December 31, 2019

Ms. Martha Frisone, 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 Wake County, Health Service Area IV; CON Project ID Numbers:
J-011820-19, Pinnacle Health Services of North Carolina, LLC
J-011821-19, EmergeOrtho, P.A.
J-011825-19, Raleigh Radiology, LLC (Cary)
J-011826-19, Raleigh Radiology, LLC (Knightdale)
J-011829-19, Duke University Health System, Inc.
J-011830-19, Wake Radiology Diagnostic Imaging, Inc.

Dear Ms. Frisone and Mr. Yakaboski,

On behalf of Raleigh Radiology, LLC, Project IDs J-011825-19 and J-011826-19, thank you for the opportunity to comment on the above referenced applications for a fixed MRI scanner in Wake County. During your review of the projects, I trust that you will consider these comments thoughtfully.

The Agency received six applications for the need identified in the *2019 State Medical Facilities Plan* ("SMFP") for one fixed MRI scanner in Wake County. Each proposes a different approach. Wake is one of the two largest counties in the state and may soon be the largest; yet, it has less MRI service than other urban areas in the state, and the 2019 SMFP need determination permits only one award. Hence, the decision will significantly influence access to MRI service in Wake County.

We believe that the applications submitted confirm and support Raleigh Radiology as the most qualified applicant to address the identified need. Our reasons are detailed in the Raleigh Radiology applications and reiterated in this letter. In 2018, Raleigh Radiology provided more than 12,000 MRI scans in Wake County. Yet, it is the only major radiology group in Wake County, or North Carolina, that does not own an MRI. In spite of the obstacles associated with leasing MRI units, Raleigh Radiology offers consumer-oriented, American College of Radiology-accredited multi-specialty MRI services in Wake County, and has for 13 years. Failure to make an award to Raleigh Radiology Cary would be inconsistent with the Value Basic Principle found in the 2019 SMFP (at page 3). That application clearly demonstrates that the proposed project would reduce the unit cost of providing MRI services.

We understand that the State's Certificate of Need ("CON") award for the proposed fixed MRI scanner must be based upon the State's CON health planning objectives, as outlined in G.S 131E-183. In comparing the applications, we request that the CON Section 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 Wake County and patients of Wake County physicians who care for patients from other places as well.

WHY APPROVE RALEIGH RADIOLOGY

Context

Raleigh Radiology submitted an application to replace a leased "Grandfathered Fixed" 1.5T MRI scanner with a Raleigh Radiology-owned new fixed 3T MRI at Raleigh Radiology Cary. Raleigh Radiology submitted a second application to acquire a fixed 1.5T MRI for Raleigh Radiology Knightdale, where we recently received a CON to develop a diagnostic center. The most urgent need, with the largest impact is to replace the high-overhead leased Cary MRI that is providing about 6,700 scans a year with a new state of the art 3T MRI that can be in service shortly after approval. If the Agency rejects the notion of allocating this fixed MRI need determination for that purpose, Raleigh Radiology believes that a new fixed MRI in Knightdale would produce the next most significant contribution to access, value, and quality in Wake County. There is no freestanding MRI in eastern Wake County.

Industry Leader

Raleigh Radiology has demonstrated long-term and sustained commitment to and leadership in the Wake County imaging field. Raleigh Radiology was the first practice in the county to introduce: 3D breast tomosynthesis mammography, Positron Emission Tomography, and high-field 1.5T open bore MRI. Raleigh Radiology 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, Raleigh Radiology has developed strong relationships with groups that traditionally serve low-income persons, making specific commitments to accept referrals from these groups (see correspondence in Exhibit I.2 of the Raleigh Radiology Cary and Raleigh Radiology Knightdale applications).

History of Quality

The American College of Radiology ("ACR") accredits all Raleigh Radiology MRI locations. Accreditation by ACR subjects the facility's images to peer review, supports quality assurance, and provides an external standard of quality review. Raleigh Radiology has 39 board certified and specialized radiologists on staff who interpret the MRI exams and are available to consult personally with referring physicians and patients. Three of its radiology practice locations provide 200+ hours of MRI services per week in Wake County. Radiologists are on site 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.

Need for 3T in Wake County

As demonstrated in the Raleigh Radiology Cary application, Section C, 3T MRI scans provide superior image quality and scan speeds; these features have advantages for both diagnosing physicians and patients. Yet, Wake County, a major health care referral center, and second most populous county in the state, has only one 3T MRI in service in a private orthopedic practice[1]. As a result, physicians are sending patients out of the county to academic medical centers such as Duke University Hospital, where an **outpatient MRI can exceed $8,000** (See Attachment 6 to this letter.)

According to the 2020 SMFP, 93 percent of North Carolina MRI Scans done in 2018 were outpatient. Table 1 below compares both MRI and 3T MRI access to other major health care referral centers in North Carolina. Per capita, Wake County trails not only Mecklenburg, but also significantly smaller counties, such as Orange and Durham.

Table 1 – Comparison of MRI Access in Major North Carolina Health Care Referral Centers

County	Population 2019	Fixed MRIs	MRI/1000 pop	Approved 3T MRIs	3T/10,000 pop	Comparison of 3T ratio to Wake
	a	b	c	d	e	f
Wake	1,096,408	16	0.01	2	0.02	1.0
Buncombe	265,586	11	0.04	1	0.04	2.1
Durham	316,293	15	0.05	1	0.03	1.7
Forsyth	381,379	17	0.04	1	0.03	1.4
Guilford	538,851	10	0.02	1	0.02	1.0
Mecklenburg	1,115,571	26	0.02	4	0.04	2.0
Orange	145,910	10	0.07	1	0.07	3.8

Notes:
a. NCOSBM 2019 estimated population
b. 2019 LRAs and EIFs
c. b/a*1000
d. 2019 LRAs and EIFs
e. d/a*10,000
f. County value in col e for County divided by Wake value in col e.

The population of Wake County is 7.5 times that of Orange County; but the per capita supply of 3T MRI in Orange County is 3.8 times that of Wake County – a clear access disparity. One approved Wake 3T scanner (Duke Raleigh Hospital) is not yet on line. **Mecklenburg**, which is comparable in population to Wake, has **four operational 3T scanners**. With 3T MRI now mainstream, Wake County should have a freestanding 3T MRI scanner that is accessible to any referring physician and his/her patients.

When the Duke Raleigh Hospital 3T MRIs comes on line, it will bill at the high DUHS hospital technical fee schedule and patients will get bills for high Duke Private Diagnostic Clinic physician fees (Attachment 6).

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[1] The Bone and Joint Surgery Clinic

Only two applications in this batch propose 3T MRI – Raleigh Radiology Cary and Pinnacle Health Services of North Carolina Wake Forest ("PHSNC"). However, Raleigh Radiology Cary is more accessible. (See comments on Pinnacle application, Attachment 4). Raleigh Radiology Cary is a proven, high-volume location supported by letters promising referrals that exceed the application's procedure forecasts. Proposed Pinnacle Wake Forest has a history of fewer procedures. Attachment 12 to this letter is a population density map that confirms the value of putting the next 3T in Cary, closer to a larger portion of Wake County's population.

Similarly, with Wake County MRI access limited, awarding the 2019 SMFP Fixed MRI need allocation to a site that would serve only limited physicians and their patients, would not address the access problem. Two applications clearly focus on restricted physician groups: EmergeOrtho, which would serve only orthopedic patients of Emerge Ortho and Duke University Health System, which proposes a site focused on serving patients of DUHS.

Although we believe that applications submitted by Pinnacle, DUHS, EmergeOrtho, and Wake Radiology do not conform to all required statutory review criteria, for discussion purposes, we compared the applications on metrics that represented similar facts sets in each application. Tables 2 and 3 in this letter present that comparison. Accompanying Attachments provide the calculations and references.

COMPARATIVE REVIEW

Statutory Review Criteria Comparison

Raleigh Radiology's applications conform to all statutory review criteria. The remaining four applications in this batch, failed to conform completely. Table 2 below compares applications by criterion.

Table 2 – Comparison of Applicants' Conformance to Statutory Criteria

Statutory Criterion	Raleigh Radiology (Cary)	Raleigh Radiology (Knightdale)	Duke University Health System	Emerge Ortho	Pinnacle	Wake Radiology
1	C	C	NC	NC	NC	NC
3	C	C	NC	NC	NC	NC
3a	C	C	NC	C	C	C
4	C	C	C	C	NC	C
5	C	C	NC	NC	NC	NC
6	C	C	C	NC	NC	NC
7	C	C	NC	C	C	C
8	C	C	C	C	C	C
9	C	C	C	C	C	C
12	C	C	NC	NC	C	NC
13	C	C	NC	NC	NC	NC
14	C	C	C	C	C	C
18(a)	C	C	NC	NC	NC	NC
20	C	C	C	NC	C	C

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

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

Competitive Metrics

Raleigh Radiology understands that the Agency may consider any metric in its competitive review of the applications. We believe that the Agency should consider metrics that represent the spirit and intent of the SMFP regarding value, quality, and accessibility. The following summary presents a strong and reasonable comparison of the six applications with regard to these elements. The first metric, "New competitor," is particularly important. Numerous studies demonstrate the importance of competition to maintain access, value, and quality. With more than a million residents, Wake County is large enough for the benefits of competition.

For ease of presentation, the following Table 3 ranks applications 1 to 6, with 1 being the most favorable with regard to the metric and 6 being the least favorable. All scores are based on six 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: 10. For detail supporting scores for each metric, please see Attachment 1.

Table 3 – Summary Comparison of Applicants on Access, Quality, and Value Metrics

Metric	Raleigh Radiology (Cary)	Raleigh Radiology (Knightdale)	Duke University Health System	Emerge Ortho	Pinnacle	Wake Radiology
a. New competitor	1.5	1.5	4.5	4.5	4.5	4.5
b. Number of promised annual referrals	1	3	5.5	2	4	5.5
c. Referrals from any physician practice	2.5	2.5	5.5	5.5	2.5	2.5
d. Confirmed support from Project Access	2	2	5	2	5	5
e. Radiologists on site	3	3	3	6	3	3
f. Most operating hours per week	1	5	6	2	3	4
g. Offers 3T	1.5	4.5	4.5	4.5	1.5	4.5
h. Located in an area with no MRI	4	1	4	4	4	4
i. Demonstrates means of construction is most effective	2	2	5	5	2	5
j. Lowest technical revenue per scan	2	1	5	4	3	6
Total Score	**20.5**	**25.5**	**48**	**39.5**	**32.5**	**44**

Metrics Considered and Rejected

Several comparative metrics that the Agency has used in other competitive reviews would be difficult for this review. Specifically:

- Total MRI Procedures in the Third Year of Operation: This measure of access is reasonable if all applications have reasonable forecasts of Utilization. However, DUHS forecast utilization based on shifts from a facility that is not yet open; EmergeOrtho is a single specialty provider that would limit access to its own orthopedic patients; Wake Radiology does not attempt to associate its forecast utilization with need of the population to be served; and Pinnacle forecast high unreasonable utilization from counties outside Wake.

- Total Medicare and Medicaid Procedures in the Third Year of Operation: This measure of access to two traditionally medically underserved groups is reasonable if all applications have reasonable forecasts of payor mix. However, two applicants used unsupported assumptions to inflate their percentage of Medicare patients, DUHS and Wake Radiology.

- Total Charge per Procedure in Third Year of Operation: This measure of access to all residents in the service area is not available in this review because one applicant, DUHS, provided only the technical fees for proposed services. Moreover, EmergeOrtho proposes only orthopedic procedures and relatively few contrast studies. These features will automatically reduce charges for this applicant and would rank it unreasonably better than the others.

- Net Revenue per Procedure in Third Year of Operation: This measure of access to all residents in the service area is not available in this review because one applicant, DUHS, provided only the technical fees for proposed services. These features will automatically reduce revenue for this applicant and would rank it unreasonably better than the others. For this reason, we recommend comparing technical net revenue per scan.

The applications propose relatively similar start dates, with one exception. The application for Duke Radiology Green Level delays the start of service two years longer than the others. This applicant, DUHS, also has approval for two MRIs in the area it proposes to serve with the proposed Duke Radiology Green Level MRI; and, neither of those is operational. In other competitive reviews, the Agency has denied other applicants who have delayed implementation of CONs.[2] That standard should apply to the DUHS application for DRGL.

[2] See Mecklenburg Operating Room CON review, 2019.

CONCLUSION

Raleigh Radiology Cary, is clearly the most cost-effective and highest value option among all applications in this batch. Raleigh Radiology Cary and Raleigh Radiology Knightdale alone fully conform to the statutory review criteria; therefore, because the rules permit only one award, the Agency should approve Raleigh Radiology Cary.

Thank you for your time and consideration. Please do not hesitate to call me if you have any questions.

Sincerely,

Joanne Watson

Joanne Watson
Chief Operating Officer

Attachment(s)

ATTACHMENTS

1. Detail of Metrics for Comparative Review
2. J-011829-19, Duke University Health System, Inc.
3. J-011821-19, EmergeOrtho, P.A.
4. J-011820-19, Pinnacle Health Services of North Carolina, LLC
5. J-011820-19, WR Imaging, LLC and Wake Radiology Diagnostic Imaging Inc.
6. Duke MRI Charges, Blinded Patient Estimate for 3T MRI
7. Duke University Hospital and Duke Raleigh Hospital 2019 Hospital License Renewal Applications
8. ProScan Imaging Lawsuit Articles
9. American College of Radiology Practice Parameter for the Use of IV Contrast and Center for Medicare and Medicaid Services, Statute 410.32-410.33
10. Wake Radiology 2019 Equipment Inventory Reports and UNC REX 2019 Hospital License Renewal Application, Excerpts
11. Wake Radiology and UNC REX MRI Charges, Blue Cross Blue Shield NC Treatment Cost Estimator
12. Wake County 2018 Population Density by Census Tract Map
13. Chatham County Development Plan

ATTACHMENT 1

Detail of Metrics for Comparative Review

ATTACHMENT 1: COMPARATIVE MATRIX SUPPORT

As explained in the cover letter, Raleigh Radiology understands the Agency may consider any metric in its comparative review of the applicants. Raleigh Radiology believes these metrics are the best representation of the spirit and intent of the statute and the 2019 SMFP regarding value, quality, and accessibility.

Why these Metrics are Important

a. New market entrant:
   A new market entrant enhances competition. Saturation of a single provider affects the negotiated insurance rates. In a market dominated by one or two providers, patients and payors have little to no leverage with which to reduce rates for services. As health care in North Carolina, and particularly in Wake County, increasingly consolidates to a few providers, like Duke and UNC who have a history of very high charges, competition is very important. Even among freestanding MRI providers, competition is important, especially for a diagnostic tool used as frequently as MRI.

b. Number of annual promised referrals:
   Promised referrals from providers provide quantifiable demonstration that a calculated need and utilization are realistic. While methodologies use projected data to estimate the need and utilization of MRI services within a market, promised referrals from providers who independently estimate their patient needs and indicate specific intent to use the service are demonstrated evidence of the projected need. Furthermore, promised referrals show faith in the applicant to provide quality services to the providers' patients.

c. Expects referrals from any physician (Referrals from outside the applicant's practice):
   Applicants with referrals only from providers within their own practice demonstrate that the MRI will offer limited access to patients. Patients not in the provider's network, or who have diagnoses outside the applicant's specialty, are less likely to benefit from that proposed fixed MRI. This comparative criterion is important in this Wake batch where the supply of fixed MRI units is so limited compared to other North Carolina medical referral centers.

d. Confirmed support from Project Access:
   Project Access is a Wake County-based agency supported by the Wake Johnston Medical Associates that connects low-income and uninsured patients with providers that offer sliding scale discounts tied to Federal Poverty Guidelines. In addition to a commitment to serve Medicare and Medicaid, participation in this program shows an applicant's commitment to providing access to MRI services to all residents in the service area, including traditionally underserved groups. Because participation in Project Access requires the provider to offer discounted services to patients, oftentimes providing full charity discounts, evidence of Project Access support demonstrates that the project will sustain full access.

e. Radiologists on site:
   Contrast agents can cause immediate and dangerous reactions in some people. Though all providers screen for these risks, physician presence to intervene immediately in the case of adverse reaction is required. It is a standard for American College of Radiology accreditation and CMS payment for Medicare and Medicaid. The more hours that physicians are on site, the more convenient the site is for patients. With radiologists on site, the MRI schedule is more efficient because it has more flexibility to offer contrast MRIs. Quality of the scan image and quality of the interpretation determine patient value. Access to specialist radiologists, on site and on call, speeds the time in which essential diagnostic communication transmits to the referring physician, and to the patient. This is a clear access metric.

f. Most operating hours per week:
   Working patients need flexible hours that fit into their livelihood. Those who are not working often depend on others or unwieldy transportation systems to bring them to health care providers. Patient need for MRI services does not fall neatly into "regular business hours." Applicants that provide longer hours and / or weekend appointments increase access and provide value to patients.

g. Offers 3T:
   As explained in the cover letter and the Raleigh Radiology Car application, 3T MRI scans provide stronger, superior image quality and scan speeds, which have advantages for both diagnosing physicians and patients. As a referral hub and second most populous county in the state, Wake County lacks adequate access to 3T MRI. A provider offering to add 3T MRI services to Wake County is adding both access and quality.

h. Located in an area with no MRI service:
   The *2019 SMFP* Wake County need determination covers one Fixed MRI Scanner. As population density in Wake County increases, the importance of convenient locations increases.

i. Cost design and means of construction is most reasonable alternative:
   All projects involve construction of some type. Information in the applications shows the extent to which the construction effort will risk time delays, cost increases, or disruptions to other services. Any delays will affect access, any unnecessary space will add to cost of operations.

j. Lowest technical revenue per scan:
   One of the applicants, DUHS, did not follow instructions and provide the professional component of the MRI expense to patients. However, the Agency can compare technical net revenue across all applicants. This is a measure of the average collected income per scan.

The following Table 1 contains the raw data used in this comparison. Where applicable, all data is for Project Year 3.

