COMPETITIVE COMMENTS ON WAKE COUNTY 2019 MRI NEED DETERMINATION SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.

Duke University Health System, Inc. proposes to acquire a MRI to be located in Green Level/Wake County ("Duke Green Level") (Project ID No. J-011829-19). Five additional applications were submitted in response to the need determination in the 2019 State Medical Facilities Plan ("SMFP") for one new MRI in Wake County:

	Applicant	Comments Begin on page #
1.	Pinnacle Raleigh Radiology Wake Forest (RR Wake Forest) Project ID No. J-011820-19 Acquire one fixed MRI scanner pursuant to the need determination in the 2019 SMFP	12
2.	EmergeOrtho, P.A. (EmergeOrtho) Project ID No. J-011821-19 Acquire one fixed MRI scanner pursuant to the need determination in the 2019 SMFP for a total of one fixed MRI scanner and one mobile MRI scanner	17
3.	Raleigh Radiology Cary (RR Cary) Project ID No. J-011825-19 Acquire one fixed MRI scanner pursuant to the need determination in the 2019 SMFP	24
4.	Raleigh Radiology Knightdale (RR Knightdale) Project ID No. J-011826-19 Acquire one fixed MRI scanner pursuant to the need determination in the 2019 SMFP	31
5.	Duke Radiology Green Level (Duke Green Level) Project ID No. J-011829-19 Acquire one fixed MRI scanner pursuant to the need determination in the 2019 SMFP	NA
6.	Wake Radiology Cary (Wake Cary) Project ID No. J-011830-19 Acquire one fixed MRI scanner pursuant to the need determination in the 2019 SMFP	39

These comments are submitted by Duke 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.

COMPARATIVE COMMENTS

Conformity to CON Review Criteria

Six CON applications have been submitted seeking a total of six additional MRIs in Wake County. Based on the 2019 SMFP's need determination for only 1 additional MRI, not all applications can be approved. Only applicants demonstrating conformity with all applicable Criteria can be approved, and only the application submitted by Duke Green Level demonstrates conformity to all Criteria:

Conformity of Proposed Facilities

Applicant	Project I.D.	Proposed New MRIs	Conforming/Non- Conforming
RR Wake Forest	J-011820-19	1	No
EmergeOrtho	J-011821-19	1	No
RR Cary	J-011825-19	1	No
RR Knightdale	J-011826-19	1	No
Duke Green Level	J-011829-19	1	Yes
Wake Cary	J-011830-19	1	No
Total		6	

The Duke Green Level application for a new MRI is based on reasonable and supported volume projections premised on the historical utilization and growth of Duke imaging facilities. As discussed below, projections in the competing applications are based on unreasonable and unsupported assumptions and/or have unreasonable payor mixes or other problems; these and other issues result in one or more non-conformities with statutory and regulatory review Criteria. Therefore, Duke Green Level is the most effective alternative on conformity with the Criteria.

Historical Growth Rates

All six applicants currently provide MRI services, therefore a comparison of current and historical utilization of assets is a reasonable comparative point. The following table reflects historical growth by provided from 2016 through 2018.

Wake County MRI Provider	Weighted MRI 2016	Weighted MRI 2018	Actual Increase in Weighted MRI Volume 2016-2018	Weighted MRI CAGR 2016-2018
Duke	14,576	19,402	4,826	15.37%
Wake Radiology Cary	3,986	4,562	576	6.98%
UNC Rex Wake Radiology Combined	27,517	30,381	2,864	5.08%
Raleigh Radiology Cary	6908	7,511	603	4.27%
Wake Radiology All Locations	15,146	16,657	1,511	2.41%
Raleigh Radiology All Locations	19,876	19,142	-734	-1.86%
Raleigh Radiology Wake Forest (Pinnacle)	2,838	2,598	-240	-4.32%
Emerge Ortho	4,384	3,744	-640	-7.59%

Source: SMFP data

Duke MRI volumes have increase at more than twice the rate of the next highest provider growing at a CAGR of 15% during the last two years from 2016 to 2018. The actual volume increase in procedures for Duke was 4,826 weighted MRIs which alone justifies approval of the additional MRI for Duke Green Level.

Wake Radiology Cary increased 7% and RR Wake Forest MRI utilization increased 5% during the same timeframe. However, overall total Raleigh Radiology decreased nearly 2%. Therefore, when comparing historical growth to determine need, Duke Green Level is the most effective alternative.

Current Utilization of MRI Assets

All six applicants currently provide MRI services in Wake County, therefore a comparison of current and historical utilization of MRI assets is a reasonable comparative point. The following table reflects 2018 utilization of MRI assets based upon data in the 2020 SMFP.

Wake County MRI Provider	Weighted MRI Scans	Total Fixed and Fixed Equivalent MRIs	Percent Utilization Fixed MRI 2018	Percent Utilization Fixed and Mobile 2018
Raleigh Radiology	19,142	3.66	93.0%	80.6%
RR Cary	7,511	1	109.4%	109.4%
RR Wake Forest Pinnacle	2,598	0.5	NA	108.1%
Emerge Ortho	3,744	1	NA	77.9%
Duke	19,402	3.99	94.2%	76.5%
Duke Operational	19,402*	2.99	141.3%	105.0%
UNC Rex Wake Radiology	30,381	7.72	63.2%	59.0%
UNC Rex Wake Radiology Operational	30,381	5.72	88.5%	80.4%
Wake Radiology Total	16,657	4.45	60.7%	56.2%
Wake Radiology Cary	4,562	1.08	66.5%	62.9%

^{*}Includes fixed grandfathered MRI scanners

Capacity of fixed MRI = 6,864; Capacity of mobile MRI = 4,805

Gray rows are subsets of preceding white row

Source: 2020 SMFP

Total fixed and fixed equivalent MRI scanners at the combined Raleigh Radiology locations had the highest utilization of fixed and fixed equivalent MRIs in Wake County in 2018. The RR Cary and the RR Wake Forest locations had the greatest utilization of all applicants. However, the RR Cary, RR Knightdale and the RR Wake Forest applications are non-conforming to several criteria

^{**}EmergeOrtho owns its mobile and therefore it is counted as 1.0 MRI equivalent

^{*}Duke's internal data used in its application reflect a slightly lower total number of MRI scans for FY 18 (18,662), reflecting the fact that Duke maintains and reports annual data based its fiscal year of July-June and Alliance Imaging reports the utilization on its mobile scanners at Duke and other locations on an October-September timeframe. Even with Duke's internal data for the earlier timeframe, Duke's utilization remains above 100% of existing capacity.

as discussed below. While EmergeOrtho's utilization of its mobile scanner was slightly greater than Duke, the projected utilization for the new fixed MRI plus the existing EmergeOrtho mobile MRI was unreasonable. Duke utilized its existing fixed MRIs (including one that is not yet operational) at 94.0% of capacity; the Duke fixed and fixed equivalent was 76.5%. Calculating utilization based upon operational equipment at Duke reflects much higher utilization of its existing operational fixed MRIs at 141.3% of capacity; operational Duke fixed and fixed equivalent MRI equipment was utilized at 105.0% of capacity in 2018. Wake Radiology and UNC Rex have the lowest overall utilization in 2018 as shown in the previous table.

