Comments by EmergeOrtho Regarding 2019 Wake County Fixed MRI Review

In response to the 2019 State Medical Facilities Plan need determination for one fixed MRI scanner in Wake County, a total of six Certificate of Need (CON) applications were submitted. These are summarized in the following chart:

Applicant	EmergeOrtho	Pinnacle - Raleigh Radiology Wake Forest	Raleigh Radiology Knightdale	Raleigh Radiology Cary	Duke Radiology Green Level	Wake Radiology Cary
Project ID#	**J-11821-19**	**J-1120-19**	**J-11826-19**	**J-11825-19**	**J-11829-10**	**J-11830-19**
Address	3100 Duraleigh Rd, Raleigh NC 28612	839 Durham Rd. Wake Forest NC 27587	1101 Great Falls Court, Knightdale NC 27545	150 Parkway Court Suite 100 Cary NC 27518	3208 Green Level W. Road Cary, NC 27519	300 Ashville Ave. Cary NC 27518

Pursuant to G.S. 131E-183(a)(1) and the 2019 State Medical Facilities Plan, no more than one additional fixed MRI scanner may be approved in this Wake County review. EmergeOrtho provides the following analysis based on its review of the project applications and the comparative factors that are recommended to be most relevant to this review.

Demonstration of Need

EmergeOrtho has the only application that is conforming to all the applicable CON Review Criteria and the MRI Performance Standards. The Pinnacle Raleigh Radiology Wake Forest (PRRWF) application is nonconforming to CON Review Criteria and the Performance Standards 10A NCAC 2703 due to unreasonable assumption for its patient origin, utilization, and financial projections. The Raleigh Radiology Knightdale (RR Knightdale) application is nonconforming to CON Review Criteria and the Performance Standards 10A NCAC 2703 based on its contrived patient origin, flawed methodology, unreasonable payor mix and inaccurate financial projections. Raleigh Radiology Cary's (RR Cary) application is nonconforming to CON Review Criteria and the Performance Standards 10A NCAC 2703 based on overstated projections, unreasonable assumptions, incorrect representations, and unreliable payor mix. Duke Radiology Green Level's application is nonconforming to the CON Review Criteria and Performance Standards based on its unreasonably delayed project schedule, unreasonable utilization projections and payor mix projections that lack adequate support. Wake Radiology Cary's application does not conform to the CON Review Criteria because its financial projections are incorrect and unreasonable; these projections are inconsistent with the applicant's own assumptions.

For these reasons, the EmergeOrtho application is the most affective proposal for this factor.

Summary of Comparative Data

Applicant	EmergeOrtho	PRRWF	Raleigh Radiology Knightdale	Raleigh Radiology Cary	Duke Radiology Green Level	Wake Radiology Cary
Project ID#	J-11821-19	J-1120-19	J-11826-19	J-11825-19	J-11829-10	J-11830-19
Address	3100 Duraleigh Rd, Raleigh NC 28612	839 Durham Rd. Wake Forest NC 27587	1101 Great Falls Court, Knightdale NC 27545	150 Parkway Court Suite 100 Cary NC 27518	3208 Green Level W. Road Cary, NC 27519	300 Ashville Ave. Cary NC 27518
MRI Model Tesla	Siemens Magnetom Aera 1.5T	Siemens Magnetom Skyra 3.0T	Siemens Magnetom Altea 1.5T	Siemens Magnetom Lumina 3T	Siemens Magnetom Sola 1.5T	Siemens Magnetom Sola 1.5T
Conformity to CON Criteria	Yes	No	No	No	No	No
Geographic Distribution	Raleigh	Wake Forest	Knightdale	Cary	Cary	Cary
Access by Medicaid (YR 3)	6.80%	3.40%	6.86%	3.37%	3.90%	1.20%
Access by Medicare (YR 3)	22.67%	23.10%	31.40%	25.95%	37.80%	43.30%
Combined % Medicare and Medicaid	29.47%	26.50%	38.26%	29.32%	41.70%	44.50%
Ownership of Fixed MRI in Wake	None (Owns 1 Mobile MRI in Wake)	Owns 1 Fixed MRI Cedarhurst and 1 Mobile MRI	None	None	2 Fixed MRI at Duke Raleigh Plus CON-approved for 1 Fixed Holly Springs	2 Fixed at Wake Radiology and mobile MRI
New Fixed MRI Provider / Owner	Yes	No	Yes	Yes	No	No
Total Weighted Scans per Scanner (YR 3)	Yr 3 (2023) 5,298	Yr 3 (2023) 5,074	Yr 3 (2023) 4,986	Yr 3 (2023) 8,030	Yr 3 (2025) 5,069	Yr 3 (2023) 5,106
Total Unweighted MRI Scans (YR 3)	5,078	4,685	4,269	6,946	4,408	4,424
Average Total Gross Revenue per Scan	$1,200	$1,841	$1,528	$1,553	$1,560	$2,512
Average Net Revenue per Scan	$393	$490	$407	$423	$650	$675
Average Operating Expense per Scan	$257	$374	$347	$291	$339	$653

Geographic Accessibility with Consideration for Available Fixed MRI Capacity

The following table is provided to show the geographic distribution and the utilization of the existing and approved fixed MRI scanners in Wake County.

Faciltiy	Location	# of Existing and Approved Fixed MRI Units	Unweighted MRI Scans	Adjusted Total MRI Procedures	Average Adjusted MRI Procedures / Per Unit
Duke Raleigh Hospital	Raleigh	2	10,956	13,892	6,946
Rex Hospital - Main	Raleigh	1	8,624	11,525	11,525
WakeMed - New Bern	Raleigh	2	9,849	12,949	6,475
Raleigh Neurology Associates (Alliance Healthcare Services)	Raleigh	1	4,739	5,634	5,634
Raleigh Neurology Associates	Raleigh	1	5,103	5,988	5,988
Raleigh Radiology (Alliance Healthcare Services)	Raleigh	1	5,292	6,004	6,004
Raleigh Radiology Cedarhurst (Pinacle Health Services)	Raleigh	1	7,477	8,111	8,111
The Bone & Joint Surgery Clinic	Raleigh	1	106	106	106
Wake Radiology	Raleigh	1	2,882	3,330	3,330
Wake Radiology MRI Center (Wake Radiology Diagnostic Imaging)	Raleigh	1	2,884	3,445	3,445
Combined Raleigh MRI Subtotal	**Raleigh**	**12**	**57,912**	**70,984**	**5,915**
Rex Hospital-UNC Rex Health Care of Cary	Cary	1	456	532	532
WakeMed Cary	Cary	1	3,763	4,855	4,855
Raleigh Radiology Cary (Alliance Healthcare Services)	Cary	1	6,743	7,511	7,511
Wake Radiology Diagnostic Imaging (Alliance Healthcare Services)	Cary	1	3,653	4,123	4,123
Combined Cary MRI Subtotal	**Cary**	**4**	**14,615**	**17,021**	**4,255**
Wake Radiology Garner (Alliance Healthcare Services)	**Garner**	**1**	**2,882**	**3,300**	**3,300**
Duke Radiology Holly Springs (2016 SMFP Need Deterrmination)	**Holly Springs**	1	0	0	0
UNC Rex Holly Springs Hospital	**Holly Springs**	1	0	0	0
Combined Holly Springs		**2**	**0**	**0**	**0**
Fixed Totals	**Wake County**	**18**	**75,409**	**91,305**	**5,073**
2019 SMFP Need Determination	**Wake County**	**1**	**NA**	**0**	**0**

Source: 2020 SMFP

The above table includes the Rex MRI scanner that is to be transferred to UNC Rex Holly Springs Hospital and the CON-approved Duke Radiology Holly Springs fixed MRI scanner. While the majority of the fixed MRI scanners are located in Raleigh, these fixed MRI scanners have high combined utilization that is 120 percent of the MRI capacity of 4805 adjusted MRI procedures. Thus the combined fixed MRI scanners in Raleigh do not have sufficient available capacity to provide adequate patient access in future years. In contrast, the existing and approved fixed MRI scanners in Cary, Garner, and Holly Springs have available capacity.

EmergeOrtho proposes to acquire a fixed MRI scanner in northwest Raleigh to replace its mobile MRI service that is highly utilized at this site. Its proposal would add a new fixed MRI location in Wake County where demand is high.

PRRWF proposes to acquire a fixed MRI scanner in Wake Forest where no fixed MRI scanners are located. However, the applicant's utilization projections are not based on reasonable assumptions.

RR Knightdale proposes to acquire a fixed MRI scanner in Knightdale where no fixed MRI scanners are located. However, the applicant's utilization projections and payor mix are not based on reasonable assumptions.

RR Cary proposes to acquire a fixed MRI scanner in Cary to replace the Alliance-installed MRI. Thus, this proposal does not provide a new location option. Furthermore, the applicant's utilization projections and payor mix are not based on reasonable assumptions.

Duke Green Level proposes to acquire a fixed MRI scanner in Cary at a new location. However, there are multiple existing fixed MRI scanners located in Cary with available capacity. Duke projects a delayed implementation for the Green Level project so that other previously approved Duke fixed MRI scanners at Arrington and Holly Springs have time to ramp up volumes. The utilization projections for the Green Level MRI are not based on reasonable and adequately supported assumptions.

Wake Radiology Cary proposes to acquire a fixed MRI scanner in Cary where there are multiple fixed MRI scanners that have available capacity. Moreover, the Wake Radiology Cary application is not an approvable application due to its erroneous financial projections that are inconsistent with its own assumptions.

In summary, EmergeOrtho provides the most effective application regarding geographic access with consideration for the utilization of existing fixed MRI scanners which is the basis for the need determination in the 2019 SMFP.

Access by Underserved Groups

The following table summarizes the projected payor percentages for the competing applications.

Applicant	EmergeOrtho	PRRWF	Raleigh Radiology Knightdale	Raleigh Radiology Cary	Duke Radiology Green Level	Wake Radiology Cary
Access by Medicaid	6.80%	3.40%	6.86%	3.37%	3.90%	1.20%
Access by Medicare	22.67%	23.10%	31.40%	25.95%	37.80%	43.30%
Combined % Medicare and Medicaid	29.47%	26.50%	38.26%	29.32%	41.70%	44.50%

The EmergeOrtho application provides its projected payor mix based on historical data with no adjustments. The applicant projects the second highest Medicaid percentage and the lowest Medicare percentage.

PRRWF application provides its projected payor mix based on historical data with no adjustments. The applicant projects 3.4% Medicaid and 23.10% Medicare with the lowest combined Medicaid and Medicare

percentages. The PRRWF application is not an approvable application due to unreasonable utilization projections and other nonconformities.

RR Knightdale's projected Medicaid and Medicare percentages are not based on reasonable and adequately supported assumptions. The RR Knightdale application is not an approvable application as explained in the application-specific comments.

RR Cary's projected Medicaid and Medicare percentages are not based on reasonable and adequately supported assumptions. The RR Cary application is not an approvable application as explained in the application-specific comments.

Duke Green Level's projected Medicaid and Medicare percentages are not based on reasonable and adequately supported assumptions. The Duke Green Level application is not an approvable application as explained in the application-specific comments.

Wake Radiology Cary's projects the lowest Medicaid and the highest Medicaid percentages. The Wake Radiology Cary application is not an approvable application as explained in the application-specific comments.

The EmergeOrtho application is the most effective alternative regarding access to the medically underserved because the application projects the highest Medicaid percentage based on reasonable assumptions.

Ownership of Fixed MRI Scanners in Wake County

PRRWF, Duke Green Level and Wake Radiology Cary submitted proposals by applicants that have existing and approved fixed MRI scanners in Wake County and are less effective alternatives. Applications by EmergeOrtho, RR Knightdale and RR Cary are proposals by applicants that have no fixed MRI scanners in Wake County and are equally effective proposals under this factor.

Projected Average Gross Revenue per MRI Procedure

EmergeOrtho projects the lowest total average gross revenue per MRI procedure and is the most effective alternative. Wake Radiology Cary projects the highest total average gross charge per MRI procedure and is the least effective alternative.

Projected Average Net revenue per MRI Procedures

EmergeOrtho projects the lowest total average net revenue per MRI procedure and is the most effective alternative. Wake Radiology Cary projects the highest total average net revenue per MRI procedure and is the least effective alternative.

Projected Average Operating Expense per MRI Procedure

EmergeOrtho projects the lowest average operating expense per MRI procedure and is the most effective alternative. Wake Radiology Cary projects the highest average operating per MRI procedure and is the least effective alternative.

