DELIVERED VIA EMAIL

December 1, 2021

Ms. Lisa Pittman, Assistant Chief
Mr. Greg Yakaboski, Project Analyst
Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Comments on Competing Applications for a Certificate of Need for a fixed MRI scanner in Orange County, Health Service Area IV; CON Project ID Numbers:
J-012141-21, Raleigh Radiology Chapel Hill, LLC
J-012145-21, NC Imaging Centers, LLC
J-012155-21, Duke University Health System, Inc.

Dear Ms. Pittman and Mr. Yakaboski,

On behalf of Raleigh Radiology Chapel Hill, LLC, ("RRCH") Project ID J-012141-21, thank you for the opportunity to comment on the above referenced applications for a fixed MRI scanner in Orange County. During your review of the projects, I trust that you will consider these comments thoughtfully.

We believe that the applications submitted confirm and support RRCH as the most qualified applicant to address the identified need. Our reasons are detailed in the RRCH application and reiterated in this letter.

We understand that the State's Certificate of Need ("CON") award for the proposed fixed MRI scanner must be based upon the statutory criteria outlined in G.S 131E-183 and that the Agency has discretion in choice of comparative factors, when all applicants conform to the statutory criteria. In comparing the applications, we request that the Agency give careful consideration to the extent to which each applicant, not only meets all statutory review criteria, but also offers sustainable, cost-effective, high-value, quality, multi-specialty MRI imaging services easily accessible to the residents of Orange County and patients of Orange County and other nearby physicians who care for patients from places outside Orange County.

WHY APPROVE RALEIGH RADIOLOGY

Choice in the Market

RRCH submitted an application to acquire a fixed 1.5T MRI for its recently approved Chapel Hill diagnostic center (J-012062-21). If approved, RRCH will provide the **only non-UNC affiliated MRI scanner in Orange County**.

Currently, Orange County has only one freestanding outpatient MRI. As detailed in the RRCH MRI application, when freestanding outpatient MRI services are unavailable, high-cost, or in limited supply locally, patients may be forced to use the nearest hospital-based diagnostic imaging, even if the procedure is clinically appropriate for a freestanding center. Alternatively, patients travel substantial distances to providers who offer less expensive MRI scans. All Orange County MRI scanners, including the one that operates as a freestanding radiology office, are affiliated with UNC Hospitals. Orange County residents clearly lack choice. In this environment, hospital charges are high; and the freestanding office, Wake Radiology Chapel Hill, can and does maintain high charges. Because the 2021 SMFP need determination permits only one award, it is important to consider which applicant will break the monopoly within the county, and provide greater patient value, for the widest scope of services.

Industry Leader

RRCH's related entity, Raleigh Radiology, LLC ("RRLLC") has demonstrated long-term and sustained commitment to and leadership in the imaging field. RRLLC was the first practice in Wake County to introduce: 3D breast tomosynthesis mammography, Positron Emission Tomography, and high-field 1.5T open bore MRI. RRLLC took the lead in making MRI imaging affordable to patients by introducing a competitively **low-price fee schedule alongside a generous discount policy**. Matching actions with intent, RRLLC has developed strong relationships with groups such as Project Access and Federally Qualified Health Centers, that traditionally serve low-income persons, making specific commitments to accept referrals from these groups.

History of Quality

Raleigh Radiology Associates, Inc. ("RRA") has 45+ board certified and specialized staff radiologists who interpret the MRI exams and are available to consult personally with referring physicians via the "Radiologist Hotline" (see the section "Service Program Features" beginning on page 31 of the RRCH application). RRCH will operate as a radiologist office. Radiologists will be on site at RRCH in order to accommodate patient need for flexible schedules for contrast studies. Physicists regularly review and calibrate imaging equipment owned by Raleigh Radiology, a quality standard that would extend to any MRI that Raleigh Radiology would own.

COMPARATIVE REVIEW

Statutory Review Criteria Comparison

RRCH's application conforms to all statutory review criteria. The remaining two applications in this batch, failed to conform completely. Table 2 below compares applications by criterion.

Table 1 – Comparison of Applicants' Conformance to Statutory Criteria

Statutory Criterion	RRCH	DUHS	UNC
1	C	NC	NC
3	C	NC	NC
3a	N/A	N/A	N/A
4	C	NC	NC
5	C	NC	NC
6	C	NC	NC
7	C	NC	NC
8	C	NC	NC
9	C	C	C
12	C	NC	NC
13	C	NC	NC
14	C	C	NC
18(a)	C	NC	NC
20	C	C	NC
Performance Standard	C	NC	NC

Notes: "C" means conforming, "NC" means non-conforming

For explanations of non-conformity, see detailed comments attached to this letter.

Competitive Metrics

RRCH understands that the Agency may consider any metric in its competitive review of CON applications. We believe that the Agency should consider metrics that represent the spirit and intent of the *2021 State Medical Facilities Plan* and the CON Statute regarding value, quality, and accessibility. The following summary presents a strong and reasonable comparison of the three applications regarding these elements.

The first metric, "New competitor," is particularly important. Numerous studies demonstrate the importance of competition to maintain access, value, and quality. In fact, several studies show that recent consolidation in the health care industry is directly associated with increased or sustained high prices. One provider, UNC Health, owns all of the MRI inventory in Orange County. DUHS controls 14 of the 17.5 MRI scanners in adjacent Durham County. This region need competition to maintain healthy economic and quality balance. The UNC application argues that scanners at the hospital sites have long wait times – 20 days (page 50); yet the freestanding site in which UNC has an interest, operates below capacity. This suggests that the UNC applicant does not have the systems necessary to direct patients to lower cost alternatives. The DUHS application notes that it intends to offer a narrow scope of services at the proposed new MRI IDTF. Clearly competition is important.

Other metrics compare applicants' responsiveness to access, quality, and / or value. For example, the applications from UNC and Duke, indicate throughout that their primary purpose is to **expand access to patients of their own health care system physicians**. Both institutions are academic medical centers with concentrated substantial health care resources under the higher revenue producing academic medical center licenses. Only one application, RRCH, is clear about intent to and experience with organizing services to care for any patient regardless of the referring physician or qualified provider's system affiliation. Approval of the RRCH application would provide access to patients of Duke and UNC, as well as patients of providers who are not directly affiliated with either Duke or UNC. Orange County residents have demonstrated their desire for independence with very high outmigration rates for MRI. Thus, the applicant who puts highest priority on Orange County residents should get the highest consideration. Measuring this in two ways – total count and percent of total – reflects the extent to which the applicant places priority on residents.

Two applicants talk about "shifting" patients. At the end of the day, patients, not institutions, make the decision about service location, and patients make that decision each time they seek a service. In this context, we propose several metrics for Agency consideration.

Only one application proposes to have a radiologist on site. The IDTF applications from Duke (page 34) and UNC (page 36) propose to place the MRI in a physician office building, but make no mention of having a radiologist in the facility. Moreover, the applications from Duke and UNC indicate that the proposed MRI equipment would be placed in buildings that are to be developed. RRCH is the only applicant proposing to locate in an existing building.

MRI is now a standard health care diagnostic tool, used by physicians across specialties to inform diagnoses of new problems and monitor progress of treatment protocols. Because of MRI's frequent use, it is important to keep patient and operator costs as low as possible.

According to National Expenditure Data kept by CMS. Health care costs represented 17.7 percent of the Gross Domestic Product in 2019. Government and private parties alike are seeking ways to minimize that percentage. In line with that effort, and in support of patient interest and the General Policies of the 2021 SMFP, we encourage use of two comparative financial metrics for this review: Projected Average Net Revenue per Weighted MRI Procedure and Proforma Average Cost per Weighted MRI procedure. Measuring both in the third operating year will minimize the effect of lower volume start up years. Attachment C to this letter provides details on the metrics and calculations.

For ease of presentation, the following Table 2 ranks applications 1 to 3, with 1 being the most and 3 being the least favorable. All scores are based on three possible ranks. In case of a tie, the score equals the sum of the tied ranks divided by the number of ties; e.g., two tied for first place = (1+2)/2=1.5. Best possible score: 8.

Table 2 – Summary Comparison of Applicants on Access, Quality, and Value Metrics

Metric	RRCH	DUHS	UNC
a. Access by Service Area Residents (Total Patients)	1	2	3
b. Access by Service Area Residents (Percent of Total)	1	2	3
c. Projected Average Net Revenue per Weighted MRI Procedure, PY3	1	2	3
d. Proforma Average Cost per Weighted MRI Procedure, PY3	1	2	3
e. Competition (Access to New or Alternative Provider)	1.5	1.5	3
f. Coordination of Care (Demonstrated Intent to Serve Patients of / Support from Providers Outside the Applicant's System)	1	2.5	2.5
g. Radiologist on site	1	2.5	2.5
h. Proposed site exists and is ready for immediate MRI development.	1	2.5	2.5
Total Score	***8.5***	***17***	***22.5***

For detail supporting scores for each metric chosen and rejected, please see Attachment C.

Sincerely,

Joanne Watson
Chief Operating Officer
Raleigh Radiology

Attachment(s)

ATTACHMENTS

Competitive Review of: Duke Coley Hall Imaging Project ID# J-012155-21 ..... A

Competitive Review of: NC Imaging Centers, LLC Project ID# J-012145-21 ..... B

Comparative Metrics: Recommendations and Rejections, Supportive Detail..... C

UNC Hospitals 2021 Hospital License Renewal Application, Excerpts..... D

Wake Radiology Chapel Hill (Chapel Hill Diagnostic Imaging, LLC) 2021 Registration and Inventory Equipment Form .....E

Duke Hospital System 2021 Hospital License Renewal Applications, Excerpts .....F

Attachment A

Competitive Review of:
Duke Coley Hall Imaging Project ID# J-012155-21

OVERVIEW

Duke University Health Systems, Inc.'s ("DUHS") application to develop a fixed Magnetic Resonance Imaging scanner ("MRI"), is non-conforming with statutory review criteria 1, 3, 4, 5, 6, 7, 8, 12, 13, 18a, and Performance Standard 10A NCAC .2703.

This application proposes to acquire a fixed 1.5 Tesla ("1.5T") at a planned new building called Duke Coley Hall Imaging in Chapel Hill, North Carolina. The Applicant proposes to serve 4,310 patients from Orange and other North Carolina counties by Full Project Year 3, July 1, 2025 through June 30, 2026.

DUHS has previously submitted an Agency approved application to develop Duke Coley Hall as a diagnostic center offering mammography and ultrasound imaging. At the time of this application, the project was awaiting issuance of its Certificate of Need ("CON") after summary judgment dismissed an appeal to the project. The Applicant notes that regardless of that outcome, acquisition of the proposed MRI at this location will create a new diagnostic center.

CON REVIEW CRITERIA

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

Policy GEN-3: Basic Principles

Policy GEN-3 states that a

> *"…certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the identified need identified in the State Medical Facilities Plan as well as addressing the needs of* ***all residents in the proposed service area****."*[1] [Emphasis added]

Please see the discussion under Criterion 3 explaining how DUHS' application failed to demonstrate how projected volumes incorporate the concepts in meeting the need of all residents in the proposed service area. As a result, the application does not meet Policy GEN-3 and should be found non-conforming to Criterion 1.

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[1] *2021 State Medical Facilities Plan*; Chapter 4 Statement of Policies; Policy GEN-3: Basic Principles. Page 29.

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.

Demonstration of Need

The DUHS application identifies a population to be served as Orange, Alamance, and other counties in North Carolina. The DUHS application appropriately recognizes significant outmigration of Orange County residents to MRI equipment located in other counties (page 31). It also notes that approximately 2,000 Alamance resident MRI scans a year have occurred in Durham County in the years 2018 through 2020. Regarding Alamance, the application fails to recognize the impact of a CON approved in 2020 for a new freestanding MRI in Alamance County (G-11999-20). The application notes population growth rate in Alamance, but fails to note that the growth will result in only about 817 more total Alamance County resident scans at 89.5 scans per 1000 residents. (For rate, see Duke North Raleigh MRI CON application p 95).

The application describes need of the population to be served as need of patients who have and would in the future use services of DUHS hospitals for a lower cost, more convenient MRI option. DUHS would "shift" these patients to the proposed new Coley Hall MRI. In the first full project fiscal year. these "shifted" patients represent 85 percent of total Alamance and Orange County procedures for the proposed MRI (2,255 outpatient procedures shifted per Methodology step 5 / 2,653 Total FY2025 procedures per Form C). It could represent all proposed patients. The entire methodology depends on a core assumption that patients who have used DUHS MRI units in the past will not alter their patterns of care seeking, their use will increase, and those future patients will follow the same pattern.