Duke Green Level is therefore the most effective alternative on conformity with this comparative factor.

Service Area Penetration vs. Percent of Total MRIs

All six applicants currently provide MRI services in one or more locations; therefore a comparison of service area penetration and control of MRI assets is a reasonable comparative point. The following table reflects 2018 service area penetration compared to percent of total Wake County MRI capacity based upon data in the Proposed 2020 SMFP.

Wake County MRI Provider	2018 Weighted MRI Cases	Total Fixed and Fixed Equivalent	Difference % MRIs vs. Service area penetration
Raleigh Radiology (including Pinnacle)	19,142	3.66	
% Service area penetration and % Total MRIs	16.1%	14.5%	-1.6%
Raleigh Radiology Wake Forest (Pinnacle)	2,598	0.5	
% Service area penetration and % Total MRIs	2.2%	2.0%	-0.2%
Raleigh Radiology Cary	7,511	1	
% Service area penetration and % Total MRIs	6.3%	4.0%	-2.3%
Duke	19,402	3.99	
% Service area penetration and % Total MRIs	16.3%	15.8%	-0.5%
EmergeOrtho*	3,744	1	
% Service area penetration and % Total MRIs	3.1%	4.0%	0.9%
UNC Rex Wake Radiology	30,381	8.46	
% Service area penetration and % Total MRIs	26.4%	37.0%	10.6%
Wake Radiology	16,657	4.35	
% Service area penetration and % Total MRIs	14.5%	19.0%	4.5%
Wake Radiology Cary	16,657	4.35	

% Service area penetration and % Total MRIs			
All Other	46,380	8.56	
Total	119,049	25.23	

^{*}EmergeOrtho mobile counted as 1.0 fixed equivalent since it is owned by EmergeOrtho

Gray rows are subsets of preceding white row

Source: 2020 SMFP

Duke provided 16.3% of total weighted MRIs in Wake County with 15.8% of the total available fixed and fixed equivalent MRI capacity in the county. However, this 16.3% includes one MRI under development and not yet operational at Holly Springs. Based upon operational MRI equipment, Duke provided 16.3% of total weighted MRIs in Wake County with 12.3% of the total available fixed and fixed equivalent MRI capacity in the county in 2018, a difference of 4% percentage points when compared, which supports Duke Green Level as the most reasonable alternative.

Based upon 2018 data Raleigh Radiology (all locations) provided 16.1% of total weighted MRIs in Wake County with 14.5% of the total available fixed and fixed equivalent MRI capacity in the county. However, of the three proposed locations, the RR Wake Forest location provided 2.2% of total weighted MRI scans with 2.0% of MRI equipment; a difference of 0.2% and RR Cary provided 6.3% of total weighted MRI scans with 4.0% of MRI equipment; a difference of 2.3%. RR Knightdale does not currently provide MRI services.

UNC Rex and Wake Radiology control 37.0% of total MRI scanners in Wake County but provided only 26.4% of total weighted MRI scans. Within the Wake Radiology Rex UNC partnership Wake Radiology Cary controls 19.0% of total MRI scanners in Wake County but provided only 14.5% of total weighted MRI scans in the county. Therefore, the Wake Cary application is the least effective alternative when comparing percent of total MRI assets in Wake County to the provider's percent of service area penetration.

Geographic Accessibility

All six applications are for freestanding MRI imaging centers located across Wake County. Existing/approved fixed MRI imaging centers in Wake County currently are located as follows:

Location/Utilization of Existing/Approved Wake County Fixed MRI Facilities

Surgical Drawidar	Туре	Wake County	Number of MRI
Surgical Provider		Location	Scanners
Duke Raleigh Hospital	Hospital Based	Central	2
UNC REX Hospital	Hospital Based	Central	2
UNC REX Hospital – Holly Springs	Hospital Based	Holly Springs	1
WakeMed New Bern	Hospital Based	Central	2
Wake Med Cary	Hospital Based	Cary	1
Duke Holly Springs (under development)	Freestanding Fixed	Holly Springs	1
Raleigh Neurology Associates (1st owned by Raleigh Neurology; 2nd is an Alliance Grandfathered)	Freestanding Fixed	Central	2
Raleigh Radiology Cary (Alliance Grandfathered)	Freestanding Fixed	Cary	1
Raleigh Radiology Cedarhurst (Pinnacle Health)	Freestanding Fixed	Central	1
The Bone and Joint Surgery Clinic	Freestanding Fixed	Central	1
Wake Radiology MRI Center	Freestanding Fixed	Central	2
Wake Radiology Diagnostic Imaging Cary (Alliance Grandfathered)	Freestanding Fixed	Cary	1
Wake Radiology Garner (Alliance Grandfathered)	Freestanding Fixed	Garner	1

Source: Proposed 2020 SMFP

Central is within or proximate to the I-40/ I-440 beltline

Central Wake County has 12 fixed MRIs located within or proximate to the I-40/ I-440 beltline.

Cary has three fixed MRI locations.

Garner has one fixed MRI location.

Northern Wake County has no fixed MRI location.

Western Wake County has no fixed MRI location.

Eastern Wake County has no fixed MRI location.

Southern Wake County has two approved fixed MRI locations at Duke Holly Springs and UNC Rex Holly Springs.

The following table identifies the proposed location of all six proposed MRI scanners. Only three will improve the geographic accessibility to outpatient MRI scanners in Wake County.

Locations for Proposed Facilities

Applicant	Project I.D.	Proposed Location	Improves Geographic Access
RR Wake Forest	J-011820-19	Wake Forest	Yes
EmergeOrtho	J-011821-19	Central	No
RR Cary	J-011825-19	Cary	No
RR Knightdale	J-011826-19	Eastern Wake	Yes
Duke Green Level	J-011829-19	Western Wake Green Level	Yes
Wake Cary	J-011830-19	Cary	No

Source: Wake MRI Applications

Central is within or proximate to the I-40/ I-440 beltline

Therefore, Duke Green Level (western Wake County), RR Wake Forest (northern Wake County) and RR Knightdale (eastern Wake County are the most effective alternatives for improving geographic accessibility.

Access by Underserved Groups

Charity Care

The following table shows the percent of charity care/self-pay patients projected for each of the applicants in Project Year 2 as reflected in Section L Question 3(a). Certain applicants combine Charity Care and Self Pay. Therefore, the following table reflects combined Charity Care and Self Pay.

Rank	Applicant	Project I.D.	Charity Care/Self Pay PY2
5	RR Wake Forest	J-011820-19	1.1%
3	EmergeOrtho	J-011821-19	2.15%
2	RR Cary	J-011825-19	2.99%
1	RR Knightdale	J-011826-19	4.22%
4	Duke Green Level	J-011829-19	1.6%
6	Wake Cary	J-011830-19	0.2%

The RR Knightdale application is the most effective alternative with the highest charity care/self-pay percentage (4.25%). However, projected payor mix for the RR Cary, RR Knightdale and RR Wake Forest applications are unreasonable as discussed below and therefore do not provide a reliable basis for comparison. The Wake Cary application is the least effective alternative.

Medicare

The following table shows the percent of Medicare patients projected for each of the applicants in Project Year 2 as reflected in Section L Question 3(a) and in Forms F.4 and F.5.

