## COMPETITIVE COMMENTS ON WAKE COUNTY 2021 FIXED MRI SCANNER NEED DETERMINATION SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM JUNE 1, 2021

## OVERVIEW

Three applicants submitted CON applications in response to the need identified in the 2021 SMFP for one additional MRI scanner in Wake County: CON Project ID# J-012073-21 Duke Imaging North Raleigh (DINR), CON Project ID# J-012068-21, WR Imaging, LLC (Wake Radiology), and CON Project ID# J-012063-21 Pinnacle Health Services of North Carolina (PHSNC).

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

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## **COMPARATIVE ANALYSIS**

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

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

## **Conformity to CON Review Criteria**

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

Applicant	Project I.D.	Conforming/ Non-Conforming
Duke Imaging North Raleigh	J-012073-21	Yes
	J-012073-21	165
Wake Radiology Garner	J-012068-21	No
Cardinal Points Imaging Wake Forest/PHSNC	J-012063-21	No

## **Conformity of Competing Applications**

The DUHS application for a fixed MRI scanner is based on reasonable and supported volume projections and adequate projections of cost and revenues. As discussed below, the Wake Radiology application contains errors and flaws which result in multiple non-conformities with the Criteria. Among other issues, Wake Radiology's projected utilization is not reasonable and adequately supported. Therefore, DUHS is the most effective alternative regarding conformity with the Criteria.

## Scope of Services

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

Applicant	Type of Fixed MRI Scanner	Hospital Based or Freestanding
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Duke Imaging North Raleigh	1.5T	Freestanding
Wake Radiology Garner	1.5T	Freestanding
Cardinal Points Imaging Wake Forest/PHSNC	1.5T	Freestanding

However, neither WGR nor PHSNC comply with all applicable statutory and regulatory criteria and therefore neither WGR nor PHSNC are approvable. Therefore, regarding this comparative factor, the

applications the **DUHS** application is more effective than the applications submitted by WRG and Wake Radiology.

## Historical Utilization

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

	# of Fixed MRI	Unweighted	Weighted	Weighted MRI
Facility	Scanners*	Procedures	Procedures	Procedures per Scanner
Duke Raleigh Hospital	2	11,023	13,935	6,968
Rex Hospital	2	8,173	11,125	5,563
Rex Hospital-				
UNC Rex Health Care of Cary	1		0	0
WakeMed Cary Hospital	1	4,020	4,950	4,950
WakeMed-New Bern Ave	2	10,522	16,395	8,198
Duke Radiology Holly Springs	1		0	0
Raleigh Neurology Associates, P.A.				
(Raleigh Neurology Associates)	1	4,898	5,767	5,767
Raleigh Neurology Imaging	1	5,306	6,176	6,176
Raleigh Radiology Blue Ridge				
(Alliance Healthcare Services)	1		6,004	6,004
Raleigh Radiology Cary				
(Alliance Healthcare Services)	1	6,336	7,253	7,253
Raleigh Radiology Cedarhurst				
(Pinnacle Health Services of NC, LLC)	1	6,816	7,532	7,532
The Bone & Joint Surgery Clinic	1	1,745	1745	1,745
Wake Radiology Diagnostic Imaging				
(Alliance Healthcare Services)	1	3,725	4,287	4,287
Wake Radiology MRI (WR Imaging)	1	3,177	3,863	3,863
Wake Radiology MRI				
(formerly Raleigh MRI Center)	1	3,176	3,862	3,862
Wake Radiology Garner				
(Alliance Healthcare Services)	1	3,055	3,540	3,540
Totals	19			

## MRI Utilization 2021 SMFP (FY2019 Data)

Source: 2021 SMFP, Chapter 17, Table 17E-1 (pages 361-362)

WGR is an existing facility that currently provides fixed MRI services. CPIC Wake Forest is an existing imaging facility that provides MRI services via mobile MRI service contract. DUHS proposes to create a new diagnostic center with a fixed MRI scanner, operated as an independent diagnostic testing facility (IDTF). Therefore, DINR does not have historical MRI utilization. Thus, the result of this comparison is inconclusive.

## Geographic Accessibility (Location within the Service Area)

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

	# of Fixed MRI	Hospital Based	
Facility (Owner)	Scanners	or Freestanding	Location
Raleigh Radiology – Cary	1	Freestanding	Cary
Wake Radiology Diagnostic Imaging (Alliance)	1	Freestanding	Cary
WakeMed Cary Hospital (WakeMed)	1	Hospital	Cary
TOTAL FOR CARY***		3	
Wake Radiology – Garner (Alliance)	1	Freestanding	Garner
TOTAL FOR GARNER		1	
Duke Radiology Holly Springs (Duke University Health System) *	1	Freestanding	Holly Springs
Rex Hospital – UNC Rex Health Care of Cary (UNC Health System)**	1	Hospital	Holly Springs
TOTAL FOR HOLLY SPRINGS**		2	
Duke Raleigh Hospital			
(Duke University Health System)	2	Hospital	Raleigh
Rex Hospital – Main (UNC Health System)	2	Hospital	Raleigh
WakeMed (WakeMed)	2	Hospital	Raleigh
Raleigh Neurology Associates	1	Freestanding	Raleigh
Raleigh Neurology Imaging (Alliance)	1	Freestanding	Raleigh
Raleigh Radiology – Blue Ridge (Alliance)	1	Freestanding	Raleigh
Raleigh Radiology – Cedarhurst (Pinnacle)	1	Freestanding	Raleigh
The Bone and Joint Surgery Center (Bone & Joint)	1	Freestanding	Raleigh
Wake Radiology (Wake Radiology)	1	Freestanding	Raleigh
Wake Radiology Raleigh MRI Center (Wake Radiology)	1	Freestanding	Raleigh
TOTAL FOR RALEIGH	13		
2021 Need Determination			
Proposed: PHSNC	1	Freestanding	Wake Forest
Proposed: DUHS	1	Freestanding	Raleigh
Proposed: Wake Radiology	1	Freestanding	Garner

\* Under development.

\*\* Per Wake Radiology which formed a joint venture with UNC Rex HealthCare in late February 2019 the fixed MRI scanner at UNC Rex Healthcare of Cary is being relocated to the UNC REX Holly Springs Hospital upon completion of UNC REX Holly Springs Hospital in 2021.

Area	Population	Total Fixed MRI Scanners	Total Freestanding (Fixed) MRI Scanners	Average Population per Total Fixed Scanner	Average Population per Total Freestanding (Fixed) MRI Scanners
Raleigh	471,745	13	7	36,288	67,392
Cary	167,223	3	2	55,741	83,612
Wake Forest	38,641	0	0	38,641	38,641
Knightdale	17,264	0	0	17,264	17,264
Holly Springs	36,385	2	1	18,193	36,385
Garner	32,213	1	1	32,213	32,213

Source: North Carolina Office of State Management and Budget. Population estimates from July 1, 2019.

Based on the Wake County population estimates as of July 1, 2019, Raleigh has the highest population by far in Wake County. Moreover, 67,392 people are using the freestanding fixed MRI scanners located in Raleigh on a per capita basis as opposed to only 32,213 in Garner. Moreover, while there are no fixed MRI scanners in Wake Forest, Wake Forest's population is only 38,641. Based on this analysis, the geographic location of the MRI scanner in Raleigh is a better option for MRI services in Wake County.

DUHS proposes to locate the new fixed MRI scanner in Raleigh, Wake County. PHSNC proposes to locate the additional fixed MRI scanner in Wake Forest, Wake County. Wake Radiology proposes to locate the additional fixed MRI scanner in Garner, Wake County. Thus, with respect to geographic accessibility, the **DUHS** proposal is the most effective alternative.