Table 1. Raw Data for the Comparative Scores

Metric	Raleigh Radiology (Cary)	Raleigh Radiology (Knightdale)	Duke University Health System	Emerge Ortho	Pinnacle	Wake Radiology
a. New market entrant	yes	yes	no	no	no	no
b. Number of promised referrals	7,098	5,670	-	5,734	1,916	-
c. Expects referrals from any physician (Referrals from providers outside of practice)	yes	yes	no	no	yes	yes
d. Confirmed support from Project Access	yes	yes	no	yes	no	no
e. Radiologists on site	yes	yes	yes	no	yes	yes
f. Most operating hours per week	90.0	58.0	-	72.0	65.0	61.5
g. Offers 3T	yes	no	no	no	yes	no
h. Located in an area with no MRI	no	yes	no	no	no	no
i. Cost design and means of construction is most reasonable alternative	yes	yes	no	no	yes	no
j. Lowest technical net revenue per scan	$338	$326	$650	$393	$387	$675

Sources and Notes

Table 2. Sources of Raw Data for Table 1

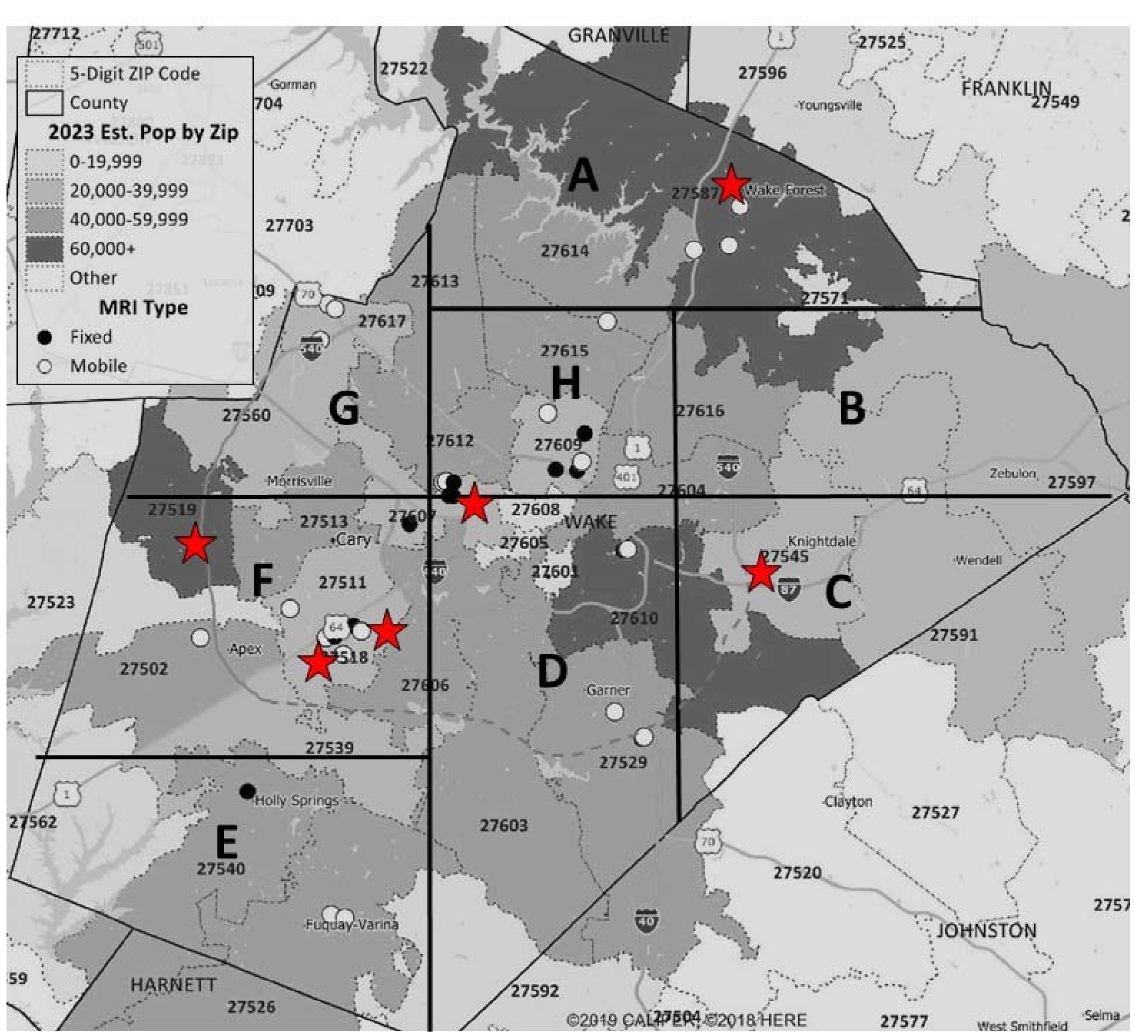
Metric	Raleigh Radiology (Cary)	Raleigh Radiology (Knightdale)	Duke University Health System	Emerge Ortho	Pinnacle	Wake Radiology
a. New market entrant	p67	p67	pp32, 80, & 97	pp62, 142, &180	p42 & 131	pp50, 51, & 99
b. Number of promised referrals	p282	p187	p133	p193	p262	p207
c. Expects referrals from any physician (Referrals from providers outside of practice)	p282	p187	p133	p193	p262	p207
d. Confirmed support from Project Access	p280	p185	n/a	p282	n/a	n/a
e. Radiologists on site	pp101 & 278	pp99 & 183	p55	p88	p72	p72
f. Most operating hours per week	p56	P54	p123	p73	p20	p24 & "f" below
g. Offers 3T	p31	p30	p197	pp28 & 289	p17	p24
h. Located in an area with no MRI	See "h" & Figure 1 below	See "h" & Figure 1 below	See "h" & Figure 1 below	See "h" & Figure 1 below	See "h" & Figure 1 below	See "h" & Figure 1 below
i. Cost design and means of construction is most reasonable alternative	p107	p105	p59, Exhibit K.2, & see "i" below	p93; see "i" below	p75	p75; see "i" below
j. Lowest technical net revenue per scan	See "j" & Table 5 below	See "j" & Table 5 below	See "j" & Table 5 below	See "j" & Table 5 below	See "j" & Table 5 below	See "j" & Table 5 below

f. <u>Most operating hours per week:</u>
Wake Radiology notes in its application that the proposed scanner will replace the Alliance owned fixed scanner in its Cary location. It did not provide hours of operation. However, Alliance did report 3,200 annual operating hours at the Wake Radiology Cary location on its 2019 EIF (See Attachment 10). The commenter assumed this a reasonable proxy to estimate operating hours.

(Annual Hours Reported / 52 Weeks = Hours per Week)

h. <u>Located in an area with no MRI:</u>
Raleigh Radiology Knightdale applied a grid system to a map of Wake County population by zip code to determine voids in MRI service. Figure 1 below is that map from p43 with an overlay of the MRI sites proposed by the six applications. Areas B and C have no MRI equipment. Only one application proposes a location in B or C, Raleigh Radiology Knightdale.

Figure 1. Location of all Proposed MRI Scanners in Relation to Underserved Sectors of Wake County



i. Cost design and means of construction is most reasonable alternative:

- DUHS – Exhibit K.2 shows extra storage space not explained; adds to construction and operating costs.
- EmergeOrtho – Gauss lines in Exhibit K.3 show magnetic field in access corridors, multiple entries to the MRI equipment indicate potential risk for patients and staff; no provisions to control access to MRI as required by current Facility Guidelines Institute guidelines.
- Wake Radiology – did not consider the delay and expense associated with removing an existing MRI unit.

j. Lowest technical net revenue per scan:

With the exception of DUHS, all applicants provided professional fees as a percent of net revenue. This metric backs out the professional fee from net revenue and divides the remainder by total projected procedures.

*(1- Professional Fee Percentage) * Total Net Revenue / Total Procedures = Technical Net Revenue per Scan*

DUHS did not include professional fees in its DRGL application; therefore, the commenter achieved the same result by dividing net revenue by total procedures.

Table 3. Project Year 3 Technical Net Revenue per MRI Procedure by Applicant

Application	Total Procedures	Net Rev	Professional Fee % of Net Revenue	Technical Net Revenue / Procedure
	a	b	c	d
Raleigh Radiology (Cary)	6,946	$2,935,153.00	20.0%	$338
Raleigh Radiology (Knightdale)	4,269	$1,737,496.00	20.0%	$326
Duke University Health System (DRGL)	4,408	$2,866,862.00	n/a	$650
EmergeOrtho Duraleigh	3,759	$2,729,933.00	26.9%	$531
Pinnacle Wake Forest	4,685	$2,296,037.00	21.0%	$387
Wake Radiology Cary	4,424	$4,266,508.00	30.0%	$675

Notes:

a. Form C unweighted procedure
b. Total Net Revenue Form F.2, Service Component
c. See below
d. (1 – c) * b / a

Sources:

- Raleigh Radiology Cary - Form F.3 and assumptions; professional fees are 20% of net revenue
- Raleigh Radiology Knightdale - Form F.3 and assumptions; professional fees are 20% of net revenue
- Duke University Health System (DRGL) - Professional fees are not included in application; technical only provided
- EmergeOrtho Duraleigh - Form F.2, Net Revenue of Professional and Technical Fees detailed; Professional is 26.9% of total net revenue ($734,898 / $2,729,933 = 26.9%)
- Pinnacle Wake Forest - Form F.3 and assumptions; professional fees are 21% of net revenue
- Wake Radiology Cary - Form F.3 and assumptions; Professional Net Rev / Total Net Revenue

ATTACHMENT 2

Comments: J-011829-19, Duke University Health System, Inc

Competitive Review of:
Duke University Health Systems, Inc.; J-011829-19

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, 3a, 5, 7, 12, 13, and 18a.

This application proposes to acquire a fixed 1.5 Tesla ("1.5T") at a new facility called Duke Radiology Green Level ("DRGL") in Cary, North Carolina. The applicant proposes to serve 4,407 patients from Wake and other North Carolina counties by Project Year 3, July 1, 2024 through June 30, 2025. Acquisition of this equipment will create a new diagnostic center at this location.

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] *2019 State Medical Facilities Plan*; Chapter 4 Statement of Policies; Policy GEN-3: Basic Principles. Page 31.

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 applicant proposes to serve southwestern Wake, Durham, Chatham, Lee, and other counties in the state. It proposes that less than 70 percent of procedures will be from Wake County residents, and that nine percent will in-migrate from other North Carolina counties. However, the application fails to define a need for MRI services for the 21 percent of its patients residing in the remaining portions of the primary service area outside of Wake County. (See projected patient origin on page 17 of DUHS application.) Table 1 below summarizes DUHS's PY3 patient origin by county.

Table 1 – Summary of Patient Origin for DRGL, Project Year 3, 2025

Service Area	County	Number of Patients	Percent of Total
Primary Service Area	Wake	3,031	69%
	Durham	451	10%
	Orange	212	5%
	Chatham	167	4%
	Lee	90	2%
Other Service Area	Other Wake	55	1%
	In-migration	401	9%
Subtotals	*Subtotal Primary Service Area Wake*	*3,031*	*69%*
	Subtotal Primary Service Area Not Wake	*3,951*	*21%*
	Subtotal Remainder of Service Area	*456*	*10%*
	Grand Total	***4,408***	***100%***

Source: Table "Projected Patient Origin for Entire Facility or Campus," application page 17.
On page 17 of its application and page 1 of its Utilization Methodology in Section Q, DUHS lists zip code "27330 Chatham County" as part of its primary service area; 27330 is actually in Lee County as shown in the map in Figure 1 below.

The Methodology in Section Q of the application is difficult to follow. Some pages have no numbers. Some elements are in Steps, others are in assembled paragraphs and tables. This makes it difficult for anyone to follow the application's logic.

The application's need calculations start with the populations of the identified zip codes for the proposed primary service area. Using the 2018 state MRI procedure use rate, DUHS estimates the number of MRI procedures in the primary service area population. Then, it develops a series of "shift" calculations based on market share "assumptions."

The DUHS Methodology recognizes only four DUHS Wake County MRI units: two in the proposed primary zip codes: Duke Cary Parkway ("Cary Parkway"), Duke Holly Springs ("Holly Springs"), and two at Duke Raleigh Hospital ("DRAH"). Then it develops a proposed "shift" of patients among these facilities. See Step 8 on page 5 of the Utilization Methodology in Section Q. The application contains insufficient information to match use of existing DUHS MRI scanners to proposed "shifts."

However, DUHS proposes that DRGL will serve portions of Durham, Chatham, Lee, and Orange counties. The DUHS Methodology does not show that residents of those zip codes need additional MRI services. According to the 2020 State Medical Facilities Plan ("SMFP"), Orange, Lee, and Chatham counties have excess MRI capacity. Furthermore, DUHS has approvals for two freestanding MRI facilities located in Durham County within the primary zip codes proposed for DRGL: Duke Radiology at Arringdon ("Arringdon"), and Duke University Hospital Imaging Services at Southpoint ("Southpoint"). See Figure 1 below.

Figure 1 – Duke Green Level Proposed Primary Service Area and Current Freestanding Duke MRI Locations

Source: Maptitude Software, Duke Green Level Application, p. 17

Nowhere in this application does DUHS explain the need for additional MRI services, or the impact that DRGL volumes would have on its own or other existing providers in the non-Wake portion of the application's proposed primary service area.

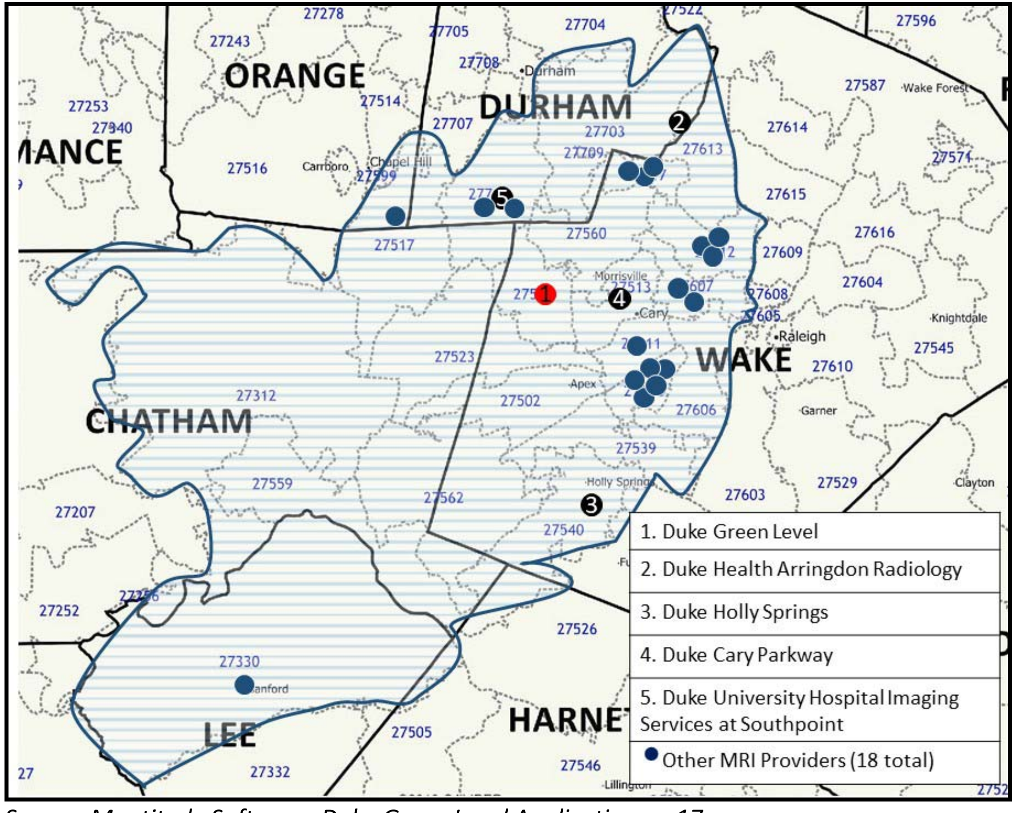
Pages 27 and 43 of the application, as well as page 4 of the Utilization Methodology in Section Q, DUHS reference patient convenience, not patient need for service, to support the zip codes and procedures from the proposed primary service area. By this standard, there are other freestanding MRI service providers – including four DUHS locations – that are equally, or more, convenient for the patients of the identified target zip codes. See Figure 2 below.

The DUHS application proposes 2,895 net new MRI procedures for the proposed new, un-shifted, fixed MRI by the year 2025 (Methodology page 2).

The application provides no discussion of population need associated with the proposed delay of project start until July 2022 (application page 77). The project need justification focuses instead on DUHS desire to place diagnostic centers throughout Wake County. The application limits discussion of need of the population to be served to a calculation of MRI use estimates for the population of the proposed primary service area. As illustrated in Figure 2 below, placement of the proposed fixed freestanding MRI and Diagnostic Center, along with the delayed implementation, suggests that the real DUHS interest is to serve future planned development in eastern Chatham County.[2] At the time of the application DUHS had two approved and not yet operational freestanding fixed MRI units and Diagnostic Centers in that same proposed service area, Arringdon (J-111718-19) and Holly Springs (J-11167-16).

[2] https://www.chathampark.com/maps/ And http://www.chathamnc.org/home/showdocument?id=31151 See Attachment 13

Figure 2 – All MRI Providers within the DRGL Primary Service Area (Includes Hospitals)



Source: Maptitude Software, Duke Green Level Application, p. 17

Because DUHS failed to demonstrate adequately the need of MRI services for the population to be served, it should be found non-conforming to Criterion 3.

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

In application Section D, the DUHS application indicates that when the proposed project becomes operational, DUHS will terminate MRI service at the DUHS Cary location. The application then declares this Criterion is "NA."

The proposed project clearly contemplates closure of one MRI service and relocation of the service to another location. Failure to "demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care" *renders the application non-conforming to Criterion 3a.*

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.

Assumptions to Forms F.2 and F.3 indicate that “outpatient Revenue is budgeted to average $2,750 per outpatient encounter in FY2020 and is expected to remain relatively unchanged.” By extension, this would apply to the proposed DRGL diagnostic center. However, the financial forecasts presented in these forms for the proposed MRI increase annually. They are also substantially less than the assumption of $2,750 per encounter.

Table 2 – DRGL Gross Revenue per Procedure

2023	2024	2025
$1,481	$1,510	$1,539

Source: Gross Revenue Form F.2 / Total Procedures Form C

Perhaps more important, is the fact that proposed utilization is not supported and the projections of total revenue are not reasonable.

Overstated Medicare and understated private insurance also cast doubt on the reasonableness of revenue forecasts. For details, see discussion of Criterion 13 below.

Staffing in Form H also shows partial FTE’s in every year, but the application provides no indication of how the proposed facility will provide the part time staff. The application shows only MRI service in the proposed diagnostic center.

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

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

DUHS projects MRI scans with contrast at the proposed DRGL 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."*** [3]
> [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."* [4] [Emphasis added]

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

In Form F.3 (Service Component) of its application, DUHS indicates a line item for "Professional Fees (Medical Director Fees)." However, the application, nor its supporting documentation, provides specific information regarding presence of qualified physician coverage at the IDTF. No physicians are included on Form H in Section Q. The letter provided in Exhibit I.3 states only that images will be read both "on site and remotely." The letter does not mention presence of a qualified physician during MRI scans. It does not mention the frequency with which "Duke Radiologists will rotate through this location…"; nor does the application quantify the cost of "as necessary to provide medical coverage (at page55)." Yet, the application is very specific about the number of contrast studies proposed.

