



## **NC Imaging Centers, LLC**

**Comments on Competing Applications for an  
Additional Fixed MRI Scanner in Orange County**

**December 1, 2021**

**Competitive Comments on Orange County  
Fixed MRI Scanner Applications**

*submitted by*

**NC Imaging Centers, LLC**

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), NC Imaging Centers, LLC<sup>1</sup> (NC Imaging) submits the following comments related to competing applications to acquire a fixed MRI scanner to meet the need identified in the *2021 State Medical Facilities Plan (SMFP)* for an additional fixed MRI scanner in Orange County. NC Imaging's comments on these applications include *"discussion and argument regarding whether, in light of the material contained in the applications and other relevant factual material, the applications comply with the relevant review criteria, plans and standards."* See N.C. GEN. STAT. § 131E-185(a1)(1)(c). To facilitate the Agency's review of these comments, NC Imaging has organized its discussion by issue, noting the Certificate of Need (CON) statutory review criteria creating the non-conformity relative to each issue. NC Imaging's comments relate to the following applications:

- **RR WM Imaging Chapel Hill, LLC (Raleigh Radiology), Acquire one fixed MRI to be located at Raleigh Radiology Chapel Hill (RRCH),<sup>2</sup> Project ID # J-12141-21**
- **Duke University Health System, Inc. (DUHS or Duke), Change of scope for Project ID # J-12001-20 (develop a new diagnostic center, Duke Coley Hall Imaging) by acquiring one fixed MRI to be located at Duke Coley Hall Imaging,<sup>3</sup> Project ID # J-12155-21**

NC Imaging's detailed comments include general comments about the competing applications as well as application-specific comments related to each competing application and a comparative analysis related to its application:

- **NC Imaging Centers, LLC, Develop a new diagnostic center – UNC Health Imaging Center<sup>4</sup> – by acquiring one fixed MRI pursuant to the need determination in the *2021 SMFP*, Project ID # J-12145-21**

As detailed above, given the number of applications and the number of proposed additional fixed MRI scanners, all of the applications cannot be approved as proposed. The comments below include substantial issues that NC Imaging believes render both Raleigh Radiology's and DUHS's applications non-conforming with applicable statutory and regulatory review criteria. However, as presented at the end of these comments, even if all these applications were conforming, the application filed by NC Imaging is comparatively superior to the applications filed by Raleigh Radiology and DUHS and represents the most effective alternative for expanding access to MRI services in Orange County.

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<sup>1</sup> NC Imaging Centers, LLC is a wholly owned entity of the University of North Carolina Health System, formerly known as UNC Health Care, now known as UNC Health.

<sup>2</sup> Throughout these comments, Raleigh Radiology is used to refer to the applicant and RRCH is used to refer to the facility.

<sup>3</sup> Throughout these comments, DUHS or Duke is used to refer to the applicant and Duke Coley Hall Imaging is used to refer to the facility.

<sup>4</sup> Throughout these comments, NC Imaging is used to refer to the applicant and UNC Health Imaging Center is used to refer to the proposed facility.

## **GENERAL COMMENTS ON THE COMPETITIVE REVIEW AND COMPARATIVE ANALYSIS**

Among the three competing applications in this review, all propose to develop a fixed MRI scanner in a freestanding (i.e. non-hospital based) setting, which is a lower cost environment compared to existing hospital-based scanners. On a cursory level, all of the applications appear to expand access to non-hospital-based outpatient MRI services. However, the comparative factors should be considered in light of the issues with Raleigh Radiology's and DUHS's applications, as well as the overall need for additional MRI capacity in Orange County. The competing applications are not conforming with various statutory and regulatory review criteria and should be found to be less effective on a comparative basis for those factors derived from statutory review criteria with which they are not conforming.

## **RALEIGH RADIOLOGY, PROJECT ID # J-12141-21**

### **General Comment**

On page 31 of its application, Raleigh Radiology states: “The proposed MRI will bring a new MRI provider to Orange County. It will be the only Orange County freestanding MRI equipment operated by an entity that is not associated with an academic medical center or a company that shares diagnostic imaging equipment ownership with an academic medical center.” It is important for the Agency to note that this statement is incorrect. Raleigh Radiology appears to suggest that Wake Radiology’s facility in Chapel Hill “shares diagnostic imaging equipment ownership with an academic medical center,” but this statement is untrue. UNC Medical Center, the only academic medical center in Orange County, has no ownership in any Wake Radiology facility or its diagnostic imaging equipment, including the facility in Chapel Hill.

### **Issue-Specific Comments**

The Raleigh Radiology application fails to demonstrate the reasonableness of its projected utilization.

The utilization projections in the Raleigh Radiology application are based on three key assumptions involving: (1) MRI use rates, (2) market share, and (3) in-migration rates. As discussed in detail below, each of these three assumptions is overstated and unreasonable. Moreover, it is only by overstating these assumptions, each of which is discussed in turn below, that Raleigh Radiology is able to meet the applicable performance standards.

