

**COMPETITIVE COMMENTS ON ORANGE COUNTY
2021 FIXED MRI SCANNER NEED DETERMINATION
SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM
DECEMBER 1, 2021**

OVERVIEW

Three applicants submitted CON applications in response to the need identified in the 2021 SMFP for one additional MRI scanner in Orange County: CON Project ID# J-012141-21 Raleigh Radiology Chapel Hill (RRCH), CON Project ID# J-012145-21, UNC Health Imaging Center (NCIC), and CON Project ID# J-012155-21 Duke Coley Hall Imaging (DCHI).

These comments are submitted by Duke University Health System (DUHS) in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the applications, including a comparative analysis and a discussion of the most significant issues regarding the applicants' conformity with the statutory and regulatory review criteria ("the Criteria") in N.C. Gen. Stat. §131E-183(a) and (b). Other errors and non-conformities in the competing applications may exist and DUHS reserves the right to develop additional opinions, as appropriate upon further review and analysis.

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COMPARATIVE ANALYSIS

The Healthcare Planning and Certificate of Need Section developed a list of suggested comparative factors for competitive batch reviews. The following factors are suggested for all reviews regardless of the type of services or equipment proposed:

- Conformity with Statutory and Regulatory Review Criteria
- Scope of Services
- Historical Utilization
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area Residents
- Access by Underserved Groups: Charity Care
- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare
- Competition (Access to a New or Alternate Provider)
- Projected Average Net Revenue
- Projected Average Total Operating Cost

Conformity with Statutory and Regulatory Review Criteria

Three CON applications have been submitted, each seeking a fixed MRI scanner in Orange County. Based on the 2021 SMFP's need determination for one additional fixed MRI scanner, only one application can be approved. Only applicants demonstrating conformity with all applicable Statutory and Regulatory Review Criteria can be approved, and only the application submitted by DUHS demonstrates conformity to all Statutory and Regulatory Review Criteria:

Conformity of Competing Applications

Applicant	Project I.D.	Conforming/ Non-Conforming
Raleigh Radiology Chapel Hill	J-012141-21	No
UNC Health Imaging Center	J-012145-21	No
Duke Coley Hall Imaging	J-012155-21	Yes

The DUHS application for a fixed MRI scanner is based on reasonable and supported volume projections and adequate projections of cost and revenues. As discussed separately in these comments, the RRCH and UNC applications contain errors and flaws which result in multiple non-conformities with applicable

Statutory and Regulatory Review Criteria. Therefore, regarding this comparative factor, **DUHS** is the most effective alternative.

Scope of Services

All three applicants propose to develop dedicated outpatient fixed MRI services in a freestanding outpatient setting. None of the applicants propose to offer inpatient services.

Applicant	Type of Fixed MRI Scanner	Hospital Based or Freestanding
Raleigh Radiology Chapel Hill	1.5T	Freestanding
UNC Health Imaging Center	1.5T	Freestanding
Duke Coley Hall Imaging	1.5T	Freestanding

However, neither RRCH nor UNC comply with all applicable statutory and regulatory criteria and therefore neither RRCH nor UNC are approvable. Therefore, regarding this comparative factor, the **DUHS** application is most effective.

Historical Utilization

The following table illustrates the total MRI scans and the adjusted total of MRI scans of each applicant as published in Table 17E-1 of the 2021 SMFP.

**MRI Utilization
2021 SMFP (FY2019 Data)**

Facility	# of Fixed MRI Scanners*	Unweighted Procedures	Weighted Procedures	Weighted MRI Procedures per Scanner
UNC	9	37,648	49,265	5,474
Wake Radiology UNC REX – Chapel Hill	1	1,413	1,646	1,646

Source: 2021 SMFP, Chapter 17, Table 17E-1 (page 359)

UNC is an existing provider fixed MRI services in Orange County. The parent company of NCIC is The University of North Carolina Health System d/b/a UNC Health. See application page 16. UNC Health also

wholly owns UNC REX Healthcare.¹ UNC REX Healthcare and Wake Radiology announced plans in 2017 to form a joint venture (Wake Radiology UNC REX Healthcare) that would combine their outpatient imaging services. That partnership became official on February 23, 2019.² See also Attachment 1. Wake Radiology UNC REX Healthcare now operates Wake Radiology UNC REX – Chapel Hill. Thus, consistent with the definition of related entity described in 10A NCAC 14C .2701(16) – as well as the clear marketing of the parties that Wake Radiology is part of the UNC system and network, Wake Radiology UNC REX – Chapel Hill is a related entity of UNC Health. UNC Healthcare cannot avoid this relationship, and its effect, merely be creating additional subsidiaries to operate new projects. As shown in the previous table, Wake Radiology UNC REX – Chapel Hill performed only 1,646 weighted MRI procedures during FY2019, which is below the regulatory performance standard of 4,805 weighted MRI procedures. Therefore, NCIC is the least effective alternative regarding historical utilization.

As described in its CON application (See application page 96), DUHS provided 3,856 MRI procedures to patients from Orange County during FY2021.

As described on application page 36 of the RRCH application, Raleigh Radiology served fewer than 700 patients from Orange, Alamance, Chatham, and Durham Counties combined during 2021. RRCH did not specify how many of this number were from Orange County. Nonetheless, Raleigh Radiology has the lowest historical utilization of the competing applicants.

Furthermore, the RRCH application included zero letters of support from Orange County physicians. Specifically, Exhibit I.1 of the RRCH application contains letters from physicians residing only in Durham County. RRCH failed to obtain documentation from a single physician located in Orange County. The DUHS application included letters of support from physician practices physically located in Orange County as well as other physician practices with a documented history of treating patients from Orange County.

For the reasons previously described, **DUHS** is the most effective alternative for this comparative.

¹ UNC Rex Healthcare is part of UNC Health Care. UNC Health Care comprises UNC Hospitals and its provider network, the clinical programs of the UNC School of Medicine, and nine hospitals across the State including UNC REX. <https://www.rexhealth.com/rh/about/collaboration-within-unc-health-care/>

² <https://www.wakerad.com/feature-stories/partnership/>; see announcement attached to these comments.

Geographic Accessibility (Location within the Service Area)

The 2021 SMFP identifies the need for one fixed MRI scanner in Orange County. The following table identifies the existing and approved fixed MRI scanner locations in Orange County.

Facility (Owner)	# of Fixed MRI Scanners	Hospital Based or Freestanding	Location
UNC Hospitals – Medical Center	6	Hospital	Chapel Hill
UNC Hospitals – Imaging Center	2	Hospital	Chapel Hill
Wake Radiology UNC-Rex – Chapel Hill	1	Freestanding	Chapel Hill
TOTAL FOR Chapel Hill	9		
UNC Hospitals - Hillsborough	1	Hospital	Hillsborough
TOTAL FOR Hillsborough	1		
2021 Need Determination			
Proposed: RRCH	1	Freestanding	Chapel Hill
Proposed: UNC	1	Freestanding	Chapel Hill
Proposed: DUHS	1	Freestanding	Chapel Hill

All three applications propose to develop a fixed MRI scanner in Chapel Hill. Therefore, the proposals are equally effective regarding this comparative.