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[3] American College of Radiology, "ACR-SPR Practice Parameter for the use of Intravascular Contrast Media;" Revised 2017 (Resolution 5). Page 2. https://www.acr.org/-/media/ACR/Files/Practice-Parameters/IVCM.pdf Attachment 9.

[4] 42 CFR Ch. IV (10-1-03 Edition); Centers for Medicare and Medicaid Services; 410.32(b)(3)(ii) "Diagnostic X-ray Tests, Diagnostic Laboratory Tests, and Other Diagnostic Tests: Conditions; Levels of supervision, Direct supervision." Page 253. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/downloads/410_32.pdf Attachment 9

Similarly, the application provides no information about how DUHS will provide the part-time non-physician staff at this IDTF location that initially will offer only MRI services.

Because DUHS 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.

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.

Construction

DUHS did not explain how the cost, design, and means of construction represent the most reasonable alternative for the proposal. It gave no information regarding how it determined size of the building. The applicant indicated on page 26 that the building will house other services, including GI endoscopy. According to the GI endoscopy CON (Project ID J-11709-19), it will be offering services by April 1, 2022, three months prior to the proposed start date of MRI services. DUHS did not address how renovation of space would affect operations of other services, like GI endoscopy, or how the space would be used prior to award of the CON. DUHS failed to discuss why the chosen alternative is the most reasonable alternative.

Exhibit K.2 shows two large storage areas, but the application provides no justification for this space or its future use.

Exhibit K.4 indicates that "Duke Health" owns the site. The application provides no information about the owner of the land; and Duke Health includes many entities. [5] With land ownership unclear, the application provides insufficient information for the reader to determine if the project should involve a rent expense. Further, with no information about total cost of the building in which the proposed diagnostic center will be located, it is impossible to evaluate construction cost. For example, will the project involve an allocated common area cost of the building?

Exhibit K.4 also shows **planned**, but **not approved**, water and sewer. Information about plan approvals for the utilities is missing. Permits in the Town of Cary involve lengthy processes and sometimes require major modifications to applicant plans.

Because DUHS did not demonstrate that the cost, design, and means of construction proposed in its application represent the most reasonable alternative, it should be found non-conforming to Criterion 12.

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[5] Duke Health. Who We Are. (https://corporate.dukehealth.org/who-we-are). Accessed December 30, 2019.

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:

(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

DRGL proposes to serve 37.8 percent Medicare at its proposed location (Project Year 2, p69). The applicant assumed that payor mix would be the same for the MRI service component as the entire facility because MRI will be the only service at the proposed IDTF facility (p121, Form F.3 assumptions).

The proposed percent Medicare is, by the application's admission, a guess. It is not supported by other information in the application. According to Question F.3(b) on page 69 of the application,

> *Based on input from DUHS Corporate Finance, the projections include an anticipated shift of 3.8% of private insurance patients to Medicare per year through FY 2022 to reflect the aging of the population and resulting utilization patterns of MRI services.*

The assumptions in Section Q with Form F.2, page 121, provide no additional information to support this shift. This assumption means that, for the third project year 2025, the application proposes a 25 percent shift from private insurance to Medicare over six years (1.038 ^ 6 = 1.25). Data from national demographer Claritas shows the population of Wake County over age 65 will increase only 3.3 percent between 2020 and 2025 (from 136,997 to 174,337 people ((174,337-136,997) / 136,997 = 0.0334)). Clearly, the assertion in the DUHS application assumptions is overstated.

DUHS's Medicare is overinflated and unsupported. As a result, <u>*the applicant has not adequately explained how the proposed MRI will serve the elderly groups in this subdivision or the extent to which this group will utilize the service.*</u> <u>*It is therefore non-conforming to Criterion 13.*</u>

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 proposes to begin offering services in July 2022 for an identified need in the 2019 SMFP. It is effectively requesting an MRI placeholder.

This proposal would give additional control of the Wake County MRI market in which DUHS is already a substantial provider.

The application provides only part of the story. DUHS controls operations of 20 MRI scanners that serve Wake County patients. The application accounts for only ***three*** of them. For example, though in Durham County, Duke University Hospital is only 20 minutes from the proposed site, and Duke Southpoint is 14 minutes according to Google Map data[6].

The application substantially understates DUHS estimated market share. Table 3 below **conservatively** estimates that DUHS would control more than 27 percent of the Wake County market if the proposed project were approved. Calculations are conservative because the commenter does not have access to patient origin information for three of the 20 DUHS MRIs that serve Wake; and the calculations assume no increase in the number of Wake County residents using Duke University Hospital or Duke Arringdon.

[6] Google Maps https://www.google.com/maps/dir/Duke+Health+Center+at+Southpoint,+6301+Herndon+Rd,+Durham,+NC+27713/3208+Green+Level+W+Rd,+Cary,+NC+27519/@35.845662,-78.9551707,12z/data=!3m1!4b1!4m13!4m12!1m5!1m1!1s0x89ace8b6a3ce8b47:0x89fb8e7599e89be8!2m2!1d-78.9352561!2d35.9067647!1m5!1m1!1s0x89acecfbcf1151ed:0xd56394d8e1698ac4!2m2!1d-78.89145!2d35.78457 And https://www.google.com/maps/dir/Duke+University+Hospital,+2301+Erwin+Rd,+Durham,+NC+27710/3208+Green+Level+W+Rd,+Cary,+NC+27519/@35.8999725 accessed Dec 29, 2019.

Table 3—DUHS Market Share of Wake County MRI Patients, 2025

Provider	Address	City	Zip	County	Total MRIs	Mobile / Fixed	Est. Wake County Procedures 2025	Source
Proposed DRGL	*3208 Green Level W Road*	*Cary*	*27519*	*Wake*	*1*	*Fixed*	*4,408*	*p84, Section Q Methodology, DRGL application*
Duke Raleigh Hospital	3400 Wake Forest Road	Raleigh	27609	Wake	2	Fixed	12,078	p87, Section Q Methodology, DRGL application
Duke Holly Springs	401 Irving Parkway	Holly Springs	27540	Wake	1	Fixed	4,236	p87, Section Q Methodology, DRGL application
Alliance at DRAH	3400 Wake Forest Road	Raleigh	27609	Wake	1	Mobile	--	Included in DRAH above
Alliance at Cary Parkway	3700 NW Cary Parkway	Cary	27513	Wake	--	Mobile	--	(a) no source for patient origin DUHS proposes to discontinue use of this scanner if DRGL is approved
Duke University Hospital	2301 Erwin Road	Durham	27710	Durham	9	Fixed	5,255	pp31 and 58, DUHS 2019 LRA, Attachment 7; commenter assumes procedures will stay flat from FY2018
Duke Health Center at Southpoint	6301 Herndon Road	Durham	27713	Durham	1	Fixed	--	(b) no source for patient origin
Lenox Baker Clinic	3000 Erwin Road	Durham	27705	Durham	1	Mobile	--	(b) no source for patient origin
Duke Regional Hospital	3643 North Roxboro Road	Durham	27704	Durham	2	Fixed	481	pp 28 and 44, DRAH 2019 LRA, Attachment 7; commenter assumes procedures will stay flat from FY2018
Duke Arringdon	5601 Arringdon Drive	Morrisville	27560	Durham	1	Fixed	4,009	p245, Form C Utilization; CON #J-117145-19; commenter assumes procedures will stay flat from 2023
Alliance at DUHS	2301 Erwin Road	Durham	27710	Durham	1	Mobile	--	Included in DUH above

Provider	Address	City	Zip	County	Total MRIs	Mobile / Fixed	Est. Wake County Procedures 2025	Source
Total DUHS MRI procedures **in** Wake County or **involving** Wake County patients							30,467	Sum of above
Total estimated MRI procedures in Wake County in 2025							112,934	commenter assumes 2018 Wake County MRI use rate (93.7/1,000 pop) and 2025 NCOSBM population
DUHS Market Share of MRI procedures **in** Wake County or **involving** Wake County patients							**27%**	

Notes:

(a) Alliance does not report patient origin. Application did not report patient origin at Cary Parkway. At application p39, "DUHS currently intends to discontinue mobile services at Cary Parkway."

(b) Alliance does not report patient origin and application does not report patient origin at these two DUHS MRI scanners.

As discussed in Criterion 3 of these comments, DUHS has approved CONs for two fixed MRI scanners at two new diagnostic centers in the proposed service area that are not yet operational. DRGL will not increase competition. Saturation of a single provider affects negotiated insurance rates. In a market dominated by one or two providers, insurance companies and patients have little to no leverage with which to reduce the contract rates for services.[7] This negatively affects employers within the market forcing them to pay higher rates for health insurance coverage.

According to the Kaiser Family Foundation, the number of insured persons is dropping because of the cost of acquiring insurance.[8] In fact, in 2018 North Carolina is among states with the highest number uninsured nonelderly persons. Without competition in the marketplace, there is no incentive to change this trend.

Moreover, The US Department of Justice has a history of anti-trust investigations in situations where health care mergers result in control of 30 percent or more of a market.[9] As the table above illustrates, conservatively, if awarded the DRGL scanner, DUHS will have more than 27 percent of the Wake County MRI market. DUHS' application does not enhance competition.

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

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[7] Gee, Emily, Gurwitz, Ethan, "Provider Consolidation Drives Up Health Care Costs: Policy Recommendations to Curb Abuse of Market Power and Protect Patients". *Center for American Progress,* Dec 2018, https://www.americanprogress.org/issues/healthcare/reports/2018/12/05/461780/provider-consolidation-drives-health-care-costs/

[8] Tolbert, Jennifer, et al. "Key Facts about the Uninsured Population." *The Henry J. Kaiser Family Foundation*, 13 Dec. 2019, https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/.

[9] lexisnexis.com/lexis-practice-advisor/the-journal/b/lpa/posts/healthcare-providers-and-insurers-ftc-approach-to-provider-mergers-and-acquisitions

ATTACHMENT 3

Comments: J-011821-19, EmergeOrtho, P.A.

Competitive Review of: EmergeOrtho, P.A.; J-011821-19

OVERVIEW

EmergeOrtho, P.A.'s ("Emerge") application to develop a fixed Magnetic Resonance Imaging scanner ("MRI"), is non-conforming with statutory review criteria 1, 3, 5, 6, 12, 13, 18a, and 20.

This application proposes to acquire a new fixed 1.5 Tesla ("1.5T") to be located in what is now a therapy pool at the Emerge orthopedic physician office at Duraleigh Road in Raleigh, North Carolina. The proposed project would also qualify that office as a new Diagnostic Center. The applicant proposes to serve 5,082 patients from Wake and other North Carolina counties, as well as other states, by Project Year 3, calendar year 2023.

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 that Emerge failed to demonstrate how its projected volumes address the need of all residents in the proposed service area for the proposed project. *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] *2019 State Medical Facilities Plan*; Chapter 4 Statement of Policies; Policy GEN-3: Basic Principles. Page 31.

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

Emerge does not adequately identify the need for the population to be served. In Section B of the application, under Policy Gen-3 on page 21, the application states that Emerge is "the largest physician owned orthopedic practice in North Carolina." It goes on to say that the practice offers, "…advanced expertise in all orthopedic subspecialties…" (Page 21).

In this position as a large statewide orthopedic provider, Emerge should be able to demonstrate the need that the population to be served has for orthopedic MRI scans. Yet, there is no place in the application where Emerge identifies need of the population it proposes to serve for orthopedic scans. On page 34, the application defines the population to be served as Wake and 44 other North Carolina Counties plus residents of Georgia, South Carolina, and other states. Emerge forecasts a need for MRI scans in Wake County, but the forecast addresses all types of MRI scans in Wake County (page 40). The application makes clear that the purpose of the proposed new fixed Duraleigh MRI is to provide diagnostic information for EmergeOrtho patients at that location, but the forecasts in Section C and in the Methodology do not quantify that population or its specific needs.

Even the future forecasts for all MRI procedures in Wake County have credibility issues. The application fails to note the missing data from Raleigh Radiology in the 2019 SMFP when it calculates the increase in Wake procedures between 2017 and 2018. Then it makes a blanket unsupported statement that future Wake County MRI procedures will increase at 4.3 percent annually (page 113).

The application mentions "a backlog," but fails to quantify its magnitude in number of people. The application mentions only the "7-day backlog" on the 3-day current schedule at Duraleigh.

The Methodology (at page 114) forecasts increased market shares from 2.6 percent to 4.3 percent, but provides no support for the forecast. The only supporting assumption is the increase in number of days of service. The Methodology makes no adjustment for the continued deployment of EmergeOrtho's mobile MRI in Wake County (page 40). The calculation of Emerge market share on page 114 is overstated, because the total number of Wake County MRI scans is underreported.

Because the application does demonstrate the need the population has for the services proposed, it should be found non-conforming to Criterion 3.

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.

Financial

Emerge's application did not correctly answer Question F.4a. On page 79, the applicant is required to:

> *"Complete a separate Form F.2 and Form F.3 in Section Q for the entire health service facility (all services)* ***and each service component****."*
> [Emphasis added]

Emerge showed its financials only for the facility and not the service component, which is MRI. *By not answering the question in Section F correctly, the application is incomplete and information is insufficient to determine if projections for the service are reasonable.*

Moreover, although the utilization forecast in the Methodology clearly indicates an intent to increase the number of mobile days leased by 2 (a 66 percent increase), the financial pro formas in Form F.3 show only an inflationary increase in the line item, "Contract services" (at page 134).

As noted in the discussion of Criterion 3 above, utilization forecasts are overstated and unsupported, making revenue forecasts unreasonable. In just one example, on page 122, which discusses conformance to Performance Standards, the application **assumes** that a new mobile site at Brier Creek will start out at 10 scans per day.

With missing costs and overstated revenue, the feasibility of the proposal, is not based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service and 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

Emerge's proposed MRI is in a location surrounded by other freestanding multi-specialty MRI providers. Emerge is within a 3-minute drive of Raleigh Radiology Blue Ridge, a competitively priced and multi-specialty MRI provider. Raleigh Radiology Blue Ridge has one grandfathered fixed "mobile" MRI scanner. Figure 1 shows the drive time from Emerge to Raleigh Radiology Blue Ridge as 3 to 5 minutes.

Figure 1 – Drive Time from Emerge to Raleigh Radiology Blue Ridge

Source: Google Maps

As shown in Figure 1 above, Emerge is also close to UNC Rex Hospital, another MRI provider. UNC REX Hospital has two fixed MRI scanners and one mobile MRI scanner. With Raleigh Radiology Blue Ridge and UNC Rex Hospital together, there are four MRI scanners within a few miles of Emerge. As stated in Criterion 3, Emerge is a single specialty provider so it would not accommodate patients needing MRI scans for non-orthopedic subspecialties. Its proposed low prices would apply only to orthopedic scans. Therefore, it would offer a very limited alternative to hospital-based providers such as UNC REX Hospital. EmergeOrtho forecasts appear to propose duplication of services provided by nearby, freestanding multi-specialty Raleigh Radiology Blue Ridge.

Furthermore, as explained in Criterion 3, the applicant did not explain the need for the forecast orthopedic MRI scans in the service area. In fact, the application uses unrealistic assumptions about market share and future growth, thus over-projects the number of scans that would be reasonable for EmergeOrtho Duraleigh.

Because Emerge has not adequately demonstrated that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities, it should be found non-conforming to Criterion 6.

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.

Section K.2 omitted the answer to subsection (a), making it difficult to evaluate the application against this criterion. Exhibit K.3 mentions a required crane for moving materials, but no cost is included. The plans show at least six doors entering into the Gauss field, but the capital costs include only one ferromagnetic detector. The application does not discuss, nor do the plans show how other patients and staff will be protected from the magnetic fields in the proposed configuration. The application includes no documentation from an architect, engineer, or physicist to show that the proposed reuse of the therapy pool in this location will meet required FGI safety standards for MRI. This is important because the proposed location has not yet been in use for MRI scanning.

Plans show no patient waiting area, no reading room, no MRI consultation area, and no staff support area. Nor does the narrative discuss these. In Section K.3(a) the application dismisses the possibility that unforeseen conditions could escalate the cost of renovations… because the facility is relatively new. The application does not define “relatively new.”

The applicant does not own the facility and the application provides no documentation of permission from the owner to make the proposed building alterations.

Clearly, the application fails to demonstrate that the cost, design, and means of construction represent the most reasonable alternative.

Thus, 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:

Access

(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

Emerge is a single-specialty provider, as explained in Criterion 3 of these comments. While its application does show that Emerge has provided, and plans to continue to provide, services to elderly and other medically underserved groups, the application forecasts are incorrect and misleading.

Because EmergeOrtho is a single specialty provider, access to the proposed MRI and diagnostic center will be limited to patients who need orthopedic-related diagnoses. The application fails to discuss the needs of the elderly and members of underserved groups for orthopedic-related MRI services.

Moreover, the discussion on Charity care and Project Access on page 99 indicates that charity care will be available through Project Access to ambulatory surgery. The application does not mention Project Access in relation to MRI services.

The proposed MRI would restrict access for the elderly and /or 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.

Hence, the application should be found non-conforming to Criterion 13 (c).

(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.

As evidenced by referral letters in Exhibit C.4, referrals for services at Emerge come from Emerge physicians. The application provides no evidence that the proposed fixed MRI would accept referrals from physicians who are not associated with or members of EmergeOrtho. Because the proposed MRI would not be open to *all patients* needing MRI services, it cannot meet the health-related needs of the elderly and other medically underserved groups in the proposed service area.

As shown in Exhibit I.1, Emerge's MRI scans are read by an outside teleradiology group called ProScan Imaging. ProScan Imaging is located in Cincinnati, Ohio and has no offices in NC. This means that Emerge patients cannot see, in person, the radiologists who read their MRI scans. Therefore, although patients could obtain MRI scans at the proposed location, it seems the patients they will not have direct access to the reading radiologist. This in turn, limits patients' access to MRI services.

The application offers only one means by which a person will have access to the proposed services. They must be patients of EmergeOrtho physicians.

Emerge does not offer a range of means by which a person will have access to its services*, the application should be found non-conforming to Criterion 13(d).*

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

This is not a new competitor in Wake County. **Emerge owns and operates** one mobile MRI scanner in the county.

The application asserts that the proposed project will enable EmergeOrtho to provide increased MRI capacity to respond to increased demand and respond to timely diagnoses. However, as demonstrated with regard to Criterion 3, the "increased demand" is not supported.

The quote from Dr. Pomeranze, which is intended to support the competitive value, is not supported by any documentation to show that these services are not already available in freestanding centers in Wake County.

> **"This proposed high field scanner will provide the ability for appropriate MRI imaging without sedation, accommodate larger and claustrophobic patients, and allow cartilage mapping and templating for total joint replacement."**

Source: EmergeOrtho Application at page 102

Because the applicant claims that the proposed project will enhance competition, but fails to 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; it *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.

