZIP Code and a ramp-up period is also applied.

Step 9. In-Migration: DUHS also assumes a 10% in-migration rate from outside the primary service area 50% of which the applicant projects will come from ZIP Codes in Durham County which are not part of the primary service area and 50% of which will come from other counties based on Duke-Arrington being DUHS's only non-hospital based imaging center in Durham County, convenient to patients who work in RTP and with Duke-Arrington having easy access to I-40.

Step 10. The applicant combines projected volumes from all the previous steps and assumes both MRI scanners are in operation as of the beginning of FY2022 (7/1/2021).

Step 11. Adjusted projected overall MRI volume to account for the second MRI not projected to be in service for the full FY2022 as Steps 1-10 assume both MRI scanners would be operational for the full FY2022 and the second MRI scanner is only projected to be operational for 10 months of FY2022.

Step 12. Calculated weighted MRI Scans: Duke-Arrington will be an IDTF. The only other DUHS IDTF with significant historical MRI volume is DUHS's IDTF located off of Cary Parkway so the applicant utilized a weighted average of 1.15/procedure based on outpatient MRI procedures performed in FY2019 at the Cary Parkway location. The actual weighted average at the Cary Parkway location for FY2019 was 1.18 per procedure.

The assumptions and methodology summarized in Steps 1-12 above are illustrated in the following table:

**Duke-Arrington: Projected MRI Utilization**

	<b>OY1 (FY2022)</b>	<b>OY2 (FY2023)</b>	<b>OY3 (FY2024)</b>
Page Road Shift	725	739	754
Non-Page Road Shift	741	1,668	2,629
Incremental Growth	2,034	3,428	4,876
Sub-Total	3,500	5,835	8,260
10% Projected In-Migration	.10	.10	.10
	350	583	826
Unweighted Scans-Total	3,850	6,418	9,086
Weighting Assumption	1.15	1.15	1.15
Weighted Scans-Total	7,132	10,189	10,445
# of MRI Scanners	2	2	2
Weighted Procedures/ Scanner	3,566	5,095	5,223

Source: Table prepared by Project Analyst based on information in Section Q.

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

- There is a need determination in the 2020 SMFP for a fixed MRI scanner in the Durham/Caswell multicounty MRI service area and this proposed project will meet that need determination by developing a fixed MRI scanner in Durham County.
- The proposed MRI services will be located in a non-hospital based IDTF which provides for lower-costs than a hospital-based service. This will be the first non-hospital based facility offering MRI services through DUHS in Durham County. Payors continue to prefer or require plan participants to obtain services at non-hospital based facilities.
- The methodology and assumptions utilized by the applicant were reasonable and adequately supported.
- Continued growth in DUHS MRI volumes.
- The weighted average of 1.15 is less than the weighted average of outpatient MRI procedures performed at DUHS's Cary Parkway location for FY2019.
- The projected population growth in the service area.
- The MRI scanners will be co-located with new and existing primary, specialty and surgical services that will be relocated to an approved MOB that is currently under development which is in a convenient geographic location.



- The facility will offer a broad range of MRI services and will serve as an MRI center as the MRI scanner being relocated from Page Road (Project I.D. #J-11718-19) will be a 3.0T magnet and the MRI scanner being developed with this application will be a 1.5T magnet. Further, two MRI scanners enhance scheduling flexibility and the ability to respond to maintenance and equipment down-time.

### Access

In Section C.11, page 28, the applicant states, “*There is no discrimination on the basis of race, ethnicity, age, gender, or disability. Policies to provide access to services by low income, medically indigent, uninsured, or underinsured patients are described and provided elsewhere in this application.*”

In Section L, page 62, the applicant projects the following payor mix during the second full fiscal year of operation (FY2024) following completion of the project, as illustrated in the following table.

<b>Payor Category</b>	<b>MRI Services as Percent of Total</b>
Self-Pay	1.2%
Charity Care	2.0%
Medicare*	37.5%
Medicaid*	5.9%
Insurance*	50.4%
Workers Compensation	0.4%
TRICARE	0.8%
Other (commercial, other government payors)	1.8%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 62 of the application.

\*Includes any managed care plans.

The projected payor mix is reasonable and adequately supported.

### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

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

- The applicant adequately identifies the population to be served.