Access By Service Area Residents

On page 344, the 2021 SMFP defines a fixed MRI scanner as “an MRI scanner that is not a mobile MRI scanner.” The 2021 SMFP defines the service area for a fixed MRI scanner as “the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.” Therefore, for this review, Orange County is the service area because it has at least one licensed acute care hospitals. Facilities may also serve residents of counties not included in their service area. The following table compares access by service area residents during the third full fiscal year following project completion for each applicant.

MRI Access by Service Area Residents, PY3	RRCH	NCIC	DUHS
Orange County Residents Served	2,996	1,308	2,581
% of Orange County Patients as a % of Total Patients	67%	27.9%	60.0%

Source: Form C and Section C.3 of the respective applications

As shown in the table above, NCIC projects to serve the lowest number and percentage of Orange County residents during the third project year. RRCH projects to serve the highest number and percentage of

Orange County residents; however, RRCH's application does not conform to applicable Statutory and Regulatory Review Criteria and cannot be approved. DUHS projects to serve the second highest number of Orange County residents and the highest percentage of service area residents. Therefore, regarding access by service area residents, **DUHS** is the most effective alternative.

Access By Underserved Groups

Underserved groups are defined in G.S. 131E-183(a)(13) as follows: *"Medically underserved groups, such as medically indigent or low-income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority."*

For access by underserved groups, applications are compared with respect to three underserved groups: charity care patients (i.e., medically indigent, or low-income persons), Medicare patients, and Medicaid patients. Access by each group is treated as a separate factor.

The Agency typically uses one or more of the following metrics to compare the applications:

- Total charity care, Medicare or Medicaid patients
- Charity care, Medicare or Medicaid patients as a percentage of total patients
- Charity care, Medicare or Medicaid patients per MRI procedure
- Total charity care, Medicare or Medicaid dollars
- Charity care, Medicare or Medicaid dollars as a percentage of total gross or net revenues
- Charity care, Medicare or Medicaid dollars per MRI procedure

Which of the above metrics the Agency uses is determined by whether the applications included in the review provide data that can be compared as presented above and whether such a comparison would be of value in evaluating the alternative factors.

As a preliminary remark, Duke would note that its own financial projections were closely tied to the patient population it currently serves in the service area. The other two applicants appear to have crafted payor mix projections without regard to the most relevant data available to them, perhaps with an eye to "winning" a comparative analysis.

Projected Charity Care

The following table compares projected charity care in the third full fiscal year following project completion.

Applicant	Gross Revenue	MRI Scans (Unweighted)	Charity Care	Charity Care as a % of Gross Revenue
RRCH	\$8,443,087	4,471	\$42,215	0.5%
NCIC	\$20,958,410	4,684	\$2,118,674	10.1%
DUHS	\$8,340,144	4,310	\$35,111	0.4%

Source: Section Q Form C and Form F.2 of the respective applications

As a preliminary matter, charity care is not a defined term in the application, and the parties may have different assumptions about how charity care is calculated. Additionally, RRCH and NCIC did not provide payor mix projections for the percent of charity care patients served during project year 3. See Section L.3 of the respective applications.

Regarding NCIC’s projected charity care payor mix, application page 104 states, “*payor mix for the proposed fixed MRI scanner is based on the SFY 2021 payor mix for outpatient MRI services at UNC Hospitals Hillsborough Campus.*” However, NCIC’s assumption is unreasonable. Specifically, the payor mix for a hospital population that includes emergency department patients will be very different than the payor mix for a freestanding, off-campus facility several miles away. As set forth in UNC’s 2021 license renewal application, Section E for the Hillsborough campus, charity care patients constituted almost 18% of emergency department visits, and 6% of outpatient visits excluding ED and surgical cases. Using “all” outpatient MRI procedures at the Hillsborough campus to project payor mix at the new facility is not a reasonable proxy.

In addition, regarding NCIC’s projected charity care revenue and its percentage of gross revenue, the assumptions for Form F.2b state projected gross charges were based on “*UNC’s FY2021 experience with outpatient MRIs at the UNC Hospitals Hillsborough Campus.*” It is illogical to base projected gross charges for a freestanding fixed MRI service based on a related entity’s experience providing hospital-based fixed MRI services. NCIC had access to its related entity’s experience providing freestanding fixed MRI services (*i.e.*, Wake Radiology UNC REX – Chapel Hill), but opted to ignore it. Instead NCIC assumed projected gross charges that are comparable to hospital-based charges instead of freestanding charges. This is unrealistic and results in grossly overstated revenues for NCIC’s proposed fixed MRI service. NCIC states in the assumptions for Form F.2b that charity care is the difference between gross and net revenue for self-pay; thus, NCIC’s projected charity care is overstated and not supported. Therefore, NCIC cannot be an effective alternative regarding access for charity care patients.

As a percent of net revenue, RRCH purports to project the second highest percentage of charity care as a percent of net revenue, but those projections are not reasonable. RRCH does not comply with all

applicable statutory and regulatory criteria and therefore RRCH is not approvable. Thus, RRCH cannot be an effective alternative regarding access for charity care patients.

As described in its application, DUHS’s payor mix assumptions and financial projections were closely tied to the patients that it already served from the service area. DUHS also provided adequate information in the application as submitted to evaluate the number of charity care patients served during the third project year. For these reasons, **DUHS** is the more effective alternative regarding access for charity care patients.

Projected Medicare

The following table compares projected access by Medicare patients in the third full fiscal year following project completion.

Applicant	Gross Revenue	MRI Scans (Unweighted)	Medicare Gross Revenue	Medicare Gross Revenue as a % of Total Gross Revenue	Medicare / MRI Scan	Medicare MRI Procedures as a % of Total MRI Procedures	Medicare MRI Procedures
RRCH	\$8,443,087	4,471	\$3,382,607	40.1%	\$757	40.0%	1,788
NCIC	\$20,958,410	4,684	\$7,737,592	36.9%	\$1,652	36.9%	1,728
DUHS	\$4,708,917	4,310	\$1,828,383	38.8%	\$424	38.8%	1,672

Source: Form C, Section L.3, and Form F.2 of the respective applications

Regarding NCIC’s projected Medicare payor mix, application page 104 states, “*payor mix for the proposed fixed MRI scanner is based on the SFY 2021 payor mix for outpatient MRI services at UNC Hospitals Hillsborough Campus.*” However, NCIC’s assumption is unreasonable. Specifically, as set forth above, the payor mix for a hospital population that includes emergency department patients will be very different than the payor mix for a freestanding, off-campus facility several miles away. Using “all” outpatient MRI procedures at the Hillsborough campus to project payor mix at the new facility is not a reasonable proxy. Therefore, NCIC’s Medicare MRI procedures are not supported and cannot be an effective alternative.