## Access By Service Area Residents

On page 418, the 2021 SMFP defines a fixed MRI scanner as "an MRI scanner that is not a mobile MRI scanner." The 2021 SMFP defines the service area for a fixed MRI scanner as "the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1." Therefore, for this review, Wake County is the service area because it has multiple licensed acute care hospitals. Facilities may also serve residents of counties not included in their service area. The following table compares access by service area residents during the third full fiscal year following project completion for each applicant.

Access by Service Area Residents, PY3	Duke Imaging North Raleigh	Wake Radiology Garner	Cardinal Points Imaging WF /PHSNC
Wake County Residents Served	2,913	2,462	2,817
% of Wake County Patients as a % of Total Patients	66%	55%	62%

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

As shown in the table above, DUHS projects to serve both the highest number of Wake County residents and the highest percentage of service area residents. Therefore, regarding access by service area residents, **DUHS** is the most effective alternative.

## Access By Underserved Groups

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

As compared to DUHS's application, Wake Radiology's proposal is inferior with respect to medically underserved access. Wake Radiology projects comparatively lower charity care and Medicaid access than DUHS.

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

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

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

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

## Projected Charity Care

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

Applicant	Gross Revenue	Net Revenue	MRI Scans (Unweighted)	Charity Care	Charity Care as a % of Gross Revenue	Charity Care as a % of Net Revenue	Charity Care / MRI Scan
DUHS	\$5,247,866	\$2,316,231	4,428	\$81,876	1.56%	3.53%	\$18.49
Wake Radiology	\$11,831,997	\$4,111,848	3,858	\$18,533	0.16%	0.45%	\$4.80
PHSNC	\$8,340,144	\$2,298,271	4,547	\$119,994	1.44%	5.22%	\$26.39

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

As a percent of net revenue, PHSNC proposes the highest percentage of charity care as a percent of net revenue. PHSNC also projects the highest dollar amount of charity care per MRI. However, PHSNC does not comply with all applicable statutory and regulatory criteria and therefore PHSNC is not approvable. Therefore, regarding the highest percentage of charity care as a percent of net revenue **DUHS** is the more effective alternative and regarding the dollar amount of charity care per MRI scan **DUHS** is the more effective alternative.

## Projected Medicare

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

Applicant	MRI Scans (Unweighted)	Medicare MRI Procedures	Medicare MRI Procedures as a % of Total MRI Procedures	Gross Revenue	Medicare Gross Revenue	Medicare Gross Revenue as a % of Total Gross Revenue
DUHS	4,428	1,979	44.69%	\$5,247,866	\$2,345,173	44.69%
Wake Radiology	3,858	1,620	42.00%	\$11,831,997	\$5,043,210	42.62%
PHSNC	4,547	1,137	25.00%	\$8,340,144	\$2,082,498	24.97%

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

DUHS proposes the highest 1) number of Medicare MRI procedures, 2) percentage of Medicare MRI procedures as a percent of total MRI procedures, and 3) Medicare gross revenue as a percent of total gross revenue. Thus, regarding access by Medicare patients, **DUHS** is the most effective alternative.

## Projected Medicaid

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

Applicant	MRI Scans (Unweighted)	Medicaid MRI Procedures	Medicaid MRI Procedures as a % of Total MRI Procedures	Gross Revenue	Medicaid Gross Revenue	Medicaid Gross Revenue as a % of Total Gross Revenue
DUHS	4,428	240	5.42%	\$5,247,866	\$284,617	5.42%
Wake Radiology	3,858	123	3.20%	\$11,831,997	\$358,892	3.03%
PHSNC	4,547	177	3.90%	\$8,340,144	\$329,310	3.95%

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

DUHS proposes the highest 1) number of Medicaid MRI procedures, 2) percentage of Medicaid MRI procedures as a percent of total MRI procedures, and 3) Medicaid gross revenue as a percent of total gross revenue. Thus, regarding access by Medicaid patients, **DUHS** is the most effective alternative.

## Competition (Access to a New or Alternate Provider)

All the applicants and/or related entities already provide MRI services in the service area of Wake County; therefore, none of the applicants would qualify as a new or alternative provider in the service area. However, the applications submitted by WRDI and PHSNC are not conforming with all applicable statutory and regulatory review criteria. An application that is not conforming to all applicable statutory and regulatory review criteria cannot be approved. Therefore, regarding this comparative factor, the application submitted by **DUHS** is more effective than the applications submitted by WRDI and PHSNC.

## Projected Average Net Revenue per MRI Procedure

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

Applicant	Net Revenue	MRI Scans (Unweighted)	Average Net Revenue per MRI Procedure
DUHS	\$2,316,231	4,428	\$523
Wake Radiology	\$4,111,848	3,858	\$1,066
PHSNC	\$2,298,271	4,547	\$505

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

As shown in the previous table, PHSNC projects the lowest net revenue per MRI procedure in the third operating year. However, PHSNC does not comply with all applicable statutory and regulatory criteria and therefore PHSNC is not approvable. Therefore, regarding this comparative factor, the proposal by **DUHS**, which proposes the second lowest average net revenue per unweighted MRI procedure in the third full year following project completion and is not materially higher than PHSNC in any event, is the more effective alternative.

## Projected Average Total Operating Cost per MRI Procedure

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

Applicant	Operating Expense	MRI Scans (Unweighted)	Average Operating Expense per MRI Procedure
DUHS	\$1,690,587	4,428	\$382
Wake Radiology	\$2,879,377	3,858	\$746
PHSNC	\$1,576,415	4,547	\$347

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

As shown in the previous table, PHSNC projects the lowest operating expense per MRI procedure in the third operating year. However, PHSNC does not comply with all applicable statutory and regulatory criteria and therefore PHSNC is not approvable. Therefore, regarding this comparative factor, the proposal by **DUHS**, which proposes the second lowest average operating expense per unweighted MRI procedure in the third full year following project completion, is the more effective alternative.

## <u>Summary</u>

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

Comparative Factor	Duke Imaging North Raleigh	Wake Radiology Garner	Cardinal Points Imaging WF /PHSNC
Conformity with Statutory and Regulatory Review Criteria	Yes	No	No
Scope of Services	Equally Effective	Equally Effective	Equally Effective
Historical Utilization	Inconclusive	Inconclusive	Inconclusive
Geographic Accessibility	Most Effective	Less Effective	Less Effective
Access by Service Area Residents: Number of Residents	Most Effective	Less Effective	Less Effective
Access by Service Area Residents: Percentage of Residents	Most Effective	Less Effective	Less Effective
Access by Charity Care as a percent of net revenue	More Effective	Less Effective	Most Effective*
Charity Care per MRI Scan	More Effective	Less Effective	Most Effective*
Access by highest number of Medicare MRI procedures	Most Effective	Less Effective	Less Effective
Access by Medicare highest dollar amount	Most Effective	Less Effective	Less Effective
Access by Medicare as a % of Gross Revenue	Most Effective	Less Effective	Less Effective
Access by highest number of Medicaid MRI procedures	Most Effective	Less Effective	Less Effective
Access by Medicaid highest dollar amount	Most Effective	Less Effective	Less Effective
Access by Medicaid as a % of Gross Revenue	Most Effective	Less Effective	Less Effective
Competition (Access to New or Alternative Provider)	Equally Effective	Equally Effective	Equally Effective
Projected Average Net Revenue per MRI procedure	More Effective	Less Effective	Most Effective*
Projected Average Operating Expense per MRI procedure	More Effective	Less Effective	Most Effective*

\*The applicant does not conform to statutory and regulatory review criteria; thus, it cannot be approved.