Comparative Analysis Summary

The EmergeOrtho MRI application is the most effective application in this review because:

- It is the only application that conforms to the CON review criteria.
- The application proposes a fixed MRI scanner at a new location in Raleigh where the existing fixed scanners are operating at far above capacity.
- The applicant's Medicaid projections are the second highest of all applicants and are reasonably based on historical data.
- The applicant does not own any existing fixed MRI scanner in Wake County.
- EmergeOrtho projects the lowest total average gross revenue per MRI procedure of all applicants.
- EmergeOrtho projects the lowest total average net revenue per MRI procedure of all applicants.
- EmergeOrtho projects the lowest average operating expense per MRI procedure of all applicants.

Factors Irrelevant to this Review

Model and Tesla Strength of Proposed MRI Scanner

Some applicants in this review will likely argue that the model and/or Tesla strength of the proposed MRI scanners should be a comparative factor that should be considered by the Agency. This argument is not valid for the following reasons:

1) The need determination for an additional fixed MRI scanner is based on the standard MRI methodology and not a petition for a specific type of MRI scanner.
2) There are no requirements to compare the proposed MRI equipment types between the applicants because the Agency will individually evaluate the alternatives considered by each applicants under Criterion 4 analysis.
3) The benefits and drawbacks of different types of MRI models and Tesla strengths include subjective factors including preferences of radiologists and the types of MRI procedures for their anticipated patient populations.
4) The model and Tesla strength of MRI scanners are not subject to CON conditions unless the need determination is in response to a petition for an adjusted need determination for a very specific type of MRI scanner. This is not applicable to this review that resulted from the standard MRI need methodology.
5) Existing fixed MRI providers can choose to replace their existing MRI scanner through the equipment replacement exemption process with different MRI models and Tesla units.

Proposed Project Schedule

Some applicants may comment that the project applications should be compared based on the schedule for when the proposed MRI project will be implemented. However, the applicants' proposed project schedule is not a compelling comparative factor because many competitive CON reviews for MRI scanners result in appeals which can delay the project schedules for any and all applicants. Instead, the project schedule should be considered by the Agency in the context of its analysis under Criterion 3 regarding the need the population has for the proposed project. In other words, the Agency can determine that an applicant that significantly delays the development of its proposed MRI project will not improve patient access for medically underserved patients in a timely manner.

Comments by EmergeOrtho Regarding Pinnacle Health Services of North Carolina Raleigh Radiology Wake Forest (PRRWF), CON Project ID # J-11820-19

The PRRWF application is nonconforming to CON Review Criteria 1, 3, 4, 5, 6, 18a and the Performance Standards 10A NCAC 2703. Specific comments are provided as follows:

Criterion 1 - The information provided by the PRRWF application fails to demonstrate that the applicant's proposal would maximize healthcare value because the utilization projections are not based on reasonable and adequately supported assumptions. The discussion regarding utilization found in Criterion 3 is incorporated herein by reference. Therefore, the PHNC-RRWF application fails to conform to Criterion 1 and Policy GEN-3.

Criterion 3 - The PRRWF application is nonconforming to Criterion 3 due to unreliable patient origin percentages and overstated utilization projections that are derived from a flawed methodology and assumptions.

Unreliable Patient Origin

The applicant's patient origin projections are unreliable because the projected percentages for the proposed project do not correspond to the historical percentages and the applicant fails to adequately explain the basis for the projected changes. Even though the proposed fixed MRI will be located at the same Knightdale location as the current mobile MRI service, the applicant unreasonably projects to increase the percentage of patients from Wake County.

	Actual	Projected	Variance
Wake	58.9%	62.5%	3.5%
Franklin	29.2%	28.2%	-0.9%
Vance	4.4%	3.5%	-1.0%
Nash	2.5%	2.0%	-0.6%
Granville	1.5%	1.2%	-0.3%
Warren	1.0%	0.8%	-0.2%
Johnston	0.4%	0.3%	-0.1%
Halifax	0.3%	0.2%	-0.1%
Wilson	0.2%	0.2%	-0.1%
Other NC	0.9%	1.2%	0.2%
Other States	0.5%	0%	-0.5%
Totals	100.0%	100.0%	NA

Despite the historical data, the applicant inflated the percentage of patients that would originate from Wake County by 3.5% and decreased the percentages for the other counties to hopefully gain a comparative advantage. However, the application fails to provide the methodology and assumptions that would enable the Agency to check the accuracy of the projected percentages.

Flawed Methodology and Assumptions

MRI utilization at PRRWF shows substandard growth as compared to the other sites that utilized the Pinnacle mobile MRI scanner. If the Wake Forest location had a genuine need for additional MRI capacity, the mobile MRI scanner (Project ID # CON J-8268-08) would have been assigned to this location for additional services. Instead the mobile MRI was assigned to alternate sites where demand has increased.

PHS RR Wake Forest	**2016**	**2017**	**2018**	**2019**	**2020**	**4 YR**
Mobile MRI J-8268-08	**SMFP**	**SMFP**	**SMFP**	**SMFP**	**SMFP**	**CAGR**
Unweighted MRI Scans	**2195**	**2081**	**2584**	**2564**	**2404**	**2.30%**
RR Clayton	2016	2017	2018	2019	2020	4 YR
Mobile MRI J-8268-08	SMFP	SMFP	SMFP	SMFP	SMFP	CAGR
Unweighted MRI Scans	2730	3628	3889	4400	4581	13.81%
RR Cedarhurst	2016	2017	2018	2019	2020	1 YR %
Mobile MRI J-8268-08	SMFP	SMFP	SMFP	SMFP	SMFP	Increase
Unweighted MRI Scans	0	0	0	545	779	42.9%

Sources: 2016 to 2020 SMFP

Section Q of the PRRWF Application is fraught with erroneous math, unsubstantiated assumptions and overstated projections.

Step 1 of the methodology in Section Q includes a table that misleadingly reports a 7.02% CAGR that <u>does not take into consideration</u> the major downturn that decreased utilization from 8,353 MRI procedures in 2018 to 6,366 annualized procedures in 2019 for a 23.8 percent decrease.

Pinnacle Health Services of North Carolina
Historical Cedarhurst MRI Utilization, CY2015 - CY2019

Historical RRC	2015	2016	2017	2018	2019*	3-YR CAGR
fixed unwtd procedures	6,814	7,147	7,228	7,624	6,186	
mobile unwtd procedures	-	67	639	729	180	
total unwtd procedures	6,814	7,214	7,867	8,353	6,366	7.02%
weighted procedures	7,836	8,300	8,374	9,103	7,022	
weighting ratio	1.15	1.15	1.06	1.09	1.103	

Data reported for calendar years, which differs from data shown in SMFPs, which is federal fiscal year.
*Annualized based on 8 months of data, through August 31, 2019.

While the applicant is hopeful that this **<u>23.8 percent decrease in volume</u>** is a "one-time event", this decrease in MRI utilization changes the **4 year CAGR to -1.69.** Furthermore, this decrease in MRI utilization will likely extend into 2020 because The Bone & Joint Surgery Clinic obtained its replacement MRI in 2018 and will continue to ramp up its utilization and shift more MRI procedures away from Raleigh Radiology locations.

Due to this 23.8% decrease PRRWF does not have a "stable and reliable base of referring physicians" as it claims on page 24. Referring physicians can chose to:

1) refer to their own fixed MRI scanner such as Bone & Joint Clinic;
2) implement mobile MRI services at their own practices; and
3) change their MRI referral practices for other reasons.

Step 2 of the methodology unreasonable predicts that the PRRWF utilization will remain steady even though the applicant admitted that RR Cedarhurst now has available capacity on its fixed MRI due to the loss of MRI referrals to the Bone & Joint Clinic. Thus, the decline in referrals from Bone and Joint Clinic is expected to continue into 2020.

Step 3 of the methodology incorrectly calculates market share for RR Cedarhurst based on the 2018 MRI volumes and ignores the 2019 decrease caused by Bone & Joint Surgery Clinic shifting cases away from Raleigh Radiology. Step 3 unreasonably predicts that the proposed fixed MRI's market share will increase by 3.11% annually for no other reason than because this is more conservative than the Wake County CAGR. On top of this growth, the applicant also predicts it will increase market share because it will have greater MRI capacity and its location in Wake Forest is supposedly convenient. However, the PRRWF office location has very limited parking and Highway 1 (Capital Boulevard) has its share of traffic congestion. Step 3 of the methodology makes no sense because it predicts annual percentage growth and then compounds this growth by assuming further market share increases.

Step 4 of the PRRWF methodology assumes that hundreds of <u>additional patients</u> who reside in certain zip codes in Wake and Franklin Counties shift from RR Cedarhurst to PRRWF due to the availability of a fixed MRI at Wake Forest. However, the application lacks sufficient documentation to support the expected shift due the minimal growth that has occurred at this location over previous years.

Step 5 summarizes the PRRWF utilization projections that are derived from its blatant attempt to "goose the numbers" by manipulating the assumptions as follow:

- ignoring the current year's downturn in MRI utilization
- predicting "organic growth" for the proposed fixed MRI that is not adequately supported
- forecasting market share gains that are not adequately explained
- expecting additional shifts of hundreds of MRI patients with no substantiating data

In summary the PRRWF utilization projections are based on an assumptions and methodology that are not adequately supported and are internally inconsistent.

Criterion 4 - The PRRWF application fails to conform to Criterion 4 because the utilization projections are unreasonable, and the proposed project is not an effective alternative. The option to acquire a 3T MRI scanner for the Wake Forest location is not convenient for the majority of the population of Wake County. Contrary to the applicant's assertions that the average gross revenue per MRI and average net revenue per MRI are exceedingly high. Thus, the proposed project would not be cost effective.

Criterion 5 – The PRRWF application fails to demonstrate that its operational and financial projections are based on reasonable assumptions. Thus, the project application does not conform to Criterion 5 because it fails to demonstrate financial feasibility. The financial statement includes specific errors as follows:

- The maintenance service expense and utilities and are understated and unreasonable for the proposed fixed MRI based on comparisons to the applicant's historical expenses for the total facility.

- Depreciation assumptions are unreasonable because the depreciation life for the building and site is incorrectly calculated based on 25 years instead of the 15 years that should be used for leasehold improvements. Page 11 of the application documents that the building is leased. Generally Accepted Accounting Principles (GAAP) assigned 15 years for leasehold improvements.

Criterion 6 – PRRWF does not adequately demonstrate that it has a need for the proposed fixed MRI scanner because the utilization projections are overstated and unreasonable. The discussion regarding need and projected utilization found in Criterion 3 is incorporated herein by reference. Therefore, the applicant fails to adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant does not adequately demonstrate that the utilization projections and assumptions are reasonable and adequately supported.

- The applicant does not adequately demonstrate that the proposed fixed MRI is needed at the Wake Forest location in addition to the existing fixed MRI at Cedarhurst and its mobile MRI scanner that operated in Wake County.

Based on this analysis, the PHSNC-RRWF application is nonconforming to Criterion 6.

Criterion 18a – PRRWF fails to adequately demonstrate how any enhanced competition in the service area would have a positive impact on the cost effectiveness of the proposal because it does not adequately demonstrate the need the population to be served has for the proposed services. The application is based on unreasonable patient origin percentages, a defective methodology and erroneous assumptions.

MRI Performance Standards 10A NCAC 2703 (b) (3), (4), (5) and (6) – The PRRWF application is nonconforming to these performance standards due to unreliable patient origin percentages and overstated utilization projections that are derived from a flawed methodology and assumptions. It is entirely unreasonable for the applicant to pretend that the sudden loss of thousands of MRI referrals from Bone & Joint Clinic will not have a long-term impact on its future MRI utilization at both the Wake Forest and Cedarhurst locations. The discussion regarding need and projected utilization found in Criterion 3 is incorporated herein by reference.

Comments by EmergeOrtho Regarding Raleigh Radiology Knightdale (RR Knightdale), CON Project ID # J-11826-19

The RR Knightdale application is nonconforming to CON Review Criteria 1, 3, 4, 5, 6, 13(c), 18a and the Performance Standards 10A NCAC 2703 (b) (3), (4), (5) and (6). Specific comments are provided as follows:

Criterion 1 – RR Knightdale fails to demonstrate that its proposal would maximize healthcare value because the utilization projections are not based on reasonable and adequately supported assumptions. The discussion regarding utilization found in Criterion 3 is incorporated herein by reference. Therefore, the PHNC-RRWF application does not conform to Criterion 1 and Policy GEN-3.

Criterion 3 - The RR Knightdale application is nonconforming to Criterion 3 due to unreliable patient origin percentages and overstated utilization projections that are derived from an unreasonable methodology and assumptions.

The RR Knightdale patient origin percentages are contrived to make it appear that unlike every other fixed MRI scanner in Wake County, the proposed MRI project will be utilized by 98 percent of patients from Wake County and 2 percent patients from other counties. The applicant's false patient origin projections are based on the unreasonable assumption that the service area for the project is comprised of a handful of zip codes and not the entire Wake County MRI service area as defined in the 2020 SMFP.