NCIC proposes the highest Medicare revenue per MRI procedure. However, as previously stated, NCIC’s assumptions for Form F.2b state projected gross charges were based on “*UNC’s FY2021 experience with outpatient MRIs at the UNC Hospitals Hillsborough Campus.*” It is illogical to base projected gross charges for a freestanding fixed MRI service based on a related entity’s experience providing hospital-based fixed MRI services. NCIC had access to its related entity’s experience providing freestanding fixed MRI services (*i.e.*, Wake Radiology UNC REX – Chapel Hill), but opted to ignore it. Instead NCIC assumed projected gross charges that are comparable to hospital-based charges instead of freestanding charges. NCIC’s assumptions are unrealistic and result in grossly overstated Medicare revenues for NCIC’s proposed fixed MRI service. Additionally, NCIC does not comply with all applicable statutory and regulatory criteria and,

thus, NCIC is not approvable. Therefore, NCIC cannot be an effective alternative regarding access for Medicare patients.

RRCH proposes the highest Medicare gross revenue as a percent of total gross revenue. However, RRCH will bill globally and includes “professional fees” which cover professional interpretation of MRI studies by radiologists as an expense line in their pro formas. DUHS does not bill for “professional fees” nor does DUHS include an expense line in its pro formas for professional fees. These differences in billing, which impact revenue (both gross and net) and expenses, does not allow for a comparison between the applications. Furthermore, NCIC does not comply with all applicable statutory and regulatory criteria and therefore NCIC is not approvable. Thus, RRCH cannot be an effective alternative regarding access for Medicare patients.

For these reasons, **DUHS** is the more effective alternative regarding access for Medicare patients.

Projected Medicaid

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for each of the applicants.

Applicant	Gross Revenue	MRI Scans (Unweighted)	Medicaid Gross Revenue	Medicaid Gross Revenue as a % of Total Gross Revenue	Medicaid/MRI Scan	Medicaid MRI Procedures as a % of Total MRI Procedures	Medicaid MRI Procedures
RRCH	\$8,443,087	4,471	\$415,215	4.92%	\$93	4.90%	219
NCIC	\$20,958,410	4,684	\$1,667,614	7.96%	\$356	8.00%	375
DUHS	\$4,708,917	4,310	\$258,820	5.50%	\$60	5.50%	237

Source: Form C, Section L.3, and Form F.2 of the respective applications

Regarding NCIC’s projected Medicaid payor mix, application page 104 states, “*payor mix for the proposed fixed MRI scanner is based on the SFY 2021 payor mix for outpatient MRI services at UNC Hospitals Hillsborough Campus.*” However, NCIC’s assumption is unreasonable. Specifically, as set forth above, the payor mix for a hospital population that includes emergency department patients will be very different than the payor mix for a freestanding, off-campus facility several miles away. Using “all” outpatient MRI procedures at the Hillsborough campus to project payor mix at the new facility is not a reasonable proxy. Therefore, NCIC’s Medicaid MRI procedures are not supported and cannot be an effective alternative.

NCIC proposes the highest Medicaid gross revenue as a percent of total gross revenue and the highest Medicaid revenue per MRI procedure. However, as previously stated, the assumptions for Form F.2b state projected gross charges were based on “*UNC’s FY2021 experience with outpatient MRIs at the UNC Hospitals Hillsborough Campus.*” It is illogical to base projected gross charges for a freestanding fixed MRI service based on a related entity’s experience providing hospital-based fixed MRI services. NCIC had access to it related entity’s experience providing freestanding fixed MRI services (*i.e.*, Wake Radiology

UNC REX – Chapel Hill), but opted to ignore it. Instead, NCIC assumed projected payor mix and gross charges that are comparable to hospital-based charges instead of freestanding charges. Such assumptions are unrealistic and result in grossly overstated Medicaid revenues and Medicaid MRI procedures for NCIC's proposed fixed MRI service. Furthermore, NCIC does not comply with all applicable statutory and regulatory criteria and therefore NCIC is not approvable. Therefore, NCIC cannot be an effective alternative for this comparative factor.

RRCH will bill globally and includes "professional fees" which cover professional interpretation of MRI studies by radiologists as an expense line in their pro formas. DUHS does not bill for "professional fees" nor does DUHS include an expense line in its pro formas for professional fees. These differences in billing, which impact revenue (both gross and net) and expenses, does not allow for a comparison between the applications. RRCH projects to serve the lowest number of Medicaid MRI procedures Thus, RRCH cannot be an effective alternative regarding access for Medicaid patients.

As described in its application, DUHS's payor mix assumptions and financial projections were closely tied to the patients that it already served from the service area. DUHS projects to serve the second highest number of Medicaid MRI patients among the competing applicants. Therefore, **DUHS** is the more effective alternative regarding access for Medicaid patients.

Competition (Access to a New or Alternate Provider)

UNC is an existing provider of MRI services in Orange County. In addition, UNC via a related entity has existing MRI capacity on an existing freestanding fixed MRI scanner. See comments regarding NCIC and Criterion 3. RRCH and DUHS do not currently provide fixed MRI services in Orange County. However, the application submitted by RRCH is not conforming with all applicable statutory and regulatory review criteria. An application that is not conforming to all applicable statutory and regulatory review criteria cannot be approved. Therefore, regarding this comparative factor, the application submitted by **DUHS** is the most effective alternative.

Projected Average Net Revenue per MRI Procedure

The following table shows the projected average net revenue per procedure in the third year of operation for each applicant, based on the information provided in the applicants’ pro forma financial statements (Section Q). Generally, the application proposing the lowest average net revenue is the more effective alternative regarding this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

Applicant	Net Revenue	MRI Scans (Unweighted)	Average Net Revenue per MRI Procedure
RRCH	\$2,096,210	4,471	\$469
NCIC	\$3,060,935	4,684	\$653
DUHS	\$2,433,066	4,310	\$565

Source: Form C and Form F.2 of the respective applications

NCIC proposes the highest the highest net revenue per MRI procedure. However, NCIC does not comply with all applicable statutory and regulatory criteria and therefore NCIC is not approvable. Furthermore, the assumptions for Form F.2b state projected gross charges were based on “*UNC’s FY2021 experience with outpatient MRIs at the UNC Hospitals Hillsborough Campus.*” It is illogical to base projected gross charges for a freestanding fixed MRI service based on a related entity’s experience providing hospital-based fixed MRI services. NCIC had access to it related entity’s experience providing freestanding fixed MRI services (*i.e.*, Wake Radiology UNC REX– Chapel Hill), but opted to ignore it. Instead NCIC assumed projected gross charges that are comparable to hospital-based charges instead of freestanding charges. This is unrealistic and results in overstated gross and net revenues for NCIC’s proposed fixed MRI service.

RRCH will bill globally and includes “professional fees” which cover professional interpretation of MRI studies by radiologists as an expense line in their pro formas. DUHS does not bill for “professional fees” nor does DUHS include an expense line in its pro formas for professional fees. These differences in billing, which impact revenue (both gross and net) and expenses, does not allow for a comparison between the applications. Thus, the result of this analysis is inconclusive.

Projected Average Total Operating Cost per MRI Procedure

The following table compares the projected average operating expense per MRI procedure for the third year of operation following project completion for each applicant, based on the information provided in the applicants’ pro forma financial statements (Section Q).