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

- Conformity with Review Criteria
- Geographic Access
- Access by Service Area Residents: Number of Residents
- Access by Service Area Residents: Percentage of Residents

- Access by Medicare: Highest Medicaid Procedures
- Access by Medicare: Highest Medicaid Percentage
- Access by Medicare: Percentage of Gross Revenue
- Access by Medicaid: Highest Medicaid Procedures
- Access by Medicaid: Highest Medicaid Percentage
- Access by Medicaid: Percentage of Gross Revenue
- Projected Average Net Revenue per MRI procedure
- Projected Average Total Operating Cost per MRI Procedure

## COMMENTS SPECIFIC TO WR IMAGING, LLC (WAKE RADIOLOGY) PROJECT ID No. J-12068-21

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

## POLICY GEN-3: BASIC PRINCIPLES states:

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

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

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

## Assumptions & Methodology for Projecting MRI Procedures

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

Wake Radiology states on page 1 of Section Q Form C Utilization – Assumptions and Methodology (PDF page 128), that its MRI utilization "during March, April, and May was significantly lower due to the COVID-19 pandemic and associated restrictions." Consequently, Wake Radiology excluded March, April, and May MRI utilization from its CY2020 data and replaced it with what it termed "normalized data". However, upon review of data contained in Exhibit C.5-Monthly MRI Utilization, Wake Radiology actually experienced an increase in MRI utilization during March 2020 as compared to March 2019. The following table summarizes March 2019 and March 2020 MRI utilization as reported in Exhibit C.5.

MRI Unit	March 2019	March 2020
Wake Radiology Garner	271	283
Wake Radiology Cary	330	360
Wake Radiology Raleigh	572	636
WR Mobile #1	201	233
WR Mobile #2	118	177

Source: J-012068-21, Exhibit C.5

Closer examination of the information contained in Wake Radiology's application reveals March 2020 MRI utilization was not "significantly lower" than the prior year; thus, it is puzzling as to why Wake Radiology would purposefully omit March 2020 data from its assumptions and methodology. If Wake Radiology now contends the March 2020 MRI utilization was "significantly lower" and omitted it from CY2020 data, then it must have replaced the March 2020 data with comparatively higher "normalized data." Absent any explanation or analysis of the March 2020 data, it is unreasonable to exclude the March 2020 data from Wake Radiology's methodology. Moreover, it calls into question the reasonableness of Wake Radiology's utilization projections overall.

For illustrative purposes, using data from Exhibit C.5, DUHS recalculated Wake Radiology's CY2020 "normalized" MRI procedures by assuming January-March and June-December data represented in the same proportion in CY2020 as it did in CY2019.

		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
	Wake Radiology Garner													
	Outpatient No Contrast	152	129	152	131	151	151	174	180	146	175	166	137	1,844
	Outpatient With Contrast	74	82	119	110	120	116	104	125	98	128	111	109	1,296
	Total 2019 Scans	226	211	271	241	271	267	278	305	244	303	277	246	3,140
	Outpatient No Contrast	152	129	152			151	174	180	146	175	166	137	1,410
	Outpatient With Contrast	74	82	119			116	104	125	98	128	111	109	947
	Jan-Feb Jun-Dec 2019 Scans	226	211	271			267	278	305	244	303	277	246	2,357
	Outpatient No Contrast								Jan-Mar.	lun-Dec a	s % of 20	)19 Total		84.7%
2019	Outpatient With Contrast							Jan-Feb Jun-Dec as % of 2019 Total				82.3%		
	Outpatient No Contrast	150	173	157	86	106	176	156	175	164	183	134	160	1,820
	Outpatient With Contrast	121	109	126	95	122	137	135	131	128	137	136	125	1,502
	Total 2020 Scans	271	282	283	181	228	313	291	306	292	320	270	285	3,322
	Outpatient No Contrast	150	173	157			176	156	175	164	183	134	160	1,628
	Outpatient With Contrast	121	109	126			137	135	131	128	137	136	125	1,285
	Jan-Feb Jun-Dec 2020 Scans	271	282	283			313	291	306	292	320	270	285	2,913
	Outpatient No Contrast		Jan-Mar Jun-Dec 2020 ÷ (Jan-Mar Jun-Dec 2019 as % of 2019 Total)						1,922					
	Outpatient With Contrast			Jan-Mar Jun-Dec 2020 ÷ (Jan-Mar Jun-Dec 2019 as % of 2019 Total) 1					1,562					
	Normalized 2020 Scans													3,484
2020	Normalized 2020 Adj. Scans													4,109

As the previous table presents, including March 2020 in the methodology results in 3,484 "normalized" CY2020 MRI procedures, which equates to 26 fewer unweighted MRI procedures and 35 fewer weighted MRI procedures compared to Wake Radiology's calculations which excluded March 2020 data (3,510 unweighted/4,144 weighted).

The same unreliability of the CY 2020 "normalized" data undermines the Wake Radiology's future projections, which use that normalized utilization as the baseline for projecting future utilization at Wake Radiology Garner. The applicant states in Section Q, Form C Utilization - Assumptions and Methodology page 1, "While the months following May 2020 resulted in a rebound in volume, levels have not yet returned to those expected under normal, non-COVID operating conditions, particularly as the effects of the pandemic continue to the present." First, Wake Radiology failed to describe the extent to which June-December MRI volume reflects "rebound" volume. For example, if the June-December MRI volume reflects "rebound" volume. For example, if the June-December MRI volume based on June-December volume as a percent of total, the total "normalized" CY2020 data is similarly inflated. Absent any information or explanation regarding the "rebound in volume" during June-December, Wake Radiology's assumption to determine baseline projections from its "normalized" CY2020 MRI volume is not supported.

After manipulating its CY2020 MRI utilization to establish a favorable baseline and CAGR, Wake Radiology applies a 4.8 percent growth rate to project MRI procedures at Wake Radiology Garner through the third project year. This growth rate is based on one-half of Wake Radiology's calculated CAGR for outpatient MRI procedures with contrast performed at Wake Radiology Garner during CY2016 through CY2020 (using manufactured "normalized" data). However, the resulting 4.8 percent CAGR is applied to both outpatient MRI procedures with contrast and outpatient MRI procedures without contrast. This is problematic because Wake Radiology Garner's outpatient MRI procedures without contrast experienced a CAGR of only 2.4 percent during CY2016 through CY2020 (according to data contained in its application). In other words, Wake Radiology projects outpatient MRI procedures without contrast will increase by a growth rate that is 2x higher than the historical CAGR presented in the application. Approximately 50 percent of Wake Radiology Garner's CY2019 MRI procedures were without contrast; thus, application of an inflated, contrast-based growth rate to non-contrast MRI procedures results in significantly overstated utilization projections.

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

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

Wake Radiology is nonconforming with at least the following statutory review criteria: Criteria 1, 3, 5, 6, 7, 8, 18a, and 20. See these Criteria for discussion. In addition, Wake Radiology has significant excess capacity on its existing mobile MRI scanners that could be deployed at the proposed location to meet patient needs. Therefore, Wake Radiology failed to adequately demonstrate that its proposal is an effective alternative for development of a fixed MRI scanner in Wake County. Consequently, the Wake Radiology application is nonconforming to Criterion 4.

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

For the reasons set forth above, the Wake Radiology application fails to provide reasonable and adequately supported assumptions for its financial and operational projections and, as a result, fails to demonstrate conformity with Criterion 5.

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

Wake Radiology failed to adequately demonstrate the need for the proposed services (*See* Criterion 3). In addition, the project duplicates its <u>own</u> existing unused mobile MRI capacity and fixed capacity available in the Wake Radiology-UNC Rex Healthcare joint venture. Therefore, Wake Radiology failed to adequately demonstrate that its proposal will not result in an unnecessary duplication of existing or approved MRI services and is nonconforming to this criterion.

**Criterion 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 the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact."

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

## N.C. Gen. Stat. §131E-183(b)

Wake Radiology's application also fails to meet the performance thresholds of the applicable MRI regulatory criteria and cannot be approved on that basis.

