

Pinnacle Health Services of North Carolina

December 31, 2019

Gregory Yakaboski, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Comments on Wake County Fixed MRI Scanner CON Applications

Dear Mr. Yakaboski:

Enclosed please find the Pinnacle Health Services of North Carolina written comments regarding the competing CON applications for one fixed MRI scanner for Wake County, to meet the need identified in the *2019 State Medical Facilities Plan*. We appreciate your consideration of these public comments during your review of the applications.

If you have any questions, please contact me at 919.877.5428. I look forward to seeing you at the public hearing.

Sincerely,

A handwritten signature in black ink that reads "Amber George". The signature is written in a cursive, flowing style.

Amber George
Administrator

**COMMENTS ABOUT COMPETING CERTIFICATE OF NEED APPLICATIONS
WAKE COUNTY FIXED MRI SCANNER NEED DETERMINATION**

**Submitted by Pinnacle Health Services of North Carolina
December 31, 2019**

Six applicants submitted Certificate of Need (CON) applications in response to the need identified in the *2019 State Medical Facilities Plan (SMFP)* for one fixed MRI scanner in Wake County. These include:

- J-11820-19 Pinnacle Health Services of North Carolina, LLC
- J-11821-19 EmergeOrtho, P.A.
- J-11825-19 Raleigh Radiology, LLC d/b/a Raleigh Radiology Cary
- J-11826-19 Raleigh Radiology, LLC d/b/a Raleigh Radiology Knightdale
- J-11829-19 Duke University Health System, Inc. d/b/a Duke Radiology Green Level
- J-11830-19 WR Imaging, LLC & Wake Radiology Diagnostic Imaging, Inc. d/b/a Wake Radiology Cary

In accordance with N.C.G.S. §131E-185(a.1)(1), PHSNC submits these written comments which address representations in the competing applications, and a discussion about whether the material in the applications complies with the Certificate of Need review criteria. These comments also address the issue of which of the competing proposals represents the comparatively most effective alternative for development of an additional fixed MRI scanner in Wake County. These comments submitted by Pinnacle Health Services of North Carolina, LLC are not intended to include any additional information that would represent an amendment to its application.

The Agency typically performs a comparative analysis when evaluating competing fixed MRI scanner applications in a need determination batch review. The purpose is to identify the applicant that would bring the greatest overall benefit to the community. The table on the following page summarizes 11 metrics that the Agency should use for comparing the applications in this Wake County MRI batch review.

Wake County Fixed MRI Scanner Application Comparative Analysis

| | PHSNC | DUHS | EO | Wake Rad | RR Cary | RR Knightdale |
|--|-----------------------|-----------------|-----------------|-----------------|-----------------|----------------|
| Conformity with Review Criteria & Rules | Yes | No | No | No | Yes | Yes |
| Ownership of Fixed MRI Scanners in County | Effective | Least Effective | Effective | Least Effective | Effective | Effective |
| Increases Geographic Accessibility | Most Effective | Least Effective | Least Effective | Least Effective | Least Effective | Effective |
| 3 Tesla Technology | Most Effective | No | No | No | Effective | No |
| Date of Offering of Services | Effective | Least Effective | Effective | Effective | Effective | Effective |
| Diversity of Referral Base & Physician Support | Most Effective | Effective | Least Effective | Effective | Effective | Effective |
| Provision of Charity Care | Most Effective | Effective | Less Effective | Least Effective | Less Effective | Effective |
| Projected Medicare | Effective | More Effective | Effective | Most Effective | Effective | Effective |
| Projected Medicaid | Effective | Effective | Effective | Effective | Effective | Most Effective |
| Projected Average Net Revenue per Scan | Effective | Not approvable | Not approvable | Not approvable | Effective | Effective |
| Projected Average Operating Expense per Scan | Effective | Not approvable | Not approvable | Not approvable | Effective | Effective |

As the table portrays objectively, the PHSNC application is overall the most effective alternative. In other words, the Agency will enable the greatest benefit to local residents by approving the PHSNC application. Specifically:

