### REQUIRED STATE AGENCY FINDINGS

**FINDINGS** 

C = Conforming

CA = Conforming as Conditioned NC = Nonconforming

NA = Not Applicable

Decision Date: September 20, 2024 Findings Date: September 20, 2024

Project Analyst: Cynthia Bradford Co-Signer: Mike McKillip

#### **COMPETITIVE REVIEW**

Project ID #: J-12504-24

Facility: Raleigh Radiology Clayton

FID #: 240314 County: Johnston

Applicant: RR WM Imaging Clayton, LLC

Project: Acquire a fixed MRI scanner pursuant to the 2024 SMFP need determination

Project ID #: J-12507-24

Facility: Johnston Imaging

FID #: 240316 County: Johnston

Applicant: Johnston Imaging, LLC

Project: Acquire a fixed MRI scanner pursuant to the 2024 SMFP need determination

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

### **REVIEW CRITERIA**

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

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

### **Need Determination**

The 2024 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for an additional fixed MRI scanner in North Carolina by service area. Application of the need methodology in the 2024 SMFP identified a need for one fixed MRI scanner in the Johnston County fixed MRI scanner service area. Two applications were received by the Healthcare Planning and Certificate of Need Section (CON Section), each proposing to acquire one fixed MRI scanner, for a total of two fixed MRI scanners. However, pursuant to the need determination, only one fixed MRI scanner may be approved in this review.

### **Policies**

There is one policy in Chapter 4 of the 2024 SMFP is applicable to both applications: *Policy GEN-3: Basic Principles*.

There is a second policy only applicable to application Project ID# J-12507-24: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

### **Policy GEN-3**

Policy GEN-3 on page 29 of the 2024 SMFP states:

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

Policy GEN-4 on page 30 of the 2024 SMFP states:

"Any person proposing a capital expenditure greater than \$4 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."

# J-12504-24 / Raleigh Radiology Clayton/ Acquire one fixed MRI scanner

RR WM Imaging Clayton, LLC, hereinafter referred to as "the applicant", or Raleigh Radiology Clayton, proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at an existing diagnostic center, Raleigh Radiology Clayton in Clayton.

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

*Policy GEN-3*. In Section B, pages 27-30, the applicant provides information to show its application is conforming to Policy GEN-3.

#### Conclusion

The Agency reviewed the:

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

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

- The applicant does not propose to develop 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 for the following reasons:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in the service area.
  - The applicant adequately documents how the project will promote equitable access to MRI services in the service area; and

• The applicant adequately documents how the project will maximize healthcare value for the resources expended.

# J-12507-24 / Johnston Imaging / Acquire one fixed MRI scanner

Johnston Imaging, LLC., hereinafter referred to as "the applicant", or Johnston Imaging, proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at a new diagnostic center, Johnston Imaging, in Smithfield.

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

*Policy GEN-3*. In Section B, pages 26-30, the applicant the applicant provides information to show its application is conforming to Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is greater that \$4 million. In Section B, page 31, the applicant describes the project's plan to assure improved energy efficiency and water conservation. The applicant states it will ensure the facility and the proposed fixed MRI service will be designed and developed in compliance with all applicable federal, state and local building codes and requirements for energy efficiency and consumption.

## **Conclusion**

The Agency reviewed the:

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

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

- The applicant does not propose to develop 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 for the following reasons:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in the service area;
  - The applicant adequately documents how the project will promote equitable access to MRI services in the service area; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

- The applicant adequately demonstrates that the application is consistent with Policy GEN-4 and includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, persons with disabilities, the elderly, and other underserved groups are likely to have access to the services proposed.

C Both Applications

# J-12504-24 / Raleigh Radiology Clayton / Acquire one fixed MRI scanner

Raleigh Radiology Clayton proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP.

### **Patient Origin**

On page 335, the 2024 SMFP defines the fixed MRI service area as "... the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1." Therefore, for the purpose of this review, the fixed MRI service area is Johnston County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 41, the applicant states it does not currently own or operate any fixed MRI scanners in Johnston County.

The applicant states on page 41 that it currently provides mobile MRI services through a third-party vendor at the Clayton location and provides historical patient origin for the mobile MRI services. The following table from page 41 illustrates historical patient origin for existing mobile MRI services at Raleigh Radiology Clayton for the last full fiscal year (FY), calendar year (CY) 2023:

Raleigh Radiology Clayton Mobile MRI Services
Historical Patient Origin – CY 2023

| ZIP CODE/CITY                | CY 2023 |            |  |
|------------------------------|---------|------------|--|
|                              | # PTS.  | % OF TOTAL |  |
| Johnston                     | 1,220   | 66.0%      |  |
| Other States and NC Counties | 808     | 34.0%      |  |
| Total                        | 2,028   | 100.0%     |  |

The following tables from page 44 illustrate projected patient origin for the proposed fixed MRI services and for all imaging services, respectively, at Raleigh Radiology Clayton for the first three full FY 2026-2028:

| Raleigh Radiology Clayton Projected Patient Origin |  |              |       |        |           |        |
|--|--|--------------|-------|--------|-----------|--------|
|  | Fixed I  | MRI Services |       | ,      |           |        |
| County   | 1 <sup>ST</sup> FULL FY (CY 2026) 2 <sup>ND</sup> FULL FY (CY 2027) 3 <sup>RD</sup> FULL FY (CY 20 |              |       |        | (CY 2028) |        |
|  | # PTS. % OF TOTAL # PTS. % OF TOTAL # PTS. % OF TO   |              |       |        |           |        |
| Johnston County                                    | 2,399  | 90.0%        | 3,213 | 90.0%  | 3,864     | 90.0%  |
| Other^   | 267  | 10.0%        | 357   | 10.0%  | 429       | 10.0%  |
| Total  | 2,666  | 100.0%       | 3,571 | 100.0% | 4,293     | 100.0% |

Percentages may not sum due to rounding.

In Section C, page 43 and in Section Q, the applicant states projected patient origin for the proposed fixed MRI services are based on Raleigh Radiology's historical experience providing mobile MRI services. The applicant's assumptions are reasonable and adequately supported because they are based on the applicant's historical experience providing mobile MRI services and the applicant's projected utilization methodology is Section Q, pages 134-145.

### **Analysis of Need**

In Section C.4, pages 45-67, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- There is a need in the 2024 SMFP for one fixed MRI scanner in the Johnston County fixed MRI scanner service area. See application pages 47-48.
- There is increasing demand for MRI services at Raleigh Radiology Clayton, despite the availability of mobile MRI services at that location. See application page 49.
- The location and availability of MRI scanners in Johnston County indicates a need for MRI competition in the Johnston County area. Utilizing data from the 2024 SMFP, the applicant identified that none of the fixed MRI scanners in Johnston County is located in a freestanding outpatient clinic. The applicant states that Johnston County has quantitative need for another MRI and needs a new provider who will offer freestanding outpatient MRI value-based fee schedule to keep the cost of services under control. See application pages 49-50.
- Population growth and aging in Johnston County The applicant examined Claritas data that shows the Johnston County population as a whole is projected to increase from 2024-2028, and the ZIP codes projected to be served by Raleigh Radiology Clayton are projected to expected to add approximately 27,108 residents between 2024 and 2028. The Claritas data utilized by the applicant also shows the 65 + population in the ZIP codes in the applicant's primary service area will grow by 7,500 residents which comprises approximately 28% of total estimated population growth in these ZIP codes by 2028, thereby indicating a need for additional MRI services in the area. Older population groups are more likely to need MRI services than younger cohorts. See application pages 51-55.

<sup>^ &</sup>quot;Other" includes all other NC counties and other states.

- Increasing MRI use rates in the state as a whole have increased steadily since FY 2018-2022, which indicates a need for additional MRI services. The applicant states that MRI imaging is ideal for imaging all types of tissue, is non-invasive and emits no radiation, making it an increasingly desirable imaging tool for physicians. See the table that illustrates the data on application on pages 55-57.
- Community access to MRI services in Johnston County The applicant states cost concerns; Johnston County traffic congestion issues combine to make the Raleigh Radiology Clayton location an accessible choice for providing MRI services to the community. See application pages 57-59.
- Medicaid beneficiaries in Johnston County The applicant states Medicaid beneficiaries are more prevalent in Johnston than Wake County. Therefore, a new MRI scanner should provide access accommodations for Medicaid beneficiaries. See application page 60.
- Referring provider interest In Exhibit I.2, referring providers have expressed an interest in referring more than 10,000 annual MRI scans to Raleigh Radiology Clayton. See application page 60.
- Social determinants of health that affect the increasing need for MRI services in the Raleigh Radiology Clayton service area, such as disease incidence, obesity, poverty, and low education levels are prevalent in the county and are factors that contribute to the overall health risk status of a community. The applicant cites data that shows the risk factors for poorer overall health are higher in the proposed service area than in the county as a whole. The availability of additional MRI services in the service area will help diagnose and treat health conditions the service area is likely to experience, such as heart disease, cancer, liver disease and musculoskeletal problems. See application pages 60-66.

The information is reasonable and adequately supported for the following reasons:

- The 2024 SMFP identifies the need for one additional fixed MRI scanner in the Johnston fixed MRI scanner service area.
- The applicant provides information and data to support its assertions regarding service area population growth and aging, as well as disease risk factors and the relative lack of MRI services in the service area.

#### **Projected Utilization**

In Section Q, Form C.2b, the applicant provides projected utilization of the proposed fixed MRI scanner, as illustrated in the following table:

**Projected MRI Utilization, First Three Project Years** 

|                         | Partial FY<br>10/1/25-12/31/25 | 1 <sup>st</sup> Full FY<br>CY 2026 | 2 <sup>ND</sup> FULL FY<br>CY 2027 | 3 <sup>RD</sup> FULL FY<br>CY 2028 |
|-------------------------|--------------------------------|------------------------------------|------------------------------------|------------------------------------|
| Number of Units         | 1                              | 1                                  | 1                                  | 1                                  |
| MRI Procedures          | 529                            | 3,647                              | 4,884                              | 5,873                              |
| Adjusted MRI Procedures | 563                            | 3,881                              | 5,198                              | 6,250                              |

The applicant projects the proposed fixed MRI scanner will perform more than 6,250 adjusted MRI procedures in the third full fiscal year of operation following the completion of the proposed project, which exceeds the utilization thresholds required in 10A NCAC 14C .2703(a)(7)(a).