Rank	Applicant	Project I.D.	Medicare PY2
5	RR Wake Forest	J-011820-19	23.1%
6	EmergeOrtho	J-011821-19	22.67%
4	RR Cary	J-011825-19	25.95%
3	RR Knightdale	J-011826-19	30.81%
2	Duke Green Level	J-011829-19	37.8%
1	Wake Cary	J-011830-19	43.3%

Wake Cary is the most effective alternatives, proposing more than 40% Medicare. The Duke Green Level application is the next most effective Medicare alternative (37.8%). RR Wake Forest, EmergeOrtho, and RR Cary are the least effective with less than 30% Medicare. However, projected payor mix for the RR Cary, RR Knightdale and RR Wake Forest applications are unreasonable as discussed below and therefore do not provide a reliable basis for comparison. The Wake Cary application is the least effective alternative.

Medicaid

The following table shows the percent of Medicaid patients projected for each of the applicants in Project Year 2 as reflected in Section L Question 3(a) and in Forms F.4 and F.5.

Rank	Applicant	Project I.D.	Medicaid PY2
4	RR Wake Forest	J-011820-19	3.4%
1	EmergeOrtho	J-011821-19	6.8%
5	RR Cary	J-011825-19	3.37%
1	RR Knightdale	J-011826-19	6.79%
3	Duke Green Level	J-011829-19	3.9%
6	Wake Cary	J-011830-19	1.2%

RR Knightdale and EmergeOrtho are the most effective with 6.8% Medicaid projected. Wake Cary is the least effective with less than 2% Medicaid. However, projected payor mix for the RR Cary, RR Knightdale and RR Wake Forest applications are unreasonable as discussed below and therefore do not provide a reliable basis for comparison.

Projected Gross Revenue per MRI

Rank	Applicant	Project I.D.	Gross Revenue per MRI Technical Only PY2
2	RR Wake Forest	J-011820-19	\$ 1,122
1	EmergeOrtho	J-011821-19	\$ 907
5	RR Cary	J-011825-19	\$ 1,553
4	RR Knightdale	J-011826-19	\$ 1,528
3	Duke Green Level	J-011829-19	\$ 1,529
6	Wake Cary	J-011830-19	\$ 1,707

Source: Form F.2

Projected Net Revenue per MRI

Rank	Applicant	Project I.D.	Net Revenue per MRI Technical Only PY2
4	RR Wake Forest	J-011820-19	\$ 490
1	EmergeOrtho	J-011821-19	\$ 393
3	RR Cary	J-011825-19	\$ 439
2	RR Knightdale	J-011826-19	\$ 416
5	Duke Green Level	J-011829-19	\$ 639
6	Wake Cary	J-011830-19	\$ 655

Source: Form F.2

Projected Expense per MRI

Rank	Applicant	Project I.D.	Expense per MRI Technical Only PY2
5	RR Wake Forest	J-011820-19	\$ 379
1	EmergeOrtho	J-011821-19	\$ 285
2	RR Cary	J-011825-19	\$ 298
6	RR Knightdale	J-011826-19	\$ 415
3	Duke Green Level	J-011829-19	\$ 371
4	Wake Cary	J-011830-19	\$ 372

Source: Form F.2

Duke would note that on the commonly applied comparative factors of projected gross and net revenues and projected expenses per procedure, the deficiencies with each applicant's projections described in these comments affect the reliability of those calculations. Erroneous or unreasonable assumptions regarding payor mix and average weighting, for example, undermine projected net revenues and expenses.

COMMENTS SPECIFIC TO PINNACLE RALEIGH RADIOLOGY WAKE FOREST PROJECT ID No. J-011820-19

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."

RR Wake Forest fails to conform with Criterion 1 and Policy GEN-3 because its projected payor mix is unreasonable and unsupported. See the discussion regarding payor mix in Criterion 13.

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."

RR Wake Forest failed to adequately identify the population to be served by the proposed project. Step 3 of the methodology utilized to project future MRI volume, on page 103 of the application, reflects projected growth from 2020 to 2023 of 3.11% for current volumes at RR Wake Forest and also includes an increase in volume resulting from increasing RR Wake Forest's share of the Wake County service area. Step 4 of the methodology shifts volume from Pinnacle RR Cedarhurst and shifts over 1,000 patients to the new fixed location in Wake Forest. This volume originates from zip codes in both Wake County and Franklin County. Actions taken in both Step 3 and Step 4 will impact the projected patient origin as shown in the following table.

County	Patie	al FY 2018 ent Origin age 21	Estimated CY 2019 page 100	Estimated CY 2020 page 100	Projected CY 2023 page 103	Resulting CY 2023 PO	CAGR 2020- 2023	2023 Wake County Share increase Page 103	2023 Volume Shifted page 105	Project Vo page Corr	2023 Ited MRI lume 105 and rected It Origin
Wake	1,209	58.9%	1,512	1,512	1,658	58.9%	3.11%	783	821	3,262	69.6%
Franklin	598	29.2%	748	748	820	29.2%			269	1,089	23.2%
Vance	91	4.4%	114	114	125	4.4%				125	2.7%
Nash	52	2.5%	65	65	71	2.5%				71	1.5%
Granville	30	1.5%	38	38	41	1.5%				41	0.9%
Warren	20	1.0%	25	25	27	1.0%				27	0.6%
Johnston	9	0.4%	11	11	12	0.4%				12	0.3%
Halifax	7	0.3%	9	9	10	0.3%				10	0.2%
Wilson	5	0.2%	6	6	7	0.2%				7	0.1%
Other NC	19	0.9%	24	24	26	0.9%				26	0.6%
Other	11	0.5%	14	14	15	0.5%				15	0.3%
Total	2,051		2,565	2,565	2,812	100.0%				4,685	100.0%

Notes/Assumptions: Assumes patient origin for "natural growth", discussed in Step 3 page 103, will remain the same through 2023.

The projected patient origin reflected in the previous table is substantially different from that included in the application on page 23. RR Wake Forest incorrectly calculated Wake County patient origin to be 62.8% of total patients based upon its own assumptions included in the application. RR Wake Forest incorrectly calculated Franklin County patient origin to be 28.2% of total patients based upon its own assumptions included in the application. Therefore, RR Wake Forest failed to adequately identify the population to be served by the proposed project and is non-conforming to Criterion 3.

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This error is substantive as it will impact payor mix and, as discussed in Criterion 13, will

negatively impact access to the proposed services for low income persons and other underserved

groups.

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."

RR Wake Forest's use of unsupported payor mix negatively impacts the financial viability of the

project. RR Wake Forest failed to demonstrate its payor mix is reasonable and is therefore non-

conforming 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."

RR Wake Forest's use of unsupported payor mix negatively impacts the financial viability of the

project. RR Wake Forest failed to demonstrate its payor mix is reasonable and is therefore non-

conforming to Criterion 5.

Criterion 13c "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:

COMPETITIVE COMMENTS ON WAKE COUNTY 2019 MRI NEED DETERMINATION SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.

(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."

RR Wake Forest fails to conform with Criterion 13c because its projected payor mix percentages

were not correctly adjusted to reflect the influx of patients from three northern Wake County zip

codes and three Franklin County zip codes. On pages 23 and 24 of the RR Wake Forest

application, the applicant fails to identify the population to be served as discussed in Criterion 3

but did attempt to modify its patient origin from Wake County increasing it 4%. However, as

discussed above the actual projected increase in patient from Wake County is significantly

greater.