Quality

The applicant fails to address evidence that quality care has been provided in the past. As stated in the application discussion of Criterion 13d, Emerge patients' MRI scans are read by ProScan Imaging, an outside teleradiology group based in Cincinnati, Ohio. According to a federal whistleblower lawsuit, ProScan Imaging was recently accused of fraud.

The lawsuit alleges that ProScan Imaging recruited unqualified people to read MRI scans and submitted thousands of fraudulent claims to Medicare, Medicaid, and Tricare (See Attachment 8). According to the Center for Medicare and Medicaid Services IDTF rule 410.33(b)(2) in Attachment 9:

> *"…the supervising physician must evidence proficiency in the performance and interpretation of each type of diagnostic procedure…. The proficiency may be documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier…."*[2]

In order for participation in Medicare and Medicaid, a physician must supervise and interpret the MRI scan. It is unclear if Emerge patients have had their MRI scans accurately read by a physician since the lawsuit alleged that there were no certified professionals to do this. This demonstrates a possible lapse in quality of MRI care and potentially hundreds of cases of inappropriately interpreted patient MRIs scans. The application does not address this issue.

The applicant should be found non-conforming to Criterion 20, because there is public evidence that quality of MRI care may not have been provided in the past and the application does not provide supporting evidence to the contrary.

[2] 42 CFR Ch. IV (10-1-03 Edition); Centers for Medicare and Medicaid Services; 410.33(b)(2) "Independent diagnostic testing facility." Page 255. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/downloads/410_32.pdf

Performance Standard

10NCAC 14C. 2703

(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;

(2 demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];

(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,

(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;

(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;

(5) demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and

(6) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

Emerge owns one mobile MRI scanner in Wake County and proposes to own one additional fixed MRI scanner in Wake County.

All forecasts related to these Performance Standards are based on unsupported assumptions about growth and market share. Some forecasts are based on one-year increases that have no supporting documentation. Moreover, the application assumes these one-time increases will continue annually five years into the future. The supporting assumption on page 123 that "annual growth percentages that are less than the North Carolina statewide CAGR" will continue is incorrect because, as noted in discussion of Criterion 3, Emerge incorrectly calculated that CAGR metric.

<u>*For these reasons, the application should be found non-conforming to performance standards 10NCAC 14C 2703:(b) 2,3,4 and 5.*</u>

ATTACHMENT 4

Comments: J-011820-19, Pinnacle Health Services of North Carolina, LLC

Competitive Review Of:
Pinnacle Health Services of North Carolina, Inc.; J-011820-19

OVERVIEW

Pinnacle Health Services of North Carolina, Inc.'s ("PHSNC") application to develop a fixed Magnetic Resonance Imaging scanner ("MRI"), is non-conforming with statutory review criteria 1, 3, 4, 5, 6, 13, and 18a.

This application proposes to acquire a fixed 3 Tesla ("3T") at its facility Raleigh Radiology Wake Forest ("RRWF"). The applicant proposes to serve 4,685 patients from Wake and other North Carolina counties by Project Year 3, calendar year 2023.

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.**

   Overview

   Although the application proposes to address the points in Policy Gen-3, Basic Principles, it does not "document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan ("SMFP") as well as addressing the needs of all residents of the proposed service area." [emphasis added]

   Access

   As defined in the 2019 SMFP, the proposed service area is Wake County. The applicant, Pinnacle Health Services of North Carolina ("PHSNC"), proposes to locate the only full-service outpatient 3T MRI in Wake County at the county's northernmost boundary. In Section C, the application goes to great lengths to discuss the unique features of the 3T, and the value it brings to Wake County. In that same Section C (page 31), the application describes the access barriers associated with getting from Wake Forest to fixed MRIs near the Raleigh Beltline. By extension, it will be even more difficult for patients from near the Raleigh Beltline and other more distant locations in Wake County to reach Wake Forest. Maps in the application on pages 31-33 actually demonstrate significant difficulty that Wake County residents and visitors outside of northern Wake County alone will encounter in reaching this location. Furthermore, the applicant neglected to include its Cedarhurst location on these maps. Patients residing in the Wake Forest area could more easily access the Cedarhurst location, than the mapped locations on pages 31-33. As such, patients near the Beltline are also more likely to visit the Cedarhurst location for MRI services than PHSNC Wake Forest.

The application indicates that Wake Forest / Rolesville area has no fixed MRI. The area does have four mobile MRI locations, including the mobile MRI services provided at PHSNC Wake Forest. According to the 2019 SMFP, these mobile units offered a total of 5,949 MRI services in FY 2018. Wake Forest/Rolesville is not underserved.

In the application, the patient origin data show that only 62 percent of the users will be Wake County residents. Success of the project depends on drawing 38 percent of procedures from Granville, Vance, Franklin, and Nash Counties, presumably attracted to the lower charges and/or 3T capabilities. The application fails to discuss how the proposed MRI scanner will meet a need in these counties, or how it meets the requirement in GEN-3 to demonstrate how projected volumes accommodate need in these counties.

Value

On page 53, the application acknowledges that "RRWF does not pay a fee for the mobile scanner (which PHSNC owns and operates) …." Hence, the proposed project to replace a mobile does not represent a cost savings. In fact, the additional capital costs will increase the cost of operating the MRI service at PHSNC Wake Forest office, as demonstrated in Section Q, Proforma Form F.3. Service Component.

If forecast procedures do not materialize, unit costs could be much higher than projected in the application.

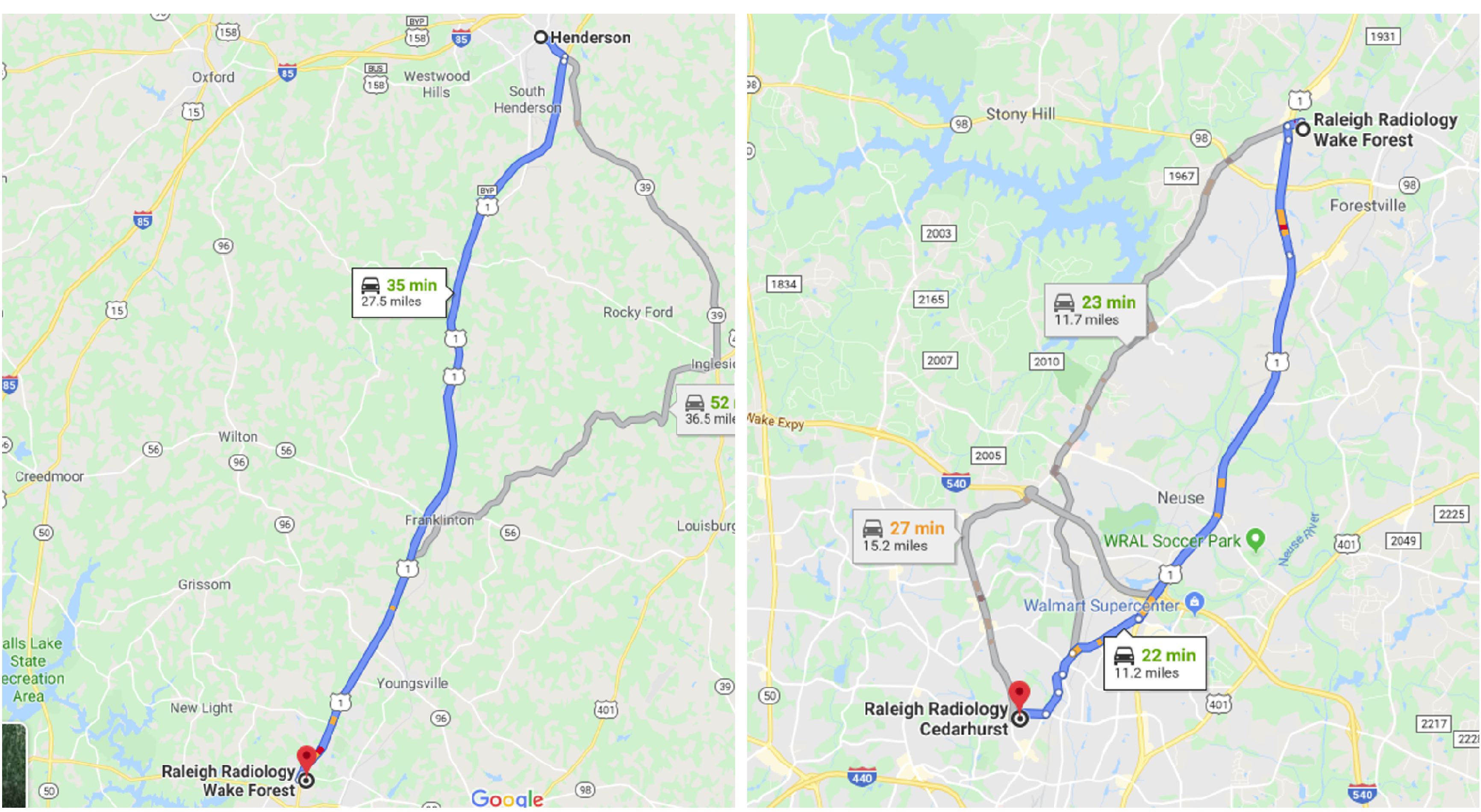
For these reasons, the application should be found non-conforming to Criterion 1.

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.

The application identifies the population to be served in the patient origin on page 22 and 23; clearly including a large geography outside Wake County. Yet the application speaks only to needs of the Wake County population, and does not quantitatively explain how that translates to its proposed utilization. Discussions of underserved groups on page 80 speak only to Wake County and not to other 38 percent of patients the application proposes to serve. The missing analysis coupled with the fact that letters from physicians indicating intent to refer patients total only 1,916 procedures of the 4,685 that the application forecasts for the Wake Forest location cast doubt on the reasonableness of this application's forecast utilization in Wake Forest.

On page 55 of the application, PHSNC proposes to "beneficially redirect" patients from Cedarhurst to its "convenient" Wake Forest location. This implies it is inconvenient for patients to drive 24 minutes from Wake Forest to Cedarhurst (see map below). However, some parts of the proposed service area in Granville, Vance, and Warren Counties are farther from the proposed Wake Forest location than PHSNC Cedarhurst is from PHSNC Wake Forest. According to Google, the distance from Henderson, in Vance County, to Wake Forest is 27 to 33 miles and takes 34 to 48 minutes. Other parts of Vance County are farther away. If 24 minutes is an unreasonable travel time, then, by the applicant's own argument, expecting patients to travel from as far away as Henderson to PHSNC Wake Forest is also unreasonable.

Figure 1 — Distance between PHSNC Wake Forest and PHSNC Cedarhurst; Distance between PHSNC Wake Forest and Henderson, Vance County



Source: Google Maps, accessed 12-20-19 at 4:47pm

The Methodology in Section Q is built on Wake County MRI use rates and an increase of 1.5 percent market share over five years, when, in fact, market share has dropped at both Cedarhurst and Wake Forest. The following Table 1 is based on data in Section Q of the PHSNC Methodology and shows market share for Cedarhurst dropped every year except 2016 to 2017.

Table 1 — PHSNC Cedarhurst Market Share of Wake County MRI Procedures

Notes	Metric	2015	2016	2017	2018	2019 annualized
a.	Fixed unwt procedures	6,814	7,147	7,228	7,624	6,186
b.	Wake County procedures	85,731	92,547	90,481	97,057	
c.	Wake County Projected MRI Procedures					96,285
d.	Market share	7.95%	7.72%	7.99%	7.86%	6.42%
e.	Percent change		-2.84%	3.44%	-1.67%	-18.21%

Notes:

a. Page 98 application
b. Page 99 application
c. Page 100 application
d. a/b for years 2015-2018 and a/c for 2019
e. Row d: (current year – prior year)/prior year

In methodology Step 1, the 3-year CAGR on page 98 is also misleading. It is based on the years 2015-2018. However, between 2016 and 2019 total unweighted procedures and market share decreased from 7,214 to 6,366, a CAGR of -4.1% ((6366/7214)^(1/3))-1 = -0.04083.

The application indicates that procedures decreased in 2019 when Bone and Joint initiated service on its 3Tscanner. Future forecasts expect both number of procedures and market share to reverse the pattern from decrease in 2018-2019, and to increase in future years. The market share increase does not indicate from which providers the share would shift. Calculations in steps 3 and 4 **indicate that the market share increase is in addition to the shift** of PHSNC Cedarhurst procedures from six zip codes to Wake Forest. Step 6 of the Methodology, p.105, does not provide the baseline utilization for the six zip codes. This step provides only the forecast. Moreover, the growth forecast for the PHSNC mobile MRI is also based on flawed logic.

Table 2— Annual Percentage Change in Total PHSNC Mobile MRI Procedures 2015-2019

Year	2015	2016	2017	2018	2019	4-yr CAGR
Procedures	5,945	6,592	7,639	7,759	7,059	0.043873
Annual % change		10.9%	15.9%	1.6%	-9.0%	

Source, Section Q of application, page 108; annual percent change calculated by commenter

The three-year CAGR for 2017 through 2019 is 0.023078, (2.3%) and, more importantly, the annual percent change illustrated in the table above shows that the number of mobile procedures dropped in 2019 and the rate of change has gradually dropped since 2017, going negative in 2019. Thus, growth forecasts on page 102 are not supported by recent trends; and the application does not address the slow down.

In addition, page 100 of the application, the Methodology in Section Q, indicates that MRI use applied in the need forecast are use rates for Wake County MRI providers, not residents. With 38 percent of patients at PHSNC Wake Forest expected to originate from outside Wake County, forecasting an increasing market share of Wake County's total MRI's in future years is not supported by any logic or facts in the application. Together these realities and the absence of referral support for this application, cast doubt on the reasonableness of the application's 2.19 percent annual growth forecast through 2023.

Because the forecast utilization is inconsistent with need of the population to be served, the application should be found non-conforming to Criterion 3.

Criterion 3 also speaks to "all residents of the area to be served." A close look at Franklin, Granville, Vance, and Warren Counties shows a socioeconomic profile that differs significantly from Wake County. These counties are older and less wealthy, as illustrated in Table 3 below.

Table 3 —Demographic Comparison of Proposed PHSNC MRI Service Area, 2018

	Metric	Wake	Franklin	Granville	Vance	Warren
a	Median Household Income	$76,956	$53,175	$55,628	$37,282	$35,962
b	Medicaid Eligible Percent	11.3%	18.0%	16.8%	34.6%	23.4%
c	Percent persons in poverty	8.4%	12.7%	13.0%	36.3%	19.8%
d	% persons over 65	4.7%	15.6%	54.4%	46.3%	0.2%
e	% non-white	31.9%	29.8%	35.5%	54.8%	59.5%

Sources

a. *US Census Bureau QuickFacts, 2018, https://www.census.gov/quickfacts/fact/table/US/PST045218*
b. *NC Division of Health Benefits, NC Medicaid, Annual Unduplicated Enrollment Counts by County, SFY2018, https://medicaid.ncdhhs.gov/documents/reports/enrollment-reports/medicaid-and-health-choice-enrollment-reports*
c. *US Census Bureau QuickFacts, 2018, https://www.census.gov/quickfacts/fact/table/US/PST045218*
d. *NCOSBM, NC Projections by Age 2018*
e. *US Census Bureau QuickFacts, 2018, https://www.census.gov/quickfacts/fact/table/US/PST045218*

Yet, the proposed payor mix in Section L, page 81, is more consistent with Wake County than these other counties; and the application offers no documentation to show that the proposed payor mix is consistent with the needs of residents of all counties served.

Because it also fails to address the need of the population to be served for the proposed project, the extent to which all residents of the proposed area to be served, 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, the application 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.

The application discusses alternative solutions, but does not address them in the context of meeting the needs for the project, specifically the needs of the 38 percent of patients from outside Wake County (page 23).

Further, on page 53, the application acknowledges that "RRWF does not pay a fee for the mobile scanner (which PHSNC owns and operates) …" Hence, the proposed project does not represent a cost savings in the health care delivery system.

The application speaks generically to growing numbers of primary and specialty medical care offices in the Wake Forest/ Rolesville area (p 54) but does not quantify the number of new physicians; nor does it indicate how many of these practices would refer to the proposed project. Many of these practices are in closed systems like UNC Health and Duke University Health System, and those practices are encouraged to refer patients to MRI equipment owned by those systems. This is important because referrals promised in Exhibit I.2 are fewer than the procedures forecast on Form C Utilization in Section Q of the application.

For this reason, the application 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.

The Agency should find this application non-conforming to Criterion 5 for two reasons. First, the applicant failed to document need for 38 percent of its proposed procedures. Thus, projections of charges are unreasonable. See details in the discussion of Criterion 3. Second, the application failed to demonstrate that the applicant will have the cash required for the project, as claimed on pages 56 and 57.

The application refers to a letter in Exhibit F.1. from Outpatient Imaging Associates, Inc ("OIA"), indicating that the CEO of OIA can and will commit funds to PHS for the project. The letter does not describe the mechanism for this transfer of funds and the application does not contain documents that detail the financial relationship between OIA and PHSCNC. Hence, the cost of the funds transfer to the applicant is not clear in the application. Exhibit F.1 contains a letter on

OIA letterhead from Cannon King, who signs as the Managing Member of PHSNC. The letter indicates that financing will be provided by OIA. However, OIA is not listed an applicant for the project and OIA is not a financial institution. OIA is a different company from the applicant, as shown on page 11 of the application. Agency practice has been to require all parties providing capital required for the project to be applicants. The exception is lending institutions. Moreover, on page 58, the application clearly states that "the PHSNC bank account is a sweep account that goes to OIA every night." This indicates that PHS has no operating reserves. Clearly, the application does not **demonstrate** availability of funds for capital needs. In fact, it demonstrates that the applicant, PHSCNC will have no accumulated reserves. Exhibit F.2 provides a bank cash statement for OIA, not for the applicant.

Exhibit F.2 is a copy of a one-day cash statement for OIA. The application provides no financial statement, balance sheet, or letter from a financial institution to show OIA obligations against that cash. The application contains no information about ownership relationships between OIA and PHSNC. Public information on the OIA website provides no supporting detail.

*Because PHSNC failed to **demonstrate** availability of funds for capital and operating needs, it should be found non-conforming to Criterion 5.*

Finally, proforma expense statements in Form F.3 and staffing Form H have no assumptions for the Entire Facility. Without any assumptions, it is difficult to evaluate the impact of the proposed shifts of a substantial number of procedures from Cedarhurst to the Wake Forest facility or the proposed impact of new use of the mobile unit. These are integral parts of this proposed project and without more detail, it is impossible to evaluate the "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**."**

For this additional reason, the project 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.

PHSNC failed to mention the existence of Raleigh Radiology MRI scanners at Blue Ridge and Cary in its list on page 63.

