**Comments on Competing Applications for a Fixed MRI Scanner in Wake County**

*submitted by*

**WR Imaging, LLC and Wake Radiology Diagnostic Imaging, Inc.**

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), WR Imaging, LLC and Wake Radiology Diagnostic Imaging, Inc. (collectively, "Wake Radiology" or "WR") submit the following comments related to competing applications to develop one additional fixed MRI scanner in Wake County. WR's comments on these competing applications include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards*[1]." *See* N.C. GEN. STAT. § 131E-185(a1)(1)(c). To facilitate the Agency's review of these comments, WR has organized its discussion by issue, noting some of the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity on the following applications:

- **Duke University Health System, Inc. ("Duke"), Project ID # J-12073-21**
- **Pinnacle Health Services of North Carolina, LLC ("PHSNC"), Project ID # J-12063-21**

**GENERAL COMMENTS ON COMPETITIVE REVIEW**

Among the three competing applications in this review, all propose to develop a fixed MRI scanner in a freestanding (i.e. non-hospital based) setting, which is a lower cost environment compared to existing hospital-based scanners. While all three applications proport to be applying to meet the need that is currently being served at their proposed site of care, WR's proposal is the only one that is needed to guarantee the long-term accessibility of MRI capacity at its proposed site. Specifically, the proposal by Duke is to expand fixed MRI capacity on the campus of Duke Raleigh Hospital, which already is home to a Duke owned hospital-based MRI. The proposal by PHSNC would replace the MRI service at CPIC Wake Forest which is currently provided by its own mobile MRI unit. By contrast, WR proposes to develop a fixed MRI unit at its Wake Radiology Garner location where the MRI scanner that currently operates is owned by Alliance Healthcare Services (Alliance). As a contracted service, Wake Radiology cannot guarantee the long term accessibility of this MRI scanner at Wake Radiology Garner. In addition, the annual cost to contract for the MRI scanner at Wake Radiology Garner alone is approximately $1.1M. As such, WR's proposal is the only one that would ensure the long-term accessibility of MRI services in an area of the county, Garner, which does not have any other fixed MRI capacity.

**COMMENTS REGARDING COMPARATIVE ANALYSIS**

On a cursory level, all of the applications appear to expand access to non-hospital-based outpatient MRI services. However, the comparative factors should be considered in light of the issues with several of the applications, as well as the overall need for additional MRI capacity in Wake County. For the comparative factors involving financial metrics, WR notes that the competing applications have errors or omissions that render their projected financial statements

[1] Wake Radiology is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to its application as filed April 15, 2021.

invalid, including projected revenue, expenses and payor mix; therefore, a meaningful comparison is not possible. Further, the competing applications should be found to be less effective on a comparative basis for those factors derived from statutory review criteria with which they are non-conforming.

**COMMENTS ON DUKE IMAGING NORTH RALEIGH**

**Issue-Specific Comments**

Duke fails to demonstrate that its utilization projections are reasonable.

On page 92 of its application, Duke estimates its FY 2021 MRI utilization at Duke Raleigh Hospital (DRAH) at 13,632 procedures based on an annualizing the first seven months of FY 2021 utilizing volumes for July to Jan (FY 2021) as shown below.

Step 1
DUHS first projected anticipated Duke Raleigh Hospital MRI utilization absent any shifts to other new, approved, or proposed MRI facilities. DUHS calculated existing MRI volume at Duke Raleigh Hospital for the first 7 periods of FY 2021 (July 2020-January 2021).

| | FY2021 |
|---|---|
| FY21 DRAH MRI Volume (IP) | 1,209 |
| FY21 DRAH MRI Volume (OP) | 6,743 |
| FY21 DRAH MRI Volume (ED) | 50 |
| **FY21 DRAH MRI Volume (Total)** | **8,002** |

However, this utilization appears to contradict data previously provided by Duke total procedures by month for DRAH for CY 2020. As shown on page 35 (excerpted below), DRAH's total MRI procedure count for the months of July to December 2020 was 5,702 (or only 11,404 procedures annualized).

Monthly data for Duke Raleigh Hospital MRI utilization in calendar 2020 clearly demonstrates the trend in utilization that led to this decrease in total volume from FY 2019, as well as the return to more typical utilization patterns by the end of calendar 2020:

**Duke Raleigh Hospital total MRI procedure by month (2020)**

| | |
|---|---|
| January | 1066 |
| February | 934 |
| March | 725 |
| April | 256 |
| May | 549 |
| June | 944 |
| July | 917 |
| August | 886 |
| September | 1036 |
| October | 988 |
| November | 940 |
| December | 935 |

In order for DRAH to provided 8,002 procedures in the first seven months of FY21 as stated on page 92, it would have needed to perform 2,300 procedures in January 2021. As shown in the monthly procedure counts above, DRAH highest monthly total since January 2020 was 1,066 procedures. Thus, it is unlikely that DRAH performed more than double that number in January 2021.