#### *MRI Use Rate Assumption*

In Step 2 of the application’s utilization methodology (see Raleigh Radiology’s Form C Assumptions and Methodology, in particular, the discussion beginning on page 120), Raleigh Radiology relies on Orange County use rates to determine MRI procedures per 1,000 resident population. As detailed below, there are several problems with this assumption.

Under this step, Raleigh Radiology calculates a North Carolina MRI use rate as well as an Orange County MRI use rate. The North Carolina MRI use rate identified by Raleigh Radiology of 96.36 MRI procedures per 1,000 population is incorrectly calculated. As illustrated in Table C.7 excerpted below from page 48 of the Raleigh Radiology application, the total population of North Carolina (see row “a” in the table below), is clearly incorrect as it remains constant every year from 2014 through 2019. This incorrectly calculated North Carolina MRI use rate is then used to justify the purported “reasonableness” of Raleigh Radiology’s Orange County MRI use rate.

**Table C. 7 – Statewide Unadjusted MRI Use Rates, FY2014-2019**

Notes	Metric	2014	2015	2016	2017	2018	2019
a	Total Population	9,841,848	9,841,848	9,841,848	9,841,848	9,841,848	9,841,848
b	Total Unadjusted MRIs	800,182	848,142	856,324	872,498	910,132	948,320
c	North Carolina MRIs per 1,000 Population	81.30	86.18	87.01	88.65	92.48	96.36

*Notes and Sources:*

- a. 2014 – 2019 Population Estimates per NCOSBM
- b. Total Unadjusted MRI Scans per 2015-2021 SMFPs
- c.  $b/a * 1,000$

Notably, as shown in the table below – which includes correct statewide population data reported by the NC Office of State Budget and Management (NC OSBM) – the calculated use rate was actually lower than what is presented in Raleigh Radiology’s Table C.7 in each year.

**Corrected Table C.7**

	2014	2015	2016	2017	2018	2019
Total Population	9,931,358	10,029,904	10,152,837	10,266,633	10,378,602	10,487,088
Total Unadjusted MRIs	800,182	848,142	856,324	872,498	910,132	948,320
North Carolina MRIs per 1,000 Population	80.57	84.56	84.34	84.98	87.69	90.43

Source: Raleigh Radiology Application Table C.7 and NC OSBM.

Next, Raleigh Radiology calculates an Orange County MRI use rate of 68.08 MRI procedures per 1,000 population from reported patient origin data, which it characterizes as “conservative” given that it “is considerably lower than the state rate.” See the Raleigh Radiology application, page 121. Thereafter, Raleigh Radiology grows the use rate by the change in Orange County population aged 65 and older, which results in an Orange County MRI use rate of 85.50 MRI procedures per 1,000 population. Once again, Raleigh Radiology is quick to point out that this Orange County MRI use rate is still below the North Carolina MRI use rate. Notably, this a deviation from Raleigh Radiology’s approach taken in its previously approved application (Project ID # J-12062-21) to develop the diagnostic center – RRCH – which will house the proposed fixed MRI scanner. In its diagnostic center application, Raleigh Radiology used a consistent or flat use rate methodology in projecting procedures for X-ray, ultrasound, bone density, mammography, and tomosynthesis. Despite having the same patient population, these use rates were not increased as done in the MRI application at issue in this review. Interestingly, relative to the proposed MRI scanner, Raleigh Radiology would not be able to meet the applicable performance standards in this review if its Orange County MRI use rate of 68.08 MRI procedures per 1,000 population were to remain constant. Raleigh Radiology did not explain why it was reasonable to grow the use rate in this application when that is inconsistent with the approach it took in its diagnostic center application. Furthermore, the application fails to demonstrate that Orange County’s MRI use rate should be expected to grow substantially following development of its proposed project, as one might expect if there were a lack of MRI scanners in the service area. As shown in the 2021 SMFP, however, despite the need for an additional MRI scanner in the service area, Orange County residents have access to multiple MRI scanners, including those available at one of the state’s academic medical centers, UNC Health. As shown in Table 17E-1, Orange County, with approximately 150,000 residents, has in-county access to more than 10 equivalent fixed scanners, compared to Randolph County, with a similar population, which has only two fixed MRI scanners. As such,

it is impossible to believe, and certainly Raleigh Radiology does not even attempt to assert, that Orange County residents lack access to MRI services, such that the MRI use rate would be artificially low and might be expected to grow significantly in the future.

Moreover, as Raleigh Radiology states on page 122 of its application, “[t]his is a calculation of need, not a forecast of use.” *[emphasis added]* However, notwithstanding such statement, and as discussed above, the Raleigh Radiology application does in fact adjust its so-called need forecast to forecast use. Further, the “reasonableness” of its use rate is supposedly justified by comparing it to a North Carolina MRI use rate that was incorrectly calculated and artificially inflated. In light of the foregoing, the Orange County MRI use rate presented by Raleigh Radiology is unsupported, overstated, unreasonable, and should not be relied upon.