As a result of projected growth, service area share increases and the increased shift of Wake

County residents an additional 1,604 patients from Wake County were added to the projected

volume for determining future payor mix; of these 821 patients were from three relatively

wealthy zip codes in Wake County as reflected on page 105 of the application. The additional

Wake County volume more than doubles the volume from Wake County which the current payor

mix is based upon. Wake County zip codes 27571, 27587, and 27614 represent a higher income

population. The median income for Wake County based upon data from American Factfinder

was \$73,577 for 2017. The median income for these three Wake County zip codes based upon

the same data from American Factfinder was \$96,304 for 27571, \$88,414 for 27587 and \$102,950

for 27614 for 2017.¹

The projected influx of additional patients from these zip codes will impact payor mix at the

proposed facility. RR Wake Forest deemed it necessary to adjust its patient origin to meet the

needs of these patients but did not address the impact this change would have on its payor mix.

Therefore, the payor mix for the proposed project is unreasonable and unsubstantiated.

¹ US Census American Fact Finder: 2013-2017 American Community Survey 5-Year Estimates 2013-2017

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

Based on the facts which result in RR Wake Forest being non-conforming with Criteria 1, 3, 4, and 5 and 13a it should also be found non-conforming with Criterion 18a. RR Wake Forest did not adequately identify the population to be served and as such did not demonstrate the need the population projected to be served has for the proposed project. RR Wake Forest did not adequately demonstrate the financial feasibility of the proposal was based on reasonable and supported assumptions.

COMMENTS SPECIFIC TO EMERGEORTHO PROJECT ID No. J-011821-19

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."

EmergeOrtho fails to conform with Criterion 1 and Policy GEN-3 because its projected volumes are unreasonable and unsupported. See the discussion regarding projected utilization in Criterion 3.

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."

EmergeOrtho's utilization projections and assumptions are unreasonable, causing the proposal to be non-conforming with Criterion 3. EmergeOrtho utilizes a 19.1% overall growth rate for its combined fixed and mobile MRIs, which is not supported by the data and information presented in the application or in the SMFP.

EmergeOrtho projects that its total overall volume will increase by over 1,200 patients per year, or 19.1% annually for the four years from 2019 to 2023. This is unreasonable and is not supported by information in the application or the annual SMFPs.

MRI Provider	Actual MRI 2019	Projected MRI 2023	Actual Average Annual MRI Volume Increase	CAGR MRIs 2019-2023
Total Emerge Ortho Fixed and Mobile Projected Utilization	4,753	9,561	1,202	19.09%
Emerge Ortho Duraleigh	2,592	5,078	622	18.31%
Total Emerge Ortho Mobile w/o Duraleigh Fixed Volume	2,161	3,931	443	16.13%

As shown in the previous table, the fixed MRI scanner at Duraleigh Road is projected to increase at a rate of 622 cases per year, or 18.3% annually. This is not a sustainable rate of growth and is not reasonable. As shown below, in the last five years EmergeOrtho has averaged only a growth of only 381 additional MRI scans annually.

MRI Provider	Total MRI 2014	Total MRI 2016	Total MRI 2017	Total MRI 2018	Total MRI 2019
Total Emerge Ortho Mobile Volume	2,871	3,584	4,041	4,463	4,753
Annual Growth		357	457	422	290
5 Year Avg Annual Growth 2014-2019					381

Therefore, EmergeOrtho has not justified the use of an 18.3% growth rate for the fixed MRI nor have they justified the use of a 16.1% growth rate for the mobile MRI.

Further, EmergeOrtho's growth rates are not supported by overall MRI growth for total Wake County MRI, which is substantially lower at 4.3% as reflected on page 40 of the EmergeOrtho application.

In Section Q Emerge Ortho projects future MRI volume for the proposed fixed MRI scanner based upon projecting future Wake County MRI volume and an increasing market share. The first mistake EmergeOrtho makes is in calculating service area share in Step 3. EmergeOrtho calculates its "market penetration rate" of total MRI performed in Wake County, not service area share. Service area share is specific to the number of MRIs performed only on Wake County residents.

EmergeOrtho then assumes that its "market penetration rate" will increase 65%, from 2.6% in 2019 to 4.3% in 2023, based upon a number of factors. (Note that this service area penetration rate increase does not include the additional share increase assumed for growth elsewhere in the application for MRI volumes at EmergeOrtho Apex in Wake County; so in reality EmergeOrtho's projected service area penetration rate is projected to increase more than 65%.) EmergeOrtho attempts to justify the 65% increase in service area penetration rate by including a "market share" comparison with other EmergeOrtho service areas. However, this comparison is not reasonable. EmergeOrtho does not identify the counties for which the data is presented and provides no data regarding the in- or out-migration of MRI patients from these counties. Because Wake County has a large population, with more than 25 MRI scanners, and is a major referral center for central North Carolina, in-migration is very high, and out-migration is very low. Comparisons to other counties often are not reasonable. Therefore, the "market area penetration rate" calculated by EmergeOrtho for Wake County would not be comparable to that in other counties and the data presented on page 115 of Section Q does not support increasing the EmergeOrtho Duraleigh fixed MRI service area share 65% to project future MRI volume.

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EmergeOrtho's use of unsupported growth rates negatively impact the entire need analysis and

subsequent financial viability. EmergeOrtho failed to demonstrate its utilization projections are

reasonable and is therefore non-conforming 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."

EmergeOrtho's use of unsupported growth rates negatively impacts the entire need analysis and

subsequent financial viability. EmergeOrtho failed to demonstrate its utilization projections are

reasonable and is therefore non-conforming 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."

EmergeOrtho's use of unsupported growth rates negatively impacts the entire need analysis and

subsequent financial viability. EmergeOrtho failed to demonstrate its utilization projections are

reasonable and is therefore non-conforming to 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."

EmergeOrtho's use of unsupported growth rates, and incorrect data, negatively impacts the

entire need analysis and subsequent financial viability. EmergeOrtho failed to demonstrate its

utilization projections are reasonable and is therefore non-conforming to Criterion 6.

Criterion 18a "The applicant shall demonstrate the expected effects of the proposed services on

competition in the proposed service area, including how any enhanced competition will have a

positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact."

Based on the facts which result in EmergeOrtho being non-conforming with Criteria 1, 3, 4, 5, and 6, it should also be found non-conforming with Criterion 18a. EmergeOrtho did not adequately demonstrate the need the population projected to be served has for the proposed project and did not adequately demonstrate that its proposal would not result in the unnecessary duplication of MRI services in Wake County. EmergeOrtho did not adequately demonstrate that the financial feasibility of the proposal was based on reasonable and supported assumptions.

10A NCAC 14C .2703 PERFORMANCE STANDARDS

- (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:

. . . .

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

Projected utilization for the EmergeOrtho fixed MRI scanner was unreasonable as discussed in response to Criterion 3. Therefore, the application is non-conforming to this rule.

(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:

. . . .

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

Projected utilization for the EmergeOrtho fixed MRI scanner was unreasonable as discussed in response to Criterion 3. Therefore, the application is non-conforming to this rule.