Applicant	Operating Expense	MRI Scans (Unweighted)	Average Operating Expense per MRI Procedure
RRCH	\$1,842,566	4,471	\$412
NCIC	\$2,645,982	4,684	\$565
DUHS	\$1,428,780	4,310	\$332

Source: Form C and Form F.3 of the respective applications

RRCH will bill globally and includes “professional fees” which cover professional interpretation of MRI studies by radiologists as an expense line in their pro formas. DUHS does not bill for “professional fees” nor does DUHS include an expense line in its pro formas for professional fees. These differences in billing, which impact revenue (both gross and net) and expenses, does not allow for a comparison between the applications. Thus, the result of this analysis is inconclusive.

Summary

The following table lists the comparative factors and indicates whether each application was more effective, less effective, or equally effective for each factor.

Comparative Factor	RRCH	NCIC	DUHS
Conformity with Review Criteria	No	No	Yes
Scope of Services	Not Approvable	Not Approvable	More Effective
Historical Utilization	Not Approvable	Not Approvable	More Effective
Geographic Accessibility	Not Approvable	Not Approvable	More Effective
Access by Service Area Residents	Not Approvable	Least Effective	More Effective
Access by Charity Care Patients	Not Approvable	Not Approvable	More Effective
Access by Medicare Patients	Not Approvable	Not Approvable	More Effective
Access by Medicaid Patients	Not Approvable	Not Approvable	More Effective
Competition (Access to New or Alternative Provider)	Not Approvable	Least Effective	More Effective
Projected Average Net Revenue per MRI procedure	Inconclusive	Inconclusive	Inconclusive
Projected Average Operating Expense per MRI procedure	Inconclusive	Inconclusive	Inconclusive

The DUHS application is conforming to all applicable statutory and regulatory review criteria, and thus the application is approvable standing alone. In addition, for each of the comparative factors previously discussed, DUHS's application is determined to be the more effective alternative with the following comparative metrics:

- Conformity with Review Criteria
- Access by Service Area Residents: Number of Residents
- Access by Service Area Residents: Percentage of Residents
- Access by Medicare Patients
- Access by Medicaid Patients
- Projected Average Net Revenue per MRI procedure
- Projected Average Total Operating Cost per MRI Procedure

**COMMENTS SPECIFIC TO RR WM Imaging Chapel Hill, LLC (RRCH)
PROJECT ID No. J-012141-21**

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

POLICY GEN-3: BASIC PRINCIPLES states:

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

RRCH fails to conform with Criterion 1 and Policy GEN-3 because the application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. See discussion regarding Criteria 3, 4, 5, 6, 12, and 18a. Therefore, the application is nonconforming to this criterion and cannot be approved.

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

Projected Patient Origin

In Section C.3 (CON application page 37), RRCH projects 1,476, or 33% of its MRI patients, will originate from outside the MRI service area in Project Year 3. However, this assumption is not supported by Raleigh Radiology’s experience providing MRI services. Furthermore, the assumption is inconsistent with patient origin assumptions for RRCH’s approved diagnostic center (Project ID #J-12062-21).

On CON application page 127, RRCH assumes *“[T]hirty-three percent in-migration is reasonable and conservative compared to other Orange County providers.”* However, other Orange County providers are not comparable to RRCH’s proposed MRI service. UNC Health owns and operates nine fixed MRI scanners under the UNC Hospitals license. UNC Hospitals is a tertiary and quaternary academic medical center and teaching hospital. The in-migration patterns for UNC Health’s existing hospital-based fixed MRI scanners

are not a reasonable proxy for assessing the reasonableness of RRCH's projected MRI in-migration. Simply asserting that a lower in-migration percentage compared to UNC Health's existing hospital based fixed MRI scanners is insufficient to demonstrate the reasonableness of a 33% in-migration assumption.

Wake Radiology UNC Rex – Chapel Hill operates one freestanding fixed MRI scanner in Chapel Hill. According to the 2021 SMFP, this facility provided only 1,413 fixed MRI procedures. This small sample size is not a comparable proxy for assessing the reasonableness of RRCH's projected MRI in-migration. Indeed, RRCH opines on application page 84 that the provider *"appears to have capacity issues."* Furthermore, Wake Radiology UNC Rex – Chapel Hill is owned in part by UNC Health. UNC REX Healthcare³ and Wake Radiology announced plans in 2017 to form a joint venture (Wake Radiology UNC REX Healthcare) that would combine their outpatient imaging services. That partnership became official on February 23, 2019.⁴ Wake Radiology UNC REX Healthcare now operates Wake Radiology UNC Rex – Chapel Hill. Thus, Wake Radiology UNC Rex – Chapel Hill is an extension of UNC Health, and its large percentage of in-migration is consistent with the high percentage of in-migration for the existing hospital-based MRI scanners of UNC Health.

RRCH's projected in-migration is significantly higher compared to Raleigh Radiology's experience providing MRI services. RRCH application page 36 states, *"Wake County, similar to Orange, has a high concentration of physician specialists and is a medical referral center. Raleigh Radiology MRI locations Wake County averaged 19.3 percent in-migration from outside Wake County for that same four-year period."* RRCH elected to ignore its own MRI experience and instead select an arbitrary in-migration percentage that is over 70% higher than its historical in-migration.

RRCH did not provide reasonable physician support for its patient origin projections. All of its physician letters come from practices in Durham and Wake County, and do not reference any significant Orange County patient volume. Notably, Durham and Wake County have significant MRI capacity and RRCH does not document any reason why patients would travel from Durham and Wake County to Orange County for the proposed services.

RRCH's projected MRI in-migration is also markedly higher compared to the projected in-migration for its approved diagnostic modalities. Application page 38 provides RRCH's projected patient origin for the entire facility, which includes MRI, X-ray, ultrasound, bone density, and mammography. See also the following table.

³ UNC Rex Healthcare is part of UNC Health Care. UNC Health Care comprises UNC Hospitals and its provider network, the clinical programs of the UNC School of Medicine, and nine hospitals across the State including UNC REX.
<https://www.rexhealth.com/rh/about/collaboration-within-unc-health-care/>

⁴ <https://www.wakerad.com/feature-stories/partnership/>

Entire Facility or Campus	<Raleigh Radiology Chapel Hill > *					
	1 st Full FY		2 nd Full FY		3 rd 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	6,590	86.4%	8,748	85.1%	10,781	85.1%
Out-of-Area	1,036	13.6%	1,480	14.9%	1,886	14.9%
Total	7,626	100%	9,958	100%	12,666	100%

Source: RRCH application page 38

Notably, projected in-migration for the entire RRCH facility is only 14.9% during the third project year, which is less than half of its projected MRI in-migration during the same period. This is because RRCH projected only 5% in-migration in its approved diagnostic center application. The table below summarizes RRCH’s projected patient origin for X-ray, ultrasound, bone density, and mammography in Project ID #J-12062-21.