### *Market Share Assumption*

In Step 6 of the application’s utilization methodology (see Raleigh Radiology’s Form C Assumptions and Methodology, in particular, the discussion beginning on page 125), Raleigh Radiology assumes an MRI market share of 23 percent in the third project year. As detailed below, Raleigh Radiology’s market share assumption is overly aggressive, unsupported, and unreasonable.

As noted previously, the proposed location of the fixed MRI scanner – RRCH – was the subject of a previously approved application submitted by Raleigh Radiology to develop a diagnostic center (Project ID # J-12062-21). Below is an excerpt from page 115 of Raleigh Radiology’s diagnostic center application (Project ID # J-12062-21):

#### Assumptions:

1. Market share is reasonable because:
  - a. The forecast is based on a growing geography;
  - b. Based on information at the date of file, RRCH will be one of only four (25%) freestanding outpatient diagnostic centers located in the service area.
  - c. The proposed PY3 market share (15%) represents one in seven of the ultrasounds forecast in Table 6 would be performed at RRCH.
2. Letters of support from physicians indicate intent to refer to this location. See Exhibit I.2.
3. A realistic marketing budget and RRLLC’s marketing team experience with comparable diagnostic centers, can reasonably achieve these forecasts.
4. The presence of a respected regional radiology group with established third-party relationships, and the WakeMed partner, will make this an attractive option for patients and referring physicians.

As noted in the excerpt above, in its previously approved diagnostic center application, Raleigh Radiology assumed 15 percent market share in project year three relative to the equipment proposed in its diagnostic center application (X-ray, ultrasound, bone density, mammography, and tomosynthesis). Interestingly, a number of the arguments included in the excerpt above from Raleigh Radiology’s previously approved diagnostic center application are used to support its 23 percent market share assumption in its current application – despite the fact that its assumed market share is eight percentage points higher than that assumed in its previously approved application. In its diagnostic center application, Raleigh Radiology references the fact that RRCH will be one of only four (25 percent) freestanding outpatient diagnostic centers in the service area as support to justify its 15 percent market share. Relative to its application at issue in this review, if Raleigh Radiology were approved, RRCH would

have one of 11 fixed MRI scanners in the service area (representing 9.1 percent), yet it claims to expect a 23 percent market share. While some of the MRI scanners in the service area are used for inpatient scans, 81.5 percent of the scans in the 2021 SMFP were outpatient. Raleigh Radiology is not just competing with the one freestanding MRI provider in the service area as it seemingly implies in its application; rather, with regard to market share, it is competing with 10 other MRI scanners capable of performing outpatient scans. This further confirms that a market share of 23 percent is overly aggressive, unsupported, and unrealistic.

Raleigh Radiology may respond that the market share for each piece of equipment should be considered independently. However, NC Imaging believes that it is informative to note that in its previously approved diagnostic center application, Raleigh Radiology assumed 15 percent market share for each of the five imaging modalities it proposed to develop. Of note, those five modalities are significantly less competitive than MRI services and are not even independently regulated by CON law. Further, if each unit of equipment needs to be considered independently relative to market share, it would seem that there would have been some variation in market share assumptions among the five imaging modalities included in Raleigh Radiology's previously approved diagnostic center application. Given that RRCH is not yet operational and has not yet had any actual experience from which to base updated, more aggressive market share assumptions, an eight percentage point increase to its previously approved market share assumption warrants discussion and explanation, but Raleigh Radiology's current application provides neither.

Moreover, it is important to note that if Raleigh Radiology were to assume the 15 percent market share from its previously approved diagnostic center application applied to its proposed MRI scanner, Raleigh Radiology would not be able to meet the applicable performance standards in its current MRI application. In fact, the only way for Raleigh Radiology to meet the applicable performance standards would be to assume a market share of 22 percent or greater. This seems to suggest that the 23 percent market share assumed by Raleigh Radiology was arbitrarily selected in order for its proposal to meet applicable performance standards. Of note, according to data reported in the 2021 SMFP, Raleigh Radiology held 24 percent market share of total fixed MRI scans performed in Wake County in 2019 (18,683 Raleigh Radiology fixed scans / 77,503 total fixed scans) while operating 20 percent of the total fixed scanners in the county (4 Raleigh Radiology fixed scanners / 20 total fixed scanners). In its application in the Orange County MRI review, Raleigh Radiology proposes to operate one fixed MRI scanner in Orange County, which will represent less than one-tenth of the 11 total fixed MRI scanners in the county (10 existing fixed MRI scanners + 1 from the 2021 SMFP need determination). It is unreasonable for Raleigh Radiology to assume it will achieve a similar market share in Orange County – with less than one-tenth of the total fixed MRI capacity in the county – as it has in Wake County where it operates 20 percent of the county's total fixed MRI capacity.

#### *In-Migration Rate Assumption*

In Step 7 of the application's utilization methodology (see Raleigh Radiology's Form C Assumptions and Methodology, in particular, the discussion beginning on page 126), Raleigh Radiology determines in-migration of 33 percent from outside of Orange County to RRCH. As detailed below, Raleigh Radiology's in-migration rate assumption is overly aggressive, unsupported, and unreasonable.

