

Comments on Raleigh Radiology Imaging Network, LLC and Raleigh Radiology, LLC's Application for a New Diagnostic Center in Wake County (Project ID #J-11756-19)

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, multi-million dollar diagnostic center in close proximity to several other facilities that are capable of providing the same services. The applicants are existing providers in the service area, yet the application contains scarce information about their existing operations, utilization, or patient population. 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. While Wake County is no doubt growing, it is also already served by numerous facilities with existing capacity. Approval of the proposed project will not meet an unmet need in Wake County, but will result in unnecessary duplication of existing resources, including facilities owned by the applicant.

Issue-Specific Comments

1. The application fails to demonstrate the need that patients have for the proposed project.
 - a. *No demonstration of lack of access to the proposed services*

The application includes several unsupported assertions as the basis of its need analysis for the project, including:

"The unavailability of freestanding imaging services forces patients to use the nearest hospital for diagnostic imaging..."

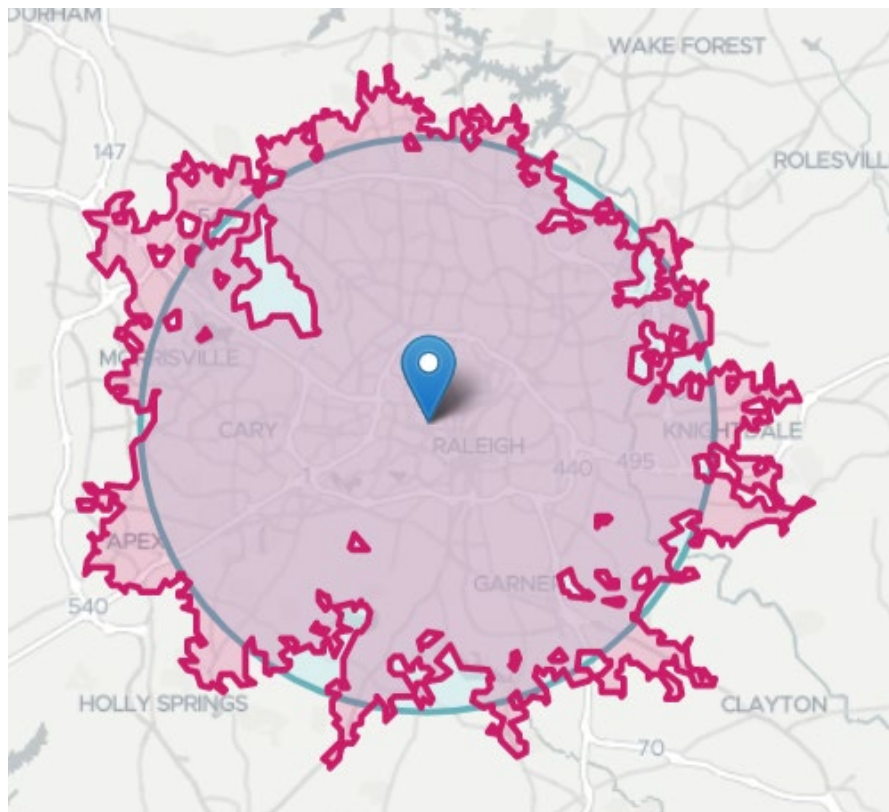
See application at page 32. The application includes no evidence to support this assertion, nor is it logical. Wake County residents have access to numerous freestanding imaging facilities geographically dispersed throughout the county, some of which are included in the list of existing facilities in Section G of the application. Some of these facilities are closer to the proposed site than any hospitals. These include facilities owned by the applicant and others within a short distance from the site of the proposed project, as shown in the table below.