The PHSNC application shows four MRI locations in Wake Forest: Wake Radiology, PHSNC Wake Forest, Rex Hospital-Wakefield, and Orthopedic Specialists of NC. Other than the tesla difference, the application does not address whether or not the proposed facility will necessarily or unnecessarily duplicate services at these Wake Forest mobile MRI facilities.

The application also fails to mention the MRI facilities in Franklin, Granville, and Vance Counties. There are four of them, according to the 2019 State Medical Facilities Plan, two at Maria Parham Hospital in Vance, one at Granville Medical Center and one at Franklin Hospital in Louisburg.

<u>Because the application failed to address whether the proposed PHSNC Wake Forest MRI would result in unnecessary duplication of facilities in the proposed service area for the project, the application is non-conforming to Criterion 6</u>.

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;

The application indicates that PHSNC serves the proposed service area with its mobile unit. However, as discussed with regard to Criterion 3, the patient origin profile for the mobile unit does not reflect the economic profile of the communities it serves. In Section L, the application addresses only Wake County.

Raleigh Radiology Wake Forest
CY2018 Patient Demographics Compared to Wake County

______________ (Name of Facility)	Last Full Fiscal Year	
	Percentage of Total Patients Served by PHSNC*	Percentage of the Population of the Service Area
Female	80.2%	51.3%
Male	19.7%	48.7%
Unknown	0.1%	0.0%
64 and Younger	73.7%	88.4%
65 and Older	26.3%	11.6%
American Indian	*	0.8%
Asian	*	7.5%
Black or African-American	*	21.0%
Native Hawaiian or Pacific Islander	*	0.1%
White or Caucasian	*	60.3%
Other Race	*	10.3%
Declined / Unavailable	*	0.0%

*PHSNC does not track racial and ethnic minority data on its patients.
Sources: PHSNC, and United States Census Bureau QuickFacts for Wake County, July 1, 2018 estimate.

Source: PHSNC application page 80

Because the application does not address the other counties in the PHSNC service area, it is impossible to evaluate the extent to which the application conforms to Criterion 13(a).

The application also erroneously indicates, on page 80, that PHSNC is not proposing to expand the existing Wake Forest facility. In this case, "facility" refers to the MRI service, which the application clearly does propose to expand from three days of mobile part time to fixed full time MRI service.

(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

Because the application does not address the other counties in the PHSNC service area, it is impossible to evaluate the extent to which the application conforms to Criterion 13(c).

For these reasons, the application should be found 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

PHSNC does not propose a new MRI competitor in Wake County. PHSNC owns one mobile and one fixed MRI scanner. The project will not add to competition. The application says only that the "project will enable PHSNC to better meet the needs of RRWF's existing patient population (page 86)." It does not demonstrate that the existing population has difficulty accessing existing PHSNC MRI service at Wake Forest. Nor does it demonstrate how the proposed MRI scanner will address an access problem at that location.

Cost Effectiveness

The application proposes to use applicant cash for part of the funding, but provides no evidence **that the applicant has** the Accumulated Reserves proposed in Section F.2. See discussion with Criterion 5 of these comments.

Access

In Section C, the application discusses increasing age of the population as justification for growth in procedure forecasts, but in Section L, the application shows no increase in the proportion of Medicare patients served. Hence, the proposed project forecasts are internally inconsistent and the project does not appear to increase access to all persons. Moreover, the application refers to dependence on existing referral physicians on page 81, but the promised referrals in Exhibit I.2 do not match the number of procedures forecast.

Because PHSNC's application will not enhance competition, have a positive impact on cost-effectiveness or access to the proposes serves, it should be found non-conforming to 18a.

Attachment 5

Comments: J-011820-19, WR Imaging, LLC and Wake Radiology Diagnostic Imaging Inc.

Competitive Review of:
WR Imaging, LLC & Wake Radiology diagnostic Imaging, Inc.; J-011830-19

Overview

WR Imaging, LLC and Wake Radiology Diagnostic Imaging, collectively referred to as Wake Radiology ("WR"), propose to acquire a fixed MRI scanner pursuant to the need determination for Wake County in the *2019 SMFP* and to locate it in a building owned by Healthcare Trust of America, Inc. at 200 Asheville Avenue in Cary. WR's application to develop a fixed Magnetic Resonance Imaging scanner ("MRI"), is non-conforming with statutory review criteria 1, 3, 5, 6, 12, 13, and 18(a) and does not meet the performance standard in 10A NCAC 14C .2703.

This application proposes to acquire a fixed 1.5 Tesla ("1.5T") at its facility Wake Radiology Cary ("WR Cary") in Cary, North Carolina. The applicant proposes to serve 4,424 patients from Wake, other North Carolina counties, and other states by Project Year 3, calendar year 2023.

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.**

   <u>Policy GEN-3: Basic Principles</u>

   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* ***<u>all residents in the proposed service area</u>****."*[1] [emphasis added]

   <u>Access</u>

   Please see the discussion under Criterion 3 explaining how WR failed to demonstrate the need of all residents in the proposed service area.

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[1] *2019 State Medical Facilities Plan*; Chapter 4 Statement of Policies; Policy GEN-3: Basic Principles. Page 31.

Value

Although the application claims cost savings associated with replacement of the Alliance contract, the application contradicts this statement on page 24. "Wake Radiology intends to continue the contract with Alliance…." Approval of this application would both retain the existing high-cost arrangement and provide additional capacity that is not supported by demonstrated need of the population to be served.

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

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 application does not adequately demonstrate the need the population to be served has for the proposed project. All of the forecasts are tied to historical patterns at applicant facilities. The application makes no attempt to relate its forecast utilization quantitatively to need of the population it proposes to serve.

Instead, the application makes the simple assumption that past increases in use of WR Imaging's MRI justify an assumption that future use will follow the same pattern. (Form C Utilization Methodology page 1). Even the pattern is questionable. On page 1 of the Form C Utilization Methodology and Assumptions, WR shows historical utilization at WRCary from CY16 through CY19. WR's adjusted MRI scans grew 4.0 percent annually from CY2016 to 2019. CY 2019 scans are an estimate based on only six months of 2019 actual utilization (March to August) after the formation of the joint venture ("JV") between WR and UNC REX. Table 1 shows the reported historical utilization at WRCary as reported in the application.

Table 1 – WRCary Historical Utilization CY16-CY19 from Form C Methodology

	CY16	CY17	CY18	CY19 *	CAGR^
Outpatient No Contrast	2,207	2,201	2,479	2,326	1.8%
Outpatient With Contrast	1,677	1,593	1,585	2,041	6.8%
Total Scans	3,405	3,339	3,611	3,784	3.6%
Total Adjusted Scans**	3,884	3,794	4,064	4,367	4.0%
Adjusted Scans Annual Growth	N/A	-2.3%	7.1%	7.5%	

*CY 2019 data based on March to August utilization annualized.
^Compound annual growth rate.
**Adjusted scans based on 1.0 weight for outpatient no contrast and 1.4 weight for outpatient with contrast.

Note: Wake Radiology Cary Fixed MRI utilization shown above <u>does not include</u> MRI scans performed on mobile MRI units at Wake Radiology Cary.
Source: Wake Radiology internal data.

WR then forecast the future scans by type at WRCary using the Total Adjusted Scan CY16-CY19 CAGR. Table 2, below has the application's forecast procedures from CY20 through CY23.

Table 2 – WRCary Projected Utilization, CY20-CY23 from Form C Methodology and Assumptions, p. 2

	CY20	CY21	CY22	CY23	CAGR
Outpatient No Contrast	2,419	2,515	2,615	2,719	4.0%
Outpatient With Contrast	1,516	1,576	1,639	1,705	4.0%
Total Scans	3,935	4,092	4,255	4,424	4.0%
Total Adjusted Scans*	4,541	4,722	4,910	5,106	4.0%

*Adjusted scans based on 1.0 weight for outpatient no contrast and 1.4 weight for outpatient with contrast.

Formation of the JV between WR and UNC REX in February 2019 does not change the fact that the fixed MRI scanner at WRCary was in use in the months preceding and following formation of the JV. The application provides no defensible rationale for annualizing CY19 MRI utilization from only six months of data (March to August) when data were available for 12 months. Because the application provides no reasonable support for the assumption regarding CY19, the projections going forward are unreasonable. It is impossible to determine from information provided in the application, if the change that occurred in six months of 2019 represent a brief aberration or a trend. A closer look at Table 1 shows that the rate of growth in annual contrast scans declined from CY2016 through 2018. The CAGR for adjusted scans in those years is only 2.3 percent ((4064/3884) ^ (1/2)-1 =0.023).

Similarly, the statement on page 24 that “WR intends to continue contracting with Alliance” for the scanner in use at the Cary location proposed for this facility is also confusing. The application contains no discussion of impact that yet another WRCary MRI or increase in capacity would have on the number of scans occurring at the Cary location. Hence, any forecasts contained in the application are unsupported. At best, this represents unnecessary duplication, which would make the application non-conforming to Criterion 6.

Historical data at application page 34 is incorrect because it excludes the 5,292 scans at Raleigh Radiology Blue Ridge (Table 17 E-1 page 435, 2020 SMFP and data table in WR application Exhibit C.4-2). With those added, the data table on page 4 tells a different story. The fastest growth is in the freestanding facilities at a CAGR of 8.4%. The basis for the need is incorrect, as is the underlying justification. The application narrative creates the mistaken impression that a radiology practice or a hospital can control where patients are referred for imaging services. Hospitals and radiologists do not refer patients. Non-radiology physicians work with patients to determine where to refer for MRI images. The application also fails to acknowledge that some hospital outpatient MRIs originate from the very emergency room and observation outpatients that the application acknowledges on page 32.

The application presents Wake Radiology as if it unique in scope of practice. It is not. Raleigh Radiology is also a Wake County multi-specialty radiology practice and has similar subspecialty capabilities. The application mentions “firsts” but offers no specifics.

The application says that it spends $1.1 M on Alliance for WRCary (page 34) but clearly states its intent to retain that contract (page 24).

The assertion that WR Imaging is uniquely organized to direct patients to its outpatient imaging facilities is a clear statement of intent to direct patients to facilities that, for the consumer, are among the most expensive in Wake County. See Attachment 11.

Because WR does not adequately demonstrate the need the population has for the services proposed, it should be found non-conforming to Criterion 3.

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.

Financial

As discussed in Criterion 3, the utilization projections are unreasonable and based on unsupported assumptions. *Unreasonable projections compromise the financial viability of the project; therefore, the application should be found non-conforming to Criterion 5.*

The application fails to discuss the terms by which the applicants can terminate or relocate their contract with Alliance. Without such information, it is impossible to evaluate the project schedule or the costs associated with the proposed project.

Absent reasonable projections of utilization and costs, the project is 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.

Information in Form A of the application is incomplete. The form lists MRI equipment owned by Wake Radiology, but not MRI equipment owned by UNC REX Healthcare or UNC Health Care. Applicant 1 is partially owned by UNC REX Healthcare (application page 6), which is in turn owned by UNC Health Care.

Failure to include this information and to discuss why the proposed project would not unnecessarily duplicate any of the UNC or UNC REX MRI capacity in Wake County should be sufficient reason alone to find this project non-conforming to Criterion 6.

The application argues for parity of MRI supply in Cary, but makes no attempt to show that Cary residents will use the facility. In fact, the Section Q utilization methodology associated with Section C makes no mention of the population to be served.

Page 24 indicates clear intent to retain the Alliance scanner, but the methodology does not demonstrate impact of the retained scanner volume on the forecast scans for applicant and related party facilities.

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

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.

<u>Construction</u>

The application is very clear on page 75 that the Alliance scanner the proposed project would replace is located "within the WR Cary building." The application does not explain the process for moving it out: who is responsible, how long it will take, what happens to operations in the interim?

Thus, the application did not explain how the cost, design, and means of construction represent the most reasonable alternative for the proposal. The application indicates on page 76 that the proposed MRI scanner will replace the existing Alliance-owned MRI scanner at WRCary. The application does not address how renovation of space would affect current operations of MRI and other imaging services in the building. The construction estimate quote in Exhibit F.1, lists individual item costs associated with the renovation. The total construction cost is consistent with application Form F.1a. However, the application does not explain what work is associated with each line item involved. In fact, Exhibit F.1, a contractor cost estimate, clearly notes at the bottom, the exclusion of costs associated with structural changes to the building.

The application also contains no evidence that the building owner will agree to the proposed renovations.

WR failed to demonstrate how or why the chosen alternative means of construction is the most reasonable alternative or that it will not unduly increase the cost of offering the proposed services.

<u>*Because WR did not demonstrate that the cost, design, and means of construction proposed in its application represents the most reasonable alternative, it should be found non-conforming to Criterion 12.*</u>

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:

Access

(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

WR proposes to serve 43.3 percent Medicare for the MRI service component at its proposed location in Project Year 3 (page 81). The applicant based payor mix for MRI on CY2019 experience at WRCary. There is no documentation in the application to support this payor mix. On page 80, the applicant provides the payor mix for CY2018, which lists Medicare at 37.5 percent for the MRI. There is no calculation to show the growth from 37.5 percent Medicare in CY2018 to the 43.3 percent Medicare in CY2023

(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.

WR states on page 80 that it does not include charity care in its financial statements because any patient in each payer mix can qualify for charity care. The application indicates that in CY2019 WR "provided over $700,000 in charity care through Project Access, Alliance Medical Ministry, the Open-Door Clinic and contributions through its association with UNC REX (page 86). It is unclear if any of this was for MRI services. Nor is it clear how the amount was calculated.

The history of providing charity care related to MRI is more questionable because, WR does not include any charity care for the MRI service component in application Form F.2 under contractual adjustments. Yet, WR provides charity care for whole facility Form F.2. It appears that WR may not provide charity care to MRI patients. This suggests that patients who need charitable assistance to afford MRI services will not have access to the proposed MRI scanner at WRCary.

According to Census Quick facts, 5.6 percent of Cary residents have incomes below poverty. [2]

WR did not did not adequately demonstrate the contribution of the proposed service in meeting the health-related needs of medically underserved groups; the application should be found non-conforming to Criterion 13.

[2] https://www.census.gov/quickfacts/fact/table/carytownnorthcarolina,US/PST045218

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

WR operates four fixed and two mobile MRI scanners at its own locations. Per page 34 of the application, WR owns and operates two fixed MRI scanners at Wake Radiology Raleigh MRI Center and two MRI mobile scanners that serves other WR sites in Wake County. Alliance Healthcare Services owns and operates the other two fixed MRI scanners, which are at WRCary and WRGarner, respectively. WR joint venture partner, UNC REX owns and operates four more MRI scanners: two fixed MRI scanners at the UNC REX main campus, one fixed MRI scanner at REX Healthcare of Cary, and one mobile MRI scanner at UNC REX Wakefield. The commenter noted that WR does not have an EIF on file for one of its mobile MRI scanners (CON J-11291-17) See Attachment 10 for the 2019 Hospital License Renewal Applications (“LRA”) and Registration and Inventory of Medical Equipment Forms. (“EIF”)

If the Agency were to approve WR’s application, together WR and UNC REX would own and operate six fixed MRI scanners in Wake County. Based on data from the 2019 LRAs and EIFs this would represent 30 percent (6/20 = 30%) of the fixed MRI scanners in the entire county, the most of any provider. This percentage does not include the three mobile MRI scanners owned by WR and UNC REX. The US Department of Justice has a history of anti-trust investigations in situations where health care mergers result in control of 30 percent or more of a market. [3] WR’s application does not enhance competition and is indicative of future MRIs falling under control of a single provider system.

Saturation of a single provider affects the negotiated insurance rates. In a market dominated by one or two providers, the insurance companies and patients have little to no leverage with which to reduce the contract rates for services.[4] This in turn, affects what employers in that market are forced to pay for health insurance coverage. It also affects who will continue to enroll in employee health insurance programs.

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[3] lexisnexis.com/lexis-practice-advisor/the-journal/b/lpa/posts/healthcare-providers-and-insurers-ftc-approach-to-provider-mergers-and-acquisitions

[4] Gee, Emily, Gurwitz, Ethan, “Provider Consolidation Drives Up Health Care Costs: Policy Recommendations to Curb Abuse of Market Power and Protect Patients”. *Center for American Progress,* Dec 2018, https://www.americanprogress.org/issues/healthcare/reports/2018/12/05/461780/provider-consolidation-drives-health-care-costs/

According to the Kaiser Family Foundation, the number of insured persons is dropping because of the cost of acquiring insurance.[5] In fact, in 2018 North Carolina is among states with the highest number uninsured nonelderly persons.[6] Without competition in the marketplace, there is no incentive to change this trend.

One could read this WR Imaging application as a means for the related party, UNC Rex to maintain high charge structures at its hospital locations, by controlling access to outpatient MRI.

Cost Effectiveness

WR proposes the highest global charge per MRI procedure among all applicants. WR has a history of high charges at WRCary and its prices continue to increase. Table 3 compares the charges for all applicants in this batch. WR also proposes the highest operating expense per MRI procedure among all applicants. Table 4 compares the operating costs.

Table 3 – Charge per MRI Procedure for All Applicants, 2019 vs. Project Year 3

	Current Year (2019)			Project Year 3		
Applicant	**Gross Revenue**	**Unweighted Procedures**	**Charge per Procedure**	**Gross Revenue**	**Unweighted Procedures**	**Charge per Procedure**
Pinnacle Health Services	$4,721,597.00	2,565	$1,840.78	$8,624,545.00	4,685	$1,840.88
EmergeOrtho	$3,110,400.00	2,592	$1,200.00	$6,093,600.00	5,078	$1,200.00
Raleigh Radiology (Cary)	$12,121,068.00	6,424	$1,886.84	$10,788,293.00	6,946	$1,553.17
Raleigh Radiology (Knightdale) (a)	-	-	-	$6,522,524.00	4,269	$1,527.88
Duke University Health System (b)	-	-	-	$6,874,811.00	4,408	$1,559.62
Wake Radiology	$8,446,028.00	3,784	$2,232.04	$11,113,991.00	4,424	**$2,512.20**

Source: Forms C and F.2 of all applicants

Notes: Charge per procedure = gross revenue / projected unweighted procedures
a. RR Knightdale is not yet operational; therefore, has no history.
b. DUHS charges are technical only; professional fees are billed directly by the PDC

[5] Tolbert, Jennifer, et al. "Key Facts about the Uninsured Population." *The Henry J. Kaiser Family Foundation*, 13 Dec. 2019, https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/.
[6] Ibid

Table 4 – Operating Cost per Procedure for All Applicants, 2019 vs. Project Year 3

	Current Year (2019)			Project Year 3		
Applicant	**Total Expenses**	**Unweighted Procedures**	**Cost per Procedure**	**Total Expenses**	**Unweighted Procedures**	**Cost per Procedure**
Pinnacle Health Services	$770,294.00	2,565	$300.31	$1,749,875.00	4,685	$373.51
EmergeOrtho	$608,396.00	2,592	$234.72	$1,305,249.12	5,078	$257.04
Raleigh Radiology (Cary)	$2,021,044.00	6,424	$314.61	$2,021,044.00	6,946	$290.97
Raleigh Radiology (Knightdale) (a)	-	-	-	$1,482,189.00	4,269	$347.20
Duke University Health System	-	-	-	$1,495,477.00	4,408	$339.26
Wake Radiology	$2,895,629.00	3,784	$765.23	$2,890,428.00	4,424	$653.35

Source: Forms C and F.3 of all applicants

Notes: Cost per procedure = total expenses / projected unweighted procedures
a. RR Knightdale is not yet operational; therefore, has no history.