**10A NCAC 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." The MRI service area is Wake County. In Section C, page 64, Wake Radiology states "WR Imaging owns two fixed MRI scanners located at Wake Radiology Raleigh in Wake County. WRDI does not own any fixed MRI scanners. Rex Hospital, Inc. (UNC REX), a related entity through its membership in WR Imaging, owns three fixed MRI scanners in Wake County, two at UNC REX Hospital and one formerly operated at UNC REX Cary Outpatient Imaging that is approved ultimately to be relocated to UNC REX Holly Springs Hospital."

Wake Radiology failed to provide utilization data for the existing Wake Radiology and UNC REX fixed MRI scanners during the most recent 12 month period preceding submission of the CON application. Wake Radiology and UNC Rex Healthcare are members of a joint venture to provide medical imaging in Wake County and therefore UNC Rex Healthcare's utilization, as an acknowledged related entity, is relevant to Wake Radiology's utilization.

On page 64 of its application, Wake Radiology contends 10A NCAC 14C .2703(b)(1) does not apply because of the public health emergency. Wake Radiology references the Governor's "Safer at Home" executive order and states that because "the particular circumstances surrounding the public health emergency that has existed for the past 12 months and is continuing, Wake Radiology believes this rule is not applicable."

Wake Radiology is wrong in stating this Rule does not apply to it because of the public health emergency due to the COVID-19 pandemic. The Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700, are applicable to this review. Wake Radiology does not have authority to suspend applicability of regulatory review criteria for MRI scanners. Duke does not believe that Wake Radiology has sought a declaratory ruling that the performance standards do not apply.

For the Rule to apply: 1) the applicant must be proposing to "acquire a fixed magnetic resonance imaging (*MRI*) scanner". Wake Radiology is proposing to acquire a fixed MRI scanner; and 2) own a fixed MRI scanner in the service area. Wake Radiology states that it owns two fixed MRI scanners in Wake County. Therefore, Wake Radiology meets all the criteria for this Rule to apply.

Next, to conform with this Rule, Wake Radiology must demonstrate that the two MRI scanners it owns in Wake County performed an average of 3,328 weighted MRI procedures in the most recent 12-month period for which the applicant has data. Wake Radiology did not provide any data for the two fixed MRI scanners for *"the most recent 12 month period for which the applicant has data"*. Wake Radiology also failed to provide data for the three fixed MRI scanners owned by UNC REX, which is a related entity in which it participates in a joint venture, for *"the most recent 12 month period for which the applicant has data"*. Furthermore, Wake Radiology does not demonstrate that it does not have access to or does not know the historical data for a 12-month period for the two fixed MRI scanners it owns and the three fixed MRI scanners which it (or a related entity) owns in Wake County performed an average of 3,328 weighted MRI procedures for the most recent 12 month period for which Wake Radiology has such historical data nor did Wake Radiology demonstrate that it could not provide historical data for the existing fixed MRI scanners which it (or a related entity) in Wake County for a 12 month period. Therefore, the application is non-conforming to this Rule.

**10A NCAC 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:

(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.];."

Just as Wake Radiology was found non-conforming to this rule in the 2019 Wake County MRI batch review, Wake Radiology is again non-conforming to this rule in the 2021 Wake County MRI batch review.

The MRI service area is Wake County. In Section C, page 64, Wake Radiology states "WR Imaging owns two mobile MRI scanners operating in Wake County." On page 64 of its application, Wake Radiology does not deny that it cannot meet this historical performance threshold, but contends 10A NCAC 14C .2703(b)(2) does not apply because of the public health emergency. Wake Radiology references the Governor's "Safer at Home" executive order and states that because "the particular circumstances surrounding the public health emergency that has existed for the past 12 months and is continuing, Wake Radiology believes this rule is not applicable." However, there is no basis for this contention, and Wake Radiology does not have authority to suspend applicability of regulatory review criteria for MRI scanners.

For the Rule to apply: 1) the applicant must be proposing to "acquire a fixed magnetic resonance imaging *(MRI) scanner*". Wake Radiology proposes to acquire a fixed MRI scanner; and 2) own a mobile MRI scanner in the service area. Wake Radiology states that it owns two mobile MRI scanners in Wake County; therefore, Wake Radiology must meet the requirements of this Rule in order to have an approvable application.

Next, to conform with this Rule, Wake Radiology must demonstrate that the two mobile MRI scanners it owns in Wake County performed an average of 3,328 weighted MRI procedures in the most recent 12-month period for which the applicant has data. It cannot do so.

Moreover, it is notable that the Wake Radiology's pre-COVID volumes on its mobile scanner did not meet the required performance standard. In the reporting year reflected in the 2021 SMFP, Wake Radiology's two mobile MRI scanners did not meet this threshold, performing a total of 2649 weighted procedures on the scanner subject to CON J-7012-04 and a total of 1196 weighted procedures on the scanner subject to J-1129-17. Therefore, it is not COVID that prevents Wake Radiology from meeting this regulatory criterion, but instead its own historically low utilization. This low volume further undercuts the need for Wake Radiology's project; it has significant capacity on its existing mobile scanners to meet patient needs at its service locations.

**10A NCAC 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:

(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

Wake Radiology does not adequately demonstrate that projected utilization is reasonable and adequately supported. Please see discussion regarding Criterion (3).

## COMMENTS SPECIFIC TO PINNACLE HEALTH SERVICES OF NORTH CAROLINA, LLC (PHSNC) PROJECT ID No. J-12063-21

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

## POLICY GEN-3: BASIC PRINCIPLES states:

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

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

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

## **Population to be Served**

PHSNC failed to adequately identify the population to be served by the proposed project. On page 120 of its CON application, PHSNC projects "some PHSNC MRI patients will shift from PHSNC's CPIC midtown facility to the CPIC Wake Forest fixed MRI scanner during the initial 3 project years." On page 120, the applicant provides a map illustrating the zip codes projecting to shift; however, PHSNC failed to identify the historical or projected volume of MRI procedures for these zip codes. This information is critically important because the applicant assumes a portion of MRI volume will shift to the new fixed MRI scanner. PHSNC assumes a 65 percent patient shift for PY1, 75 percent for PY2, and 85% for PY3; however, the PY1-PY3 total MRI projections for the identified zip codes are not contained in the PHSNC application as submitted. Therefore, the assumptions and resulting projections cannot be evaluated or validated. Therefore, in as much as the zip code projections are incorporated into PHSNC's projected patient origin, the applicant's projected patient origin is not supported.

For these reasons, PHSNC failed to adequately identify the population to be served by the proposed project and is non-conforming to Criterion 3.

## Assumptions & Methodology for Projecting MRI Procedures

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

#### Impact of Business Relationship with Raleigh Radiology

It is notable that PHSNC's utilization methodology closely tracks the methodology used in its previous application filed in the 2019 Wake County review. While relying on the same methodology, however PHSNC ignores significant changes to its business that make its assumptions now unreasonable.

On page 117 of its application, PHSNC explains that it held CY2019 MRI utilization constant to project CY2021 MRI procedures at CPIC Wake Forest. However, this is problematic because CY2019 MRI utilization reflected MRI referrals to PHSNC's imaging center when it was branded as **Raleigh Radiology Wake Forest**, with professional interpretations provided by Raleigh Radiology. The imaging center no longer operates under the Raleigh Radiology brand name, instead, the imaging center is marketed as Cardinal Points Imaging Wake Forest, and offers professional services from a different radiology practice with no ties to the service area. The difference is far more than a name change.

During CY2020, Raleigh Radiology ended its long-standing business relationship with PHSNC and its contract to provide professional services to PHSNC imaging centers, including Raleigh Radiology Wake Forest. Further, upon dissolution of the business relationship, PHSNC relinquished its privilege to use the "Raleigh Radiology" brand name and was forced to change its name. These facts are pertinent to PHSNC's projection methodology because the historical MRI referral volume to PHSNC locations, including the Wake Forest imaging center, is attributable to the experience and trust associated with the "Raleigh Radiology" name and physician reputations, not with the out-of-state investors PHSNC.

