Comments on Competing Application for One Additional Fixed MRI Scanner in Johnston County

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submitted by

Johnston Imaging, LLC

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Johnston Imaging, LLC ("Johnston Imaging") submits the following comments related to the competing application submitted by RR WM Imaging Clayton, LLC ("Raleigh Radiology", "RR Clayton"), to develop a fixed MRI scanner at its existing imaging facility, Raleigh Radiology Clayton, which, if approved, will be developed as a diagnostic center (Project ID # J-012504-24). This proposed project is in response to a need determination identified in the *2024 State Medical Facilities Plan (2024 SMFP)*. Johnston Imaging's comments on Raleigh Radiology's competing application include "discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards."[1] *See* N.C. GEN. STAT. § 131E-185(a1)(1)(c). To facilitate the Agency's review of these comments, Johnston Imaging has organized its discussion by issue, identifying the general Certificate of Need (CON) statutory review criteria and specific regulatory criteria creating the non-conformity in the Raleigh Radiology application.

[1] Johnston Imaging is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to the application filed on April 15, 2024 by Johnston Imaging (Project ID # J-012507-24).

GENERAL COMMENTS

As noted above, Raleigh Radiology proposes to develop one fixed MRI scanner at Raleigh Radiology Clayton, an existing, freestanding imaging facility. Johnston Imaging also proposes to locate one fixed MRI scanner at a freestanding facility, located at the Johnston Medical Mall across from the UNC Health Johnston – Smithfield Campus.[2] Johnston Imaging acknowledges and agrees with Raleigh Radiology's assertion that there are advantages to developing MRI services at a freestanding center. These advantages, including lower overall costs to patients and better accessibility, are described in both Johnston Imaging's and Raleigh Radiology's applications. In other words, Johnston Imaging concurs with Raleigh Radiology that the best way to serve the patients of Johnston County and ensure that those patients have access to high quality, accessible, and cost-effective care is through the introduction of a freestanding imaging facility.

However, upon review of Raleigh Radiology's methodology and assumptions, as well as its projected patient origin and other factors, Johnston Imaging believes that Raleigh Radiology's application does not conform with multiple statutory and regulatory review criteria, and as such is not the most effective applicant for the additional fixed MRI scanner allocated in the *2024 SMFP*. Further, Johnston Imaging compares favorably for multiple comparative factors, proposes a more effective location within the county, and proposes to serve a patient population with a greater need.

In short, while Johnston Imaging and Raleigh Radiology's applications are somewhat similar – both propose to establish freestanding fixed MRI services – Johnston Imaging believes that Raleigh Radiology's application contains various flaws and inconsistencies, and that the Johnston Imaging application is superior to Raleigh Radiology's for multiple comparative factors. A detailed explanation of the errors in Raleigh Radiology's application, all of which lead to non-conformity, follows below.

[2] See Johnston Imaging application, p. 32.

APPLICATION-SPECIFIC COMMENTS

The Raleigh Radiology application contains methodological flaws that invalidate its analysis of the need for its proposed services. As a result of these flaws, its application is non-conforming with multiple statutory and regulatory review criteria, as noted below, and the application is not approvable. The specific errors in the Raleigh Radiology application are as follows:

- Raleigh Radiology's methodology is unsupported by its included assumptions;
- Raleigh Radiology's projected patient origin is unreasonable and is not adequately supported;
- Raleigh Radiology's proposal limits access to MRI services in Johnston County;
- Raleigh Radiology's proposed service hours do not provide the required capacity for its utilization projections;
- Raleigh Radiology does not assess all alternative methods for meeting the need for MRI services in Johnston County; and
- Raleigh Radiology's financial assumptions and projections do not adequately support the proposed project.

These issues are discussed in further detail below.

1. Raleigh Radiology's methodology is unsupported by its included assumptions.

Selection of Historical MRI Use Rate

In its "Section Q, Raleigh Radiology Clayton Need & Utilization Methodology," beginning on page 134, Raleigh Radiology details the methodology assumptions for its proposed fixed MRI scanner to meet the MRI performance standards by the proposed project's third full project year, which is calendar year (CY) 2028. One of Raleigh Radiology's assumptions is to apply an MRI use rate per 1,000 population to project the unadjusted MRI procedure utilization in Johnston County. Raleigh Radiology then uses this rate-based utilization to project MRI volume at its proposed diagnostic center. As explained in Step 2 of its methodology, located on page 136, Raleigh Radiology chooses to use the *statewide* MRI use rate per 1,000 population for federal fiscal year (FFY) 2022, which was 95.47 MRI scans per 1,000 population:

Data in Table 2 show that annual MRI use rates increased every year since 2018, except for 2020, when COVID-19 quarantines stopped non-emergency procedures. Because the pattern shows an upward trend in use rate, the applicant considers it reasonable and conservative to forecast need with an assumption that the MRI use rate will remain constant at FFY 2022 rates of **95.47 per 1,000 residents** through the third project year.

Table 2: Statewide 5-Year Average MRI Scan Use Rate per 1,000 Population, 2018-2022

Notes	Metric	FFY18	FFY19	FFY20	FFY21	FFY22
a	Total Population	10,284,335	10,381,670	10,472,553	10,571,934	10,705,403
b	Total Unadjusted MRIs	910,132	948,320	885,496	975,892	1,021,998
c	***NC MRIs per 1K Pop***	***88.50***	***91.35***	***84.55***	***92.31***	***95.47***

Notes:

a) 2018-2022 Population Estimates per NCOSBM.
b) Total Unadjusted MRI Scans per 2020-2024 SMFP.
*c) b / a * 1000*

Source: Raleigh Radiology application, p. 136.

The statewide MRI use rate per 1,000 population is significantly higher than that of Johnston County over the same time, which, as Raleigh Radiology presents in Section C.4 of its application, was only 52.81 per 1,000 population in FFY 2022.

While Johnston Imaging agrees that this low use rate indicates a need for a freestanding fixed MRI scanner in Johnston County, Raleigh Radiology's error is in applying that statewide use rate to the Johnston County population immediately, starting in CY 2024 and projecting it through CY 2028. Then in subsequent steps, Raleigh Radiology applies an assumed market share to these figures to calculate its projected MRI utilization. Johnston Imaging does believe that its proposed development of a freestanding MRI scanner in Smithfield will increase the number of patients—from Johnston County and elsewhere—having their MRI scan in Johnston County; however, it is simply unreasonable to make the assumptions underlying Raleigh Radiology's method. Simply put, Raleigh Radiology makes the following unreasonable assumptions:

- The number of MRI scans "needed" by the Johnston County population will be 23,839 in 2024 and grow to 26,427 in 2028. As shown in the *2024 SMFP* (Table 15E-2, page 357), in 2022 only 14,079 MRI scans (adjusted) were performed in Johnston County. There is simply no basis to assume that number will increase so dramatically by 2024, prior to the development of Raleigh Radiology's (or Johnston Imaging's) proposed freestanding fixed MRI scanner. While the *SMFP* figure includes scans performed on patients from anywhere within Johnston County, patient origin data for the same year shows that approximately 10,400 Johnston County residents had MRI scans anywhere in the state.[3] These assumptions are detailed in Steps 3 (page 137), 5 (page 138) and 6 (page 140) and impact the utilization projections for the proposed project.

- Not only will Johnston County residents need MRI scans at the same rate as the state overall, beginning immediately, but Raleigh Radiology will immediately have an increasing share of those scans from CY 2024 through CY 2028. While the Raleigh Radiology application states that its projected market share allows for unserved patients, or patients outmigrating from Johnston County, there simply is no reasonable basis to assume that the actual need for Johnston County

[3] https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2023/30-PatientOrigin_MRI-2023.pdf

residents—that is, the number of scans they should be getting—is so much higher than what has historically been provided.

As stated in its application, Johnston Imaging does believe that the development of its proposed project will increase the number of MRI scans performed in Johnston County. It does not, however, project that the number of Johnston County residents that should be receiving MRI scans will increase from 10,400 in 2022 to 25,250 by 2026, as Raleigh Radiology clearly projects. This is an essential component of Raleigh Radiology's methodology, because, as shown in Table 6 on page 140, it projects to derive its entire Johnston County market share from this number. As shown in the table below, Raleigh Radiology assumes that MRI utilization will more than double from 2022 to 2024, representing an annual growth rate of more than 51 percent:

Johnston County Assumed MRI Use Rate Growth Rate
FFY 2022 - 2024

County	*2022 Johnston County MRI Patients*	*2024 Johnston County MRI Patients*	*CAGR**
Johnston	10,400	23,839	51.4%

Source: Healthcare Planning and CON Section Patient Origin Reports; Raleigh Radiology application, page 140. Projected patients equal unadjusted procedures.
* Compound annual growth rate.