Clearly, the proposed WR project is not cost effective. It has high operating costs and charges. The purpose of WR's joint venture with UNC REX, which is to:

> *"…. decrease the need for patients to access hospital-based MRI scanners when they are appropriate for a freestanding setting, which improves overall convenience for patients because they do not have to navigate a busy hospital campus and reduces the cost of this service for patients and payors alike" (page 34).*

According to the Blue Cross Blue Shield of North Carolina Treatment Cost Estimator, it may be less expensive to receive MRI scans at UNC REX, than at a WR facility.[7] See Table 5 below and Attachment 11. WR charges and operating costs increase every year, as demonstrated in its Forms F.2 and F.3.

Table 5 – Comparison of UNC REX and Wake Radiology MRI Treatment Costs

Treatment	UNC REX	Wake Radiology
MRI Abdomen	$2,246	$2,495
MRI Brain w/ & w/o Contrast	$1,854	$2,531
MRI Breast	$1,074	$2,249

Source: BCBSNC Treatment Cost Estimator, accessed 12.18.19

[7] BCBSNC Treatment Cost Estimator;
http://www.bcbsnc.com/content/providersearch/treatments/index.htm#/?distance=25&treatment=MRI%20Breast&location=27605&categorycode=17801

Because WR's proposed scanner will not foster or enhance competition, nor have a positive impact on cost effectiveness in the service area, it should be found non-conforming to Criterion 18a.

PERFORMANCE STANDARDS

10 NCAC 14C.2703(b)

(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:

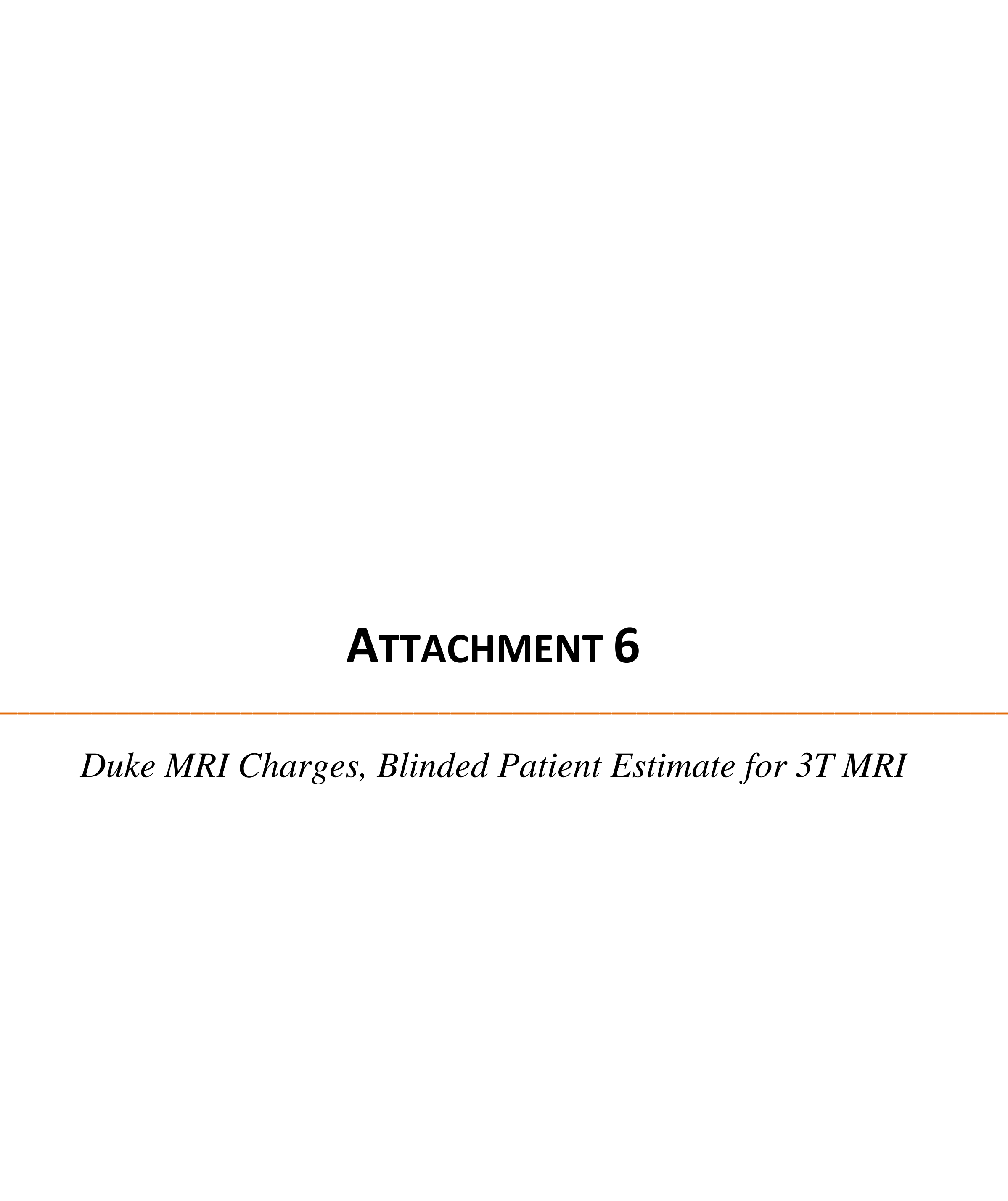
(1) demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12-month period for which the applicant has data.

The applicant claims that this criterion does not apply because the applicant, WR Imaging, has not owned an MRI for more than 12 months. However, UNC Rex is by the applicant's admission a related party (application page 6).

In the table on page 51 of the application, the applicant rolls together the weighted MRI scans provided at UNC Rex, attempting to show that, in the aggregate, scanners at different locations meet the required performance test. The application fails to provide information for individual UNC Rex scanners. However, the application notes (at page 51) that the MRI scanner for UNC Rex Outpatient imaging was out of service between November 2018 and August 2019. The application does not indicate that the UNC Rex Cary Hospital MRI was back in service at the time of this application.

In fact, the application provides no information to support the page 51 calculations and no specific information about the UNC Rex Holly Springs / UNC Rex Outpatient MRI unit. Forecasts for UNC Rex Holly Springs on page 53 of the application and in the methodology suggest that that scanner was not in service and will not be for a while. Forecasts for 2024 show only 1,455 total annual scans. Thus, the application did not demonstrate that the average annual utilization for that particular approved MRI scanner, which is located at a separately licensed facility, did met the average annual utilization performance standard an **average of 3,328 weighted MRI procedures in the most recent 12-month period for which the applicant has data**.

For that reason, the application should be found non-conforming to this performance standard.



ATTACHMENT 6

Duke MRI Charges, Blinded Patient Estimate for 3T MRI

Duke University Health System
Private Diagnostic Clinic, P.L.L.C.

11/07/2019

Estimate of Patient Portion

Patient Name:
Medical Record:
Estimate Date: 11/7/2019
Valid Until: 12/7/2019
Service Date:

	Estimated Charges	Patient Portion
Hospital case at DUKE UNIVERSITY PARENT HOSP		
CPT® 72197 - MRI PELVIS WOW CNTRST	$7,651.18	$419.57
Total	$7,651.18	$419.57
Professional charges at Duke Medicine Pavillion MRI		
CPT® 72197 - MRI, PELVIS, COMBO	$649.00	$0.00
CPT® 76377 - 3D RENDERING W/INTERP&POSTPROC DIFF WORK STATION	$93.00	$0.00
Total	$742.00	$0.00
Total	**$8,393.18**	**$419.57**

The above amount reflects estimates of the charges for the services to be rendered and an estimate of the patient portion for the patient named herein. We can only estimate charges. You may incur additional charges resulting from your visit/service.

If I am solely responsible (no insurance responsibility) for the services above, I understand that the Estimated Total Patient Portion printed above must be received on or prior to the day of service or the service may be cancelled or postponed.

The total amount of charges for which I/we are agreeing to be responsible for will depend on the services actually rendered to the patient and may vary from the above estimate.

I understand the above estimate and the patient portion.

Patient/Guarantor Signature:______________________________ Date:____________

ATTACHMENT 7

Duke University Hospital and Duke Raleigh Hospital 2019 Hospital License Renewal Applications

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Effective January 01, 2019, 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

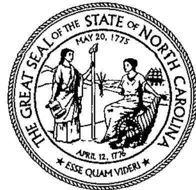
License Number: H0015

Bed Capacity: *957*
General Acute 938, 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

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*:** DUH Campus (1)(4)

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	6,025	3,588	9,613	18,722	7,964	26,686	36,299
Mobile (performed **only at this site**)	0	0	0	0	0	0	0
TOTAL**	6,025	3,588	9,613	18,722	7,964	26,686	36,299

* 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*:** DUH Campus

Fixed Scanners (1), (4)	Number of Units
Number of fixed MRI scanners-closed, including open-bore scanners (*do not include any* Policy AC-3 scanners)	4
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	5
Total Fixed MRI Scanners	9

Number of grandfathered fixed MRI scanners on this campus: 3

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: J-6108-99, J-6958-02, J-8030-07, J-8275-08 (2 scanners), J-8466-10

Patient Origin - MRI Services

In an effort to document patterns of utilization of MRI Services in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. Submit one record for the licensed hospital. **DO NOT SUBMIT SEPARATE RECORDS FOR EACH CAMPUS.**

The total number of patients reported here should be equal to or less than the total number of MRI procedures reported in the "MRI Procedures" table on page 17.

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance	1045	37. Gates	10	73. Person	610
2. Alexander	20	38. Graham	6	74. Pitt	158
3. Alleghany	2	39. Granville	688	75. Polk	5
4. Anson	14	40. Greene	35	76. Randolph	97
5. Ashe	18	41. Guilford	536	77. Richmond	46
6. Avery	11	42. Halifax	166	78. Robeson	311
7. Beaufort	62	43. Harnett	222	79. Rockingham	69
8. Bertie	23	44. Haywood	29	80. Rowan	43
9. Bladen	65	45. Henderson	47	81. Rutherford	24
10. Brunswick	204	46. Hertford	18	82. Sampson	109
11. Buncombe	104	47. Hoke	61	83. Scotland	45
12. Burke	55	48. Hyde	4	84. Stanly	19
13. Cabarrus	56	49. Iredell	62	85. Stokes	15
14. Caldwell	31	50. Jackson	15	86. Surry	29
15. Camden	1	51. Johnston	353	87. Swain	6
16. Carteret	156	52. Jones	19	88. Transylvania	13
17. Caswell	139	53. Lee	159	89. Tyrrell	6
18. Catawba	88	54. Lenoir	72	90. Union	54
19. Chatham	381	55. Lincoln	25	91. Vance	429
20. Cherokee	3	56. Macon	20	92. Wake	3,824
21. Chowan	9	57. Madison	5	93. Warren	133
22. Clay	4	58. Martin	33	94. Washington	26
23. Cleveland	25	59. McDowell	19	95. Watauga	23
24. Columbus	77	60. Mecklenburg	195	96. Wayne	192
25. Craven	130	61. Mitchell	12	97. Wilkes	20
26. Cumberland	671	62. Montgomery	19	98. Wilson	165
27. Currituck	16	63. Moore	167	99. Yadkin	7
28. Dare	56	64. Nash	216	100. Yancey	7
29. Davidson	76	65. New Hanover	259		
30. Davie	12	66. Northampton	36	101. Georgia	174
31. Duplin	73	67. Onslow	215	102. South Carolina	629
32. Durham	6868	68. Orange	1680	103. Tennessee	167
33. Edgecombe	84	69. Pamlico	24	104. Virginia	1422
34. Forsyth	134	70. Pasquotank	27	105. Other States	968
35. Franklin	212	71. Pender	74	106. Other	51
36. Gaston	55	72. Perquimans	12	**Total No. of Patients**	26,416

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Effective January 01, 2019, 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

THE GREAT SEAL OF THE STATE OF NORTH CAROLINA MAY 20, 1775 APRIL 12, 1776 ESSE QUAM VIDERI

Director, Division of Health Service Regulation

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*:** ____________

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	725	1,311	2,036	2,989	4,009	6,998	9,034
Mobile (performed only at this site)				696	1,130	1,826	1,826
TOTAL**	725	1,311	2,036	3,685	5,139	8,824	10,860

* 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)	2
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	2

Number of grandfathered fixed MRI scanners on this campus: 1 Acquired in 1989 prior to DUHS lease of facility

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:
J-6201-00

All responses should pertain to ~~October~~ July 1, 2017 through ~~September~~ June 30, 2018.

Patient Origin - MRI Services

In an effort to document patterns of utilization of MRI Services in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. Submit one record for the licensed hospital. **DO NOT SUBMIT SEPARATE RECORDS FOR EACH CAMPUS.**

The total number of patients reported here should be equal to or less than the total number of MRI procedures reported in the "MRI Procedures" table on page 17.

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance	364	37. Gates	3	73. Person	701
2. Alexander	4	38. Graham	1	74. Pitt	17
3. Alleghany		39. Granville	572	75. Polk	1
4. Anson	2	40. Greene	3	76. Randolph	19
5. Ashe	1	41. Guilford	97	77. Richmond	6
6. Avery	1	42. Halifax	31	78. Robeson	21
7. Beaufort	13	43. Harnett	28	79. Rockingham	13
8. Bertie	5	44. Haywood	5	80. Rowan	6
9. Bladen	20	45. Henderson	9	81. Rutherford	4
10. Brunswick	21	46. Hertford	4	82. Sampson	20
11. Buncombe	9	47. Hoke	6	83. Scotland	10
12. Burke	2	48. Hyde		84. Stanly	4
13. Cabarrus	7	49. Iredell	7	85. Stokes	3
14. Caldwell	5	50. Jackson	3	86. Surry	3
15. Camden	1	51. Johnston	17	87. Swain	
16. Carteret	16	52. Jones		88. Transylvania	1
17. Caswell	57	53. Lee	26	89. Tyrrell	
18. Catawba	6	54. Lenoir	8	90. Union	5
19. Chatham	38	55. Lincoln	4	91. Vance	135
20. Cherokee	1	56. Macon	1	92. Wake	338
21. Chowan	1	57. Madison		93. Warren	45
22. Clay	2	58. Martin	3	94. Washington	3
23. Cleveland	4	59. McDowell	2	95. Watauga	5
24. Columbus	6	60. Mecklenburg	24	96. Wayne	22
25. Craven	14	61. Mitchell	2	97. Wilkes	3
26. Cumberland	44	62. Montgomery	6	98. Wilson	14
27. Currituck	3	63. Moore	24	99. Yadkin	2
28. Dare	2	64. Nash	35	100. Yancey	1
29. Davidson	9	65. New Hanover	28		
30. Davie	2	66. Northampton	9	101. Georgia	13
31. Duplin	9	67. Onslow	22	102. South Carolina	70
32. Durham	3,410	68. Orange	543	103. Tennessee	24
33. Edgecombe	8	69. Pamlico	4	104. Virginia	300
34. Forsyth	16	70. Pasquotank	4	105. Other States	97
35. Franklin	74	71. Pender	6	106. Other	2
36. Gaston	7	72. Perquimans	1	**Total No. of Patients**	7,630

ATTACHMENT 8

ProScan Imaging Lawsuit Articles

FOR LEADERS NAVIGATING VALUE-BASED CARE

Lawsuit accuses ProScan of fraud

Michael Walter

In a whistleblower lawsuit recently unsealed by a federal judge, ProScan Imaging has been accused of committing fraud by using physician assistants instead of radiologists to read MRI scans.

The alleged wrongdoing involved hundreds of MRI being “ghost read” on a daily basis, according to a new report from WCPO Cincinnati. Jason Taylor, a former radiology assistant at ProScan, and radiologist Peter Rothschild, MD, filed the lawsuit back in October 2017. The lawsuit alleges that ProScan submitted thousands of fraudulent claims to Medicare, Medicaid and Tricare.

“ProScan prides itself on its integrity and quality of care,” according to a statement from ProScan CEO Stephen Pomeranz and ProScan President Michael O’Brien, as quoted by WCPO Cincinnati. “We have always operated our business within strict adherence to compliant policies and procedures and will continue to do so. The allegations of the complaint are devoid of merit. ProScan is confident that the lawsuit will be dismissed.”

The lawsuit also alleges that Pomeranz worked to “recruit” Taylor to read MRI scans for ProScan. Taylor has stated that he declined the offer. He did not renew his contract with the company when it ran out in 2016.

Click below to read the full story from WCPO Cincinnati.

Full Story URL

Whistleblower lawsuit accuses ProScan of fraud, misdiagnosing patient MRIs

Source URL: *https://www.radiologybusiness.com/topics/healthcare-economics/lawsuit-accuses-proscan-fraud*

HealthImaging
INSIGHTS IN IMAGING & INFORMATICS

Lawsuit accuses ProScan of misdiagnosing patient MRI scans

Matt O'Connor

A recently unsealed whistleblower lawsuit accuses MRI-reading company ProScan of using physician assistants, instead of radiologists, to read “hundreds” of MRI scans daily, incorrectly diagnosing patients, according to reporting done by WCPO Cincinnati.

Former ProScan radiology assistant Jason Taylor and Peter Rothschild, MD, filed the False Claims Act lawsuit in October 2017 after Rothschild, a California-based radiologist, reviewed multiple ProScan reports and received numerous calls from doctors expressing “grave concerns,” WCPO reported.

According to the lawsuit, Cincinnati-based ProScan submitted thousands of fraudulent Medicare, Medicaid and Tricare reimbursements claims for MRIs not read by qualified doctors. The report alleges this cost the government “hundreds of millions.”

“This lack of proper review has caused injury to patients whose images were mistakenly read as normal by the unlicensed readers and not properly reviewed by a qualified physician. Likewise, ProScan frequently misdiagnoses as serious – and even life-threatening – imaging findings that are of no consequence,” according to the lawsuit filed in U.S. District Court in Cincinnati.

ProScan refuted these claims, insisting all of its radiology reports are “reviewed and finalized by licensed-certified physicians.”

ProScan runs 25 freestanding imaging centers in seven states. It’s teleradiology branch, ProScan Reading, interprets 2,000 MRIs each day for 500 hospitals and imaging centers around the world, according to the lawsuit.