- **Conformity with Review Criteria.** The PHSNC application is conforming to all CON review criteria. In contrast, the DUHS, EmergeOrtho and Wake Radiology applications each fail to conform to multiple review criteria and the administrative rules, and their respective applications are not approvable.
- **Ownership of Fixed MRI Scanners in County.** According to the 2019 SMFP, 17 fixed MRI scanners currently operate in Wake County, and as stated in its application, DUHS is approved for one additional fixed MRI scanner, which it is in the process of developing in Holly Springs. Between them, DUHS and the members of WR Imaging (Wake Radiology and UNC Rex) currently control 10 of the 18 existing and approved fixed MRI scanners in Wake County. Control of 56% of the fixed MRI scanner inventory represents a dominant position in the marketplace between these providers, and the Agency should seek to create greater market balance with this fixed MRI review. By contrast, PHSNC currently operates one fixed MRI scanner (at its Cedarhurst location), which represents just 6% of the inventory. Competition in the marketplace will be enhanced with approval of PHSNC for a second fixed scanner, and approval of either DUHS or Wake Radiology for an 11th fixed scanner in the county will not have a positive effect on competition in Wake County.
- **Increase Geographic Accessibility.** DUHS, Wake Radiology and Raleigh Radiology each proposes to locate an additional fixed MRI scanner in Cary. EmergeOrtho proposes to locate an additional fixed MRI scanner in Raleigh. As described in the PHSNC CON application on page 30, 16 fixed MRI scanners are already located in Raleigh and Cary, with yet another currently under development in Holly Springs, which is proximate to Cary. Approval of any of these four proposals would establish a 17th fixed scanner in Raleigh/Cary, which would be 89% (17/19) of the Wake County fixed MRI scanner inventory. There is no enhanced geographic benefit achieved by the DUHS, Wake Radiology, Raleigh Radiology Cary, or EmergeOrtho proposals. In sharp contrast, PHSNC proposes to develop a fixed MRI scanner in Wake Forest, a community that does not currently host a fixed MRI scanner. Raleigh Radiology submitted one application to develop a fixed scanner in Knightdale, a community which also does not currently host a fixed MRI scanner. However, as the following table portrays, the Wake Forest/Rolesville area is the largest population center in Wake County that does not currently host a fixed MRI scanner, more populous than the Knightdale area. Therefore, the PHSNC proposal provides the greatest benefit to Wake County residents from the perspective of improved geographic access.

Wake County Fixed MRI Scanners by Location

| City/Town | 2018 Population | # of Existing & Approved Fixed MRI Scanners | Population/Scanner |
|----------------------------------|-----------------|---|--------------------|
| Raleigh | 469,298 | 13 | 36,100 |
| Cary/Morrisville | 195,613 | 3 | 65,204 |
| Apex/Holly Springs/Fuquay-Varina | 119,801 | 1 | 119,801 |
| Wake Forest/Rolesville | 52,157 | 0 | -- |
| Garner | 30,502 | 1 | 30,502 |
| Knightdale/Wendell/Zebulon | 30,878 | 0 | -- |
| Wake County | 1,073,993 | 18 | 59,666 |

Source: US Census Bureau (2018 population is the most recent data available via www.uscensus.gov), Proposed 2020 SMFP

3 Tesla Technology. Two applicants propose to acquire a 3T MRI scanner, and the other four applications are planning for a 1.5T scanner. A 3 Tesla (3T) MRI scanner offers several clinical advantages that will bring the greatest benefit to MRI patients, including:

- higher resolution which produces more detailed images, which are beneficial when diagnosing pathological conditions involving the brain, spine, and musculoskeletal system.
- lower risk of distorted images, thus eliminating the need for repeated scans. The resolution and clarity enable radiologists to identify smaller lesions and anatomical structures that cannot be seen with less powerful machines.
- more sophisticated imaging procedures with more accurate diagnosis.
- shorter examination times due to the efficiency of the 3T magnet, which maximizes patient comfort without compromising quality.