The applicant chose to use a methodology with a handful of zip codes with arbitrary market share assumptions that excludes the majority of the population of Wake County and ignores the fact that physicians and patients from within the target zip codes are free to choose to utilize existing fixed and mobile MRI scanners in all Wake County zip codes. Also, the RR Knightdale methodology has no connection to historical MRI utilization because the proposed fixed MRI would be installed in a Diagnostic Center that is now in development.

The multiple reasons why the RR Knightdale methodology is flawed and unreliable are listed below:

1) The applicant fails to adequately demonstrate that the statewide MRI use rate is appropriate to use for health planning purposes for the selected population that is represented by the subset zip codes in Wake County. The populations in these selected zip codes do not have the same demographic characteristics and disease incidence as the overall North Carolina population.
2) RR Knightdale fails to demonstrate why it is reasonable to use the average State weighting factor of 1.19 for its MRI projections when it has access to actual Raleigh Radiology data for RR Cary of 1.156, which is lower.
3) The applicant erroneously assumes that the target area zip codes have an unmet need of approximately 2.5 MRI scanners because the applicant's methodology ignores the availability of fixed and mobile MRI scanner throughout the entire Wake County MRI service area.
4) Based on the contrived five zip code service area, RR Knightdale assumes it will capture a 11% market share in Year 1, 17% market share in Year 2 and 22% market share in Year 3. These market share projections have no validity because the applicant's physician letters of support do not verify that their MRI referral volumes are based on the population from the zip codes 27545, 27591. 27597, 27604 and 27610. Furthermore, most portions of Raleigh zip codes 27604 and 27610 (where the majority of the applicant's contrived service area population resides) have short travel distances to existing hospital-based and freestanding MRI scanners.
5) Wake County has eighteen existing and approved fixed MRI scanners plus numerous mobile MRI sites for a total of 45.89 Fixed Equivalent MRI scanners. This capacity makes it most unreasonable for a new

fixed MRI scanner in Knightdale to carve out 22 percent market share in a 5 zip codes service area. Patients and physicians certainly don't consider zip codes to be relevant to where they choose to obtain healthcare services.

6) The applicant's assumptions regarding in-migration from outside of Wake County (Step 7) makes no sense whatsoever because the proposed RR Knightdale service area consists of five zip codes of Wake County and not the entirety of Wake County. Thus, the projected in-migration for a five zip code region is not adequately defined or based on reasonable assumptions.
7) The applicant's market share projections are not reasonable because Knightdale is a small municipality. Furthermore, the application fails to evaluate its market share projections taking into consideration the other locations of Raleigh Radiology Wake Forest, Raleigh Radiology Cedarhust and Raleigh Radiology Cary that have existing market share.
8) The applicant's assumption regarding market share is not reasonable and adequately supported because the Raleigh Radiology Knightdale location does not have existing referral relationships.

Criterion 4 - The RR Knightdale application fails to conform to Criterion 4 because the utilization projections are unreasonable, and the proposed project is not an effective alternative. The option to acquire a 1.5T MRI scanner for the Knightdale location is not convenient for the majority of the population of Wake County. The RRC Cary application contends that it is a more effective location to acquire a fixed MRI scanner due to higher historical utilization.

Criterion 5 –RR Knightdale's application fails to demonstrate that its operational and financial projections are based on reasonable assumptions. Thus, the project application does not conform to Criterion 5 because it fails to demonstrate financial feasibility. The financial statement includes specific errors including:

- Projected payor percentages are incorrect and unreasonable.
- Depreciation assumptions are unreasonable because the depreciation life for the building and site is incorrectly calculated based on 30 years instead of the 15 years that should be used for leasehold improvements. Page 11 of the application documents that the building is leased. GAAP assigned 15 years for leasehold improvements.

Criterion 6 – RR Knightdale fails to demonstrate that it has a need for the proposed fixed MRI scanner because the utilization projections are overstated and unreasonable. The discussion regarding need and projected utilization found in Criterion 3 is incorporated herein by reference. Therefore, the applicant fails to adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant does not adequately demonstrate that the assumptions used to project MRI scans are reasonable and adequately supported.
- The applicant does not adequately demonstrate that the proposed fixed MRI is needed at the Knightdale location in addition to the existing fixed MRI at other Raleigh Radiology locations including Cedarhurst, Cary and Wake Forest.
- The RRC Knightdale application is competitive with and duplicative of the Cary CON application, which reportedly is the more effective location.

Based on this analysis, the RR Knightdale application is nonconforming to Criterion 6.

Criterion 13 (c) – The RR Knightdale projections for its payor mix percentages as described on pages 115 to 117 are based on faulty methodology and assumption that result in ongoing annual increases for Medicare and Medicaid that are not reasonable or adequately supported. The following table provides the unreasonable payor mix percentages.

Table L. 5 – Raleigh Radiology Knightdale Projected Payor Mix at Average Annual Percentage Change, Balanced, 2021-2023

Payor Class	FY2020	FY2021	FY2022	FY2023	FY2024
Self-Pay	2.75%	2.76%	2.78%	2.80%	2.81%
Insurance	57.66%	57.00%	56.33%	55.68%	55.03%
Medicare (a)	*29.44%*	*30.05%*	*30.66%*	*31.25%*	*31.84%*
Medicaid	6.64%	6.71%	6.78%	6.84%	6.91%
Other	2.09%	2.05%	2.01%	1.98%	1.94%
Charity	1.42%	1.43%	1.44%	1.45%	1.46%
Total	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**

Notes:

a. Medicare projected payor mix by year (Step 3) + Balancing percentage by year (Step 3)

Given that the applicant has cherry picked its patient population based on a small number of zip codes and not the applicant's overall historical utilization for Wake County MRI Service Area, the data has clearly been manipulated. The applicant's five zip codes for where it believes it MRI patient will originate are unreasonable as discussed in the Criterion 3 comments. Based on this subset of MRI patients, the application contends that the historical trend for increased numbers of patient from these zip codes can be used to predict the future payor mix for the proposed project.

However, the above projections are unreasonable because RR Knightdale predicts higher Medicare and Medicaid percentages than it has ever historically achieved as reported on page 115. Because the numbers of MRI scans in total (and for specific payor categories) are relatively small, very modest numerical changes in FY 2017, FY 2018 and FY2019 translate to large percentages of change. This is most notable with the number of Medicaid patients and corresponding percentages. The increase from 4.5% to 6.6% represents a 45% change in Medicaid percentages ((6.6% - 4.5%) / 4.5%) based on an increase of only 24 patients. The applicant takes advantage of this misleading statistical attribute to make unreasonable forecasts of ever higher Medicare and Medicaid percentages for the future years 2020 to 2024 as seen in the above table.

	FY 2017	%	FY 2018	%	FY 2019	%
Self Pay	14	1.5%	12	1.3%	27	2.7%
Insurance	549	60.7%	561	60.0%	577	58.3%
Medicare	248	27.4%	271	29.0%	285	28.8%
Medicaid	41	4.5%	52	5.6%	65	6.6%
Other	51	5.6%	37	4.0%	21	2.1%
Charity	2	0.2%	2	0.2%	14	1.4%
	905	100.0%	935	100.0%	989	100.0%

It is incorrect to rely on year-to-year changes in small numbers of patients as explained in the attached publication from the State Center for Health Statistics, "Problems with Rates Based on Small Numbers" by Paul Buescher. Please see Attachment A.

A more reasonable and statistically sound approach to calculate the payor percentages for the project would be to use the average of the volumes by payor category for FY 2017 , FY 2018 and FY 2019 as seen in the following:

Payor Class	FY 2017	FY 2018	FY 2019	**Combined**	**Combined %**
Self Pay	14	12	27	**53**	**1.9%**
Insurance	549	561	577	**1687**	**59.6%**
Medicare	248	271	285	**804**	**28.4%**
Medicaid	41	52	65	**158**	**5.6%**
Other	51	37	21	**109**	**3.9%**
Charity	2	2	14	**18**	**0.6%**
Totals	905	935	989	**2829**	**100.0%**

FY 2017 , FY, 2018 and FY 2018 are based on page 115 data from the RR Knightdale application.

Because RR Knightdale chose to project unreasonable payor percentages, the application should be denied. For all of these reasons the RR Knightdale application is nonconforming to Criterion 13 (c).

Criterion 18a – RR Knightdale fails to adequately demonstrate how any enhanced competition in the service area would have a positive impact on the cost effectiveness of the proposal because it does not adequately demonstrate the need the population to be served has for the proposed services. The application is based on unreasonable patient origin percentages, a defective methodology and erroneous assumptions.

MRI Performance Standards 10A NCAC 2703 (b) (3), (4), (5) and (6) – The RR Knightdale application is nonconforming to these performance standards due to unreliable patient origin percentages and overstated utilization projections that are derived from a flawed methodology and assumptions. Since RR Knightdale has no historical MRI utilization, its projections are based on a five zip code service area that is inconsistent with the MRI service area definition and its market share projections have no merit. The discussion regarding need and projected utilization found in Criterion 3 is incorporated herein by reference.

Comments by EmergeOrtho Regarding Raleigh Radiology Cary (RR Cary), CON Project ID # J-11825-19

The RR Cary application is nonconforming to CON Review Criteria 1, 3, 4, 5, 6, 13(c), 18a and the Performance Standards 10A NCAC 2703 (b) (3), (4), (5) and (6). Specific comments are provided as follows:

Criterion 1 - The information provided by the RR Cary application fails to demonstrate that the applicant's proposal would maximize healthcare value because the utilization projections are not based on reasonable and adequately supported assumptions. The discussion regarding utilization found in Criterion 3 is incorporated herein by reference. RR Cary's proposal would replace an existing fixed MRI that is installed under a services agreement with one that is owned by the applicant. This arrangement does not improve patient access at RR Cary. For these reasons, the RR Cary application does not conform to Criterion 1 and Policy GEN-3.

The Alliance MRI scanner that is proposed to be removed is a grandfathered unit that could be relocated anywhere in the State. Therefore, the RR Cary application does not guarantee that its proposed project would result in an additional fixed MRI scanner in the Wake County MRI inventory. Even if the Alliance grandfathered MRI scanner that is presently installed at RR Cary were to remain in Wake County at another location, its relocated capacity could diminish RR Cary's future market share.

Criterion 3 - The RR Cary application is nonconforming to Criterion 3 due to unreliable patient origin percentages and overstated utilization projections that are derived from flawed methodology and assumptions.

Unreliable Patient Origin

Even though the proposed fixed MRI will be located at the same Cary location as the current leased MRI scanner from Alliance, the applicant unreasonably projects to increase the percentage of patients from Wake County. Pages 39 and 40 of the RR Cary application demonstrate the variance in the actual and projected patient origin percentages:

	Actual	Projected	Variance
Wake	85.4%	86.5%	1.1%
Harnett	2.4%	1.8%	-0.7%
Chatham	2.0%	2.5%	0.4%
Lee	2.0%	1.8%	-0.2%
Johnston	1.8%	1.2%	-0.6%
Durham	1.1%	1.1%	0.0%
Orange	1.0%	1.0%	0.1%
Nash	0.3%	0.3%	0.0%
Other NC Counties	2.7%	2.7%	-0.1%
Other States	0.6%	1.1%	0.6%
Unknown	0.6%	0.0%	-0.6%
Total	100.0%	100.0%	NA

Despite the historical data, the applicant inflated the percentage of patients that would originate from Wake County by 1.1% and decreased the percentages for some other counties simply to hopefully gain a

comparative advantage. However, the application fails to adequately explain the Section Q methodology that forecasts the patient origin because:

1) The applicant's methodology does not accurately reflect the recent changes in physician referral patterns including the loss of MRI referrals from RR Cary Bone and Joint.
2) Actual RR Cary patient origin data for many of the counties other than Wake County are small numbers. It is incorrect to rely on year-to-year changes in small numbers of patients as explained in the attached publication from the State Center for Health Statistics, "Problems with Rates based on Small Numbers" by Paul Buescher. Please see **Attachment A.**
3) MRI referrals are based on physician and patient preference and not the MRI capacity of a given County. Therefore, the applicant's assumptions regarding MRI volumes by County are nonsense.
4) A more reasonable approach would be to average the applicant's patient origin statistics for the previous three years and determine the future patient origin based on the three-year cumulative patient numbers and resulting percentages.

Overstated and Unreasonable Utilization Projections

RR Cary currently has a fixed MRI scanner installed in its facility that is provided by Alliance Healthcare Services under a services agreement. The proposed project would simply substitute a 3.0T fixed MRI scanner at the same location with no real net increase in capacity at this location. Thus, the proposed project could potentially save money for the applicant but provide no increased access for patients.

MRI historical utilization for Raleigh Radiology Cary is reported in Section Q step 6 page 140. The annual percentages change in MRI scans and the 3 Year Compound Annual Growth Rate (CAGR) are calculated for the following table.