**Projected Patient Origin, Raleigh Radiology Chapel Hill
 X-ray, Ultrasound, Bone Density, Mammography**

County	1 ST FULL FY (CY 2023)		2 ND FULL FY (CY 2024)		3 RD FULL FY (CY 2025)	
	# Pts.	% OF TOTAL	# Pts.	% OF TOTAL	# Pts.	% OF TOTAL
Orange	5,023	95%	6,126	95%	7,785	95%
Other*	264	5%	322	5%	410	5%
Total	5,287	100.0%	6,449	100.0%	8,194	100.0%

*The applicant states “other” includes all other North Carolina counties and other states

Source: Agency Findings Project ID #J-12062-21, page 3

The Agency Findings for Project ID #J-12062-21 state the diagnostic center projected patient origin is reasonable because it is “based on the historic patient origin for other diagnostic centers operated by RRA physicians in the area.” RRCH provides no explanation why in-migration for MRI services will be dramatically different compared to in-migration for X-ray, ultrasound, bone density, and mammography.

For the foregoing reasons, RRCH’s projected in-migration is unreasonable and not supported. Consequently, RRCH failed to adequately identify the population to be served by the proposed project.

Assumptions & Methodology for Projecting MRI Procedures

RRCH does not adequately demonstrate that projected utilization is reasonable and adequately supported.

Market Share Projections

RRCH’s MRI market share projections included in Section Q, Form C assumptions and methodology are not reasonable or supported. On application page 125, RRCH states it assumes it will attain 12% market share in Project Year 1, 17% market share in Project Year 2, and 23% market share in Project Year 3. RRCH opines a market share of 23% in Project Year 3 is reasonable because it “*accommodates less than one in four of MRI scans needed by Orange County residents at RRCH.*” However, RRCH proposes to develop a fixed MRI scanner that would reflect one in 11 fixed MRI scanners in Orange County, or 9% of the fixed MRI inventory during Project Year 3. At the same time, RRCH provides no physician support from Orange County. Thus, RRCH’s market share assumption is arbitrary and not supported.

Furthermore, Raleigh Radiology’s historical data fails to support RRCH’s aggressive market share projections. Application page 36 states, “[I]nternal records show that Raleigh Radiology regularly serves patients from Orange, Alamance, Chatham, and Durham counties; together, almost 700 patients from these counties in 2020.” RRCH did not identify how many patients were served from each of the identified counties, thus, it is impossible to evaluate the extent to which Raleigh Radiology currently provides MRI services to Orange County residents.

On application page 125, RRCH asserts its projected MRI market share is reasonable because “*more than 40 percent of reported Orange County residents go out of county for MRI services.*” However, 90% of Orange County residents leaving the county travel to Durham County for MRI services.

**Orange County MRI Patients
County Destination of Service, FY2019**

County of Service	MRI Patients	% of Total
Orange	5,541	58.4%
Durham	3,538	37.3%
Wake	250	2.6%
Other	165	1.7%
Total	9,494	100.0%

Source: DHSR Healthcare Planning MRI Patient Origin Report, FY2019 data

The majority of Orange County residents that travel to Durham County utilize DUHS MRI services.

**Orange County MRI Patients
 County Destination of Service: Durham County, FY2019**

Facility of Service	MRI Patients	% of Total Orange County Residents Traveling to Durham County
DUH	1,799	50.8%
DRH	546	15.4%
Other	1,193	33.7%
Total	3,538	100.0%

Source: DHSR Healthcare Planning MRI Patient Origin Report, FY2019 data

As shown in the previous tables, DUHS serves the majority share of Orange County residents leaving the county for MRI services. This share is supported by Duke Health physicians who typically refer to DUHS for imaging services. The notion that RRCH will achieve 23% market share during its third project year, or 3,074 fixed MRI procedures, is not supported by Orange County out-migration patterns because there is insufficient outmigration MRI volume outside of the DUHS network. RRCH’s own experience shows that patients leaving Orange County are not choosing Raleigh Radiology services in significant numbers, and there is no basis for assuming they will do so in the future.

Furthermore, RRCH’s MRI market share projections are vastly higher compared to its market share projections for its X-ray, ultrasound, bone density, and mammography services. In Project ID #J-12062-21, RRCH projected no more than 15% market share during Project Year 3 as shown in the following table.

RRCH Projected Market Share, 2022-2055

Modality	2022	2023	2024	2025
X-ray	5%	10%	12%	15%
Ultrasound	5%	10%	12%	15%
Bone Density	5%	5%	5%	5%
Mammogram	5%	10%	12%	15%

Source: Agency Findings, Project ID #J-12062-21

RRCH’s projected MRI market shares are inconsistent and substantially higher compared to the market share projections for its other diagnostic imaging services. RRCH failed to address these discrepancies despite numerous references to its approved diagnostic center application throughout the instant application.

DUHS notes its proposed fixed MRI scanner will developed in an approved diagnostic center (Project ID #J-12001-20). Unlike RRCH, DUHS’s utilization for the proposed fixed MRI scanner is based on a shift of its existing base of Orange and Alamance County MRI patients. Thus, DUHS’s assumptions are rooted in historical experience and reasonably supported.

Finally, the RRCH application lacked sufficient documentation to support its market share projections. Specifically, the RRCH application included zero letters of support from Orange County physicians. Exhibit

I.1 of the RRCH application contains only 23 letters from physicians, all of whom are located in Durham or other counties. The following table summarizes the RRCH letters of support and the locations of the physician practices.

Practice	# of Physician Letters	Address	County
Bull City Family Medicine and Pediatrics	2	4003 N Roxboro St, Durham, NC 27704	Durham County
Central Carolina Orthopaedic	1	1139 Carthage St #101, Sanford, NC 27330	Lee County
Garlick and Murray Family Medicine	1	200 E Salisbury St, Pittsboro, NC 27312	Chatham County
Imperial Center Family Medicine	7	4309 Emperor Blvd #125, Durham, NC 27703	Durham County
Shanahan Rheumatology & Immunotherapy	1	2222 E, NC-54 #200, Durham, NC 27713	Durham County
WakeMed Primary Care - Brier Creek	10	8001 TW Alexander Dr #216, Raleigh, NC 27617	Wake County
Avance Health Care, Durham	1	1821 Martin Luther King Jr. Pkwy. Durham, NC 27707	Durham County

Source: RRCH application, Exhibit I.1

As shown in the previous table, RRCH failed to obtain documentation from a single physician located in Orange County. RRCH lacks an established history of attracting and treating patients from Orange County. RRCH lacks evidence of sufficient support from potential referral sources treating Orange County patients. Patients do not self-refer for MRI services (unlike for screening mammography, for example) but instead are reliant on physician referrals. Therefore, without any documented physician support from the service area, RRCH failed to reasonably or adequately demonstrate it can achieve 23% MRI market share during the third year following completion of its proposed project.

For these reasons, the RRCH failed to furnish sufficient information in its application, as submitted, to allow the Project Analyst to conclude that its MRI market share projections are reasonable and adequately supported. Consequently, the application does not conform to Criterion 3.

MRI In-Migration

As previously described, in Section C.3 (CON application page 37), RRCH projects 1,476 patients will originate from outside the MRI service area in Project Year 3. This projection is based on RRCH's assumption that 33 percent of its MRI patients will originate from outside the MRI service area. However, this assumption is not supported by Raleigh Radiology's experience providing MRI services. Specifically,

- The in-migration patterns for Orange County's existing fixed MRI scanners are not a reasonable proxy for assessing the reasonableness of RRCH's projected MRI in-migration.
- RRCH does not provide physician support for such significant in-migration volume.