In fact, according to publicly available information, Raleigh Radiology filed a trademark complaint in the US District Court for the Eastern District of North Carolina against Outpatient Imaging Affiliates, PHSNC's parent company, and PHSNC. The attached Complaint outlines Raleigh Radiology's allegations against PHSNC. According to the Complaint, "Raleigh Radiology is Wake County, North Carolina's first Radiology practice. Raleigh Radiology has a reputation for being a leader in technological imaging. Consumers know Raleigh Radiology offers the best imaging technologies with the best physicians in the area. As a result, they seek out Raleigh Radiology for their radiology and imaging needs, looking for the RALEIGH RADIOLOGY name."

Raleigh Radiology physicians no longer provide physician coverage at the Wake Forest imaging center. PHSNC now contracts with Greensboro Radiology for physician coverage and professional interpretation services. Greensboro Radiology is based in Guilford County and does not have the same referral relationships with physicians in Wake County as Raleigh Radiology. Absent the Raleigh Radiology name recognition <u>and</u> the affiliation with Raleigh Radiology physicians, there is no reasonable basis to conclude that PHSNC will attract the historical MRI referral volume at its Wake Forest imaging center. Wake County patients that want to obtain services from Raleigh Radiology and the referring physicians who refer to

Raleigh Radiology practices will now likely seek MRI services at other locations that are staffed by Raleigh Radiology physicians.

PHSNC attempts to address this in its application. For example on page 31 of its application PHSNC states, *"PHSNC has provided local MR imaging for nearly 18 years, and has a stable and reliable base of referring clinicians who refer patients to PHSNC MRI locations in Wake and Johnston counties."* However, historical referrals were made to PHSNC MRI locations branded as "Raleigh Radiology" and not Cardinal Points Imaging. The potential effect on referral patterns that will result from this change in professional affiliation is evident in the types of letters of support provided in PHSNC's application. While assuming that its 2021 volume will reflect its previous 2019 volume, PHSNC's 2021 application includes only 2/3 of the total number of letters it provided in its 2019 application. Additionally, PHSNC's 2021 CON application includes approximately 27 letters from chiropractors, or 25 percent of total letters of support. Data from the Advisory Board<sup>1</sup> indicates chiropractors typically refer a relatively low number of annual MRI procedures compared to other provider specialties. Specifically, the Advisory Board data indicates chiropractors average 9.2 referrals per provider to MRI <u>annually</u> (2.2 MRI Bone/Joint & 7.0 MRI Spine). PHSNC's reliance on this practice area for support reflects its thin support from other providers who would be anticipated to refer more significant MRI volume.

The following tables compare PHSNC's letters of support included in the 2019 Wake County MRI CON application (i.e., when PHSNC used the Raleigh Radiology brand name for its Wake Forest imaging center) vs. PHSNC's letters of support included in the 2021 Wake County MRI CON application (i.e., subsequent to PHSNC and Raleigh Radiology ending their business relationship). The tables also compare potential annual MRI referrals based on the letters of support and average annual MRI referrals per provider (based on Advisory Board data).

2019 PHSNC Letters of Support							
Specialty	# of Letters	% of Total Letters	Avg Annual Referrals Per Provider*	Potential Annual Referrals			
Family Medicine	50	30.9%	28.4	1,420			
Chiropractic	22	13.6%	9.2	202			
Internal Medicine	21	13.0%	28.4	596			
Primary Care	19	11.7%	28.4	540			
Podiatry	11	6.8%	31.8	350			
Orthopaedics	9	5.6%	161.7	1,455			
Physical Medicine & Rehabilitation	8	4.9%	9.7	78			
Pediatrics	6	3.7%	7.7	46			
Endocrinology	4	2.5%	19.6	78			
ENT	3	1.9%	47.5	143			
Ophthalmology	2	1.2%	7.2	14			
Rheumatology	2	1.2%	38.8	78			
Neurology	1	0.6%	176.5	177			
Dermatology	1	0.6%	N/A				

<sup>&</sup>lt;sup>1</sup> The Advisory Board Company is a best practices firm that used a combination of research, technology, and consulting to improve the performance of health care organizations.

#### COMPETITIVE COMMENTS ON WAKE COUNTY 2021 MRI SCANNER SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.

Optometrist	1	0.6%	0	0
Gastroenterology	1	0.6%	15.6	16
Hematology Oncology	1	0.6%	40.1	40
Total	162			5,232

\*Based on Advisory Board Data

Source: J-11820-19

2021 PHSNC Letters of Support							
Specialty	# of Letters	% of Total Letters	Avg Annual Referrals Per Provider*	Potential Annual Referrals			
Family Medicine	30	28%	28.4	852			
Chiropractic	27	25%	9.2	248			
Internal Medicine	16	15%	28.4	454			
Primary Care	9	8%	28.4	256			
Orthopaedics	4	4%	161.7	647			
Physical Medicine & Rehabilitation	3	3%	9.7	29			
Podiatry	3	3%	31.8	95			
Gynecology	2	2%	6.3	13			
Neurology	2	2%	176.5	353			
OB/GYN	2	2%	6.3	13			
Ophthalmology	2	2%	7.2	14			
Urology	2	2%	13	26			
Dermatology	1	1%	N/A				
Endocrinology	1	1%	19.6	20			
ENT	1	1%	47.5	48			
General Surgery	1	1%	16.5	17			
Optometrist	1	1%	0	0			
Pediatrics	1	1%	7.7	8			
Plastic Surgery	1	1%	N/A				
Total	109			3,092			

\*Based on Advisory Board Data Source: J-12063-21

As the previous tables clearly portray, PHSNC now has a dramatically different referral base without the Raleigh Radiology affiliation and branding, but it does not address this change in its assumptions. The letters of support in the 2021 application indicate a less diverse array of provider support and a heavy reliance on chiropractic referrals. More importantly, the 2021 letters of support indicate a dramatically lower annual MRI referral potential compared to PHSNC's 2019 Wake County MRI CON application.

DUHS acknowledges there is no rule or statute that requires applicants to include letters of support to demonstrate conformity; however, the letters of support contained in PHSNC's 2021 Wake County MRI

CON application reflect that PHSNC now has a fundamentally different referral base as a result of Raleigh Radiology ending its relationship with PHSNC. Again, this information is pertinent when evaluating the reasonableness of PHSNC's assumption that its Wake Forest imaging center will experience identical MRI volume in CY2021 as it did in CY2019.

PHSNC failed to describe the extent to which the decrease in CY2020 MRI utilization was attributable to the loss of its brand identity vs. the temporary interruption in MRI service due to the COVID-19 pandemic. Also, PHSNC failed to provide any data regarding CY2021 monthly MRI utilization at its Wake Forest imaging center to support its assumption that CY2021 MRI volume would be equivalent to CY2019 MRI volume. Consequently, for the reasons previously stated, PHSNC's assumptions for projecting MRI utilization at CPIC Wake Forest are not supported.

## Errors in Use Rate Calculations, Growth Rates, and Projected MRI Procedures

PHSNC's methodology contains numerous errors which render its utilization projections unreliable. Specifically, on page 118, PHSNC erroneously calculates the FFY2019 Wake County MRI utilization rate. The table on page 118 states the number of FFY2019 MRI procedures performed in Wake County was 108,970; however, according to the 2021 SMFP the correct number of Wake County MRI procedures is actually 107,570. This results in a FFY2019 MRI utilization rate of 99.1. PHSNC's calculated FFY2019 MRI utilization rate of 100.4 is incorrect. This error cascades through the remainder of PHSNC's methodology.

The following table summarizes the *corrected* historical Wake County MRI use rates upon which PHSNC's methodology is based.