<i>Facility</i>	<i>Distance to Proposed Site</i>	<i>Drive Time to Proposed Site</i>
Raleigh Radiology Blue Ridge	4.3 miles	10 minutes
Wake Radiology North Hills	3.7 miles	11 minutes
Wake Radiology West Raleigh	3.9 miles	9 minutes
Raleigh Radiology Cedarhurst	6.1 miles	15 minutes
Raleigh Radiology Cary	8.0 miles	13 minutes
Wake Radiology Cary	9.5 miles	15 minutes

Source: Applicant’s website; Google maps.

Of note, **there are at least six existing freestanding diagnostic centers within 20 minutes of the proposed site**, along with many others located elsewhere within Wake County, the service area. Since the application projects that most of its patients will originate from within a 20-minute drive of the proposed site, it has failed to demonstrate why these existing facilities are not meeting the need of the patient population.

As the following drive time map shows, a 20-minute drive of the proposed site encompasses a large portion of Wake County, including Cary, Morrisville, Apex, Garner, North Raleigh and parts of Knightdale. All four existing hospitals are included in this map, as well as numerous freestanding facilities. Although the application fails to provide a similar map, the map clearly shows that this area is much more than just the immediate “Cameron Village” area.



Source: <https://radiusmap.traveltimeplatform.com/>

Moreover, the application fails to demonstrate that the proposed facility is needed in the “Cameron Village” area. Certainly, throughout Wake County there are numerous discreet census tract groupings in which few or no diagnostic centers exist. The application fails to demonstrate any reason that patients cannot access services at any of the existing diagnostic centers in Wake County. As shown in the table above, there are numerous facilities within a 20-minute drive of the proposed facility, indicating reasonable access to the services proposed in the application.

b. Failure to provide any analysis or information regarding its own existing diagnostic centers

Notably missing from the application is any information regarding Raleigh Radiology’s existing diagnostic centers in the service area. According to its website (<https://www.raleighrad.com/locations/>), there are six existing locations in Wake County at which Raleigh Radiology provides diagnostic imaging services, with an seventh under development¹. As shown in the table above, three of these locations are within a 15-minute drive of the proposed site. The application provides no information regarding these facilities, including the number of patients it treats from the Cameron Village area, the existing capacity and utilization of the imaging equipment at its existing facilities, or any difficulties these facilities are having meeting the needs of their patients. It should also be noted that this issue is perpetuated elsewhere in the application with incorrect assertions, such as the notion that the proposed facility would introduce a “new” freestanding competitor to the service area, when that is clearly incorrect.

Information regarding its existing facilities is most notably missing from the application in Section G, which asks applicants to “[i]dentify all existing and approved facilities that provide the same service components proposed in this application and are located in the proposed service area.” The application provides a list of facilities in Table G.1, but **none of the existing Raleigh Radiology imaging centers are included in that list**. This error continues in Section G.2, which asks for utilization data for existing facilities. The application provides publicly available data for other facilities but **fails again to list its existing facilities or to provide their complete utilization data**. Finally, in Section G.3, the application fails to explain why it would not result in unnecessary duplication, not only of the existing facilities in the county, but its own imaging centers.

In fact, the only information provided in the application regarding Raleigh Radiology’s existing diagnostic centers is its historical CT volume, provided on page 62 and in Exhibit C.12. In that exhibit, the application provides limited information regarding the number of CT scans that have historically originated from ZIP codes that it assumes will be shifted to the proposed facility. This information demonstrates that patients from the “Cameron Village” area do have access to the proposed services, at existing Raleigh Radiology facilities in addition to others within the service area. It also demonstrates that Raleigh Radiology could have provided similar information for all its proposed modalities but failed to do so.

¹ The application lists only two other facilities as “diagnostic centers” that it owns on Form A; however, the applicant’s website shows more facilities that provide diagnostic imaging services for which the applicant should have data.