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

In Project I.D. #J-11718-19, the applicants were found conforming with this criterion. The applicant proposes no changes in the current COS application that would affect that determination.

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

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

CA

DUHS proposes a COS for the approved, but undeveloped, Duke-Arrington project (Project I.D. #J-11718-19) which authorized the development of a new diagnostic center with CT, mammography, ultrasound, X-ray and DEXA equipment and replacement and relocation of one existing MRI scanner from Page Road. In the current COS application, DUHS proposes to add a second MRI scanner to the Duke-Arrington project pursuant to a need determination in the 2020 SMFP for one fixed MRI scanner in the Durham/Caswell multicounty MRI service area.

In Section E, page 39, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Do Not Develop New MRI Services- The applicant states that this alternative would fail to meet the growing demand for DUHS imaging services. Therefore, this was not an effective alternative.
- Develop MRI Services at a Different Location- The applicant has already been approved for, and is currently developing, a diagnostic center, Duke-Arrington, in southern Durham County. The applicant states that the southern part of Durham County is the

fastest growing area of Durham County. Further, the applicant DUHS already offers imaging services in northern and central Durham County. The applicant determined that developing the MRI services in another area of Durham County would not enhance patient access and convenience; would not take advantage of economies of scale; nor would it take advantage of co-locating in a medical office building that will house a wide variety of urgent, primary and specialty services. Therefore, this was not the least costly or most effective alternative.

- Contract with a Mobile Provider for MRI Services- The applicant determined that this was not the least costly alternative nor most effective alternative as the applicant would have to pay a service fee to the mobile provider and be subject to the terms and conditions of the provider contract hindering availability and the ability to unilaterally expand hours of service.

On page 39, the applicant states that its proposal is the most effective alternative because the proposed location in southern Durham County is the fastest growing area in the county, the MRI services will be co-located with urgent care, primary care, surgery, endoscopy and specialty services thus enhancing patient convenience and coordination of care. Additionally, the proposal is able to take advantage of economies of scale by co-locating the proposed MRI scanner in a diagnostic center that has already received approval and is underdevelopment.

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Duke University Health Systems, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application, the representations in Project I.D. #J-11718-19 and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**

- 2. The certificate holder shall acquire a fixed MRI scanner pursuant to the need determination in the 2020 SMFP which is a change of scope for Project ID#J-11718-19 (which authorized the development of a new diagnostic center with CT, mammography, ultrasound, X-ray and DEXA equipment and replacement and relocation of one existing MRI scanner from Page Road).**
  - 3. Upon completion of the project, Duke Health Arrington Radiology shall be licensed for no more than two fixed MRI scanners.**
  - 4. Progress Reports:**
    - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
    - b. The certificate holder shall complete all sections of the Progress Report form.**
    - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
    - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on January 1, 2021. The second progress report shall be due on April 1, 2021 and so forth.**
  - 5. The certificate holder shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
  - 6. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
    - a. Payor mix for the services authorized in this certificate of need.**
    - b. Utilization of the services authorized in this certificate of need.**
    - c. Revenues and operating costs for the services authorized in this certificate of need.**
    - d. Average gross revenue per unit of service.**
    - e. Average net revenue per unit of service.**
    - f. Average operating cost per unit of service.**
  - 7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (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

DUHS proposes a COS for the approved, but undeveloped, Duke-Arrington project (Project I.D. #J-11718-19) which authorized the development of a new diagnostic center with CT, mammography, ultrasound, X-ray and DEXA equipment and replacement and relocation of one existing MRI scanner from Page Road. In the current COS application, DUHS proposes to add a second MRI scanner to the Duke-Arrington project pursuant to a need determination in the 2020 SMFP for one fixed MRI scanner in the Durham/Caswell multicounty MRI service area.

In the original Duke-Arrington project, Project I.D. #J-11718-19, the application was conforming to this criterion with approved capital costs of \$9,310,000 and no working capital costs, as shown below.