Year	County Population	Number of Procedures	Use Rate/1000			
FFY2013	963,920	74,803	77.6			
FFY2014	983,855	82,107	83.5			
FFY2015	1,005,995	85,731	85.2			
FFY2016	1,028,364	92,547	90.0			
FFY2017	1,049,711	90,481	86.2			
FFY2018	1,068,112	100,643	94.2			
FFY2019	1,085,297	107,570*	99.1*			
Average Wake C	Average Wake County MRI Use Rate FFY2016-FFY2019					

## Wake County Historical MRI Use Rate, FFY2013-FFY2019

\*Corrected based on data provided in the 2021 SMFP

PHSNC states on page 117 that the average Wake County MRI use rate for the last four years is 92.7; however, this was calculated based on erroneous FFY2019 data. The actual average Wake County MRI use rate for the last four years is 92.38. The corrected number of projected Wake County MRI procedures (based on PHSNC's methodology assumptions) are provided below.

	2019	2020	2021	2022	2023	2024
Wake County MRI Procedures*	107,570*	101,878	103,243	105,119	107,006	108,912
Erroneous PHSNC Projections	108,970	102,234	103,603	105,486	107,380	109,292
Difference	-1,400	-356	-360	-367	-374	-380

\*Corrected based on data provided in the 2021 SMFP

Next, PHSNC states on page 118 that its CPIC Wake Forest fixed MRI scanner will increase utilization in CY2022-CY2024 based on "50 percent of the 3-year CAGR for the Wake County MRI use rate." However, PHSNC calculated the 3-year CAGR based on erroneous FFY2019 data, thus, the PHSNC growth rate assumption is similarly erroneous.

The 3-year CAGR for the Wake County MRI use rate is 3.3 percent; 50 percent of the 3-year CAGR is 1.64 percent. On page 118, PHSNC erroneously states 50 percent of the 3-year CAGR is 1.86 percent.

On pages 119-120, PHSNC projects incremental market share increases based on projected number of Wake County MRI procedures. However, as previously explained, the projected number of Wake MRI procedures forecasted in PHSNC's table on pages 117 and 119 are wrong. Therefore, application of PHSNC's projected market share increases yield inaccurate incremental MRI projections.

On page 120 of its CON application, PHSNC projects "some PHSNC MRI patients will shift from PHSNC's CPIC midtown facility to the CPIC Wake Forest fixed MRI scanner during the initial 3 project years." On page 120, the applicant provides a map illustrating the zip codes projecting to shift; however, PHSNC failed to identify the historical or projected total volume of MRI procedures for these zip codes. This information is critically important because the applicant assumes a portion of total CPIC Midtown MRI volume by zip code will shift to the new CPIC Wake Forest fixed MRI scanner. PHSNC assumes a 65 percent patient shift for PY1, 75 percent for PY2, and 85% for PY3; however, the PY1-PY3 CPIC Midtown MRI projections for the identified zip codes are not contained in the PHSNC application as submitted. Therefore, the assumptions and resulting projections cannot be validated.

Based on the foregoing reasons, the PHSNC application failed to demonstrate its utilization projections are based on reasonable and adequately supported assumptions. Therefore, the application is non-conforming to Criterion 3.

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

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

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

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

**Criterion 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 that its application is for a service on which competition will not have a favorable impact."

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

## N.C. Gen. Stat. §131E-183(b) CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER 10A NCAC 14C .2703

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

## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NORTH CAROLINA Case No: 4:20-cv-216

RALEIGH RADIOLOGY ASSOCIATES, INC. and RALEIGH RADIOLOGY LLC,	)
Plaintiff,	)
v.	)
OUTPATIENT IMAGING AFFILIATES, LLC, and PINNACLE HEALTH SERVICES OF NORTH CAROLINA, LLC,	

COMPLAINT

## Defendants.

Plaintiffs Raleigh Radiology Associates, Inc. and Raleigh Radiology LLC (collectively "Raleigh Radiology") by and through its counsel, complaining of Defendants alleges and says:

## PARTIES

1. Raleigh Radiology Associates, Inc. is a North Carolina corporation with its

principal place of business in Raleigh, North Carolina.

2. Raleigh Radiology LLC is a North Carolina limited liability company with its principal place of business in Raleigh, North Carolina.

3. Defendant Outpatient Imaging Affiliates ("OIA") LLC is a Tennessee corporation with its principal place of business in Franklin, Tennessee.

4. Pinnacle Health Services of Carolina LLC d/b/a Cardinal Points Imaging of the Carolinas ("Pinnacle") is a Tennessee corporation with its principal place of business in Franklin, Tennessee.

5. Upon information and belief, OIA owns a controlling interest in Pinnacle and has had direct oversight and knowledge of the actions complained of herein and has profited from the same. Upon further information and belief, Defendants worked in concert in furtherance of their illegal actions set forth herein.

#### JURISDICTION AND VENUE

6. This is an action for cybersquatting and false advertising arising under the Lanham Act, 15 U.S.C. §§ 1051 <u>et seq</u>., and the North Carolina Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. § 75-1.1 <u>et seq</u>. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1367.

7. Defendants are regularly engaging in business in this judicial district, engaging in unfair and deceptive trade practices in this judicial district, engaging in false advertising in this judicial district, and directing their cybersquatting activities to consumers in this judicial district.

8. This court has personal jurisdiction over Defendants.

9. Venue is proper in this District pursuant to 28 U.S.C. § 1391.

#### FACTS

Raleigh Radiology is Wake County, North Carolina's first Radiology practice.
 Raleigh Radiology began approximately fifty (50) years ago with Dr. Worth at Rex Hospital.

11. Over its decades of existence, Raleigh Radiology has been and remains very successful. Its renowned physicians treated patients with the best technologies and developed a reputation as being a top option for radiology services, first in Wake County and then in the greater "Research Triangle" area. As patients shared their positive experiences with Raleigh Radiology, more patients wanted to use Raleigh Radiology as their provider, and more primary care doctors referred patients to Raleigh Radiology. Raleigh Radiology grew and expanded. Today, Raleigh Radiology has over forty physicians offering services at multiple offices in North Carolina's Triangle region.

12. Raleigh Radiology strived and continues to strive to be the most trusted provider

of high value imaging services in the communities it serves.

13. Raleigh Radiology has a reputation for being a leader in technological imaging. Raleigh Radiology is constantly adopting the latest advancements in imaging technology to ensure that its patients are obtaining the best technology and results. Often, Raleigh Radiology is the first imaging practice in Wake County to obtain these new, cutting-edge technological products and services.

14. Among Raleigh Radiology's "firsts," Raleigh Radiology was the first imaging center in Wake County devoted to women's health (1985); first in Wake County to receive ACR accreditation for mammography (1989) and in North Carolina for stereotactic breast biopsy (2000); first in Wake County to offer Cardiac Scoring (2001) and CAD for mammography (2002); first in Raleigh to offer Positron Emission Tomography (2003), outpatient PACS (2004), and digital mammography (2005); and first in the Triangle to offer high field 1.5T open bore MRI (2008-2011), 3D breast tomosynthesis mammography (2013), and outpatient 3T MRI imaging (2020).

15. Raleigh Radiology engages in recruitment efforts to ensure its physicians and staff are the top of their fields. Recruiting is not limited to North Carolina but extends across the country in order to obtain the top-rated practitioners. Raleigh Radiology's commitment to hiring only the best physicians is well known in the community.

16. Since its founding, Raleigh Radiology and its predecessors in interest have used the RALEIGH RADIOLOGY brand to offer its services. The RALEIGH RADIOLOGY brand is used in advertisements and marketing material to promote Raleigh Radiology's services. Examples of advertisements and branded materials are shown below:

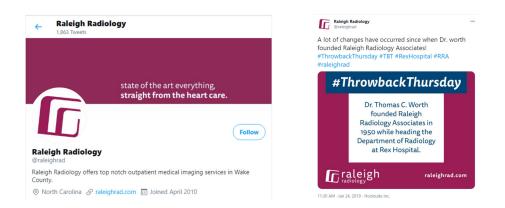


17. Raleigh Radiology's physicians treat patients in RALEIGH RADIOLOGY

branded clinics.