Raleigh Radiology proposes a 3T scanner in its Cary application; however, its proposed Siemens Lumina scanner is more costly than the Siemens Skyra 3T

proposed by PHSNC. Thus, PHSNC's proposal is the most effective alternative from a scanner technology perspective.

- **Date of Offering of Services.** The 2019 SMFP determined a need right now for one additional fixed MRI scanner in growing Wake County; therefore, the timeliness of the proposals is an important comparative consideration. As shown on the table below, five applicants, including PHSNC, project to develop their respective MRI projects by January 1, 2021, six months earlier than DUHS. Thus, the DUHS application is the least effective alternative in terms of offering timely access to fixed MRI services for local residents.

Projected Operational Date

| 5 applications | DUHS |
|----------------|----------|
| 1/1/2021 | 7/1/2021 |

Source: CON Applications, Section P.

- **Diversity of Referral Base and Physician Support.** EmergeOrtho is an orthopedic physician practice that relies on its own physicians to support the proposed fixed MRI scanner. Patient referrals from non-EmergeOrtho physicians will be limited, and likely non-existent. In fact, all the letters of support included with the EmergeOrtho application were from EmergeOrtho providers; none were from any other physicians. Therefore, the EmergeOrtho application is the least effective alternative in terms of providing equal access to all physicians in the community.
- **Access for the Medically Underserved.** All the applicants project Medicare and Medicaid access based on their historical experience. Therefore, all are effective alternatives as to access for the medically underserved.

PHSNC projects the greatest percentage of charity care and self-pay write offs as a percentage of gross revenues, as shown in the following table, and is therefore the most effective alternative with regard to provision of charity care. By contrast, Wake Radiology projects zero charity care with its project, and EmergeOrtho projects a tiny amount of charity care.

Projected Charity Care/Self-Pay Access

| Year 3 | PHSNC | DUHS | EO | Wake Rad | RR Cary | RR Knightdale |
|-----------------|------------------|----------|---------|----------|----------|---------------|
| Charity Care \$ | \$143,385 | \$86,525 | \$6,896 | \$0 | \$21,902 | \$94,698 |
| Charity Care % | 1.66% | 1.26% | 0.11% | 0.0% | 0.20% | 1.45% |

Source: CON Applications, Section Q, Form F.2.

- Projected Average Revenue per Scan.** PHSNC and Raleigh Radiology propose comparable charges for their fixed MRI scanner services, with market-competitive net revenue per scan. The DUHS, EmergeOrtho and Wake Radiology applications each project utilization that are not based on reasonable projections or unnecessary duplication. The discussion of each application regarding need and projected utilization found in Criterion (3), Criterion (6), and the Administrative Rules, are incorporated herein by reference. Therefore, the applications submitted by DUHS, EmergeOrtho and Wake Radiology are not approvable and therefore are not effective alternatives with regard to projected average revenue per MRI scan.
- Projected Average Operating Cost per Scan.** PHSNC and Raleigh Radiology project compelling and market-competitive operating expenses for their respective proposed fixed scanner service. The DUHS, EmergeOrtho and Wake Radiology applications each project average expense per scan that are not based on reasonable utilization projections. The discussion of each application regarding need and projected utilization found in Criterion (3) and the Administrative Rules is incorporated herein by reference. Therefore, the applications submitted by DUHS, EmergeOrtho and Wake Radiology are not approvable and therefore are not effective alternatives with regard to projected average expense per MRI scan.

Specific comments regarding the EmergeOrtho application (J-11821-19)

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

EmergeOrtho does not adequately demonstrate the need for the proposed project based on reasonable utilization projections. Therefore, EmergeOrtho fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2019 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, EmergeOrtho is not consistent with Policy GEN-3. The EmergeOrtho application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

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

EmergeOrtho’s projections for MRI procedures are unreasonable and unrealistic. On page 113 of its CON application, EmergeOrtho includes a table showing projected MRI procedures in Wake County. EmergeOrtho projected 118,085 unweighted MRI scans in Wake County in 2023. Based on the projected Wake County population of 1,188,474 (from NCOSBM), the projected MRI use rate in the EmergeOrtho projection methodology is 99.36 (118,085/1,188,474 x 1,000). This MRI use rate is much higher than the historical Wake County MRI use rate, as shown in the table below.