As noted previously, the proposed location of the fixed MRI scanner – RRCH – was the subject of a previously approved application submitted by Raleigh Radiology to develop a diagnostic center (Project

ID # J-12062-21). Below is an excerpt from page 116 of Raleigh Radiology's diagnostic center application (Project ID # J-12062-21):

Assumptions:

1. In-migration remains constant at five percent per year through 2025.
2. Five percent in-migration is conservative because RRA physicians have historically served an average of 19.2 percent of x-ray patients from outside Wake County; and Orange County, like Wake County, is a regional referral center.
3. The proposed location close to I-40 and NC-86 will provide easy access for both in- and out-of-county patients.

As noted in the excerpt above, in its previously approved diagnostic center application, Raleigh Radiology assumed a five percent in-migration rate relative to its proposed X-ray equipment. In its diagnostic center application, Raleigh Radiology examined its experience in Wake County and noted 19.2 percent in-migration relative to X-ray services from outside Wake County. Then Raleigh Radiology went on to compare Wake County to Orange County as a regional referral center as well as to discuss the ease of access to the new diagnostic center facility. In its application at issue in this review, Raleigh Radiology examined MRI data for its existing Raleigh Radiology locations in Wake County, which show that (similar to the X-ray discussed above), approximately 19.3 percent of Raleigh Radiology MRI patients originated from outside of Wake County between January 2017 and December 2020. Although the X-ray equipment will be part of the same facility that will house the proposed fixed MRI scanner, Raleigh Radiology does not assume a five percent in-migration rate as it did in its previously approved diagnostic center application despite almost identical historical in-migration experience for X-ray and MRI. Rather, Raleigh Radiology notes on page 127 of its MRI application that it believes that RRCH will have more in-migration in Orange County than reflected by its experience in Wake County (19.3 percent in-migration), but less in-migration than existing Orange County MRI providers (noting that UNC Health shows 85 percent in-migration and that Wake Radiology shows 51 percent in-migration). Raleigh Radiology then notes that it *"conservatively estimates that 33 percent of MRI procedures at RRCH will come from outside Orange County."* See the Raleigh Radiology application, page 127. Despite Raleigh Radiology's vague references to specialist concentration and the proximity of Chatham, Durham, and Alamance counties as supporting its 33 percent in-migration assumption, such assumption is nevertheless overstated and unreasonable – in particular, given its previously approved assumption of five percent in-migration relative to X-ray (and other imaging equipment) and Raleigh Radiology's historical experience in Wake County of approximately 19.3 percent in-migration of MRI patients from outside of Wake County. In addition, the use of UNC Health's historical in-migration is inappropriate, given its position as an academic medical center and the state's only public health care system with a mission to serve all residents of the state who need care; these factors certainly contribute to UNC Health's in-migration and are not applicable to Raleigh Radiology's proposed project.

Moreover, it is important to note that if Raleigh Radiology were to use either the five percent in-migration rate from its previously approved diagnostic center application or the 19.3 percent in-migration rate based on its historical MRI experience in Wake County, Raleigh Radiology would not be able to meet the applicable performance standards. In fact, the only way for Raleigh Radiology to meet the applicable performance standards would be to assume an in-migration percentage of 28 percent or greater. This seems to suggest that the 33 percent in-migration rate assumed by Raleigh Radiology was arbitrarily selected in order for its proposal to meet applicable performance standards.



Based on the discussions above, it is clear that Raleigh Radiology's projected utilization is unsupported. As such, **the Raleigh Radiology application is non-conforming with Criteria 1, 3, 4, 5, 6, 18a, and the performance standards in the MRI rules (10A NCAC 14C .2703) and should be denied.**

The Raleigh Radiology application fails to demonstrate the immediate and long-term financial feasibility of its proposal.

As detailed below, Raleigh Radiology's financial assumptions are either incorrectly stated, unsupported, or unreasonable.

- **Overstated Expenses** – While on page 142 of its application Raleigh Radiology indicates that professional fees are “[b]ased on a contracted percent of net collections (net revenue before bad debt) of 20%,” the calculation shown in Form F.3.b utilizes a higher percentage than the 20 percent referenced in its assumptions on page 142 of its application. This inconsistency calls into question the validity of Raleigh Radiology's expense assumptions.
- **Overstated Marketing Fees** – As noted previously, the proposed location of the fixed MRI scanner – RRCH – was the subject of previously approved application submitted by Raleigh Radiology to develop a diagnostic center (Project ID # J-12062-21). In its previously approved diagnostic center application marketing fees were \$10,000 per year; however, in the application at issue in this review – which involves the same facility – marketing fees are projected to be over \$100,000 in 2023. This inconsistency calls into question the validity of Raleigh Radiology's expense assumptions.

