

**Comments on Raleigh Radiology, LLC's Application for a New Diagnostic Center in Wake County
(Project ID #J-11800-19)**

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 "WR") submit the following comments related to the above-referenced application to develop a diagnostic center in Wake County. WR's comments on this application 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."* 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 creating the non-conformity in the application.

General Comments

The proposed project would establish a new diagnostic center **less than one mile from an existing facility** providing the same services, and in close proximity to several other facilities that provide these services. The development of a new diagnostic center is regulated by the CON statute for a reason, and WR believes that the application should be scrutinized with the same intensity of any other application, including the issues highlighted below. Approval of the proposed project will not meet an unmet need in Wake County, but will result in unnecessary duplication of existing resources, which the application has failed to adequately address.

Issue-Specific Comments

1. The application fails to adequately identify the patient population to be served.

The application contains inconsistent and conflicting information regarding the proposed patient population. In Section C.3, the application projects 95 percent of its patients to come from Wake and Harnett counties, with the remaining five percent from out of the service area. Wake County is in Health Service Area (HSA) IV; Harnett County is in HSA V.

In Section Q, page 115, the application projects that seven percent of its patients will come from outside its service area.

In Section J, page 81, the application states that "26.4 percent of its patients will come from outside of the HSA where the project is located and from non-adjacent HSAs." Section J.2 identifies the non-adjacent HSAs for HSA IV (site of the proposed project) as HSAs I and III. Therefore, since the application projects 26.4 percent of its patients will come from non-adjacent HSAs, 26.4 percent of its patients will come from HSAs I and III, which are located in the western part of the state. The closest county seat to the proposed project in HSA III is Albemarle, in Stanley County, over 100 miles and two hours from the proposed project. The closest County seat in HSA I is Hickory, in Catawba County, approximately 175 miles and three hours away. The application fails to demonstrate the need patients from this distance have for the proposed project, given the number of diagnostic centers and CT scanners closer to them. Moreover, it is completely

unreasonable for the application to assume that over one-quarter of its patient population will originate from such distant locations. The application makes no attempt to explain why patients from these areas will travel to the proposed location for a CT scan or any other service.

Thus, the application states inconsistently that either five, seven or 26.4 percent of its patients will originate from outside the service area, perhaps from as far away as western North Carolina.

Based on both the inconsistencies and the unreasonable assumptions, the application should be found non-conforming with Criteria 1, 3, 4, 5 and 6.

2. The application fails to demonstrate the need the patient population has for the proposed project.

a. *No demonstration of lack of access to the proposed services*

The application provides no evidence that patients cannot currently access CT or other services. While the application states that there are at least two existing CT providers in the service area, it fails to adequately describe the existing and approved services that are available to residents of the Fuquay-Varina area. As shown in the following table, there are numerous existing and approved facilities available to serve patients from the service area.

<i>Facility</i>	<i>Distance to Proposed Site</i>	<i>Drive Time to Proposed Site</i>
Wake Radiology Fuquay-Varina	0.7 miles	3 minutes
UNC REX Hospital Holly Springs (under construction)	5.3 miles	12 minutes
Valley Radiology	7.3 miles	12 minutes
ECMC	7.0 miles	Not provided
Central Harnett Hospital	13.9 miles	21 minutes

Sources: Google maps; Application Exhibit C.4, page 44

As shown, several providers are approved to provide CT services in the area. Further, while the distance/drive times shown are to the proposed site, it should be noted that some of these providers are closer to parts of the service area than the proposed location. For example, much of the Harnett County portion of the service area is closer to Central Harnett Hospital or Valley Radiology than to the proposed facility. The majority of the service area, which extends well north and east of the town of Fuquay-Varina, is closer to Wake Radiology Fuquay-Varina.

The application fails to provide any discussion or rationale as to why patients cannot access these existing facilities, particularly Wake Radiology Fuquay-Varina, **which is less than one mile from the proposed facility** and has capacity to serve additional patients.