	FY2016	FY2017	FY2018	FY2019	3 YR CAGR
RR Cary MRI Unweighted	6,212	6,664	6,742	6,392	0.96%
% Annual Change from Previous	NA	7.28%	1.17%	-5.19%	NA

The applicant does not adequately explain the five percent decrease in utilization during the most recent year and why MRI referrals will increase during the interim years. Decreased MRI referrals to RR Cary are likely due to increased competition from other MRI scanners including The Bone & Joint Clinic which has obtained an equipment replacement exemption for a 3.0T MRI. Other fixed MRI scanners are in development in Wake County including the Duke Radiology Holly Springs project J-11167-16.

The RR Cary methodology and assumptions erroneously assume that population growth in Wake and other Counties will drive increases in its MRI utilization even though its proposed project does not add capacity. As seen in the above table, MRI utilization at RR Cary experienced a sharp decline in FY2019 even though population growth has been occurring for recent years.

The application fails to explain why its methodology and assumptions are reasonable because:

- There is no information provided by the applicant to explain why the FY2019 decrease in MRI utilization will be reversed during the interim years.
- The 3-YR CAGR for RR Cary is only 0.96 percent which is far less than the 2.0 percent projected rate of population growth used in Step 5 of the application.
- No additional MRI capacity is proposed at RR Cary that could not otherwise be accomplished with an equipment replacement exemption.

- RR Cary fails to explain how it can gain market share when its existing and proposed replacement MRI scanners are already fully scheduled during the normal hours of the day that most patients would want to obtain appointments.
- Other MRI providers in Wake County have gained MRI capacity (Bone & Joint Clinic and Duke Radiology Holly Springs) with real potential to diminish the RR Cary market share.
- The methodology and assumptions fail to project the loss of capacity during the weeks or months in 2020 (interim year) when it removes its current fixed MRI and installs the proposed MRI scanner.

For all of these reasons, the RR Cary application is nonconforming to Criterion 3 due to overstated and unreasonable utilization projections as well as inaccurate payor mix percentages.

Criterion 4 - The RR Cary application fails to conform to Criterion 4 because the utilization projections are unreasonable and the proposed project is not an effective alternative. The option to replace its existing MRI scanner (Alliance grandfathered unit) that is installed in the facility could be accomplished with an equipment replacement exemption.

The RR Cary application makes false statements with regard to Criterion 4 on pages 78 of the application. Here the applicant predicts that Alliance could cancel its current contract. **But RR Cary cannot point to a single instance where Alliance Healthcare Services has ever cancelled a services agreement for an installed grandfathered MRI scanner because this has never occurred.**

RR Cary incorrectly contends that Alliance has continued to increase its charges without improving its equipment. This is inconsistent with the documentation in **Attachment B**. Between 2012 and 2015, Alliance has spent nearly $300,000 on MRI equipment upgrades with no price increases to Raleigh Radiology. Also, Alliance Healthcare Services documents that Raleigh Radiology has routinely given Alliance 100% for customer satisfaction scores since 2017.

The RR Cary application complains about staffing costs. As seen in the **Attachment B**, Alliance made reductions in overtime rates to allow Raleigh Radiology to more affordably increase hours of service.

RR Cary also failed to demonstrate that a long-term services agreement from Alliance would be more costly as compared to its proposed purchase of a 3T MRI, <u>because no proposal was ever requested from Alliance for purposes of comparison</u>. Therefore, the RR Cary assertion that the proposed project is the more cost-effective alternative as compared to maintaining the status quo is <u>entirely speculative.</u>

The RR Cary financial pro forma fails to demonstrate that any future cost savings from the proposed project would be passed on to the patients or payors.

For all of these reasons, the RR Cary application is nonconforming to Criterion 4.

Criterion 5 –RR Cary's application fails to demonstrate that its operational and financial projections are based on reasonable assumptions. Thus the project application does not conform to Criterion 5 because it fails to demonstrate financial feasibility based on reasonable assumptions. The financial statement includes specific errors including:

- Payor percentages are not based on reasonable assumptions causing the projected revenues to be unreliable.

- Medical supplies expenses are bewilderingly projected to decrease in Years 2021 to 2023 as compared to the 2020 interim year even though MRI utilization is expected to increase; no assumptions are provided by the applicant for annual inflation for supplies.
- Depreciation assumptions are unreasonable because the depreciation life for the building and site is incorrectly calculated based on 30 years instead of the 15 years that should be used for leasehold improvements. Page 13 of the application documents that the building is leased. GAAP assigned 15 years for leasehold improvements.

Criterion 6 – RR Cary fails to demonstrate that it has a need for the proposed fixed MRI scanner because the utilization projections are overstated and unreasonable. The discussion regarding need and projected utilization found in Criterion 3 is incorporated herein by reference. Therefore, the applicant fails to adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- RR Cary fails to demonstrate that the assumptions used to project the number of MRI scans are reasonable and adequately supported.
- The applicant does not adequately demonstrate that the proposed fixed MRI is needed at the Cary location where it currently has a fixed MRI that is provided through a services agreement.
- The RR Knightdale proposal seeks to obtain CON approval for a fixed MRI scanner that is competitive with and duplicative of the proposed RR Cary project.

Based on this analysis, the RR Cary application is nonconforming to Criterion 6.

Criterion 13 (c) – The RR Cary projections for its payor mix percentages, as described on pages 112 to 116, are based on incorrect methodology and assumption that result in ongoing annual increases for Medicare and Medicaid that are not reasonable or adequately supported. The following table provides the unreasonable payor mix percentages as presented on page 116 of the application.

RRCary first three project years will operate on a calendar year beginning January 1, 2020. Therefore, the applicant converted the MRI payor mix determined in Step 4 from federal fiscal years to calendar years. The result is the projected payor mix for Raleigh Radiology Knightdale, 2020-2023.

Table L. 4 – Raleigh Radiology Knightdale Projected MRI Payor Mix, 2020-2023

Payor Class	2021	2022	2023
Self-Pay	2.08%	2.43%	2.79%
Insurance	66.55%	65.68%	64.81%
Medicare	25.36%	25.65%	25.95%
Medicaid	2.63%	3.00%	3.37%
Other	3.22%	3.05%	2.88%
Charity	0.17%	0.19%	0.20%
Total	**100.0%**	**100.0%**	**100.0%**

Notes:

*(Current Fiscal Year Step 2 * 0.75) + (Next Fiscal Year Step 2 * 0.25) = Calendar Year*

*For example, Medicare 2023: (25.88% * 0.75) + (26.17% * 0.25) = 25.95%*

However, the above projections are unreasonable because RR Cary predicts higher Medicare and Medicaid percentages than it has ever historically achieved as reported on page 115.

Because the numbers of MRI scans for Self Pay Medicaid and Other are relatively small, very modest numerical changes in FY 2017, FY 2018 and FY2019 translate to large percentages of change.

Table L. 2 – RRCary Historic Payor Mix, FY2017-FY2019

Payor Class	FY17		FY18		FY19	
	Procedures	% of Total	Procedures	% of Total	Procedures	% of Total
Self-Pay	30	0.45%	77	1.14%	74	1.16%
Insurance	4,719	70.82%	4,596	68.23%	4,395	69.08%
Medicare	1,603	24.06%	1,651	24.51%	1,568	24.65%
Medicaid	65	0.98%	108	1.60%	109	1.71%
Other	241	3.62%	294	4.36%	209	3.29%
Charity	5	0.08%	10	0.15%	7	0.11%
Total	**6,663**	**100.00%**	**6,736**	**100.00%**	**6,362**	**100.00%**

Source: Raleigh Radiology internal data;

Other includes TriCare, VA, Government, MedSolutions, worker's comp, and railroad

As seen in the Medicaid numbers of patients and corresponding percentages, the increase from 65 patients in 2017 to 109 patients represents a 75.5% change in Medicaid percentages from 0.98% to 1.71% based on an

increase of only 54 patients. The applicant takes advantage of this misleading statistical attribute to make unreasonable forecasts of ever higher Medicare and Medicaid percentages for the future years 2020 to 2024. It is incorrect to rely on year-to-year changes in small numbers of patients as explained in the attached publication from the State Center for Health Statistics, "Problems with Rates Based on Small Numbers" by Paul Buescher. Please see **Attachment A**.

A more reasonable and statistically sound approach to calculate the payor percentages for the project would be to use the average of the volumes by payor category for FY 2017 , FY 2018 and FY 2019 as seen in the following:

	FY2017	FY2018	FY2019	Combined	Combined %
Self Pay	30	77	74	181	0.9%
Insurance	4719	4596	4395	13710	69.4%
Medicare	1603	1651	1568	4822	24.4%
Medicaid	65	108	109	282	1.4%
Other	241	294	209	744	3.8%
Charity	5	10	7	22	0.1%
Totals	6663	6736	6362	19761	100.0%

Because the RR Cary chose to project unreasonable payor percentages, the application should be denied. For all of these reasons the RR Cary application is nonconforming to Criterion 13 (c).

Criterion 18a – RR Cary fails to adequately demonstrate how any enhanced competition in the service area would have a positive impact on the cost effectiveness of the proposal because it does not adequately demonstrate the need the population to be served has for the proposed services.

The application is based on unreasonable patient origin percentages, a defective methodology and erroneous assumptions. RR Cary offers no new location, no additional capacity and no enhance competition because RR Cary is simply replacing an existing fixed MRI provided by Alliance with a new MRI that it would own. The application demonstrates no true cost savings to patients.

MRI Performance Standards 10A NCAC 2703 (b) (3), (4), (5) and (6) – The RR Cary application is nonconforming to these performance standards due to unreliable patient origin percentages and overstated utilization projections that are derived from a flawed methodology and assumptions. The discussion regarding need and projected utilization found in Criterion 3 is incorporated herein by reference.

Comments by EmergeOrtho Regarding Duke Radiology Green Level, CON Project ID # J-11829-19

The Duke Radiology Green Level application is nonconforming to CON Review Criteria 1, 3, 4, 5, 6, 13 (c), 18a and the Performance Standards 10A NCAC 2703 (b) (3), (4), (5) and (6). Specific comments are provided as follows:

Criterion 1 – The Duke Green Level application fails to demonstrate that the applicant's proposal would maximize healthcare value because the utilization projections are not based on reasonable timeframe assumptions. Furthermore, while the need for additional MRI scanners in Wake County is documented in the 2020 SMFP based on utilization data that occurred more than a year ago, Duke's proposal fails to address that unmet need for MRI services until 2023 because it needs at least two additional interim years to inflate its MRI utilization projections to reach its target scan volumes. The discussion regarding utilization found in Criterion 3 is incorporated herein by reference.

Criterion 3 –MRI utilization projections for the Duke Green Level MRI project are premised on the delayed implementation of the proposed MRI scanner until 2023. This extended time frame allows for the CON-approved Duke Radiology Holly Springs MRI and Duke Arringdon MRI projects to be developed and ramp up their volumes without diminishing the overall Duke MRI utilization from Wake and Durham Counties that could later be shifted to the proposed Duke Green Level MRI. It is optimal for Duke to defer the development of the Duke Green Level MRI scanner to suppress competition in Wake County.

Duke undermines its own need arguments because it chooses to postpone the development of the proposed MRI project until 2023. So while the Duke MRI utilization projections might appear credible based on the overextended timeframe for development of the project, the application fails to demonstrate the extent to which underserved groups in Wake County will have adequate access to fixed MRI services in 2021 and 2022, prior to the development of the Duke Green Level MRI.

Given the close proximity of the proposed MRI scanner at Duke Green Level to the previously approved MRI scanners at Arringdon and Holly Springs, Duke's assumptions regarding the expected shifts of patients from the various zip codes are speculative.

Duke Health Arringdon Radiology 5601 Arrington Park Rd. Durham NC 27506	12.5 miles to the North of the Proposed Duke Green Level MRI
Duke Radiology Holly Springs New Hill Rd and NC Highway 55 Bypass Holly Springs NC 27540	13.3 miles to the South of the Proposed Duke Green Level MRI

Diving distances and times are not the sole criteria for which patients may choose to obtain MRI procedures. Since the Duke application did not provide the mathematical basis for the expected shifts by each zip code, the application is based on guesswork and not an actual methodology and assumptions that can be analyzed by the Agency. Duke's assumptions regarding the expected shits of patients from the various zip codes are not adequately supported. Therefore its MRI utilization projections are not reasonable.

For these reasons the Duke Green Level application is nonconforming to Criterion 3.

Criterion 4 - The Duke Green Level application fails to conform to Criterion 4 because the utilization projections are based on an excessively delayed timeframe and the proposed project is not an effective alternative. Duke's proposal prioritizes its business interest to develop profitable fixed MRI scanners over multiple years and postpones responding to the need the population of Wake County has for timely and cost-effective MRI service.