- RRCH’s projected in-migration is significantly higher compared to Raleigh Radiology’s experience providing MRI services.
- RRCH’s projected MRI in-migration is also markedly higher compared to the projected in-migration for its approved diagnostic modalities (Project ID #J-12062-21).
- See previous discussion regarding projected patient origin.

MRI in-migration is a critical assumption in RRCH’s methodology because without it, RRCH fails to reach the minimum performance standard outlined in 10A NCAC 14C .2703. Please see the following table.

RRCH Projected MRI Procedures & Patient Origin, Project Year 3

	Unweighted MRI Scans	Adjusted (Weighted) MRI Scans*
Orange County	2,996	3,436
In-Migration (33%)	1,476	1,693
Total	4,587	5,128

* Adjusted (weighted) MRI procedures are based on RRCH’s assumption that 36.7% of procedures will have contrast with a weighting factor of 1.4.

Source: RRCH application page 128-129

As shown above, RRCH must utilize an in-migration percentage that is higher than its historical experience providing MRI services. RRCH application page 36 states, “Wake County, similar to Orange, has a high concentration of physician specialists and is a medical referral center. Raleigh Radiology MRI locations Wake County averaged 19.3 percent in-migration from outside Wake County for that same four-year period.” Based on RRCH’s MRI methodology and assumptions, RRCH had to select in-migration percentage that is over 70% higher than its historical in-migration to reach the minimum performance standard of 4,805 weighted MRI procedures during Project Year 3. However, for the reasons previously stated, an in-migration percentage of 33% is not supported.

For these reasons, the RRCH failed to furnish sufficient information in its application, as submitted, to allow the Project Analyst to conclude that its projected MRI procedures are reasonable and adequately supported. Consequently, the application does not conform to Criterion 3.

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

RRCH is nonconforming with at least the following statutory review criteria: Criteria 1, 3, 5, 6, and 18a. See these Criteria for discussion. Therefore, RRCH failed to adequately demonstrate that its proposal is an effective alternative for development of a fixed MRI scanner in Orange County. Consequently, the RRCH application is nonconforming to Criterion 4.

Criterion 5 “Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal,

based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”

RRCH failed to adequately demonstrate the need for the proposed services (See Criterion 3).

Form F.1.a failed to include any expense for furniture or non-medical equipment. As discussed in these comments under Criterion 12, RRCH identified only 831 square feet for the proposed MRI scanner equipment. The applicant did not identify or allocate any space for administrative or support services. Furthermore, the electronic copy of the application failed to include a legible line drawing for MRI scanner and support spaces. See Exhibit K.2.

RRCH proposes to develop the fixed MRI scanner within the diagnostic center proposed in Project ID #J-12062-21, which was conditionally approved but under appeal. Thus, RRCH has not yet received a CON to develop the diagnostic center where it proposes to locate the fixed MRI scanner. Furniture and non-medical equipment are necessary to operate a fixed MRI service. Failure to include these necessary expenses results in insufficient capital cost to make the proposed fixed MRI service operational.

For these reasons, the RRCH application fails to provide reasonable and adequately supported assumptions for its financial and operational projections and, as a result, fails to demonstrate conformity with Criterion 5.

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

RRCH failed to adequately demonstrate the need for the proposed services (See Criterion 3). Therefore, RRCH failed to adequately demonstrate that its proposal will not result in an unnecessary duplication of existing or approved MRI services and is nonconforming to this criterion.

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

As shown in Section K.2, RRCH identified only 831 square feet for the proposed MRI scanner. The applicant did not identify or allocate any space for administrative or support services. RRCH proposes to develop the fixed MRI scanner within the diagnostic center proposed in Project ID #J-12062-21, which was conditionally approved but under appeal. Thus, RRCH has not yet received a CON to develop the diagnostic center where it proposes to locate the fixed MRI scanner. Administrative and support spaces are necessary to operate a fixed MRI service. Failure to include or allocate a portion of these necessary spaces results in underestimated capital costs for construction/renovation. Furthermore, Exhibit K.2 contains a line drawing for a mobile MRI pad. The electronic copy of the application failed to include a legible line drawing for MRI scanner and support spaces.

For these reasons, the application does not conform to Criterion 12.

Criterion 18a *“The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.”*

Based on the facts which result in RRCH being non-conforming with Criteria 1, 3, 4, 5, 6, and 12 RRCH should also be found non-conforming with Criterion 18a.

N.C. Gen. Stat. §131E-183(b)

CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

10A NCAC 14C .2703

Based on the same facts that cause RRCH to fail to conform with Criterion 3 it should also be found non-conforming with the criteria and standards for MRI scanners, specifically 10A NCAC 14C .2703.

**COMMENTS SPECIFIC TO NC IMAGING CENTERS, LLC (NCIC)
PROJECT ID No. J-12145-21**

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

POLICY GEN-3: BASIC PRINCIPLES states:

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

NCIC fails to conform with Criterion 1 and Policy GEN-3 because the application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. See discussion regarding Criteria 3, 4, 5, 6, and 18a. Therefore, the application is nonconforming to this criterion and cannot be approved.

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

Population to be Served

NCIC proposes to develop a fixed MRI scanner in Chapel Hill to serve patients that have been historically served at UNC Hospitals Hillsborough Campus. As described on application page 39, *“projected MRI utilization for the proposed UNC Health Imaging Center is based on a shift of MRI patients from the UNC Hospitals Hillsborough Campus to the new freestanding MRI scanner. As such, patient origin for patients projected to receive MRI scans using the proposed fixed MRI scanner is based on the CY 2020 patient origin for outpatient MRI services at UNC Hospitals Hillsborough Campus.”* The proposed fixed MRI scanner will be developed in Chapel Hill, approximately seven miles from the UNC Hospitals Hillsborough Campus. NCIC failed to adequately demonstrate why patients historically served at UNC Hospitals Hillsborough (located in Hillsborough) need a fixed MRI scanner in Chapel Hill, in addition not only to UNC’s hospital-based scanners at two locations but also to the existing freestanding fixed MRI scanner located in Chapel Hill which a related entity owns and operates. NCIC does not project to decant any procedure volume

from UNC's Chapel Hill-based MRI scanners. Thus, the proposed project relies solely on a shift of UNC Hospitals Hillsborough patient volume. UNC Hospitals Hillsborough patients already have access to a freestanding fixed MRI scanner in UNC's network in Chapel Hill at Wake Radiology UNC REX Healthcare - Chapel Hill, which has ample capacity.⁵ According to the 2021 SMFP, during FY2019 the fixed MRI scanner located at Wake Radiology UNC REX Healthcare - Chapel Hill performed 1,646 weighted MRI procedures. NCIC failed to demonstrate why it is reasonable to assume UNC Hospitals Hillsborough patient utilization patterns will change as a result of the proposed project when these patients do not access the existing freestanding fixed MRI scanner in Chapel Hill.