Wake County Historical MRI Utilization

| Year | County Population | Number of Procedures | Use Rate/1000 |
|--------|-------------------|----------------------|---------------|
| FY2013 | 964,771 | 74,803 | 77.5 |
| FY2014 | 985,056 | 82,107 | 83.4 |
| FY2015 | 1,007,641 | 85,731 | 85.1 |
| FY2016 | 1,030,326 | 92,547 | 89.8 |
| FY2017 | 1,052,120 | 90,481 | 86.0 |
| FY2018 | 1,073,993 | 97,057 | 90.4 |

Source: Population data from NCOSBM; MRI volume data from SMFPs
Totals may not foot due to rounding.

A much more reasonable and realistic methodology for projecting Wake County MRI procedures is to multiply the projected population by the historical Wake County MRI use rate (average use rate of 87.8 for the past three years). This more accurate approach results in a projection of the following MRI procedures in Wake County.

**Wake County
Projected MRI Procedures, CY2019 - CY2023**

| | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 |
|---------------------|--------|--------|--------|---------|---------|---------|
| Wake Co. procedures | 97,057 | 96,285 | 98,283 | 100,301 | 102,332 | 104,370 |

The Wake County MRI procedure calculation, which is step 2 of EmergeOrtho’s methodology, forms the basis for its projected utilization for the proposed fixed MRI scanner at the Duraleigh Road facility. In step 4 of its methodology, EmergeOrtho applies its annual market share assumption to the Wake County Total Unweighted MRI scans (calculated in step 2) to arrive at the projected unweighted MRI scans at EmergeOrtho Duraleigh through Project Year 3. The table below portrays EmergeOrtho’s projected unweighted procedures at EmergeOrtho Duraleigh based on the more accurate, realistic and reasonable growth assumption shown in the previous table (for example, $104,370 \times 4.3\% = 4,488$ unweighted MRI scans at EmergeOrtho Duraleigh in 2023).

EmergeOrtho – Projected Fixed MRI Procedures

| Duraleigh | CY20 | CY21 | CY22 | CY23 |
|--------------|-------|-------|-------|-------|
| Market share | 2.8% | 3.3% | 3.8% | 4.3% |
| Unweighted | 2,752 | 3,310 | 3,889 | 4,488 |
| Weight Ratio | 1.043 | 1.043 | 1.043 | 1.043 |
| Weighted | 2,870 | 3,452 | 4,056 | 4,681 |

With the EmergeOrtho projections adjusted to this more reasonable and historically accurate methodology, the resulting PY3 fixed MRI weighted scan utilization total is 4,681. This projection does not meet the required performance standard of 4,805 weighted MRI procedures per fixed scanner.

In summary, EmergeOrtho failed to demonstrate that its projected fixed MRI scanner procedure volume is based on reasonable and supported assumptions. Therefore, the EmergeOrtho application is nonconforming to Criterion 3.

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

EmergeOrtho does not adequately demonstrate that the alternative proposed in its application is the most effective to meet the need because the application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative. Therefore, the EmERGEOrtho application is not conforming to Criterion (4).

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

EmergeOrtho’s financial projections are not based on reasonable utilization projections as discussed in the Criterion 3 comments, and also are based on inadequate staffing, as discussed in the Criterion 7 comments. Consequently the financial projections are unreliable.

Further, EmERGEOrtho did not include all necessary capital costs, and did not demonstrate adequate funding for the project capital costs. Specifically, the capital cost table F.1a did not include any consultant fees associated with preparing and filing the CON application, did not include any project financing costs, and included no costs to cover interest during construction. As a result, the capital cost of \$1,973,097 is not accurate, and the funding letter is therefore insufficient for the actual project capital cost requirement. All of these errors and omissions result in the application not conforming to Criterion 5.

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

EmergeOrtho fails to demonstrate that its proposal would not result in unnecessary duplication of fixed MRI service because the utilization projections are unreliable. Therefore the application is not conforming to Criterion (6).