In Section Q, pages 134-145, the applicant provides the assumptions and methodology used to project utilization for the proposed fixed MRI scanner, as summarized below:

- **Step 1: Determine Johnston County Service Area Population**—The 2024 SMFP defines the service area as Johnston County. The population is served by only two fixed MRI scanners, both of which are hospital-based. The applicant states 90.6 percent of all scans done in Johnston County were outpatient, as shown in Exhibit G.1. Furthermore, NCDHSR reported patient origin for FY2022 shows that 4,503 Johnston County residents received MRI services outside Johnston County (Exhibit C.4). The table in Section Q, page 135, shows the Raleigh Radiology Clayton MRI Service Area Population, Johnston County, CY2024-CY2028.
- Step 2: Estimate Statewide MRI Scan Use Rate per 1,000 Population—Utilizing data from the North Carolina Office of State Budget and Management (NCOSBM) and the 2020-2024 SMFPs, the applicant calculated a statewide MRI use rate of 95.47 procedures per 1,000 population. The applicant states MRI utilization increased each year, notwithstanding the anomalous time during the COVID-19 pandemic when use rates were lower. The applicant used five-year state-wide MRI use rate based on the increase in MRI utilization and the high growth of older population cohorts in Johnston County. The table in Section Q, page 136, shows the average MRI scanner use rates per 1,000 population.
- **Step 3: Determine Need for MRI Procedures by Johnston County Residents** The applicant multiplied the annual Johnston County population from Step 1 by the calculated FY22 statewide MRI use rate in Step 2, to forecast MRI procedure need for Johnston County residents for the years 2024-2028.
- **Step 4: Estimate the Average State MRI Adjustment Factor**—Relying on Tables 17E-1 and 15E-1 in the 2024 SMFP, the applicant examined MRI utilization of unadjusted and adjusted MRI scans in the state and calculated a weighting ratio of 1.21 based on that data. Section Q, Table 4, page 138 illustrates those calculations.
- Step 5: Determine Adjusted MRI Procedures Needed by Johnston County Residents The applicant multiplied the unadjusted procedures in Step 3 by the weighting factor in Step 4 to calculate adjusted MRI procedures by year. Table 5, page 138, illustrates the adjusted MRI procedures needed by Johnston County residents for 2024-2028.

- Step 6: Determine Market Share and Unadjusted MRI Utilization— The applicant states that Raleigh Radiology Clayton market share of scans needed by Johnston County residents was approximately 5.1% in 2023. The applicant states that the proposed fixed MRI scanner will become operational in October 2025. October through December represents three months or 25 percent of operation on the new fixed MRI scanner and 75 percent on the mobile MRI scanner. The applicant projects their market share to grow to 5.3% prior to the proposed fixed MRI scanner becoming operational in October 2025. The applicant projects that once the proposed fixed MRI scanner is operation, market share growth will increase to 7.3% before the end of CY 2025. The applicant projects that their market share for MRI services will increase to 20% by the end of the third operating year of the project. Section Q, Table 6, page 140 illustrates these calculations.
- Step 7: Determine In-migration to Raleigh Radiology Clayton The applicant assumes that some MRI procedures at Raleigh Radiology Clayton will originate from outside Johnston County. Because place of origin for this "in-migration" cohort changes from year to year, the applicant assumes that this group will originate from all other North Carolina counties and out of state. The applicant states that the percentage of in-migration patients decreased over the last four years. The applicant estimates that estimates that 10 percent of MRI procedures at Raleigh Radiology Clayton will be for with non-Johnston County residents. Section Q, Table 8, page 142 illustrates that data.
- Step 8: Determine Adjusted MRI Procedures Using Weighting Factors— To calculate the adjusted scans, the applicant first estimated the distribution of scan types. The proposed new MRI Scanner will have technical capabilities that are the same as or better than capabilities available at other Raleigh Radiology locations in 2023. The same radiologists will read and interpret MRI scans for all Raleigh Radiology locations. The proposed new fixed scanner will operate similar to those at existing Raleigh Radiology locations. The applicant uses total MRI scan history for all Raleigh Radiology locations to determine the average distribution of scan types. The 2024 SMFP provides for two MRI outpatient scan types; "base" and "complex." The applicant assumed distribution of base and complex scans will remain constant at Raleigh Radiology locations' four-year average (2020-2023) through 2028. See the tables that illustrate the calculations on page 143 of the application.
- Step 9: Forecast Adjusted MRI Scans at Raleigh Radiology Clayton, CY24 CY28 The applicant calculated annual adjusted MRI Procedures at Raleigh Radiology Clayton by multiplying the total annual unadjusted scans from Step 7 by the four-year average percent distribution of scan types from Step 8, then multiplying that product by the weighting factor from the 2024 SMFP (page 337). Section Q, Table 10, page 144 illustrates those calculations.
- Step 10: Calculate Patient Origin The applicant divided the number of unadjusted scans from Step 7, by the average Raleigh Radiology scans per patient for the years CY20 through CY23, which was 1.37. Section Q, Table 11, page 145 illustrates those calculations.

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

- The applicant's projections are based on population projections for the proposed service area from the NCOSBM, statewide MRI use rates, and statewide ratios of adjusted to unadjusted MRI procedure from data in the State Medical Facilities Plan for 2020 to 2024.
- The applicant's projections of adjusted MRI procedures for the proposed fixed MRI scanner are calculated based on the applicant's historical experience at its existing locations with regard to the types of outpatient MRI scans to be provided.
- The applicant provides letters of support from referring physicians in Exhibit I.2 of the application.

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

In Section C, page 72, the applicant states:

"(The applicant) serves Medicare and Medicaid beneficiaries through certification of the Raleigh Radiology physician's CMS NPI participation. With this relationship, the proposed MRI will have approval to provide services to Medicare, Medicaid, TriCare military, Veterans Administration beneficiaries, and people covered by Workers Compensation programs."

The applicant provides additional information regarding service to medically underserved groups on pages 72-74. On page 75, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

Raleigh Radiology Clayton Estimated Percentages

| Raicign Radiology clayton Estimated i creentages |  |  |  |  |  |
|--|--|--|--|--|--|
| PAYOR GROUP                                      | ESTIMATED PERCENTAGE                   |  |  |  |  |
|  | OF PATIENTS IN 3 <sup>RD</sup> FULL FY |  |  |  |  |
| Low Income Persons                               | 10.0%                                  |  |  |  |  |
| Racial and Ethnic Minorities                     | 38.4%                                  |  |  |  |  |
| Women  | 51.1%                                  |  |  |  |  |
| Persons with Disabilities                        | 9.1%                                   |  |  |  |  |
| Persons 65 and Older                             | 38.4%                                  |  |  |  |  |
| Medicare Beneficiaries                           | 28.4%                                  |  |  |  |  |
| Medicaid Beneficiaries                           | 8.0%                                   |  |  |  |  |

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant has historically provided access to its mobile MRI services to underserved groups.
- The applicant states that all patients will continue to receive equitable access to MRI services.

## Conclusion

The Agency reviewed the:

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

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

# J-12507-24 / Johnston Imaging/ Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at a new diagnostic center, Johnston Imaging, in Smithfield.

#### **Patient Origin**

On page 335, the 2024 SMFP defines the fixed MRI service area as "... the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1." Therefore, for the purpose of this review, the fixed MRI service area is Johnston County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 35, the applicant states the proposed diagnostic center is under development and thus has no historical patient origin. UNC Health Johnston currently owns and operates two hospital-based fixed MRI scanners at UNC Johnston Health-Smithfield, and UNC Johnston Health Clayton. The applicant provides historical patient origin for its existing MRI services for most recent fiscal year (2023), as shown in the following table:

| UNC HEALTH JOHNSTON |  |               |  |  |  |  |
|---------------------|--|---------------|--|--|--|--|
| HISTOR              | HISTORICAL PATIENT ORIGIN - MRI SERVICES |               |  |  |  |  |
|                     | LAST                                     | FULL FY       |  |  |  |  |
| ZIP CODE/COUNTY     | 07/01/2022                               | то 06/30/2023 |  |  |  |  |
|                     | PATIENTS                                 | % OF TOTAL    |  |  |  |  |
| Johnston            | 4,800                                    | 78.1%         |  |  |  |  |
| Wake                | 412                                      | 6.7%          |  |  |  |  |
| Wayne               | 277                                      | 4.5%          |  |  |  |  |
| Harnett             | 215                                      | 3.5%          |  |  |  |  |
| Sampson             | 160                                      | 2.6%          |  |  |  |  |
| Other*              | 283                                      | 4.6%          |  |  |  |  |
| Total               | 6,146                                    | 100.0%        |  |  |  |  |

<sup>\*</sup>Other Includes Bladen, Brunswick, Buncombe, Chatham, Craven, Cumberland, Duplin, Edgecombe, Franklin, Greene, Hoke, Jackson, Johnson, Jones, Lee, Lenoir, Nash, New Hanover, Onslow, Pamlico, Pasquotank, Pender, Pitt, Raleigh, Robeson, Wake, Warren, Watauga, and Wilson counties in NC as well as other states.

In Section C, page 37, the applicant provides projected patient origin for the first three project years, FYs 2028-2030, for the proposed fixed MRI services, as summarized below:

| Johnston Imaging MRI Services<br>Projected Patient Origin by County |          |  |                   |          |            |        |  |
|---|----------|--|-------------------|----------|------------|--------|--|
| ZIP CODE/COUNTY   |          | 1 <sup>ST</sup> FULL FY 2ND FULL FY 3 <sup>RD</sup> FULL FY 07/01/2027-06/30/2028 07/01/2028-06/30/2029 07/01/2029-06/30/30/2029 |                   |          |            |        |  |
|   | PATIENTS | % OF TOTAL   | PATIENTS          | PATIENTS | % OF TOTAL |        |  |
| Johnston  | 3,062    | 85.6%  | 3,495             | 85.6%    | 3,588      | 85.6%  |  |
| Wayne   | 140      | 3.9%   | 159               | 3.9%     | 163        | 3.9%   |  |
| Harnett   | 118      | 3.3%   | 135               | 3.3%     | 138        | 3.3%   |  |
| Sampson   | 100      | 2.8%   | 114               | 2.8%     | 117        | 2.8%   |  |
| Other*  | 157      | 4.4%   | 4.4% 180 4.4% 185 |          |            |        |  |
| Total   | 3,577    | 100.0%   | 4,083             | 100.0%   | 4,191      | 100.0% |  |

<sup>\*</sup>Other Includes Bladen, Brunswick, Buncombe, Chatham, Craven, Cumberland, Duplin, Edgecombe, Franklin, Greene, Hoke, Jackson, Johnson, Jones, Lee, Lenoir, Nash, New Hanover, Onslow, Pamlico, Pasquotank, Pender, Pitt, Raleigh, Robeson, Wake, Warren, Watauga, and Wilson counties in NC as well as other states.

In Section C, page 37, and in Section Q, Form C, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on the applicant's historical patient origin for MRI services at UNC Health Johnston-Smithfield.

## **Analysis of Need**

In Section C, pages 38-50, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Need identified in the 2024 SMFP for a fixed MRI scanner in Johnston County. See application pages 39-40.
- Growth and Aging of the Johnston County Population According to data from the North Carolina Office of State Budget and Management (NC OSBM), Johnston County's population was the second fastest-growing by percentage from 2014 to 2024. Johnston County's population grew by nearly 70,000 residents and increased nearly 38 percent. This growth rate was over three times higher than for the state of North Carolina during the same period. Johnston County's population aged 65 and older is also projected to grow 25.5 percent from 2024 to 2029, the fifth-highest rate for all North Carolina counties over that period. See application pages 40-43.
- Need for Additional Fixed MRI Capacity in Johnston County The applicant states that in Johnston County, the fixed MRI unit at UNC Health Johnston Smithfield Campus performed the highest number of total adjusted MRI scans in FFY 2022. The applicant states UNC Health Johnston's two fixed MRIs at the Smithfield and Clayton campuses continue to experience steady growth. The total number of adjusted scans performed at the Smithfield Campus increased by 617 adjusted scans from FFY 2019 to FFY 2022, representing a CAGR of 5.0 percent. See application pages 44-45.