Application page 39 states, "*patient origin for patients projected to receive MRI scans using the proposed fixed MRI scanner is based SFY 2020 patient origin for outpatient MRI services at UNC Hospitals Hillsborough Campus.*" NCIC's patient origin assumptions are not supported because NCIC's assertion that this project will serve patient volume shifted from Hillsborough is not reasonable. NCIC has not proposed to locate the new scanner proximate to the Hillsborough campus where it would likely serve the same patient population, instead choosing to locate it close to UNC's Chapel Hill scanners. Given that UNC's MRI patient origin for all scanners in Orange County is highly skewed to patients traveling from other counties, it appears that NCIC's focus on only one of its 11 scanners – and ignoring the patient origin experience of the freestanding MRI operated by its affiliate Wake Radiology UNC Rex Healthcare – Chapel Hill – to generate patient origin projections is simply an attempt to position NCIC more favorably in a comparative analysis on such criteria as the number of patients served from the service area. If NCIC were truly seeking to serve the population identified by projected patient origin and stated need, it fails to address why a Hillsborough location would not be a more effective option.

Need for Proposed Fixed MRI Scanner

NCIC failed to demonstrate the need it has for the proposed fixed MRI scanner in addition to the existing fixed MRI scanners owned by the applicant and related entities. The term "related entity," which is defined in 10A NCAC 14C .0202(10), means "*a person that:*

- (a) shares the same parent corporation or holding company with the applicant;*
- (b) is a subsidiary of the same parent corporation or holding company as the applicant; or*
- (c) participates with the applicant in a joint venture that provides the same type of health services proposed in the application."*

The parent company of NCIC is The University of North Carolina Health System d/b/a UNC Health. See application page 16. UNC Health wholly owns UNC REX Healthcare.⁶ UNC REX Healthcare and Wake Radiology announced plans in 2017 to form a joint venture (Wake Radiology UNC REX Healthcare) that would combine their outpatient imaging services. That partnership became official on February 23, 2019.⁷ Wake Radiology UNC REX Healthcare now operates Wake Radiology UNC REX – Chapel Hill. Thus,

⁵ Wake Radiology UNC Rex Healthcare – Chapel Hill is located at 110 S Estes Dr, Chapel Hill, NC 27514. According to the 2021 SMFP, during FY2019 the fixed MRI scanner performed 1,646 weighted MRI procedures.

⁶ UNC Rex Healthcare is part of UNC Health Care. UNC Health Care comprises UNC Hospitals and its provider network, the clinical programs of the UNC School of Medicine, and nine hospitals across the State including UNC REX.

<https://www.rexhealth.com/rh/about/collaboration-within-unc-health-care/>

⁷ <https://www.wakerad.com/feature-stories/partnership/>

consistent with the definition of related entity described in 10A NCAC 14C .0202(10), Wake Radiology UNC REX– Chapel Hill is a related entity of UNC Health.

NCIC attempts to distance itself from Wake Radiology UNC REX – Chapel Hill, referring to the facility as “Wake Radiology Chapel Hill” and omitting the “UNC REX” piece of the facility name. This appears to be a deliberate attempt to deflect attention from the relationship between UNC Health and Wake Radiology UNC REX – Chapel Hill because the Wake Radiology UNC REX – Chapel Hill fixed MRI scanner is underutilized. As previously described, NCIC failed to demonstrate why it is reasonable to assume UNC Hospitals Hillsborough patient utilization patterns will change as a result of the proposed project when these patients do not access the existing Wake Radiology UNC REX – Chapel Hill freestanding fixed MRI scanner in Chapel Hill. Consequently, the applications utilization projected are not supported.

Access for Underserved Patients

NCIC’s assumptions for Form F.2b state projected gross charges were based on “UNC’s FY2021 experience with outpatient MRIs at the UNCHospitals Hillsborough Campus.” However, it is counterintuitive for NCIC to base projected gross charges for a freestanding fixed MRI service based on a related entity’s experience providing hospital-based fixed MRI services. NCIC had access to it related entity’s experience providing freestanding fixed MRI services (*i.e.*, Wake Radiology UNC REX – Chapel Hill), but opted to ignore it. Instead NCIC assumed projected gross charges that are comparable to hospital-based charges instead of freestanding charges. This results in higher MRI charges for individuals that have no insurance or are underinsured. Please see the following table which summarizes average gross charge per procedure.

Applicant	Gross Revenue Form F.2.b	MRI Scans (Unweighted) Form C	Average Gross Charge per MRI Procedure
Raleigh Radiology	\$8,443,087	4,471	\$1,888
UNC	\$20,958,410	4,684	\$4,474
DUHS	\$4,708,917	4,310	\$1,093

Source: CON Applications, Form F.2.b

As shown in the previous table, using hospital-based charges as a proxy for NCIC’s freestanding fixed MRI services effectively restricts access for medically underserved patients.

Based on the foregoing reasons, the NCIC application does not conform to Criterion 3.

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

NCIC is nonconforming with at least the following statutory review criteria: Criteria 1, 3, 5, 6, and 18a. See these Criteria for discussion. Therefore, NCIC failed to adequately demonstrate that its proposal is an effective alternative for development of a fixed MRI scanner in Orange County.

Additionally, NCIC proposes to develop a fixed MRI scanner in Chapel Hill to serve only those patients that have been historically served at UNC Hospitals Hillsborough Campus. NCIC’s proposed fixed MRI scanner will be developed in Chapel Hill, approximately seven miles from the UNC Hospitals Hillsborough Campus. NCIC failed to adequately demonstrate why patients historically served at UNC Hospitals Hillsborough (located in Hillsborough) need a fixed MRI scanner in Chapel Hill in addition to the existing freestanding fixed MRI scanner located in Chapel Hill which a related entity owns and operates. Therefore, NCIC failed demonstrate the most effective alternative has been proposed.

Consequently, the NCIC application is nonconforming to Criterion 4.

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

The assumptions used by NCIC in preparation of the pro forma financial statements are not reasonable and adequately supported because projected utilization is not supported. The discussion regarding projected utilization found in Criterion 3 is incorporated herein by reference. Therefore, since projected revenues and expenses are based on projected utilization, projected revenues and expenses are also unsupported. As a result, NCIC fails to demonstrate conformity with Criterion 5.

In addition, NCIC did not identify any rental expense in its start-up costs. See application page 80. As described on application page 35, NCIC will lease space to operate the proposed fixed MRI scanner. Application page 81 states start-up costs were calculated based on 30 days of supplies, utilities, salaries and benefits. Section F.3.b did not identify rent in the applicant’s startup costs. Therefore, total working capital is underestimated.

NCIC’s assumptions for Form F.2b state projected gross charges were based on *“UNC’s FY2021 experience with outpatient MRIs at the UNCHospitals Hillsborough Campus.”* However, it is illogical to base projected gross charges for a freestanding fixed MRI service based on a related entity’s experience providing hospital-based fixed MRI services. NCIC had access to it related entity’s experience providing freestanding fixed MRI services (*i.e.*, Wake Radiology UNC REX – Chapel Hill), but opted to ignore it. Instead NCIC assumed projected gross charges that are comparable to hospital-based charges instead of freestanding charges. This is unrealistic and results in grossly overstated revenues for NCIC’s proposed fixed MRI service. Please see the following table which summarizes average gross charge per procedure.