**Capital and Working Capital Costs**

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

	<b>Original Costs (Project ID#J-11718-18)</b>	<b>Current Project (Project ID#J-11913-20)</b>	<b>Total</b>
Construction Costs	\$3,000,000	\$550,000	\$3,550,000
Architect/Engineering Fees	\$300,000	\$47,000	\$347,000
Medical Equipment	\$5,600,000	\$2,155,000	\$7,755,000
Miscellaneous Costs	\$410,000	\$95,000	\$505,000
<b>Total</b>	<b>\$9,310,000</b>	<b>\$2,847,000</b>	<b>\$12,157,000</b>

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

In Section F, pages 41-43 the applicant projects there will be no start-up or initial operating expenses for the project because the facility will be operated as part of the Duke University Health System and will not have separate financial statements.

**Availability of Funds**

In Section F, page 40, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

Type	DUHS	Total
Loans		
Accumulated reserves or OE *	\$2,847,000	\$2,847,000
Bonds		
Other (Specify)		
<b>Total Financing</b>	<b>\$2,847,000</b>	<b>\$2,847,000</b>

\* OE = Owner's Equity

In Section F, pages 40-41, the applicant states that the capital costs for the project will be funded by accumulated reserves of DUHS. In Section F, page 41, the applicant states that the CFO has documented the availability of funds in excess of the projected capital cost of the project. Exhibit F.2 contains a letter dated July 10, 2020 from the Chief Financial Officer for DUHS documenting that the funds will be made available for the capital costs of the project. Exhibit F.2 also contains the audited financial statements for DUHS which indicated the health system had \$251 million in cash and cash equivalents, \$6.6 billion in assets, and \$3.78 billion in net assets, as of June 30, 2019.

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

**Financial Feasibility**

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

	1 <sup>st</sup> Full Fiscal Year	2 <sup>nd</sup> Full Fiscal Year	3 <sup>rd</sup> Full Fiscal Year
Total Procedures*	6,204	8,864	9,086
Total Gross Revenues (Charges)	\$6,884,796	\$10,033,048	\$10,490,408
Total Net Revenue	\$3,303,829	\$4,804,664	\$5,013,459
Average Net Revenue per Procedure*	\$533	\$542	\$552
Total Operating Expenses (Costs)	\$1,760,494	\$1,946,136	\$1,995,796
Average Operating Expense per Procedure*	\$284	\$220	\$220
<b>Net Income</b>	<b>\$1,543,335</b>	<b>\$2,858,528</b>	<b>\$3,017,663</b>

\*Unweighted procedures

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

**Conclusion**

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (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

DUHS proposes a COS for the approved, but undeveloped, Duke-Arrington project (Project I.D. #J-11718-19) which authorized the development of a new diagnostic center with CT, mammography, ultrasound, X-ray and DEXA equipment and replacement and relocation of one existing MRI scanner from Page Road. In the current COS application, DUHS proposes to add a second MRI scanner to the Duke-Arrington project pursuant to a need determination in the 2020 SMFP for one fixed MRI scanner in the Durham/Caswell multicounty MRI service area.

On page 418, the 2020 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service Area as defined in Chapter 5, and shown in Figure 5.1.*” Thus, the service area for this facility consists of the multicounty service area of Durham/Caswell counties. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 46, the applicant identifies the providers of MRI services within the Durham/Caswell multicounty MRI service area. In addition to Duke University Hospital (main campus and off-campus locations) [11 MRI scanners] and Duke Regional Hospital [2 MRI scanners] fixed MRI services are also provided by Emerge Ortho [2 MRI scanners] and Durham Diagnostic Imaging- Independence Park [1 MRI scanner].

In Section G, page 47, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Durham/Caswell multicounty MRI service area. The applicant states:

*“The state planning process embodied in the 2020 SMFP determined that the service area needs an incremental fixed MRI scanner, supporting the conclusion that the incremental*

*MRI scanner will not unnecessarily duplicate any existing or approved facilities. ... Moreover, DUHS has carefully evaluated the locations of the existing and approved fixed MRI scanners as well as projected population growth to determine the site that will best increase access for patients for this needed service. In this instance, the population in southern Durham and surrounding areas is growing quickly and the need for convenient imaging services is growing with it...*

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

- There is a need determination in the 2020 SMFP for the proposed fixed MRI Scanner.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

**C**

In Section Q, Form H, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff- MRI		
	1 <sup>st</sup> Full Fiscal Year (1/1/22-12/31/22)	2nd Full Fiscal Year (1/1/23- 12/31/23)	3 <sup>rd</sup> Full Fiscal Year (1/1/24 to 12/31/24)
Radiology Technologists	4.48	4.48	4.48
<b>TOTAL</b>	<b>4.48</b>	<b>4.48</b>	<b>4.48</b>

Source: Section Q, Form H.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 48-49, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In supplemental information, the applicant states



that the proposed medical director from the original application (Project ID#J-11718-19) is still designated as the proposed medical director.