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

EmergeOrtho fails to show evidence of the availability of health manpower for the provision of the services proposed. The proposed staffing for the fixed MRI scanner is inadequate. Specifically, EmERGEOrtho’s staffing model in Form H does not show any staffing for support

services. In fact, support staff are non-existent, as there is no staff for patient scheduling, nor business office, nor sales. Therefore the application is not conforming to Criterion (7).

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

EmergeOrtho’s application fails to conform to Criterion (18a) because the proposal does not adequately demonstrate it will promote cost effective services. The applicant’s projected utilization is not based on reasonable and adequately supported assumptions, the staffing is inadequate, and the project capital cost is understated. The discussion regarding projected utilization, capital cost, and staffing found in Criteria (3), (5) and (7) are incorporated herein by reference.

10A NCAC 14C .2703 PERFORMANCE STANDARDS

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

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

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

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

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

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

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

The EmergeOrtho application does not conform to the performance standards applicable for the review of fixed MRI scanners. Utilization projections for the proposed EmergeOrtho fixed MRI scanner are not based on reasonable assumptions and methodology. The discussions regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Specific comments regarding the Duke Radiology Green Level application (J-11829-19)

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

DUHS does not adequately demonstrate the need for the proposed project based on reasonable utilization projections, and did not propose the least costly or most effective alternative. Therefore, DUHS fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2019 SMFP. The discussions regarding analysis of need, including projected utilization, found in Criterion (3) and regarding alternative methods in Criterion (4) are incorporated herein by reference. Therefore, DUHS is not consistent with Policy GEN-3. The DUHS application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

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

DUHS currently operates two fixed MRI scanners at Duke Raleigh Hospital, and recently received its Certificate of Need to develop a fixed MRI scanner in Holly Springs, which is not yet in operation. This additional approved MRI scanner will absorb a substantial portion of the DUHS hospital-based MRI volume. DUHS will thus have a lower cost freestanding diagnostic imaging option in Wake County for its patients who are appropriate for a freestanding setting. DUHS cannot demonstrate need for a fourth fixed MRI scanner when its third fixed scanner is not yet developed.

To produce the volume necessary to meet the MRI performance standards, DUHS relies on creative growth rates and a complex projection methodology. The application relies on convenience, not need, to support its projected shift to the Green Level location from various other DUHS locations, despite other existing or approved DUHS MRI locations being viable or yet under development as convenient alternative locations. The DUHS application appears to be designed more to preserve DUHS market share of existing MRI procedures and prevent other market entry than to serve an underserved population. Thus, the application fails to demonstrate the need of the population to be served.

Further, on page 9 of Section Q in its application, DUHS then attempts to validate its calculations with a projection of Wake County MRI utilization. However, DUHS’s projections for MRI procedures are unreasonable and unrealistic. On the table on page 9 showing projected MRI procedures in Wake County. DUHS projected 120,677 unweighted MRI scans in Wake County in 2025. Based on the projected Wake County population of 1,235,046 (from NCOSBM), the projected MRI use rate in the DUHS projection is 97.71 (120,677/1,235,046 x 1,000). This MRI use rate is much higher than the historical Wake County MRI use rate, as shown in the table below.

Wake County Historical MRI Utilization

| Year | County Population | Number of Procedures | Use Rate/1000 |
|--------|-------------------|----------------------|---------------|
| FY2013 | 964,771 | 74,803 | 77.5 |
| FY2014 | 985,056 | 82,107 | 83.4 |
| FY2015 | 1,007,641 | 85,731 | 85.1 |
| FY2016 | 1,030,326 | 92,547 | 89.8 |
| FY2017 | 1,052,120 | 90,481 | 86.0 |
| FY2018 | 1,073,993 | 97,057 | 90.4 |

Source: Population data from NCOSBM; MRI volume data from SMFPs
Totals may not foot due to rounding.

In summary, DUHS failed to demonstrate that its projected fixed MRI scanner procedure volume is based on reasonable and supported assumptions. Therefore, the DUHS application is nonconforming to Criterion 3.

