

COMMENTS OF WR IMAGING, LLC AND WAKE
RADIOLOGY DIAGNOSTIC IMAGING, INC.

REGARDING PROJECT ID J-012060-21:

A PROPOSAL BY RR WM IMAGING HOLLY SPRINGS,
LLC TO DEVELOP A NEW DIAGNOSTIC CENTER IN
HOLLY SPRINGS, WAKE COUNTY TO INCLUDE
MAMMOGRAPHY, BONE DENSITY, X-RAY, AND
ULTRASOUND SERVICES

In accordance with N.C. Gen. Stat. § 131E-185(a1)(1), WR Imaging, LLC (“WRI”) and Wake Radiology Diagnostic Imaging, Inc. (“WRDI” and, collectively with WRI, the “Commenters”) submit the following comments related to the certificate of need (“CON”) application of RR WM Imaging Holly Springs, LLC d/b/a Raleigh Radiology Holly Springs (“RRHS”) to develop a diagnostic center in Holly Springs with mammography, x-ray, bone density, and ultrasound equipment, identified by the CON Section by Project ID J-012060-21 (the “Application”). The following comments include a “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, the Commenters have organized the discussion by issue, noting the relevant issues rendering the Application non-conforming with the statutory review criteria set forth in the CON law. The Commenters request a public hearing regarding the proposed project to more fully discuss, among other things, the issues and deficiencies set forth herein.

General Issues

The Application fails to comply with multiple relevant statutory review criteria because the Application:

- (i) relies on unsupported and/or unreasonable assumptions regarding projected need and utilization and fails to demonstrate the need for the proposed project;
- (ii) due to errors and unreasonable assumptions in its methodology to project need and utilization, fails to demonstrate the financial feasibility of the project;
- (iii) fails to reasonably account for the capacity of existing imaging service providers, within and immediately adjacent to the proposed service area, to serve the needs of the population in the proposed service area;
- (iv) fails to demonstrate how the proposed services will be provided in coordination with the existing healthcare system in the proposed service area;
- (v) fails to show how the proposed project will result in increased competition and lower prices for consumers and payors, and correspondingly why the project will not result in an unnecessary duplication of health resources in the service area, which unnecessary duplication “results in costly duplication and underuse of facilities, with

the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services.” See N.C. Gen. Stat. § 131E-175(4).

Because of these deficiencies, the Application fails demonstrate that the proposed project is consistent with or does not conflict with multiple statutory review criteria set forth at N.C. Gen. Stat. 131E-183(a), including criteria (3), (4), (5), (6), (8), (13), and (18a). The Agency is required to “review all applications utilizing the criteria outlined in [N.C. Gen. Stat. 131E-183(a), and to] determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.” *Id.* Because the Application fails to meet the requirements of multiple statutory review criteria, the Agency must deny the Application.

I. The Application Relies on Unsupported and Unreasonable Assumptions Regarding Need and Utilization.

a. The Application states that Raleigh Radiology’s existing Wake County facilities performed 22,071 procedures for patients residing in the proposed service area in 2020, reflecting 35% of imaging procedures in the service area. This indicates that Raleigh Radiology is already serving the likely portion of the population that will comprise its market share at existing Raleigh Radiology-affiliated facilities. It is reasonable to expect that these existing Raleigh radiology facilities will see a decrease in procedure volumes by modality if the RRHS project is developed. This duplication of existing health service facilities will lead to underutilization at current Raleigh Radiology facilities and potentially at the new RRHS facility, if developed. The General Assembly has found that the “proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services.” (See N.C. Gen. Stat. 131E-176(4))

b. The Application states that the need for cancer screenings will increase going forward as patients who delayed such screenings due to the COVID-19 pandemic schedule those screening appointments. However, any short-term demand from rebounding cancer screenings can and will be adequately addressed by existing health service facilities in the proposed service area.

c. To project the need for ultrasounds, RRHS evaluated several national studies to project the number of ultrasounds per 1,000 people, and ultimately calculated a calculated a rate using a 2016 National Ambulatory Medical Care Survey (“NAMCS”) that presented patient-recall data related to services provided in physician offices. The applicant then increased this number by