The MRI use rate utilized by Raleigh Radiology is also unreasonably high relative to *other* statewide MRI use rates per 1,000 population for the given time period. This is relevant as Raleigh Radiology notes that using the MRI use rate per 1,000 population of 95.47 for FFY 2022 "presents a conservative estimate of need."[4] The data in Raleigh Radiology's own methodology, however – presented above – undercuts this statement. As shown in Table 2 of its methodology, *every North Carolina statewide MRI use rate per 1,000 population from FFY 2018 to FFY 2022 is lower than the MRI use rate per 1,000 population that Raleigh Radiology has chosen for calculating its projections*. Even if Raleigh Radiology did not want to use the FFY 2020 MRI use rate per 1,000 population of 84.55 – likely lower than all other years due to COVID effects, as Raleigh Radiology acknowledges[5] – Raleigh Radiology could have instead utilized the MRI use rate per 1,000 population from FFY 2018, which was "only" 88.50. In short, Raleigh Radiology's choice of the highest possible MRI use rate per 1,000 population for its methodology, considering its declaration of "present[ing] a conservative estimate of need," renders its methodology overly aggressive and therefore unreasonable and unsupported by the true historical data of Johnston County.

As stated above, Johnston Imaging agrees that the development of freestanding fixed MRI services will improve access for the residents of Johnston County. However, it also believes that Raleigh Radiology overstates the number of MRI scans that are "needed" by Johnston County residents, leading to its use of a particularly aggressive MRI use rate per 1,000 population for its methodology. In other words, Raleigh Radiology's assumption regarding this use rate does not provide a reasonable explanation for why the statewide rate should be applicable to Johnston County's population, nor does Raleigh Radiology offer a reasonable explanation of how its project will significantly improve access to MRI services, thereby rendering its application non-conforming.

[4] Raleigh Radiology application, p. 136.
[5] Ibid.

While Johnston Imaging believes that it is reasonable to expect the MRI use rate in Johnston County to increase over time – especially considering the aging present in Johnston County, as discussed in Johnston Imaging's application and Johnston Imaging's Assumptions and Methodology[6] – there are no data in Raleigh Radiology's application that support this high growth rate, nor show how the number of Johnston County residents needing MRI scans could more than double through the addition of only one fixed MRI scanner in Clayton—especially when that growth is projected to occur before the MRI is even developed, as discussed below. For comparison, the Johnston County historical population CAGR from 2014 to 2024 – which was the second-fastest growing county *in the state* by percentage over that time – was "only" 3.2 percent. Even the historical population CAGR from 2014 to 2024 for those 65 and older in Johnston County was "only" 5.3 percent – substantially lower than the 34.5 percent CAGR utilized by Raleigh Radiology. As a last point of comparison, the MRI use rate of adjusted scans in Johnston County, as analyzed in Johnston Imaging's own Assumptions and Methodologies, grew at a CAGR of only 2.8 percent from FFY 2019 to FFY 2022.

Table 4
Johnston County MRI Providers – Adjusted Scans/1,000 Population

	FFY19	*FFY20**	*FFY21*	*FFY22*	*CAGR^*
Johnston County Providers - Adjusted MRI Scans	11,718	--	11,628	14,079	6.3%
Johnston County Population	212,883	--	227,029	235,411	3.4%
Adjusted MRI Scans Rate (Per 1,000)	55.0	--	51.2	59.8	2.8%

Source: 2020, 2022, 2024 *SMFPs*.
* 2021 *SMFP* data is excluded from the calculations due to data inconsistencies related to the COVID-19 pandemic. This is consistent with the data used in the *SMFP* for the MRI Need Methodology.
^ CAGR = Compound Annual Growth Rate.

Source: Johnston Imaging application, p. 112.

In short, while it is reasonable to assume that MRI usage in Johnston County will grow, the growth rate Raleigh Radiology proposes is unrealistic and, as such, is not supported.

Further, Raleigh Radiology grows the Johnston County MRI use rate per 1,000 population to a rate of 95.47 *absent of the start of service of its proposed fixed freestanding scanner*. In its "Section P – Proposed Timetable," Raleigh Radiology notes that it will begin offering services on October 1, 2025 – exactly a year *after* the start of FFY 2024.[7] In other words, Raleigh Radiology cannot purport to address an issue of access in Johnston County solely through its addition of a fixed MRI scanner, then state that MRI use in Johnston County will increase without such a scanner in place.

MRI Market Share in Johnston County

Along with its own projections of its total MRI utilization from 2024 to 2028, Raleigh Radiology also projects unadjusted MRI procedures for all Johnston County residents from CY 2024 through CY 2028, projections that utilize its anticipated MRI use rate per 1,000 population of 95.47.

[6] Johnston Imaging application, pp. 40-43, as well as p. 113.
[7] Raleigh Radiology application, p. 128.

Table 5: Forecast Adjusted MRI Procedures Needed by Johnston County Residents, PY2021-PY2026

Notes	Metric	CY24	CY25	CY26	CY27	CY28
a	Unadjusted MRI Procedures	23,839	24,583	25,250	25,859	26,427
b	Weighting Factor	1.19	1.19	1.19	1.19	1.19
c	**Total Adjusted MRI Procedures**	**28,478**	**29,367**	**30,163**	**30,891**	**31,570**

Notes:

a. Number of Unadjusted MRI Procedures from Step 3
b. Weighting Factor from Step 4
*c. a * b*

Source: Raleigh Radiology application, p. 138.

Raleigh Radiology then applies its expected market share of total Johnston County MRI utilization. Raleigh Radiology assumes that it will grow its current Johnston County market share from 5.1 percent to 20 percent by CY 2028.

Table 6: Forecast Market Share of Johnston County Resident MRI Procedures at RRClayton, 2024-2028

Notes	Metric	CY24	Jan-Sept CY25	Oct-Dec CY25	CY26	CY27	CY28
a	Unadjusted Johnston County Scans needed	23,839	18,438	6,146	25,250	25,859	26,427
b	Market share	5.1%	5.3%	7.3%	13.0%	17.0%	20.0%
c	***Total Unadjusted Johnston MR Scans***	1,216	980	450	3,282	4,396	5,285

Notes:

a. Number of Unadjusted Johnston County MRI Procedures from Step 3
b. Projected Market Share
*c. a * b*

Source: Raleigh Radiology application, p. 140.

Raleigh Radiology attributes this significant growth to addressing Johnston County residents' low access for in-county MRI services and limited the outmigration of Johnston County patients to MRI provider locations in other counties, as discussed earlier.

- Information from the state MRI patient origin database indicates that in FY2022, more than 40 percent of reported Johnston County resident MRI scans occurred outside the county, and almost 23 percent of those patients sought care at freestanding facilities. Some went as far as Raleigh Radiology locations in western Wake County. (See Exhibit C.5, page 7 for more information).

Source: Raleigh Radiology application, p. 138.

As noted previously, while the development of a new fixed freestanding MRI scanner is likely to increase the number of MRI scans being performed in Johnston County, on residents of Johnston County and others, Raleigh Radiology's unsupported assumptions are based on an unreasonable expectation that the

need or demand for MRI scans by Johnston County residents will dramatically increase to a level such that it can then take a significant market share from that number.

In summary, the Raleigh Radiology application fails to demonstrate that its utilization methodology is based on reasonable assumptions. It provides no evidence that the number of scans "needed" by Johnston County residents—all of which must be referred by a physician after seeing a patient—will dramatically and immediately increase as projected in its application. Patient origin reports indicate that in 2022, approximately 5,900 Johnston County residents had an MRI scan performed in Johnston County across all providers—including inpatients and outpatients—yet Raleigh Radiology projects to perform approximately 5,300 unadjusted MRI scans on Johnston County residents on its own. Johnston Imaging does not believe there is any information in the application or historical precedent in the state to justify this assumption.

Projections of Other Services at Raleigh Radiology Clayton

As noted above, Raleigh Radiology Clayton is an existing imaging center, which in addition to mobile MRI services currently offers ultrasound, mammography, DEXA, CT, and X-ray services, as stated in its Section C.1 and also listed in its Form C.2a and C.2b.[8] These are existing, full-time services at Raleigh Radiology Clayton and are not limited by vendor availability like the mobile MRI scanner at Raleigh Radiology Clayton.[9]

While Raleigh Radiology provides the historical and projected utilization of these services in its Form C, nowhere does it detail the methodology and assumptions for growing these services, despite references regarding projections for all services on page 152 to "Form C.2b and assumptions for projected procedures." Given this lack of assumptions for its other modalities, the projections are completely unsupported unreasonable. Further, the financial statements for the entire facility are based on these projections.

Based on these issues, the application is non-conforming **with Criteria (1), (3), (4), (5), (6), and (18a).**

2. <u>Raleigh Radiology's projected patient origin is unreasonable and is not adequately supported.</u>

In its "Section Q, Raleigh Radiology Clayton Need & Utilization Methodology," Raleigh Radiology presents the historical distribution of Johnston County and non-Johnston County originating MRI scans at Raleigh Radiology Clayton from CY 2020 through CY 2023:

[8] Ibid, p. 33, as well as pp. 131-133.

[9] Ibid, p. 32.