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

DUHS does not adequately demonstrate that the alternative proposed in its application is the most effective to meet the need because the application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative. Also, the DUHS proposal is not the most effective or least costly option for several other reasons, including:

- DUHS’s capital cost of \$3.7M is high, the highest of all the applications.
- DUHS apparently plans to limit its hours of availability in at least the first project year, and perhaps beyond.
- DUHS projects to bring the scanner online later than every other applicant.
- DUHS is proposing a new diagnostic center with a single modality; MRI. This is a much more expensive alternative than adding MRI services to an existing facility.

- DUHS could have proposed replacing the mobile MRI service at its Cary Parkway location. But DUHS did not explain why development of the proposed fixed MRI scanner at the Cary Parkway location is not an effective alternative.

To develop a new MRI location, the more effective and less costly alternative would be to initiate the MRI service using a mobile MRI service, and after the MRI service at the prospective location is well established, replace the mobile MRI unit with a fixed MRI scanner. But DUHS did not explain why establishment of the Green Level site via use of a mobile MRI scanner -- to determine if it is a viable MRI location appropriate for future development of a fixed MRI scanner -- is not a more effective alternative.

Therefore, the DUHS application is not conforming to Criterion (4).

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

DUHS’s financial projections are not based on reasonable utilization projections as discussed in the Criterion 3 comments, and also are based on inadequate staffing, as discussed in the Criterion 7 comments. Consequently the financial projections are unreliable.

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

DUHS fails to demonstrate that its proposal would not result in unnecessary duplication of fixed MRI service because DUHS is already approved for, but has not yet developed, a third Wake County fixed MRI scanner in Holly Springs. Therefore, DUHS is proposing the unnecessary duplication of a fixed MRI scanner that the Agency has approved but that DUHS has not yet made operational. Further, with this proposal, DUHS appears to be duplicating the mobile unit service at Cary Parkway, which DUHS states will continue to operate at that location for the foreseeable future. In addition, the utilization projections are unreasonable. Therefore the application is not conforming to Criterion (6).

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

DUHS fails to show evidence of the availability of health manpower for the provision of the services proposed. The proposed staffing for the fixed MRI scanner is inadequate. Specifically, DUHS’s staffing model in Form H shows only 1.12 FTE MRI Tech in the first project year. This is insufficient to provide MRI services for more than approximately 45 hours per week. Therefore the application is not conforming to Criterion (7).

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

DUHS’s application fails to conform to Criterion (18a) because the proposal does not adequately demonstrate it will promote cost effective services. The applicant’s projected utilization is not based on reasonable and adequately supported assumptions, and the staffing is inadequate. And DUHS is proposing to unnecessarily duplicate a fixed MRI scanner that it has not yet even developed. The discussion regarding projected utilization, alternatives, unnecessary duplication and staffing found in Criteria (3), (4), (5), (6), and (7) are incorporated herein by reference.

10A NCAC 14C .2703 PERFORMANCE STANDARDS

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

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

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

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

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

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

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

The DUHS application does not conform to the performance standards applicable for the review of fixed MRI scanners. Utilization projections for the proposed DUHS fixed MRI scanner are not based on reasonable assumptions and methodology. The discussions regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Specific comments regarding the Wake Radiology Cary application (J-11830-19)

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

Wake Radiology (WR) does not demonstrate that the proposed project does not represent unnecessary duplication of existing MRI capacity at WR and UNC Rex. Therefore, WR fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2019 SMFP. The discussion regarding unnecessary duplication, found in Criterion (6) and the applicable .2700 MRI Scanner administrative rules, are incorporated herein by reference. Therefore, WR is not consistent with Policy GEN-3. The WR application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

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

WR does not adequately demonstrate that the alternative proposed in its application is the most effective to meet the need because the application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative. Therefore, the WR application is not conforming to Criterion (4).

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

WR’s financial projections are not based on reasonable staffing expenses as discussed in the Criterion 7 comments. Consequently the financial projections are unreliable.