“If these millions of MRIs were re-read by board-certified radiologists, the true scale of this tragedy would become clear,” the lawsuit read.

Read the entire story below.

Full Story URL

Whistleblower lawsuit accuses ProScan of fraud, misdiagnosing patient MRIs

Source URL: *https://www.healthimaging.com/topics/healthcare-economics/lawsuit-proscan-misdiagnosing-mri-scans*

ATTACHMENT 9

American College of Radiology Practice Parameter for the Use of IV Contrast and Center for Medicare and Medicaid Services, Statute 410.32-410.33

The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

Revised 2017 (Resolution 5) *

ACR–SPR PRACTICE PARAMETER FOR THE USE OF INTRAVASCULAR CONTRAST MEDIA

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care[1]. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

[1] Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, _ N.W.2d _ (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

Appropriately experienced physicians currently in a radiology residency or fellowship training program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) to include imaging training on all body areas, may protocol individual examinations when so instructed by their supervising faculty and departmental/institutional policy.

2. The physician should be familiar with the various contrast media available and the indications and contraindications for each. The physician should be aware of specific relative contraindications and pertinent risk factors that might increase the likelihood of adverse events from contrast media administration, and should have appropriate knowledge of alternative imaging methods (see the ACR Manual on Contrast Media [1]). The physician should also be familiar with patient preparation for the examination, including any necessary hydration or bowel preparation. He or she should have knowledge of the volume and concentration of the appropriate contrast media required for a given examination.

3. The physician is responsible for defining the examination protocol, including specifying the type, timing, dosage, rate of injection, and route of administration of contrast media. The physician should have access to pertinent medical and surgical history, as well as diagnoses under consideration by the ordering physician.

B. "Supervising Radiologist or Other Physician" (ie, physician performing direct supervision)

The radiologist or other physician supervising the injection of contrast media should be knowledgeable in the recognition and treatment of adverse events related to contrast media administration (see the ACR Manual on Contrast Media [1]). This physician must be immediately available to furnish assistance and direction throughout the performance of the procedure [5,6]. This does not mean that the physician must be present in the room where and when the procedure is performed [5]. Current CMS rules require direct physician supervision; nonphysician practitioners (eg, nurse practitioners, physician assistants) cannot perform this role even though they can prescribe medications and order imaging examinations with intravenous contrast material [5-7].

C. Registered Radiologist Assistant [8]

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled "Radiologist Assistant: Roles and Responsibilities" and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (ACR Resolution 34, adopted in 2006)

D. Technologist

Technologists performing injections of contrast media should be in compliance with existing operating policies and procedures at the imaging facility in which they are working. At a minimum, the technologist should understand the general benefits of contrast media administration, follow protocols that involve intravascular injection of contrast media, understand contraindications to intravascular injection of contrast media, and recognize adverse events following contrast media administration.

central or peripheral) to permit monitoring of beneficiaries in the future if the initial test was performed with a technique that is different from the proposed monitoring method.

(d) *Beneficiaries who may be covered.* The following categories of beneficiaries may receive Medicare coverage for a medically necessary bone mass measurement:

(1) A woman who has been determined by the physician (or a qualified nonphysician practitioner) treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings.

(2) An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.

(3) An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to 7.5 mg of prednisone, or greater, per day for more than 3 months.

(4) An individual with primary hyperparathyroidism.

(5) An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.

(e) *Denial as not reasonable and necessary.* If CMS determines that a bone mass measurement does not meet the conditions for coverage in paragraphs (b) or (d) of this section, or the standards on frequency of coverage in paragraph (c) of this section, it is excluded from Medicare coverage as not "reasonable" and "necessary" under section 1862(a)(1)(A) of the Act and § 411.15(k) of this chapter.

[63 FR 34327, June 24, 1998]

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) *Ordering diagnostic tests.* All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(1) *Chiropractic exception.* A physician may order an x-ray to be used by a chiropractor to demonstrate the subluxation of the spine that is the basis for a beneficiary to receive manual manipulation treatments even though the physician does not treat the beneficiary.

(2) *Mammography exception.* A physician who meets the qualification requirements for an interpreting physician under section 354 of the Public Health Service Act as provided in § 410.34(a)(7) may order a diagnostic mammogram based on the findings of a screening mammogram even though the physician does not treat the beneficiary.

(3) *Application to nonphysician practitioners.* Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.

(b) *Diagnostic x-ray and other diagnostic tests*—(1) *Basic rule.* Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Services furnished without the required level of supervision are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(2) *Exceptions.* The following diagnostic tests payable under the physician fee schedule are excluded from the basic rule set forth in paragraph (b)(1) of this section:

(i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.

(ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(ll)(3) of the Act.

(iii) Diagnostic psychological testing services personally furnished by a clinical psychologist or a qualified independent psychologist as defined in program instructions.

(iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.

(v) Diagnostic tests performed by a nurse practitioner or clinical nurse specialist authorized to perform the tests under applicable State laws.

(vi) Pathology and laboratory procedures listed in the 80000 series of the Current Procedural Terminology published by the American Medical Association.

(3) *Levels of supervision.* Except where otherwise indicated, all diagnostic x-ray and other diagnostic tests subject to this provision and payable under the physician fee schedule must be furnished under at least a general level of physician supervision as defined in paragraph (b)(3)(i) of this section. In addition, some of these tests also require either direct or personal supervision as defined in paragraphs (b)(3)(ii) or (b)(3)(iii) of this section, respectively. (However, diagnostic tests performed by a physician assistant (PA) that the PA is legally authorized to perform under State law require only a general level of physician supervision.) When direct or personal supervision is required, physician supervision at the specified level is required throughout the performance of the test.

(i) *General supervision* means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

(ii) *Direct supervision* in the office setting means 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.

(iii) *Personal supervision* means a physician must be in attendance in the room during the performance of the procedure.

(c) *Portable x-ray services.* Portable x-ray services furnished in a place of residence used as the patient's home are covered if the following conditions are met:

(1) These services are furnished under the general supervision of a physician, as defined in paragraph (b)(3)(i) of this section.

(2) The supplier of these services meets the requirements set forth in part 486, subpart C of this chapter, concerning conditions for coverage for portable x-ray services.

(3) The procedures are limited to—

(i) Skeletal films involving the extremities, pelvis, vertebral column, or skull;

(ii) Chest or abdominal films that do not involve the use of contrast media; and

(iii) Diagnostic mammograms if the approved portable x-ray supplier, as defined in subpart C of part 486 of this chapter, meets the certification requirements of section 354 of the Public Health Service Act, as implemented by 21 CFR part 900, subpart B.

(d) *Diagnostic laboratory tests.* (1) *Who may furnish services.* Medicare Part B pays for covered diagnostic laboratory tests that are furnished by any of the following:

(i) A participating hospital or participating RPCH.

(ii) A nonparticipating hospital that meets the requirements for emergency outpatient services specified in subpart G of part 424 of this chapter and the laboratory requirements specified in part 493 of this chapter.

(iii) The office of the patient's attending or consulting physician if that physician is a doctor of medicine, osteopathy, podiatric medicine, dental surgery, or dental medicine.

(iv) An RHC.

(v) A laboratory, if it meets the applicable requirements for laboratories of part 493 of this chapter, including the laboratory of a nonparticipating hospital that does not meet the requirements for emergency outpatient services in subpart G of part 424 of this chapter.

(vi) An FQHC.

(vii) An SNF to its resident under § 411.15(p) of this chapter, either directly (in accordance with § 483.75(k)(1)(i) of this chapter) or under an arrangement (as defined in § 409.3 of this chapter) with another entity described in this paragraph.

(2) *Documentation and recordkeeping requirements.*

(i) *Ordering the service.* The physician or (qualified nonphysican practitioner, as defined in paragraph (a)(3) of this section), who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.

(ii) *Submitting the claim.* The entity submitting the claim must maintain the following documentation:

(A) The documentation that it receives from the ordering physician or nonphysician practitioner.

(B) The documentation that the information that it submitted with the claim accurately reflects the information it received from the ordering physician or nonphysician practitioner.

(iii) *Requesting additional information.* The entity submitting the claim may request additional diagnostic and other medical information to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(3) *Claims review.* (i) *Documentation requirements.* Upon request by CMS, the entity submitting the claim must provide the following information:

(A) Documentation of the order for the service billed (including information sufficient to enable CMS to identify and contact the ordering physician or nonphysician practitioner).

(B) Documentation showing accurate processing of the order and submission of the claim.

(C) Diagnostic or other medical information supplied to the laboratory by the ordering physician or nonphysician practitioner, including any ICD–9–CM code or narrative description supplied.

(ii) *Services that are not reasonable and necessary.* If the documentation provided under paragraph (d)(3)(i) of this section does not demonstrate that the service is reasonable and necessary, CMS takes the following actions:

(A) Provides the ordering physician or nonphysician practitioner information sufficient to identify the claim being reviewed.

(B) Requests from the ordering physician or nonphysician practitioner those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed.

(C) If the ordering physician or nonphysician practitioner does not supply the documentation requested, informs the entity submitting the claim(s) that the documentation has not been supplied and denies the claim.

(iii) *Medical necessity.* The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(4) *Automatic denial and manual review.* (i) *General rule.* Except as provided in paragraph (d)(4)(ii) of this section, CMS does not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation that is submitted with the claim (for example, justifications prepared by providers, primary and secondary diagnoses, and copies of medical records).

(ii) *Exceptions.* CMS may automatically deny a claim without manual review if a national coverage decision or LMRP specifies the circumstances under which the service is denied, or

the service is specifically excluded from Medicare coverage by law.

(e) Diagnostic laboratory tests furnished in hospitals and CAHs. The provisions of paragraphs (a) and (d)(2) through (d)(4), inclusive, of this section apply to all diagnostic laboratory test furnished by hospitals and CAHs to outpatients.

[62 FR 59098, Oct. 31, 1997, as amended at 63 FR 26308, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 63 FR 58906, Nov. 2, 1998; 64 FR 59440, Nov. 2, 1999; 66 FR 58809, Nov. 23, 2001]

§ 410.33 Independent diagnostic testing facility.

(a) *General rule.* (1) Effective for diagnostic procedures performed on or after March 15, 1999, carriers will pay for diagnostic procedures under the physician fee schedule only when performed by a physician, a group practice of physicians, an approved supplier of portable x-ray services, a nurse practitioner, or a clinical nurse specialist when he or she performs a test he or she is authorized by the State to perform, or an independent diagnostic testing facility (IDTF). An IDTF may be a fixed location, a mobile entity, or an individual nonphysician practitioner. It is independent of a physician's office or hospital; however, these rules apply when an IDTF furnishes diagnostic procedures in a physician's office.

(2) *Exceptions.* The following diagnostic tests that are payable under the physician fee schedule and furnished by a nonhospital testing entity are not required to be furnished in accordance with the criteria set forth in paragraphs (b) through (e) of this section:

(i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.

(ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(ll)(3) of the Act.

(iii) Diagnostic psychological testing services personally furnished by a clinical psychologist or a qualified independent psychologist as defined in program instructions.

(iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.

(b) *Supervising physician.* (1) An IDTF must have one or more supervising physicians who are responsible for the direct and ongoing oversight of the quality of the testing performed, the proper operation and calibration of the equipment used to perform tests, and the qualification of nonphysician personnel who use the equipment. This level of supervision is that required for general supervision set forth in § 410.32(b)(3)(i).

(2) The supervising physician must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF. The proficiency may be documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area in which the IDTF is located. In the case of a procedure requiring the direct or personal supervision of a physician as set forth in § 410.32(b)(3)(ii) or (b)(3)(iii), the IDTF's supervising physician must personally furnish this level of supervision whether the procedure is performed in the IDTF or, in the case of mobile services, at the remote location. The IDTF must maintain documentation of sufficient physician resources during all hours of operations to assure that the required physician supervision is furnished. In the case of procedures requiring direct supervision, the supervising physician may oversee concurrent procedures.

(c) *Nonphysician personnel.* Any nonphysician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met.

(d) *Ordering of tests.* All procedures performed by the IDTF must be specifically ordered in writing by the physician who is treating the beneficiary,

ATTACHMENT 10

Wake Radiology 2019 Equipment Inventory Reports and UNC REX 2019 Hospital License Renewal Application, Excerpts

Summary Table of MRIs in Operation at Wake Radiology ("WR") Sites

Ownership	MRI Type	CON # or Grandfathered	Serial Number	Site/s of Service
WR Imaging	Fixed	J-05783-97	26004	WR Raleigh MRI Center
WR Imaging	Fixed	Grandfathered	25185	WR Raleigh MRI Center
Alliance Healthcare Services	Fixed	Grandfathered	27478 SYM 66	WR Cary
Alliance Healthcare Services	Fixed	Grandfathered	21216 SYM 68	WR Garner
WR Imaging	Mobile	J-11291-17	25432	WR Garner, WR Cary, WR Wake Forest, WR Fuquay-Varina
WR Imaging	Mobile	J-07012-04	25432	WR Wakefield

Source: 2019 WR EIFS

Summary Table of MRIs in Operation at UNC REX Healthcare ("UNC REX") Sites

Ownership	MRI Type	Site/s of Service
UNC REX	Fixed	UNC REX Hospital
UNC REX	Fixed	UNC REX Hospital
UNC REX	Fixed	REX Healthcare of Cary
UNC REX	Mobile	REX Healthcare of Wakefield

Source: 2019 UNC REX LRAs

Registration and Inventory of Medical Equipment
Fixed Magnetic Resonance Imaging Scanners
January 2019 SYM 66

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 25, 2019**.

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, 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:

   Alliance Healthcare Services
   (Legal Name)

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

   18201 Von Karman #600
   (Street and Number)

   Irvine CA 92612 **(800) 544-3215**
   (City) (State) (Zip) (Phone Number)

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

   Aaron Dunn **Manager Operations**
   (Name) (Title)

   (919) 474-3123 **adunn@allianceradiology-us.com**
   (Phone Number) (Email)

4. Information Compiled or Prepared by: **David French**
   (Name)

   (336) 349-6250 **djfrench45@gmail.com**
   (Phone Number) (Email)

Section 2: Equipment and Procedures Information

Time Period for Report: ☒ 10/01/2017 – 9/30/2018 ☐ Other time period: ____

	Scanner Number ____	Scanner Number ____
Manufacturer/Tesla	**Siemens 1.5T**	
Model Number	**Symphony**	
Open or Closed Scanner	**Closed**	
Serial or I.D. Number	**27478 SYM 66**	
Date of acquisition	**Installed in December 2011**	
Purchase price (if purchased)		
Certificate of Need Project ID	**Grandfathered unit with DR to install**	
Certificate Holder, as listed on Certificate of Need	**Alliance**	
If Leased or Rented, Name Owner of Equipment	**N/A**	
Service Site Information: Please include **all** of the information requested for each location.	**Wake Radiology Diagnostic Imaging** **300 Asheville Avenue Cary, NC 27518** **Wake**	
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: 0 w/out: 0 Total: 0 Outpatient: with: 1175 w/out: 2478 Total: 3653 **Total:** 3653	
Put a check by the days per week, and write in the number of hours per day, the scanner is in operation.	**Approximately 3200 hrs**	
Total number of hours in operation for report period	**Approximately 3200 hrs**	

Registration and Inventory of Medical Equipment
Fixed Magnetic Resonance Imaging Scanners
January 2019 SYM 68

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 25, 2019**.

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, 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:

   Alliance Healthcare Services
   (Legal Name)

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

   18201 Von Karman #600
   (Street and Number)

   Irvine **CA** **92612** — (City) (State) (Zip)
   (800) 544-3215 — (Phone Number)

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

   Aaron Dunn (Name) **Manager Operations** (Title)

   (919) 474-3123 (Phone Number)
   adunn@allianceradiology-us.com (Email)

4. Information Compiled or Prepared by: **David French** (Name)

   (336) 349-6250 (Phone Number)
   djfrench45@gmail.com (Email)

Section 2: Equipment and Procedures Information

Time Period for Report: ☒ 10/01/2017 – 9/30/2018 ☐ Other time period: ____

(Please make additional copies of pages of this form as needed.)

	Scanner Number ____	Scanner Number ____
Manufacturer/Tesla	**Siemens 1.5T**	
Model Number	**Symphony**	
Open or Closed Scanner	**Closed**	
Serial or I.D. Number	**21216 SYM 68**	
Date of acquisition	**Installed in June 2012**	
Purchase price (if purchased)		
Certificate of Need Project ID	**Grandfathered unit with DR to install**	
Certificate Holder, as listed on Certificate of Need	**Alliance**	
If Leased or Rented, Name Owner of Equipment	**N/A**	
Service Site Information: Please include **all** of the information requested for each location.	**Wake Radiology-Garner 300 Health Park Dr Garner, NC 27529** **Wake**	
Inpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation Outpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation	Inpatient: with: 0 w/out: 0 Total: 0 Outpatient: with: 1046 w/out: 1836 Total: 2882	
Total Number of Procedures	**Total: 2882**	
Put a check by the days per week, and write in the number of hours per day, the scanner is in operation.	**Approximately 2400 hrs**	
Total number of hours in operation for report period	**Approximately 2400 hrs**	

*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) Alliance HealthCare

Registration and Inventory of Medical Equipment
Mobile Magnetic Resonance Imaging Scanners
January 2019

Instructions
This is the legally required "Registration and Inventory of Medical Equipment" (G.S. 131E-177) for mobile magnetic resonance imaging (MRI) scanners. Please complete all sections of this form and return to Healthcare Planning by **Friday, January 25, 2019**.

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, 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.