This issue is also demonstrated by the numerous support letters from providers outside the service area, including Apex, Holly Springs and Cary. Although the letters do not state that the providers serve patients from the service area, even assuming they do, patients traveling to Apex, Holly Springs and Cary for physician services would have access to other imaging providers for CT services near those practices, including, for instance, Raleigh Radiology’s Cary

facility. Thus, it is unreasonable to assume that patients, including patients served by supporting providers, do not already have ample access to CT services.

b. Unreasonable utilization assumptions

The application’s methodology for projecting utilization includes multiple unreasonable assumptions; thus, the projected utilization based on those assumptions is not credible.

1) Unreasonable use rate

The application attempts to calculate an appropriate use rate by analyzing the number of CT scans performed in hospitals and ambulatory surgical facilities (ASFs), then discounting that number to isolate outpatient scans. The application’s methodology is unreasonable for several reasons. First, it provides no rationale for the “60 percent” adjustment, including whether it is based on any actual data analysis or just a random assumption. As such, there is no basis for the assumption or any evidence that it is reasonable. Second, at best, the calculated use rate is for outpatient CT scans in a hospital or ASF setting, not a physician office. Given the high use of CT scans for emergency patients, most of which are discharged and thus considered outpatients, the use rate includes outpatients served by emergency departments, which are inappropriate for the proposed facility.

Further, the application provides evidence that makes the use rate assumption unreasonable. In Section C.4, page 36, the application cites a *JAMA* article regarding CT use rates by age cohort. When applying these use rates by age to the Fuquay-Varina population, the following CT use rate is calculated:

Age Cohort	Use Rate	Population Percentage	Weighted Use Rate
a	b	c	d
Under 18	22	29.3%	6.446
18-64	134	58.8%	78.792
65 and Over	428	11.9%	50.932
Total CT Use Rate (All Settings)			136.17

a: cohorts provided on application page 36

b: Use rates provided by cohort on application page 36

c: population under 18 and 65+ from US Census 2018¹; population 18-64 calculated as balance

d: Use rate x Percentage of population

Using data in the application, the CT use rate for all settings is much lower than that projected in the application, and when adjusted for outpatient scans provided in a physician office setting, it would be even lower.

¹ <https://www.census.gov/quickfacts/fact/table/fuquayvarinatownnorthcarolina,US/PST045218>; Fuquay-Varina population used as proxy for service area population as application contains no data for service area population by these age cohorts.

2) Unreasonable market share assumptions

In Step 3, page 114, the application projects its CT market share for the service area to be 25 percent by the third project year. This assumption is unreasonably high, for several reasons. First, as noted above, the use rate projected by the application is also high and includes outpatient scans performed in an emergency department. The proposed facility cannot serve this patient population. Second, there are numerous existing and approved CT scanners that will compete for this market share, including those located closer to the offices of physicians who submitted letters of support; assuming that one in every four outpatient CT scans performed on residents of the service area will come to the proposed facility is simply not reasonable. Finally, the application provides no evidence that its existing long-standing facilities with CT scanners have achieved that level of market share. In fact, evidence in the application points to much lower market share for Raleigh Radiology's existing facilities. In Exhibit C.12, the application states that its Cary facility performed 3,543 CT scans in 2019. Page 35 of the application provides the Wake County population for 2019 as 1,096,408; applying the application's CT use rate of 123.63 per 1,000 to this population results in 135,549 outpatient CT scans in Wake County. Thus, the Cary facility, which has existed for many years, has achieved only 2.6 percent market share in Wake County. Similarly, based on the applicant's Blue Ridge facility, which performed 4,376 CT scans in 2019, it has only achieved 3.2 percent market share in Wake County. It is clearly unreasonable to assume the proposed facility will achieve a 25 percent market share of the service area in three years. Even if comparing the projected volume to the volume at Raleigh Radiology Cary, it is clearly unreasonable to assume that the proposed facility will perform 3,404 CT scans in year 3, which is only slightly less than the number provided at Cary in 2019. Cary has a much higher population than the Fuquay-Varina service area and the Raleigh Radiology facility in Cary has existed for a number of years.