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

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

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

### C

In Project I.D. #J-11718-19, the applicant was found conforming to this Criterion. The applicant proposes no changes in the current COS application that would affect that determination.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

### NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The

availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

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

C

In Project I.D. # J-11718-19, the application was found conforming to this criterion. In supplemental information, the applicant states that there are no changes proposed in this COS application except an updated line drawing to show the upfitted space to accommodate the second MRI scanner. The updated line drawing is provided in Exhibit K.2.

- (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

In Project I.D. #J-11718-19, the applicant was found conforming to this Criterion. The applicant proposes no changes in the current COS application that would affect that determination.

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 59-60, the applicant states that it has no obligations for uncompensated care or community services, or access by minorities and handicapped persons but that DUHS provides services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor.

In Section L.2, pages 60-61, the applicant states that during the last five years six patient civil rights access complaints have been filed against DUHS. The applicant reports that three have been closed without further investigation, one was voluntarily dismissed, and two complaints are pending.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Project I.D. #J-11718-19, the application was conforming to this criterion.

In Section L, page 62, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	MRI Services as Percent of Total
Self-Pay	1.2%
Charity Care	2.0%
Medicare*	37.5%
Medicaid*	5.9%
Insurance*	50.4%
Workers Compensation	0.4%
TRICARE	0.8%
Other (commercial, other government payors)	1.8%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 62 of the application.

\*Includes any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.2% of MRI services will be provided to self-pay patients, 2.0% to charity care patients 37.5% to Medicare patients and 5.9% to Medicaid patients.

On pages 62, the applicant provides the assumptions and methodology used to project payor mix for MRI services during the second full fiscal year of operation following completion of the project. The projected payor mix for MRI services is reasonable and adequately supported because it is based on *“For MRI services, as a baseline for its future projections, DUHS calculated the payor mix for the non-emergent outpatient MRI procedures provided to patients from the identified zip codes in the primary service area during the first 8 months of FY20 (YTD until COVID-19 based restrictions temporarily affected care patterns). Based on input from DUHS Corporate Finance, the projections include an anticipated shift of 3.8% of private insurance patients to Medicare per year for FY 2021 and FY 2022 to reflect the aging of the population and resulting utilization patterns of MRI services.”*

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

In Project I.D. #J-11718-19, the applicant was found conforming to this Criterion. The applicant proposes no changes in the current COS application that would affect that determination.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Project I.D. #J-11718-19, the applicant was found conforming to this Criterion. The applicant proposes no changes in the current COS application that would affect that determination.

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

C

DUHS proposes a COS for the approved, but undeveloped, Duke-Arrington project (Project I.D. #J-11718-19) which authorized the development of a new diagnostic center with CT, mammography, ultrasound, X-ray and DEXA equipment and replacement and relocation of one existing MRI scanner from Page Road. In the current COS application, DUHS proposes to add a second MRI scanner to the Duke-Arrington project pursuant to a need determination in the 2020 SMFP for one fixed MRI scanner in the Durham/Caswell multicounty MRI service area.

On page 418, the 2020 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service Area as defined in Chapter 5, and shown in Figure 5.1.*” Thus, the service area for this facility consists of the multicounty service area of Durham/Caswell counties. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 46, the applicant identifies the providers of MRI services within the Durham/Caswell multicounty MRI service area. In addition to Duke University Hospital (main campus and off-campus locations) [11 MRI scanners] and Duke Regional Hospital [2 MRI scanners] fixed MRI services are also provided by Emerge Ortho [2 MRI scanners] and Durham Diagnostic Imaging- Independence Park [1 MRI scanner].