Assuming patient patterns for seeking care are fixed, particularly with regard to the more expensive hospital setting, is fundamentally flawed. In fact, customer research firm, PK Global, reports in November 2021:[2]

> *"According to our own research, almost 1/3 of consumers have switched healthcare providers in the last 12 months. …Health care providers have a loyalty problem. Without brand-level loyalty, provider organizations will be more prone to shifts in the marketplace, whether that's employee attrition or consumer sentiment." (p6).*
>
> *"…. the most significant challenge to customer loyalty: the episodic nature of healthcare need." (p8)*

[2] *https://assets.asccommunications.com/whitepapers/pk-global-wp-november-2021.pdf*

The application argues for patient need for a lower cost option, one that is not based on the hospital payment rate. In FY 2025, the proposed second full year, the shift also represents 57 percent of the actual inpatient plus outpatient Orange County MRI procedures, and 90 percent of the entire count of inpatient and outpatient Orange County patients reported in the Agency's 2021 patient origin reports for Durham Regional and Duke University Hospital combined. (The Agency's database does not distinguish outpatients from inpatients). These "shifts" are larger than the 50 and 70 percent used in the DUHS methodology, because the latter involves all DUHS MRI locations, including lower-priced IDTFs.

Table 1: Comparison of Forecast Second Year Procedures to Reported MRI Patients from DUHS Durham Hospitals

County	Duke University Hospital 2020 Patients	Durham Regional 2020 Patients	Combined DUHS Durham Hospital 2020 Patients	Projected FY 2025 DUHS Coley Hall MRI Procedures	Forecast Procedures in Second full YR as % of Actual DUHS Hospital Patients FY 2020
note	***a***	***b***	***c***	***d***	***e***
Alamance	1,116	340	1,456	823	57%
Orange	1,799	546	2,345	2,104	90%

Notes

a. MRI Patient Origin Reports[3]
b. Same as a.
c. a + b
d. Form C Utilization Procedures FY2025
e. d / c

DUHS' provides little description of the nature or needs of patients who traveled from Orange and Alamance to DUHS hospital facilities in Durham and Wake Counties. Instead, it summarizes all outpatients by county of origin, regardless of where in the DUHS system those persons sought care. From this aggregate, the Methodology removes emergency and cancer patients and three percent who may need sedation. The Applicant assumes that outpatients will "shift," because the DUHS scheduling system will direct the "shift," and the patient will accept. It assumes that patients from the two counties will continue to frequent the DUHS facilities at the two thirds of the historical CAGR to calculate a "shiftable" future MRI procedure volume. Then it assumes that DUHS will successfully direct a share of the "shiftable volume" to the new Coley Hall MRI.

The Methodology in Section Q provides no basis for its assumption that 50 percent of those forecast Alamance and 70 percent of Orange would shift by FY 2026 (page 100). For example, if cost and convenience are the issue, Alamance County will have the recently approved Diagnostic Radiology and Imaging, LLC freestanding MRI available when this proposed IDTF opens. Why would Alamance patients travel farther to a facility in Orange County?

[3] *https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2021/29-Facility_MRI-2021.pdf*

The methodology suggests that the purpose of the proposed MRI is an economic one, to retain patients in the DUHS system, by developing an IDTF to which DUHS could refer patients for scans that payors might refuse coverage if the MRI is provided in a facility that bills on the hospital outpatient schedule. For reference, see Cigna Site of Care Coverage Policy announced in February 2020.[4] Other payers including BCBSNC have followed suit with this trend.

Having an IDTF in Orange County would permit DUHS to retain Hospital OPPS rates at the DUHS Southpoint location, and direct selected patients not affected by payer limitations to that higher cost location.

The application's Section Q Methodology proposes to shift patients from other DUHS freestanding locations "for convenience" (page 34).

To support the convenience rationale, the application cites one DUHS clinic with nine primary care providers in Mebane (Alamance County) and six DUHS primary care clinics with a total of 45 providers in Orange County. The application is silent about the number of those providers who are physicians. The application notes that the Duke Health Specialty Network, which has locations in Durham and Alamance Counties, primarily generates MRI referrals. However, at the time of the application, DUHS has no specialists in Orange County. The application mentions no specialists in Orange County (page 36). With regard to specialists, the application intent appears to focus more on the Duke Health Network and the desire to have a DUHS-owned IDTF MRI closer to the Duke Health Kernodle Clinic located in Burlington (Alamance County).

Another weakness in the Methodology is in the source of data for the shift estimates. The methodology in Section Q relies on data from DUHS internal billing systems. These data include procedures done on MRI equipment that DUHS leases from Alliance Medical Imaging. According to the 2021 SMFP Table 17E-1, six Alliance scanners are located at Duke University Hospital, Duke Regional Hospital, Cary Parkway, and other DUHS locations in Wake or Durham Counties. The application does not account for DUHS's contractual obligations for those MRI scanners and what the proposed shifts would do to unit costs of care at those locations.

The methodology's growth rates (CAGR) in section Q, are based on three years of recent DUHS MRI history, FY2019 through FY 2021, but, other than the stated attractiveness of the proposed IDTF location, does not explain why the population to be served would sustain 67 percent of that historical DUHS utilization growth for five more years from 2021 through 2026 (Application page 98). The CAGR in Step 2 itself has a possible flaw. Patients who delayed scans in 2020 because of COVID-19 restrictions could be artificially inflating the DUHS FY2021 data. The July fiscal year start in 2020 would have picked up the cases delayed by state mandated closures in March and April 2020. A CAGR calculation measures only the first and last points in a series.

Moreover, the CAGR used in the methodology, even with the 67 percent adjustment to 5.2 and 5.1 percent (page 99), is larger than the population growth rate for either Alamance or Orange County. This before shift growth could only occur if DUHS achieves a substantial increase in market share of MRI procedures in both counties. The application is silent about market share growth.

[4] (https://www.acr.org/Advocacy-and-Economics/Advocacy-News/Advocacy-News-Issues/In-the-February-22-2020-Issue/Cigna-Announces-Site-of-Care-Coverage-Policy-for-High-tech-Imaging)

The methodology's tables for Alamance and Orange counties historical MRI volume in section Q have no supporting data tables. The application fails to demonstrate proper support for its claims that DUHS MRI Volumes in FY19, FY20, or FY21 are accurate. For example, the NCDHHS 2020 Report "Fixed MRI Procedures: Patient Origin by Facility" suggests the number of patients served by DUHS facilities in 2019 was 1,547. The methodology's tables present 2,250 MRI procedures done in 2019. There is a difference of 703 between the tables presented by DUHS and the NCDHHS number of patients.[5]

Because it focuses on the needs of DUHS for an economic alternative, rather than on demonstrating the needs of the population to be served by the proposed facility, the application from DUHS should be found non-conforming to Criterion 3.

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.

In the DUHS application, the Applicant proposes that the current location is the most effective location and declines to pursue alternative locations. The Applicant notes that DUHS has approval to develop imaging modalities in a diagnostic center at this location. It also notes that the location will house ambulatory surgery, physical and occupational therapy, and specialty and primary care services.

DUHS has a freestanding MRI location at Southpoint, only 13 minutes away from the proposed site. The application does not explore the alternative of reducing patient cost by converting that facility from a hospital outpatient department to a freestanding IDTF.

The application does not pursue the option of relocating mobile MRI service agreement to Coley Hall. Both the application and the *2021 State Medical Facilities Plan* acknowledge that DUHS has contractual obligations to continue service arrangements with Alliance Imaging. The application is silent on that alternative and the financial impact on the DUHS Imaging Service of the proposed "shifts" of MRI scans away from those mobile scanners. Relocation of a mobile could prove less costly if the projected number of "shifted" scans does not materialize.

Failure to demonstrate why existing resources could not be use to accomplish the purpose of this application is reason to find this application non-conforming to Criterion 4.

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 schedule in Section P of the application is not accurate. It lists the first day of the review schedule as 05/01/2021. However, the application submission was not until October 15, 2021. The Applicant organizes the data by fiscal year in intervals between 07/01 to 06/30 the following year. As such, all the data in the application are off by one year.

[5] https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2020/29-Facility_MRI-2020.pdf

This also deserves thoughtful consideration since the Applicant, DUHS, has a history of obtaining CONs and not completing them until years later. For example, the Holly Springs MRI was awarded in September 2016 but only became operational in June 2020. Another example is a current DUHS CON approval for mammography and ultrasound equipment in the same Holly Springs facility, which has just recently been delayed a year to July 01, 2023. The CON application from the Applicant for an ASC facility at Coley Hall (66 Vilcom Drive, Chapel Hill) was approved in 2019 and is also yet to be operational. Furthermore, the equipment operational date for this proposed MRI is scheduled for 2023. The Applicant has a history of receiving CON approvals and failing to utilize them in a timely manner.

Expenses for the proposed MRI are not well documented. The application provides no form H or equivalent for the staff assigned to the MRI. Documentation for the extremely low equipment maintenance is a staff estimate, the application contains nothing from the manufacturer, Siemens. Yet Form F.3b assumptions reference "current Siemens agreement does not include inflation." The corporate overhead allocation is extremely low and the calculation implies that the project will require almost no corporate overhead. The working capital budget on page 57 includes no allocation for marketing costs.

The application provides no documentation to support the Architect / Engineering fees. Exhibit F.1 from the Architect is silent on A/E fees.

For these reasons, the application should be found non-conforming to Criterion 5.

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

The application does not address this criterion completely. First, with regard to this Criterion, responses in application Section G focus only on facilities located in Orange County. However, the DUHS methodology in Section Q relies on shift of patients from other facilities and on gains in market share.

The proposed project is only 13 minutes away from DUHS Southpoint (6301 Herndon Rd. Durham, NC 27713) and can be more convenient for some Orange County residents in the south Chapel Hill area than the new proposed location. According to the 2020 SMFP, that MRI has very low utilization, only 2,002 weighted MRI scans. The Applicant also fails to note that the DUHS Southpoint location bills at Duke University academic medical center hospital rates. On page 99, the application indicates that 23 percent of Southpoint patients come from Orange and Alamance, but the application does not demonstrate impact of the shift on this facility.

Similarly, the application acknowledges the recently approved DRI Burlington fixed MRI, but fails to demonstrate that the proposed DUHS Orange scanner would not duplicate resources provided by Diagnostic and Radiology Imaging, LLC (Burlington), especially to Alamance patients referred from nearby, Alamance-based Kernodle Clinic.

The reference to the 2020 SMFP need for another fixed MRI in Alamance County is misleading. The need was generated by 2019 procedures done in Alamance County. However, the DUHS need methodology relies on a procedure growth factor of patients leaving Alamance County that exceeds Alamance population growth rates. Hence, impact on that approved resource should be considered in the review of unnecessary duplication.

The application rejects the alternative of another contract with Alliance Imaging for mobile MRI Services. This is an incomplete response. The application Methodology relies on data for all outpatient MRI services billed by DUHS. According to Table 17E-1 of the *2021 SMFP*, DUHS has six Alliance MRI scanner sites in Wake and Durham counties. The application provides no information about the impact of the proposed MRI on use of MRI scanners provided under the DUHS service contract agreements with Alliance Imaging. *As* such, the application fails to provide the details of DUHS current service agreements of Alliance MRI scanners and fails this criterion.

For these reasons, the application should be found non-conforming to Criterion 6.

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

The application provides insufficient evidence to evaluate the impact of this project on staffing for the proposed MRI equipment. Application Form H is for the entire facility (diagnostic center). There is no Form H staffing documentation for the MRI service alone.

The application provides no staff policies regarding training and education for MRI techs or staff who are essential for operation of the MRI (page 69). The staff training and education policies provided by Exhibit H.3 are for nursing only.

For these reasons, the Applicant should be found non-conforming to Criterion 7.

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

Although interpretation of the MRI scans is an essential part of an MRI service, Section H of the application does not indicate what person or entity will provide that essential interpretive service to patients (page 72). It says only:

> *"DUHS works closely with the Private Diagnostic Clinic, PLLC, the Duke University School of Medicine faculty practice which provides a full range of specialty physician services across the Triangle*."

Proformas indicate minimum allocation of central resources to support this facility – see corporate overhead allocation in Form F.3 and related assumption and compare to check list in Section I.1.a

Moreover, with regard to coordination with the existing health care system, in Section I, page 72, all responses focus only on the Duke System, clearly indicating intent to make the project is a closed network service. All references to local health care and social service providers are to Durham County entities: Lincoln Community Health Center, Durham County EMS. Although the application mentions existence of DUHS services in both Orange and Alamance County, the application fails to mention any non-DUHS health care provider in either county.