Table 7: Percent Distribution of Johnston County and Non-Johnston County MRI Scans at RRClayton, 2020-2023

Metric	CY20	CY21	CY22	CY23
Johnston County MRI Scans	52.5%	55.9%	60.9%	66.3%
In-Migration MRI Scans	47.5%	44.1%	39.1%	33.7%

Source: Raleigh Radiology internal data provided February 2024; see Exhibit C.5

Source: Raleigh Radiology application, p. 141.

Raleigh Radiology assumes a much higher percentage of Johnston County patients in its utilization projections. In fact, Raleigh Radiology "conservatively estimates that 10 percent of MRI procedures at RR Clayton will associate with non-Johnston County residents."[10] This is reflected in both the remainder of its methodology and in its projected patient population in Section C.3, page 44.

However, this projected patient origin is not supported by the rest of Raleigh Radiology's application, nor by the historical patient origin at Raleigh Radiology's Clayton office, shown in its Section C.2, page 41.

First, Raleigh Radiology's historical patient origin contains a mathematical error. As shown below, Raleigh Radiology does not correctly sum its patients from Johnston County and "Other" counties, noting the total sum of all patients for CY 2023 was 1,220, which in fact is only equal to the sum of patients from Johnston County for that same year.

<MRI>	<Raleigh Radiology Clayton> *	
	Last Full FY 01/01/2023 to 12/31/2023	
County or other geographic area such as ZIP code	Number of Patients	% of Total
Johnston County	1,220	66.0%
Other (a.)	808	34.0%
Total	**1,220**	**100.0%**

* This should match the name provided in Section A, Question 4.

Notes: a. Other includes all other NC counties and other states.

Source: Raleigh Radiology application, p. 41.

This error decreases Raleigh Radiology's historical percentage of patients originating from Johnston County. If one accurately sums Raleigh Radiology's historical patient volume for 2023, as shown below, Raleigh Radiology in fact treated 2,028 total MRI patients at its Clayton location in 2023. This total results in 60.2 percent of its patients originating from Johnston County, and 39.8 percent of its patients originating from other counties – a greater inmigration percentage than the 34 percent rate that Raleigh Radiology presents in its Section C.3.

[10] Ibid, p. 141.

"Revised" MRI Patient Origin – Raleigh Radiology Clayton
CY 2023

County	*Number of Patients*	*% of Total*
Johnston	1,220	60.2%
Other	808	39.8%
Total	2,028	100.0%

Source: Raleigh Radiology application, p. 41.

While this alone demonstrates that Raleigh Radiology's historical patient origin is erroneous, additional aspects of its analysis of projected patient origin compound this non-conformity. Raleigh Radiology does not demonstrate how its MRI patient origin will so dramatically change from serving 60 percent Johnston County patients to 90 percent Johnston County patients at Raleigh Radiology Clayton. While the application notes that the mobile MRI scanner is only available on a part-time basis, the assumption that the development of a fixed scanner will result in a significant decrease in the number of scans—not just the percentage—from other counties is unreasonable.

As shown in Table 8 of its methodology, Raleigh Radiology projects substantial decreases to its total percentage of inmigrating patients, projecting to treat *only 10 percent of patients from other counties* in the first three project years.

Table 8: Forecast RRClayton MRI Utilization After In-migration, 2024-2028

Note	Metric	CY24	Jan-Sept CY25	Oct-Dec CY25	CY26	CY27	CY28
a	Unadjusted Market Share MRI Scans	1,216	980	450	3,282	4,396	5,285
b	Assumed In-migration percentage	30.9%	25.7%	15.0%	10.0%	10.0%	10.0%
c	**Total Unadjusted MRI Scans w/ In-migration**	***1,759***	***1,319***	***529***	***3,647***	***4,884***	***5,873***
d	*Estimated In-Migration Scans*	543	339	79	365	488	587

Notes:

a. Unadjusted Johnston County Procedures from Table 7 row e
b. Estimated in-migration
c. a / (1 - b)
d. c - a

Source: Raleigh Radiology application, p. 142.

While it is true that the number of MRI scans from inmigrating patients at Raleigh Radiology Clayton did decrease from 47.4 percent in CY 2020 to 33.7 percent in CY 2023, this only yields a CAGR of -10.8 percent historically, which is shown below. Further, if the correct inmigration percentage of 39.8 percent is used for CY 2023 instead of the miscalculated rate of 33.7 percent presented in Raleigh Radiology's application, then the CAGR of inmigrating patients is nearly halved (-5.7 percent).

Growth Rate of Percentage of Inmigrating Patients – Raleigh Radiology
CY 2020 – CY 2023

	CY20	*CY21*	*CY22*	*CY23*	*CAGR*
Historical % of Inmigrating Patients – RR Methodology	47.5%	44.1%	39.1%	33.7%	-10.8%
Historical % of Inmigrating Patients – Recalculation for CY23	47.5%	44.1%	39.1%	39.8%	-5.7%

Source: Raleigh Radiology application, p. 141.

Projecting this trend forward to the proposed project's third full project year – 2028 – does not yield a 10 percent inmigration rate. Rather, if one applies the correct inmigration rate for Raleigh Radiology Clayton of 39.8 percent in 2023, as shown above, and projects its inmigration rate forward using the historical CAGR for inmigrating patients of -5.7 percent from CY 2020 to CY 2023, Raleigh Radiology will experience an inmigration rate of 29.7 percent for CY 2028, nearly *three times higher* than the 10 percent inmigration rate that Raleigh Radiology proposes.

Projected Percentage of Inmigrating Patients – Raleigh Radiology
CY 2024 – CY 2028

County	*CY24*	*CY25*	*CY26*	*CY27*	*CY28*	*CAGR*
Projected % of Inmigrating Patients – RR Methodology	30.9%	20.0%	10.0%	10.0%	10.0%	-24.6%
Historical % of Inmigrating Patients – Recalculation	37.6%	35.4%	33.4%	31.5%	29.7%	-5.7%

Source: Raleigh Radiology application, p. 141.

It is unclear how Raleigh Radiology can so drastically limit the number of patients it serves that inmigrate from other counties, particularly given that Raleigh Radiology Clayton is in Clayton, which is near the border of neighboring Wake County. As such, Raleigh Radiology's projected patient origin is not adequately supported by its methodology.

Raleigh Radiology does attempt to explain this unreasonably high Johnston County patient origin, however. In its assumptions for this projected inmigration rate, Raleigh Radiology states the following:

> Assumptions:
>
> 1. Ten percent in-migration is reasonable, and conservative based on RRClayton's patient trend, planned Johnston County outreach programs and Raleigh Radiology experience with other full-time MRI sites.
> 2. Total projections are also conservative because Johnston County procedures are based on conservative use rates.
> 3. Even though Clayton is close to Wake County, most Wake County residents will gravitate to other Wake County MRI scanners, including new ones in Garner and Knightdale.

Source: Raleigh Radiology application, p. 142.

However, none of these assumptions are reasonable or supported by existing data:

"Ten percent in-migration is reasonable, and conservative based on RRClayton's patient trend, planned Johnston County outreach programs and Raleigh Radiology experience with other full-time MRI sites."

Johnston Imaging does not believe this explanation is sufficient. As shown above, Raleigh Radiology's patient trend, while indeed equating to more in-county patients and fewer inmigrating patients over time, nevertheless does not support Raleigh Radiology's projected in-county utilization rate of 10 percent.

Further, the outreach program that Raleigh Radiology has "budgeted accordingly for…to increase Johnston County resident and provider awareness of RRClayton's MRI services"[11] does not give adequate support for either Raleigh Radiology's MRI projections or its projected patient origin. This outreach plan is detailed in Section I.2, and "includes, but is not limited to" a number of factors:

> RRWMIC provides care to patients and clients of these organizations and participates in strategic and program planning initiatives. The Applicant recognizes the low access issues in Johnston County and is dedicated to developing an outreach strategy that includes residents of the entire county. This plan includes, but is not limited to:
>
> - Adding the RRClayton location to Google Maps;
> - Social media advertising;
> - Adding pictures of the new MRI service to the Raleigh Radiology website;
> - Local media, e.g., radio and print;
> - Industry media;
> - Develop a music playlist for the office;
> - Plan an open house for the new MRI scanner once operational; and,
> - Internal advertising.

Source: Raleigh Radiology application, p. 105.

While it is possible that these factors may increase patient awareness of MRI services in Johnston County and result in additional patients seeking services from in-county providers, the plan cited in Section I.2 is not sufficient tangible and quantitative proof to show how Raleigh Radiology will make up a 24 percent difference in patient origin from its existing Clayton imaging facility today to that same location in 2026 by means of only the addition of a fixed MRI scanner. In particular, it does not demonstrate that patients from nearby areas of Wake or other counties will not also be attracted by these outreach methods; they are not limited to reaching Johnston County residents only.

Raleigh Radiology further claims that this projected patient origin is reasonable and conservative based on "Raleigh Radiology's experience with other full-time MRI sites." This statement is simply false. An examination of certified representations made in Raleigh Radiology's other CON applications demonstrates that none of its other MRI sites, full-time or otherwise, have or are projected to experience only 10 percent inmigration.

[11] Ibid, p. 141.