20% between 2016 and 2022 to project 101.72 ultrasounds per 1,000 population. However, RRHS did not state why a 20% increase in the NAMCS rate would be reasonable, nor why this national data would be applicable to the proposed service area, which has demographic and health-related characteristics that substantially deviate from the national average.

d. RRHS projects bone density scan need based on the 65 and older female population located in the same service area used for projecting x-rays and ultrasounds, and divides that population by two based on the CMS recommendation for bone density scans every two years in this population. However, the applicant states that CMS approves bone density scans every two years for women in this age demographic when their physician has determined that they are estrogen deficient. Not every woman in the service area over the age of 65 will have received such a diagnosis, and not all women in this age cohort who are estrogen deficient will actually receive a bone density scan every two years. This is an important distinction, and one that is noted in the CON Application of QC Radiology, LLC to develop a new diagnostic center in Wake County known as Raleigh Radiology Midtown and identified by project ID J-11988-20. In the Raleigh Radiology Midtown application, QC Radiology, LLC noted on page 52 of the application that the United States Preventative Services Task Force (“USPSTF”) recommends DEXA screening for women aged 65 or greater and who are not estrogen deficient only once every six years. The applicant’s methodology is therefore not “conservatively reasonable”, as the applicant itself appears to understand based on its application to develop Raleigh Radiology Midtown. Rather, it significantly overstates and artificially inflates the need and the likely demand for these services.

e. The deficiencies, errors, and unsupported assumptions in the applicant’s need methodology undermines the applicant’s forecasts of need for the proposed services in the service area defined in the Application, and undermines the applicant’s projections with respect to long-term financial feasibility of the project. As result, the applicant fails to demonstrate that the project is consistent with and/or does not conflict with statutory review criteria (3), (4), (5), (8), and (13).

II. The Application Fails to Consider Alternative Methods of Meeting the Need Projected in the Application, to Demonstrate that it Proposed the Least Costly Alternative, to Demonstrate that it will not Unnecessarily Duplicate the Services of Existing Providers, to Demonstrate Integration with Existing Health Service resources in the Service Area, or to Demonstrate that the Project will Increase Competition and Reduce Prices Rather

than Result in Unnecessary and Inefficient Duplication of Health Services that will Increase Prices.

The alternatives identified by RRHS included: maintaining the status quo, developing the project in a different area, and acquiring different quantities of medical diagnostic equipment. All were based on a faulty underlying premise that there is need for diagnostic imaging services in the service area that is not being met or capable of being met by existing service providers and recently approved service providers.

a. *Maintain the Status Quo.* RRHS rejected this alternative, in part, on the basis of community health risk factors. However, the factor's noted by RRHS do not support its arguments; for each noted factor, Wake County compares favorably to state averages. RRHS further justifies rejecting this alternative because patients may have to travel outside of the proposed service area and because wait times "could also increase" at existing facilities as population grows. However, RRHS fails to account for existing resources in and around the proposed service area with capacity to meet the needs of a growing population. RRHS also fails to acknowledge that, given its own assertion that 35% of the demand for imaging services in the proposed service area is already being met by existing Raleigh Radiology facilities in Wake County, these existing Raleigh Radiology facilities will presumably experience a decrease in volume, leading to underutilization and higher costs.

Even assuming that the need projections in the Application are accurate, which commenters reject for the reasons set forth herein, RRHS failed in its Application to consider the extent to which existing providers of mammography, x-ray, DEXA, and ultrasound services located within or proximate to the proposed service area have the capacity to meet that need. Commenters, for instance, operate diagnostic centers at 781 Avent Ferry Road in Holly Springs, less than one mile from the proposed RRHS facility, and at 7636 Purfoy Road in Fuquay Varina, less than five miles from the proposed RRHS facility. These facilities also offer mammography, ultrasound, bone density, and other imaging services.

The following three-step analysis shows Commenters' average procedure volumes at these facilities from 2017-2020, the capacity of such facilities based on their present hours of operation, and finally the capacity of those facilities and modalities to perform additional procedures.

a.1 Volume. Commenters performed the following volumes of imaging studies by modality at the Holly Springs and Fuquay Varina facilities in 2019-2020.