Charity care documentation applies to Durham County providers. The application provides no information about coordination with the Orange or Alamance County Health Department or Piedmont Health, a significant Federally qualified community health center in Orange County that also serves Alamance. It is not part of the Duke Health System. Proposed DUHS coordination is instead with Lincoln Health Center – Durham, Durham EMS (page 73)

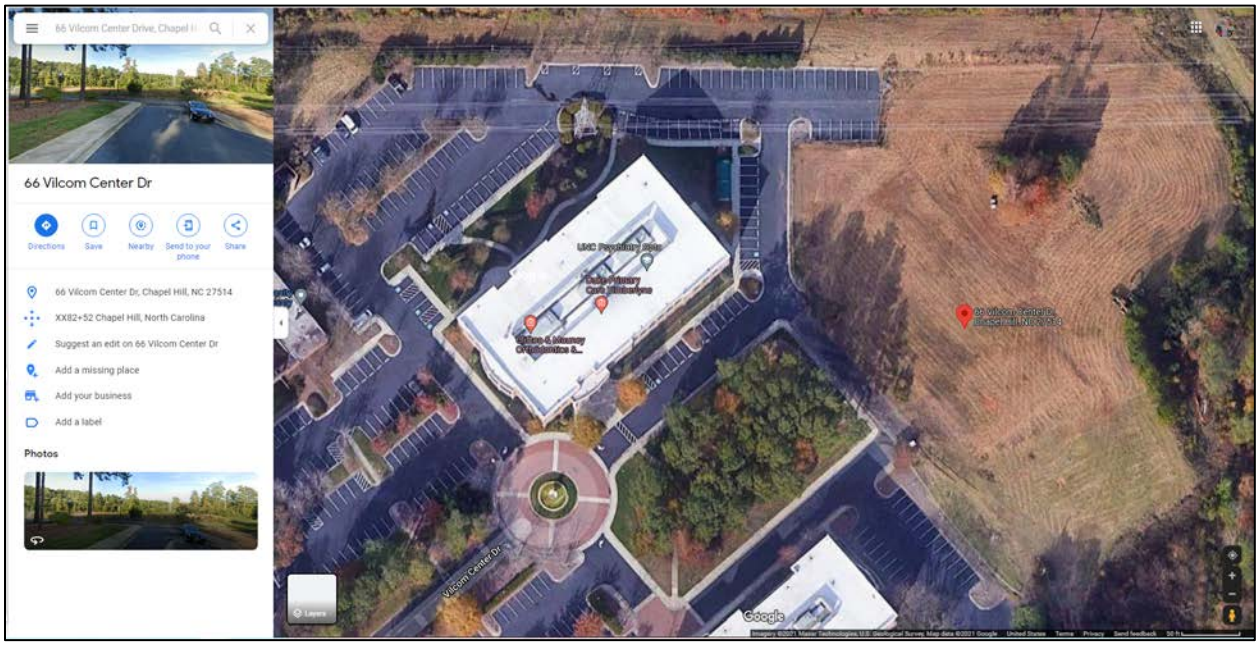
For these reasons, the Applicant should be found non-conforming to Criterion 8.

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.

The application implies that DUHS will have responsibility to lease this whole building at Coley Hall, after it is built. The application provides no evidence of a master plan, or CON's showing the square feet and capital investment approved for the other space in this building; it has no evidence of an Exemption letter to develop it as a physician office, as would be required by GS 131E-184(a)(9); hence no assurance that it will be occupied at a sufficient level to support the allocation of very little space to the proposed MRI.

The lease provided in Exhibit K.2 is for a lot. There is no mention of a building on the lot. Google shows no building at that address.

Figure 1: Google Maps Satellite View, 66 Vilcom Center Drive



Source: Google Maps; accessed December 1, 2021, Imagery ©2021 Maxar Technologies, US Geological Survey Map data.

Exhibit K.2 contains drawings showing the MRI located in a section of a large office building. The lease in Exhibit K.4 contains a right of first refusal for DUHS to acquire a building. Exhibit F.1 has a letter from Little Architects for tenant upfits to an "imaging suite that is under development." Assumptions to proforma form F.3 provide no substantive information about how the cost of this space was derived. Does DUHS propose to own this unbuilt building? If so, why would expenses include "rent" based on FY 2021 amounts – amounts for what?

F.1b has a cost estimate for the equipment from Seimens. There is no information about rigging or physicist cost to install and calibrate the equipment. The letter from Architect has no A/E fee, and does not identify the number of square feet involved.

Multiple staircases indicate that this will be a multi-story building that will house the MRI. There is no site plan to show that parking is adequate, no allocated cost of the rest of the building or department in the proforma cost estimate. Without that, it is impossible to determine whether this means of construction is 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…"

Based on the missing elements, estimated costs in Exhibit F.2 ($784,750) likely understate the cost of developing this project. The site has no parking, paving, landscaping, utility hookups. All of these costs are involved in developing a greenfield building and should have been presented in order to provide a true picture of the cost of this proposed project.

The Applicant fails to 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. Therefore, the Applicant should be found non-conforming to Criterion 12.

13. The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

Application indicates that patients will "shift" from existing DUHS locations. However, in Section L, the Applicant provides no information about the historical payor mix profile of those "shifted" patients (page 80). The application does not address how "shifted" patients compare to the demographic profile of the areas from which they originate (page 80 and 81).

Furthermore, the link to the Community benefit report on page 82 of the CON application goes to a "page not found."

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

On page 82, Section L.2.b, the application directs the Applicant to describe patient civil rights equal access complaints…[for], "<u>each facility from which existing health services will be relocated to that facility or campus.</u>" The application is built on the premise of shifting patients from existing DUHS (Applicant) facilities. Yet, the Applicant answers Section L.2.b as "not applicable, the facility is not yet operational." The application provides insufficient information for the reviewer or anyone else to evaluate the response to this statutory criterion.

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

On page 83, the application indicates that payor mix is based on "existing payor mix for…MRI scans performed in FY2021 for Orange and Alamance Counties as the baseline…" It is impossible to determine from the information provided exactly how DUHS altered that baseline information. The application does not include the baseline supporting information. The methodology cites a one-time increase in Medicare of 3.8 percent but provides no source for the calculation and no basis for holding it constant for future years. Yet the need described in Section B relies on an aging patient population.

The calculation of charity care on page 84 appears to apply to all patients of the diagnostic center regardless of modality. This is not responsive for an application that is specifically proposing an MRI service.

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

The application regularly refers to the source of admission to the facility as a directed referral through the DUHS central scheduling system. This is further evidence of the intent to keep this a closed DUHS system service. Moreover, as noted above, the application relies on DUHS Orange County and Alamance County Primary Care clinics for referrals, but does not indicate how many physicians staff the DUHS primary care clinics in Orange and Alamance County.

For these reasons, the application should be deemed non-conforming to Criterion 13.

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 the service for which competition will not have a favorable impact.

Competition

DUHS presents the project as a competitive alternative to UNC. However, it is not a full competitor. In the project scope in Section B and methodology in Section Q, the application clearly describes a limited scope of proposed DUHS MRI services – no cancer patients, for example. Yet the need on page 30 mentions cancer as one of the four listed needs for MRI referrals.

Throughout, the application mentions that the source of referrals will be DUHS practices. With only one MRI available for Orange County in the 2021 State Medical Facilities Plan, an award to DUHS would still limit competitive alternatives for patients who are not associated with DUHS.

Cost Effectiveness

On page 87, the application indicates that the proposed IDTF MRI "**may** be a more cost-effective option for appropriate outpatient procedures." The application appears uncertain whether the proposed MRI will be more cost effective." It is clear the IDTF will have a limited scope of services; low charges also suggest that the range of procedures will be limited and the application is silent about the cost of carrying such a large facility with so few identified occupants.

Further, in the summary part of the response to Criterion 5, the application states that the proposed project will: "provide a different, potentially lower cost option." The application again appears uncertain whether the proposed project will be the lower cost option.

Hospital Renewal Application data shows that DUHS (the applicant) bills 11 out of 14 of their imaging facilities at hospital rates. Attachment F includes excerpts from the DUHS 2021 Hospital License Renewal Applications showing the current DUHS clinics and hospital service locations, all of which bill at hospital rates. Thus, DUHS has a history of billing at the highest possible amount and combined with the uncertainty of providing a lower cost option in the application are reasons to *find the Applicant to be non-conforming to the cost effectiveness stipulation in Criterion 18a.*

Access

The proposed project is not designed for open access to all residents. Its intent is clearly stated to provide access to patients of DUHS network providers. Thus, the proposed project intends to add to its closed system of patients without enhancing access for non DUHS patients.

DUHS presents itself as a new competitor for MRI in the service area, all the while, throughout the application, DUHS mentions that it has practices in Orange County that routinely refer to DUHS MRI facilities in adjacent Durham County, which, the application admits, bill at hospital rates.

Because DUHS's proposed scanner will not enhance competition, cost-effectiveness, or access it should be found non-conforming to Criterion 18(a).

SPECIAL RULES 10A NCAC .2700 MAGNETIC RESONANCE IMAGING EQUIPMENT

Performance Standard 10A NCAC .2703

The application does not provide information that demonstrates conformance with performance standard 10A NCAC .2703 b(4) which applies to the third year of operation. The third operating year is not the third full fiscal year (Application page 100). Data in these tables suggest that the proposed project does not conform with the required performance standard.

Attachment B

Competitive Review of:
NC Imaging Centers, LLC Project ID# J-012145-21

OVERVIEW

NC Imaging Centers, LLC ("UNC") application to develop a fixed Magnetic Resonance Imaging scanner ("MRI"), is non-conforming with statutory review criteria 1, 3, 4, 5, 6, 7, 8, 12, 13, 14, 18a, 20, and the Performance Standard 10A NCAC 14C .2703.

This application proposes to acquire a fixed 1.5 Tesla ("1.5T") MRI in a new medical office building ("MOB") called UNC Health Imaging Center in Carraway Village. Approval of this application would result in creation of a new diagnostic center. The Applicant proposes to serve 4,684 patients from Orange and other North Carolina counties by Project Year 3, July 1, 2025 through June 30, 2026.

CON REVIEW CRITERIA

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

POLICY GEN-3: BASIC PRINCIPLES

Policy GEN-3 states that a

> *"…certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the identified need identified in the State Medical Facilities Plan as well as addressing the needs of* ***all residents in the proposed service area****."*[1] [Emphasis added]

Please see the discussion under Criterion 3 explaining how UNC failed to demonstrate accurately that they meet the need determination as outlined by the State Medical Facilities Plan.

As a result, the application does not meet Policy GEN-3 and should be found non-conforming to Criterion 1.

[1] *2021 State Medical Facilities Plan*; Chapter 4 Statement of Policies; Policy GEN-3: Basic Principles. Page 29.

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.

System Need versus Population Need

The Applicant is a wholly owned subsidiary of UNC Health and throughout the document, describes the proposed project as a response to needs of UNC Health system:

- Page 30: "*…provide capacity relief for the heavily utilized fixed MRI scanners at UNC Hospitals, particularly its Hillsborough Campus*."
- Page 31: "*As discussed further in Section C.4, Blue Cross and Blue Shield of North Carolina (BCBS NC) has announced changes that will require an added focus on cost containment and that are expected to heavily influence patient behavior…".*
- Page 34: "*As discussed in Section C.4, the proposed project will allow UNC Health to expand its fixed MRI capacity to offer a lower-cost alternative for non-emergent patients needing outpatient MRI services while simultaneously providing some capacity relief for the heavily utilized fixed MRI scanners at UNC Hospitals*."
- Page 35: **"***This approach allows the existing hospital-based MRI scanners at UNC Hospitals' two campuses in Orange County to retain sufficient capacity to accommodate growth in inpatient MRI scans."*
- Page 49: "*To afford this reduction in premiums, BCBS NC has announced a joint program with five of the largest health systems in the state, including UNC Health. The "Blue Premier" model is focused on joint accountability and tailors its cost curve to hold providers financially accountable for higher costs and inefficiencies in the healthcare system. In the proposed model, inefficiencies within each health system are turned into an expense for the provider, instead of an additional billable service." [emphasis added]*
- Page 51: **"***In fact, between May and August of this year, all three facilities within UNC Hospitals had average wait times of no less than nine days to receive care." [emphasis added]*

The application mentions a relationship of the Applicant with the MRI scanner at Wake Radiology Chapel Hill (page 44, footnote 15), but, throughout the application, dismisses opportunities to refer patients to that underused facility, presumably because, per the footnote, it "is not a subsidiary of the same parent company." Nonetheless, UNC Health is a member of the joint venture that owns Wake Radiology Chapel Hill. Additionally, the application fails to explain why the common scheduling system at UNC Health cannot refer patients to that facility. Instead, the application notes on page 50: "Currently, patients in need of outpatient MRI services from UNC Hospitals' existing scanners are being scheduled on the third next available appointments" [at UNC Health solely owned MRI scanners]. The application reports delays of up to 20 days for MRI appointments.

According to the 2021 Registration and Inventory of Medical Equipment Form Wake Radiology Chapel Hill (Chapel Hill Diagnostic Imaging, LLC) that MRI equipment provided only 1,778 MRI scans in the reporting year ending September 30, 2020, see Attachment E. The form also indicates the MRI scanner is available 45 hours per week. This translates to annual capacity for 4,491 scans, meaning this scanner *operates at only 39.6 percent capacity* (1,778 / 4,491 = 39.6%). Table 1 below shows this calculation.