(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

Projected utilization for the existing mobile EmergeOrtho MRI scanner was unreasonable as discussed in response to Criterion 3. Therefore, the application is non-conforming to this rule.

COMPETITIVE COMMENTS ON WAKE COUNTY 2019 MRI NEED DETERMINATION SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.

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

EmergeOrtho is non-conforming to this rule as they failed to provide reasonable documentation for the assumptions utilized in the methodology to project future utilization.

COMMENTS SPECIFIC TO RALEIGH RADIOLOGY CARY PROJECT ID No. J-011825-19

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."

RR Cary fails to conform with Criterion 1 and Policy GEN-3 because its projected volumes are unreasonable and unsupported. See the discussion regarding projected utilization in Criterion 3.

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."

RR Cary's utilization projections and assumptions are unreasonable, causing the proposal to be non-conforming with Criterion 3.

RR Cary justifies the need for a fixed MRI at its Cary locations based upon the high demand for MRI in Cary and several other qualitative details in Section C. However, utilization at RR Cary decreased from 2017 to 2018 as shown in the following table, and overall growth from 2016 to 2019 was only 1%.

RR Cary Historical Growth

	2016	2017	2018	2019	CAGR
Unweighted w/ Contrast	6,212	6,664	6,743	6,392	1.0%
Outpt No Contrast	4,478	4,761	4,823		
Outpt With Contrast	1,734	1,903	1,920		
Weighted	6,908	7,425	7,511	7,389	

Source: 2016 to 2018 from annual SMFPs; 2019 from page 42 of RR Cary application

In Section Q in Step 5 of the RR Cary need methodology assumptions, RR Cary calculates a weighted population growth rate of 2.0% from 2019 to 2022 and 1.9% from 2022 to 2024, which rates are used in Step 6. However, actual data presented by RR Cary in the above table and in Step 6, Table 8 reflects a CAGR of less than 1% from 2016 through 2019, with decreasing growth rates each year since 2016. Therefore, the use of the weighted population growth rate overstates actual experience at RR Cary and results in overstated and unreasonable projections.

In Section Q, Step 10 of the RR Cary methodology assumptions, RR Cary projects adjusted MRI totals based upon historical RR Cary with/without contrast split. However, the data in Step 10 does not match the historical data presented in Step 6, Table 8 on page 140. Data in Step 6 is consistent with data in the annual SMFPs. Based upon 2018-2020 data the percentage of WW Cary MRIs with contrast averaged only 28.3%, considerably less than the 39% used in Step 10. Resulting in overstating the projected volume of MRIs with contrast. This results in overstating the projected adjusted weighted MRI volume.

Actual RR Cary Contrast vs. No Contrast MRI Volume

	2016	2017	2018
Outpt No Contrast	4,478	4,761	4,823
Outpt With Contrast	1,734	1,903	1,920
Unweighted Total MRI	6,212	6,664	6,743
Weighted Total MRI	6,906	7,425	7,511
Percent w/Contrast	27.9%	28.6%	28.5%

Source: 2018 SMFP; 2020 SMFP; RR Cary MRI Application

Therefore, RR Cary utilized unreasonable assumptions to project future utilization and should be denied. RR Cary's use of unsupported growth rates, and incorrect data, negatively impacts the entire need analysis and subsequent financial viability. RR Cary failed to demonstrate its utilization projections are reasonable and is therefore non-conforming 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."

RR Cary's use of unsupported growth rates, and incorrect data, negatively impacts the entire need analysis and subsequent financial viability. RR Cary failed to demonstrate its utilization projections are reasonable and is therefore non-conforming 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."

RR Cary's use of unsupported growth rates, and incorrect data, negatively impacts the entire need analysis and subsequent financial viability. RR Cary failed to demonstrate its utilization projections are reasonable and is therefore non-conforming to Criterion 5.

SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.

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."

RR Cary's use of unsupported growth rates, and incorrect data, negatively impacts the entire

need analysis and subsequent financial viability. RR Cary failed to demonstrate its utilization

projections are reasonable and is therefore non-conforming to Criterion 6.

Criterion 13c "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."

RR Cary fails to conform with Criterion 13c because its projected utilization and payor mix

percentages are based on highly speculative and unreasonable assumptions.

RR Cary states, on 115 of the application, that future payor mix was calculated using the "Excel

automatic forecast.... Excel uses linear regression to project future payor mix percentages." In

statistical modeling, regression analysis is used to analyze large data sets to estimate

relationships between two or more independent and dependent variables. The three-year payor

mix sample provided by RR Cary is not a reliable data set for this type analysis. In addition, linear

regression frequently is accompanied by a confidence level analysis or standard deviation

analysis to illustrate the reliability of the analysis. RR Cary did not provide either.

The following table shows the wide variation in change between each of the last three years.

RR Cary Historical Payor Mix – Annual Change 2017 to 2019

	2017	2018	2019
Self	30	77	74
Annual % Change		156.7%	-3.9%
Insurance	4,719	4,596	4,395
Annual % Change		-2.6%	-4.4%
Medicare	1,603	1,651	1,568
Annual % Change		3.0%	-5.0%
Medicaid	65	108	109
Annual % Change		66.2%	0.9%
Other	241	294	209
Annual % Change		22.0%	-28.9%
Charity	5	10	7
Annual % Change		100.0%	-30.0%
	6,663	6,736	6,362

Source: RR Cary application page 115

Historical payor mix from 2017 to 2019 ranges from over 100% growth in one year to negative 4% decrease in one year for self-pay patients and charity patients. The shift in Medicaid is nearly as dramatic growing 66.2% from 2017 to 2018 and then only 0.9% from 2018 to 2019. It is unreasonable to utilize linear regression to project future payor mix with the large variable annual shifts reflected above and a small three-year data set. Further, it is particularly unreasonable to assume self pay, charity and Medicaid patients will more than double in the next five years, based on the existing payor mix of patients in Cary and the fact that these patient populations actually <u>decreased</u> at RR Cary from 2018 to 2019.

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

Based on the facts which result in RR Cary being non-conforming with Criteria 1, 3, 4, 5, 6 and 13c (and Policy GEN-3), it should also be found non-conforming with Criterion 18a. RR Cary did not adequately demonstrate the need the population projected to be served has for the proposed project and did not adequately demonstrate that its proposal would not result in the unnecessary duplication of MRI services in Wake County. RR Cary did not adequately demonstrate the availability of funds nor that the financial feasibility of the proposal was based on reasonable and supported assumptions.

10A NCAC 14C .2703 PERFORMANCE STANDARDS

- (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:

. . . .

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

Projected utilization for the Raleigh Radiology Cary MRI scanner was unreasonable as discussed in response to Criterion 3. Therefore, the application is non-conforming to this rule.

(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

COMPETITIVE COMMENTS ON WAKE COUNTY 2019 MRI NEED DETERMINATION SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.

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:

. . . .

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

Projected utilization for the Raleigh Radiology Cary MRI scanner was unreasonable as discussed in response to Criterion 3. Therefore, the application is non-conforming to this rule.

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

RR Cary is non-conforming to this rule as they failed to provide reasonable documentation for the assumptions utilized in the methodology to project future utilization.

COMMENTS SPECIFIC TO RALEIGH RADIOLOGY KNIGHTDALE PROJECT ID No. J-011826-19

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."