Duke Imaging Services at Cary Parkway is an existing Independent Diagnostic Testing Facility (IDTF) that currently provides mobile MRI service five days per week. Duke has no explanation as to why this Cary facility and mobile MRI service are unsatisfactory to the extent that a new IDTF needs to be developed 6.5 miles away at additional cost.

In Section E, page 43 of the application, Duke claims that its services agreement for mobile MRI scanner is not as cost effective as the proposed project to acquire a fixed MRI scanner. However, Duke routinely utilizes contract mobile MRI services in both Durham and Wake Counties, including the Duke Cary Parkway location. Furthermore, the application provides no analysis, documentation or Exhibit to demonstrate that the proposed $3.7 million project is less costly or more effective. Consequently, Duke fails to demonstrate that its analysis of alternatives is based on actual cost data.

The Duke Green Level location in Cary is not an effective location because of its close proximity to two previously approved MRI projects that are already in development:

Duke Health Arringdon Radiology **12.5 miles** to the North of the Proposed Duke Green Level MRI
5601 Arrington Park Rd.
Durham NC 27506

Duke Radiology Holly Springs
New Hill Rd and NC Highway 55 Bypass **13.3 miles** to the South of the Proposed Duke Green Level MRI
Holly Springs NC 27540

Given the close proximity of the proposed MRI scanner at Duke Green Level to the previously approved MRI scanners at Arringdon and Holly Springs, Duke's assumptions regarding the expected shfits of patients from the various zip codes are not adequately supported. Therefore, its utilization projections are not reasonable.

Criterion 5 –The Duke Green Level application fails to demonstrate that its operational and financial projections are based on reasonable assumptions. Thus, the project application does not conform to Criterion 5 because it fails to demonstrate financial feasibility based on reasonable assumptions.

The financial statement includes specific omissions and errors including:

- Payor percentages are unreasonable causing the revenue projections to be unreliable.
- The Form F.2 for the MRI service unreasonably projects no bad debt expense for the proposed MRI scanner which is inconsistent with the Form F.2 for the Duke Health System.
- The administrative, ancillary and support services and staff that are listed on page 55 of the Duke Green Level application are not included in the staffing tables in Section Q. Forma F.3 and Assumptions do not describe a expenses allocations for these services under a category such as Other (General and Administrative).

Criterion 6 – Duke Green level fails to demonstrate that it has a need for the proposed fixed MRI scanner because the utilization projections are overstated and unreasonable. The discussion regarding need and projected utilization found in Criterion 3 is incorporated herein by reference. Therefore, the applicant fails to adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- Duke Green Level fails to demonstrate that the project schedule assumptions used to project MRI scans in 2023 through 2025 are reasonable and adequately supported.
- The applicant does not adequately demonstrate that the proposed fixed MRI is needed at the Cary location where it will be in close proximity to the existing Duke Cary Parkway IDTF and the previously approved Duke Health Arringdon MRI and the Duke Radiology Holly Springs MRI.

For these reasons, the Duke Green Level application is nonconforming to Criterion 6.

Criterion 13(c) – In Section L of the application, Duke Green Level proffers its payor percentages for its MRI scanner that are based on unsupported assumptions. The Payor Mix Table on page 69 of the application provides the projections for 7/1/2021 to 6/30/2022, which is not the Second Full Fiscal Year for the MRI project. The application provides inconsistent payor mix information because Section L indicates that FY 2022 (7/1/2021 to 6/30/2022) is Year 2 but Section Q represents that FY 2024 (7/1/2023 to 6/60/2024 in Year 2).

Section Q of the Duke application does not appear to include any worksheet or calculations that support the payor mix methodology and assumptions that are referenced on pages 69 to 70. Based on this omission, the Agency is not able to analyze the reasonableness of the applicant's statement, **"Based on input from DUHS Corporate Finance, the projections include an anticipated shift of 3.8 % of private insurance patients to Medicare per year through FY 2022 to reflect the aging of the population and resulting utilization patterns of MRI services."** The applicant's assumptions fail to explain if this anticipated shift is going to continue for each of the Project Years beyond FY2022.

Given the inconsistent representations, the absence of historical payor mix data, and the omission of worksheets or calculations, the Duke Green Level application is nonconforming to Criterion 13(c).

Criterion 18a –Duke Green Level fails to adequately demonstrate how any enhanced competition in the service area would have a positive impact on the cost effectiveness because the application does not adequately demonstrate the need the population to be served has for the proposed services. Duke chooses to delay the development of the proposed Duke Green Level MRI project until 2023. So while the Duke MRI utilization projections might appear credible based on the overextend timeframe, , the application fails to demonstrate that the extent to which underserved groups in Wake County will have adequate access to fixed MRI services <u>in 2021 and 2022</u>, prior to the development of the proposed project.

MRI Performance Standards 10A NCAC 2703 (b) (3), (4), (5) and (6) – The Duke Green Level application is based on unreasonable assumptions. The discussion regarding need and projected utilization found in Criterion 3 is incorporated herein by reference.

Comments by EmergeOrtho Regarding Wake Radiology Cary, CON Project ID # J-11830-19

The Wake Radiology Cary application is nonconforming to CON Review Criteria 1, 4, 5, 18a. Specific comments are provided as follows:

Criterion 1 – The Wake Radiology Cary application fails to demonstrate that the applicant's proposal would maximize healthcare value because the financial projections are incorrect based on major inconsistencies with the stated assumptions. The discussion regarding financial projections found in Criterion 5 is incorporated herein by reference. Consequently, the Wake Radiology Cary application is nonconforming to Criterion 1.

Criterion 4 – Wake Radiology Cary's financial projections are incorrect based on substantial errors and inconsistencies causing the application to not be approvable. An application that cannot be approved is not an effective alternative. Therefore, the Wake Radiology Cary application is nonconforming to Criterion 4.

Criterion 5 – Major errors in the financial projections of Wake Radiology Cary cause the application to be nonconforming to Criterion 5. An applicant is not permitted to amend its application.

Wake Radiology Cary provides Financial assumptions for Forms F.2 for Wake Radiology Cary MRI that state:

"Patient Services Gross Revenue is based on projected contractuals and net revenue amounts based on Wake Radiology Cary MRI's CY 2018 experience for professional and technical components by payor, **inflated 3.0 percent annually** (emphasis added), and applied to projected volumes."

But contrary to this assumption, the 2019 increase for gross revenue is 4.6% and then that year's increase is compounded by the 3% annual increase for years 2020 through 2023 which results in overstated revenues in the hundreds of thousands of dollars per year.

Wake Radiology Cary Total MRI	2018	2019	2020	2021	2022	2023
Unweighted MRI Procedures	7,813,558	8,446,028	9,046,006	9,688,606	10,376,853	11,113,991
Gross Revenue	3,661	3,784	3,935	4,092	4,255	4,424
Gross Revenue per MRI	2,134	2,232	2,299	2,368	2,439	2,512
% Annual Increase		4.6%	3.0%	3.0%	3.0%	3.0%

An additional financial mistake contained in the application is that while the charges for the MRI procedures are projected to increase by 3% annually for the 2019 through 2023, the percentages of contractual adjustments are not increasing but remain fixed at 59.5 percent.

Wake Radiology Cary Total MRI	2018	2019	2020	2021	2022	2023
Gross Revenue	7,813,558	8,446,028	9,046,006	9,688,606	10,376,853	11,113,991
Contractual Adjustments	4,426,848	5,022,661	5,379,455	5,761,594	6,170,879	6,609,239
Percent of Total Gross Revenues	56.7%	59.5%	59.5%	59.5%	59.5%	59.5%

It is unreasonable to project that contractual adjustments will remain at the same percentages while the average MRI charges are increasing because reimbursement is not increasing by 3 percent annually. Therefore the contractuals adjustment percentages are unreasonable and the contractual dollar amounts for future years are significantly understated. Just as the contractual percentages increased from 56.7 percent in 2018 to 59.5 percent in 2019, the contractual percentages should continue to increase in future years.

As a result of the overstated revenues and understated contractual adjustments, the Wake Radiology Cary net revenue figures are not reliable.

Based on these incorrect projections, it is also unreasonable for the applicant to forecast that the proposed project will increase the profitability of its MRI service by more than 200% as seen in the following table:

Wake Radiology Cary Total MRI	2018	2019	2020	2021	2022	2023
Net Income	412,061	346,685	445,963	1,182,897	1,203,111	1,376,080
Unweighted Scans	3,661	3,784	3,935	4,092	4,255	4,424
Net Income per Scan	113	92	113	289	283	311
Percentage Increase over 2019				215.52%	208.62%	239.50%

For all these reasons, the Wake Radiology Cary application is nonconforming to criterion 5.

Criterion 18a –Wake Radiology Cary fails to adequately demonstrate how its project would enhance competition in the service area to have a positive impact on the cost effectiveness because the financial projections are unreasonable due to erroneous revenue projections that are inconsistent with the applicant's assumptions.

STATISTICAL PRIMER

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Problems with Rates Based on Small Numbers

by

Paul A. Buescher

Introduction

Most health professionals are aware that estimates based on a random sample of a population are subject to error due to sampling variability. Fewer people are aware that rates and percentages based on a full population count are also estimates subject to error. Random error may be substantial when the measure, such as a rate or percentage, has a small number of events in the numerator (e.g., less than 20). A rate observed in a single year can be considered as a sample or estimate of the true or underlying rate. This idea of an "underlying" rate is an abstract concept, since the rate observed in one year did actually occur. However, since annual observed rates may fluctuate dramatically, it is the underlying rate that health policies should seek to address. **The larger the numerator of the observed rate, the better the observed rate will estimate the underlying rate.**

Many publications of the State Center for Health Statistics contain rates or percentages with a small numerator. This is a problem with a measure such as the infant mortality rate. In a single year many counties may have only one or two infant deaths and such rates in a small population may fluctuate dramatically from year to year. One means of addressing this problem is to look at five-year rates where the numerator will be larger. Even with five-year rates, however, many counties will have few events and therefore unstable rates. Many cause-specific death rates for individual counties will have small numerators. This statistical problem is compounded when age-adjusted rates are produced because, in the process of calculating an age-adjusted rate by the direct method, the deaths and population are broken up into smaller groups. Rates are calculated for a number of specific age groups and numerators for each rate are often small.

Some customers of the State Center for Health Statistics may treat our published rates and percentages as completely accurate. Unfortunately, there is the danger of making unwarranted comparisons between geographic areas or comparisons over time when the rates or percentages have small numerators. We do not consider it feasible to completely ignore all rates based on small numbers. In one sense, the rates do describe what actually happened in a year, but you must use caution and interpret any comparisons critically. The following section provides some methods for quantifying random errors in rates as a basis for making decisions about when changes or differences in rates are meaningful.

Calculation of Errors in Rates

The formulas presented here provide a means of estimating the confidence interval around a single rate and for determining whether the difference between two rates is statistically significant.

***Definition:** A *confidence interval* is a range above and below an observed rate within which we would expect the "true" rate to lie a certain percentage of the time (usually 95%).

Calculation of a confidence interval recognizes that an observed rate is not a precise estimate of the underlying rate because the observed rate is influenced by random error. The formulas below are exactly the same as the ones used for a random sample from a larger population. The population rate for a given year based on a complete count can be considered a sample of one of a large number of possible measurements, all of which cluster in a normal distribution (bell curve) around the "true" (unknown) rate of the population. The larger the numerator of the measured rate, the better the rate will estimate the true or underlying rate of the population. The confidence interval accounts for only random measurement error. Systematic errors or biases in measurement may still be present and cannot be assessed by these formulas.

These formulas apply to any proportion or simple (crude) rate. Random errors may also be estimated for adjusted rates and other more complex measures, but a description of this is beyond the scope of the present Primer.

Proportions vs. Percentages vs. Rates

The formulas below are expressed in terms of p, or the proportion or fraction of a population that has a certain characteristic (e.g., death, low birthweight, early prenatal care). In this context, the terms proportion, percentage, and rate are used interchangeably.
For example, in 1995 Wake County had a resident population of approximately 518,000 out of which approximately 2,900 died during the year. The proportion who died is 2,900 / 518,000 or .005598. For the percentage who died, multiply by 100; the result is .5598%. A percentage is simply a rate per 100. For a rate per 1,000, multiply the proportion by 1,000; the result is 5.598 deaths per 1,000 population. The number of deaths per 100,000 is 559.8. So the multiplier is completely arbitrary, though for rare events we usually use 1,000 or higher so that the rate is not a decimal fraction.

The formulas presented below use p, or the proportion, so a percentage or rate has been converted back to the proportion (by dividing by the multiplier) in these examples.