- Need for Freestanding Fixed MRI Scanner in Johnston County The applicant states the two existing fixed MRI scanners in Johnston County are both hospital-based. The freestanding fixed MRI will offer significant cost savings to patients via lower copayments and coinsurance charges. The applicant states the proposed MRI scanner will address the gap in non-hospital based fixed MRI scanners available in Johnston County and will provide a lower cost, convenient option for fixed MRI services closer to home for many patients. See application pages 45-46.
- Need for Specialized MRI Imaging Capabilities in Johnston County The growing prevalence of breast cancer in Johnston County increases the need for diagnostic resources such as breast MRI to detect new cases at an earlier stage of development and allow patients to not require aggressive treatment. The applicant states the proposed MRI unit at Johnston Imaging will include a breast coil for detection of non-benign tumors, giving oncologists another tool for detecting and fighting cancer in Johnston County. See application page 47.
- Need to Develop Additional MRI Scanner in Smithfield The applicant states that four of the county's six total MRI sites are located in Clayton, in the northern part of Johnston County. The remaining two MRI sites are in Smithfield. The applicant states that Clayton also has access to MRI services just over the Wake County border in Garner, thereby granting Clayton access to six MRI scanning facilities, whereas Smithfield has only two. See application pages 47-49.

#### **Projected Utilization**

In Section Q, Form C.2b, page 110, the applicant provides projected utilization for the first three project years, FYs 2028-2030 (07/1-06/30), as illustrated in the following table:

| Johnston Imaging Projected Utilization-Fixed MRI Scanner |   |         |         |  |  |  |
|--|---|---------|---------|--|--|--|
|  | 1 <sup>ST</sup> FULL FY 2 <sup>ND</sup> FULL FY 3 <sup>RD</sup> FULL FY |         |         |  |  |  |
|  | FY 2028   | FY 2029 | FY 2030 |  |  |  |
| Number of Units  | 1   | 1       | 1       |  |  |  |
| MRI Procedures   | 3,577   | 4,083   | 4,191   |  |  |  |
| Adjusted MRI Procedures                                  | 1,409   | 3,911   | 4,583   |  |  |  |

In Section Q, Form C.2b, pages 107 and 109, the applicant also provides projected utilization for their other MRI service facilities, as illustrated in the following table:

| UNC Health Johnston MRI Services Projected Utilization       |  |       |       |  |  |  |
|--|--|-------|-------|--|--|--|
|  | 1 <sup>ST</sup> FULL FY 2 <sup>ND</sup> FULL FY 3 <sup>RD</sup> FU |       |       |  |  |  |
| FY 2028 FY 2029 FY 2030 UNC Health Johnston – Clayton Campus |  |       |       |  |  |  |
| Number of Units  | 1  | 1     | 1     |  |  |  |
| MRI Procedures   | 2,880  | 2,820 | 2,914 |  |  |  |
| Adjusted MRI Procedures                                      | 3,401  | 3,459 | 3,575 |  |  |  |
| UNC Health Johnston – Smithfield Campus                      |  |       |       |  |  |  |
| Number of Units  | 1  | 1     | 1     |  |  |  |
| MRI Procedures   | 1,952  | 1,750 | 1,809 |  |  |  |
| Adjusted MRI Procedures                                      | 3,007  | 2,816 | 2,911 |  |  |  |

The applicant projects that each of its existing and proposed fixed MRI scanners a will perform more than 3,494 adjusted MRI procedures in the third full fiscal year of operation following the project completion, as required by 10A NCAC 14C .2703(a)(7)(a).

In Section Q, "Form C Utilization – Assumptions and Methodology", pages 111-124, the applicant provides the assumptions and methodology used to project utilization for the proposed fixed MRI, as summarized below:

**Step 1**: Population Growth in Johnston County - According to NC Office of State Budget and Management (OSBM) data, the population of Johnston County increased at an average annual rate of 3.3 percent between FY 2019 and FY 2023. This high historical growth is expected to moderate from FY 2024 to FY 2031, coinciding with the third year for Johnston Imaging's proposed project. Johnston County population is projected to increase by 2.4 percent annually over this period.

Step 2: <u>Historical MRI Utilization in Johnston County</u> – The applicant compared the growth in Johnston County's population to the growth in MRI utilization at Johnston County facilities. According to SMFP data, the number of adjusted MRI scans performed on MRI scanners located in Johnston County increased 6.3 percent annually between FFY 2019 and FFY 2022. Since the historical growth rate is higher than population growth, this MRI utilization is reflective of not only population growth in Johnston County, but also an increase in the number of patients seeking MRI services in Johnston County as MRI capacity has increased. However, the data has shown that the number of Johnston County residents receiving an MRI scan in their home county has declined, while the overall number of adjusted MRI scans performed at Johnston County imaging facilities has increased.

Step 3: Projected MRI Growth in Johnston County – The applicant used the growth in MRI scans performed at Johnston County facilities from FFY 2019 to FFY 2022 to project the growth in adjusted MRI scans from FFY 2023 to FFY 2030. The applicant assumed that the adjusted scans rate will continue to grow at one-half the historical CAGR ( $2.8\% \times 0.5 = 1.4\%$ ). Applying the 1.4 percent CAGR in future years results in the following estimates for total adjusted MRI scans performed by Johnston County MRI providers through FFY 2030.

Step 4: Projected MRI Utilization for Johnston Imaging – The applicant calculated the percentages of adjusted MRI scans for UNC Health Johnston and other MRI providers in comparison to the total number of scans performed at Johnston County facilities. UNC Health Johnston's two existing MRI scanners performed a total of 7,450 adjusted scans, representing 52.9 percent of all adjusted scans that were performed in FFY 2022 at Johnston County MRI facilities. This percentage of total adjusted MRI scans was held constant in future years to project the growth in MRI utilization for the UNC Health Johnston system through FY 2030, the third project year. The applicant calculates that the number of adjusted MRI scans for the third fiscal year of the project to be 10,229. The applicant then converted these numbers to a State Fiscal Year period (July – June) to coincide with the reporting period for UNC Health Johnston and ensure data alignment, which changed the total adjusted MRI scans to 10,147. The applicant then allocated the total number of adjusted scans for the UNC Health Johnston system to the two respective hospital campuses, UNC Health Johnston – Smithfield Campus (5,958 adjusted MRI scans) and UNC Health Johnston – Clayton Campus (4,189 adjusted MRI scans). The applicant assumes that the UNC Health Johnston systemwide total number of adjusted MRI scans will not change with the addition of the proposed MRI scanner. Rather, this total will be redistributed among the three UNC Health Johnston MRI facilities. The applicant believes that it is reasonable to assume that this shift will occur gradually, as patients and their physicians gain knowledge of the proposed Johnston Imaging location and become familiar with the advantages of receiving MRI imaging procedures in a freestanding setting. For this reason, the applicant has built a "ramp-up" period into the utilization model to account for this transition. The applicant expects that the ramp-up will begin at 80 percent of the estimated shift in the first year of service (FY 2027), increasing to 90 percent in FY 2028, the first full project year, and 100 percent in FY 2029 and FY 2030 as illustrated in the table below.

| Johnston Imaging Shift of Outpatient Adjusted MRI Scans |                |       |       |       |  |  |
|---|----------------|-------|-------|-------|--|--|
|   | FY27 FY28 FY29 |       |       | FY30  |  |  |
|   | Partial Year   | (PY1) | (PY2) | (PY3) |  |  |
| UNC Health Johnston – Smithfi                           | eld Campus     |       |       |       |  |  |
| Smithfield Adjusted Outpatient Scans                    | 3,437          | 3,562 | 3,686 | 3,809 |  |  |
| Maximum Shift to Johnston Imaging                       | 80%            | 80%   | 80%   | 80%   |  |  |
| Ramp-Up Factor  | 0.80           | 0.90  | 1.0   | 1.0   |  |  |
| Net Percentage Shift                                    | 64%            | 72%   | 80%   | 80%   |  |  |
| Adjusted Scans Shifted to Johnston Imaging              | 2,200          | 2,565 | 2,949 | 3,047 |  |  |
| UNC Health Johnston – Clayton Campus                    |                |       |       |       |  |  |
| Clayton Adjusted Outpatient Scans                       | 2,770          | 2,871 | 2,971 | 3,070 |  |  |
| Maximum Shift to Johnston Imaging                       | 20%            | 20%   | 20%   | 20%   |  |  |
| Ramp-Up Factor  | 0.80           | 0.90  | 1.0   | 1.0   |  |  |
| Net Percentage Shift                                    | 16%            | 18%   | 20%   | 20%   |  |  |
| Adjusted Scans Shifted to Johnston Imaging              | 443            | 517   | 594   | 614   |  |  |

Source: Section Q, Table 12, page 117

The applicant expects to draw patients from freestanding imaging facilities in Wake County that perform MRI procedures on Johnston County patients. To determine the number of Johnston County residents traveling to a freestanding fixed MRI facility in Wake County, the applicant analyzed the 2023 Patient Origin Reports for Fixed MRI Procedures, selecting the report with patient origin by facility4 to only select patients at freestanding fixed MRI facilities.