In its 2021 approved application in Orange County (Project ID # J-12141-21), Raleigh Radiology projected 33 percent inmigration from other counties, as shown below (see page 37):

MRI	<Raleigh Radiology Chapel Hill > *					
	1st Full FY		2nd Full FY		3rd Full FY	
	01/01/2023 to 12/31/2023		01/01/2024 to 12/31/2024		01/01/2025 to 12/31/2025	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Orange County	1,567	67%	2,352	67%	2,996	67%
Out of Area (a)	772	33%	1,158	33%	1,476	33%
Total	**2,339**	**100%**	**3,510**	**100%**	**4,471**	**100%**

* This should match the name provided in Section A, Question 4.

** Home health agencies should report the number of unduplicated clients.

Notes:

a. Out-of-Area includes all other NC counties and other states. Specific counties will vary from year to year.

In its 2023 approved application in Wake County (Project ID # J-12393-23), Raleigh Radiology presented a table showing its historical patient origin by ZIP code, as shown below (see page 42):

<MRI>	<Raleigh Radiology Knightdale> * Last Full FY 01/01/2022 to 12/31/2022	
County or other geographic area such as ZIP code	Number of Patients	% of Total
27545 Knightdale	387	16.4%
27597 Zebulon	374	15.8%
27591 Wendell	338	14.3%
27610 Raleigh	182	7.7%
27616 Raleigh	102	4.3%
27604 Raleigh	120	5.1%
27571 Rolesville	74	3.1%
27615 Raleigh	21	0.9%
27614 Raleigh	34	1.4%
27587 Wake Forest	36	1.5%
27527 Clayton	59	2.5%
27557 Middlesex	25	1.1%
27520 Clayton	19	0.8%
27529 Garner	17	0.7%
27882 Spring Hope	32	1.4%
27549 Louisburg	61	2.6%
27596 Youngsville	19	0.8%
27856 Nashville	17	0.7%
27807 Bailey	11	0.5%
27577 Smithfield	9	0.4%
27576 Selma	11	0.5%
27896 Wilson	12	0.5%
27893 Wilson	29	1.2%
Remainder of NC	366	15.5%
Other States	11	0.5%
Total	**2,366**	**100.0%**

* This should match the name provided in Section A, Question 4.

While the totals by county are not presented, assuming the first 10 rows represent Wake County ZIP codes along with the Garner ZIP code, they total 71.2 percent from Wake County, with 28.8 percent inmigration.

Even in its approved 2019 application (Project ID # J-11825-19) for an MRI scanner in Cary, which is located more centrally in Wake County (and therefore more distant from other counties than its Knightdale or the proposed Clayton locations), Raleigh Radiology certified that it experienced approximately 15 percent inmigration from other counties, as shown below (see page 39):

Table C. 1 - Actual Patient Origin for Each Service Component: MRI Services RRCary

County	Last Full FY* 10/1/18 to 9/30/19	
	Number of Patients	% of Total
Wake	4,756	85.4%
Harnett	134	2.4%
Chatham	114	2.0%
Lee	114	2.0%
Johnston	100	1.8%
Durham	61	1.1%
Orange	54	1.0%
Nash	15	0.3%
Other NC Counties	153	2.7%
Other States	31	0.6%
Unknown	34	0.6%
Total	***5,556***	***100.0%***

**Federal Fiscal Year;*

Given these data, which Raleigh Radiology has previously certified as accurate, the assumption that the proposed project will result in only 10 percent inmigration, particularly when located less than three miles from Wake County,[12] is unreasonable.

"Total projections are also conservative because Johnston County procedures are based on conservative use rates."

As Johnston Imaging has shown above, the MRI use rate that Raleigh Radiology has chosen to use to scaffold its methodology is far from conservative and is in fact the *most* aggressive MRI use rate per 1,000 population that Raleigh Radiology could use. Therefore, this assumption – as already demonstrated above – is unfounded.

"Even though Clayton is close to Wake County, most Wake County residents will gravitate to other Wake County MRI scanners, including new ones in Garner and Knightdale."

While Johnston Imaging does not discount patient preferences to seek imaging services in their home county and believes that patients will often prefer to seek care close to home, this assumption is not entirely applicable to the proposed imaging services in Clayton. As Raleigh Radiology itself states, Clayton is quite close to Wake County – less than three miles from the Wake County border to the west. Given this proximity, it is unclear why a Wake County resident living closer to Clayton than a town in southern Wake County – such as Garner or Fuquay-Varina, for example – would automatically choose MRI services in Wake County solely because it is their county of residence.

For comparison, Johnston Imaging assessed the historical patient origin data for other freestanding MRI providers in Wake County, a county with far more existing freestanding MRI providers than Johnston

[12] Per Google Maps, with routing from Raleigh Radiology Clayton to the Wake County border, just west of 13578 US-70 BUS in Clayton.

County, and therefore more availability for its residents to seek MRI services in-county.[13] However, according to 2022 LRA data that was available[14] for Wake County freestanding MRI providers in Wake County, these providers had in-county patient populations that ranged between 66.7 and 80.9 percent – far less than the 90 percent of in-county patients that Raleigh Radiology assumes it will treat.

Patient Origin for Available Wake County Freestanding Fixed MRI Providers
2022 Data

Provider	*Patients from Wake County*	*Total Patients from All Counties*	*% from Wake County*
Cardinal Points Imaging of the Carolinas Midtown	2,836	3,806	80.9%
Duke Imaging Holly Springs	1,526	2,182	69.9%
Raleigh Neurology Associates, P.A.	2,545	3,813	66.7%
The Bone and Joint Surgery Clinic	1,659	2,274	72.9%
Wake Radiology (WR Imaging)	2,555	3,246	78.7%
Wake Radiology (formerly Raleigh MRI Center)	2,660	3,337	79.7%
Average of Wake County Providers	**13,781**	**18,658**	**73.9%**
Raleigh Radiology County Origin % for Johnston County			**90.0%**

Source: DHSR 2023 MRI Patient Origin Report by Facility, accessed at https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2023/29-Facility_MRI-2023.pdf.

In short, Raleigh Radiology's claim that "Wake County residents will gravitate to other Wake County MRI scanners," while true for many Wake County residents, nevertheless still overstates the share of patients that Raleigh Radiology can expect to utilize in-county MRI services. It is unlikely, in other words, that Raleigh Radiology – which, if its application is approved, would operate the only freestanding MRI scanner in Johnston County – will draw an in-county patient percentage significantly greater than that of *all* freestanding Wake County providers, despite there being more available options for freestanding MRI care in Wake County and therefore more ease for those patients to seek care in-county.

In summary, the Raleigh Radiology projected patient origin is not adequately supported. While this results in the application failing to adequately identify the patient population it proposes to serve, Johnston Imaging believes that the use of unreasonable projected patient population is clearly an attempt to be more favorable under the possible comparative factor for accessibility within the service area. The Agency has historically included a comparative factor evaluating access by service area residents in its review of competitive applications. This factor can be based on either the count of patients or percentage of patients. Raleigh Radiology's choice to minimize out-of-county patients directly impacts this comparative factor, as this unrealistic assumption for in-county patient origin will improve its ranking regarding the

[13] The *2024 SMFP* lists 12 existing freestanding MRI units in Wake County, not counting an MRI scanner as allocated through a *2023 SMFP* need determination. In contrast, the *2024 SMFP* lists no freestanding MRI units in Johnston County.

[14] EmergeOrtho Raleigh Radiology also provides freestanding MRI services in Wake County; however, LRA data for their MRI services do not provide patient origin data, as it contracts MRI services through Alliance Healthcare Services (Alliance). Alliance does not provide patient origin data for its contracted MRI services. This includes the other providers for which it provides freestanding fixed MRI locations: Raleigh Neurology, Raleigh Radiology, and Wake Radiology. Please see *2024 SMFP*, pp. 353.

percentage of Johnston County patients. Even if the Agency were to find Raleigh Radiology conforming with Criterion (3), Johnston Imaging believes that this deliberate manipulation of the methodology should be considered by the Agency when evaluating Raleigh Radiology for this potential comparative factor.

In short, Raleigh Radiology's projected percentage of patients served from Johnston County is unsupported by the methodology and assumptions of Raleigh Radiology's application. **As such, its application is non-conforming with Criteria (3), (5), (6), and (18a).**

3. Raleigh Radiology's proposal limits access to MRI services in Johnston County.

As noted both by Raleigh Radiology itself in its Form O listing of operational MRI facilities and in the *2024 SMFP*, Raleigh Radiology currently operates one mobile MRI scanner at its Clayton location is contracted through Akumin.[15] In Section C.1, Raleigh Radiology states the following with regards to that mobile MRI scanner:

> When the proposed project starts operations, RRWMIC will stop using the Akumin service at RRClayton and executives at Raleigh Radiology will distribute remaining Akumin contract obligations to other Raleigh Radiology imaging centers. See Exhibit C.1.

Source: Raleigh Radiology application, p. 32.