Infant Death Rates

The infant death rates (expressed per 1,000 live births) reported in State Center for Health Statistics publications are not strictly proportions since the deaths and births occurred during a particular calendar year. Though approximately one-half of infant deaths occur on the first day of life, some of the infant deaths that occur in a given year are to babies born in the previous calendar year. Technically, the more correct way to compute the proportion of babies who before their first birthday would be to use a linked birth/infant death file to track a population of births (also called a birth cohort) through the first year of life. But in practicality this difference is small. We suggest that the formulas below may reasonably be used for infant deaths rates reported as usual based on year of occurrence and expressed as the proportion of babies who die.

✐ *Formula*:

$$\text{Infant death rate} = \frac{\text{\# deaths under 1 year of age}}{\text{\# of live births}} \times 1000$$

Confidence Intervals

We can compute a confidence interval around a proportion or rate. The confidence interval is the interval within which we would expect the "true" rate to fall a certain percentage of the time. A 95% confidence interval is frequently used, which means using a multiplier ("Z" value) of 1.96. For a 99% confidence interval, one would use the multiplier 2.57. Let us say that in hypothetical Rocky County there are 20 infant deaths (d) out of a population of 1,900 live births (n) in a single year. The proportion dying (p) is 20 / 1,900 = .0105. You can also say that 1.05 percent died or that the infant death rate is 10.5 per 1,000 births for that year.

✐ *Formula:*

$$\text{95\% Confidence Interval} = p \pm 1.96 \sqrt{\frac{p\,q}{n}}$$

where q = 1-p. This formula works for any value of p, though for small values of p (.01 or less), the value of q is very close to 1 and may therefore be ignored. In the current example this calculates out to:

$$q = 1 - .0105 = .9895$$

95% Confidence Interval =

$$.0105 \pm 1.96 \sqrt{.0105 \text{ X } .9895 / 1900} = .0105 \pm .0046.$$

Expressed in the traditional way in terms of infant deaths per 1,000 live births, we can say that we are 95% sure that the true infant death rate for this population is between 5.9 and 15.1. These limits are quite large. A useful rule of thumb is that any rate with fewer than 20 events in the numerator will have a confidence interval that is wider than the rate itself. In the current example of a rate of 10.5 per 1,000 with a numerator of 20, the width of the confidence interval is 9.2.

✐ *Formula:*

Width of the confidence interval = higher limit - lower limit
In the current example this is: 15.1 - 5.9 = 9.2

Combining Data for Greater Precision

One way to reduce the error of a rate is to combine several years of data. Another way is to combine geographic areas; for example, look at regional rather than county-level rates. In the example above, let us assume that over a five year period in Rocky County we observed five times as many infant deaths and live births (100 and 9,500 respectively) as in the example above.

The five-year infant death rate would still be 10.5, but with the larger numerator, the range of the 95% confidence interval would be much smaller (8.5 to 12.5). Try the calculations so you can verify this result. In general, you have to quadruple the sample size (n) to cut the random error in half.

Differences Between Rates

When comparing rates, you might want to assess the statistical significance of a change in a rate over time, or of the difference between two rates in one period of time (for example between two geographic areas or population groups).

The **standard error of the difference between two rates** is computed as:

✐ *Formula:*

$$SE = \sqrt{\frac{p_1 q_1}{n_1} + \frac{p_2 q_2}{n_2}}$$

where p_1 and p_2 are the two rates to be compared expressed as proportions. The difference between the two proportions can be considered statistically significant at the 95% confidence level if the difference is greater than 1.96 multiplied by the standard error (computed above).

As an example, take a county where the percentage of women who smoked during pregnancy (from the birth certificates) declined from 21.4% in 2000 to 16.7% in 2005. We want to know if this change is statistically significant at the 95% confidence level. In 2000, the mother smoked for 150 births (d_1) out of 700 total births (n_1). In 2005, the mother smoked for 125 births (d_2) out of 750 total births (n_2). The proportions are $p_1 = d_1 / n_1 = .214$ and $p_2 = d_2 / n_2 = .167$ (or 21.4% and 16.7%).

Therefore, the calculation of 1.96 times the standard error of the difference is as follows:

$$1.96 \text{ X SE} = 1.96 \sqrt{\frac{.214\ (.786)}{700} + \frac{.167\ (.833)}{750}} = .0404$$

Since the difference between the two proportions of .047 (i.e. .214 - .167) exceeds 1.96 times the standard error of the difference (i.e., .0404), we can say that the decline in the smoking percentage in this county is statistically significant at the 95% confidence level. Or stated another way, the probability is less than .05 (or 5%) that the observed decline in smoking was due to chance.

The formula for the standard error of the difference can be used to solve for any unknown in the equation. For example, if you want to know what the exact level of statistical significance of an observed difference between two proportions is, solve for the multiplier (“Z”) by dividing the observed difference by the standard error of the difference and look up the probability value for Z in a table of areas under the normal curve. In the smoking example presented above, the probability that the observed decline would occur just due to random variation in the percentages is .02. Please verify this result by consulting a table of

areas under the normal curve in your statistical text or online. For assistance with this or for other questions, contact the State Center for Health Statistics.

Other Issues

These formulas are based on parameters of the normal curve and in some cases will be only an approximation. If n (sample or population size, also denominator of the proportion or rate) is less than 30, or if the number of events (numerator of the proportion) is less than 5, these formulas become less reliable and readers should contact the State Center for Health Statistics for more appropriate alternatives.

Another important consideration is the issue of practical versus statistical significance. If n is large enough, almost any difference will be statistically significant. However, the same difference may be of very little practical or clinical significance. It is the responsibility of the user of statistics to evaluate whether observed differences, which may be statistically significant, are of real public health importance.

Finally, the issue of using rates versus actual counts should be mentioned. Rates or proportions allow more standardized comparisons between populations of different size, but there may be substantial random measurement error involved. In many cases just looking at the number of events is appropriate; do not always rush to calculate a proportion or rate. If the number of infant deaths in a county increased from one in 2007 to two in 2008 and the number of births remained about the same, looking at the infant mortality rate would erroneously suggest that the problem had become twice as great. In this case, each infant death could be investigated as unique sentinel health event. Examining the numbers behind the rates is always a good idea, and in some cases just looking at the numbers makes more sense.

This section on calculation of errors in rates demonstrates that an observed rate or proportion should not be taken as an exact measure of the true value in a population. Even measures based on complete reporting from a population may have a substantial random error component.

Key Points to Remember

- If the number of events (numerator) is less than 20, your statistic may be unreliable due to random error. Interpret it with caution and look at the raw numbers too!
- You can calculate a confidence interval around your statistic to get an idea of the precision of your estimate. Narrower confidence intervals indicate more precise estimates.
- To get greater precision and increase your sample size, combine data from several years, or several places during one year.
- You can check if the difference between two rates is statistically significant at a certain level by comparing the difference between the rates to the standard error of the difference multiplied by “Z” (usually Z = 1.96).
- It is up to you, the health professional, to decide whether the difference between two rates is *clinically* important, no matter whether it is *statistically* significant or not!

Statistical Guidelines

To address the problems of rates based on small numbers, the State Center for Health Statistics has adopted the following statistical guidelines:

- All publications of the State Center for Health Statistics that contain rates or percentages should contain a caution about interpreting rates or percentages based on small numbers. This caution should be featured prominently in the introductory material, and then discussed in more detail in the methods or technical notes section. See the *2006 North Carolina Vital Statistics, Volume 1 and Volume 2,* for examples of this.

- Such a caution should accompany any information that is sent out to a customer as a special data request, if the information contains rates or percentages based on small numbers.

- When rates or percentages are published or distributed, the numerators should also be shown if possible.

- When maps of rates are produced, where possible there should be a legend warning the reader to "interpret with caution" for rates or percentages based on a very small numerator, e.g., less than 20 events.

- At every opportunity, customers of the State Center for Health Statistics should be educated about statistical issues, and especially about the potential for misinterpretation when comparisons are made using rates or percentages based on small numbers.

Readers with questions or comments about this Statistical Primer may contact Paul Buescher at (919) 715-4478 or through e-mail at Paul.Buescher@ncmail.net.

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August 8, 2019

Comments of Alliance HealthCare Services, Inc.
on the Petition of Raleigh Radiology, LLC for an
Adjusted Need Determination for an MRI Scanner

I. Alliance Supports the Standard Need Methodology

Alliance HealthCare Services, Inc. ("Alliance") supports the Standard Methodology which shows the nearly twenty-five (25) fixed equivalent MRI scanners already in Wake County are performing over four thousand (4,000+) procedures ***below*** what is necessary to trigger need determination for a new fixed MRI scanner in the 2020 Plan. Despite its sweeping claims (and numerous inaccuracies), the Raleigh Radiology, LLC ("Raleigh Radiology") Petition never questions the correctness and completeness of the data which, in accordance with proper application of the Standard Methodology, shows no need for a fixed MRI scanner for Wake County. The Raleigh Radiology Petition fails to show any basis for departing from the Standard Methodology.

The crux of the Raleigh Radiology Petition for an adjusted need is its claim that Raleigh Radiology wants to replace Alliance's contracted service to reduce Raleigh Radiology's cost of providing MRI services. The State Plan recognizes that, ***in response to a need determination***, a CON applicant can argue it wants to replace a contracted service to reduce cost; however, that argument is only properly advanced in response to an existing need determination.

The lone argument that a provider wants to replace a contracted service has **NEVER** sufficed for approval of an adjusted need determination for an MRI. When Person Memorial Hospital requested an adjusted need for an MRI in the 2014 Plan, its Petition focused on the fact that 75% of patients were traveling out of county for scans due to limited scanner availability. When Dosher Memorial requested an adjusted need for an MRI in the 2016 Plan, its Petition centered on classification of the Dosher scanner, distance to treatment, and cost to transport hospitalized patients. When Raleigh Radiology sought an adjusted need for an MRI in the 2016 Plan, its Petition illustrated that total Wake County scans would exceed the threshold for a need

determination. A "special" need determination is only appropriate in response to a "special" circumstance. Not only has Raleigh Radiology failed to articulate such a circumstance in its Petition, its Petition actually documents that it is one of many providers utilizing a vendor contract for MRI services – the opposite of a special circumstance.

The Instructions in the State Plan require a showing that "adverse effects *on the population* of the affected area" are likely to ensue absent the adjustment. Raleigh Radiology's Petition is self-defeating because it admits Raleigh Radiology already offers "extended hour schedules" and the "lowest comprehensive prices" in Wake County. Raleigh Radiology Petition, p. 5. Raleigh Radiology repeatedly admits that, even without an adjusted need, the population of the affected area has good financial and geographic access to MRI services. When the population of the affected area is already well-served, a Petition focused solely on bettering Raleigh Radiology's bottom-line does NOT present a bona fide basis for an adjusted need.

A. Adjusted Need is Not Properly Based on Scanners Per Capita

A need determination is not properly based on the number of scanners per capita in a service area. Raleigh Radiology Petition, pp. 2-3. Recognizing need on this basis would ignore the most salient fact: the number of procedures performed per scanner in the service area. Even assuming Wake County has fewer scanners per capita as compared to other service areas (such as Mecklenburg and Durham Counties), that comparison alone is not a logical basis for finding need. Not all service area populations require MRI scans at the same rates. Raleigh Radiology's comparison of number of MRI scanners per person offers no reason to identify a special need determination when procedures per scanner in Wake County do not show need.

B. Adjusted Need is Not Properly Tied to the Number of Alliance Scanners

Many years ago, Alliance became the first national provider of shared imaging services to receive accreditation from The Joint Commission. Alliance is now one of the nation's largest and most successful healthcare services organizations and a leader in providing essential services and exceptional care in radiology services. Although Alliance proudly offers access to quality

diagnostic imaging services in North Carolina (and many other States), the extent to which various areas are served by Alliance-owned scanners is irrelevant.[1] On the one hand, Raleigh Radiology argues about the extent to which Alliance has multiple scanners in operation in North Carolina while, on the other hand, it argues there are too few scanners in Wake County such that the State needs to recognize the need for one more. The Raleigh Radiology Petition arguments are either illogical or simply irrelevant to the appropriate analysis of need for a new scanner in Wake County.

II. Raleigh Radiology's Petition does Not Demonstrate a Proper Basis for its Proposed Adjustment

A. An Adjusted Need Cannot be Based on an Unsubstantiated Notion that Raleigh Radiology will be Forced to Raise its Patient Charges in the Future

Raleigh Radiology claims to offer patients in the affected area the "lowest comprehensive MRI prices." It obviously does so while paying Alliance for equipment and staff, including, when necessary, overtime charges for after-hours staff. Raleigh Radiology Petition, p. 5. And, by its own admission, Raleigh Radiology's contract with Alliance includes only modest CPI-based annual increases.[2] While Raleigh Radiology states its contract with Alliance ends in 2020, Raleigh Radiology has already willingly extended its agreement with Alliance through November of 2022.[3] As such, nothing supports the notion that, absent an adjusted need, Raleigh Radiology would be forced in the future to dramatically inflate charges for MRI services for the population of the

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[1] Alliance has 24, not 26, grandfathered MRI scanners that can be used as fixed or mobile units in North Carolina; Alliance has 4 MRI scanners that are CON-approved as mobile units which must move weekly to serve at least two sites. Two of Alliance's fixed MRI units are jointly-held installed units. Alliance also leases MRI scanners to facilities that hold CON approvals. The Proposed 2020 SMFP shows that Raleigh Radiology uses MRI scanners provided not only by Alliance but also by Foundation Health Mobile Imaging and Pinnacle Health Services. Alliance scanners operate in accordance with North Carolina CON Law, not per a "loophole."