Given the lack of data and analysis in the application, it fails to demonstrate the need for another diagnostic center or that the project would not result in unnecessary duplication.

c. Failure to consider other available facilities in the service area

As noted above, there are numerous imaging centers within a 20-minute drive of the proposed facility. This statistic is relevant because of the applicant's assumption that most of its patients will come from within 20 minutes of the proposed site. The service area for the proposed project is much broader, however; it is all of Wake County. Within Wake County, patients have access to dozens of facilities that provide some or all of the proposed services. It is unreasonable to believe that none of them, either singularly or in the aggregate, have the capacity to accommodate the proposed patient population.

In particular, Wake Radiology's North Hills facility provides all of the services proposed in the application, is located only 11 minutes from the proposed site, and has available capacity to accommodate more patients. Similarly, Wake Radiology's West Raleigh facility provides all of the proposed services except DEXA, is located only nine minutes from the proposed site, and has available capacity to accommodate more patients. Wake Radiology's Cary facility provides all of the proposed services except DEXA, is located only 15 minutes from the proposed site, and has available capacity to accommodate more patients. These are only three of the many facilities that the application proposes to duplicate without any explanation of why patients cannot access services at any of them.

While the application asserts that it will provide the proposed services at a lower cost structure, it fails to demonstrate that patients cannot access the same services at a similar or even lower cost than it proposes. In Exhibit C.4, page 36, data show that there are numerous providers of the proposed services with comparable or lower charges, which the application fails to address.

d. Unreasonable utilization assumptions

The utilization assumptions and the projections that emanate from them are unreasonable. First, the application assumes that "20 percent of the Cameron Village geographic area need would be served at the proposed facility." The application provides no basis for this assumption whatsoever. As an existing operator of imaging centers, Raleigh Radiology certainly has access to its own data regarding volume and market share²; thus, it could have easily provided this data as a basis for projecting market share for the new facility. In addition, the application states that it regards this assumption as conservative because the "proposed facility would be one of only two multi-modality imaging providers in the Cameron Village geographic service area" and because "most other providers near the Cameron Village geographic area are hospitals..." As noted above, neither of these factors is accurate, as there are at least six existing multi-modality imaging centers within a 20-minute drive of the proposed site, which is more than the number of hospitals in the entire county.

² Note, in fact, that the application does include internal data, in Step 4, for example, showing the historical percentage of patients coming from outside Wake County.

The utilization projections also calculate market share based on this unsupported 20 percent of patients, multiplied by the percentage of the county population residing in the “Cameron Village Geographic Area” census tracts. However, as shown in Table C.2 on page 40, the population of the “Cameron Village Geographic Area” is growing slower than the rest of the county, and as a result, it represents a shrinking percentage of the Wake County population. Accordingly, even if the application’s assumptions were otherwise reasonable, it should have deflated its market share projections each year to demonstrate the slower growing patient population. By failing to make such an adjustment, the application has overstated its market share and utilization projections.

The utilization projections are also unreasonable because they assume the same market share for each modality. Even assuming the market share assumptions were valid for one modality, it is simply unreasonable to assume they would be identical for each modality. For example, using Table G.1 in the application, even with the missing facilities, it is clear that there are many more facilities with X-ray units than facilities with DEXA. As such, for X-ray, the proposed facility will be competing with many more providers than it would be for DEXA, and its market share will reflect the different competitive environment.

For these reasons, the application should be found non-conforming with Criteria 1, 3, 4, 5 and 6.

2. The application fails to demonstrate conformity with Policy GEN-4.

In response to this policy in Section B, the applicant provides information for WakeMed, which is not an applicant. Whether intentional or not, this clearly does not meet the requirements of Policy GEN-4, for several reasons. First, one of the applicants, Raleigh Radiology Imaging Network, LLC, proposes more than \$800,000 in capital costs for construction/upfit and contingencies. Thus, at a minimum, Raleigh Radiology Imaging Network, LLC must provide a written plan to describe the project’s plan for energy efficiency and water conservation, which it failed to do. Next, the plans of WakeMed relating to developing the physician office building in which the proposed project will be developed are insufficient, as the project being proposed in the application is the development of a diagnostic center and expenditure of capital by Raleigh Radiology Imaging Network, LLC, not the development of a physician office building by WakeMed, which is not an applicant. Finally, the last paragraph of Policy GEN-4 clearly indicates that it must be the applicant, not a third party, that is held accountable for carrying out the conditions of this policy, by referring to “[a]ny person awarded a certificate of need...is required to submit a plan...The plan must be consistent with the applicant’s representation....” Since Raleigh Radiology Imaging Network, LLC and Raleigh Radiology, LLC are the only two applicants, and since they will be the only ones listed on the certificate of need for the project, if awarded, they must provide their plans to demonstrate conformity with this policy, which they have failed to do.