RR Knightdale fails to conform with Criterion 1 and Policy GEN-3 because its projected volumes are unreasonable and unsupported. See the discussion regarding projected utilization in Criterion 3.

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."

RR Knightdale's utilization projections and assumptions are unreasonable, causing the proposal to be non-conforming with Criterion 3. RR Knightdale utilizes a use rate methodology and assumes an unreasonable percentage of the service area in projecting future utilization.

RR Knightdale uses an estimated North Carolina MRI Use Rate (which is not adjusted for in/out-migration to/from other states), calculated using data from the 2015 through 2020 SMFPs. However, the data reported for 2018 (from the 2020 SMFP) on page 48 of the application, is incorrect. RR Knightdale reports 910,132 unadjusted MRIs for all of North Carolina. However, data in the Proposed 2020 SMFP (posted 11.6.19) reflected a total of 888,436 statewide NC unadjusted MRIs. By using the higher number RR Knightdale overstated projected MRIs in the service area by 2.4%.²

RR Knightdale is not providing inpatient MRI and did not adjust its estimated use rate to reflect the exclusion of inpatient MRIs. Inpatient MRI in 2018 represents approximately 10% of total MRIs based upon the data reported in the Proposed 2020 SMFP (posted 11.6.19). Therefore, RR Knightdale overstated projected MRIs in the service area by another 10%.

In addition, on page 115 of the RR Knightdale application, the applicant states that RR currently provides MRI services to residents of the proposed services area as shown in the following table.

Raleigh Radiology Historical Volume from Proposed RR Knightdale Service Area

	2017	2018	2019	CAGR
MRIs From Service Area	905	935	989	4.54%

Source: RR Knightdale CON application page 115

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² Total NC unadjusted MRIs in the final 2020 SMFP, released after the beginning of the review period (posted online 12.11.19), totaled 905,378 statewide MRIs. Therefore, the use rate was overstated by 1.0% using data in the final 2020 SMFP.

The proposed share of 22% in project year 3 represents a growth rate of 43.4% for RR Knightdale residents in the service area as shown in the following table.

Projected Growth Rate for RR Knightdale MRI Volume from Service Area

	2019	CAGR	2021	2022	2023	CAGR 2019- 2023
MRIs From Service Area	989	4.54%	2030	3091	4183	43.41%

Source: RR Knightdale CON Application pages 115 and 139

The share assumptions utilized by RR Knightdale are not based upon reasonable assumptions and do not support the above projected growth rate. As discussed above the volumes are based upon a use rate that is overstated and included inpatients. Further, no data or analysis of MRI patient flow in Wake County was provided to document that 22% of the defined service area would choose to seek care at RR Knightdale. The share assumptions are based solely on one reference to physician letters included in the application. While RR Knightdale does have many physician letters, many of the letters included in the RR Knightdale application are duplicates from the same physicians supporting the RR Cary application, for a facility 20 miles away. It is unreasonable to assume that physicians who currently send patients to the existing grandfathered fixed Alliance owned MRI located in Cary will redirect their patients to RR Knightdale if RR Knightdale receives the CON approval for the 2019 fixed MRI. Therefore, the service area share assumptions are overstated and unsubstantiated.

In addition, on page 141, RR Knightdale assumes that 42% of all its patients will require contrast resulting in an average weighting of 1.17, stating this is based upon RR total experience. However, in reviewing RR contrast utilization for 2018 from the Proposed 2020 SMFP (posted 11.6.19), the rate is considerably less, only 28.2% of total RR patients received contrast in 2018 resulting in an average weighting of only 1.11 as shown in the following table.

Raleigh Radiology MRI Data - Proposed 2020 SMFP

	No Contrast	Contrast	Unweighted	Weighted	Avg Weight
Fixed Locations	9,403	3,366			

Mobile					
Locations	6,081	2,714			
Total	15,484	6,080	21,564	23,996	1.11
Percent					
Contrast		28.2%			

Source: Proposed 2020 SMFP (11.6.19)

As pointed out in the RR applications, RR Cary was not included in the 2019 SMFP and was not included in the Proposed 2020 SMFP. This is discussed in the RR Cary application included in this review. The following table includes data from the final 2020 SMFP.

Raleigh Radiology MRI Data - Final 2020 SMFP

	No Contrast	Contrast	Unweighted	Weighted	Avg Weight
Fixed Locations	14,226	5,286			
Mobile					
Locations	2,360	843			
Total	16,586	6,129	22,715	25,166	1.11
Percent					
Contrast		27.0%			

Source: 2020 SMFP (12.11.19)

Actual RR experience supports a contrast percentage of 27%. RR Knightdale's assumption that 42% of all its patients will require contrast resulting in an average weighting of 1.17 is overstated and unsubstantiated by the data.

Therefore, RR Knightdale utilized unreasonable assumptions to project future utilization and should be denied.

RR Knightdale's use of unsupported growth rates and incorrect data negatively impacts the entire need analysis and subsequent financial viability. RR Knightdale failed to demonstrate its utilization projections are reasonable and is therefore non-conforming 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."

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RR Knightdale's use of unsupported growth rates, and incorrect data, negatively impacts the entire need analysis and subsequent financial viability. RR Knightdale failed to demonstrate its

utilization projections are reasonable and is therefore non-conforming 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."

RR Knightdale's use of unsupported growth rates and incorrect data negatively impacts the entire

need analysis and subsequent financial viability. RR Knightdale failed to demonstrate its

utilization projections are reasonable and is therefore non-conforming to 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."

RR Knightdale's use of unsupported growth rates and incorrect data negatively impacts the entire

need analysis and subsequent financial viability. RR Knightdale failed to demonstrate its

utilization projections are reasonable and is therefore non-conforming to Criterion 6.

Criterion 13c "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:

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(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."

RR Knightdale fails to conform with Criterion 13c because its projected utilization and payor

percentages are based on highly speculative and unreasonable assumptions.

On page 115 of the RR Knightdale application historical payor mix for residents of the service area

at all RR locations is presented. In 2019 RR provided MRI services for less than 1,000 residents

of the services area, which has a projected population of 207,719 in 2020 and an estimated

18,175 MRIs in 2020 calculated using the statewide use rate calculated by RR Knightdale on page

48 of the application.

Using this very small sample size, RR Knightdale calculated percentages of percentages to project

future payor mix. Percent growth is exaggerated with very small sample sizes and therefore

result in unreasonable projections. The percentage growth in self pay patients and charity care

utilized by RR Knightdale is based upon sample sizes of less than 30 and less than 15 respectively.

This methodology treats each payor category as a separate line item and does not take into

consideration that the compound growth for each category impacts future percentages of the

total. This is evident by the fact that there is an unexplained "Balance" in Step 3 of the payor mix

methodology which RR Knightdale randomly assigns to Medicare in Step 4.

As a result, the RR Knightdale application payor mix is unreasonable and unsubstantiated, and

the application should be denied.

Criterion 18a "The applicant shall demonstrate the expected effects of the proposed services on

competition in the proposed service area, including how any enhanced competition will have a

positive impact upon the cost effectiveness, quality, and access to the services proposed; and in

the case of applications for services where competition between providers will not have a

favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact."