[2] In fact, Alliance did not impose any CPI increase in 2016 or 2017. The price paid by Raleigh Radiology to Alliance for use of the scanner at the Blue Ridge location went down between 2014 and 2016. Raleigh Radiology's Cary location also had a similar price reduction.

[3] When Raleigh Radiology renewed its contract with Alliance in 2016, Alliance reduced monthly fees at both Raleigh Radiology locations, while adding provisions to accommodate the potential that Raleigh Radiology might obtain its own fixed MRI CON. Instead of opposing Raleigh Radiology when it proposed to obtain a CON, Alliance offered to joint venture. No one at Alliance recalls any offer by Raleigh Radiology to buy an Alliance MRI scanner.

affected area. Raleigh Radiology has never claimed to be experiencing any loss on its MRI service, or that it will need to increase charges to remain viable.

B. An Adjusted Need is Not Properly Grounded on Vague and/or Disputed Complaints about the Equipment and Staff furnished by Alliance

The Raleigh Radiology Petition is filled with loose references and comments regarding Alliance's "11-year old . . . equipment" and "inflexible" staff schedules. These attempts to paint a negative picture of the cost and the quality of the Alliance service are belied by the facts. For instance, in Cary, Raleigh Radiology has routinely given Alliance customer satisfaction scores of 100% since at least the fourth quarter of 2017. Alliance works with Raleigh Radiology and its other clients on quality management, staffing and cost containment. Alliance made a reduction in overtime rates to allow Raleigh Radiology to more affordably increase hours at its locations. By agreement, Alliance has spent hundreds of thousands of dollars on multiple equipment upgrades. Between 2012 and 2015, Alliance spent $297,000 on equipment upgrades, but Raleigh Radiology saw no price increase as a result of these expenditures. And, Alliance increased staffing for Raleigh Radiology, moving from a technologist and patient care coordinator to two technologists, without a price increase.[4] Raleigh Radiology has consistently – and happily – worked with an Alliance technologist for the last twelve-and-a-half years and recently honored her with a baby shower.

Raleigh Radiology cannot claim the population of the affected area will be adversely affected without a need determination that allows Raleigh Radiology to buy a new MRI scanner. An 11-year old MRI scanner can be expected to have several more years of strong useful life. GE Healthcare reports that only about half of installed MRI scanners will be replaced within 11 years of installation. An MRI scanner can be replaced in three years or operate for over twenty-two years. According to GE, about 20% of scanners are older than 10 years. Raleigh Radiology

[4] Alliance absorbed the approximately $125,000 per year in extra payroll costs to transition to this model without passing any of those costs along to Raleigh Radiology.

provides no statistics on the age of the scanners in use across North Carolina and offers nothing to support the notion that a scanner should automatically be retired at age 11. Raleigh Radiology specifically chose the Espree unit and, at Raleigh Radiology's request, this is the unit Alliance provides. The unit at Raleigh Radiology is American College of Radiology (ACR) accredited and Alliance is Joint Commission accredited at the Raleigh Radiology sites. In fact, due to Alliance's experience and expertise, Raleigh Radiology implemented certain Alliance quality policies after indicating Raleigh Radiology did not have the same level of sophistication as Alliance.

That a scanner at Raleigh Radiology had a recent repair need is hardly a basis to jump to the conclusion that the scanner must be scrapped in favor of new equipment to properly serve the population of the affected area. When the Alliance unit experienced an issue, Alliance had another unit in place within 24 hours. The unit Alliance brought in was a one-year-old wide-bore high-end unit. Alliance received positive feedback on the unit from the Raleigh Radiology radiologists. Alliance is left to speculate over what the Raleigh Radiology Petition means when it represents that this temporary replacement unit had its "own problems;" Raleigh Radiology fails to articulate any basis for this statement. Even before the recent equipment issue, Alliance offered to discuss the timing of a future equipment replacement; Alliance works with Raleigh Radiology to consistently manage quality. Yet, instead of fairly describing Alliance's prompt response to an equipment issue and Alliance's dependable client-service efforts, the Raleigh Radiology Petition uses sensationalized descriptions contrary to the facts.

III. The Raleigh Radiology Petition Does Not Meet Petition Requirements

The Raleigh Radiology Petition fails to properly address the requirements for a conforming Petition for a Need Determination Adjustment:

A. Failure to Properly Address Alternatives

The Raleigh Radiology Petition speaks to the "risk" associated with filing a potentially competitive 2019 CON application in response to the identified need determination for a new MRI for Wake County but conspicuously fails to state whether it will in fact apply. Raleigh Radiology

Petition, p. 8. As a result, the Raleigh Radiology Petition for a 2020 Adjusted Need Determination appears to be a hedge against the potential that Raleigh Radiology will yet again be incapable of presenting a conforming and comparatively superior CON Application for an MRI scanner in 2019 when vying against other applicants on a level playing field. The Raleigh Radiology Petition seeks to change the rules by placing limits on the potential applicant pool for a CON for a new MRI scanner in 2020.[5] Instead of committing to pursue the already-announced 2019 CON Application filing opportunity for a new Wake County MRI, Raleigh Radiology appears to be using the Petition process to attempt to better its odds in a future review in which it will seek the very same equipment it could pursue in 2019. Its Petition fails to properly address the 2019 CON alternative.

The Raleigh Radiology Petition is likewise vague as to the status of its 2016 CON Application. On May 7, 2019, the Court of Appeals affirmed the 2016 decision of the Agency to award the MRI CON to Duke University Health System instead of to Raleigh Radiology. Raleigh Radiology LLC v. N.C. Dep't of Health & Human Servs., 827 S.E.2d 337, 341 (N.C. App. 2019). On August 6, 2019, after the Raleigh Radiology Petition was filed, the Court of Appeals issued a superseding opinion, Raleigh Radiology LLC v. N.C. Dep't of Health & Human Servs., No. COA18-785.2 (N.C. App. 2019) (attached as Exhibit A), which reconsidered the appeal at Raleigh Radiology's request but reached the same result. Raleigh Radiology presumably considers the case "unresolved" based on its ability to pursue discretionary review or other relief at the North Carolina Supreme Court. To that end, it is still possible Raleigh Radiology could be awarded a CON if the Supreme Court reversed the Court of Appeals' decision. If the case over the 2016 MRI CON remains, as the Raleigh Radiology Petition describes it, "unresolved," its Petition also fails to meaningfully address this alternative.

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[5] Raleigh Radiology cherry-picks the facts that suit it best when describing its purported disadvantage in a competitive review. For instance, on page 4 of its petition, it states that it declined to apply pursuant to the MRI need in 2005 because it "**did not have the history** to compete for it." Then, in its oral remarks offered in support of its petition, Raleigh Radiology laments that the CON review process will favor "a new vendor **with no history**."

B. Failure to Address "Unnecessary Duplication" of Services

The Raleigh Radiology Petition is required to provide evidence that the scanner purchase contemplated by the proposed adjustment will not result in unnecessary duplication. If Raleigh Radiology receives CON approval to acquire a new scanner and discontinues its use of the unit provided by Alliance, the Alliance scanner could nonetheless remain in use at another location in Wake County. In fact, Raleigh Radiology's Petition does not actually commit to giving up any of the MRI scanners that Raleigh Radiology uses through contracts with Alliance, Foundation Health and Pinnacle Health. The Raleigh Radiology Petition fails to address the potential for unnecessary duplication inherent in its request for a proposed adjustment.

C. Failure to Address the SMFP Basic Principles

Raleigh Radiology's Petition fails to conform with the State Plan's Basic Principles. For instance, Raleigh Radiology's lone statement as to Safety and Quality is a remark about bringing in an option for an ACR accredited provider. As noted above, Alliance's unit at Raleigh Radiology is ACR accredited and Alliance is Joint Commission accredited. Raleigh Radiology does not demonstrate that, if approved, its proposal for a new MRI scanner would reduce any economic, time or distance barriers or promote access. Indeed, Raleigh Radiology projects serving the same population it currently serves, in the same location it currently serves them – a far cry from increasing access. Raleigh Radiology has a contract with Alliance through late 2022 and no basis to forecast any future shifts in patient charges. It will not suddenly begin serving higher proportions of Medicare, Medicaid, and private pay patients. The failure to tie the pursued special need adjustment to the State Plan's Basic Principles should render Raleigh Radiology's effort fatal.

Conclusion

Raleigh Radiology already secures comprehensive levels of MRI access from Alliance and has reported 100% satisfaction with those services over multiple years. The Raleigh Radiology Petition is riddled with mischaracterizations, inaccuracies and claims that simply do not support

an adjusted need determination that runs contrary to an appropriate application of the Standard Methodology. And, there is a need determination for a fixed MRI in the 2019 Plan that Raleigh Radiology could elect to pursue. For these reasons, Alliance opposes the Raleigh Radiology Petition for an adjusted need determination for an additional fixed MRI in the 2020 Plan.

IN THE COURT OF APPEALS OF NORTH CAROLINA

No. COA18-785-2

Filed: 6 August 2019

Office of Administrative Hearings, No. 17 DHR 04088

RALEIGH RADIOLOGY LLC d/b/a RALEIGH RADIOLOGY CARY, Petitioner,

v.

N.C. DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, HEALTH CARE PLANNING & CERTIFICATE OF NEED, Respondent,

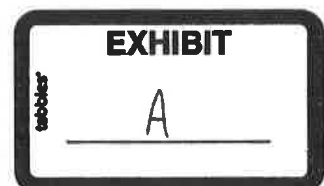
and

DUKE UNIVERSITY HEALTH SYSTEM, Respondent-Intervenor.

Appeal by Respondents and cross-appeal by Petitioner from an amended final decision entered 16 March 2018 by Judge J. Randolph Ward in the Office of Administrative Hearings. Heard originally in the Court of Appeals 13 March 2019. This matter was reconsidered in the Court pursuant to an order allowing Petitioner's Petition for Rehearing. This opinion supersedes the opinion *Raleigh Radiology v. NC DHHS*, No. 18-785, ___ N.C. App. ___, 827 S.E.2d 337 (2019), previously filed on 7 May 2019.

Brooks, Pierce, McLendon Humphrey & Leonard, L.L.P., by James C. Adams, II, for Petitioner Raleigh Radiology LLC.

Attorney General Joshua H. Stein, by Assistant Attorney General Bethany A. Burgon, for Respondent N.C. Department of Health and Human Services, Division of Health Service Regulation, Health Care Planning & Certificate of Need.



Poyner Spruill LLP, by Kenneth L. Burgess, William R. Shenton, and Matthew A. Fisher, for Respondent-Intervenor Duke University Health System.

DILLON, Judge.

Petitioner Raleigh Radiology LLC ("Raleigh") and Respondents N.C. Department of Health and Human Services, Division of Health Care Regulation, Healthcare Planning and Certificate of Need (the "Agency"), and Duke University Health System ("Duke") all appeal a final decision of the Office of Administrative Hearings ("OAH") regarding the award of a Certificate of Need ("CON") for an MRI machine in Wake County.

I. Background

In early 2016, the Agency determined a need for a fixed MRI machine in Wake County and began fielding competitive requests. In April 2016, Duke and Raleigh each filed an application for a CON with the Agency.

Section 131E-183 of our General Statutes sets forth the procedure the Agency should use when reviewing applications for a CON. N.C. Gen. Stat. § 131E-183 (2016). The Agency uses a two stage process: First, the Agency reviews each application independently to make sure that it complies with certain statutory criteria. *See Britthaven, Inc. v. N.C. Dep't of Human Res.*, 118 N.C. App. 379, 385, 455 S.E.2d 455, 460 (1995) (citing N.C. Gen. Stat. § 131E-183(a)). Typically, if only one application is found to have complied with the statutory criteria, that applicant

is awarded the CON. But if more than one application complies, the Agency moves to a second step, whereby the Agency conducts a comparative analysis of the compliant applications. *Britthaven*, 118 N.C. App. at 385, 455 S.E.2d at 461.

In the present case, the Agency approved Duke for the CON, denying Raleigh's application, on two alternate grounds. First, the Agency determined that Duke's application alone was compliant. Alternatively, the Agency conducted a comparative analysis, assuming *both* applications were compliant, and determined that Duke's application was superior.