Procedure Volumes Commenters' Holly Springs Diagnostic Imaging Center, 2019-2020*		
	2019	2020
X-Ray	2582	2697
Bone Density	407	444
Ultrasound	143	726
Mammography	1781	2244

Procedure Volumes Commenters' Fuquay Varina Diagnostic Imaging Center, 2019-2020*		
	2019	2020
X-Ray	2582	2697
Bone Density	407	444
Ultrasound	143	726
Mammography	1781	2244

a.2 Capacity. The Daily and annual capacity for Commenters' Holly Springs and Fuquay Varina facilities are provided below.

Daily and Annual Capacity Commenters' Holly Springs Diagnostic Imaging Center		
	Daily Capacity	Annual Capacity*
X-Ray	32	8,384
Bone Density	16	4,192
Ultrasound	12	3,144

Mammography	32	8,384
Bone Density		

Daily and Annual Capacity Commenters' Fuquay Varina Diagnostic Imaging Center		
	Daily Capacity	Annual Capacity*
X-Ray	32	8,384
Bone Density	16	4,192
Ultrasound	12	3,144
Mammography	32	8,384

a.3 Remaining Capacity.

Comparing the experienced volumes from 2019-2020 with actual capacity, Commenters' Holly Springs and Fuquay Varina diagnostic imaging facilities have more than sufficient capacity to fully accommodate the 3,044 ultrasound studies, 5,380 mammography studies, 3,990 x-ray studies, and 880 bone density studies that RRHS projects it will perform at RRHS by 2025, which inflated volumes rely on unsupported projections of need in the service area and market share for the applicant.

Additional Capacity Commenters' Holly Springs Diagnostic Imaging Center	
X-Ray	5,240
Bone Density	3,668
Ultrasound	1,834
Mammography	5,502

Additional Capacity Commenters' Fuquay Varina Diagnostic Imaging Center	
X-Ray	4,978

Bone Density	3,406
Ultrasound	2,620
Mammography	6,026

Notably, this does not include additional capacity at other diagnostic imaging facilities in and around the area to serve the alleged need identified in the RRHS CON Application, including Duke Imaging Holly Springs (located 1.6 miles away), WakeMed Urgent Care in Fuquay Varina (located 4.6 miles away), or Valley Radiology (located ten miles away in Angier), nor does it account for Raleigh Radiology’s existing facilities which have provided substantial services to individuals residing in the proposed service area, nor Raleigh Radiology’s Cameron Village diagnostic center, which is under development, nor the facilities of Cardinal Points Imaging located near the service area.

b. *The Proposed Project Would Increase Costs by Unnecessarily Duplicating Existing and Approved Health Service Capabilities, is not the Least Costly Alternative, and does not Demonstrate Coordination with Existing Health Services in the Service Area.*

RRHS states in its application that the presence of another freestanding diagnostic center in the area will increase competition, “organically containing the price of care.” With regard to this argument, however, the General Assembly has concluded typical free-market competition does not operate to contain costs with regard health service facilities. On this basis, it has concluded that that “the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services” and that “the financing of health care, particularly the reimbursement of health services rendered by health service facilities, limits the effect of free market competition and government regulation is therefore necessary to control costs, utilization, and distribution of new health service facilities and the bed complements of these health service facilities” See N.C. Gen. Stat. 131E- 175(1),(4)

The proposed project, rather than containing costs, would result in unnecessary duplication of existing health services. As is shown above, Commenters’ facilities alone have the capacity to serve the need projected by the applicant. In addition, there are multiple other diagnostic imaging

service providers located in and in close proximity to the proposed service area. Further, RRHS states in its Application that existing Raleigh Radiology facilities in Wake County already provide 35% of the projected demand for imaging services from the service area. It is reasonable to expect that these existing facilities will experience underuse should the new facility be approved. This unnecessary duplication of existing health services within and near the proposed service area will result in “costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services.” See N.C. Gen. Stat. 131E- 175(4) This is precisely the outcome the General Assembly sought to avoid.

For these reasons, the Application fails to demonstrate that the proposed project is consistent with statutory review criteria (4), (5), (6), and (8), and 18(a).