**Based on the discussion above, Raleigh Radiology fails to demonstrate that its financial and operational projections are based on reasonable assumptions and therefore fails to demonstrate the immediate and long-term financial feasibility of its proposal in accordance with Criterion 5. As such, the Raleigh Radiology application is non-conforming with Criteria 1, 3, and 5.**

The payor mix presented in the Raleigh Radiology application is incorrectly calculated and unsupported.

In Section L.3, Raleigh Radiology projects payor mix for its proposed project. As detailed below, the projected payor mix is unsupported and incorrectly calculated. Not only does Raleigh Radiology fail to include the historical data used to calculate payor mix in its application, but also there is a math error affecting its Medicare adjustment.

According to Raleigh Radiology's Form F.2b assumptions, its payor mix is based on “*Raleigh Radiology, LLC historical data for imaging by modality in Wake County.*” The historical data used to calculate payor mix is not provided in Raleigh Radiology's application. In Section L, Raleigh Radiology provides combined historical data for its freestanding facilities in Cary, Blue Ridge, Fuquay-Varina, and Knightdale. Notably, this data includes all modalities and is not specific to MRI. In addition, the data provided is incomplete as the percentages only sum to 95.24 percent. Given the absence of the historical data used to calculate payor mix, Raleigh Radiology's payor mix is completely unsupported.

In addition, Raleigh Radiology incorrectly increases its Medicare percentage from 27.4 percent in 2021 to 40.0 percent of patients in 2025. This error seems to have occurred as a direct result of Raleigh Radiology's use of addition where multiplication was required. According to Raleigh Radiology's Form F.2.b assumptions, “*MRI Medicare is adjusted to reflect the increase in age of the population. Respective adjustment for 2022-2025 is 3.5%, 3.25%, 3.05% and 2.86%. Increases in Medicare are offset by decreases*

*in insurance.” See the Raleigh Radiology application, page 122 (Table 3). In row C of Table 3, Raleigh Radiology shows that the population aged 65 and older in Orange County is growing. Residents aged 65 and older increase from 15.8 percent of the population in 2021 to 18.4 percent in 2026. Overall, that is a 2.6 percent increase. In row D of Table 3, Raleigh Radiology converts the increase into a growth rate. To calculate the impact on Medicare as the application states was intended, Raleigh Radiology should have **MULTIPLIED** one plus the growth rate by the current Medicare rate instead of adding. Raleigh Radiology clearly understands this principle as it used multiplication to adjust the MRI use rates in row E in the same table. By erroneously using addition, Raleigh Radiology increases Medicare from 27.4 percent in 2021 to 40.0 percent in 2025. In short, Raleigh Radiology calculates a 12.6 percent increase in Medicare based on residents aged 65 and older increasing by 2.6 percent of the population. This increase is clearly unsupported and inaccurate. The Medicare portion of the payor mix can be correctly recalculated as follows:*

<i>Year</i>	<i>Growth Rate</i>	<i>Medicare %</i>
2021		27.4%
2022	3.50%	28.4%
2023	3.25%	29.3%
2024	3.05%	30.2%
2025	2.86%	31.0%

As shown in the table above, using the correct calculations based on the application’s assumptions results in an increase in Medicare from 27.4 percent in 2021 to 31.0 percent in 2025. Raleigh Radiology presents a Medicare percentage that is significantly overstated (nine percentage points) while significantly understating insurance by that same amount. As discussed relative to the comparative factors below, this miscalculation incorrectly allows Raleigh Radiology to appear more effective in the comparative factors by presenting better than expected access by Medicare patients and by understating average net revenue per MRI procedure.

**Based on the discussion above, Raleigh Radiology fails to demonstrate that its payor mix is based on reasonable assumptions and therefore fails to demonstrate that the elderly and the medically underserved will be served by its proposal in accordance with Criterion 13c. As such, the Raleigh Radiology application should be found non-conforming with Criterion 13c.**

Raleigh Radiology fails to demonstrate that it has provided quality care during the 18 month look-back period.

In response to Section O.4 on page 110, the application provides no documentation that the health service facilities identified on Form O have provided quality care in the last 18 months. In fact, the response is largely prospective; that is, it discusses what the applicant intends to do in the future, which is not responsive to a historical “look-back” period, as has been the Agency’s practice under Criterion 20 for many years. As Raleigh Radiology’s diagnostic center will be an unlicensed facility that is not governed by the same oversight as licensed facilities like hospitals, it is critical that applicants provide accurate and complete information to the Agency to allow them to have a review under this criterion that is comparable to the review of other applicants that do have licensed facilities. Raleigh Radiology has failed to do so and should be found non-conforming on that basis. In addition, its response regarding in the last paragraph on page 110 is inaccurate. While the ACR Breast Center of Excellence designation does include breast MRI

services offered at the facility with that designation, Raleigh Radiology's response that "RRCH will enjoy this umbrella designation" implies that the proposed facility will automatically have the same designation as its other facilities, which is untrue. Like any facility, Raleigh Radiology's proposed facility must be separately reviewed to be designated as a Breast Center of Excellence. It does not receive less scrutiny because of the other facilities that are designated as such. Similar to the rest of the application's responses, this, too, is a projection of what Raleigh Radiology expects may occur in the future but it is not certain and is not responsive to the requested information from the 18 month look-back period.