According to the data in the 2023 patient origin report, 5.0 percent of MRI procedures performed at Wake County freestanding fixed MRI scanners were for patients from Johnston County for a total of 1,065 patients. The applicant assumes that the percentage of adjusted MRI scans performed on Johnston County patients at Wake County freestanding fixed MRI facilities is the same as the percentage of Johnston County patients that receive MRI services at freestanding fixed MRI facilities in Wake County (5.0 percent). Based on the data for Wake County freestanding fixed MRI facilities, the total number of adjusted MRI scans for FY 2022 was 55,882. Using this percentage of Johnston County patients, the estimated total adjusted MRI scans performed on Johnston County patients at a Wake County freestanding fixed MRI facility was 2,794 in FFY 2022. The applicant expects to shift 33% (or 922) of these adjusted MRI scans performed at Wake County freestanding fixed MRI facilities to the proposed freestanding fixed MRI facility in Johnston County by the third year of the proposed project. After summing the shifts of existing UNC Health Johnston outpatient adjusted MRI scans from the two hospital-based fixed MRI scanners with the shift of adjusted MRI scans for Johnston County patients receiving MRI services at a Wake County freestanding fixed MRI facility, the applicant projects it will perform a total of 4,583 total adjusted MRI scans in FY 2030, the third project year. The total number of adjusted MRI scans for the first three project years is summarized in the table below.

| Johnston Imaging Adjusted MRI Scans, PY 1-3 |                |       |       |       |  |  |
|---|----------------|-------|-------|-------|--|--|
|   | FY27 FY28 FY29 |       |       |       |  |  |
|   | Partial Year   | (PY1) | (PY2) | (PY3) |  |  |
| Smithfield Campus Outpatient Shift          | 917            | 2,565 | 2,949 | 3,047 |  |  |
| Clayton Campus Outpatient Shift             | 185            | 517   | 594   | 614   |  |  |
| Wake County Shift into Johnston County      | 307            | 830   | 922   | 922   |  |  |
| Total Adjusted MRI Scans                    | 1,409          | 3,911 | 4,465 | 4,583 |  |  |

Source: Section Q, Table 16, page 121

Step 5: Projected MRI Utilization for UNC Health Johnston – The applicant projected the shift in outpatient adjusted MRI scans from each facility to the new freestanding facility, including the resulting annual volume of adjusted scans, for the first three project years. The applicant projects its fixed MRI scanners will exceed the utilization thresholds required in 10A NCAC 14C.2703(a)(7)(a) throughout the projection period, with an average utilization of 3,690 adjusted scans per fixed MRI as illustrated in the table below.

| Total UNC Health Johnston Fixed MRI Utilization |       |       |       |       |       |        |        |        |
|---|-------|-------|-------|-------|-------|--------|--------|--------|
|   | FY23  | FY24  | FY25  | FY26  | FY27^ | FY28   | FY29   | FY30   |
|   |       |       |       |       |       | (PY1)  | (PY2)  | (PY3)  |
| Smithfield Adjusted Scans                       | 4,603 | 4,751 | 4,969 | 5,176 | 4,459 | 3,007  | 2,816  | 2,911  |
| Clayton Adjusted Scans                          | 3,236 | 3,341 | 3,494 | 3,640 | 3,595 | 3,401  | 3,459  | 3,575  |
| Proposed MRI Adjusted Scans                     |       |       |       |       | 1,409 | 3,911  | 4,465  | 4,583  |
| Total Adjusted Scans                            | 7,839 | 8,092 | 8,463 | 8,816 | 9,463 | 10,319 | 10,741 | 11,069 |
| Fixed MRI Scanners                              | 2     | 2     | 2     | 2     | 3     | 3      | 3      | 3      |
| Total Adjusted Per Fixed MRI Unit               | 3,920 | 4,046 | 4,232 | 4,408 | 3,154 | 3,440  | 3,580  | 3,690  |

Source: Section Q, Table 18, page 122

<sup>^</sup> Partial operating year

**Step 6:** Projected Unadjusted MRI Procedures at Johnston Imaging – The applicant calculated the ratio of unadjusted outpatient MRI procedures to adjusted MRI procedures at UNC Health Johnston – Smithfield Campus for FY 2023, which is 2,691 total outpatient procedures in FY 2023 (1,505 base outpatient + 1,186 complex outpatient = 2,691). Using the SMFP methodology, the total adjusted outpatient procedure volume was 2,943 [(1,505 x 1.0) + (1,186 x 1.2) = 2,943]. This results in the ratio of 0.915 (2,691 ÷ 2,943 = 0.915). The Smithfield campus ratio was used because it represents the majority of adjusted scans for the proposed Johnston Imaging MRI – more than 66 percent of total adjusted scans in Project Year 3. The applicant then used to estimate the number of unadjusted procedures for the proposed Johnston Imaging MRI, which is 4,191 by PY3. Finally, the number of patients treated by the proposed scanner was calculated, with the assumption that each individual patient will average 1.0 MRI procedures performed at Johnston Imaging which places the number of total MRI patients by PY3 at 4,191.

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

- The applicant's projections are based on population projections for the proposed service area from the NCOSBM, historical MRI scanner utilization for Johnston County providers from 2022 to 2024, and historical utilization of the two existing fixed MRI scanners operated by UNC Johnston Health.
- The applicant's assumptions with regard to the ratio of adjusted to unadjusted MRI procedures are based on its historical experience at the fixed MRI scanner at UNC Health Johnston Smithfield from which the applicant expects the majority of outpatient MRI patients to shift.
- The applicant provides letters of support for the proposed project from referring physicians in Exhibit I.2 of the application.

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

In Section C, page 57, the applicant states:

"...UNC Health Johnston prohibits the exclusion of services to any patient on the patient's ability to pay, in addition to the patient's age, race, sex, creed, religion, or disability. UNC Health Johnston's commitment to treating all patients regardless of their ability to pay is evidenced by its payor mix. UNC Health Johnston has a long and proud history of serving patients who require care, regardless of their ability to pay."

The applicant provides additional information on page 57 of the application. The applicant provides an estimated percentage for each category of patients to be served at Johnston Imaging, LLC during the third full fiscal year of the project. The percentages are based upon FY 2023 patients receiving outpatient MRI services at UNC Health Johnston – Smithfield Campus. The applicant states it does not have a reasonable basis to estimate the percentage of low income and handicapped patients to be served by the project

On page 57, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

| GROUP                        | ESTIMATED PERCENTAGE OF TOTAL PATIENTS DURING THE THIRD FULL FISCAL YEAR |
|------------------------------|--|
| Low-income persons           |  |
| Racial and ethnic minorities | 25.0%  |
| Women                        | 58.9%  |
| Persons with disabilities    |  |
| Persons 65 and older         | 46.0%  |
| Medicare beneficiaries       | 51.4%  |
| Medicaid beneficiaries       | 15.4%  |

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant has historically provided access to MRI services to underserved groups in the service area.
- The applicant states patients will receive appropriate medical services regardless of ability to pay and states it has policies in place to ensure access to all services, including MRI services.
- The applicant states that all patients will continue to receive equitable access to low-cost MRI services with the approval of the proposed fixed MRI.

## Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written Comments
- Response to comments

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

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

# NA Both Applications

Neither of the applicants proposes 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.

C Both Applications

# J-12504-24 / Raleigh Radiology Clayton / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP.

In Section E, pages 84-87, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo The applicant states maintaining the status quo would fail to
  address the growing need for MRI services and improved access to reasonably priced
  MRI services in the service area. Additionally, the applicant states maintaining the
  status quo would ignore the need identified in the 2024 SMFP.
- <u>Develop the Project in a Different Area</u> The applicant states it considered developing the proposed MRI scanner in a different Johnston County location but determined the proposed Clayton location has the highest need and is ideally located near major transportation arteries in the county. The selected site meets local zoning requirements and has sufficient parking. Utilities are available at the site. Thus, locating the proposed MRI scanner elsewhere is not an effective alternative.
- <u>Acquire different equipment</u> The applicant considered acquiring a 3T MRI scanner but determined the cost of the scanner, the additional heat produced by the 3T scanner and the sound produced by the larger bore scanner do not outweigh the proven benefits of the proposed 1.5T fixed MRI scanner.
- <u>Limit the proposed MRI scanner to a single specialty</u> The applicant states that with no other freestanding fixed MRI scanner in the county, and only one new scanner available in the 2024 SMFP, it is important to ensure this limited resource will provide the most access to service area residents.
- <u>Develop the Project as Proposed</u> The applicant decided that at 1.5T MRI in Clayton would best enable Raleigh Radiology Clayton to meet the needs of the population of the target area and the need determination in the 2024 SMFP.

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

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

### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments

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

# J-12507-24 / Johnston Imaging/ Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP.

In Section E, pages 68-69, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Develop the Fixed MRI as a Hospital-Based Service The proposed location will enable Johnston Imaging to introduce a new freestanding diagnostic center in Johnston County. This is a cost-effective choice that will not only increase access and improve convenience and patient satisfaction for those seeking MRI services but will also allow patients to access other ambulatory-based health services located in the facility. The lower charge structure associated with a freestanding setting increases the affordability of these services. For these reasons, the applicant states developing the proposed project as a freestanding diagnostic center was determined to be a more effective alternative.
- Develop The Fixed MRI at a New Freestanding Location The applicant considered developing the proposed fixed MRI scanner at a different location to meet the need to provide additional fixed MRI capacity in Johnston County. However, by developing the proposed project at Johnston Medical Mall, Johnston Imaging will minimize the construction costs of the proposed fixed MRI scanner in comparison to new construction costs. Additionally, the applicant states developing the proposed MRI project at a different site would not create the benefit of patients being able to obtain other co-located ambulatory healthcare services available at the Johnston Medical Mall. Johnston Imaging would not be taking advantage of the continuity of care that can be provided by developing the project as proposed. Therefore, this would be a more costly and less effective alternative for meeting the need of the proposed project.

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Comments
- Response to comments

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

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

C Both Applications

# J-12504-24 / Raleigh Radiology Clayton / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP.

## **Capital and Working Capital Costs**

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

**Raleigh Radiology Clayton Capital Cost** 

|                         | ,,          |
|-------------------------|-------------|
| Site Costs              | \$10,000    |
| Renovation Costs        | \$625,000   |
| Architect / Engineering |             |
| Fees                    | \$100,000   |
| Medical Equipment       | \$1,822,079 |
| Furniture               | \$21,000    |
| Consultant Fees (CON    | \$50,000    |
| prep)                   |             |
| Interest during         |             |
| Construction            | \$22,601    |
| Other (Contingency)     | \$476,472   |
| Total                   | \$3,127,152 |

In Section Q, page 147, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Renovation cost is based on an estimate from a general contractor which is provided in Exhibit F.1.
- Medical equipment cost is based on vendor quote in Exhibit F.1.

In Section F, page 90, the applicant states there will be no start-up costs or working capital associated with the project because Raleigh Radiology Clayton already provides MRI services through a contract with a mobile MRI service provider.

#### **Availability of Funds**

In Section F.2, page 88, the applicant states that the capital cost will be funded as shown in the table below:

**Sources of Capital Cost Financing** 

| commence or capital coort manama |                        |  |
|----------------------------------|------------------------|--|
| Түре                             | RR WM IMAGING CLAYTON, |  |
|                                  | LLC.                   |  |
| Loans                            | \$ 3,127,152           |  |
| Total Financing                  | \$ 3,127,152           |  |

In Exhibit F-2, the applicant provides a letter dated April 10, 2024, signed by the Senior Vice President of First Citizens Bank confirming the bank's willingness to consider a loan in the amount of \$3.5 million to provide funding for the proposed capital needs of the project.

In Exhibit F-2, the applicant provides a letter dated April 10, 2024, signed by the Chief Operating Officer of Raleigh Radiology, LLC. Authorizing to commit funds up to \$3.5 million in loan proceeds from First Horizon Bank to fund the proposed capital needs of the project.