However, this distribution to "other Raleigh Radiology imaging centers" is problematic. Currently, Raleigh Radiology has no other imaging facilities in Johnston County; as such, to redistribute this scanner, Raleigh Radiology will have to move the scanner *outside* of Johnston County, likely to one of its imaging centers in neighboring Wake County. As will be detailed further below, Raleigh Radiology does not discuss this possibility in its list of alternative proposals that could be more effective than its existing proposal.

More importantly, however, is that in doing so, Raleigh Radiology would be subtracting from the total units of fixed equivalent MRI scanners from the county. According to the *2024 SMFP*, the mobile MRI scanner at Raleigh Radiology Clayton accounts for 0.28 fixed equivalent MRI units.[16] If Raleigh Radiology does in fact move this mobile MRI scanner to "(an) other Raleigh Radiology imaging center" – which, as noted above, would *require* it to be moved out of Johnston County – it will not be adding a full fixed equivalent unit of MRI capacity to Johnston County, but rather, will only be adding 0.72 fixed equivalent units of MRI capacity to Johnston County (1.00 – 0.28 = 0.72). The Johnston Imaging application, meanwhile, will add a full unit of fixed equivalent MRI capacity to Johnston County without any associated relocation of mobile MRI services that reduces the net gain in MRI resources, since Johnston Imaging – and indeed all of UNC Health Johnston – does not currently operate any mobile MRI scanners.

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[15] Akumin is the owner of Alliance Healthcare Servies. As such, any reference in Raleigh Radiology's application to mobile MRI services as provided by "Akumin" also refers to mobile MRI services as provided by Alliance Healthcare Services.

[16] See *2024 SMFP*, p. 346.

Total Full Fixed Equivalent MRI Units to be Added to Johnston County From Respective CON Applications

Provider	*Proposed Fixed Equivalent MRI Units*	*Proposed Relocated Fixed Equivalent MRI Units*	*Net Fixed Equivalent MRI Units*
Johnston Imaging	1.00	0.00	1.00
Raleigh Radiology	1.00	0.28	0.72

Source: Raleigh Radiology application, p. 32.

This proposal by Raleigh Radiology has a precedent of indicating non-conformity, according to past Agency findings. In its required findings for the *2021 SMFP* need determination for one fixed MRI scanner in Wake County, the Agency found an application submitted by Wake Radiology non-conforming, in part because it did not adequately discuss its plans to relocate an existing contracted mobile MRI scanner to a Wake Radiology location:

> Under "*Scope of the Project*", in Section C.1, page 30, the applicant states,
>
> > *"...Wake Radiology intends to continue to contract with Alliance to support MRI service demand elsewhere in Wake County, the proposed fixed MRI unit will be used at Wake Radiology Garner in place of the existing contracted Alliance MRI unit."*
>
> In its application, the applicant neither discusses or addresses the impact of continuing to operate an additional mobile MRI scanner (leased from Alliance) in Wake County on the applicants projected utilization of its proposed new fixed MRI scanner at Wake Radiology Garner nor the impact on the applicants, or the applicant's related entities, fixed and mobile MRI scanners in Wake County.

Source: "Required State Agency Findings – 2021 Wake County MRI Review." September 24, 2021, page 14. Accessed at https://info.ncdhhs.gov/dhsr/coneed/decisions/2021/sept/findings/2021%20Wake%20MRI%20Review%20Findings.pdf.

Johnston Imaging believes that the action proposed in Section C.1 of Raleigh Radiology's application mirrors what Wake Radiology proposed in its non-conforming 2021 application for one fixed MRI scanner in Wake County. Nowhere in Raleigh Radiology's utilization methodology is this plan of relocation of its existing, contracted mobile MRI scanner discussed, nor is there any discussion about how the redistribution of this scanner as proposed in Section C.1 will impact projected utilization of the proposed fixed MRI scanner. In fact, Raleigh Radiology's non-conformity reaches further than that of Wake Radiology, given that – as mentioned above – Raleigh Radiology will have to move its existing mobile MRI scanner from Johnston County *entirely*, thereby subtracting access to MRI services for Johnston County residents. Given the similarities between the issues in the Wake County review and Raleigh Radiology's proposed relocation of the mobile MRI scanner from Johnston County, Johnston Imaging believes that the **Agency should also find Raleigh Radiology non-conforming with Criterion (3) and other criteria on this basis.**

4. Raleigh Radiology's proposed service hours do not provide the required capacity for its utilization projections.

In Section C.1, Raleigh Radiology notes its current MRI services at Raleigh Radiology Clayton, stating that it is able to provide mobile MRI services through Akumin, its contracted provider, "10 hours per day, two

days per week, 52 weeks per year."[17] As discussed above, it also states that it will "stop using the Akumin service at RRClayton"[18] upon the approval of its proposed project.

Raleigh Radiology also provides its FY 2022 utilization for this sole mobile scanner in its Section G, Table 16, as shown below.

Table 16: Johnston County Mobile Full Time Equivalent MRI Utilization Based On the SMFP Defined MRI Capacity, FY22

Service Type	Service Site (Provider/Owner)	Fixed MRI	Total MRI Scans	Adjusted Total	% Utilization
Mobile	Cardinal Points Imaging of the Carolinas (Pinnacle Health Service of North Carolina)	0.57	2,855	2,990	84.1%
Mobile	EmergeOrtho Clatyon (EmergeOrtho)	0.01	56	56	89.7%
Mobile	EmergeOrtho Smithfield (EmergeOrtho)	0.41	2,069	2,090	81.7%
Mobile	Raleigh Radiology Clayton (Akumin)	0.28	1,403	1,493	85.5%

Source: Table 15E-1 2024 SMFP (Adjusted Scans / Fixed Equivalent Scanners / 6,240)

Source: Raleigh Radiology application, p. 98.

Utilizing the 1,493 adjusted total scans that Raleigh Radiology performed at its Clayton location in FY 2022, the adjusted MRI scans per hour for Raleigh Radiology Clayton can be calculated as shown below, using Raleigh Radiology's stated operation time of 20 hours (10 hours for two days) per week, 52 weeks per year.

Adjusted MRI Scans per Hour – Raleigh Radiology Clayton
FY 2022

Weeks per Year	*Hours Per Week*	*Total MRI Hours**	*Adjusted MRI Scans*	*Adjusted MRI Scans per Hour***	*% Utilization*
52	20	1,040	1,493	1.44	85.5%

Source: Raleigh Radiology application, p. 98.
* Total MRI Hours = Weeks per Year x Hours per Week
** Adjusted MRI Scans per Hour = Adjusted MRI Scans ÷ Total MRI Hours

Given that its proposed MRI scanner will be a fixed scanner that is not a contracted service, Raleigh Radiology claims that this will result in a significant expansion of its MRI capacity. Specifically, Raleigh Radiology states that it will "operate [the MRI scanner] Monday through Friday 12 hours per day, and 10 hours on Saturday (70 hours per week), 52 weeks per year."[19]

In other words, Raleigh Radiology's total possible MRI hours for its proposed scanner, given this schedule, are as shown below.

17 Raleigh Radiology application, p. 32.
18 Ibid.
19 Ibid.

Total Maximum MRI Hours – Raleigh Radiology Clayton

Weeks per Year	*Hours Per Week*	*Total MRI Hours**
52	70	3,640

Source: Raleigh Radiology application, p. 98.
* Total MRI Hours = Weeks per Year x Hours per Week

The maximum number of available hours that Raleigh Radiology can perform MRI procedures is 3,640. When calculating the number of MRI scans it can expect to perform using its historical adjusted MRI scans per hour rate of 1.44, Raleigh Radiology implicitly projects, through this schedule, that the *maximum* amount of MRI scans that it can perform is 5,226 adjusted MRI scans.

Potential Adjusted MRI Scans – Raleigh Radiology Clayton

Total MRI Hours	*Adjusted MRI Scans per Hour*	*Total Adjusted MRI Scans**
3,640	1.44	5,226

* Total Adjusted MRI Scans = Total MRI Hours x Adjusted MRI Scans per Hour

Notably, however, this projected MRI scan capacity is insufficient to accommodate the applicant's projected adjusted scans, which are 6,250 in the third project year (CY 2028), as presented in its Form C.2b. This is problematic, as Raleigh Radiology claims that "[t]he forecasts on Form C in Section Q of this application reflect the proposed 70-hour schedule."[20]

This discrepancy effectively prevents Raleigh Radiology from having a positive impact on access to MRI services in Johnston County, while also compromising the staffing and financial projections as proposed in its application. Raleigh Radiology does indeed claim that "[s]hould demand exceed forecasts, [Raleigh Radiology] will meet demand with longer hours. If conditions warrant, [it] will adjust the schedule to better accommodate patients."[21] However, it provides no contingencies for the fact that its forecasted volume already exceeds its ability to accommodate the patients given its projected hours of operation and staffing. It is also unclear how this adjustment will affect the financial projections for Raleigh Radiology Clayton, as these contingencies are not detailed in Form H Staffing or Form F Financials in Section Q of Raleigh Radiology's application.