Based on the facts which result in RR Knightdale being non-conforming with Criteria 1, 3, 4, 5, 6 and 13c (and Policy GEN-3), it should also be found non-conforming with Criterion 18a. RR Knightdale did not adequately demonstrate the need the population projected to be served has for the proposed project and did not adequately demonstrate that its proposal would not result in the unnecessary duplication of MRI services in Wake County. RR Knightdale did not adequately provide a reasonable payor mix nor demonstrate that the financial feasibility of the proposal was based on reasonable and supported assumptions.

10A NCAC 14C .2703 PERFORMANCE STANDARDS

- (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:

. . . .

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

Projected utilization for the Raleigh Radiology Knightdale MRI scanner was unreasonable as discussed in response to Criterion 3. Therefore, the application is non-conforming to this rule.

(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:

. . . .

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

Projected utilization for the Raleigh Radiology Knightdale MRI scanner was unreasonable as discussed in response to Criterion 3. Therefore, the application is non-conforming to this rule.

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

RR Knightdale is non-conforming to this rule as they failed to provide reasonable documentation for the assumptions utilized in the methodology to project future utilization.

COMMENTS SPECIFIC TO WAKE RADIOLOGY CARY PROJECT ID No. J-011830-19

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 Cary fails to conform with Criterion 1 and Policy GEN-3 because its projected volumes are unreasonable and unsupported. See the discussion regarding projected utilization in Criterion 3.

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."

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Wake Cary's utilization projections and assumptions are unreasonable, causing the proposal to be non-conforming with Criterion 3. Wake Cary utilizes a 4.0% overall growth rate for both outpatient MRIs with and without contrast, which is not supported by the data and information presented in the application or in the SMFP. Wake Cary provides no documentation to support the use of a 4.0% growth rate for projected no contrast MRIs in Section Q Form C Assumptions.

Historical growth of outpatient no contrast MRIs in Wake County was only 2.8% from 2016 to 2018 based upon data in the 2018 and 2020 SMFPs. Further, historical growth of no contrast MRIs at Wake Cary was only 1.8% as reflected in Section Q of the application in the assumptions for Form C. Therefore, Wake Cary has not justified the use of a 4.0% growth rate for outpatient no contrast MRI scans in the future.

Wake Cary provides questionable documentation to support the use of a 4.0% growth rate for projected contrast MRIs. While recent growth in outpatient contrast at Wake Cary has been high, this is the result of the new joint venture relationship between UNC and Wake Cary and is not expected to continue at such a high rate. This is acknowledged by Wake Cary in the use of the 4.0% growth rate.

Further, Wake Cary's growth rates are not supported by overall MRI growth for total MRI volumes within the UNC Rex Wake joint venture. As discussed in responses to the performance standards at 10A NCAC 14C .2703(b)(3), historical weighted MRI growth rates for all MRI units, fixed and mobile, within the combined UNC Rex Wake Radiology joint venture was less than 4% from 2014 to 2018 and the total Wake Radiology growth rate, at all locations was less than 2.5%.

MRI Provider	Total MRI 2014	Wgted MRI 2014	Total MRI 2018	Wgted MRI 2018	Total MRI CAGR 2014-2018	Wgted MRI CAGR 2014-2018
UNC REX						
Total UNC REX (includes Wake Radiology)	21,616	25,988	24,874	30,381	3.57%	3.98%
Total Wake Radiology	13,182	15,146	14,477	16,657	2.37%	2.41%

Source: 2016 and 2020 SMFPs

Wake Cary's use of unsupported growth rates, and incorrect data, negatively impacts the entire need analysis and subsequent financial viability. Wake Cary failed to demonstrate its utilization projections are reasonable and is therefore non-conforming 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 Cary's use of unsupported growth rates, and incorrect data, negatively impacts the entire need analysis and subsequent financial viability. Wake Cary failed to demonstrate its utilization projections are reasonable and is therefore non-conforming 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."

Wake Cary's use of unsupported growth rates, and incorrect data, negatively impacts the entire need analysis and subsequent financial viability. Wake Cary failed to demonstrate its utilization projections are reasonable and is therefore non-conforming to 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 Cary's use of unsupported growth rates, and incorrect data, negatively impacts the entire need analysis and subsequent financial viability. Wake Cary failed to demonstrate its utilization projections are reasonable and is therefore non-conforming to Criterion 6.

UNC Rex Wake Radiology currently owns 41.2% of all fixed MRI scanners in Wake County and owns and/or contracts for 37.0% of all fixed and fixed equivalent MRI scanners in Wake County.

However, in 2018 UNC Rex Wake Radiology provided only 26.4% of total weighted MRIs performed in Wake County while controlling 37% of total MRI capacity as shown in the following table.

Wake County MRI Provider	2018 Weighted MRI Cases	Total Fixed and Fixed Equivalent	Difference % MRIs vs. Service area penetration
UNC Rex Wake Radiology (includes Wake Radiology)	30,381	9.0	
% Service area penetration and % Total MRIs	26.4%	37.0%	10.6%
Wake Radiology (includes Wake Radiology Cary)	16,657	4.35	
% Service area penetration and % Total MRIs	14.5%	19.0%	4.5%
Wake Radiology Cary	4,123	1	
% Service area penetration and % Total MRIs	3.5%	4.0%	.5%

^{*}On page 34 of its application Wake Cary states that UNC Rex Wake owns 7 fixed and 2 mobile MRIs Source: Proposed 2020 SMFP

Wake Cary provided 3.5% of total weighted MRIs performed in Wake County while controlling 37% of total MRI capacity. Further, utilization of the 9.0 fixed and fixed equivalent MRI scanners owned/contracted by UNC Rex Wake and Wake Cary was 60% or less of total capacity in 2018 as shown in the following table.

Wake County MRI Provider	Weighted MRI Scans	# of Fixed MRI*	# Fixed Mobile Equivalent **	Total Fixed and Fixed Equivalent	Total Capacity Fixed MRIs x 6864	Total Capacity Mobile MRIs x 4805	Percent Utilization Fixed MRI 2018	Percent Utilization Fixed and Mobile 2018
UNC Rex Wake Radiology	30,381	7	0.72	9	48,048	3,460	63.2%	59.0%
Wake Radiology	16,657	4	0.35	4.35	27,456	1,682	60.7%	57.2%
Wake Radiology Cary	4,123	1	0	1	6,864	0	60.1%	60.1%

Therefore, approving another fixed MRI for Wake Cary would result in the unnecessary duplication of existing or approved health service capabilities or facilities in Wake County, and Wake Cary is non-conforming to Criterion 6.

Criterion 18a "The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a

positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact."

Based on the facts which result in Wake Cary being non-conforming with Criteria 1, 3, 4, 5, and 6, it should also be found non-conforming with Criterion 18a. Wake Cary did not adequately demonstrate the need the population projected to be served has for the proposed project and did not adequately demonstrate that its proposal would not result in the unnecessary duplication of MRI services in Wake County. Wake Cary did not adequately demonstrate the availability of funds nor that the financial feasibility of the proposal was based on reasonable and supported assumptions. Finally, in 2018 UNC Rex Wake Radiology provided only 26.4% of total weighted MRIs performed in Wake County while controlling 37% of total MRI capacity; increasing its MRI capacity further would have no beneficial effect on competition in the area.

