

**Comments Regarding Certificate of Need Application Filed by Durham Diagnostic Imaging, LLC
d/b/a North Carolina Diagnostic Imaging – Cary
Project No. J-10025-12**

**Submitted by:
WakeMed Health & Hospitals
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Overview

In Project No. J-10025-12, Durham Diagnostic Imaging, LLC d/b/a North Carolina Diagnostic Imaging – Cary (NCDI-Cary) proposes to acquire one unit of mammography equipment and one unit of ultrasound equipment to be located at its existing location in Cary. The cost of the medical equipment is sufficient to trigger review as a Diagnostic Center under N.C.G.S. 131E-176(7a). WakeMed believes the NCDI-Cary application does not adequately identify the population to be served, nor does it address the effect of the project on competition. For these reasons, the NCDI-Cary application must be denied.

Review 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.

Cary/Apex Area Well-Served by Mammography and Ultrasound Providers

NCDI-Cary defines its service area as a 3-ZIP Code region in western Wake County and eastern Chatham County, specifically ZIP Codes 27513 (Cary), 27519 (Cary) and 27523 (Apex). NCDI-Cary notes, several times in its application, that “there are no accredited mammography units and only one ultrasound in NCDI-Cary’s proposed diagnostic center service area.”

NCDI-Cary gerrymandered its service area to *exclude* ZIP Codes where there are existing providers of diagnostic imaging. The Cary/Apex area in western Wake County is served by a number of mammography and ultrasound providers, all conveniently located to the NCDI-Cary service area. Some residents of the service area may be closer to existing providers than to NCDI-Cary’s site. These providers, along with their address and distance to NCDI-Cary, are included in the table below.



<u>Mammography</u> --		Driving Distance to NCDI-Cary¹	
Provider	Address	Road Miles	Minutes
Cary Diagnostic Radiology	101 SW Cary Parkway, Suite 40, Cary, 27511	5.6	12
Raleigh Radiology-Cary	150 Parkway Office Ct., Suite 100, Cary, 27518	6.3	16
Rex Primary Care & Wellness Ctr.	1515 SW Cary Parkway, Suite 120, Cary, 27511	4.1	9
Wake Radiology Diag. Imaging	300 Ashville Avenue, Suite 260, Cary, 27518	6.4	14
Wake Radiology – Morrisville	1101 Grace Park Drive, Morrisville, 27560	4.1	9
WakeMed Apex Healthplex	120 Healthplex Way, Apex, 27502	6.7	14
WakeMed Cary Hospital	1900 Kildaire Farm Road, Cary, 27518	6.0	13
<u>Ultrasound</u> --		Driving Distance to NCDI-Cary¹	
Provider	Address	Road Miles	Minutes
Cary Diagnostic Radiology	101 SW Cary Parkway, Suite 40, Cary, 27511	5.6	12
Raleigh Radiology-Cary	150 Parkway Office Ct., Suite 100, Cary, 27518	6.3	16
Rex Diagnostic Services of Cary	1515 SW Cary Parkway, Suite 120, Cary, 27511	4.1	9
Triangle Interventional Services	2501 Weston Parkway, Cary, 27513	4.9	11
Wake Radiology Diag. Imaging	300 Ashville Avenue, Suite 260, Cary, 27518	6.4	14
WakeMed Apex Healthplex	120 Healthplex Way, Apex, 27502	6.7	14
WakeMed Cary Hospital	1900 Kildaire Farm Road, Cary, 27518	6.0	13

Note: Rex Healthcare also operates a mobile mammography unit that operates throughout Wake County.

Of these providers, only Triangle Interventional Services is located in NCDI-Cary’s defined service area. However, it is evident that there are number of other providers, adjacent to the service area, that are very close to NCDI-Cary and capable of serving residents of the service area.

The maps contained in Attachments 1 and 2 illustrate the locations of these existing providers and their respective proximities to the NCDI-Cary site.

Volume Projections Overstated/Equipment Capacity Understated

Ultrasound

The NCDI-Cary application provides a need methodology and projections for mammography and ultrasound cases. For ultrasound, NCDI-Cary obtained use rates per 1000 population from the American College of Radiology (ACR). NCDI-Cary based its projections on population growth in the service area and incremental increases in market share. NCDI-Cary then multiplies this use rate by the projected population of the service area to obtain the potential ultrasound procedures originating in this area. These assumptions are unreliable and unfounded for the following reasons:

¹ Source: Google Maps, www.google.com/maps. When more than one route was provided, the shortest distance in road miles was selected.

- The ultrasound use rate of 522 procedures per 1000 population is for Medicare Part B enrollees aged 65 and older, not the population at-large. Although NCDI-Cary arbitrarily lowers this use rate by one-half for persons under age 65, there is no evidence that this adjustment is correct or even reasonable.
- Likewise, NCDI-Cary estimates that the capacity for its ultrasound equipment, found on page 52, as 8 procedures per day. Given the facility is projected to be open 7.5 hours per day (9:30 a.m. – 5:00 p.m.), this equates to 1.07 ultrasound procedure per hour [calculation: 8 procedures per day ÷ 7.5 hours per day = 1.0667 = 1.07], or approximately 56 minutes per procedure [calculation: 60 minutes per hour ÷ 1.07 procedure per hour = 56.1]. This appears to overstate the length of time required to perform an ultrasound procedure. Generally, ultrasound procedures require 20-30 minutes each, meaning one unit of equipment could perform up to 3 procedures per hour. Assuming 7.5 hours of operation per day, 250 days per year, such equipment could be expected to perform up to 5,625 procedures a year [calculation: 50 weeks x 5 days per week x 7.5 hours per day x 3 procedures per hour = 6000], as opposed to 2,000 procedures per year documented in the NCDI-Cary application.
- The market share estimates for mammography on page 39 are completely arbitrary and not grounded in any mathematical or statistical data. NCDI-Cary states: “The estimate market share of 5% in Year 1, 6% in Year 2 and 7% in Year 3 take into account the extremely limited availability of imaging services in the proposed service area that are planned for NCDI-Cary...”. There is simply no justification provided in the application to support these percentages.
- Also on page 39, NCDI-Cary states: “Physician support for this project indicates monthly referrals of approximately 264 patients. Assuming one patient has one ultrasound procedure, NCDI-Cary can project an annual referral estimate of 3,168 patients. In Year 1, NCDI-Cary has used only 40 percent of this referral estimate in order to be very conservative.” What is the basis for the 40 percent referral estimate? Without documentation that this percentage is reasonable, one cannot conclude that NCDI-Cary’s projected ultrasound procedures are realistic.