As shown in the table below, when utilizing Raleigh Radiology's projected adjusted MRI scans for its third full project year – 6,250 – and dividing that total by its adjusted number of scans per hour as performed historically on its sole mobile scanner, Raleigh Radiology will require 4,340 MRI hours in its third full project year. Dividing this total by 52 weeks/year shows that Raleigh Radiology must operate its MRI service a minimum of 83 hours per week to sufficiently accommodate this volume. In other words, it must operate an additional 13 hours per week beyond what is budgeted in its proposed project. Given that it has proposed that this scanner will already operate for 12 hours on weekdays and given that this analysis requires Raleigh Radiology to accommodate nearly two additional hours of operation seven days per week, it is unclear how Raleigh Radiology will accommodate these additional and necessary hours. This significant increase in capacity will require additional staffing and operational costs, which Raleigh Radiology does not address nor adequately support in its application.

[20] Ibid.
[21] Ibid.

Projected Surplus of MRI Hours – Raleigh Radiology Clayton

CY 2028 Adjusted MRI Scans	*Adjusted MRI Scans per Hour*	*Total MRI Hours**	*Weeks per Year*	*Required Hours per Week**	*Surplus above 70 hours per Week*
6,250	1.44	4,340	52	83	13

Source: Raleigh Radiology application, p. 144.
* Total MRI Hours = CY 2028 Adjusted MRI Scans ÷ Adjusted MRI Scans per Hour
** Required Hours per Week = Total MRI Hours ÷ Weeks per Year

Given the analysis above, the Raleigh Radiology application is non-conforming with Criteria (3), (4), (5), (7), and (18a).

5. Raleigh Radiology does not assess all alternative methods for meeting the need for MRI services in Johnston County.

In Section E, Raleigh Radiology notes that there are no alternative methods of meeting the need for additional MRI services other than its project as proposed. It discusses maintaining the status quo, developing the project in a different area, acquiring different equipment, and limiting its services to a single specialty, concluding that none of these alternatives is more effective than its project as proposed.[22]

However, Raleigh Radiology does *not* in fact list all possible alternatives, including one alternative that Johnston Imaging believes would be both more effective and less costly than developing a new fixed MRI scanner at its facility: relocating one of its operated, contracted mobile MRI scanners in Wake County to its imaging center in Clayton.

According to the *2024 SMFP*, Raleigh Radiology operates eight mobile MRI scanners in Wake County, as listed in Table 15E-1.[23] It is also currently approved to develop two additional fixed MRI scanners in Wake County, as noted in Section A.6.a:

- Raleigh Radiology, LLC has two approved CONs for fixed MRIs in Wake County.
  - Raleigh Radiology Cary: will replace the current third-party owned and operated installed legacy scanner. It is expected to be operational in late 2024.
  - Raleigh Radiology Knightdale: will replace part-time third-party mobile services. It is expected to be operational in late 2024.

Source: Raleigh Radiology application, p. 24.

This inventory is noted in Raleigh Radiology's Form O Facilities.[24]

As also noted in its Form O Facilities, the MRI scanner at Raleigh Radiology Cary is a stationary (full-time) mobile unit that is owned and operated by the same third-party vendor that provides mobile MRI services at Raleigh Radiology Clayton. The installation of Raleigh Radiology's approved fixed MRI scanner in Cary

22 Ibid, pp. 84-87.
23 See *2024 SMFP*, p. 354.
24 Raleigh Radiology application, p. 169.

will free that legacy MRI scanner to be relocated to another facility, such as Raleigh Radiology Clayton. Raleigh Radiology Clayton could also utilize the mobile MRI services it currently has in Knightdale once the mobile contract at its Knightdale location is terminated. Despite having this scanner available to contract and serve other Raleigh Radiology sites, Raleigh Radiology does not discuss the possibility of using either one of these scanners to serve its Clayton patients more adequately – either in substitution for or alongside its existing mobile MRI scanner.

Given that not all alternatives are proposed, Raleigh Radiology's application is non-conforming with Criterion (4).

6. Raleigh Radiology's financial assumptions and projections do not adequately support the proposed project.

In "Section P – Proposed Timetable," Raleigh Radiology lists the date it will obtain Medicare and/or Medicaid certification as October 1, 2026. Of note, this is one year *after* the "Services Offered" date – October 1, 2025.[25] Nowhere else in its application does Raleigh Radiology note this potential delay in Medicare reimbursement from its start of service dates.

More importantly, in its Form F.2b, Raleigh Radiology lists both Medicare *and* Medicaid revenue for its first full fiscal year of its proposed project, which is January 1 through December 31, *2026*. Raleigh Radiology does not note that these projected revenues represent partial years of Medicare or Medicaid revenue. In fact, it notes that it will "increase the Medicare payor mix by 0.75% starting in 2025."[26]

Given this, the projected payor mix information that Raleigh Radiology presents in Section L cannot be accurate, which, in turn, affects the projected revenues that Raleigh Radiology presents in Form F.2b.

Additional elements of payor mix are not supported by existing data. In Form F.2b, Raleigh Radiology notes that the projected percentage of Medicaid patients for the proposed MRI services is 8.0 percent from 2025 to 2028.

Patient Services Gross Revenue - MRI Only

Payor Mix

	PY25 (3mos)	2026	2027	2028
MRI				
Self Pay	2.0%	2.0%	2.0%	2.0%
Insurance (including any managed care plans)	55.9%	55.1%	54.4%	53.6%
Medicare (including any managed care plans)	26.1%	26.9%	27.6%	28.4%
Medicaid (including any managed care plans)	8.0%	8.0%	8.0%	8.0%
Other (Champus, Tricare, MedSolutions, Workers Comp)	8.0%	8.0%	8.0%	8.0%
Total	100%	100%	100%	100%

Source: Raleigh Radiology application, p. 155.

[25] Ibid, p. 128.

[26] Ibid, p. 155.

This payor mix is replicated in Section L.3.b.[27]

Of note, the historical Medicaid patient percentage for the entire Raleigh Radiology Clayton facility was only 1.7 percent in CY 2023 – in other words, this increase in Medicaid beneficiaries from 2023 to 2028 represents an increase of more than *four times* the Medicaid percentage rate of 2023.

In its assumptions for its Form F.2b, Raleigh Radiology states this increase in Medicaid beneficiaries is "to bring it more in line with RRLLC's total operations and for the expected impact of Medicaid expansion."[28] This explanation is insufficient for a fourfold increase in Medicaid-insured patients receiving MRI services, particularly since its projected payor mix for the entire facility includes only 2.3 percent Medicaid. Moreover, Raleigh Radiology does not provide the historical payor mix for its MRI service as a means of projecting future payor mix, rendering its payor mix assumptions unsupported.

Given Raleigh Radiology's unsupported payor mix and financials, **its application is non-conforming with Criteria (5) and (13c)**.

In conclusion, the discussion above demonstrates that Raleigh Radiology application is non-conforming with multiple statutory review criteria, specifically criteria (1), (3), (4), (5), (6), (7), (13c), and (18a).

[27] Ibid, p. 117.

[28] Ibid, p. 155.

COMPARATIVE ANALYSIS FOR FIXED MRI SCANNER

As noted above, Johnston Imaging believes that Raleigh Radiology's application is non-conforming with multiple statutory and regulatory review criteria and should not be approved. Further, Johnston Imaging believes that its application will better serve the patients of Johnston County by providing accessible and cost-effective freestanding imaging services in Smithfield, co-located with UNC Health Johnston's existing healthcare services in the Johnston Medical Mall on the UNC Health Johnston – Smithfield Campus.

Given that both Johnston Imaging and Raleigh Radiology's applications propose to develop an additional fixed MRI scanner in Johnston County in response to a *2024 SMFP* need determination for one MRI scanner in that county, only one can be approved. To determine the comparative factors that are applicable in this review, Johnston Imaging examined the recent Agency findings for competitive MRI reviews. In particular, it examined the "Required State Agency Findings" for the need for one fixed MRI scanner in Wake County via a need determination in the *2023 SMFP* and examined the "Required State Agency Findings" for one fixed MRI scanner in New Hanover County, also via a need determination in the *2023 SMFP*. In both of those findings, the following comparative factors were utilized:

- Conformity with Review Criteria
- Geographic Accessibility
- Competition (Access to a new or alternate provider)
- Access by Medicare Patients
- Access by Medicaid Patients
- Average Net Revenue per MRI Procedure
- Average Operating Expense per MRI Procedure[29]

Based on its analysis and the facts and circumstances of Raleigh Radiology's competing application, Johnston Imaging believes that the factors presented above and discussed in turn below should be used by the Project Analyst in reviewing the competing applications.

Conformity with Review Criteria

As noted above, Raleigh Radiology's application is non-conforming with at least Criteria (1) (3), (4), (5), (6), (7), (13), and (18a), while Johnston Imaging's application is conforming with all review criteria. As such, the Johnston Imaging application is more effective for this comparative factor.

Geographic Accessibility

Johnston Imaging proposes to locate its new diagnostic imaging center in Smithfield, while Raleigh Radiology proposes to locate its fixed MRI scanner in Clayton, at its existing Raleigh Radiology Clayton center.