**Based on the discussion above, Raleigh Radiology fails to demonstrate that it has provided quality care during the 18 month look-back period in accordance with Criterion 20. As such, the Raleigh Radiology application should be found non-conforming with Criterion 20.**

**In summary, based on the issues detailed above, Raleigh Radiology has failed to demonstrate that its project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183 and that the project is needed, and the Raleigh Radiology application should be found non-conforming with Criteria 1, 3, 5, 13c, and 20. The Raleigh Radiology application should not be approved.**

## DUKE COLEY HALL IMAGING DIAGNOSTIC CENTER, PROJECT ID # J-12155-21

### Issue-Specific Comments

The DUHS application fails to demonstrate the immediate and long-term financial feasibility of its proposal.

As detailed below, DUHS's financial assumptions are either incorrectly stated, unsupported, or unreasonable.

- Understated Depreciation – DUHS's total facility depreciation expense-equipment is understated by \$48,100 per year. DUHS's total facility depreciation comprises two separate components, MRI and ultrasound/mammography. The MRI scanner depreciation is calculated based on a \$2,269,000 equipment expense depreciated over a useful life of five years. That equates to \$453,800 of depreciation expense per year which matches DUHS's Form F.3.b. According to DUHS's Form F.1.b, the previously approved diagnostic center application included medical equipment costs of \$526,000 and non-medical equipment costs of \$174,000. This combined \$700,000 in medical equipment costs from its previously approved application should be depreciated over five years for a total of \$140,000 per year. For the entire facility, equipment depreciation should be \$593,800 per year (\$453,800 + \$140,000). However, Form F.3b includes depreciation of only \$545,700 for each of the first three project years. Thus, expenses are understated by \$48,100 per year.
- Understated Start-Up Costs – DUHS's start-up costs are understated by \$12,641. DUHS identifies that start-up costs should include six months of rental (lease) expense for the MRI portion of the facility. This is the result of the facility opening six months before the MRI service will be offered. To calculate this cost, DUHS takes 50 percent of the 2023 MRI rental expense. The 2023 MRI services Form F.3.b represents the period from January 1 to June 30, 2023, a period of six months. By taking 50 percent of that figure, DUHS only includes three months of MRI rental expense in the start-up costs which understates start-up costs by three months of MRI rental expense.
- Understated Capital Costs – DUHS's capital costs are understated by \$900. In its funding letter included in Exhibit F.1(a), reference is made to other/contingency costs of \$328,900. However, DUHS's Form F.1.b only includes a contingency cost of \$328,000. As such, capital costs for DUHS's proposed project are understated.

**Based on the discussion above, DUHS fails to demonstrate that its financial and operational projections are based on reasonable assumptions of costs and charges and therefore fails to demonstrate the immediate and long-term financial feasibility of its proposal in accordance with Criterion 5. As such, the DUHS application should be found non-conforming with Criteria 1, 3, and 5.**

**In summary, based on the issues detailed above, DUHS has failed to demonstrate that its project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183 and that the project is needed, and the DUHS application should be found non-conforming with Criteria 1,3, and 5. The DUHS application should not be approved.**

## COMPARATIVE ANALYSIS

The NC Imaging application (Project ID # J-12145-21), the Raleigh Radiology application (Project ID # J-12141-21), and the DUHS application (Project ID # J-12155-21) each propose to acquire a fixed MRI scanner in response to the 2021 SMFP need determination for Orange County. Given that multiple applicants propose to meet the need for the additional fixed MRI scanner in Orange County, not all can be approved. To determine the comparative factors that are applicable in this review, NC Imaging examined recent Agency findings for competitive MRI reviews. Based on that examination and the facts and circumstances of the competing applications in this review, NC Imaging considered the following comparative factors:

- Conformity with Applicable Statutory and Regulatory Review Criteria
- Scope of Services
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area Residents (Geographic Reach)
- Access by Underserved Groups
- Revenues
- Operating Expenses

NC Imaging believes that the factors presented above and discussed in turn below should be used by the Project Analyst in reviewing the competing applications. In addition, please note that while NC Imaging also considered the comparative factors listed below, it ultimately discarded these factors, which have historically involved an evaluation by the Agency of historical utilization, as two of the three applicants involved in this review do not currently provide fixed MRI services at a facility in Orange County and thus review of such comparative factors is inconclusive.

- Historical Utilization
- Meeting the Need for Additional MRI Capacity
- Demonstration of Need

### Conformity with Applicable Statutory and Regulatory Review Criteria

The NC Imaging application adequately demonstrates that its proposal is conforming to all applicable statutory and regulatory review criteria. By contrast, and as discussed in the application-specific comments above, the Raleigh Radiology application and the DUHS application are non-conforming with multiple statutory and regulatory review criteria. An application that is not conforming to all applicable statutory and regulatory review criteria cannot be approved. Therefore, the NC Imaging application is the most effective alternative with regard to conformity with statutory and regulatory review criteria.