## **Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years (FY), of operation, calendar years (CY) 2026-2028. In Form F.2b, the applicant projects that

revenues will exceed operating expenses for MRI services in the second and third fiscal years following project completion, as shown in the table below:

Raleigh Radiology Clayton - MRI Scanner Services

|   | 1 <sup>ST</sup> PY | 2 <sup>ND</sup> PY | 3 <sup>RD</sup> PY |
|---|--------------------|--------------------|--------------------|
|   | CY 2026            | CY 2027            | CY 2028            |
| MRI Procedures ^                        | 3,647              | 4,884              | 5,873              |
| Total Gross Revenues (Charges)          | \$7,048,220        | \$9,439,303        | \$11,349,040       |
| Total Net Revenue                       | \$1,268,680        | \$1,699,075        | \$2,042,827        |
| Average Net Revenue per Procedure       | \$348              | \$348              | \$348              |
| Total Operating Expenses (Costs)        | \$1,305,506        | \$1,609,730        | \$1,750,923        |
| Average Operating Expense per Procedure | \$358              | \$330              | \$298              |
| Net Income                              | (\$36,827)         | \$89,344           | \$291,904          |

^Source: Section Q, Form C.2b

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 152-153. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Patient services gross revenue is based on the applicant's historical MRI payor mix at its Clayton location.
- Charity care revenue is projected at 1% of gross revenue annually based on the applicant's CY2023 historical experience operating diagnostic centers in Johnston County.
- Bad debt is represented as 3% of gross revenue annually based on the applicant's CY 2023 historical experience operating diagnostic centers in Johnston County.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments

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

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

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

# J-12507-24 / Johnston Imaging/ Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP.

# **Capital and Working Capital Costs**

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

**Johnston Imaging Capital Cost** 

| Construction/Renovation Costs | \$1,340,885 |
|-------------------------------|-------------|
| Architect / Engineering Fees  | \$310,112   |
| Medical Equipment             | \$1,888,848 |
| Non-Medical Equipment         | \$17,550    |
| Furniture                     | \$15,817    |
| Consultant Fees (CON prep)    | \$22,500    |
| Other (Contingency)           | \$442,819   |
| Total                         | \$4,038,531 |

In Section Q, page 126, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Renovation cost is based on an estimate from a general contractor which is provided in Exhibit F.1.
- Medical equipment cost is based on vendor quotations in Exhibit F.1.

In Section F.3, pages 72-74, the applicant projects start-up costs for the proposed project as \$83,445. On page 73, the applicant provides the assumptions and methodology used to project the working capital needs of the project. In Section F.3, pages 72-74, the applicant projects that start-up costs will be \$83,445 and initial operating expenses will be \$256,752 for a total working capital of \$340,197. On page 73, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant provides additional information regarding cost estimates for equipment and professional services in Exhibit F.1. The applicant adequately demonstrates that the projected working capital needs of the project are based on the following:

- The applicant identifies the types of costs included in the start-up costs.
- The applicant provides a detailed line-item breakdown of the start-up costs, including staff wages/salaries, ACR accreditation, equipment training, and contingency.

## **Availability of Funds**

In Section F.2, page 70, the applicant states that the capital cost will be funded as shown in the table below:

**Sources of Capital Cost Financing** 

| Түре                             | JOHNSTON IMAGING |
|----------------------------------|------------------|
| Cash and Cash Equivalents,       |                  |
| Accumulated Reserves, or Owner's | \$4,038,531      |
| Equity                           |                  |
| Total Financing                  | \$4,038,531      |

In Section F.3, page 73, the applicant states that the working capital will be funded as shown in the table below:

**Sources of Working Capital** 

| Түре                             | JOHNSTON IMAGING |
|----------------------------------|------------------|
| Cash and Cash Equivalents,       | \$335,132        |
| Accumulated Reserves, or Owner's |                  |
| Equity                           |                  |
| Total Financing                  | \$335,132        |

In Exhibit F.2-1, the applicant provides a letter dated April 15, 2024, signed by the UNC Health Johnston Vice President of Finance authorizing to commit accumulated reserves from the Johnston Health Services Corporation up to \$4,038,531 to fund the proposed capital needs of the project. Exhibit F.2-2 contains the most recent Johnston Health Services Corporation audited financial statements documenting the availability of the necessary funds. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital need of the proposed project.

#### **Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years (FY), of operation (2028-2030), following project completion for MRI scanner services at Johnston Imaging. In Form F.2b, the applicant projects that revenues will exceed operating expenses for MRI services for each of the first three fiscal years following project completion, as shown in the table below:

**Johnston Imaging MRI Scanner Services** 

|   | 1 <sup>ST</sup> PY | 2 <sup>ND</sup> PY | 3 <sup>RD</sup> PY |
|---|--------------------|--------------------|--------------------|
|   | FY 2028            | FY 2029            | FY 2030            |
| MRI Procedures^                         | 3,577              | 4,083              | 4,191              |
| Total Gross Revenues (Charges)          | \$9,066,560        | \$10,659,845       | \$11,270,994       |
| Total Net Revenue                       | \$1,338,060        | \$1,573,200        | \$1,663,394        |
| Average Net Revenue per Procedure       | \$374              | \$385              | \$397              |
| Total Operating Expenses (Costs)        | \$993,365          | \$1,094,060        | \$1,117,908        |
| Average Operating Expense per Procedure | \$278              | \$268              | \$267              |
| Net Income                              | \$344,695          | \$479,140          | \$545,486          |

^Source: Section Q, Form C.2b, page 110

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 129-130. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Patient services gross revenue is based on the FY 2023 payor mix of UNC Health Johnston Smithfield campus (Smithfield) outpatient MRI services.
- Projected average charge per procedure is based on expected average net revenue per procedure, inflated 3.0 percent annually.
- Bad debt is based on UNC Health Johnston FY 2023 bad debt percentage of total patient services gross revenue, applied to gross revenue.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments

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

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

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

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

 $\mathbf{C}$ 

**Both Applications** 

The 2024 SMFP defines the service area for a fixed MRI scanner as "the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county." Therefore, for the purpose of this review, the fixed MRI scanner service area is Johnston County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners currently located in the Johnston County service area, summarized from Table 15E-1, page 346 of the 2024 SMFP:

| Johnston County Fixed MRI Scanners                        |              |                |       |       |  |
|---|--------------|----------------|-------|-------|--|
| PROVIDER/OWNER # OF FIXED SERVICE TYPE TOTAL MRI ADJUSTED |              |                |       |       |  |
|   | MRI SCANNERS |                | SCANS | TOTAL |  |
| Johnston Health - Smithfield                              | 1            | Hospital Fixed | 3,556 | 4,500 |  |
| Johnston Health - Clayton                                 | 1            | Hospital Fixed | 2,399 | 2,950 |  |

Source: 2024 SMFP, Table 15E-1. Page 346

# J-12504-24 / Raleigh Radiology Clayton / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP.

In Section G, page 96, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in the Johnston County fixed MRI service area. The applicant states:

"This proposal will not result in unnecessary duplication of existing MRI services in the service area. RRWMIC does not propose to acquire or operate more fixed MRI scanners than are determined to be needed in the 2024 SMFP."

On pages 96-99, the applicant states the service area has limited fixed and mobile MRI capacity, increasing need and the proposed service area is currently underserved. The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2024 SMFP for the proposed fixed MRI scanner in the Johnston County fixed MRI scanner service area.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners in the service area.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Response to comments
- Information publicly available during the review and used by the Agency

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

# J-12507-24 / Johnston Imaging / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP.

In Section G, page 79, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in the Johnston County fixed MRI service area. On page 79 the applicant states:

"By developing the proposed scanner at the Johnston Medical Mall, Johnston Imaging will secure consistent, long-term availability of outpatient MRI services while improving access and affordability to MRI services for its patients. The proposed project will improve the quality of care, enhance the scope of services provided with the scanning capabilities of the proposed equipment, and reduce the expenses associated with offering fixed MRI services. The proposed project thus represents a unique option for MRI imaging in Johnston County that will expand the choices available to patients and will not unnecessarily duplicate any existing facilities."

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

- There is a need determination in the 2024 SMFP for the proposed fixed MRI scanner in the Johnston County fixed MRI scanner service area.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners in the service area.

#### Conclusion

The Agency reviewed the:

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

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

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

C Both Applications

# J-12504-24 / Raleigh Radiology Clayton / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP.

In Section Q Form H Staffing, the applicant provides the projected full-time equivalent (FTE) positions for the proposed fixed MRI service for the partial interim and first three full fiscal years (FY), calendar years (CY) 2025-2028 as summarized below:

Raleigh Radiology Clayton Proposed Staffing

| maiology clayton i roposca staring |  |                                    |                                    |                        |
|------------------------------------|--|------------------------------------|------------------------------------|------------------------|
| Position                           | Partial Year<br>(10/1/25-<br>12/31/25) | 1 <sup>ST</sup> FULL FY<br>CY 2026 | 2 <sup>ND</sup> FULL FY<br>CY 2027 | 3RD FULL FY<br>CY 2028 |
| Radiology Technologist             | 1.52                                   | 6.16                               | 6.25                               | 6.35                   |
| Clinical Supervisor                | 0.06                                   | 0.25                               | 0.25                               | 0.25                   |
| Clerical                           | 0.47                                   | 1.86                               | 3.61                               | 3.61                   |
| Total                              | 2.05                                   | 8.27                               | 10.11                              | 10.21                  |

The assumptions and methodology used to project staffing are provided in Section Q, page 168. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, page 101, the applicant states it currently has staff in place, but will hire three to four new MRI radiology technologists. In Section H, page 101, the applicant describes the methods used to recruit or fill new positions. The applicant provides examples of its proposed training and continuing education programs on page 102 and referenced exhibits.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately demonstrates it currently provides mobile MRI services and has staff in place to accommodate the proposed fixed MRI services.
- The applicant adequately demonstrates its methods to train and retain staff, as well as its methods to ensure staff certification based on its historical experience.

### **Conclusion**

The Agency reviewed the:

Application

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

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

# J-12507-24 / Johnston Imaging / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP.

In Section Q Form H Staffing, the applicant provides the projected full-time equivalent (FTE) positions for the proposed fixed MRI services at Johnston Imaging for the first three full fiscal years, as summarized below:

**Johnston Imaging MRI Scanner Staffing** 

| Position                    | 1 <sup>st</sup> FULL FY<br>FY 2028 | 2 <sup>ND</sup> FULL FY<br>FY 2029 | 3 <sup>RD</sup> FULL FY<br>FY 2030 |
|-----------------------------|------------------------------------|------------------------------------|------------------------------------|
| Registrar                   | 2.0                                | 2.0                                | 2.0                                |
| Radiology Technologist- MRI | 2.0                                | 2.0                                | 2.0                                |
| Total                       | 4.0                                | 4.0                                | 4.0                                |

The assumptions and methodology used to project staffing are provided in Section Q, "Form H Assumptions". Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, page 81, the applicant states UNC Health Johnston will assist the applicant in recruiting the staff needed for the proposed facility. In Section H, pages 81-82, the applicant describes the methods used to recruit or fill new positions. The applicant provides examples of its proposed training and continuing education programs on page 82.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately demonstrates it currently provides fixed MRI services and has adequate staff recruitment practices in place to be able staff the proposed fixed MRI services.
- The applicant adequately demonstrates its methods to train and retain staff, as well as its methods to ensure staff certification based on its historical experience.

#### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Responses to comments

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

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

C

## **Both Applications**

# J-12504-24 / Raleigh Radiology Clayton / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP.

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

In Section I, page 103, the applicant identifies the necessary ancillary and support services for the proposed services. On page 104, the applicant explains how each ancillary and support service is and will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently contracts for mobile MRI services at Raleigh Radiology Clayton and currently provides the necessary ancillary and support services.
- The applicant states it will continue to provide the necessary ancillary and support services following the addition of the proposed fixed MRI scanner and provides a letter in Exhibit I.1 from Raleigh Radiology, LLC attesting to the ongoing availability of these services.

#### Coordination

In Section I, page 105, the applicant states it maintains a vast network of relationships with local health care and social services providers in the service area. The applicant provides letters of support and letters confirming provision of ancillary and support services in Exhibits I.1. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant currently has established relationships with other local healthcare and social services providers.
- The applicant confirms it will continue those relationships upon project completion.

#### Conclusion

The Agency reviewed the:

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

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

# J-12507-24 / Johnston Imaging / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP.

## **Ancillary and Support Services**

In Section I, page 84, the applicant identifies the necessary ancillary and support services for the proposed services. On page 84, the applicant explains how each ancillary and support service is and will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently provides all necessary ancillary and support services are currently provided by either Wake Radiology (image interpretation) or UNC Health Johnston, and currently provide the necessary ancillary and support services.
- The applicant states it will continue to provide the necessary ancillary and support services following the addition of the proposed fixed MRI scanner and provides a letter in Exhibit I.1 from the Chief Executive Officer for UNC Health Johnston attesting to the ongoing availability of these services.

### Coordination

In Section I, page 85, the applicant states it has established relationships with other local healthcare and social service providers, and these relationships will continue through Johnston Imaging and be enhanced following completion of the proposed project. The applicant provides letters of support and letters confirming provision of ancillary and support services in Exhibit I.2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant currently has established relationships with other local healthcare and social services providers.
- The applicant confirms it will continue those relationships upon project completion.

#### Conclusion

The Agency reviewed the:

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

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

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

# NA Both Applications

Neither of the applicants projects to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, none of the applicants projects 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 Both Applications

Neither of the applicants is an HMO. Therefore, Criterion (10) is not applicable to this review.

(11) Repealed effective July 1, 1987.

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

C Both Applications

# J-12504-24 / Raleigh Radiology Clayton / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP.

In Section K, page 108, the applicant states the project involves renovating 1,405 square feet of existing space to accommodate the proposed fixed MRI and support space. Line drawings are provided in Exhibit K-2.

On page 109, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states the project involves relatively inexpensive renovation to the existing space in the existing diagnostic center with no service interruption for patients.
- The applicant provides a letter from a construction company in Exhibit K.2 verifying the construction plans.

On page 109, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states the project will reduce the cost of providing MRI services because
  it will no longer bear an obligation to a third-party vendor for mobile MRI services and
  will provide increased accessibility to fixed MRI services for its patients.
- The applicant states it will operate the proposed fixed MRI services with no increase in revenue per scan.

On page 110, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans. This is supported by vendor documentation found in Exhibit F.1.

### **Conclusion**

The Agency reviewed the:

• Application

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

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

# J-12507-24 / Johnston Imaging / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP.

In Section K, page 88, the applicant states the project involves renovating 1,489 square feet of existing space in the Johnston Medical Mall. Line drawings are provided in Exhibit C.1-1.

On pages 88-89, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the applicant's statement that the project architect and project manager reviewed the necessary construction plans and provided an estimate based on that review. The applicant provides a cost estimate from a licensed architect in Exhibit F.1.

On page 89, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states that developing the fixed MRI scanner at Johnston Medical Mall will have lower fixed expenses at this location.
- The applicant states that keeping MRI in an ambulatory location away from the hospital campus will have lower operating costs for staffing.
- MRI procedures performed at a freestanding facility also have a lower reimbursement level than when performed at a hospital-licensed facility, resulting in lower costs to patients.
- The applicant states the project will not increase charges or projected reimbursement for the proposed services.

On pages 88, the applicant identifies any applicable energy saving and water conservation features that will be incorporated into the construction plans.

#### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

### • Responses to comments

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

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

C

### **Both Applications**

# J-12504-24 / Raleigh Radiology Clayton / Acquire one fixed MRI scanner

In Section L, page 112, the applicant provides the historical payor mix during CY 2023 for all imaging modalities at its existing diagnostic center, as shown in the table below:

Raleigh Radiology Clayton
Diagnostic Imaging Historical Payor Mix CY 2023

| PAYOR CATEGORY | DIAGNOSTIC IMAGING SERVICES AS PERCENT OF TOTAL |
|----------------|---|
| Self-Pay       | 7.4%  |
| Charity Care*  | 1.0%  |
| Medicare**     | 66.4%   |
| Medicaid**     | 1.7%  |
| Insurance**    | 18.9%   |
| Other^         | 4.6%  |
| Total          | 100.0%  |

<sup>\*</sup>On application page 112, the applicant states charity care is 1% of net patient revenue.

In Section L, page 114, the applicant provides the following comparison:

<sup>\*\*</sup>Includes managed care plans

<sup>^</sup>On application page 112, the applicant states "other" includes Worker's Compensation, TriCare, VA and other payors

|                                     | PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY | PERCENTAGE OF THE POPULATION OF THE SERVICE AREA |
|-------------------------------------|---|--|
| Female                              | Not available   | 51.1%  |
| Male                                | Not available   | 48.9%  |
| Unknown                             | Not available   | 0%   |
| 64 and Younger                      | 61.6%   | 84.5%  |
| 65 and Older                        | 38.4%   | 15.5%  |
| American Indian                     | Not available   | 0.9%   |
| Asian                               | Not available   | 1.0%   |
| Black or African-American           | Not available   | 17.6%  |
| Native Hawaiian or Pacific Islander | Not available   | 0.1%   |
| White or Caucasian                  | Not available   | 61.6%  |
| Other Race                          | Not available   | 18.9%  |
| Declined / Unavailable              | Not available   | 1  |

On page 114 the applicant states Raleigh Radiology, LLC locations do not collect patient data regarding gender or race.

The Agency reviewed the:

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

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

# J-12507-24 / Johnston Imaging / Acquire one fixed MRI scanner

In Section L, page 92, the applicant provides the historical payor mix during CY 2023 for its existing for the UNC Health Johnston MRI services, as shown in the table below:

# UNC Health Johnston MRI Services Historical Payor Mix CY 2023

| PAYOR CATEGORY | PERCENTAGE OF TOTAL |
|----------------|---------------------|
|                | PATIENTS SERVED     |
| Self-Pay       | 6.8%                |
| Medicare**     | 50.4%               |
| Medicaid**     | 11.6%               |
| Insurance**    | 25.1%               |
| Other^         | 6.1%                |
| Total          | 100.0%              |

<sup>\*\*</sup>Includes managed care plans

In Section L, page 93, the applicant provides the following comparison:

|                                     | PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY | PERCENTAGE OF THE POPULATION OF THE SERVICE AREA |
|-------------------------------------|---|--|
| Female                              | 60.6%   | 50.6%  |
| Male                                | 39.4%   | 49.4%  |
| Unknown                             | 0.1%  | 0.0%   |
| 64 and Younger                      | 64.4%   | 85.9%  |
| 65 and Older                        | 35.6%   | 14.1%  |
| American Indian                     | 0.3%  | 1.0%   |
| Asian                               | 0.3%  | 1.1%   |
| Black or African-American           | 22.7%   | 18.9%  |
| Native Hawaiian or Pacific Islander | 0.1%  | 0.1%   |
| White or Caucasian                  | 64.2%   | 76.3%  |
| Other Race                          | 11.3%   | 2.6%   |
| Declined / Unavailable              | 1.0%  | 0.0%   |

#### The Agency reviewed the:

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

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

<sup>^</sup>On application page 93, the applicant states "other" includes Worker's Compensation, TriCare, Department of Corrections, and other payors

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

C Both Applications

## J-12504-24 / Raleigh Radiology Clayton / Acquire one fixed MRI scanner

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 116, the applicant states it is under no obligation under federal regulations to provide uncompensated care or community service or access by minorities and handicapped persons.

In Section L, page 116, the applicant states that no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina in the last five years.

The Agency reviewed the:

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

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

# J-12507-24 / Johnston Imaging / Acquire one fixed MRI scanner

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 94, the applicant states it is under no obligation under federal regulations to provide uncompensated care or community service or access by minorities and handicapped persons.

In Section L, page 95, the applicant states that no patient civil rights access complaints have been filed against any facility or any similar facilities owned by the applicant or a related entity and located in North Carolina in the previous 18 months. The Agency reviewed the:

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

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

(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 Both Applications

# J-12504-24 / Raleigh Radiology Clayton / Acquire one fixed MRI scanner

In Section L, page 117, the applicant projects the following payor mix for the proposed MRI services during the third full fiscal year of operation following project completion, as shown in the table below:

Raleigh Radiology Clayton
MRI Services Projected Payor Mix CY 2028

| PAYOR CATEGORY | MRI SCANNER SERVICES AS |  |  |
|----------------|-------------------------|--|--|
|                | PERCENT OF TOTAL        |  |  |
| Self-Pay       | 2.0%                    |  |  |
| Charity Care*  | -                       |  |  |
| Medicare**     | 28.4%                   |  |  |
| Medicaid**     | 8.0%                    |  |  |
| Insurance**    | 53.6%                   |  |  |
| Other^         | 8.0%                    |  |  |
| Total          | 100%                    |  |  |

<sup>\*</sup>On application page 117, the applicant states Charity care is one percent of net patient revenue

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.0% of total fixed MRI services will be provided to self-pay patients, 28.4% to Medicare patients and 8.0% to Medicaid patients.

In Section Q, page 152, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on Raleigh Radiology Clayton's historical payor mix during CY 2023.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

<sup>\*\*</sup>Includes managed care plans

<sup>^</sup>On application page 117, the applicant states "other" includes Worker's Compensation, TRICARE, VA and other payors

#### • Responses to comments

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

## J-12507-24 / Johnston Imaging / Acquire one fixed MRI scanner

In Section L, pages 95-96, the applicant projects the following payor mix for the proposed fixed MRI services for Johnston Imaging in the third full fiscal year of operation following project completion, as shown in the table below:

Johnston Imaging, LLC. Projected Payor Mix MRI Services FY 2030

| PAYOR CATEGORY | MRI SERVICES AS PERCENT OF |  |
|----------------|----------------------------|--|
|                | TOTAL                      |  |
| Self-Pay       | 3.4%                       |  |
| Medicare*      | 51.4%                      |  |
| Medicaid*      | 15.4%                      |  |
| Insurance*     | 22.5%                      |  |
| Other**        | 7.3%                       |  |
| Total          | 100.0%                     |  |

<sup>\*</sup>Includes managed care plans

As shown in the tables above, during the third full fiscal year of operation, the applicant projects that 3.4% total MRI services will be provided to self-pay patients, 51.4% total MRI services, respectively to Medicare patients and 15.4% total MRI services, to Medicaid patients.