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[29] Please see "Required State Agency Findings – 2023 Wake MRI," p. 85, November 27 2023, accessed at https://info.ncdhhs.gov/dhsr/coneed/decisions/2023/nov/findings/2023%20Wake%20MRI%20Findings.pdf; also see "Required State Agency Findings – 2023 New Hanover MRI," p. 99, September 27 2023, accessed at https://info.ncdhhs.gov/dhsr/coneed/decisions/2023/sept/findings/2023%20New%20Hanover%20MRI%20Findings.pdf.

In Section C.4, Raleigh Radiology notes that its location in Clayton is "ideally located for Johnston County residents."[30] It demonstrates this by analyzing the total drive times from Clayton to all other cities in Johnston County, showing that "the most distant location [from Raleigh Radiology Clayton] is within, at most, 45.0 minutes."[31]

Table 9: Average Drive Times in Minutes to Selected Johnston County Cities from RRClayton, Specific Arrival Times

ZIP Code	City	8am	10am	1pm	3pm
27504	Benson	37.5	35.0	37.5	37.5
27520	Clayton	15.0	15.0	15.0	15.0
27524	Four Oaks	42.5	42.5	42.5	42.5
27524	Bentonville	42.5	42.5	45.0	45.0
27527	Clayton	15.0	15.0	15.0	15.0
27569	Princeton	34.0	34.0	37.5	37.5
27576	Selma	25.0	25.0	25.0	25.0
27577	Smithfield	27.5	27.5	27.5	27.5
27527	Clayton	13.0	13.0	13.0	13.0
27542	Kenly	37.5	35.0	37.5	37.5
27555	Micro	32.0	34.0	34.5	32.0
27568	Pine Level	27.5	28.5	31.0	32.0

Source: Google Maps, accessed March 2024

Source: Raleigh Radiology application, p. 58.

However, this discussion of access does not offer any specific information as to why Clayton, and Clayton in particular, is the optimal geographic location for additional MRI services in Johnston County. As stated above, Clayton is near Wake County, a county with multiple existing MRI providers. Smithfield, meanwhile – the location of Johnston Imaging's proposed fixed MRI scanner – is centrally located in Johnston County, and is easily accessible from the county's flagship hospital, UNC Health Johnston – Smithfield Campus.

Additionally, the drive time data does not adequately prove that Raleigh Radiology Clayton is "ideally" located in Johnston County. Johnston Imaging replicated Raleigh Radiology's analysis of drive times, but for its proposed diagnostic imaging center, Johnston Imaging, which will be in Smithfield. As shown below, just as there is no Johnston County municipality that is over 45 minutes from Clayton, there is also no Johnston County municipality that is over 45 minutes from Smithfield – in fact, there is no Johnston County municipality that is even over *30 minutes* from Smithfield. In other words, by drive-time measures, Smithfield is in fact *more* accessible to Johnston County residents than Clayton.

Average Drive Time in Minutes to Johnston Imaging* from Select Johnston County Cities

ZIP Code	*City*	*8AM*	*10AM*	*1PM*	*3PM*
27504	Benson	24.0	24.0	25.0	25.0
27520	Clayton	20.0	20.0	20.0	21.0
27524	Four Oaks	21.0	22.0	23.0	21.0

30 Raleigh Radiology application, p. 58.

31 Ibid.

27524	Bentonville	23.0	26.0	23.0	23.0
27527	Clayton	28.5	26.0	26.0	28.5
27569	Princeton	22.0	22.0	23.0	23.0
27576	Selma	16.0	16.0	16.0	18.0
27577	Smithfield	6.5	7.0	8.0	8.0
27542	Kenly	25.0	25.0	26.0	26.0
27555	Micro	14.0	15.0	16.0	15.0
27568	Pine Level	12.5	13.5	15.0	15.0

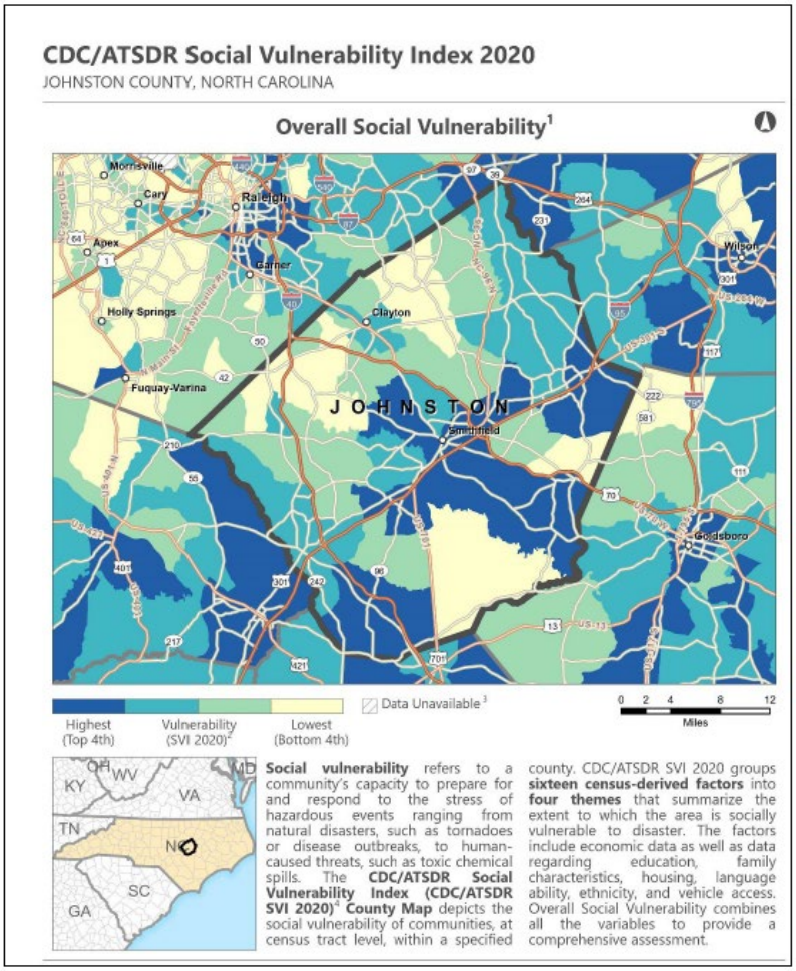
Source: Google Maps, accessed May 2024. Drive times are averages of minimum and maximum drive times as given by Google Maps, using fastest route available.
* As stated in its application, the proposed address for Johnston Imaging is 514 North Bright Leaf Blvd, Suite 1304, Smithfield.

Smithfield also performs similarly to Clayton in terms of other points of comparisons presented in Raleigh Radiology's application. For example, Raleigh Radiology cites numerous Social Determinants of Health (SDoH) in its assessment of Raleigh Radiology Clayton as deserving of MRI need. While Johnston Imaging agrees that SDoH are a significant factor in assessing where and how healthcare services should be provided to any given community, it also believes that Raleigh Radiology's discussion of demographic and health data do not adequately support its purported need for MRI services in Clayton, particularly when compared to the social need for freestanding fixed MRI services in Smithfield.

For example, Raleigh Radiology discusses the social vulnerability of Johnston County, utilizing the CDC / ATSDR Social Vulnerability Index from 2020. Raleigh Radiology notes that "many of the Johnston County census tracts have high social vulnerability and many of those with high vulnerability are close to Clayton. Clayton itself scores high."[32]

[32] Ibid, p. 62.

Figure 11: Wake County CDC / ATSDR Social Vulnerability Index by Census Tract



Source:
https://svi.cdc.gov/Documents/CountyMaps/2020/North%20Carolina/NorthCarolina2020_Johnston.pdf

Source: Raleigh Radiology application, p. 63.

While Clayton *does* have areas in and around it that score on the second-highest tier of social vulnerability, it is important to note that <u>much of the geographic area in and around Smithfield scores the *highest* in terms of social vulnerability.</u> This includes the approximate location of Johnston Imaging's proposed diagnostic center. In short, by its own presented metrics, MRI services are needed more acutely in Smithfield than in Clayton.

Raleigh Radiology also notes "geographic area income levels and access to outpatient" care in its discussion of demographic factors. Specifically, it shows the poverty levels and median household incomes of select Johnston County cities and the county overall.

Table 14: Social Determinants in Select Johnston County Cities and Johnston County compared to NC, 2017-2021

Geography	Persons in poverty, %	Median household income (in 2022 dollars)	Employed persons w/out health ins., age 19-64 years, %	With a disability, age 18-64, %	Persons aged 25+ with high school diploma or higher, %
Benson	37.7	$56,054	23.3	0.8	80.3
Clayton	7.8	$71,698	15.6	4.2	94.7
Four Oaks	11.9	$66,014	37.4	7.7	88.1
Kenly	22.3	$51,250	12.0	0.7	83.4
Pine Level	7.3	$65,347	22.5	5.2	91.2
Princeton	11.1	$34,315	29.8	8.1	80.5
Selma	27.3	$29,325	26.9	0.3	85.3
Smithfield	27.8	$37,000	18.9	10.6	79.3
Johnston County	9.6	$81,725	14.7	9.1	90.4
North Carolina	12.8	$83,448	11.9	11.4	90.2

Source: U.S. Census Bureau, 2013-2017 American Community Survey 5-Year Estimates[22]

Source: Raleigh Radiology application, p. 66.