Table 1: Estimated Excess Capacity of Wake Radiology Chapel Hill's MRI Scanner

Hours / Week	Weeks / Year	MRI Units	Max Operating Hours	Annual Holiday Hours	Total Operating Hours	MRI Scans / Hour	Maximum Capacity	Actual 2021 Scans	Excess Capacity
a	b	c	d	e	f	g	h	i	j
45.0	52.0	1.0	2,340.0	72.0	2,268	2.0	4,491	1,778	**2,713**

Notes:

a. Hours of availability per 2021 Registration and Inventory of Medical Equipment Form
b. Assume every week
c. One fixed scanner per Table 17E-1 of the 2021 SMFP
*d. a * b * c*
*e. Assume location is closed 8 holiday days per year (8 * 9 = 72)*
f. d - e
g. Number of scans per hour per 10A NCAC 14C (2)
*h. f * g*
i. Total annual scans in FY2020 per 2021 Registration and Inventory of Medical Equipment Form
j. h - i

The rationale for patient origin is confusing. On page 39, the project patient origin table identifies six specific counties to be served, and notes that Orange County will represent 27 percent of patients. This is inconsistent with a later analysis on page 47 showing that 15 percent of patients served in the past originated from Orange County. The application does not explain the rationale for increasing the Orange County patient origin percentage in the proposed new facility to 27 percent between FY 2020 and FY 2024.

With regard to needs of the population to be served, the application mentions aging in Orange County, but does not mention needs of residents of other counties it proposes to serve.

Need Methodology Issues

The need methodology in Section Q has several logic issues. It indicates that, to guide use of the proposed new MRI scanner at Carraway Village, a central scheduling office can shift outpatients from UNC Hillsborough Campus to the proposed new scanner (page 5). On pages 3 and 4, the methodology develops growth factors for MRI scans at UNC Medical Center and UNC Hillsborough Campus. Both history and forecasts involve Compound Annual Growth Rates ("CAGR") for fiscal years 2017 through 2021. On page 3, the methodology clearly shows that UNC Medical Center Outpatient scans are declining. But the methodology on page 4 cuts the decline to one-third of the CAGR, claiming this is conservative. Mathematically, the reduction is not conservative. One third of a negative number provides a more liberal estimate.

The historical CAGRs for MRI scans on UNC Hillsborough campus are very high (23.5 percent total for the period shown on page 3). But CAGR calculations involve only the first and last numbers, and this table on page 3 includes the startup years for the Hillsborough MRI. The first years of a new business commonly have rapid growth. That usually stabilizes, as it does in the table. In FY2019, 2020 and 2021, the number of MRI scans on UNC Hillsborough campus is almost constant, up 5 percent total, or 2.5 percent CAGR.

For the proposed project MRI utilization, the forecast scans on page 6 involve "shifting" half (50 percent) of the forecast UNC Hillsborough Campus outpatient scans to the new facility. But the forecast is flawed because its Growth Factor is based on an inflated CAGR. Even reducing the Growth Factor to one-third of the flawed CAGR, produced a forecast annual growth rate of 7.8 percent, or three times the actual recent growth.

A more reasonable utilization forecast would apply the recent CAGR growth to estimate the UNC Hillsborough Campus scans. In that scenario, the proposed new scanner falls short of meeting the required performance Standard of 4,805 weighted MRI scans in the third operating year. The following table shows that after applying these adjustments to the methodology, UNC Hillsborough Campus outpatient scans in the third year would be 7,291, not the 9,776 presented on page 4; and, the new MRI would have only 3,646 annual MRI scans.

Table 2: Adjusted MRI Methodology

Metric	History			CAGR	Adjusted Forecast MRI Procedures Using Recent CAGR				
	FY 2019	FY 2020	FY 2021	FY 2019 - 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
UNC Hillsborough MRI Scans	6,431	6,454	6,753	2.5%	6927	7105	7288	7475	7667
UNC Hillsborough Outpatient MRI	6,104	6,142	6,422	2.6%	6587	6757	6930	7109	7291
Shift Half of Outpatient							3465	3554	**3,646**

Source: Data for FY 2019 through FY 2021 from Section Q Need Methodology and Utilization Assumptions
Adjusted Forecast = Prior year times 1+ CAGR
Shifted Scans = UNC H Outpatient MRI times 50%

Moreover, with the Alliance MRI service agreement, which UNC indicates it plans to retain, UNC Health system would not need the proposed new MRI scanner to meet volume requirements. The application acknowledges the Alliance MRI service agreement in Hillsborough and notes that UNC Health will retain that scanner (Methodology page 5).

Forecasts assume that UNC will have physicians in place in the new building. For patient safety, ACR standards require presence of a physician during contrast injections. There is no evidence in the application to demonstrate that UNC will have the necessary physician in place when the MRI construction project is complete.

For all of these reasons, the application does not demonstrate need of the population to be served for the proposed services and should be found non-conforming to Criterion 3.

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.

Alternatives

The Applicant states in several places throughout the document, and confirms on its 2021 Hospital License Renewal Application ("LRA"), that UNC Health contracts with Alliance to support the overflow of scans at both the Hillsborough Campus and the Imaging and Spine Center. Reported number of scans on each of these Alliance scanners is very low, barely 100 annual scans, according to the 2021 LRA. The Applicant did not explore the alternative of relocating the mobile scanner to the outpatient setting in Chapel Hill.

UNC also fails to demonstrate how its proposal is the least costly alternative. It appears instead to be a costly addition. It provides a new MRI service and proposes to continue providing the third-party MRI services at both Hillsborough Campus and the Imaging Spine Center. With addition of a fixed MRI at the proposed new diagnostic center, by its own admission UNC expects to shift patients from Hillsborough to service at UNC Health Imaging Center, while also continuing to carry the cost of the Alliance Imaging MRI service agreement scanner.

- *"The proposed project seeks to… [develop] UNC Health's first freestanding fixed MRI scanner in a new diagnostic center, UNC Health Imaging Center, which will… provide capacity relief for the heavily utilized fixed MRI scanners at… its Hillsborough Campus." Page 30 of the application.*
- *"UNC Health intends to continue to contract with Alliance for mobile MRI services as needed at both UNC Hospitals Hillsborough Campus and the Imaging and Spine Center." Page 8 of the Methodology.*

Finally, the number of scans forecast is substantially overstated and current capacity would adequately absorb the volume. Moving the third-party service arrangement to the new site would enable UNC Health to offer the desired freestanding organizational option with use of existing resources.

Because it did not adequately demonstrate that the proposed project is the least costly or most effective alternative, UNC should be found non-conforming to Criterion 4.

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.

Page 36 and Exhibit C.1 show that UNC Health will lease the entire Carraway Village MOB to UNC Health, which will in turn sublease to NC Imaging, LLC. The financials do not show revenue sufficient to cover UNC Health's cost of supporting the full building lease.

Similarly, the financials do not appear to cover the cost of maintaining the Alliance service agreement.

The MRI would be the only service in the diagnostic center, so it will not have the advantage of sharing technical radiology staff with other modalities. The solo MRI must carry more overhead than an MRI located in a multi-modality imaging center.

Most importantly, the application appears to overstate the number of scans. At the reduced number, cost per scan would be much higher.

Financial proformas are based on the technical component of bills only. They do not include the cost or revenue associated with the professional fees. Yet, the application clearly states that professional fees will be separately billed by UNC Health System physicians. These individuals are not employees of the Applicant, but they are employees of the sole member of the Applicant. The application provides no information by which the public or the Agency could evaluate the true cost of the costs and charges.

For these reasons the application should be found non-conforming to Criterion 5.

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

Unnecessary Duplication

According to Exhibit G.1, excerpts from Table 17E-1 of the 2021 State Medical Facilities Plan, approximately 95 percent of the MRI scans performed at UNC Hillsborough were outpatient. The application fails to explain the full impact of the proposed scanner on the Hillsborough Campus, despite acknowledging the potential shift. As described on page 77,

> *"…the proposed site also represents a convenient location that is geographically situated in between UNC Medical Center and UNC Hospitals Hillsborough Campus very close to I-40, allowing for a fluid continuum of care that provides premier diagnostic imaging services equal to either hospital at a lower cost…".*

The Applicant failed to demonstrate that the proposed MRI will not unnecessarily duplicate services at the Hillsborough Campus.

On page 5 of Form C – Assumptions and Methodology, the Applicant claims,

> *"UNC Hospitals Hillsborough Campus, in particular, operates its single fixed MRI scanner significantly in excess of the threshold of 4,805 weighted scans per fixed MRI scanner per year defined in the MRI performance standards at 10A NCAC 14C .2701 (a)(3) and (4)."*

The Applicant plans to shift 50 percent of the outpatient MRI volume from this "over-utilized" MRI scanner to the newly planned facility outlined in this CON application to, "alleviate capacity restraints at UNC Hospitals Hillsborough Campus…" According to the performance standard listed in 10A NCAC 14C (2), the annual capacity of a fixed MRI scanner is **6,864** weighted MRI procedures (66 hours per week * 52 weeks per year * 2.0 procedures per hour). The Applicant admits to running all nine of its fixed scanners in Orange County 12 hours a day, 7 days a week (84 hours/week). After adjusting for the significant increase in hours, the annual capacity would be **8,736** weighted MRI procedures per MRI.

However, the SMFP MRI need determination methodology adjusts this annual capacity to tiered thresholds based on the number of fixed equivalent MRI scanners present in the service area. The original tiered planning thresholds based on an annual capacity of 6,864 are listed in the table below:

Table 3: Tiered Planning Thresholds (Annual Capacity of 6,864)

Service Area Fixed Scanners	Inpatient and Contrast Weighted Thresholds	Planning Threshold
4 and over	4,805	70.0%
3	4,462	65.0%
2	4,118	60.0%
1	3,775	55.0%
0	1,716	25.0%

The tiered planning thresholds based on the adjusted annual capacity as 8,736 (84 hours per week * 52 weeks * 2.0 procedures per hour) is listed in the table below:

Table 4: Tiered Planning Thresholds (Adjusted Annual Capacity of 8,736)

Service Area Fixed Scanners	Inpatient and Contrast Weighted Thresholds	Planning Threshold
4 and over	6,115	70.0%
3	5,678	65.0%
2	5,242	60.0%
1	4,805	55.0%
0	2,184	25.0%

In its own methodology, UNC states that FY 2021 weighted MRI procedures at the UNC Hospitals Hillsborough Campus totaled 5,994. This is less than the adjusted tiered planning threshold value of 6,115 identified in Table 4 above.

These calculations indicate that the Applicant's Hillsborough Hospital Campus fixed MRI is **not over-utilized** and therefore failed to demonstrate the need to shift outpatient MRI procedures to the newly proposed location, resulting in unnecessary duplication.

Shifted patients would also have less convenient hours. The new facility would run 12 hours a day, 5 days a week; not 7 days a week.

These are sufficient reasons to find the application non-conforming to Criterion 6.

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

Availability of Resources

UNC projects MRI scans with contrast at the proposed UNC Health Imaging Center location. According to the American College of Radiology, the accrediting entity for MRI, during an MRI scan requiring contrast, the

> *"…health care professional performing the injection must be a certified and/or licensed radiologic technologist, MRI technologist, registered radiologist assistant, nurse, physician assistant, physician, or other appropriately credentialed health care professional* ***under the direct supervision of a radiologist or his or her physician designee****." [Emphasis added]*

CMS defines "Direct Supervision" in the office setting as

> *"…the physician* ***must be present in the office suite*** *and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed." [Emphasis added]*

Therefore, to comply with CMS rules, the Applicant must arrange for a radiologist or his or her physician designee in office during all contrast MRI procedures.

Page 36 of the application states that establishment of the proposed project will "… coincide with establishment of various physician practices in the MOB, ensuring that a physician is onsite in the building for provision of contrast MRI scans." However, this does not provide specific information regarding these physician's specialties, nor their presence at the IDTF. It suggests that any physician may be anywhere in the building. No information is provided regarding the location of the radiologists that will read the images. In fact, page 85 specifically indicates that the facility – UNC Health Imaging Center – will not bill patients for professional fees "such as interpretation of radiological studies by a radiologist," suggesting no radiologists will be in the building at any time. Furthermore, no physicians are included on Form H in Section Q.

Because UNC Health does not show evidence of the availability of resources for the provision of the services proposed to be provided, it should be found non-conforming to Criterion 7.

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

In Exhibit I.2, the letters of support given by the Applicant to demonstrate coordination within the existing health care system are all from providers that directly work with or have ties to the UNC Health Care system. This reasonably shows a lack of support from outside the Applicant's system, ultimately demonstrating the presence of a closed system.

As explained above, the application contains no evidence of attempts by this new applicant to establish coordination with the health care delivery system external to UNC Health. All references to the existing health care system are internal to UNC Health.

For this reason, the Applicant should be found non-conforming to Criterion 8.

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.