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 65, the applicant states:

*“This project will benefit competition by creating additional capacity for outpatient/non-hospital based MRI services in southern Durham County, increasing choice for patients and providers.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 65, the applicant states:

*“The proposed IDTF structure typically has lower reimbursement than hospital facilities and is more cost-effective for many payors and patients depending on their plan terms. Operating 2 MRI scanners in the same convenient location reduces overhead and operating expenses by allowing for shared staffing and other overhead.”*

Regarding the impact of the proposal on quality, in Section N, page 65, the applicant states:

*“DUHS is committed to delivering high-quality care at all of its facilities, and will continue to maintain the highest standards and quality of care, consistent with the standards that DUHS has sustained throughout its illustrious history of providing patient care.”*

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 65, the applicant states:

*“...DUHS will continue to have a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved. ... With the recent expansion of Medicaid reimbursement for IDTF services, this will provide an attractive option for Medicaid patients as well as other underserved groups.”*

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

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

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information provided by the applicant (if applicable)
- Information which was publicly available during the review and used by the Agency

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

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

C

In Section Q, Form A, in addition to Duke Health Arrington Radiology the applicant identifies Duke Health Heritage Radiology, Duke Imaging Services at Cary Parkway and Duke Health Holly Springs Radiology as diagnostic centers that are owned or managed by DUHS

In Section O.3, page 68, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred at and DUHS facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at the DUHS facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

The application is conforming with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700. The specific criteria 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-** The applicant does not propose to acquire a mobile MRI scanner. Therefore, this rule is not applicable to this review.

- (b) *An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:*
- (1) *demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;*

**-C-** The MRI service area is the multicounty service area of Durham/Caswell counties. In Section C, pages 31, the applicant states that it owns and operates thirteen fixed MRI scanners in Durham/Caswell counties; 11 MRI scanners at DUH Hospital and 2 MRI scanners at Duke Regional Hospital. During the most recent 12-month period for which DUHS has data (June 2019 to May 2020) DUHS performed 66,460.2 weighted MRI procedures for an average of 5,112 ( $66,460.2 / 13 = 5,112$ ) which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.

- (2) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];*



**-NA-** The MRI service area is the multicounty service area of Durham/Caswell counties. The applicant states that neither the applicant or a related entity owns a controlling interest in an existing mobile MRI scanner in the multicounty service area of Durham/Caswell counties.

(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 2020 SMFP shows that there are more than four (4) fixed MRI scanners located in the Durham/Caswell multicounty service area. Therefore, DUHS 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 the Durham/Caswell multicounty service area will be at least 4,805 weighted MRI procedures in the third operating year.

**-C-** In Section Q and Form C, the applicant identifies a total of fourteen existing or proposed fixed MRI scanners in the Durham/Caswell multicounty service area. In Section Q, DUHS projects weighted MRI volume of 75,054 scans in the third year of operation (FY2025) or 5,361 MRI scans per MRI scanner [ $75,054/14 = 5,361$ ] which exceeds the required average of 4,805 weighted MRI procedures per scanner in this performance standard. The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.

(4) *if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*

- (A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
- (B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
- (C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
- (D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*

(E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

**-C-** The proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or related entity. Therefore, pursuant to the rule, the applicant must demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform 4,805 weighted MRI procedures in the third year of operation following completion of the proposed project. The third of operation following completion of the proposed project is FY2025 (7/1/2024 to 6/30/2025). In Section Q, the applicant projects that the proposed MRI scanner will perform 5,223 weighted MRI procedures in the third year of operation, which is greater than the 4,805 weighted MRI procedures required by the Rule.

(5) *demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and*

**-NA-** The applicant states that neither the applicant or a related entity owns a controlling interest in an existing, approved or proposed mobile MRI scanner in the multicounty service area of Durham/Caswell counties.

(6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

**-C-** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q.

(c) *An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*

(1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure per hour times 40 hours per week times 52 weeks per year; and*

(2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

**-NA-** The applicant does not propose to acquire a dedicated fixed breast MRI scanner. Therefore, this Rule is not applicable to this review.

(d) *An applicant proposing to acquire a fixed extremity MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*

- (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(f)(7); and*
- (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

**-NA-** The applicant does not propose to acquire a dedicated fixed extremity MRI scanner. Therefore, this Rule is not applicable to this review.

(e) *An applicant proposing to acquire a fixed multi-position MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for a demonstration project shall:*

- (1) *demonstrate annual utilization of the proposed multi-position MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(g)(7); and*
- (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

**-NA-** The applicant does not propose to acquire a dedicated fixed multi-position MRI scanner. Therefore, this Rule is not applicable to this review.