Applicant	Gross Revenue Form F.2.b	MRI Scans (Unweighted) Form C	Average Gross Charge per MRI Procedure
Raleigh Radiology	\$8,443,087	4,471	\$1,888
UNC	\$20,958,410	4,684	\$4,474
DUHS	\$4,708,917	4,310	\$1,093

Source: CON Applications, Form F.2.b

The assumptions used by NCIC in preparation of the pro forma financial statements are not reasonable and adequately supported. Therefore, projected revenues and expenses are unsupported. As a result, NCIC fails to demonstrate conformity with Criterion 5.

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

NCIC failed to adequately demonstrate the need for the proposed services (See Criterion 3). Therefore, NCIC failed to adequately demonstrate that its proposal will not result in an unnecessary duplication of existing or approved MRI services and is nonconforming to this criterion.

Additionally, NCIC failed to demonstrate the need it has for the proposed fixed MRI scanner in addition to the existing fixed MRI scanners owned by the applicant and related entities. The term “related entity,” which is defined in 10A NCAC 14C .2701(16), means “the parent company of the applicant, a subsidiary company of the applicant (i.e., the applicant owns 50 percent or more of another company), a joint venture in which the applicant is a member, or a company that shares common ownership with the applicant (i.e., the applicant and another company are owned by some of the same persons).

The parent company of NCIC is The University of North Carolina Health System d/b/a UNC Health. See application page 16. UNC Health wholly owns UNC REX Healthcare.⁸ Accordingly, NCIC and UNC Rex Healthcare share common ownership. UNC REX Healthcare and Wake Radiology announced plans in 2017 to form a joint venture (Wake Radiology UNC REX Healthcare) that would combine their outpatient imaging services. That partnership became official on February 23, 2019.⁹ That announcement specifically includes reference to the facility now operated by Wake Radiology UNC REX Healthcare now operates Wake Radiology UNC REX – Chapel Hill. Thus, consistent with the definition of related entity described in 10A NCAC 14C .2701(16), Wake Radiology UNC REX – Chapel Hill is a related entity of UNC Health. According to the 2021 SMFP, during FY2019 the fixed MRI scanner performed only 1646 weighted procedures. Similarly, according to the facility’s 2021 equipment registration form, it performed only 2125 procedures in FY 2020, demonstrating ongoing underutilization and excess capacity.

For the sake of argument, even if Wake Radiology UNC Rex were not technically considered a “related party” for purposes of the regulatory performance standards, it is clear that these providers hold Wake Radiology UNC Rex out to the public as part of the UNC network, and the existing capacity at that facility is directly relevant to the consideration of the unnecessary duplication of services in the UNC imaging network created by UNC’s project.

As described previously, NCIC failed to demonstrate why it is reasonable to assume UNC Hospitals Hillsborough patient utilization patterns will shift as a result of the proposed project when these patients do not access the existing freestanding “UNC Rex” fixed MRI scanner in Chapel Hill. Therefore, UNC’s proposed project would unnecessarily duplicate existing capacity in the identified service area. Consequently, the application does not conform to Criterion 6.

⁸ UNC Rex Healthcare is part of UNC Health Care. UNC Health Care comprises UNC Hospitals and its provider network, the clinical programs of the UNC School of Medicine, and nine hospitals across the State including UNC REX.
<https://www.rexhealth.com/rh/about/collaboration-within-unc-health-care/>

⁹ <https://www.wakerad.com/feature-stories/partnership/>

Criterion 18a *“The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.”*

Based on the facts which result in NCIC being non-conforming with Criteria 1, 3, 4, 5, and 6 it should also be found non-conforming with Criterion 18a.

N.C. Gen. Stat. §131E-183(b)

CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

10A NCAC 14C .2703

Based on the facts which result in NCIC being non-conforming with Criterion 3, it should also be found non-conforming with the criteria and standards for MRI scanners, specifically 10A NCAC 14C .2703.

Attachment 1

Wake Radiology and UNC REX Healthcare Formally Launch Partnership for Medical Imaging

February 25, 2019

Subjects: General News

*New joint
venture
improves
access to
specialized
imaging
services,
reduces costs*



for patients

RALEIGH, N.C. – Feb. 25, 2019 – UNC REX Healthcare and Wake Radiology are joining forces to improve access to specialized imaging services and reduce costs for thousands of patients a year.

The two organizations announced plans in 2017 to form a joint venture that would combine their outpatient imaging services. That partnership becomes official as of February 23. Wake Radiology UNC REX Healthcare will now operate 14 outpatient imaging offices in communities throughout the greater Triangle area, with plans for future expansion.

Most locations will provide comprehensive, diagnostic imaging services such as MRIs, CT scans, X-rays, ultrasounds and more — greatly expanding access to advanced medical imaging in

an outpatient setting. All of the combined locations will also offer 3D mammography, an advanced technology for detecting breast cancer at its earliest possible stage.

For many patients, the partnership means they will no longer be required to go to the hospital for medical imaging that can be done in an outpatient setting. That shift will reduce patients' costs approximately \$7 million a year by eliminating hospital-based fees.

“We want to be a leader in value-based care and finding new ways to keep health-care costs down,” said Steve Burriss, president of UNC REX. “We believe that this partnership with Wake Radiology will bring great benefits for our patients and our community.”

Wake Radiology is the oldest and largest outpatient imaging provider in the Triangle. Its nearly 50 radiologists are organized in clinical teams trained in specific subspecialties such as breast imaging, sports and orthopedic imaging, interventional radiology and vein therapy, neuroradiology, pediatric imaging, and chest, abdomen and pelvis imaging.

The Wake Radiology UNC REX Healthcare partnership will improve the coordination and delivery of medical imaging services by providing faster access to imaging and reports desired by referring physicians, by reducing the need for duplicate exams, and by making outpatient imaging more convenient for patients.

“We are proud to partner with UNC REX to improve access to advanced diagnostic imaging for all patients in our area,” said Dr. Lyndon K. Jordan

III, President of Wake Radiology. “Our physicians and staff are excited to be a part of this partnership as we strive to enhance service through specialized radiology and value-based, compassionate care.”

Starting February 23, all patients who receive imaging at the partnership’s outpatient offices will now see Wake Radiology UNC REX Healthcare on all patient and provider correspondence. To schedule an appointment, call (919) 232-4700.

About UNC REX Healthcare

For 125 years, UNC REX Healthcare has provided expert care for the Wake County community and surrounding areas. With more than 7,000 co-workers, UNC REX is a private, not-for-profit health care system and is a member of UNC Health Care. UNC REX provides

various health care services throughout Wake County with facilities in Apex, Cary, Garner, Holly Springs, Knightdale, Wakefield and Raleigh. To learn more, [click here](#).

About Wake Radiology

Founded in 1953 by Albert M. Jenkins, MD, FACR, Wake Radiology is proud to be the oldest and largest outpatient imaging provider in the Triangle. Since then, Wake Radiology has expanded to include nearly 50 radiologists at multiple locations in Wake County and beyond. Wake Radiology has been first to introduce numerous methods of imaging as well as introducing subspecialized radiology to Wake County. To learn more, [click here](#).

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