According to documents in Exhibit C.1, UNC Health plans to lease 17,000 square feet from NR Edge Property Owner, LLC at Carraway Village MOB. UNC Health will then sub-lease 4,230 square feet of this property to the Applicant for use as an MRI scanner. The Applicant fails to discuss this in response to Criterion 12, Section 3a. Leasing 17,000 square feet would likely demonstrate that this is not the most reasonable alternative for the proposal. These costs would likely be offloaded to patients and payors, further discussed in Section 3b.

The application presents the 17,000 square foot building as a physician office building that will have an MRI to support physicians in the building. However, the application provides no evidence that the owner or Applicant filed the Exemption request required by GS 131E-184 to develop a physician office building.

The Applicant's response in Section K.3b explains why the cost of a new freestanding fixed MRI scanner would help reduce payors' cost, which is unrelated to the prompt. In failing to correctly respond to the prompt outlined in Criterion 12, Section K.3b, UNC neglects to demonstrate how the construction of 4,230 SF does not unduly increase the costs to patients and payors. UNC's renovation plans call for nearly **three times** the amount of space involved in Duke's proposed construction plans and over **five times** the amount of space identified in Raleigh Radiology's plans. The specific amounts of square feet planned for each Applicant are listed in the table below:

Table 5: Comparison of Square Feet Allocated to Proposed New MRI Equipment

DUHS	UNC Health	RRCH
1,513	4,230	831

Source: CON Applications, Section K

In fact, note g to the UNC proforma Form F.3 (page 15), presents construction cost depreciation at on a 30- year schedule, without providing any justification for the extended term. The lease in C.1.1 is for 12 years.

Because of the failure to demonstrate how the renovation of 4,230 square feet would not unduly raise the prices of health services provided by the Applicant, the application should be found non-conforming to Criterion 12.

13. The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

Although the Applicant has only one member, UNC Health, and that member is associated with all of the MRI scanners located in Orange County, the application provides no details about the extent to which medically underserved populations currently use the Applicant's existing services in comparison to the percentage of the population in the Applicant's service area which is medically underserved

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

The application indicates that the Applicant has no obligation to provide uncompensated care. However, UNC Health is a **not-for-profit integrated health care system** owned by the state of North Carolina. As a tax-exempt entity, it has an obligation under IRS rules to provide community service. The application is silent on this matter. See Section L.1 and L.2.

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

The application indicates on page 106 that "*Patients of UNC Health Imaging Center will be either self-referred, referred by their personal physicians or referred by a member of the medical staff at UNC Hospitals."* Patients cannot self-refer to MRI. The application is silent about provisions for persons who do not have a physician.

For these reasons the application should be found non-conforming to Criterion 13 a, b and d.

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

The application presents the Applicant as a new entity. The response to Section M questions about training, indicate simply that

> *"UNC Hospitals is a teaching institution with obligations to all of the Health Science Schools at UNC. The relationship between UNC Hospitals, the School of Medicine, and NC Imaging's proposed project is evident in the organization and structure of UNC Health." (*page 108).

Other responses indicate that the proposed site will be available to only UNC Health training programs.

For these reasons the application should be found non-conforming to Criterion 14.

18 a. 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 the service for which competition will not have a favorable impact.

Competition and Access

Approval of this application would give UNC Health and its related parties a monopoly with regard to ownership of fixed MRI equipment in Orange County. It presents the Applicant as a new competitor, because it will offer UNC Health's first freestanding MRI imaging service in Orange County and Orange County residents are leaving Orange County for this service. Hence the proposed MRI will compete with providers outside the service area.

First, the Applicant states in a footnote on page 23 that "No other diagnostic center in North Carolina … [is a] related entity…". However, UNC seems to have overlooked its relationship with Wake Radiology, while the Applicant claims no relation, all appearances are to the contrary. The lone freestanding diagnostic center with MRI services in Orange County is WakeRad UNC Rex – Chapel Hill. Both in its name and on its website, Wake Radiology freely advertises itself as affiliated with UNC Healthcare.[2]

Moreover, the application provides incomplete information about other freestanding MRI services offered by UNC Health. The footnote on page 23 admits that the Applicant **owns** UNC Health Care Panther Creek Diagnostic Center. Simple internet research will show that this location is also a Wake Radiology UNC Rex Healthcare location.[3]

Furthermore, the UNC Hospitals 2021 Hospital License Renewal Application claims the "Burlington Imaging" as a location that offers MRI services, as does its website, yet this UNC MRI location is not mentioned anywhere in the application (see Attachment D).[4] The application offers no explanation as to why UNC Health claims ownership of Panther Creek, but not Chapel Hill or Burlington.

The statement on footnote 15 page 44 explains that NC Imaging is not a related party to UNC REX, but both UNC Rex and NC Imaging are wholly owned by UNC Health.

The above claim has substantial value as this would demonstrate the UNC Healthcare System's monopoly in the Orange County MRI scanner service area. The Applicant admits to owning nine of the 10 fixed MRI scanners in Orange County (the 10th being owned by Wake Radiology, Chapel Hill). This would place all 10 of the fixed MRI scanners in UNC Healthcare's possession, eliminating all competition.

The Applicant states on page 31, and reiterates on page 110, that payors are not only encouraging providers to keep outpatient services in outpatient settings, but are even "restrict[ing] hospital-based reimbursement to services developed on hospital (inpatient) campuses." UNC goes on to claim that their freestanding location will increase patient choice and foster competition within the service area. However, if approved, regardless of setting, this will be UNC's tenth MRI in the service area.

This proposed MRI would enable UNC Health to be very selective with its centralized referral system and send to the proposed new equipment only those patients for which it might be penalized by a particular payer.

The application is correct that major national insurers have instated policies that penalize or refuse to pay for certain outpatient imaging provided in hospital settings.[5] It could only implement this policy because non-hospital providers offer the competitive option.

[2] https://www.wakerad.com/locations/chapel-hill/

[3] https://www.wakerad.com/locations/cary/panther-creek/

[4] https://www.uncmedicalcenter.org/uncmc/hospitals-locations/profile/unc-hospitals-burlington-imaging-and-breast-center/

[5] United Health CMOs target lower-cost sites of service Becker's Payer Issues, June 17, 2021.. https://www.beckershospitalreview.com/payer-issues/unitedhealth-cmos-target-lower-cost-sites-of-service-care-gaps.html, accessed Nov 30, 2021

Because this Applicant would have a monopoly in the Orange County service area and could selectively control which patients are referred to the proposed facility through its centralized scheduling, the application should be found non-conforming to Criterion 18a.

20. An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

Again, UNC appears to be selective when discussing its affiliations with other facilities.

Question O.1 asks applicants to,

> *"Identify all existing and approved facilities **providing the same service components included in this proposal that are owned, operated or managed by the applicant or a related entity in North Carolina** by completing Form O Facilities, which is found in Section Q," (emphasis added).*

However, Form O lists only hospitals that UNC owns in North Carolina. The question is directed at the **service component**, meaning, in the very least, it failed to include Panther Creek in its form, but Form O likely misses Wake Radiology Chapel Hill, Burlington Imaging and Breast Center, and two other locations listed in the page 23 footnote.

Furthermore, Question O.5 asks the applicant to address any quality issues for the facilities listed in Form O. UNC claims the question to be not applicable because "[t]he proposed project does not involve hospitals…," but the form *only* lists hospitals.

Therefore, by not listing its non-hospital facilities on Form O, and claiming the project to not involve hospitals, the Applicant artfully dodges addressing any quality issues at any of its locations, despite being asked directly to provide that information.

The application provides insufficient information for the Agency to rule on this Criterion.

PERFORMANCE STANDARD

10A NCAC 14C .2703 CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

For reference, see pages 64 to 68. The Applicant must meet three tests:

1. (b) An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:

(1) demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;

Historical data appear to meet this performance test for the period ending June 2021. This is a long delay for an application filed in October 2021. We question whether the Applicant provided the most recent data available.

2. (3) demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:

(A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,

(B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,

(C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,

Data forecasts are overstated for UNC Medical Center, UNC Hospitals Hillsborough Campus, and UNC Health Imaging Center because the application relies on inflated Growth Factors. See discussion with regard to Criterion 3.

Hence the table on page 66 is over inflated.

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

(A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,

(B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,

(C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,

(D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or

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

At the reasonable forecast growth rate for the UNC Hillsborough Campus, the weighted scans for the proposed MRI do not meet the required performance standard of 4805. The weighting factor used in the UNC application on pdf page 138 is 1.235696 or (5788/4684), Applied to 3,646 scans, this produces 4,505 weighted scans. See further discussion of calculations in Criterion 3 of these comments.

The application clearly fails the third test and may fail the others. For that reason the application should be found non-conforming to at least the last test of this performance standard.

Attachment C

Comparative Metrics Recommended

The following sections explain why RRCH believes these eight comparative metrics should be used in the CON application review for a new fixed MRI in Orange County.

ACCESS BY SERVICE AREA RESIDENTS: TOTAL PATIENTS AND PERCENT OF TOTAL

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 and shown in Figure 5.1." Based on that definition, the fixed MRI service area is **a single county**, except where there is no licensed acute care hospital located within the county. Orange County has more than one licensed acute care hospital. Therefore, for the purpose of this review, Orange County is the service area because it has multiple licensed acute care hospitals.

This suggests that the applicant proposing to serve the highest number of patients from the service area – both total number of patients and highest percent of total – is the most effective applicant. Table ## below shows that, comparatively, in project year 3, RRCH is the most effective applicant.

	Project Year 1		Project Year 2		Project Year 3	
Applicant	**Total Patients**	**Percent**	**Total Patients**	**Percent**	**Total Patients**	**Percent**
RRCH	1,567	67.0%	2,352	67.0%	2,996	67.0%
UNC	562	27.9%	909	27.9%	1,308	27.9%
Duke	1,668	62.9%	2,104	61.1%	2,581	59.9%

PROJECTED AVERAGE NET REVENUE AND OPERATING COST PER WEIGHTED MRI PROCEDURE, PY3

In past reviews, the Agency has taken the position that certain comparisons are inconclusive when some applicants bill globally and others bill technical only. However, RRCH suggests that, in this review, although applicants' billing approaches differ, two metrics should be considered: projected average net revenue per weighted MRI procedure and projected average total operating cost per MRI procedure.

Table 1 below summarizes the difference in these two billing types.

Table 1: Global versus Technical Billing – MRI

	Global (Professional and Technical)	Technical Only
Billing	Patient receives a single bill for the technical portion – actual scan – and the professional fees – reading of scan – from the provider where the scan occurred.	Patient receives two bills. One for the technical portion – actual scan – from the location where the service occurred, and a second for professional fees – reading of scan. The professional fee usually comes from a radiologist who may or may not be where the scan occurred.
Operating	The pro forma in the CON application provides a line-item accounting for the expense associated with the professional fee.	The pro forma in the CON application does not provide a line-item accounting for the expense associated with the professional fee.

Projected Average Net Revenue per Weighted MRI Procedure

Table 2 compares the projected average net revenue per weighted MRI procedure for the third year of operation for all the applicants. Historically, the Agency has deemed the applicant with the lowest average net revenue per MRI procedure the more effective alternative, noting that a lower average might indicate a lower cost to the patient or third-party payor.

Table 2: Comparison of Applicants' Third Year Net Revenue per Weighted MRI Procedure

Applicant	Net Revenue	# of Weighted MRI Procedures	Average Net Revenue
	a	b	c
RRCH	$2,096,210	5,128	$408.78
UNC	$3,060,935	5,788	$528.84
Duke	$2,433,066	4,914	$495.13

Notes:

a. Form F.2, Third full operating year
b. Form C Third full operating year
c. a/b.

RRCH bills globally, while UNC and Duke do not. The billed amount in the RRCH application is the entire amount for the service. The patient or third-party payor will not receive a second, follow up bill for professional fees after receiving service from RRCH. Using the weighted procedure accounts for possible differences in case mix. Among these applicants, RRCH proposes the lowest average net revenue per weighted MRI procedure in the third full fiscal year following project completion.

UNC and Duke propose a higher average net revenue per weighted MRI procedure and the patient or third-party payor will receive a second bill for professional fees. Further, there is no way to estimate the total cost to the patient or third-party payor based on the UNC and Duke applications. **RRCH is the lowest of the three, even with the professional fee included.** Therefore, RRCH is the more effective alternative regarding this important comparative factor.

Projected Average Total Operating Cost per MRI Procedure

Generally, the application proposing the lowest average operating expense per MRI procedure is the more effective alternative because a lower average indicates better capacity to provide and sustain low actual charge structures. Table ## compares projected average total operating cost per weighted MRI procedure for the third full year of operation following project completion for all the applicants. To allow for comparison between the applications, the table reduces RRCH's total operating expenses by the Professional Fees -Physician expense line ($1,842,566 - $451,326 = $1,391,241). Because UNC and Duke pro formas do not include a professional fees expense line, no adjustment is necessary.