For these reasons, the application should be found non-conforming with Criterion 1.

3. The application fails to demonstrate the availability of funds for capital and operating needs.

The application provides inconsistent information regarding the source of funds for the \$460,406 in working capital for the project. Table F.2 indicates that these funds will come from “cash or cash equivalents, accumulated reserves, or owner’s equity.” The response to Question F.3(f)

states that “[a]ccumulated reserves will fund working capital.” The response to Question F.3(g) states that “operating income will provide funding.” The response to Question F.3(h) states that the “applicants have accumulated reserves to fund working capital.” As a foundational matter, there is a significant difference between accumulated reserves, which are funds held and set aside for particular purposes, and operating income, which is the amount of profit generated, which may or may not be held and set aside for a later purpose. Thus, it is unclear what the actual source of these funds may be, either cash currently in-hand and being held for this purpose, or cash expected to be generated in the future.

In Exhibit F.2, the bank letter refers to the ability to fund the project through “cash flow.” While the bank does state that it examined the applicant’s most recent financials, there is no indication that it reviewed any pro forma statements of future operations, which would be needed to understand whether the applicant would reasonably have the cash flow—in the future—to fund the working capital needs for the proposed project. The lack of this information is critical, as the applicant must demonstrate that the funds are “reasonably likely to be available when needed,” as expressed in Question F.3(g). Absent any financial statements demonstrating the availability of reserve funds or other documentation showing the likely availability of funds in the future, the application fails to demonstrate the availability of these funds.

Based on this issue, the application should be found non-conforming with Criterion 5.

4. The application fails to demonstrate that the medically underserved will have adequate access to the proposed services.

In Section L.3, the application projects its payor mix, by modality, for the proposed project. In Section Q, page 157, the application states that payor mix is based on its “historical data for imaging by modality in Wake County.” Thus, the application assumes the same payor mix for the proposed facility as its other facilities in Wake County. This is unreasonable, based on the application’s analysis of need and the demographics of the service area. Specifically, Section C.4 refers to higher poverty rates, lower median incomes, higher minority population, and other social determinates of health in the area near the proposed site that are worse than the county overall. As such, if the applicant actually intends to expand access to this underserved population, its payor mix should reflect a higher percentage of care to the medically underserved. Since the application projects that most of its patients will come from within 20 minutes of the proposed site, it is reasonable to assume that the payor mix should reflect the different demographics of the area, upon which the application bases the need for the proposed project.

Based on this issue, the application should be found non-conforming with Criterion 13(c).

5. **The application fails to consider a more cost effective alternative to the proposed project.**

As noted in several comments above, there are numerous facilities throughout Wake County providing the same services as proposed in the application. Several of these facilities are Raleigh Radiology facilities, some of which are located a short distance from the proposed site. According to data provided in the application regarding CT utilization at these facilities, patients from the “Cameron Village Geographic Area” have historically been served at Raleigh Radiology’s Blue Ridge and Cary facilities. Given the proximity of these facilities to the proposed site (10 minutes and 13 minutes, respectively), a more cost effective alternative would be to add capacity at these

sites rather than spend capital on the upfit of new space, as well as incurring the ongoing operational cost of a lease expense in perpetuity.

Based on the failure to consider this less costly alternative, the application should be found non-conforming with Criterion 4.