For these reasons, the application should be found non-conforming with Criteria 1, 3, 5, 6, and 18a.

3. The application fails to demonstrate sufficient staffing for the proposed project.

In Section C.7, page 43, the application states that the proposed service will be available 9.5 hours per day, five days per week, operating 51 weeks per year. The same section states that one person will be hired to staff the CT scanner.

Form F.3 assumptions, page 132, states that the tech is expected to have three weeks of paid time off per year.

Form H Staffing, pages 136 to 137, shows only 1.0 FTE for the CT tech in years 1 and 2, increasing to 1.5 FTEs in year 3.

Given the proposed operation of 9.5 hours per day, which is 47.5 hours per week, the application fails to demonstrate sufficient staffing to cover the hours of operation with only 1.0 FTE. Further, page 138 of the application assumes that the CT tech is also "covering" X-ray (presumably for lunch and other breaks) and could also do bone density scans. While CT techs are often able to perform X-rays and other types of similar scans, it would be unlikely that the other techs could

perform CT scans, and even if they could, there are not enough techs (2.0 additional FTEs) to cover CT and the four other modalities proposed in the application. As such, the application fails to demonstrate reasonable assumptions or sufficient staffing to cover the proposed service.

Based on this issue, the application should be found non-conforming with Criteria 3, 5, and 7.

4. The application fails to demonstrate the financial feasibility of the project.

The financial statements in the application contain numerous errors and omissions that render its projections unreasonable.

a. Unreasonable and unsupported revenue projections

The proposed project is a new site, which has been open less than one year. According to the income statement for 2019, the applicant is projecting to have negative net income in 2019. To overcome this loss, the application projects utilization and revenue to dramatically increase through the third project year, driven primarily by non-CT services for which the application provides no rationale or assumptions. Given the financial results for the current year and the reliance of the facility on the utilization and revenue from non-CT services, the application fails to demonstrate the financial feasibility of the project by omitting its assumptions for these services.

The application provides no assumptions or any explanation of how the non-CT utilization and revenue was calculated. The financial statements include over \$9.4 million in revenue in year 3, only \$3 million of which, or less than one-third, is attributable to the proposed CT service. Therefore, the majority of the revenue for the proposed facility is derived from other services, for which the application provides no historical basis or assumptions for projecting future volume.

The application provides no gross revenue for the current year, even though the facility has been operating since January 1, 2019. Therefore, there is no foundation for the projected utilization and revenue for these services. According to the patient origin table in Section C.2, in the first eight months of the year, the applicant provided nearly 4,000 non-CT imaging procedures, which is 6,000 on an annualized basis. The application projects nearly 8,000 non-CT procedures in 2020 without any rationale for the basis of this projection. By the third project year, these procedures are projected to exceed 12,000 scans, again without any explanation or rationale to support the reasonableness of these assumptions. The application cannot demonstrate that its projections are reasonable given the complete lack of rationale for these projections, which encompass the majority of revenue for the proposed facility. As such, the application fails to demonstrate the financial feasibility of its proposal.

b. Understated expenses

- Staffing: the assumptions to the financial statements, page 132, state that salaries are increased by three percent per year; however, between 2019 and 2021, the first project year, salaries are only increased by approximately one-half that amount, resulting in understated expenses for salary and benefits, since the benefits are calculated as a percentage of salaries.

- Benefits: the financial statements project benefits to *decrease* in 2020 compared to 2019, then *decrease* again in the second project year compared to previous years. Given the increase in overall expenses, including staffing costs, the decrease in benefits cost is unreasonable.
- Housekeeping and laundry: this expense is projected to *decrease* over the current cost, yet the proposed project involves increasing the square footage of the facility. Moreover, the application projects significant increases in patient volume as described above, which would reasonably result in higher laundry expense. This expense item is therefore unreasonably low.
- Other expenses (office expenses): these expenses total more than \$50,000 in the current year (2019), yet the application fails to project any expense through the third project year, nor does it provide any reason that this expense will no longer be incurred.

Based on these issues, the application should be found non-conforming with Criteria 1, 5, and 18a.