In October 2016, Raleigh filed a Petition for Contested Case Hearing. After a hearing on the matter, the administrative law judge (the "ALJ") issued a Final Decision, determining that both applications were compliant *but that*, based on its own comparative analysis, Raleigh's application was superior. Accordingly, the ALJ reversed the decision of the Agency and awarded the CON to Raleigh.

Duke and the Agency timely appealed. Raleigh also timely cross-appealed.

II. Standard of Review

We review a final decision from an ALJ for whether "substantial rights of the petitioners may have been prejudiced[.]" N.C. Gen. Stat. § 150B-51(b) (2018). We use a *de novo* standard if the petitioner appeals the final decision on grounds that it violates the constitution, exceeds statutory authority, was made upon unlawful procedure, or was affected by another error of law. N.C. Gen. Stat. § 150B-51(b)(1)-

(4), (c) (2018). And we use the whole record test if the petitioner alleges that the final decision is unsupported by the evidence or is "[a]rbitrary, capricious, or an abuse of discretion." N.C. Gen. Stat. § 150B-51(b)(5)(6), (c) (2018).

III. Analysis

On appeal, Duke and the Agency argue that the ALJ erred in reversing the Agency's decision. Though successful in its appeal before the ALJ, Raleigh cross-appeals certain aspects of the ALJ's decision and with the process in general. We address the issues raised in the appeal and cross-appeal below.

A. ALJ's Finding that Duke's Application Conformed

We first address Raleigh's cross-appeal challenge to the ALJ's finding that Duke's application complied with the Agency criteria. That is, though the ALJ awarded Raleigh the CON based on a determination that Raleigh's compliant application was superior to Duke's compliant application, Raleigh contends that the ALJ should have determined that Duke's application was not compliant to begin with. Specifically, Raleigh contends that Duke did *not* conform with Criteria 3, 5, 12, and 13(c) found in Section 131E-183(a). For the following reasons, we disagree.

We review this argument under the whole record test, N.C. Gen. Stat. § 150B-51(b)(5)(6), (c), and properly "take[] into account the administrative agency's expertise" in evaluating applications for a CON. *Britthaven*, 118 N.C. App. at 386, 455 S.E.2d at 461.

A review of the whole record reveals that the evidence presented by Duke in its CON application, the Agency hearings, and the Office of Administrative Hearings amounts to substantial evidence of Duke's compliance with the review criteria.

In conformity with Criteria 3, Duke "identif[ied] the population to be served by the proposed project, and . . . demonstrate[d] the need that this population has for the services proposed, and the extent to which all residents of the area . . . are likely to have access to the services proposed." N.C. Gen. Stat. § 131E-183(a)(3). More specifically, in its application, Duke illustrated the current levels of accessibility to MRI scanners in Wake County and identified the location of its proposed MRI, the Holly Springs/Southwest Wake County area, as one in need of increased access to scanners, particularly due to its rapidly growing population. Duke also laid out the current travel burdens faced by Wake County residents in the Duke Health System who require access to an MRI scanner and how the addition of a new MRI scanner in its proposed location could have a favorable impact on those geographic burdens. Duke coupled those factors with the historically consistent utilization rate for MRIs in Wake County to demonstrate the need in the area for the MRI scanner.

In conformity with Criteria 5, Duke provided financial and operational projections that demonstrated "the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal[.]" N.C. Gen. Stat. § 131E-183(a)(5). For example, Duke set forth the anticipated source

of financing for the project, with all the funding projected to be drawn from its accumulated reserves. Duke also provided five-year projections for its financial position and income statements, as well as three-year projections for the revenues to be produced by the new MRI scanner. The Chief Financial Officer of Duke also certified the existence and availability of funding for the project and referenced Duke's most recent audited financial statement to demonstrate the availability of such funds.

Duke also conformed with Criteria 12 by delineating that the construction "cost, design, and means" were reasonable by comparing its proposed project with potential alternatives. N.C. Gen. Stat. § 131E-183(a)(12). Essentially, Duke compared its proposal to potential alternatives, including maintaining the status quo, developing the proposed MRI scanner in a different location, developing a mobile MRI service in Holly Springs, and pursuing the current project.

Lastly, Duke conformed with Criteria 13(c) by "demonstrat[ing] the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups . . . [and] show[ing] [t]hat the elderly and the medically underserved groups identified in this subdivision will be served by [its] proposed services and the extent to which each of these groups is expected to utilize the proposed services[.]" N.C. Gen. Stat. § 131E-183(a)(13)(c). Duke demonstrated that it expects almost one-third (1/3) of its patients to be

Medicare or Medicaid recipients and that it has the support of community programs, which help in providing healthcare access to low-income, uninsured residents of Wake County. In addition, Duke provided statistics regarding its interactions with female and elderly patients, along with its policy of non-discrimination against handicapped persons. Using this data, Duke asserted that these kinds of patients will receive the same access to the new MRI scanner at the Holly Springs location.

In accordance with our previous holdings in CON cases, this Court "cannot substitute our own judgment for that of the Agency if substantial evidence exists." *Total Renal Care of N.C., LLC v. N.C. Dep't of Health & Human Servs.*, 171 N.C. App. 734, 739, 615 S.E.2d 81, 84 (2005). Indeed, Duke met this threshold by putting forth the aforementioned evidence; and the Agency is entitled to deference, as Duke put forth substantial evidence of its conformity with these criteria. Thus, we affirm the ALJ's finding of fact number 24 that Duke's application was compliant.

B. Comparative Analysis Review

Duke and the Agency argue that the ALJ erred in conducting its own comparative analysis review of the two CON applications. That is, they argue that the ALJ should have given deference to the Agency' determination that Duke's application was superior. We review this question of law *de novo*. *Cumberland Cty. Hosp. Sys. v. N.C. Dep't of Health & Human Servs.*, 242 N.C. App. 524, 527, 776 S.E.2d 329, 332 (2015).

Our Court has held that where the Agency compares two or more applications which otherwise comply with the statutory criteria, "[t]here is no statute or rule which requires the Agency to utilize *certain* comparative factors." *Craven Reg'l Med. Auth. v. N.C. Dep't of Health & Human Servs.*, 176 N.C. App. 46, 58, 625 S.E.2d 837, 845 (2006) (emphasis added). But, rather, the Agency has discretion to determine factors by which it will compare competing applications. *Id.*

However, the ALJ on appeal of an Agency decision does not have this same discretion to conduct a comparative analysis. That is, where an unsuccessful applicant appeals an Agency decision in a CON case, the ALJ does *not* engage in a *de novo* review of the Agency decision, but simply reviews for correctness of the Agency decision, pursuant to N.C. Gen. Stat. § 150B-23(a). *E. Carolina Internal Med., P.A. v. N.C. Dep't of Health & Human Servs.*, 211 N.C. App. 397, 405, 710 S.E.2d 245, 252 (2011). Indeed, "there is a presumption that 'an administrative agency has properly performed its official duties.' " *Id.* at 411, 710 S.E.2d at 255 (quoting *In re Cmty. Ass'n*, 300 N.C. 267, 280, 266 S.E.2d 645, 654 (1980)).

In the present case, the Agency reviewed Duke's application and Raleigh's application for the CON independently. *Britthaven*, 118 N.C. App. at 385, 455 S.E.2d at 460 (citing N.C. Gen. Stat. § 131E-183(a)). This review revealed that Duke's application conformed with all criteria and that Raleigh failed to conform with respect to certain criteria. At that point, assuming that Raleigh's application indeed failed

to conform to certain criteria, it would have been appropriate for the Agency to proceed with issuing the CON to Duke. Nevertheless, the Agency, as stated in its seventy-four (74) pages of findings, additionally "conducted a comparative analysis of [Duke's and Raleigh's applications] to decide which [one] should be approved," assuming that Raleigh's application did satisfy all of the criteria. *See id.* at 385, 455 S.E.2d at 461.

The Agency, in its discretion, used seven comparative factors in reviewing the CON applications: (1) geographic distribution, (2) demonstration of need, (3) access by underserved groups, (4) ownership of fixed MRI scanners in Wake County, (5) projected average gross revenue per procedure, (6) projected average net revenue per procedure, and (7) projected average operating expense per procedure. This comparative analysis led the Agency to approve and award the CON to Duke.

However, on appeal to the OAH, the ALJ deviated from the above factors by considering two additional factors: (1) the types of scanners proposed by each applicant, and (2) the timeline of each proposed project. Admittedly, there was evidence that Raleigh's proposed MRI machine was superior to the machine which Duke would use. It is this deviation and the reliance on additional comparative factors by the ALJ which we must conclude was error.

Indeed, adding two additional comparative factors is not affording deference to the Agency, but rather constitutes an impermissible *de novo* review of this part of the

Agency's decision. Such a substitute of judgment by the ALJ is not allowed. *E. Carolina Internal Med.*, 211 N.C. App. at 405, 710 S.E.2d at 252.

Evidence was provided that the factors utilized by the Agency have been used in two previous MRI CON decisions and that the additional factors used by the ALJ have not been a part of the Agency's policies and procedures for many years. We note that information pertaining to Raleigh's allegedly superior MRI machine was not included in Raleigh's application, though it was otherwise presented at the Agency public hearing, but without an expert testifying as to the machine's medical efficacy. Even so, the Agency has the discretion to pick which factors it evaluates in conducting its own comparative analysis. *Craven Reg'l Med. Auth.*, 176 N.C. App. at 58, 625 S.E.2d at 845. Further, regarding the timeline factor used by the ALJ, there was testimony that the Agency puts little, if any, weight to this factor as the factor disadvantages new providers. The ALJ did not determine that the Agency acted arbitrarily and capriciously, but rather simply substituted his own judgment in weighing the factors. We cannot say, though, that the Agency abused its discretion to rely on the factors that it did. Therefore, we conclude that the ALJ exceeded its authority conducting a *de novo* comparative analysis of the competing applications.

Separately, Raleigh argues that the Agency erred by concluding that its application was not conforming. But even assuming that the Agency incorrectly made a determination that Raleigh's application did not conform to certain statutory

criteria, such error was harmless: the Agency proceeded with a comparative analysis of both applications as if Raleigh's application did comply and, in its discretion, determined that Duke's application was superior.

Therefore, we reverse the Final Decision and reinstate the decision of the Agency.[1]

C. Motion in Limine – Spoliation of Evidence

In its cross-appeal, Raleigh argues that the ALJ erred in denying its motion in limine to apply adverse inference based on Duke's alleged spoliation of certain evidence. We disagree.

"[W]hen the evidence indicates that a party is aware of circumstances that are likely to give rise to future litigation and yet destroys potentially relevant records without particularized inquiry, a factfinder may reasonably infer that the party probably did so because the records would harm its case." *McLain v. Taco Bell Corp.*, 137 N.C. App. 179, 187-88, 527 S.E.2d 712, 718, *disc. rev. denied*, 352 N.C. 357, 544 S.E.2d 563 (2000). This inference is a permissible adverse inference. *Id.* "To qualify for [an] adverse inference, the party requesting it must ordinarily show that the spoliator was on notice of the claim or potential claim at the time of the destruction."

[1] We note that additional arguments were made on appeal. For instance, Duke and the Agency contend that Raleigh did not establish substantial prejudice and that the Final Decision was incomplete and untimely by thirty-seven (37) minutes. However, in light of the ALJ's comparative analysis error and our subsequent reversal of the Final Decision, we need not address these arguments.

McLain, 137 N.C. App. at 187, 527 S.E.2d at 718 (internal citations omitted). However, "[i]f there is a fair, frank and satisfactory explanation" for the absence of the documents, an adverse inference will not be applied. *Yarborough v. Hughes*, 139 N.C. 199, 211, 51 S.E. 904, 908 (1905).

In the present case, Duke contracted with a third-party consultant, ("Keystone"), to perform and draft its CON application. Keystone's practice is to discard all useless documentation and application references so as to keep only relevant, accurate applications and data. This practice is consistent with most consultants in this field, it is not disputed, and amounts to "a fair, frank and satisfactory explanation[.]" *Id.*

Moreover, as Duke and the Agency correctly point out, these documents would not be the subject of review or an appeal. Rather, the ALJ's review of the Agency's decision is limited to its seventy-four pages of findings and conclusions. We conclude that the ALJ did not err in not applying an adverse inference based on the absence of certain documents.

IV. Conclusion

The ALJ erred in not deferring to the comparative analysis performed by the Agency and conducting its own comparative analysis. However, the ALJ did not err in finding and concluding that Duke conformed with the applicable review criteria nor in not applying an adverse inference against Duke regarding certain information.

Thus, we reverse the Final Decision and reinstate and affirm the decision of the Agency awarding the CON to Duke.[2]

REVERSED.

Judges BRYANT and ARROWOOD concur.

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[2] We acknowledge Raleigh's motion for leave to file a supplemental brief regarding the ALJ's authority to remand a contested case to the Agency. We deny this motion as our resolution has rendered such an issue moot.