18. Raleigh Radiology advertises online. Raleigh Radiology owns the domain www.raleighrad.com, through which it offers its services. It also participates in social media, such as Twitter.



19. Raleigh Radiology LLC owns two North Carolina state trademark registrations for its RALEIGH RADIOLOGY name and logo. True and accurate copies of these trademark registrations are attached hereto at Exhibits A and B.

20. Consumers know Raleigh Radiology offers the best imaging technologies with the best physicians in the area. As a result, they seek out Raleigh Radiology for their radiology and imaging needs, looking for the RALEIGH RADIOLOGY name.

21. Approximately 15 years ago, Defendant OIA sought to offer an imaging clinic in North Carolina. OIA formed Defendant Pinnacle to own such clinics, and purchased a clinic on Cedarhurst Drive in Raleigh, North Carolina.

22. Defendants needed physicians to staff the Cedarhurst Drive location, and Raleigh Radiology had a deep bench of talented physicians. Therefore, Raleigh Radiology and Defendants decided to enter an agreement whereby Defendants provided the clinic space, and Raleigh Radiology provided the physicians and agreed to allow its RALEIGH RADIOLOGY trademarks to be used at the clinic. The parties agreed and Defendant paid Raleigh Radiology for its professional services for the Cedarhurst Drive clinic.

23. Approximately 11 to 12 years ago, Defendants and Raleigh Radiology decided to expand their agreement to two new locations, one in Clayton, North Carolina and one in Wake Forrest, North Carolina. As with the Cedarhurst Drive location, Defendants owned the physical

clinic space and Raleigh Radiology provided the physicians and RALEIGH RADIOLOGY name. The parties shared revenue. The parties also opened another clinic as part of a joint venture; Raleigh Radiology owned 50% of that venture.

24. As part of their expanded relationship, the parties entered into an amended Professional Services Agreement, with an effective date of July 1, 2009. That agreement allowed Defendant Pinnacle "to use the name 'Raleigh Radiology' as a dba for its centers upon request and only when [Raleigh Radiology] is contracted to provide professional services to the Centers."

25. As the owner of the RALEIGH RADIOLOGY marks and keeper of more than half a century of goodwill and reputation, Raleigh Radiology needed to maintain brand standards for its marks. Initially, when the parties were operating less clinics, it was easier for Raleigh Radiology to review marketing and make sure Raleigh Radiology's high standards were being met. As the parties continued to expand their locations, this became more difficult. Raleigh Radiology, therefore, requested that Defendants seek Raleigh Radiology's approval for marketing that used the RALEIGH RADIOLOGY mark so that Raleigh Radiology could ensure its brand standards would continue to be met. Defendants balked at Raleigh Radiology's request.

26. Over this time, Raleigh Radiology learned that Defendants had been engaging in interests that were no longer aligned with Raleigh Radiology's interests and that eroded Raleigh Radiology's trust in and desire to continue doing business together.

27. Raleigh Radiology and Defendants held a meeting to try to work out the issues between them. Ultimately, the issues could not be resolved, and the parties agreed to separate. For the locations that Raleigh Radiology and Defendants operated pursuant to their business agreements, the parties decided to operate on a transition plan. During the transition period, Raleigh Radiology would staff the clinics while Defendants found a new service provider. At the end of the transition period, Raleigh Radiology physicians would no longer work at these locations and Defendants would not make further use of the RALEIGH RADIOLOGY brand.

28. The parties completed their transition period in October 2020. Thereafter, Defendants were to operate under the CARDINAL POINTS IMAGING brand.

29. Defendants quickly discovered that patients like Raleigh Radiology and look for the RALEIGH RADIOLOGY name. Patients had many questions when the clinic they visited was no longer a RALEIGH RADIOLOGY clinic.

30. When patients asked Defendants where Raleigh Radiology was and why Defendants' clinics were no longer called RALEIGH RADIOLOGY, Defendants could have told the patients the truth – that Defendants and Raleigh Radiology had decided to split ways and Defendants entered into a relationship with different medical professionals. Instead, Defendants routinely misrepresented the truth.

31. Defendants told some patients enquiring into how the patients could find Raleigh Radiology that Raleigh Radiology no longer existed.

32. The statement that Raleigh Radiology no longer existed was and is false. Raleigh Radiology continues to offer its RALEIGH RADIOLOGY services in the Triangle region at all its locations that it had traditionally operated without Defendants. Raleigh Radiology is also in the process of expanding and opening new offices.

33. Defendants told patients that Defendants were the same provider as RaleighRadiology, and that they had simply rebranded.

34. This statement is false. Defendants are not the same physician providers that provided (and continue to provide) services under RALEIGH RADIOLOGY. Defendants now

staff their offices with a completely different physician team.

35. In addition to telling patients that Defendants were the same provider and had simply changed their name as part of a rebranding campaign, Defendants began advertising on the Internet with this messaging.

36. Defendants took out Google AdWords advertisements for their clinics, such as the advertisement shown below. The advertisement gives the impression that the only thing that has changed is Defendants' name. In reality, Defendants are no longer offering the services of the physicians that provided the experiences patients received in the past.

Ad • www.cardinalpointsimaging.com/ 👻 (877) 974-6730

Cardinal Points Imaging - New Name, Same Experience Be Prepared, Know Your Cost First With Our Online Calculator. Learn More Today. Expect Convenience, Exceptional Care, Superior Technology & Accurate Results. Affordable w/o Compromise. Accurate Results. Conveniently Located. Exceptional Care. CT Scan · X-Ray Services · View Costs · Services Offered · MRI Services

37. To further their scheme, Defendants also purchased the domain

<u>www.raleighradiology.com</u>. Defendants directed traffic from <u>www.raleighradiology.com</u> to Defendants' webpage, <u>www.cardinalpointsimaging.com</u>.

38. When someone types in <u>www.raleighradiology.com</u>, trying to find Raleigh Radiology, they are immediately sent to Defendants' website and greeted by Defendants' website's pop-up screen. That screen reads:



39. Defendants' pop-up window claims that Defendants' clinics are providing the "same team to provide exceptional service." This statement is false. The physician team that had previously worked at Defendants' clinics was supplied by Raleigh Radiology. The Raleigh Radiology physician team no longer works at any of these clinics.

40. Although Defendants' claims on their website pop-up window are false in and of themselves, the falsity is compounded by Defendants' use of <u>www.raleighradiology.com</u> to direct patients to this page. Patients must click the "close" button upon seeing this screen, making it more likely they read it and believe they have found the provider they are looking for (Raleigh Radiology) when, in fact, they have found the website for physicians who are not part of Raleigh Radiology.

41. The combination of the <u>www.raleighradiology.com</u> URL and Defendants' website further cements the false impression that Defendants are Raleigh Radiology and simply rebranded. In truth, Defendants' clinics are operated by a separate and distinct physician group in competition with Raleigh Radiology.

42. Occasionally, instead of denying Raleigh Radiology's ongoing existence, Defendants tell Raleigh Radiology's patients that Raleigh Radiology provided sub-par services. For example, Defendants contacted a patient of Raleigh Radiology and told the patient that she should change her radiology appointment to Defendants. Defendants told the patient that Raleigh Radiology physicians were "missing" diagnoses of breast cancer.

43. Not only is this statement false, but it falsely accuses Raleigh Radiology of medical malpractice.

44. Patients are upset by Defendants' false statements. When patients contact Raleigh Radiology to demand answers, Raleigh Radiology must reassure their patients that it is not committing medical malpractice and that it is still the high-quality radiology practice that has served the area for more than fifty years.

45. In an attempt to resolve these matters, Raleigh Radiology wrote to Defendants and asked Defendants to stop their false statements and to stop using Raleigh Radiology's trademark as Defendants' URL in order to compete with Raleigh Radiology. Defendants refused.