Table 3: Comparison of Applicants' Third Year Average Operating Expense per Weighted MRI Procedure

Applicant	Operating Expense (Less Professional Fees)	# of Weighted MRI Procedures	Average Operating Expense
	a	b	c
RRCH	$1,391,241	5,128	$271.30
UNC	$2,645,981	5,788	$457.15
Duke	$1,428,780	4,914	$290.76

Notes:

a. Form F.3 Third full year, minus line item Professional fees for physicians
b. Form C Third full operating year
c. a/b.

RRCH proposes the lowest average operating expense per weighted MRI procedure, when professional fees are excluded. Therefore, RRCH is the most effective alternative regarding this comparative factor.

COMPETITION: ACCESS TO NEW OR ALTERNATIVE PROVIDER

Generally, the application proposing to increase competition in the service area is the more effective alternative with regard to this comparative factor. The introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or reduce costs in order to compete for patients.

This metric is important because one applicant, UNC, controls nine of the ten fixed MRI scanners in Orange County, and has ownership interest in the tenth. Awarding UNC this scanner will only increase its monopoly.

Duke would technically be a new competitor in Orange County, awarding it the MRI scanner misses the spirit of this metric. The Duke scanner, while freestanding, would still be part of the higher-priced academic medical center health system. Furthermore, the Duke application, and support for its proposal, clearly shows that this location will be part of a closed system – Duke physicians referring to Duke equipment.

Only the RRCH proposal brings true open competition to the Orange County market.

COORDINATION OF CARE

For this metric, applicants must demonstrate that the "proposed service will be coordinated with the existing health system."[1] Frequently, applicants demonstrate this through letters of support from physicians within and around the proposed service area that plan to refer patients to the proposed service.

[1] Criterion 8

Both the UNC and Duke applications provide substantial numbers of support letters, suggesting a strong effort from each applicant to gain support for its proposal. However, closer inspection will show that all the letters provided are from within their respective systems. There is no indication that applicants reached out to, or garnered support from, physicians or other providers not affiliated with their own system.

Again, this speaks to the spirit of the need for Orange County residents. Not every resident within the county is a UNC or Duke patient, but that does not discount their need for MRI services. Orange County needs an MRI provider willing to work with the entire health system, not just part. RRCH is prepared to do that.

RADIOLOGIST ON-SITE

UNC projects MRI scans with contrast at the proposed UNC Health Imaging Center location. According to the American College of Radiology, the accrediting entity for MRI, during an MRI scan requiring contrast, the

> *"…health care professional performing the injection must be a certified and/or licensed radiologic technologist, MRI technologist, registered radiologist assistant, nurse, physician assistant, physician, or other appropriately credentialed health care professional* ***under the direct supervision of a radiologist or his or her physician designee****." [Emphasis added]*

CMS defines "Direct Supervision" in the office setting as

> "…the physician **must be present in the office suite** and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed." [Emphasis added]

Therefore, to comply with CMS rules, the applicant must arrange for a radiologist or his or her physician designee to be in office during all contrast MRI procedures.

RRCH's MRI will operate from within its diagnostic center with a **radiologist** on-site (page 31). In contrast, Duke and UNC have each claimed "a physician in the building" without speaking to the physician's specialty or proximity to the MRI service.

PROPOSED FACILITY EXISTS (READY FOR DEVELOPMENT)

RRCH proposes to install the MRI in an approved diagnostic center in an existing building. Both Duke and UNC are proposing locations in medical office buildings under construction. As a result, **RRCH can begin offering services as much as 14 months sooner** than the other applicants. Clearly RRCH is the more effective alternative.

Comparative Metrics Rejected

Several comparative metrics that the Agency has used in other competitive reviews would be difficult to apply in this review. The following sections detail why.

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.

Projected Charity Care

Generally, the application proposing to provide the most charity care is the more effective alternative with regard to this comparative factor. However, the applicants compute charity care in different ways, making the analysis inconclusive. Further, RRCH bills globally, while UNC and Duke do not. The agency has taken the position in the past that these differences in billing do not allow for a comparison between the applications regarding this metric.

Projected Medicaid

Historically, the Agency has deemed the application proposing to provide a higher dollar amount of Medicaid, the highest amount of Medicaid per MRI scan, and the highest amount of Medicaid as a percentage of gross revenue as the more effective alternative with regard to this comparative factor. RRCH bills globally, while UNC and Duke do not. The agency has taken the position in the past that these differences in billing do not allow for a comparison between the applications regarding this metric. Moreover, UNC and Duke use *hospital* history to forecast *IDTF* payor mix. Neither provides an adjustment for the difference.

Projected Medicare

Total Medicare patients and Medicare patients as a percentage of total patients cannot be compared because the total number of Medicare patients was not provided by the applicants. In this review, the Agency can only compare Medicare as a percentage of gross revenue. Historically, the Agency has deemed the application proposing to provide a higher dollar amount of Medicare, the highest amount of Medicare per MRI scan, and the highest amount of Medicare as a percentage of gross revenue as the more effective alternative with regard to this comparative factor. RRCH bills globally, while UNC and Duke do not. The agency has taken the position in the past that these differences in billing do not allow for a comparison between the applications regarding this metric.

SCOPE OF SERVICES / GEOGRAPHIC ACCESSIBILITY

Generally, the application proposing to provide the broadest scope of services is the more effective alternative with regard to this comparative factor. With regard to scope of services, all applications submitted are in response to the 2021 State Medical Facilities Plan (SMFP) which includes a need determination for one fixed MRI scanner. All the applicants propose to:

- Operate a fixed MRI scanner in a freestanding outpatient setting;
- Acquire a 1.5 Tesla strength MRI scanner;
- Perform various types of scans on all patients; and,
- Locate the scanner in Chapel Hill (within 1.5 miles of each other).

From this perspective, all applicants are equally effective.

For another reason, this metric *might* be used. Duke clearly states in its methodology that the proposed MRI will not serve cancer patients. RRCH and UNC make no such service restrictions and would be equally effective.

WOULD ADD TO THE MRI INVENTORY

None of the applicants propose to use this CON award to replace an existing third-party owned and operated MRI scanner. Therefore, each of them would add to the Orange County MRI inventory making each equally effective.

HISTORICAL UTILIZATION OF THE FACILITY

Neither Duke nor RRCH have existing operations in Orange County. Historical use cannot be compared.

Attachment D

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Effective January 01, 2021, this license is issued to

University of North Carolina Hospitals at Chapel Hill

to operate a hospital known as

University of North Carolina Hospitals

located in Chapel Hill, North Carolina, Orange County.

This license is issued subject to the statutes of the State of North Carolina, is not transferable and shall remain in effect until amended by the issuing agency.

Facility ID: 923517

License Number: H0157

Bed Capacity: *923*

General Acute 817, Rehabilitation 30 , Psych 76,

Dedicated Inpatient Surgical Operating Rooms: 3
Dedicated Ambulatory Surgical Operating Rooms: 6
Shared Surgical Operating Rooms: 37
Dedicated Endoscopy Rooms: 9

Authorized by:

Secretary, N.C. Department of Health and Human Services

Director, Division of Health Service Regulation

JAN 13 2021

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
Regular Mail: 1205 Umstead Drive
2712 Mail Service Center
Raleigh, North Carolina 27699-2712
Overnight UPS and FedEx only: 1205 Umstead Drive
Raleigh, North Carolina 27603
Telephone: (919) 855-4620 Fax: (919) 715-3073

For Official Use Only
License # H0157 Medicare # **340061**
FID #: 923517
PC CT Date 1/14/21

License Fee: **$17,102.50**

2021
HOSPITAL LICENSE
RENEWAL APPLICATION

Legal Identity of Applicant: **University of North Carolina Hospitals at Chapel Hill**
(Full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service.)

Doing Business As
(d/b/a) name(s) under which the facility or services are advertised or presented to the public:

PRIMARY: **University of North Carolina Hospitals**
Other: UNC Hospitals;
Other: _____

Facility Mailing Address: 101 Manning Dr
Chapel Hill, NC 27514

Facility Site Address: 101 Manning Dr
Chapel Hill, NC 27514
County: Orange
Telephone: (984)974-5111
Fax: (984)974-7772

Application Rec'd Date 1-13-21
Fee Paid-Ck # 270916
Amount $17,102.50
Initials
DHSR Acute and Home Care L&C

Administrator/Director: Janet Hadar
Title: President
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive Officer: J Hadar **Title:** President
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Name of the person to contact for any questions regarding this form:

Name: Elizabeth Runyon **Telephone:** 984-215-3622

E-Mail: elizabeth.runyon@unchealth.unc.edu

Instructions for Hospitals with multiple campuses: For MRI Services, (Sections 10b-10e, pp 17-18), do not provide cumulative/combined data for all campuses. Provide data for individual campuses only.

b. MRI Procedures

Indicate the number of procedures performed on MRI scanners (units) operated during the 12-month reporting period at your facility. For hospitals that use equipment at multiple sites/campuses, please copy the MRI pages and provide separate data for each site/campus. **Campus – *if multiple sites*:** Medical Center

Procedures	Inpatient Procedures*			Outpatient Procedures*			TOTAL Procedures
	With Contrast or Sedation	Without Contrast or Sedation	TOTAL Inpatient	With Contrast or Sedation	Without Contrast or Sedation	TOTAL Outpatient	
Fixed	4,261	2,540	6,801	8,807	4,359	13,166	19,967
Mobile (performed only at this site)							
TOTAL**	4,261	2,540	6,801	8,807	4,359	13,166	19,967

* An **MRI procedure** is defined as a single discrete MRI study of one patient (single CPT-coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom.
** Totals must be greater than or equal to the totals in the MRI Patient Origin Table on page 30 of this application.

Note: Healthcare Planning and Certificate of Need may request CPT codes for MRI procedures if further clarification is needed.

c. Fixed MRI Scanners

Indicate the number of MRI scanners (units) operated during the 12-month reporting period at your facility. For hospitals that operate medical equipment at multiple sites/campuses, please copy the MRI pages and provide separate data for each site/campus. **Campus – *if multiple sites*:** Medical Center

Fixed Scanners	Number of Units
Number of fixed MRI scanners-closed, including open-bore scanners (*do not include any* Policy AC-3 scanners)	6
Number of fixed MRI scanners-open (*do not include any* Policy AC-3 scanners)	0
Number of Policy AC-3 MRI scanners used for general clinical purposes	0
Total Fixed MRI Scanners	6

Number of grandfathered fixed MRI scanners on this campus: 1 Acquired in 1986 with FDA approval

For questions, please contact Healthcare Planning and Certificate of Need at 919-855-3873.

CON Project ID numbers for all other fixed MRI scanners on this campus: UNCH 9MRIS #1 acquired in 1986 with FDA approval; #2 J-4048-90; #3-#4 J-5900-98; #5 J -7028-04; #6 J-73001-05; #7 J-8136-08; J-8391-09; #9 J-10314-14

Instructions for Hospitals with multiple campuses: For MRI Services, (Sections 10b-10e, pp 17-18), do not provide cumulative/combined data for all campuses. Provide data for individual campuses only.

b. MRI Procedures

Indicate the number of procedures performed on MRI scanners (units) operated during the 12-month reporting period at your facility. For hospitals that use equipment at multiple sites/campuses, please copy the MRI pages and provide separate data for each site/campus. **Campus – *if multiple sites*:** Hillsborough

Procedures	Inpatient Procedures*			Outpatient Procedures*			TOTAL Procedures
	With Contrast or Sedation	Without Contrast or Sedation	TOTAL Inpatient	With Contrast or Sedation	Without Contrast or Sedation	TOTAL Outpatient	
Fixed	216	84	300	2,372	1,595	3,967	4,267
Mobile (performed **only at this site**)	0	0	0	1,060	799	1,859	1,859
TOTAL**	216	84	300	3,432	2,394	5,826	6,126

* An **MRI procedure** is defined as a single discrete MRI study of one patient (single CPT-coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom.
** Totals must be greater than or equal to the totals in the MRI Patient Origin Table on page 30 of this application.

Note: Healthcare Planning and Certificate of Need may request CPT codes for MRI procedures if further clarification is needed.

c. Fixed MRI Scanners

Indicate the number of MRI scanners (units) operated during the 12-month reporting period at your facility. For hospitals that operate medical equipment at multiple sites/campuses, please copy the MRI pages and provide separate data for each site/campus. **Campus – *if multiple sites*:** Hillsborough

Fixed Scanners	Number of Units
Number of fixed MRI scanners-closed, including open-bore scanners (*do not include any* Policy AC-3 scanners)	1
Number of fixed MRI scanners-open (*do not include any* Policy AC-3 scanners)	0
Number of Policy AC-3 MRI scanners used for general clinical purposes	0
Total Fixed MRI Scanners	1

Number of grandfathered fixed MRI scanners on this campus: SEE MED CENTER RESPONSE PG 17

For questions, please contact Healthcare Planning and Certificate of Need at 919-855-3873.