### Scope of Services

The following table illustrates the scope of services proposed by each of the applicants in this review.

	<i>NC Imaging</i>	<i>Raleigh Radiology</i>	<i>DUHS</i>
Type of MRI Scanner	1.5T	1.5T	1.5T
Hospital-Based or Freestanding*	Freestanding	Freestanding	Freestanding

\*Freestanding means not operated as part of a hospital license.

As illustrated in the table above, with regard to scope of services, all three applicants propose to acquire and operate a 1.5T fixed MRI scanner in a freestanding outpatient setting. However, NC Imaging believes that its application is unique with regard to scope of services for reasons discussed in its application. Given the demand for the premier healthcare services provided at UNC Hospitals, UNC Health, through NC Imaging, will develop the proposed UNC Health Imaging Center as an equal extension of and complement to the high caliber care provided at UNC Hospitals. This will allow patients to receive advanced MRI scans in a lower cost freestanding setting that would typically only be available in a hospital setting, which will enable UNC Health Imaging Center to function as a complement to the quality diagnostic imaging services provided at UNC Hospitals, rather than a freestanding outlet for only low acuity, low complexity cases.

As such, the NC Imaging application is more effective than the applications submitted by Raleigh Radiology and DUHS with regard to scope of services.

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

The service area for the MRI is Orange County. All three applicants propose to locate the additional fixed MRI scanner in Chapel Hill, Orange County. Therefore, while the applications would be equally effective with regard to geographic accessibility based on how the Agency has evaluated this factor historically, as discussed previously, neither the Raleigh Radiology application nor the DUHS application can be approved as proposed. As noted in NC Imaging's application, its proposed location in north Chapel Hill will provide convenient access to patients in northern Orange County as well as Chapel Hill. For reference, NC Imaging's proposed location is less than 7 miles and 12 minutes away from UNC Hospitals Hillsborough Campus. Given the complementary location of this imaging center to other UNC Health facilities, the NC Imaging application is more effective than the applications submitted by Raleigh Radiology and DUHS with regard to geographic accessibility.

#### Access by Service Area Residents (Geographic Reach)

The Agency historically has evaluated this comparative factor in competitive MRI reviews by comparing each applicant's projected number of service area residents to be served as a percentage of total patients. However, in recent acute care bed and operating room reviews, the Agency has determined that this comparative factor is of little value and has not considered it. NC Imaging believes a comparison of each applicant's geographic reach is an appropriate consideration in this review.

As discussed on page 48 of NC Imaging's application, according to patient origin reports published by the Healthcare Planning and Certificate of Need Section, only 52.1 percent of patients served by Orange County fixed MRI providers originated from within the county from 2016 to 2020. As such, the demand for MRI services originating from outside of Orange County contributes significantly to the need for an additional fixed MRI scanner to be located in Orange County. As such, NC Imaging believes that the Agency should recognize that the need for additional MRI capacity in Orange County is driven by residents across the region and evaluate the applicants' geographic reach in assessing the need for additional MRI capacity in Orange County. As demonstrated by each applicant's projected patient origin in Section C.3b of the respective applications, NC Imaging proposes a broader geographic reach and therefore is the most effective alternative with respect to this factor.

Access by Underserved Groups

*Projected Charity Care*

The following table compares charity care in the third full fiscal year for all of the applicants. Two of the applicants, NC Imaging and DUHS, do not bill for the professional component. The third applicant, Raleigh Radiology, bills globally. As a result of these billing differences, charity care per patient does not allow for a comparison between the applicants. However, charity care as a percentage of gross revenue is still applicable and is shown below.

	<b>NC Imaging</b>	<b>Raleigh Radiology</b>	<b>DUHS</b>
Gross Charges	\$20,958,410	\$8,443,087	\$4,708,917
Charity Care	\$2,118,674	\$42,215	\$35,111
Charity Care as a % of Gross Revenue	10.1%	0.5%	0.7%

Source: Form F.2b of the respective applications.

As shown above, NC Imaging proposes the highest percentage of charity care by a significant margin. Therefore, with respect to charity care, NC Imaging is the most effective alternative.

*Projected Medicaid*

The following table illustrates the percent of total MRI procedures to be provided to Medicaid patients as stated in Section L.3 of the respective applications.

	<b>NC Imaging</b>	<b>Raleigh Radiology</b>	<b>DUHS</b>
Percent of Total MRIs to be provided to Medicaid Recipients	8.0%	4.9%	5.5%

Source: Sections L.3 of the respective applications.

As shown above, NC Imaging projects to serve the highest percentage of Medicaid MRI patients. As such, NC Imaging is the most effective alternative in regard to this comparative factor.

*Projected Medicare*

The following table illustrates the percent of total MRI procedures to be provided to Medicare patients as stated in Section L.3 of the respective applications.

	<b>NC Imaging</b>	<b>Raleigh Radiology</b>	<b>DUHS</b>
Percent of Total MRIs to be provided to Medicare Recipients	36.9%	40.0%	38.8%

Source: Sections L.3 of the respective applications.