Although Raleigh Radiology does note that "the town of Clayton is relatively better" in terms of comparisons of poverty, it is in fact the *least* impoverished municipality in Johnston County by multiple metrics, as shown in Raleigh Radiology's Table 14. It has the highest median household income out of all Johnston County municipalities at $71,698 and has the highest percentage of persons aged 25+ with a high school diploma or higher at 94.7 percent. Further, Clayton has the second-lowest percentage of persons in poverty and employed persons without health insurance, age 19-64 out of all Johnston County municipalities. When assessing Clayton as a deserving community regarding economic SDoH, it cannot be argued that it is particularly deserving of additional healthcare resources relative to other Johnston County communities.

In comparison, Smithfield – the proposed location of Johnston Imaging's MRI services – scores low on multiple metrics shown in Raleigh Radiology's Table 14. Its median household income in 2022 dollars is only $37,000, which is *well* below that of Clayton and represents the third-lowest median household income out of all Johnston County municipalities. It also has *the* lowest percentage of persons aged 25+ with a high school diploma or higher, at only 79.3 percent.

Given these facts, as well as the more central location in Smithfield, Johnston Imaging is the more effective alternative for the Geographic Accessibility comparative factor.

Competition (Access to a New or Alternate Provider)

Both Johnston Imaging and Raleigh Radiology currently provide MRI services in Johnston County: Johnston Imaging through fixed MRI services at both UNC Health Johnston – Smithfield Campus and UNC Health Johnston – Clayton Campus, and Raleigh Radiology through mobile MRI services at its location in Clayton. Given this, neither applicant is a "new or alternate provider," making them both equally effective for this comparative factor.

Access by Medicare Patients

The table below compares access by Medicare patients in project year three for both applicants:

Medicare Revenue – Project Year 3

Applicant	*Projected Medicare Gross Revenue*	*Weighted MRI Scans*	*Medicare Revenue per Weighted MRI Scan**	*Total Gross Revenue*	*Projected Medicare % of Gross Revenue***
Johnston Imaging	$5,787,921	4,583	$1,263	$11,270,994	51%
Raleigh Radiology	$3,218,056	6,250	$515	$11,349,040	28%

Source: Forms C.2b and F.2b of respective applications.
* Medicare Revenue per Weighted MRI Scan = Projected Medicare Gross Revenue ÷ Weighted MRI Scans
** Projected Medicare % of Gross Revenue = Projected Medicare Gross Revenue ÷ Total Gross Revenue

Historically, the application proposing to provide a higher percentage of services to Medicare patients is the more effective alternative with regards to this comparative factor.[33] As shown above, Johnston Imaging projects a higher amount of gross revenue for Medicare patients as well as a higher percentage of total gross revenue attributable to Medicare patients. As such, the Johnston Imaging application is more effective for this comparative factor.

Access by Medicaid Patients

The table below compares access by Medicaid patients in project year three for both applicants:

Medicaid Revenue – Project Year 3

Applicant	*Projected Medicaid Gross Revenue*	*Weighted MRI Scans*	*Medicaid Revenue per Weighted MRI Scan**	*Total Gross Revenue*	*Projected Medicaid % of Gross Revenue***
Johnston Imaging	$1,739,299	4,583	$380	$11,270,994	15.4%
Raleigh Radiology	$907,923	6,250	$145	$11,349,040	8.0%

Source: Forms C.2b and F.2b of respective applications.
* Medicaid Revenue per Weighted MRI Scan = Projected Medicaid Gross Revenue ÷ Weighted MRI Scans
** Projected Medicaid % of Gross Revenue = Projected Medicaid Gross Revenue ÷ Total Gross Revenue

Historically, the application proposing to provide a higher percentage of services to Medicaid patients is the more effective alternative with regards to this comparative factor.[34] As shown above, Johnston Imaging projects a higher amount of gross revenue for Medicaid patients as well as a higher percentage of total gross revenue attributable to Medicaid patients. As such, the Johnston Imaging application is more effective for this comparative factor.

[33] "Required State Agency Findings – 2023 Wake MRI," p. 83, and "Required State Agency Findings – 2023 New Hanover MRI," pp. 96-7.

[34] Ibid.

Average Net Revenue per MRI Procedure

The following table shows the projected net revenue per MRI procedure in project year three for both applicants, based on the information provided in each applicant's pro forma Financial Statements (Form F.2b):

Average Net Revenue per MRI Procedure – Project Year 3

Applicant	*Total Net Revenue*	*Weighted MRI Scans*	*Average Net Revenue per MRI Scan**
Johnston Imaging	$1,663,394	4,583	$363
Raleigh Radiology	$2,042,827	6,250	$327

Source: Forms C.2b and F.2b of respective applications.
* Average Net Revenue per MRI Scan = Total Net Revenue ÷ Weighted MRI Scans

Historically, the application proposing the lowest average net revenue per weighted MRI procedure is the more effective alternative with regards to this comparative factor.[35] As shown above, Johnston Imaging projects a higher average net revenue per MRI procedure in its third full project year than Raleigh Radiology in its third full project year. However, Raleigh Radiology's application is unclear regarding its projected revenue. On page 94, the application states that the facility will not bill for professional fees, and then it states that it will bill for fees that include professional and technical charges. Johnston Imaging will bill only for the technical component. Based on Raleigh Radiology's unclear responses, a comparison of revenue between the applicants would be invalid, and the comparative factor is inconclusive. Moreover, as noted above, Raleigh Radiology's projected utilization is unreasonable, and therefore the calculation of net revenue per scan cannot be accurately determined.

Average Operating Expense per MRI Procedure

The following table shows the projected operating costs per MRI procedure in project year three for both applicants, based on the information provided in each applicant's pro forma Financial Statements (Form F.3b):

Average Operating Expense per MRI Procedure – Project Year 3

Applicant	*Total Operating Expenses*	*Weighted MRI Scans*	*Average Operating Expense per MRI Scan**
Johnston Imaging	$1,117,908	4,583	$244
Raleigh Radiology	$1,295,018	6,250	$207

Source: Forms C.2b and F.3b of respective applications.
* Average Operating Expense per MRI Scan = Total Operating Expenses ÷ Weighted MRI Scans

[35] "Required State Agency Findings – 2023 Wake MRI," p. 84, and "Required State Agency Findings – 2023 New Hanover MRI," pp. 98.

Historically, the application proposing the lowest average operating expense per weighted MRI procedure is the more effective alternative with regards to this comparative factor.[36] However, Raleigh Radiology's application is unclear regarding its projected revenue, and by extension, its expenses. On page 94, the application states that the facility will not bill for professional fees, and then it states that it will bill for fees that include professional and technical charges. Raleigh Radiology includes professional fees for physicians and other services in its operating costs summary in Form F.3a; however, it states that those fees are based on a percentage of revenue. As such, the Agency has previously found that a comparison of expenses between applicants with different billing approaches is not possible. Per page 79 of the Agency Findings in the 2021 Orange County MRI review (which included Raleigh Radiology as an applicant), the Agency stated,

> "*RR-Imaging derives its professional fees expense, which is included as part of its operating expenses, based on a formula which includes net revenue (see page 142 of the RR-Imaging application). Therefore, in the case of RR-Imaging, the expense line of professional fees is impossible for the Project Analyst to simply "break out" from the overall expenses with the degree of certainty needed to be fair to both RR-Imaging and the other applicants*."

The same fact pattern is present in this review, and Johnston Imaging believes the Agency should consistently apply the same approach to its analysis. Moreover, as noted above, Raleigh Radiology's projected utilization is unreasonable, and therefore its revenue projections are unreasonable, which are used to calculate its professional fee expenses.

Summary of Comparative Analysis

The following table summarizes the comparative analysis for the competing applications.

Comparative Factor	*Johnston Imaging*	*Raleigh Radiology*
Conformity with Review Criteria	**Yes**	No
Geographic Accessibility	**More Effective**	Less Effective
Competition (Access to a new or alternate provider)	Equally Effective	Equally Effective
Access by Medicare Patients	**More Effective**	Less Effective
Access by Medicaid Patients	**More Effective**	Less Effective
Average Net Revenue per MRI Procedure	Inconclusive	Inconclusive
Average Operating Expense per MRI Procedure	Inconclusive	Inconclusive

As shown above, Johnston Imaging is the more effective alternative for three comparative factors, while both applicants are equally effective for one comparative factor. Additionally, Johnston Imaging is conforming with all applicable review criteria, while Raleigh Radiology is non-conforming with multiple criteria, including at least criteria (1), (3), (4), (5), (6), (7), (13c), and (18a). As such, Johnston Imaging is the most effective alternative for the one fixed MRI scanner as determined through the need determination in the *2024 SMFP*, and its application should be approved.

[36] "Required State Agency Findings – 2023 Wake MRI," p. 85, and "Required State Agency Findings – 2023 New Hanover MRI," pp. 98.