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

WR fails to demonstrate that its proposal would not result in unnecessary duplication of fixed MRI service. WR is a joint venture of Wake Radiology and UNC Rex, which combined currently operate seven fixed MRI scanners in Wake County. The WR application appears to be designed to preserve WR/UNC Rex market share of existing MRI procedures, and prevent

other market entry, and thus represents unnecessary duplication of existing MRI capacity at WR and UNC Rex. Therefore the application is not conforming to Criterion (6).

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

WR fails to show evidence of the availability of health manpower for the provision of the services proposed. The proposed staffing for the fixed MRI scanner is unreasonable. Specifically, WR’s staffing model in Form H does not allocate any administrator time/expense to the fixed MRI scanner. This appears to be an attempt to reduce the WR MRI operating expenses to make the WR application seem more competitive for the Agency Comparative Analysis. Therefore the application is not conforming to Criterion (7).

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

WR’s application fails to conform to Criterion (18a) because the proposal does not adequately demonstrate it will promote cost effective services. The applicant’s staffing is inadequate. The discussion regarding projected alternatives, unnecessary duplication, and staffing found in Criteria (4), (5), (6) and (7) are incorporated herein by reference.

10A NCAC 14C .2703 PERFORMANCE STANDARDS

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

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

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

(3) demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI

service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:

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

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

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

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

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

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

The WR application does not conform to the performance standards applicable for the review of fixed MRI scanners. Utilization projections for the existing WR fixed and mobile MRI scanners are not based on reasonable assumptions and methodology. And in fact, WR tries to cover this up by claiming on pages 50 and 51 of its application that the MRI Performance Standards .2703(b)(1) and (b)(2) do not apply to its application. This of course, is nonsense, as the applicant owned the relevant fixed and mobile MRI scanners as of the time of submission of the CON application, and in fact, a related entity owned the relevant scanners prior. The Agency has applied this standard in a recent fixed MRI scanner batch review. Specifically, in the 2016 Guilford County MRI review, one of the applicants (WFBI) stated that it expected one of its members (WFBH) would acquire Cornerstone during the review of the CON application, gaining control of Cornerstone's existing assets, including its existing fixed MRI scanner in Guilford County. Therefore, as WFBH was a related entity, the applicant provided the relevant historical utilization for Cornerstone's fixed MRI scanner. The Agency included this information in the Agency Findings when reviewing the WFBI application as to conformity to the .2703(b)(1) Performance Standards.

In Exhibit C.12-1 of its application, WR provides a confusing narrative of the fixed MRI scanner that will be located at UNC Rex Holly Springs hospital. This magnet only projects to perform 1,455 weighted MRI scans by Project Year 3. This data shows that the utilization of that fixed MRI scanner did not meet the required performance standard (.2703(b)(1)) of 3,328 weighted scans for the most recent 12-month period.

In Exhibit C.12-3 of its application, WR summarizes its historical utilization of the two existing mobile MRI scanners. This data shows that the utilization of neither existing WR mobile scanner met the required performance standard (.2703(b)(2)) of 3,328 weighted scans for the most recent 12-month period, with just 2,383 and 1,803 weighted scans, respectively, during CY2018.

Regarding projected mobile MRI scanner utilization, WR states that one of its two existing mobile MRI scanners will serve a new Panther Creek location. Thus, this site is not a proven site for provision of MRI services, with no historical utilization. Yet in its application, WR projects that this mobile scanner will increase its current utilization by an astounding average annual rate of growth of 11.9%. This is neither realistic nor reasonable.

In addition, WR attempts to use some sleight-of-hand in its presentation of historical use data for the second mobile unit. As shown on page 2 of Exhibit C12-3, for CY2019 data, WR opts only to use historical data from March – August 2019, and not January – February 2019. WR does not explain why in its application. One can only surmise that this is because the data for those months is not helpful to WR in manufacturing its already fanciful utilization projection methodology.

In summary, WR did not meet the performance standards in .2703(b)(1) and (2), and the application is therefore non-conforming. Also, the mobile MRI projection is clearly not reasonable, and the application is not conforming to .2703(b)(5).