46. Raleigh Radiology is harmed, and will continue to be harmed, by Defendants deceptive and unfair acts.

## COUNT I CYBERSQUATTING 15 USC § 1125(d)

47. Raleigh Radiology repeats and realleges, as if fully set forth herein, each and every allegation contained in the foregoing paragraphs.

48. Raleigh Radiology owns a common law RALEIGH RADIOLOGY trademark.

49. Raleigh Radiology owns two North Carolina State Trademark Registrations for

## the RALEIGH RADIOLOGY trademark, Reg Nos. T-23040 and T-23088.

50. Defendants have knowledge of the RALEIGH RADIOLOGY marks and Raleigh Radiology's ownership of those marks.

51. Defendants do not have permission to use Plaintiff's RALEIGH RADIOLOGY mark or name.

52. Defendants are competitors of Plaintiff.

53. Defendants registered and used the domain <u>www.raleighradiology.com</u> without the right to use the RALEIGH RADIOLOGY name.

54. The domain <u>www.raleighradiology.com</u> is identical to and confusingly similar with the RALEIGH RADIOLOGY marks.

55. At the time Defendants registered <u>www.raleighradiology.com</u>, Defendants knew that Raleigh Radiology owned the RALEIGH RADIOLOGY marks.

56. Defendants use the <u>www.raleighradiology.com</u> domain to direct patients of Raleigh Radiology to Defendants' competing imaging clinics.

57. Because Defendants use <u>www.raleighradiology.com</u> to redirect Raleigh Radiology's patients to Defendants' competing clinics, Defendants are making commercial use of <u>www.raleighradiology.com</u>.

58. Defendants' use of <u>www.raleighradiology.com</u> is not fair use.

59. Defendants' use of <u>www.raleighradiology.com</u> is not undertaken in good faith.

60. Defendants do not have reasonable grounds to believe they are using

www.raleighradiology.com in good faith.

61. Defendants are engaging in cybersquatting.

62. On information and belief Defendants' cybersquatting is done willfully,

intentionally, maliciously, and in bad faith.

63. Raleigh Radiology cannot be adequately compensated for these injuries by damages alone, and Raleigh Radiology has no adequate remedy at law for Defendants' cybersquatting. Raleigh Radiology is entitled to injunctive relief, as well as damages and attorneys' fees.

## COUNT II FALSE ADVERTISING 15 USC § 1125(a)

64. Raleigh Radiology repeats and realleges, as if fully set forth herein, each and every allegation contained in the foregoing paragraphs.

65. In conjunction with offering their radiology services, Defendants made false statements of fact in advertisements.

66. In particular, Defendants placed a pop-up window on their website that all website visitors see when the travel to Defendants' website. The pop-up window includes the statement that Defendants' clinics are staffed by the "Same team to provide exceptional service."

67. This statement is false. The physician team that formerly provided services at Defendants' locations no longer works at any of those locations. Those physician teams are Raleigh Radiology teams that work at Raleigh Radiology offices.

68. Defendants' website is commercial advertising or promotion.

69. Defendants' website is misrepresenting the nature, characteristics, qualities and origin of Defendants' services. In particular, Defendants are misrepresenting that their services are provided by the same team that had traditionally provided services. In reality, that team no longer works at Defendants' clinics.

70. Defendants are engaging in false advertising.

71. On information and belief Defendants' false advertising is done willfully, intentionally, maliciously, and in bad faith.

72. Raleigh Radiology cannot be adequately compensated for these injuries by damages alone and has no adequate remedy at law for Defendants' false advertising. Raleigh Radiology is entitled to injunctive relief, as well as damages and attorneys' fees.

## COUNT III N.C. GEN. STAT. § 75-1.1

73. Raleigh Radiology repeats and realleges, as if fully set forth herein, each and every allegation contained in the foregoing paragraphs.

74. Defendants are engaging in cybersquatting as set forth above.

75. Cybersquatting is an unfair and deceptive trade practice.

76. Defendants are engaging in false advertising as set forth above.

77. False advertising is an unfair and deceptive trade practice.

78. When Raleigh Radiology patients call Defendants clinics, Defendants make false statements to those patients.

79. Defendants told Raleigh Radiology patients that Defendant was the same provider and simply changed its name.

80. That statement is false. The physicians providing services at Defendants' clinics are not Raleigh Radiology physicians.

81. Defendants told Raleigh Radiology patients that Raleigh Radiology no longer exists.

82. That statement is false. Raleigh Radiology exists and continues to serve the community.

83. Defendants told Raleigh Radiology patients that Raleigh Radiology missed breast

cancers.

84. That statement is false. Raleigh Radiology was and is not committing medical malpractice.

85. Patients believed Defendants' false statements. At least some of the patients shared their belief of these false statements with Raleigh Radiology.

86. Raleigh Radiology's hard-earned reputation was harmed and continues to be harmed by Defendants' false and defamatory statements.

87. Defendants' conduct constitutes unfair or deceptive acts, practices, and methods of competition in violation of N.C. Gen. Stat. § 75-1.1(a).

88. On information and belief, Defendants' acts are done willfully, intentionally, maliciously, and in bad faith.

89. Although Raleigh Radiology wrote to Defendants and requested Defendants cease these bad acts, Defendants refused to stop. Defendants' cybersquatting, false advertising, and defamation continue to this day.

90. Defendants' wrongful conduct has caused Raleigh Radiology to suffer and, absent intervention of the Court, will cause Raleigh Radiology to continue to suffer actual damages and damage to its business, reputation, and goodwill.

91. Defendants' wrongful conduct has caused Raleigh Radiology to suffer and, absent intervention of the Court, will cause Raleigh Radiology to continue to suffer irreparable harm for which there is no adequate remedy at law.

## **PRAYER FOR RELIEF**

WHEREFORE Raleigh Radiology respectfully prays the Court to:

(a) issue preliminary and permanent injunctive relief, enjoining Defendants and all

agents, servants, employees, successors and assigns, and other persons acting in concert with or in conspiracy with or affiliated with Defendants, from: (1) using the <u>www.raleighradiology.com</u> URL; (2) making any statement, express or implied, that Defendants are the same provider or team that previously staffed Defendants' clinics; (3) making false statements to Raleigh Radiology patients, to include statements, express or implied, that Raleigh Radiology commits malpractice, that Raleigh Radiology does not exist, or that Defendants are the same provider as Raleigh Radiology;

- (b) Order Defendants to run corrective advertising;
- (c) Order Defendants to transfer <u>www.raleighradiology.com</u> to Raleigh Radiology;
- (d) Find that Defendants' acts were willful and intentional;
- Require Defendants to account to Raleigh Radiology for their profits and the damages suffered by Raleigh Radiology as a result of Defendants' acts alleged herein;
- (f) Order that Defendants pay statutory damages of up to \$100,000 per domain name for violation of 15 U.S.C. § 1125(d), pursuant to 15 U.S.C. § 1117(d);
- (g) Order that any monetary award be trebled pursuant to N.C. Gen. Stat. § 75-16;
- (h) Award Raleigh Radiology its taxable costs and disbursements in this action pursuant to 15 U.S.C. §1117;
- (i) Award pre-judgment and post-judgment interest as allowed by law;
- (j) Award Raleigh Radiology its reasonable attorneys' fees and expenses pursuant to 15 U.S.C. § 1117 and N.C. Gen. Stat. § 75-16.1; and
- (k) Afford Raleigh Radiology such other relief to which it is entitled and as this Court

deems just and equitable.

## **DEMAND FOR JURY TRIAL**

Raleigh Radiology demands a trial by jury be held on all issues so triable.

Respectfully submitted, this the 19th day of November, 2020.

Michael Best & Friedrich LLP Attorneys for Raleigh Radiology Associates, Inc and Raleigh Radiology LLC

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