CON Project ID numbers for all other fixed MRI scanners on this campus:

SEE MED CENTER RESPONSE PG 17

Instructions for Hospitals with multiple campuses: For MRI Services, (Sections 10b-10e, pp 17-18), do not provide cumulative/combined data for all campuses. Provide data for individual campuses only.

b. MRI Procedures

Indicate the number of procedures performed on MRI scanners (units) operated during the 12-month reporting period at your facility. For hospitals that use equipment at multiple sites/campuses, please copy the MRI pages and provide separate data for each site/campus. **Campus – *if multiple sites*:** Imaging Center - Hwy 54

Procedures	Inpatient Procedures*			Outpatient Procedures*			TOTAL Procedures
	With Contrast or Sedation	Without Contrast or Sedation	TOTAL Inpatient	With Contrast or Sedation	Without Contrast or Sedation	TOTAL Outpatient	
Fixed	0	0	0	5,316	2,918	8,234	8,234
Mobile (performed **only at this site**)	0	0	0	562	321	883	883
TOTAL**	0	0	0	5,878	3,239	9,117	9,117

* An **MRI procedure** is defined as a single discrete MRI study of one patient (single CPT-coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom.
** Totals must be greater than or equal to the totals in the MRI Patient Origin Table on page 30 of this application.

Note: Healthcare Planning and Certificate of Need may request CPT codes for MRI procedures if further clarification is needed.

c. Fixed MRI Scanners

Indicate the number of MRI scanners (units) operated during the 12-month reporting period at your facility. For hospitals that operate medical equipment at multiple sites/campuses, please copy the MRI pages and provide separate data for each site/campus. **Campus – *if multiple sites*:** Imaging Center - Hwy 54

Fixed Scanners	Number of Units
Number of fixed MRI scanners-closed, including open-bore scanners (*do not include any* Policy AC-3 scanners)	2
Number of fixed MRI scanners-open (*do not include any* Policy AC-3 scanners)	0
Number of Policy AC-3 MRI scanners used for general clinical purposes	0
Total Fixed MRI Scanners	2

Number of grandfathered fixed MRI scanners on this campus: SEE MED CENTER RESPONSE PG.17

For questions, please contact Healthcare Planning and Certificate of Need at 919-855-3873.

CON Project ID numbers for all other fixed MRI scanners on this campus:

SEE MED CENTER RESPONSE PG. 17

Instructions for Hospitals with multiple campuses: For MRI Services, (Sections 10b-10e, pp 17-18), do not provide cumulative/combined data for all campuses. Provide data for individual campuses only.

b. MRI Procedures

Indicate the number of procedures performed on MRI scanners (units) operated during the 12-month reporting period at your facility. For hospitals that use equipment at multiple sites/campuses, please copy the MRI pages and provide separate data for each site/campus. **Campus – *if multiple sites*:** Burlington Imaging- leased from Alliance medical

Procedures	Inpatient Procedures*			Outpatient Procedures*			TOTAL Procedures
	With Contrast or Sedation	Without Contrast or Sedation	TOTAL Inpatient	With Contrast or Sedation	Without Contrast or Sedation	TOTAL Outpatient	
Fixed							
Mobile (performed **only at this site**)				49	146	195	195
TOTAL**				49	146	195	195

* An **MRI procedure** is defined as a single discrete MRI study of one patient (single CPT-coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom.
** Totals must be greater than or equal to the totals in the MRI Patient Origin Table on page 30 of this application.

Note: Healthcare Planning and Certificate of Need may request CPT codes for MRI procedures if further clarification is needed.

c. Fixed MRI Scanners

Indicate the number of MRI scanners (units) operated during the 12-month reporting period at your facility. For hospitals that operate medical equipment at multiple sites/campuses, please copy the MRI pages and provide separate data for each site/campus. **Campus – *if multiple sites*:**

Fixed Scanners	Number of Units
Number of fixed MRI scanners-closed, including open-bore scanners (*do not include any* Policy AC-3 scanners)	
Number of fixed MRI scanners-open (*do not include any* Policy AC-3 scanners)	
Number of Policy AC-3 MRI scanners used for general clinical purposes	
Total Fixed MRI Scanners	

Number of grandfathered fixed MRI scanners on this campus: _____

For questions, please contact Healthcare Planning and Certificate of Need at 919-855-3873.

CON Project ID numbers for all other fixed MRI scanners on this campus: _____

_____

d. Mobile MRI Services **Campus – *if multiple sites*:** _____

During the reporting period,

1. Did the facility own one or more mobile MRI scanners? ____ Yes ____ No

If Yes, how many? _____ Of these, how many are grandfathered? _____
CON Project ID numbers for non-grandfathered mobile scanners owned by facility:
_____

Did the facility contract for mobile MRI services? ____ Yes ____ No

If Yes, name of mobile vendor: _____

e. Other MRI

Patients served on units listed in the next table should not be included in the MRI Patient Origin Table on page 30 of this application. For hospitals that operate medical equipment at multiple sites/campuses, please copy the MRI pages and provide separate data for each site/campus.
Campus – *if multiple sites*: _____

Other Scanners	Units	Inpatient Procedures*			Outpatient Procedures*			TOTAL Procedures
		With Contrast or Sedation	Without Contrast or Sedation	TOTAL Inpatient	With Contrast or Sedation	Without Contrast or Sedation	TOTAL Outpatient	
Other Human Research MRI scanners								
Intraoperative MRI (iMRI)								

* An **MRI procedure** is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom.

f. Computed Tomography (CT). **Campus – *if multiple sites*:** Med Center

How many fixed CT scanners does the hospital have? 7

Does the hospital contract for mobile CT scanner services? ____ Yes ✓ No

If yes, identify the mobile CT vendor _____

Complete the following table for fixed and mobile CT scanners.

	Type of CT Scan	FIXED CT Scanner # of Scans	MOBILE CT Scanner # of Scans	
1	Head without contrast	8,199		
2	Head with contrast	69		
3	Head without and with contrast	637		
4	Body without contrast	16,515		
5	Body with contrast	16,492		
6	Body without contrast and with contrast	4,385		
7	Biopsy in addition to body scan with or without contrast	433		
8	Abscess drainage in addition to body scan with or without contrast	2		
	Total	46,732		

d. Mobile MRI Services **Campus – *if multiple sites*:** Hillsborough

During the reporting period,

1. Did the facility own one or more mobile MRI scanners? ____ Yes ✓ No

If Yes, how many? _____ Of these, how many are grandfathered? _____
CON Project ID numbers for non-grandfathered mobile scanners owned by facility:

_____

Did the facility contract for mobile MRI services? ✓ Yes ____ No

If Yes, name of mobile vendor: Alliance

e. Other MRI

Patients served on units listed in the next table should not be included in the MRI Patient Origin Table on page 30 of this application. For hospitals that operate medical equipment at multiple sites/campuses, please copy the MRI pages and provide separate data for each site/campus.

Campus – *if multiple sites*: _____

Other Scanners	Units	Inpatient Procedures*			Outpatient Procedures*			TOTAL Procedures
		With Contrast or Sedation	Without Contrast or Sedation	TOTAL Inpatient	With Contrast or Sedation	Without Contrast or Sedation	TOTAL Outpatient	
Other Human Research MRI scanners								
Intraoperative MRI (iMRI)								

* An **MRI procedure** is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom.

f. Computed Tomography (CT). **Campus – *if multiple sites*:** Hillsborough

How many fixed CT scanners does the hospital have? 2

Does the hospital contract for mobile CT scanner services? ____ Yes ✓ No

If yes, identify the mobile CT vendor _____

Complete the following table for fixed and mobile CT scanners.

	Type of CT Scan	FIXED CT Scanner # of Scans	MOBILE CT Scanner # of Scans	
1	Head without contrast	1,589		
2	Head with contrast	23		
3	Head without and with contrast	101		
4	Body without contrast	3,861		
5	Body with contrast	5,868		
6	Body without contrast and with contrast	1,178		
7	Biopsy in addition to body scan with or without contrast	0		
8	Abscess drainage in addition to body scan with or without contrast	1		
	Total	12,621		

d. Mobile MRI Services **Campus – *if multiple sites*:** Imaging Center Hwy 54

During the reporting period,

1. Did the facility own one or more mobile MRI scanners? ____ Yes ✓ No

If Yes, how many? _____ Of these, how many are grandfathered? _____
CON Project ID numbers for non-grandfathered mobile scanners owned by facility:

_____

Did the facility contract for mobile MRI services? ✓ Yes ____ No

If Yes, name of mobile vendor: Alliance

e. Other MRI

Patients served on units listed in the next table should not be included in the MRI Patient Origin Table on page 30 of this application. For hospitals that operate medical equipment at multiple sites/campuses, please copy the MRI pages and provide separate data for each site/campus.

Campus – *if multiple sites*: _____

Other Scanners	Units	Inpatient Procedures*			Outpatient Procedures*			TOTAL Procedures
		With Contrast or Sedation	Without Contrast or Sedation	TOTAL Inpatient	With Contrast or Sedation	Without Contrast or Sedation	TOTAL Outpatient	
Other Human Research MRI scanners								
Intraoperative MRI (iMRI)								

* An **MRI procedure** is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom.

f. Computed Tomography (CT). **Campus – *if multiple sites*:** Imaging Center Hwy 54

How many fixed CT scanners does the hospital have? 1

Does the hospital contract for mobile CT scanner services? ✓ Yes ____ No

If yes, identify the mobile CT vendor Alliance

Complete the following table for fixed and mobile CT scanners.

	Type of CT Scan	FIXED CT Scanner # of Scans	MOBILE CT Scanner # of Scans
1	Head without contrast	257	158
2	Head with contrast	30	0
3	Head without and with contrast	122	0
4	Body without contrast	3,254	327
5	Body with contrast	5,258	28
6	Body without contrast and with contrast	698	0
7	Biopsy in addition to body scan with or without contrast	0	0
8	Abscess drainage in addition to body scan with or without contrast	0	0
	Total	9,619	513

d. Mobile MRI Services **Campus – *if multiple sites*:** Burlington Imaging

During the reporting period,

1. Did the facility own one or more mobile MRI scanners? ____ Yes ✓ No

If Yes, how many? _____ Of these, how many are grandfathered? _____
CON Project ID numbers for non-grandfathered mobile scanners owned by facility:

_____

Did the facility contract for mobile MRI services? ✓ Yes ____ No

If Yes, name of mobile vendor: Alliance

e. Other MRI

Patients served on units listed in the next table should not be included in the MRI Patient Origin Table on page 30 of this application. For hospitals that operate medical equipment at multiple sites/campuses, please copy the MRI pages and provide separate data for each site/campus.

Campus – *if multiple sites*: _____

Other Scanners	Units	Inpatient Procedures*			Outpatient Procedures*			TOTAL Procedures
		With Contrast or Sedation	Without Contrast or Sedation	TOTAL Inpatient	With Contrast or Sedation	Without Contrast or Sedation	TOTAL Outpatient	
Other Human Research MRI scanners		0	0	0	0	0	0	0
Intraoperative MRI (iMRI)		0	0	0	0	0	0	0

* An **MRI procedure** is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom.

f. Computed Tomography (CT). **Campus – *if multiple sites*:** Burlington Imaging

How many fixed CT scanners does the hospital have? 1

Does the hospital contract for mobile CT scanner services? ____ Yes ✓ No

If yes, identify the mobile CT vendor _____

Complete the following table for fixed and mobile CT scanners.

	Type of CT Scan	FIXED CT Scanner # of Scans	MOBILE CT Scanner # of Scans	
1	Head without contrast	14		
2	Head with contrast	1		
3	Head without and with contrast	1		
4	Body without contrast	105		
5	Body with contrast	108		
6	Body without contrast and with contrast	10		
7	Biopsy in addition to body scan with or without contrast	0		
8	Abscess drainage in addition to body scan with or without contrast	0		
	Total	239		

Attachment E

Registration and Inventory of Medical Equipment
Fixed Magnetic Resonance Imaging Scanners
January 2021

Instructions
This is the legally required "Registration and Inventory of Medical Equipment" (G.S. 131E-177) for fixed magnetic resonance imaging (MRI) scanners. Please complete all sections of this form and return to Healthcare Planning by **Friday, January 29, 2021**.

1. **Submit one completed Registration and Inventory form per MRI scanner.**
2. Complete and sign the form
3. Return the form by one of two methods:
   a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.
   b. Mail the form to Trenesse Michael, Healthcare Planning, 2704 Mail Service Center, Raleigh, NC 27699-2704.

If you have questions, call Trenesse Michael in Healthcare Planning at (919) 855-3867 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.

Note: Fixed equipment operated in a facility licensed under a hospital should be reported on that hospital's license renewal application, and not duplicated on this form.