Additionally, Duke provides unreasonable volume projections for Duke Imaging Holly Springs. While that facility has been operational since May 2020 (per page 65), Duke provides no actual utilization for the facility and assumes that it will provide 4,656 procedures in FY 2021 based on market projections. As shown above, Duke had utilization data for DRAH through January 2021 for DRAH and would have had similar actual recent historical data for Duke Imaging Holly Springs. Duke makes no attempt to evaluate its actual performance in the market since it opened Duke Imaging Holly Springs or explain why it could not do so. As Duke failed to provide such information, its projected utilization for Duke Imaging Holly Springs is unsupported.

**Based on these issues, the application should be found non-conforming with Criteria 1, 3, 4, 5, 6 and 18(a), as well as the performance standards at 10A NCAC 14C .2103, and the Duke application should be denied.**

**COMMENTS ON PINNACLE HEALTH SERVICES OF NC**

**Issue-Specific Comments**

PHSNC fails to demonstrate that its project schedule is reasonable.

As described on page 26 of its application, PHSNC proposes to "*renovate vacant shell space to install and operate the fixed MRI scanner at the facility.*" On page 106, PHSNC indicates that the construction contract would be executed on November 2, 2021 and that construction would be completed December 17, 2021, 45 days later.

| Milestone | | Date mm/dd/yyyy |
|---|---|---|
| 1 | Financing Obtained | 10/01/2021 |
| 2 | Drawings Completed | 10/01/2021 |
| 3 | Land Acquired | N.A.* |
| 4 | Construction / Renovation Contract(s) Executed | 11/02/2021 |
| 5 | 25% of Construction / Renovation Completed (25% of the cost is in place) | 11/12/2021 |
| 6 | 50% of Construction / Renovation Completed | 11/24/2021 |
| 7 | 75% of Construction / Renovation Completed | 12/06/2021 |
| 8 | Construction / Renovation Completed | 12/17/2021 |
| 9 | Equipment Ordered | 11/02/2021 |
| 10 | Equipment Installed | 12/17/2021 |
| 11 | Equipment Operational | 12/20/2021 |
| 12 | Building / Space Occupied | 12/17/2021 |
| 13 | Licensure Obtained | N.A.* |
| **14** | **Services Offered** * | 01/01/2022 |
| 15 | Medicare and / or Medicaid Certification Obtained | N.A.* |
| 16 | Facility or Service Accredited | 01/01/2023 |
| 17 | First Annual Report Due * ^ | 04/01/2023 |

* Required

PHSNC does provide reasonable support that the proposed 45-day construction timeline to install all infrastructure and shielding is reasonable.

By contrast, in its 2019 CON application to develop a fixed MRI, with an identical scope (renovation of vacant shell space at the same location), PHSNC indicated it would take 108 days between contract execution and construction completion, almost 2.5 times longer than its currently assumed timeline.

| | | |
|---|---|---|
| 1. | **Financing for Project Obtained** | 06/15/2020 |
| 2. | **Drawings Completed** | 11/15/2019 |
| 3. | **Land Acquired** | NA* |
| 4. | **Construction / Renovation Contract(s) Executed** | 08/15/2020 |
| 5. | **25% of Construction / Renovation Completed (25% of the cost is in place)** | 09/01/2020 |
| 6. | **50% of Construction / Renovation Completed** | 10/01/2020 |
| 7. | **75% of Construction / Renovation Completed** | 11/01/2020 |
| 8. | **Construction / Renovation Completed** | 12/01/2020 |

Source: Project ID # J-11820-19

**Based on these issues, the application should be found non-conforming with Criterion 12 and the PHSNC application should be denied.**

PHSNC fails to demonstrate that its utilization projections are reasonable.

The utilization projections and assumptions in Form C including several unreasonable and unsupported assumptions, as detailed below.

First, in Step 1, the application states that its "MRI utilization at CPIC Midtown decreased during CY2019 due to Bone & Join Surgery Clinic (BJSC) obtaining its own 3T MRI scanner to replace a previously approved limited-use Extremity MRI and performing their spine and other MRI scans on their new magnet. The departure of BJSC referrals was a one-time impact, and frees up PHSNC to serve other referral sources" (page 115). However, PHSNC does not adequately demonstrate that the impact of the BJSC was "one-time" or that other referral sources will choose to be served by PHSNC. According to its historical utilization table on page 115, PHSNC's CAGR from 2015 to 2019 at CPIC Midtown was -3.8 percent for fixed unweighted MRI procedures. PHSNC performed 5,830 fixed unweighted MRI procedures in 2019 and, subsequently, 4,240 fixed unweighted MRI procedures in 2020 at CPIC Midtown.