10A NCAC 14C .2703 PERFORMANCE STANDARDS

- (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;

WR Imaging, LLC and Wake Radiology Diagnostic Imaging (the applicants) state that this rule is not applicable since they purchased the two MRI units currently owned less than 12 months ago and the rule refers to a 12-month time period. This is incorrect. The timeframe included in the rule is related to the time the equipment was operational, not

the timeframe it was owned by the applicants, and both MRIs acquired by the applicants have been in operation for more than 12 months. Therefore, the rule is applicable to the equipment now owned by the applicant. Further, the applicants acquired the equipment from a related entity and therefore, the equipment should be included under this rule.

As a matter of fact, the two MRI scanners at Wake Radiology Raleigh performed, on average, an excess of 3,328 weighted MRI scans and meet the requirements of this rule. The three MRI scanners owned and operated by UNC Rex also performed, on average, an excess of 3,328 weighted MRI scans and meet the requirements of this rule.

It appears the real reason the applicants asserted that this rule was not applicable to the project was to be consistent with its determination that rule, 10A NCAC 14C .2703(b)(2) which addresses the utilization of the two mobile scanners owned by the applicants, was not applicable.

(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.];

The applicants state that this rule is not applicable since they purchased the two mobile MRI units currently owned less than 12 months ago and the rule refers to a 12-month time period. This is incorrect. The timeframe included in the rule is related to the time the equipment was operational, not the timeframe it was owned by the applicants, and both mobile MRIs acquired by the applicants have been in operation for more than 12 months. Therefore, the rule is applicable to the equipment now owned by the applicant; this equipment is, in fact, capacity available to the applicant. Further, the applicants,

COMPETITIVE COMMENTS ON WAKE COUNTY 2019 MRI NEED DETERMINATION SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.

acquired the mobile equipment from a related entity and therefore, the equipment

should be included under this rule.

As reflected on page 2 of Exhibit C.12-3, the average utilization of the WR Imaging Mobile

#1 MRI unit was 2,844 weighted scans in 2019. As reflected on page 3 of Exhibit C.12-3,

the average utilization of the WR Imaging Mobile #2 MRI unit was 2,033 weighted scans

in 2019.

The average utilization of the two mobile units owned by the applicants is less than 3.328

weighted MRI scans. Therefore, the application is non-conforming to this rule.

It should be noted that in the 2016 Wake County MRI review, the Wake Radiology

application was denied because these same two mobile MRI units were non-conforming

to this rule. In that review the Agency concluded in response to the Wake Radiology

application that, "However, the Rule is necessary as it would not be consistent with the

premise of the CON Law to approve an applicant to acquire an additional MRI scanner

(fixed or mobile) when the applicant has access to an existing mobile MRI scanner which

has the capacity to serve more patients than it is currently serving."

(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:

. . . .

(E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP

shows four or more fixed MRI scanners are located;

45

As reflected in the following table historical MRI volume and adjusted MRI volume growth rates for all MRI units, fixed and mobile, within the combined UNC Rex Wake Radiology joint venture was less than 4% from 2014 to 2018. The Wake Radiology Cary location growth rate was less than 3%, and the total Wake Radiology growth rate, at all locations was less than 2.5%.

Historical Growth Rate All MRI Volume UNC Rex Wake 2014-2018

Wake County MRI Provider	Total MRI 2014	Wgted MRI 2014	Total MRI 2018	Wgted MRI 2018	Total MRI CAGR 2014- 2018	Wgted MRI CAGR 2014-2018
UNC Rex Wake Radiology Combined	21,616	25,988	24,874	30,381	3.57%	3.98%
Wake Radiology Cary	3,245	3,681	3,653	4,123	3.01%	2.88%
Wake Radiology All Locations	13,182	15,146	14,477	16,657	2.37%	2.41%

Source: SMFPs

Throughout the application, Wake Cary analyzes data for the timeframe 2016 to 2019 to justify the proposed MRI at Wake Cary. The following table reflects historical growth for the fixed/fixed equivalent MRIs within the UNC Rex Wake joint venture for the same timeframe.

Historical Growth Rate Fixed MRI Volume and Fixed/Fixed Equivalent UNC Rex Wake 2016-2019

	Weighted MRI 2016	Weighted MRI 2019	Weighted MRI CAGR 2016-2019
Total UNC REX Fixed	21,219	23,069	2.8%
Total UNC REX Fixed/Fixed Equivalent	24,717	27,946	4.1%

Source: 2018 SMFP; Wake Cary application Excludes Wake Radiology Garner only

On page 2 of Exhibit C.12-1 the applicants utilized an unreasonable nine percent growth rate to project future utilization for the two fixed MRIs at Wake Radiology Raleigh based

upon the last two years growth at Wake Cary. However, this growth is not consistent across the UNC Rex Wake joint venture, it reflects relocating volume from one facility to another as reflected on page 3 of Exhibit C.12-1 and results in overstated growth for UNC Rex Wake.

As shown in the following table the applicant utilized an overall 5.83% CAGR to project utilization for all five fixed MRIs within the UNC Rex Wake joint venture which is unreasonable and unsupported as the actual three year growth of MRI volume on the same fixed equipment was only 2.8% from 2016 to 2019 as discussed above.

	Wgted MRI 2019	Wgted MRI 2023	Wgted MRI CAGR 2019-2023
	UNC REX Wak	ie .	
Rex Hospital	10,626	10,968	0.80%
Rex Holly Springs	0	1,455	NA
Wake Radiology Raleigh	8,076	11,411	9.03%
Wake Radiology Cary	4,367	5,106	3.99%
Total UNC REX	23,069	28,940	5.83%

Source: Wake Radiology Application Exhibits C.12-1

Therefore, the proposed project is non-conforming to this rule.

(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:

. . . .

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

COMPETITIVE COMMENTS ON WAKE COUNTY 2019 MRI NEED DETERMINATION SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.

Projected utilization for the Wake Radiology Cary MRI scanner was unreasonable as discussed in response to Criterion 3. Therefore, the application is non-conforming to this rule.

(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

As reflected in the following table historical weighted MRI growth rates for all MRI units, fixed and mobile, within the combined UNC Rex Wake Radiology joint venture was less than 4% from 2014 to 2018.

Historical Growth Rate All MRI Volume UNC Rex Wake 2014-2018

Wake County	Weighted MRI	Weighted MRI	Weighted MRI
MRI Provider	2014	2018	CAGR 2014-2018
Total UNC Rex Wake Radiology Combined – including mobile and Wake Radiology Garner	25,988	30,381	3.98%

Source: SMFPs

Historical Growth Rate All MRI Volume UNC Rex Wake 2016-2019

	Weighted MRI	Weighted MRI	Weighted MRI
	2016	2019	CAGR 2016-2019
Total UNC Rex Wake Radiology Combined – including mobile excluding Wake Radiology Garner	24,717	27,946	4.1%

Source: 2018 SMFP; Wake Cary application Exhibit

Wake Cary had to utilize a double-digit growth rate to project sufficient mobile volume to meet this rule. The projections are unreasonable. Therefore, the application is non-conforming to this rule.

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

Wake Cary is non-conforming to this rule as they failed to provide reasonable documentation for the assumptions utilized in the methodology to project future utilization.