On page 95 the applicant provides the assumptions and methodology used to project MRI payor mix during the third full fiscal year of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical payor mix for outpatient MRI services.

The Agency reviewed the:

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

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

<sup>\*\*</sup>Includes Workman's Comp and TRICARE

C Both Applications

## J-12504-24 / Raleigh Radiology Clayton / Acquire one fixed MRI scanner

In Section L, pages 118-119, the applicant adequately describes the range of means by which patients will have access to the proposed fixed MRI services.

The Agency reviewed the:

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

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

## J-12507-24 / Johnston Imaging / Acquire one fixed MRI scanner

In Section L, page 97, the applicant adequately describes the range of means by which patients will have access to the proposed fixed MRI services.

The Agency reviewed the:

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

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

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

 $\mathbf{C}$ 

#### **Both Applications**

# J-12504-24 / Raleigh Radiology Clayton / Acquire one fixed MRI scanner

In Section M, page 120, the applicant describes the extent to which health professional training programs in the area have or will have access to the facility for training purposes and provides supporting documentation in the referenced exhibits.

## J-12507-24 / Johnston Imaging / Acquire one fixed MRI scanner

In Section M, page 98, the applicant describes the extent to which health professional training programs in the area have or will have access to the facility for training purposes and provides supporting documentation in the referenced exhibits.

The Agency reviewed the:

- Applications
- Exhibits to the applications
- Written comments
- Responses to comments

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

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

# C Both Applications

The 2024 SMFP defines the service area for a fixed MRI scanner as "the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county." Therefore, for the purpose of this review, the fixed MRI service area is Johnston County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners currently located in the Johnston County service area, summarized from Table 15E-1, page 346 of the 2024 SMFP.

| Johnston County Fixed MRI Scanners   |   |                |       |       |  |
|--|---|----------------|-------|-------|--|
| PROVIDER/OWNER # OF FIXED SERVICE TYPE TOTAL MRI ADJUSTED MRI SCANNERS TOTAL |   |                |       |       |  |
| Johnston Health - Smithfield   | 1 | Hospital Fixed | 3,556 | 4,500 |  |
| Johnston Health - Clayton  | 1 | Hospital Fixed | 2,399 | 2,950 |  |

Source: 2024 SMFP, Table 15E-1. Page 346

# J-12504-24 / Raleigh Radiology Clayton / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP.

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

"RRWMIC will offer Johnston County a new fixed MRI competitor. RRWMIC does not own or operate an MRI scanner and no related entity owns or operates an MRI scanner in Johnston County. MRI services currently provided at RRClayton [Raleigh Radiology Clayton] are owned and operated by Akumin. As a new freestanding competitor in Johnston County, RRWMIC can sustain market competition. With full time fixed MRI presence, RRWMIC will offer competitive price, value, access and quality. For consumers and others for whom price is a concern RRClayton will increase their awareness and may cause them to request the same from other providers. This dynamic should work to contain prices at other MRI providers in the area. Like other Raleigh Radiology network facilities, RRClayton has and will maintain American College of Radiology ("ACR") accreditation for MRI, maintaining a high standard for competitors."

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

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

...RRWMIC's MRI will contain administrative costs by sharing overhead with RRLLC and with the rest of the RRClayton diagnostic center. RRWMIC will give it direct and immediate access to staff skilled in policies and procedures, billing, third-party contract negotiations, human resources, and facility management. Sharing in this talent pool will enable the center to function with a lean staff."

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

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

"The Applicant will pursue American College of Radiology accreditation for the proposed MRI scanner. This third party, peer reviewed oversight will provide transparency to the proposed project's technical quality. The project will automatically participate in the Raleigh Radiology ACR Breast Center of Excellence program ....

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

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

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

"The facility will accept referred patients without regard to source of payment and has plans to provide charity for medical necessity. It will accept most third-party commercial payors, including the State Employees Medical plan, Tricare for military veterans, Medicaid and Medicare."

See also Sections B, C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

#### **Conclusion**

The Agency reviewed the:

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

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

# J-12507-24 / Johnston Imaging / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 99, the applicant states:

"By developing the proposed 1.5T fixed MRI scanner at a freestanding location, Johnston Imaging will secure dependable long-term accessibility to MRI services for its patients, improve the quality of care, and reduce the expenses associated with offering fixed MRI services at a hospital-based location. The freestanding scanner will provide high quality images at an ambulatory location with a full Monday-Friday weekday schedule that enables patients to schedule appointments quickly and have convenient parking and access to the facility. This will ensure greater efficiency as well as a better experience for patients. The proposed Johnston Imaging fixed MRI scanner will promote competitive access to high-quality, lower cost MRI services in Johnston County, particularly in the Smithfield area."

Regarding the impact of the proposal on cost effectiveness, in Section N, page 99, the applicant refers to Section B.20.c, which states:

"As a member of the larger UNC Health system, UNC Health Johnston benefits from significant cost saving measures through the consolidation of multiple services and large economies of scale. This efficiency results in lower costs that are passed to patients in the form of lower charges."

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

Regarding the impact of the proposal on quality, in Section N, page 99, the applicant refers to Section B.20.a, which states:

"As part of UNC Health Johnston, Johnston Imaging will utilize these or similar policies with a focus on providing high quality care to its patients. As UNC Health Johnston continues to expand its services, it maintains the importance of continuous quality monitoring. Each new unit and service is subject to review under the existing policies."

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 100, the applicant refers to Section B.20.b, which states:

"The proposed project will expand access to lower-cost freestanding MRI services in the service area, including to historically medically underserved groups. UNC Health Johnston prohibits the exclusion of services to any patient on the basis of age, race,

sex, creed, religion, disability, or the patient's ability to pay, and this will apply to Johnston Imaging's proposed facility as well. This is detailed further in UNC Health Johnston's Civil Rights – Notice of Nondiscrimination Policy."

See also Sections B, C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services.
- Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

#### Conclusion

The Agency reviewed the:

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

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

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

C Both Applications

# J-12504-24 / Raleigh Radiology Clayton / Acquire one fixed MRI scanner

In Section Q, Form O, the applicant identifies the diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of nine of these types of facilities located in North Carolina.

In Section O, page 125, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that occurred in either of its facilities. Diagnostic centers are not subject DHSR license requirements. After reviewing and considering information provided by the applicant, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

# J-12507-24 / Johnston Imaging / Acquire one fixed MRI scanner

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

In Section O.4, page 104, the applicant states that the facilities listed on Form O have provided quality care during the 18 months immediately preceding submission of this application. 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 UNC Health Johnston facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183(b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

#### C- Both Applications

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

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

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

- (a) An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:
  - (1) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;

- -NA- **Raleigh Radiology Clayton.** In Section C, page 77, the applicant states it does not currently own or operate any fixed MRI scanners in the fixed MRI scanner service area.
- -C- **Johnston Imaging.** In Section B, page 22, the applicant states Johnston Health Services Corporation, the sole member of Johnston Imaging, owns and operates two fixed MRI scanners in the proposed fixed MRI scanner service area.
  - (2) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;
- -NA- **Raleigh Radiology Clayton.** In Section C, page 77, the applicant states that there are no approved fixed MRI scanners that it owns or operates in the proposed fixed MRI scanner service area.
- -NA- **Johnston Imaging.** The applicant does not identify any approved fixed MRI scanners that it owns or operates in the proposed fixed MRI scanner service area.
  - (3) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service area during the 12 months before the application deadline for the review period;
- -NA- **Raleigh Radiology Clayton.** In Section C, page 77, the applicant states that neither the applicant nor any related entity owns or operates a mobile MRI scanner in the proposed fixed MRI scanner service area.
- -NA- **Johnston Imaging.** The applicant does not identify any mobile MRI scanners owned and operated by the applicant or related entity.
  - (4) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area;
- -NA- **Raleigh Radiology Clayton.** In Section C, page 77, the applicant states that neither the applicant nor any related entity has been approved to own or operate a mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.
- -NA- **Johnston Imaging.** The applicant does not identify any approved mobile MRI scanners owned or operated by the applicant in the proposed fixed MRI scanner service area.
  - (5) provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed MRI scanner during each of the first three full fiscal years of operation following completion of the project;

- -C- Raleigh Radiology Clayton. In Section Q, Form C.2b, the applicant provides projected utilization for its proposed fixed MRI scanner during each of the first three full fiscal years of operation following project completion.
- -C- **Johnston Imaging.** In Section Q, Form C.2b, page 110, the applicant provides projected utilization for its existing fixed MRI scanners in Johnston County and the proposed fixed MRI scanner during each of the first three full fiscal years of operation following project completion.
  - (6) provide the assumptions and methodology used to project the utilization required by Subparagraph (5) of this Paragraph;
- -C- Raleigh Radiology Clayton. In Section Q, "Raleigh Radiology Clayton Need & Utilization Methodology", pages 131-145, the applicant provides projected utilization of the proposed fixed MRI scanner through the first three full fiscal years of operation following project completion.
- -C- **Johnston Imaging.** In Section Q, "Form C.2a and C.2b Utilization Assumptions and Methodology", pages 111-125, the applicant provides the assumptions and methodology used to project utilization of its existing and proposed fixed MRI scanners.
  - (7) project that the fixed MRI scanners identified in Subparagraphs (a)(1) and (a)(2) of this Paragraph and the proposed fixed MRI scanner shall perform during the third full fiscal year of operation following completion of the project as follows:
    - (a) 3494 or more adjusted MRI procedures per MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area;
    - (b) 3058 or more adjusted MRI procedures per MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or
    - (c) 1310 or more adjusted MRI procedures per MRI scanner if there are no existing fixed MRI scanners in the fixed MRI scanner service area; and

According to Table 15E-1, page 346 of the 2024 SMFP, there are currently 2 existing fixed MRI scanners in the Johnston County fixed MRI scanner service area. Therefore, Subparagraph (a) applies to this review.

- -C- Raleigh Radiology Clayton. In Section Q, Form C.2b, page 132, the applicant projects to provide more than 3,494 adjusted MRI procedures on the proposed fixed MRI scanner during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- -C- **Johnston Imaging.** In Section Q, Form C.2b, page 110, the applicant projects to provide more than 3,494 adjusted MRI procedures per fixed MRI scanner during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (8) Project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform 3120 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal year of [operation following] completion of the proposed project.
- -NA- **Raleigh Radiology Clayton.** Neither the applicant nor any related entity owns or operates a mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.
- -NA- **Johnston Imaging.** Neither the applicant nor any related entity owns or operates a mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.
- (b) An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:
  - (1) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;
  - (2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;
  - (3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;
  - (4) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that will be located in the proposed mobile MRI scanner service area;
  - (5) identify the existing and proposed host sites for each mobile MRI scanner identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner;
  - (6) provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph and the proposed mobile MRI scanner during each of the first three full fiscal years of operation following completion of the project;
  - (7) provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;
  - (8) project that the mobile MRI scanners identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner shall perform 3120 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operations following completion of the project; and
  - (9) project that the fixed MRI scanners identified in Subparagraphs (b)(3) and (b)(4) of this Paragraph shall perform during the third full fiscal year of operations following completion of the project:
    - (a) 3494 or more adjusted MRI procedures per fixed MRI scanner if there are four or more fixed MRI scanners in the fixed MRI scanner service area;

- (b) 3058 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI scanners in the fixed MRI scanner service area;
- (c) 1310 or more adjusted MRI procedures per MRI scanner if there are two fixed MRI scanners in the fixed MRI scanner service area;
- -NA- Raleigh Radiology Clayton. The applicant does not propose to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- -NA- **Johnston Imaging.** The applicant does not propose in this application to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period.