Section 1: Contact Information

1. Full legal name of corporation, partnership, individual, or other legal entity that acquired the equipment by purchase, donation, lease, transfer, or comparable arrangement:

   Chapel Hill Diagnostic Imaging, LLC
   (Legal Name)

2. Address of the corporation, partnership, individual, or other legal entity that acquired the equipment:

   110 S Estes Drive
   (Street and Number)

   Chapel Hill — (City); NC — (State); 27514 — (Zip); (919) 942-3196 — (Phone Number)

3. Chief Executive Officer or approved designee who is certifying the information in this registration form:

   Kelly A. Israel — (Name); Sr, Mgr Development & Mobile Ops — (Title)

   3480 Preston Ridge Rd, Ste 600 — (Street and Number); Alpharetta — (City); GA — (State); 30005 — (Zip)

   (770) 300-0101 — (Phone Number); kisrael@medquestmail.com — (Email)

4. Information Compiled or Prepared by: Kelly A. Israel
   (Name)

   (770) 300-0101 — (Phone Number); kisrael@medquestmail.com — (Email)

Section 2: Equipment and Procedures Information

Reporting Period: ☑ 10/01/2019 – 9/30/2020 ☐ Other time period: _____

Do not make extra copies of this page if the entity has multiple MRIs in the same county. Submit a complete, separate R&I form for each scanner.

DHSR Planning Use Only	
Manufacturer / Tesla	Siemens / **1.5T**
Model Number	Espree 7391167
Open or closed (including open bore) scanner	☐ Open ☑ Closed
Serial or I.D. number	25460
Date of acquisition	11/2013
Purchase price (if purchased)	$600,000
Certificate of Need Project ID (or grandfathered)	☑ Grandfathered
Certificate holder, as listed on Certificate of Need	Chapel Hill Diagnostic Imaging, LLC
If this equipment was originally a mobile scanner, check box if it is now • permanently parked ("wheels off" or on) or • installed in a building	☐ Parked ☐ Installed
Service Site Information: Please include **all** the information requested.	Service Site Wake Radiology Address 110 S. Estes Drive City: Chapel Hill Zip 27514 County Orange
Inpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation Outpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation **Total Number of Procedures**	Inpatient: with: _____ w/out: _____ Total: _____ Outpatient: with: 867 w/out: 911 Total: 1,778 **Total**: 1,778
For each day of the week, enter the **number of hours** the scanner is in operation.	___ Sunday _9__ Monday _9__ Tuesday _9__ Wednesday _9__ Thursday _9__ Friday ___ Saturday
Total number of hours in operation for reporting period	2,340 Hours

*An **MRI procedure** is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom. **The total number of procedures should be equal to or greater than the total number of patients reported on the MRI Patient Origin Table on page 3 of this form.**

Name of entity that acquired the equipment (from page 1) Chapel Hill Diagnostic Imaging, LLC

Section 3: Patient Origin Data

Please provide the county of residence for each patient who received MRI services during the time period of this report. The total number of patients receiving services should be equal to or less than the total number of procedures reported on page 2 of this form.

County in which service was provided: Wake

Patient County	Number of Patients	Patient County	Number of Patients	Patient County	Number of Patients
1. Alamance	58	37. Gates		73. Person	19
2. Alexander	1	38. Graham		74. Pitt	3
3. Alleghany		39. Granville	4	75. Polk	
4. Anson		40. Greene		76. Randolph	10
5. Ashe	2	41. Guilford	7	77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett	9	79. Rockingham	
8. Bertie		44. Haywood		80. Rowan	
9. Bladen		45. Henderson	1	81. Rutherford	
10. Brunswick		46. Hertford		82. Sampson	4
11. Buncombe	1	47. Hoke	1	83. Scotland	2
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell	2	85. Stokes	
14. Caldwell		50. Jackson	1	86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	
17. Caswell	2	53. Lee	12	89. Tyrrell	
18. Catawba		54. Lenoir	1	90. Union	1
19. Chatham	142	55. Lincoln		91. Vance	7
20. Cherokee		56. Macon		92. Wake	554
21. Chowan		57. Madison		93. Warren	2
22. Clay		58. Martin		94. Washington	
23. Cleveland		59. McDowell		95. Watauga	2
24. Columbus		60. Mecklenburg	1	96. Wayne	2
25. Craven	1	61. Mitchell		97. Wilkes	
26. Cumberland	6	62. Montgomery		98. Wilson	3
27. Currituck		63. Moore	8	99. Yadkin	
28. Dare		64. Nash	5	100. Yancey	
29. Davidson	3	65. New Hanover			
30. Davie		66. Northampton	1	101. Georgia	3
31. Duplin	1	67. Onslow		102. South Carolina	3
32. Durham	209	68. Orange	610	103. Tennessee	1
33. Edgecombe		69. Pamlico		104. Virginia	8
34. Forsyth	3	70. Pasquotank		105. Other	16
35. Franklin	17	71. Pender			
36. Gaston		72. Perquimans	1	**Total Number of Patients**	1,778

Section 4: Certification and Signature

The undersigned Chief Executive Officer or approved designee certifies the accuracy of the information contained on all pages of this form.

Signature _____*Kelly A Israel*_____

Print Name _____Kelly A. Israel_____

Date signed _____January 29, 2021_____

Note: Healthcare Planning and Certificate of Need may request CPT codes for MRI procedures if further clarification is needed.

Section 5: COVID-19 Addendum to Registration and Inventory of Medical Equipment

This special section of the 2021 Registration and Inventory Forms seeks information regarding the facility's experience with COVID-19. This data will assist Healthcare Planning in projecting the need for equipment in the 2022 State Medical Facilities Plan.

The addendum is not asking for procedures performed on patients diagnosed with or suspected of having COVID-19. Rather, it covers <u>all</u> patients seen at the site entered on page 2 between April 1, 2020 and September 30, 2020.

Enter the number of procedures for the period <u>April 1, 2020 through September 30, 2020 only</u>.

Manufacturer / Tesla	Siemens / **1.5T**
Model Number	Espree
Open or closed (including open bore) scanner	☐ Open ☑ Closed
Serial or I.D. number	25460
Inpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation Outpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation **Total Number of Procedures**	Inpatient: with: _____ w/out: _____ Total: _____ Outpatient: with: 412 w/out: 397 Total: 809 **Total**: 809

Name of entity that acquired the equipment (from page 1) Chapel Hill Diagnostic Imaging, LLC

AUTHENTICATING SIGNATURE: The undersigned submits the COVID-19 Addendum as part of the 2021 Registration and Inventory of Medical Equipment and certifies the accuracy of this information.

Signature Kelly A Israel

Print Name Kelly A. Israel

Date signed January 29, 2021

Please complete all sections of this form and return to Healthcare Planning by **Friday, January 29, 2021**.

1. Complete and sign the form
2. Return the form by one of two methods:
   a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.
   b. Mail the form to Trenesse Michael in Healthcare Planning, 2704 Mail Service Center, Raleigh, NC 27699-2704.

If you have questions, call Trenesse Michael in Healthcare Planning at (919) 855-3867 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.

Attachment F

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Effective January 01, 2020, this license is issued to

Duke University Health System, Inc.

to operate a hospital known as

Duke University Hospital

located in Durham, North Carolina, Durham County.

This license is issued subject to the statutes of the State of North Carolina, is not transferable and shall remain in effect until amended by the issuing agency.

Facility ID: 943138

License Number: H0015

Bed Capacity: *979*

General Acute 960, Psych 19,

Dedicated Inpatient Surgical Operating Rooms: 6
Dedicated Ambulatory Surgical Operating Rooms: 9
Shared Surgical Operating Rooms: 50
Dedicated Endoscopy Rooms: 11

Authorized by:

Secretary, N.C. Department of Health and Human Services

Director, Division of Health Service Regulation

Duke University Hospital License Renewal Application 2021
Footnote for Page 4

***NC facilities that are part of Duke University Health System, Inc. are:**

Duke University Hospital

Duke Regional Hospital

Davis Ambulatory Surgical Center

Duke Ambulatory Surgery Center Arringdon

Duke Raleigh Hospital

Duke Home Health

Duke Home Infusion

Duke Hospice (Durham Office)

Duke Hospice (Raleigh Office)

Duke Hospice (Oxford Office)

Hock Family Pavilion (Hospice Inpatient Facility)

Duke Hospice at the Meadowlands (Inpatient Facility)

Duke Hospice Unicorn Bereavement Center

Duke University Hospital License Renewal Application 2021
Footnote 2 for Page 3

Duke University Hospital's Durham County clinic and other hospital service locations (including those meeting business occupancy standards as well as ambulatory or healthcare occupancy standards):

Name:	Address:
Duke South Hospital Clinic	40 Duke Medicine Circle
Morris Building	30 Duke Medicine Circle
Duke Cancer Center	20 Duke Medicine Circle
Duke Children's Health Center	2301 Erwin Road
Duke Eye Center	2351 Erwin Road
North Pavilion	2400 Pratt Street
Pickens Clinic	2100 Erwin Road
Duke Adult Psychiatry Clinic/Substance Abuse Outpatient Services/Duke Family Care	Civitan Building 2213 Elba Street
Duke Health Center at South Durham	234 Crooked Creek Parkway
Lenox Baker Clinic	3000 Erwin Road
Sleep Disorders Clinic	2800 Campus Walk Ave
Duke Health Center at N. Duke Street	3116 N. Duke Street
Pepsico Fitness Center/Center for Living/Wallace Clinic	3475 Erwin Road
Duke Primary Care & Pediatric Clinic	4020 N. Roxboro Road
Duke Outpatient Clinic	4220 N. Roxboro Road
Morreene Road Clinic/Pain Evaluation Treatment	932 Morreene Road
Duke Radiology at Patterson Place	5324 McFarland Dr., Suite 160
Fetal Diagnostic Center and Duke Child and Family Studies Duke Children's Evaluation Center	2608 Erwin Road
Duke Diet & Fitness Center	501 Douglas Street
Biochemical Genetics Laboratory	801 Capitola Drive, Suite 6
Duke Medical Plaza at Page Road (Riverbirch)	4709 Creekstone Drive, Suite 250
Duke Cardiopulmonary Rehabilitation at Croasdaile Commons	1821 Hillandale Rd., Suite 25B (Opened after June 30, 2013)
Duke Health Center at NC Orthopedic Clinic/ Duke Physical Therapy and Occupation Therapy	3609 Southwest Durham Dr.
Duke Pain Clinic	4309 Medical Park Dr.
Duke Student Health PT/OT	305 Towerview Dr., Suite 316
Duke Health Center at Southpoint	6301 Herndon Rd.

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Effective January 01, 2021, this license is issued to

Duke University Health System, Inc.

to operate a hospital known as

Duke Regional Hospital

located in Durham, North Carolina, Durham County.

This license is issued subject to the statutes of the State of North Carolina, is not transferable and shall remain in effect until amended by the issuing agency.

Facility ID: 923142

License Number: H0233

Bed Capacity: *369*

General Acute 316, Rehabilitation 30 , Psych 23,

Dedicated Inpatient Surgical Operating Rooms: 2
Dedicated Ambulatory Surgical Operating Rooms: 0
Shared Surgical Operating Rooms: 13
Dedicated Endoscopy Rooms: 4

Authorized by:

Secretary, N.C. Department of Health and Human Services

Director, Division of Health Service Regulation

Duke Regional Hospital
2021 Hospital License Renewal Application

Footnotes for Page 4

1. Ownership Disclosure

NC facilities that are part of Duke University Health System, Inc. are:
Duke University Hospital
Duke Regional Hospital
Davis Ambulatory Surgical Center
Duke Raleigh Hospital
Duke Home Health
Duke Home Infusion
Duke Hospice (Durham Office)
Duke Hospice (Raleigh Office)
Hock Family Pavilion (Hospice Inpatient Facility)
Duke Hospice at the Meadowlands (Inpatient Facility)

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Effective January 01, 2021, this license is issued to

Duke University Health System, Inc.

to operate a hospital known as

Duke Raleigh Hospital

located in Raleigh, North Carolina, Wake County.

This license is issued subject to the statutes of the State of North Carolina, is not transferable and shall remain in effect until amended by the issuing agency.

Facility ID: 923421

License Number: H0238

Bed Capacity: *186*

General Acute 186

Dedicated Inpatient Surgical Operating Rooms: 0
Dedicated Ambulatory Surgical Operating Rooms: 0
Shared Surgical Operating Rooms: 15
Dedicated Endoscopy Rooms: 3

Authorized by:

Secretary, N.C. Department of Health and Human Services

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Director, Division of Health Service Regulation

Duke Raleigh Hospital – License Renewal Application 2020
Footnote for Page 4

***NC facilities that are part of Duke University Health System, Inc.:**

Duke University Hospital

Duke Regional Hospital

Davis Ambulatory Surgical Center

Duke Raleigh Hospital

Duke Home Health

Duke Home Infusion

Duke Hospice (Durham Office)

Duke Hospice (Raleigh Office)

Duke Hospice (Oxford Office)

Hock Family Pavilion (Hospice Inpatient Facility)

Duke Hospice at the Meadowlands (Inpatient Facility)

Duke Hospice Unicorn Bereavement Center