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:

   Wake Radiology Diagnostic Imaging - Mobile
   (Legal Name)

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

   3949 Browning Place
   (Street and Number)
   Raleigh (City) NC (State) 27609 (Zip) (919) 787-7411 (Phone Number)

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

   Margaret King (Name) C.O.O. (Title)
   3949 Browning Place (Street and Number) Raleigh (City) NC (State) 27609 (Zip)
   (919) 787-7411 (Phone Number) mking@wakerad.com (Email)

4. Information compiled or prepared by: Kimberly Morris, RT(R)(MR) (Name)

   (919) 782-7666 (Phone Number) kmorris@wakerad.com (Email)

For DHSR Planning Use Only:
ID #: ______

Section 2: Equipment and Procedures Information

Time Period for Report: ■ 10/01/2017 – 9/30/2018 ☐ Other time period: ______

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Number 1 (One scanner per page)	
Manufacturer/Tesla	Siemens Avanto/1.5T	
Model number	7391167	
Open or closed (including open bore) scanner	Closed	
Serial or I.D. Number	25432	
Date of acquisition	May 2005	
Purchase price (if purchased)	~$1,700,000.00	
Certificate of Need Project ID	J7012-04	
Certificate holder, as listed on Certificate of Need	Wake Radiology Services, LLC	
If leased or rented, name owner of equipment		
	Service Site Number 3	Service Site Number ___
Service Site Information: Please include **all** of the information requested for each location.	Service Site Wake Radiology Cary Address 300 Ashville Avenue, Ste 180 City, State, Zip Cary, NC 27518 County Wake	Service Site ___ Address ___ City, State, Zip ___ County ___
Inpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation	Inpatient: with: ___ w/out: ___ Total: ___	Inpatient: with: ___ w/out: ___ Total: ___
Outpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation	Outpatient: with: 91 w/out: 312 Total: 403	Outpatient: with: ___ w/out: ___ Total: ___
Total Number of Procedures	**Total:** 403	**Total:** ___
Put a check by the days per week, and enter the number of hours per day, the scanner is in operation.	___ Sun: ___ hours ___ Mon: ___ hours ___ Tue: ___ hours ___ Wed: ___ hours ___ Thu: ___ hours ___ Fri: ___ hours X Sat: 12 hours	___ Sun: ___ hours ___ Mon: ___ hours ___ Tue: ___ hours ___ Wed: ___ hours ___ Thu: ___ hours ___ Fri: ___ hours ___ Sat: ___ hours
Total number of hours in operation for report period	624	

*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) Wake Radiology Diagnostic Imaging - Mobile

Registration and Inventory of Medical Equipment
Mobile Magnetic Resonance Imaging Scanners
January 2019

Instructions
This is the legally required "Registration and Inventory of Medical Equipment" (G.S. 131E-177) for mobile magnetic resonance imaging (MRI) scanners. Please complete all sections of this form and return to Healthcare Planning by **Friday, January 25, 2019**.

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, 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.

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:

   Wake Radiology Diagnostic Imaging - Mobile
   (Legal Name)

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

   3949 Browning Place
   (Street and Number)
   Raleigh (City) NC (State) 27609 (Zip) (919) 787-7411 (Phone Number)

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

   Margaret King (Name) C.O.O. (Title)
   3949 Browning Place (Street and Number) Raleigh (City) NC (State) 27609 (Zip)
   (919) 787-7411 (Phone Number) mking@wakerad.com (Email)

4. Information compiled or prepared by: Kimberly Morris, RT(R)(MR) (Name)

   (919) 782-7666 (Phone Number) kmorris@wakerad.com (Email)

For DHSR Planning Use Only:
ID #: ____________

Section 2: Equipment and Procedures Information

Time Period for Report: ■ 10/01/2017 – 9/30/2018 ☐ Other time period: ____________
(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Number 1 (One scanner per page)	
Manufacturer/Tesla	Siemens Avanto/1.5T	
Model number	7391167	
Open or closed (including open bore) scanner	Closed	
Serial or I.D. Number	25432	
Date of acquisition	May 2005	
Purchase price (if purchased)	~$1,700,000.00	
Certificate of Need Project ID	J7012-04	
Certificate holder, as listed on Certificate of Need	Wake Radiology Services, LLC	
If leased or rented, name owner of equipment		
	Service Site Number 2	Service Site Number ___
Service Site Information: Please include **all** of the information requested for each location.	Service Site Wake Radiology Fuquay Varina Address 7636 Purfoy Rd, Ste 200 City, State, Zip Fuquay Varina, NC 27526 County Wake	Service Site ____ Address ____ City, State, Zip ____ County ____
Inpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation	Inpatient: with: ____ w/out: ____ Total: ____	Inpatient: with: ____ w/out: ____ Total: ____
Outpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation	Outpatient: with: 0 w/out: 371 Total: 371	Outpatient: with: ____ w/out: ____ Total: ____
Total Number of Procedures	**Total**: 371	**Total**: ____
Put a check by the days per week, and enter the number of hours per day, the scanner is in operation.	__ Sun: __ hours __ Mon: __ hours __ Tue: __ hours X Wed: 9 hours __ Thu: __ hours __ Fri: __ hours __ Sat: __ hours	__ Sun: __ hours __ Mon: __ hours __ Tue: __ hours __ Wed: __ hours __ Thu: __ hours __ Fri: __ hours __ Sat: __ hours
Total number of hours in operation for report period	468	

*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) Wake Radiology Diagnostic Imaging - Mobile

Registration and Inventory of Medical Equipment
Mobile Magnetic Resonance Imaging Scanners
January 2019

Instructions

This is the legally required "Registration and Inventory of Medical Equipment" (G.S. 131E-177) for mobile magnetic resonance imaging (MRI) scanners. Please complete all sections of this form and return to Healthcare Planning by **Friday, January 25, 2019**.

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, 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.

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:

   Wake Radiology Diagnostic Imaging - Mobile
   (Legal Name)

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

   3949 Browning Place
   (Street and Number)
   Raleigh (City) NC (State) 27609 (Zip) (919) 787-7411 (Phone Number)

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

   Margaret King (Name) C.O.O. (Title)
   3949 Browning Place (Street and Number) Raleigh (City) NC (State) 27609 (Zip)
   (919) 787-7411 (Phone Number) mking@wakerad.com (Email)

4. Information compiled or prepared by: Kimberly Morris, RT(R)(MR) (Name)

   (919) 782-7666 (Phone Number) kmorris@wakerad.com (Email)

For DHSR Planning Use Only:
ID #:________

Section 2: Equipment and Procedures Information

Time Period for Report: ■ 10/01/2017 – 9/30/2018 ☐ Other time period: ________

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Number 1 (One scanner per page)	
Manufacturer/Tesla	Siemens Avanto/1.5T	
Model number	7391167	
Open or closed (including open bore) scanner	Closed	
Serial or I.D. Number	25432	
Date of acquisition	May 2005	
Purchase price (if purchased)	~$1,700,000.00	
Certificate of Need Project ID	J7012-04	
Certificate holder, as listed on Certificate of Need	Wake Radiology Services, LLC	
If leased or rented, name owner of equipment		
	Service Site Number 1	Service Site Number ___
Service Site Information: Please include **all** of the information requested for each location.	Service Site Wake Radiology Wake Forest Address 3150 Rogers Rd, Ste 115 City, State, Zip Wake Forest, NC 27587 County Wake	Service Site ___ Address ___ City, State, Zip ___ County ___
Inpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation	Inpatient: with: ___ w/out: ___ Total: ___	Inpatient: with: ___ w/out: ___ Total: ___
Outpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation	Outpatient: with: 335 w/out: 1065 Total: 1400	Outpatient: with: ___ w/out: ___ Total: ___
Total Number of Procedures	**Total**: 1400	**Total**: ___
Put a check by the days per week, and enter the number of hours per day, the scanner is in operation.	__ Sun: __ hours X Mon: 9 hours X Tue: 9 hours __ Wed: __ hours X Thu: 9 hours X Fri: 9 hours __ Sat: __ hours	__ Sun: __ hours __ Mon: __ hours __ Tue: __ hours __ Wed: __ hours __ Thu: __ hours __ Fri: __ hours __ Sat: __ hours
Total number of hours in operation for report period	1872	

*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) Wake Radiology Diagnostic Imaging - Mobile

Registration and Inventory of Medical Equipment
Fixed Magnetic Resonance Imaging Scanners
January 2019

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 25, 2019**.

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, 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:
   Wake Radiology DBA Raleigh MRI Center
   (Legal Name)
2. Address of the corporation, partnership, individual, or other legal entity that acquired the equipment:
   3811 Merton Drive
   (Street and Number)
   Raleigh (City) NC (State) 27609 (Zip) (919) 782-7666 (Phone Number)
3. Chief Executive Officer or approved designee who is certifying the information in this registration form:
   Margaret King (Name) C.O.O. (Title)
   3949 Browning Place (Street and Number) Raleigh (City) NC (State) 27609 (Zip)
   (919) 787-7411 (Phone Number) mking@wakerad.com (Email)
4. Information compiled or prepared by: Kimberly Morris, RT(R)(MR) (Name)
   (919) 782-7666 (Phone Number) kmorris@wakerad.com (Email)

Section 2: Equipment and Procedures Information

Time Period for Report: ■ 10/01/2017 – 9/30/2018 ☐ Other time period: ______

(Please make additional copies of pages of this form as needed.)

	Scanner Number 1	Scanner Number 2
For DHSR Planning Use Only		
Manufacturer/Tesla	Siemens Avanto/1.5T	Siemens Avanto/1.5T
Model Number	7391167	7391167
Open or closed (including open bore) scanner	closed	closed
Serial or I.D. number	25185	26004
Date of acquisition	11/2004	05/2006
Purchase price (if purchased)	~$1,709,000.00	~$834,000.00
Certificate of Need Project ID	Grand-fathered	J5783-97
Certificate holder, as listed on Certificate of Need	Raleigh MRI, LLC	Raleigh MRI, LLC
If leased or rented, name owner of equipment		
Service Site Information: Please include **all** of the information requested for each location.	Service Site Wake Radiology Address Raleigh MRI Center 3811 Merton Dr City, State, Zip Raleigh, NC 27609 County Wake	Service Site Wake Radiology Address Raleigh MRI Center 3811 Merton Dr City, State, Zip Raleigh, NC 27609 County Wake
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: 1402 w/out: 1482 Total: 2884 **Total**: 2884	Inpatient: with: w/out: Total: Outpatient: with: 1402 w/out: 1482 Total: 2884 **Total**: 2884
Put a check by the days per week, and enter the number of hours per day the scanner is in operation.	Sun: ___ hours Mon: 13 hours Tue: 13 hours Wed: 13 hours Thu: 13 hours Fri: 13 hours Sat: 13 hours	Sun: ___ hours Mon: 13 hours Tue: 13 hours Wed: 13 hours Thu: 13 hours Fri: 13 hours Sat: 13 hours
Total number of hours in operation for report period	4056	4056

*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) Wake Radiology DBA Raleigh MRI Center

All responses should pertain to **October 1, 2017 through September 30, 2018.**

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*:** MAIN CAMPUS

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	1,302	1,503	2,805	3,146	2,673	5,819	8,624
Mobile (performed only at this site)	-	-	-	-	-	-	—
TOTAL**	1,302	1,503	2,805	3,146	2,673	5,819	8,624

* 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*:** MAIN

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)	
Number of Policy AC-3 MRI scanners used for general clinical purposes	
Total Fixed MRI Scanners	2

Number of grandfathered fixed MRI scanners on this campus: 2

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: ____

All responses should pertain to **October 1, 2017 through September 30, 2018.**

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*:** WAKE FIELD

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)	—	—	—	876	441	1,317	1,317
TOTAL**	—	—	—	876	441	1,317	1,317

* 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: ____

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*:** CARY

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	–	–	–	191	265	456	456
Mobile (performed only at this site)	–	–	–	–	–	–	–
TOTAL**	–	–	–	191	265	456	456

* 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*:** CARY

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)	
Number of Policy AC-3 MRI scanners used for general clinical purposes	
Total Fixed MRI Scanners	1

Number of grandfathered fixed MRI scanners on this campus: 1

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*:** WAKEFIELD
During the reporting period,
1. Did the facility own one or more mobile MRI scanners? ✓ Yes ___ No

If Yes, how many? 1 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*:** MAIN

How many fixed CT scanners does the hospital have? 3
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	11,452	–
2	Head with contrast	484	–
3	Head without and with contrast	96	–
4	Body without contrast	9,125	–
5	Body with contrast	14,554	–
6	Body without contrast and with contrast	1,215	–
7	Biopsy in addition to body scan with or without contrast	298	–
8	Abscess drainage in addition to body scan with or without contrast	–	–
	Total	37,724	–

ATTACHMENT 11

Wake Radiology and UNC REX MRI Charges, Blue Cross Blue Shield NC Treatment Cost Estimator

Estimated Treatment Cost Results

MRI Abdomen, 25 miles from Rex Hospital - Modify Your Search

About These Results - Disclaimers

Provider	Blue Value	Blue Options, Blue Advantage
Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	$1,806	$2,246
Triangle Medical Park 5107 S Park Dr Ste 101 Durham, NC 27713	$1,013	$1,166
UNC Hospitals 101 Manning Dr Chapel Hill, NC 27514	$2,210	$2,698
Wake Radiology Diagnostic Imaging 4301 Lake Boone Trl Suites 103 Raleigh, NC 27607	$2,495	$2,495

Feedback

Ste 100
Raleigh, NC 27609

Blue Options, Blue Advantage
$1,259

Estimated Treatment Cost Results

MRI Brain w/o & w/ contrast, 20 miles from rex hospital - Modify Your Search

About These Results - Disclaimers

Blue Value
$1,507

Rex Hospital

4420 Lake Boone Trl
Raleigh, NC 27607

Blue Options, Blue Advantage
$1,854

Feedback

Estimated Treatment Cost Results

MRI Brain w/o & w/ contrast, 20 miles from rex hospital - Modify Your Se
3643 N Roxboro St
Durham, NC 27704
About These Results | Disclaimers

Wake Radiology Diagnostic Imaging

4301 Lake Boone Trl
Suites 103
Raleigh, NC 27607

Blue Value
$2,531

Blue Options, Blue Advantage
$2,531

Wake Radiology Diagnostic Imaging

3821 Merton Dr
Raleigh, NC 27609

Blue Value
$2,531

Blue Options, Blue Advantage
$2,531

Wake Radiology Diagnostic Imaging

3811 Merton Dr
Raleigh, NC 27609

Blue Value
$2,531

Blue Options, Blue Advantage
$2,531

Wake Radiology Diagnostic Imaging

300 Ashville Ave
Ste 100
Cary, NC 27518

Blue Value
$2,531

Blue Options, Blue Advantage
$2,531

Feedback

Estimated Treatment Cost Results

MRI Breast, 20 miles from rex hospital - Modify Your Search

About These Results - Disclaimers

Rex Hospital

4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$877

Blue Options, Blue Advantage
$1,074

Independence Park

4323 Ben Franklin Blvd
Ste 500
Durham, NC 27704

Blue Value
$1,085

Blue Options, Blue Advantage
$1,249

Feedback

Estimated Treatment Cost Results

MRI Breast, 20 miles from rex hospital - Modify Your Search

About These Results - Disclaimers

Blue Value
$2,249

Wake Radiology Diagnostic Imaging

4301 Lake Boone Trl
Suites 103
Raleigh, NC 27607

Blue Options, Blue Advantage
$2,249

Blue Value
$2,249

Wake Radiology Diagnostic Imaging

3821 Merton Dr
Raleigh, NC 27609

Blue Options, Blue Advantage
$2,249

Blue Value
$2,249

Wake Radiology Diagnostic Imaging

3811 Merton Dr
Raleigh, NC 27609

Blue Options, Blue Advantage
$2,249

Blue Value
$2,249

Wake Radiology Diagnostic Imaging

300 Ashville Ave
Ste 100
Cary, NC 27518

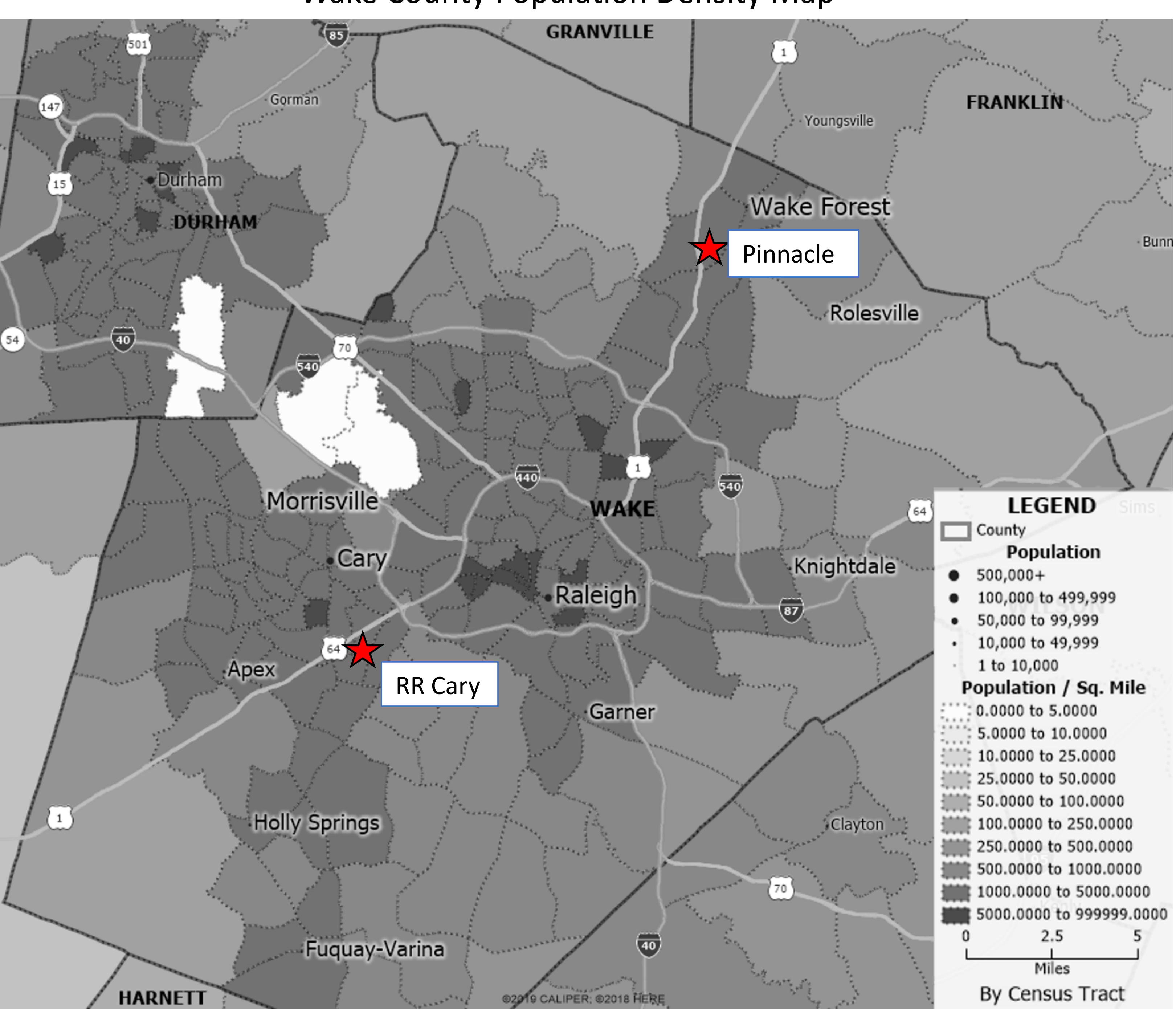
Blue Options, Blue Advantage
$2,249

Feedback

ATTACHMENT 12

Wake County 2018 Population Density by Census Tract Map

Wake County Population Density Map



ATTACHMENT 13

Chatham County Development Plan

LandDesign

FUTURE LAND USE AND CONSERVATION PLAN

SCALE: 1" = 4,666'

N