#### **COMPARATIVE ANALYSIS**

Pursuant to G.S. 131E-183(a)(1) and the 2024 State Medical Facilities Plan, no more than one fixed MRI scanner may be approved for the Johnston County fixed MRI scanner service area in this review. Because both applications in this review collectively propose to develop two additional fixed MRI scanners to be located in the Johnston County fixed MRI scanner service area, both applications cannot be approved. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of both of the proposals to decide which proposal should be approved.

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

- J-12504-24 / Raleigh Radiology Clayton / Acquire one fixed MRI scanner
  Raleigh Radiology Clayton proposes to acquire one fixed MRI scanner pursuant to the need
  determination in the 2024 SMFP located at an existing diagnostic center in Clayton.
- J-12507-24 / Johnston Imaging / Acquire one fixed MRI scanner
  Johnston Imaging proposes to acquire one fixed MRI scanner pursuant to the need
  determination in the 2024 SMFP to be installed at a new diagnostic center located in
  Smithfield.

#### **Conformity with Statutory and Regulatory Review Criteria**

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved. Both applications are conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, both applications are equally effective alternatives.

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

There are two existing fixed MRI scanners located in Johnston County. One of the of the existing fixed MRI scanners is located in Clayton, and the other fixed MRI scanner is located in Smithfield. The application submitted by **Raleigh Radiology Clayton** proposes to locate the fixed MRI scanner in Clayton. The application submitted by **Johnston Imaging** proposes to locate the fixed MRI scanner in Smithfield. Therefore, both applications are equally effective alternatives with regard to this comparative factor.

#### **Access by Underserved Groups**

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

"Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority."

For access by underserved groups, applications are compared with respect to two underserved groups: Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

#### **Projected Medicare**

The following table shows each applicant's percentage of gross revenue (charges) projected to be provided to Medicare patients in each applicant's third full fiscal year of operation following project completion, based on information provided in each applicant's pro forma financial statements in Section Q. Generally, the application proposing to provide a higher percentage of services to Medicare patients is the more effective alternative with regard to this comparative factor.

MRI Services to Medicare Patients - Project Year 3

| Applicant                 | Medicare Gross | Total Gross  | Medicare % of<br>Total Gross |
|---------------------------|----------------|--------------|------------------------------|
|                           | Revenue        | Revenue      | Revenue                      |
| Raleigh Radiology Clayton | \$3,218,056    | \$11,349,040 | 28%                          |
| Johnston Imaging          | \$5,787,921    | \$11,270,994 | 51%                          |

Source: Form F.2b for each applicant.

As shown in the table above, the application submitted by **Raleigh Radiology Clayton** projects that 28% of its fixed MRI services will be provided to Medicare patients. The application submitted by **Johnston Imaging** projects that 51% of its fixed MRI services will be provided to Medicare patients. Therefore, with regard to projected access for Medicare patients, the application submitted by **Johnston Imaging** is the more effective alternative.

#### **Projected Medicaid**

The following table shows each applicant's percentage of gross revenue (charges) projected to be provided to Medicaid patients in each applicant's third full fiscal year of operation following project completion, based on information provided in each applicant's pro forma financial statements in Section Q. Generally, the application proposing to provide a higher percentage of services to Medicaid patients is the more effective alternative with regard to this comparative factor.

**MRI Services to Medicaid Patients - Project Year 3** 

| Applicant                 | Medicaid Gross<br>Revenue | Total Gross<br>Revenue | Medicaid % of<br>Total Gross<br>Revenue |
|---------------------------|---------------------------|------------------------|---|
| Raleigh Radiology Clayton | \$907,923                 | \$11,349,040           | 8%                                      |
| Johnston Imaging          | \$1,739,299               | \$11,270,994           | 15%                                     |

Source: Form F.2b for each applicant.

As shown in the table above, the application submitted by **Raleigh Radiology Clayton** projects that 8% of its MRI services will be provided to Medicaid patients. The application submitted by **Johnston Imaging** projects that 15% of its fixed MRI services will be provided to Medicaid patients. Therefore, with regard to projected access for Medicaid patients, the application submitted by **Johnston Imaging** is the more effective alternative.

### **Competition (Access to a New or Alternate Provider)**

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

| Johnston County Fixed MRI Scanners   |   |                |       |       |
|--|---|----------------|-------|-------|
| PROVIDER/OWNER # OF FIXED SERVICE TYPE TOTAL MRI ADJUSTED SCANNERS SCANS TOTAL |   |                |       |       |
| Johnston Health - Smithfield 1 Hospital Fixed 3,556                            |   |                |       | 4,500 |
| Johnston Health - Clayton  | 1 | Hospital Fixed | 2,399 | 2,950 |

Source: 2024 SMFP, Table 15E-1. Page 346

As shown in the table above, Johnston Health Services Corporation (Johnston Health), which is the sole member of Johnston Imaging, owns both of the fixed MRI scanners in the Johnston County service area. Therefore, with regard to this comparative factor, **Raleigh Radiology Clayton** is the more effective alternative.

### Projected Average Net Revenue per Adjusted MRI Procedure

The following table compares the projected average net revenue per adjusted MRI procedure for the third year of operation following project completion for each of the applicants, based on the information provided in the applicants' pro forma financial statements (Section Q). Generally regarding this comparative factor, the application proposing the lowest average net revenue per adjusted MRI procedure is the more effective alternative.

Projected Average Net Revenue per Adjusted MRI Procedure - Project Year 3

| Applicant                 | Net Revenue | Adjusted<br>MRI<br>Procedures | Average Net<br>Revenue /<br>Adjusted MRI<br>Procedure |
|---------------------------|-------------|-------------------------------|---|
| Raleigh Radiology Clayton | \$2,042,827 | 6,250                         | \$327   |
| Johnston Imaging          | \$1,663,394 | 4,583                         | \$363   |

Source: Forms C.2b and F.2b for each application

As shown in the table above, the application submitted by **Raleigh Radiology Clayton** projects the lowest average net revenue per adjusted MRI procedure in the third operating year. The application submitted by **Johnston Imaging** projects a higher average net revenue per adjusted MRI procedure in the third operating year. Further, Raleigh Radiology Clayton includes professional fees in their net revenue projections and Johnston Imaging net revenue projections do not include professional fees. Therefore, regarding projected average net revenue per adjusted MRI procedure in the third project year, the application submitted by **Raleigh Radiology Clayton** is the more effective alternative.

#### Projected Average Operating Expense per Adjusted MRI Procedure

The following table compares the projected average operating expense per adjusted MRI procedure in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements (Section Q). Generally regarding this comparative factor, the application proposing the lowest average operating expense per adjusted MRI procedure is the more effective alternative.

Projected Operating Expense per Adjusted MRI Procedure - Project Year 3

| Applicant                 | Operating Expense * |       | Average Operating<br>Expense / Adjusted<br>MRI Procedure |
|---------------------------|---------------------|-------|--|
| Raleigh Radiology Clayton | \$1,296,961         | 6,250 | \$208  |
| Johnston Imaging          | \$1,117,908         | 4,583 | \$244  |

Source: Forms C.2b and F.3b for each application.

Raleigh Radiology Clayton includes professional fees in its operating expense projections and Johnston Imaging does not include professional fees in its operating expense projections. Therefore, professional fee expenses were deducted from the projected operating expenses for Raleigh Radiology Clayton for this comparison.

As shown in the table above, the application submitted by **Raleigh Radiology Clayton.** projects the lowest average operating expense per adjusted MRI procedure in the third operating year. The application submitted by **Johnston Imaging** projects higher average operating expenses per adjusted MRI procedure in the third operating year. Therefore, the application submitted by **Raleigh Radiology Clayton** is the most effective application with respect to projected average operating expense per adjusted MRI procedure.

#### **Summary**

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

| Comparative Factor                                   | Raleigh Radiology<br>Clayton | Johnston Imaging  |
|--|------------------------------|-------------------|
| Conformity with Statutory Review Criteria            | Equally Effective            | Equally Effective |
| Geographic Accessibility (location within the SA)    | Equally Effective            | Equally Effective |
| Access by Medicare Patients                          | Less Effective               | More Effective    |
| Access by Medicaid Patients                          | Less Effective               | More Effective    |
| Competition  | More Effective               | Less Effective    |
| Average Net Revenue per Adjusted MRI Procedure       | More Effective               | Less Effective    |
| Average Operating Expense per Adjusted MRI Procedure | More Effective               | Less Effective    |

<sup>\*</sup>For Raleigh Radiology Clayton, professional fees were deducted from the total projected operating expenses [\$1,750,923 - \$453,962 = \$1,296,961]

Both applications as submitted are conforming to all applicable statutory and regulatory review criteria, and thus all applications are approvable standing alone. However, collectively they propose a total of two fixed MRI scanners in the Johnston County fixed MRI scanner service area, but the need determination in the 2024 SMFP is for only one fixed MRI scanner. Therefore, only one fixed MRI scanner in the service area can be approved.

As shown in the table above, the application submitted by **Raleigh Radiology Clayton** was determined to be a more effective alternative for the following three factors:

- Competition
- Average Net Revenue per Adjusted MRI Procedure
- Average Operating Expense per Adjusted MRI Procedure

As shown in the table above, the application submitted by **Johnston Imaging** was determined to be a more effective alternative for the following two factors:

- Access by Medicare Patients
- Access by Medicaid Patients

#### **DECISION**

Each application is individually conforming to the need determination in the 2024 SMFP for one fixed MRI scanner in the Johnston County fixed MRI scanner service area, as well as individually conforming to all statutory and regulatory review criteria. However, G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed MRI scanners that can be approved by the Healthcare Planning and Certificate of Need Section.

Based upon the independent review of each application and the Comparative Analysis, the Agency determined that the application submitted by **Raleigh Radiology Clayton** is the more effective alternative proposed in this review for the development of one additional fixed MRI scanner in the Johnston County fixed MRI service area pursuant to the need determination in the 2024 SMFP and is approved. The application submitted by **Johnston Imaging** is denied.

The application submitted by Raleigh Radiology Clayton is approved subject to the following conditions:

- 1. RR WM Imaging Clayton, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
- 2. The certificate holder shall acquire no more than one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at Raleigh Radiology Clayton.
- 3. 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. The first progress report shall be due on March 1, 2025.
- 4. 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.
- 5. 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.