**Pinnacle Health Services of North Carolina**
**Historical CPIC Midtown MRI Utilization, CY2015 - CY2020**

| Year | 2015 | 2016 | 2017 | 2018 | 2019 | 2020* |
|---|---|---|---|---|---|---|
| fixed unweighted procedures | 6,814 | 7,147 | 7,228 | 7,624 | 5,830 | 4,240 |
| mobile unweighted procedures | - | 67 | 639 | 729 | 629 | 646 |
| total unweighted procedures | 6,814 | 7,214 | 7,867 | 8,353 | 6,459 | 4,886 |
| weighted procedures | 7,836 | 8,300 | 8,374 | 9,021 | 7,137 | 6,194 |
| weighting ratio | 1.15 | 1.15 | 1.06 | 1.08 | 1.11 | 1.27 |

Data reported for calendar years, which differs from data shown in SMFPs, which is federal fiscal year.
*This data reflects the anomalous impact of the COVID-19 pandemic, which negatively impacted CY2020 utilization.

PHSNC states that its 2020 data reflects the anomalous impact of the COVID-19 pandemic. However, a comparison of 2019 and 2020 indicates that CPIC Midtown's fixed MRI utilization has declined beyond its 2019 levels, after accounting for the impact of COVID-19. As shown below, if it is assumed that CPIC Midtown's MRI service was not offered from March through May (the three months where MRI utilization in Wake County was most impacted by COVID-19 according to WR's experience) and only was only operational for nine months of 2019, CPIC Midtown's MRI utilization per month in 2019 was 3.0 percent less than in 2020.

| | ***2019*** | ***2020*** | ***% Difference*** |
|---|---|---|---|
| Fixed Unweighted Procedures | 5,830 | 4,240 | -27.3% |
| Assumed Months of Operation | 12 | 9 | |
| Procedures per Month | 486 | 471 | -3.0% |

Despite this apparent decline, PHSNC assumes that CPIC Midtown's MRI utilization will grow 1.86 percent annually in the future. The application fails to demonstrate that its projected growth rate is reasonable, given this issue and absent any other compelling factors to support its projected growth rate.

In Step 3, the application projects total Wake County MRI procedures. While the application states that it applied a use rate to Wake County population, the application omits the population data or methodology used to calculate the projected procedures. As such, the resulting projections are unsupported and unreasonable.

In the same step, the application projects future volume at Wake Forest assuming an annual growth rate plus market share growth. While the application states that is baseline growth rate is conservative compared to its historical growth, it fails to demonstrate why it is reasonable to assume that its baseline growth does not already include any potential market share increases. In other words, the application fails to demonstrate why it is not reasonable to assume that its annual growth rate already includes market share increases.

In Step 4, the application projects additional volume growth at Wake Forest from shifts from CPIC Midtown. PHSNC does not provide data to demonstrate that the assumed shifts are reasonable. Specifically, PHSNC only provides the projected number of unweighted MRI procedures that it assumes will result from these shifts in 2022 to 2024. It does not indicate how it projected these future volumes such as what base year was used (as shown above, CPIC Midtown's volume has declined in 2019 and 2020) and how those base year volumes were projected into the future. Further, as in Step 3, the application fails to demonstrate why it is not reasonable to assume that its projected growth rate at Wake Forest percent does not already include a shift in patients from Midtown site.

The combination of the various "growth" and "shift" assumptions in the application results in an unreasonably high and unsupported growth in utilization projections for the proposed MRI at Wake Forest. Although the application fails to show this combined growth rate, the table below provides this calculation.

| | ***2019*** | ***2020*** | ***2021*** | ***2022*** | ***2023*** | ***2024*** | ***2021-2024 CAGR*** |
|---|---|---|---|---|---|---|---|
| Unweighted Procedures | 2,627 | 1,988 | 2,627 | 3,641 | 4,087 | 4,547 | 20.1% |

As shown, the application projects an incredible CAGR of more than 20 percent from 2021 to 2024, which is clearly unreasonable and unsupported.

The application projects utilization for its mobile MRI scanner starting on page 124. These projections are also unsupported and lack necessary information to demonstrate that they are reasonable. In particular, the application omits data for each site (Midtown, Wake Forest and Clayton) to demonstrate what has historically been performed and what is projected on the mobile unit by site and by year. Without these data, it is impossible to recreate or verify the application's assumptions. Further, the application states that the mobile scanner will continue to serve Midtown, without demonstrating the need to do so or the projected volume for this site. As shown in Step 1 of the methodology, only 729 mobile procedures were performed at Midtown in 2018, the highest reported volume year, and the total projected unweighted MRI procedures for the fixed unit at Midtown in 2024 (5,324) are projected to be 2,300 procedures lower than in 2018.

**Based on these issues, the application should be found non-conforming with Criteria 1, 3, 4, 5, 6 and 18(a), as well as the performance standards at 10A NCAC 14C .2103, and the PHSNC application should be denied.**