As shown above, each of the applicants propose to serve a similar percentage of Medicare MRI patients, with Raleigh Radiology projecting to serve the highest percentage. However, as discussed in the

application-specific comments above, Raleigh Radiology erroneously increases its Medicare percentage from 27.4 percent of patients in 2021 to 40.0 percent in 2025 due to using addition instead of multiplication. If the mathematical error is corrected, Raleigh Radiology’s Medicare patients will represent, at most, approximately 31.0 percent of total patients, the lowest percentage of Medicare MRI patients proposed to be served among the three applicants as shown in the table below.

	<i>NC Imaging</i>	<i>Raleigh Radiology (Corrected)</i>	<i>DUHS</i>
Percent of Total MRIs to be provided to Medicare Recipients	36.9%	31.0%	38.8%

While the remaining two applicants – NC Imaging and DUHS – propose to serve a similar percentage of Medicare MRI patients with DUHS having a slightly higher percentage, but as discussed previously, the DUHS application cannot be approved as proposed. As such, the NC Imaging application is more effective than the application submitted by DUHS with regard this comparative factor.

Revenues

The following table illustrates each applicant’s projected total net revenue per procedure in the third project year.

	<i>NC Imaging</i>	<i>Raleigh Radiology</i>	<i>DUHS</i>
Unweighted MRI Procedures	4,684	4,471	4,310
Net Revenue	\$3,060,935	\$2,096,210	\$2,433,066
<b>Net Revenue per Procedure</b>	<b>\$653</b>	<b>\$469</b>	<b>\$565</b>

As shown above, Raleigh Radiology projects lower average net revenue per MRI procedure. However, two of the applicants, DUHS and NC Imaging, do not bill for professional fees nor do they include an expense line in their respective pro formas for professional fees. In contrast, Raleigh Radiology bills globally and includes professional fees, which cover professional interpretation of MRI studies, as revenue in its pro formas. These differences in billing, which impact revenue and expenses, do not allow for a comparison between the applications. Thus, the result of this analysis is inconclusive.

Operating Expenses

The following table illustrates each applicant’s operating expenses per procedure in the third project year.

	<i>NC Imaging</i>	<i>Raleigh Radiology</i>	<i>DUHS</i>
Unweighted MRI Procedures	4,684	4,471	4,310
Operating Expenses	\$2,645,982	\$1,842,566	\$1,428,780
<b>Operating Expenses per Procedure</b>	<b>\$565</b>	<b>\$412</b>	<b>\$332</b>



As shown above, DUHS projects lower average operating expenses per MRI procedure. However, two of the applicants, DUHS and NC Imaging, do not bill for professional fees nor do they include an expense line in their respective pro formas for professional fees. In contrast, Raleigh Radiology bills globally and includes professional fees, which cover professional interpretation of MRI studies, as an expense in its pro formas. These differences in billing, which impact revenue and expenses, do not allow for a comparison between the applications. Thus, the result of this analysis is inconclusive. Further, as discussed in the application-specific comments above, DUHS understated its expenses and is not conforming with Criterion 5.

**SUMMARY**

As noted previously, NC Imaging maintains that neither the Raleigh Radiology application nor the DUHS application can be approved as proposed given their non-conformity with multiple applicable statutory and regulatory review criteria. As such, NC Imaging is the only approvable application. Based on the comparative analysis summarized below, NC Imaging believes that its application represents the most effective alternative for meeting the need in the 2021 SMFP for an additional fixed MRI scanner in Orange County.

<b>Comparative Factor</b>	<b>NC Imaging</b>	<b>Raleigh Radiology</b>	<b>DUHS</b>
Conformity with Applicable Statutory and Regulatory Review Criteria	Yes	No	No
Scope of Services	More Effective	Less Effective	Less Effective
Geographic Accessibility (Location within the Service Area)	More Effective	Less Effective	Less Effective
Access by Service Area Residents (Geographic Reach)	More Effective	Less Effective	Less Effective
Access by Underserved Groups – Projected Charity Care	More Effective	Least Effective	Less Effective
Access by Underserved Groups – Projected Medicaid	More Effective	Least Effective	Less Effective
Access by Underserved Groups – Projected Medicare	More Effective	Least Effective	Most Effective, But Not Approvable
Revenues	Inconclusive	Inconclusive	Inconclusive
Operating Expenses	Inconclusive	Inconclusive	Inconclusive

In summary, NC Imaging believes that its application is clearly the most effective alternative for an additional fixed MRI scanner needed in Orange County. NC Imaging’s application is also fully conforming to all applicable statutory and regulatory review criteria and comparatively superior on the relevant factors in this review. As such, the proposal by NC Imaging to develop a fixed MRI scanner at UNC Health Imaging Center can and should be approved.

***Please note that in no way does NC Imaging intend for these comments to change or amend its application filed on October 15, 2021. If the Agency considers any of these comments to be amending NC Imaging’s application, those responses should not be considered.***