Mammography

For mammography, NCDI-Cary identifies the female over age 40 population and applies the American Cancer Society standard that all women over the age of 40 have a mammogram every year. From this potential base of patients, NCDI-Cary assumes a market share of 7 percent in Project Year 1, growing incrementally to 9 percent by Year 3. There are inherent limitations with the steps in this method:

- The frequency which women should receive mammograms is the subject of much debate. While the American Cancer Society recommends that all women over age 40

have a mammogram every year, the National Cancer Institute recommends that mammograms be performed on women age 40 and once every 1-2 years². In 2009, the U.S. Preventive Services Task Force recommended that women age 50-74 have a mammogram once every 2-3 years³. NCDI-Cary may have overstated the number of potential candidates for annual mammograms.

- NCDI-Cary provides population projections for women over age 40 in its methodology, but it is unclear what source was used, and whether this source is reliable. Rather than using data from Claritas, ESRI, or other well-known source of ZIP Code-based population projections, the exhibits to the application contain population projections obtained from an unknown source on the Internet. The source's methodology for projecting population by ZIP Code is not provided.
- For its projections, NCDI-Cary assumes that all women over age 40 in the service area will receive an annual mammogram, which is overly ambitious and therefore unreasonable.
- The market share estimates for mammography on page 40 are completely arbitrary and not grounded in any mathematical or statistical data. NCDI-Cary states: "The estimate market share of 7% in Year 1, 8% in Year 2 and 9% in Year 3 take into account the extremely limited availability of mammography services in the NCDI-Cary diagnostic center service area...". There is simply no justification provided in the application to support these percentages.
- NCDI-Cary's projected capacity of its mammography unit is 10 procedures per day, and 2,500 procedures per year. NCDI-Cary proposes to be open 7.5 hours a day; this equates to 1.33 procedures per hour [calculation; 10 procedures per day ÷ 7.5 hours per day = 1.33], or approximately 45 minutes per procedure [calculation: 60 minutes per hour ÷ 1.33 procedures per hour = 45.1]. However, NCDI-Cary may be severely underestimating its capacity. According to the General Accounting Office and the website Breastcancer.org, one unit of mammography equipment can perform up to 3 procedures per hour (20 minutes per procedure)^{4,5}, or approximately 6,000 procedures per year. NCDI-Cary appears to have significantly underestimated its equipment capacity.

In short, the NCDI-Cary volume projections cannot be verified, and therefore cannot be assumed to be reasonable. For these reasons, the NCDI application must be found nonconforming with Review Criterion 3.

² Source: <http://www.cancer.gov/cancertopics/factsheet/detection/mammograms>

³ Source: <http://www.uspreventiveservicestaskforce.org/uspstf/uspssbrca.htm>.

⁴ *Mammography: Current Nationwide Capacity is Adequate, but Access Problems May Exist in Certain Locations*, United States Government Accountability Office, Report No. GAO-06-724, July 2006, page 23.

⁵ Source: http://www.breastcancer.org/symptoms/testing/types/mammograms/benefits_risks.jsp.

Review 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.

Due to the unreasonableness of the NCDI-Cary volume projections (outlined in response to Criterion 3), its financial projections, in turn, must also be found unreasonable. The project, which is barely break-even through Years 1-3, would operate at a financial loss if assumptions regarding population growth, use rates per 1000 population, and equipment capacity are taken into consideration. For these reasons, the application does not conform with Review Criterion 5.

Review 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.

As the analysis of Criterion 3 demonstrates, the NCDI-Cary project will duplicate existing providers of mammography and ultrasound in the Cary/Apex area. The American College of Radiology lists seven providers of mammography in Cary, Apex and Morrisville, as well as seven providers of ultrasound in Cary and Apex. Nearly all of these providers are located within a 15-minute drive of NCDI-Cary. The quote from Dr. James Womble, who states that “[o]ther diagnostic imaging services are all clustered geographically near Wake Med [sic] Cary Hospital and not convenient for patients” is misleading and disingenuous. Another provider of mammography and ultrasound in the Cary/Apex will merely dilute the volumes of existing providers.

Review Criterion 8

The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

On page 17, NCDI-Cary states that it “will work with the closest available provider to transfer a patient who develops an emergency problem while undergoing a diagnostic procedure at NCDI-Cary.” However, NCDI-Cary does not list any local providers of emergency services, nor does it include any correspondence to these providers indicating its desire to work with local providers, including acute care hospitals and EMS providers. NCDI-Cary cites Attachment G,

which contains information regarding the Town of Cary's C-TRAN bus system, and Attachment H, which outlines MedQuest Associates' policy regarding the handling of emergent situations.

For these reasons, the NCDI-Cary application does not conform with Review Criterion 8.

Review Criterion 18a

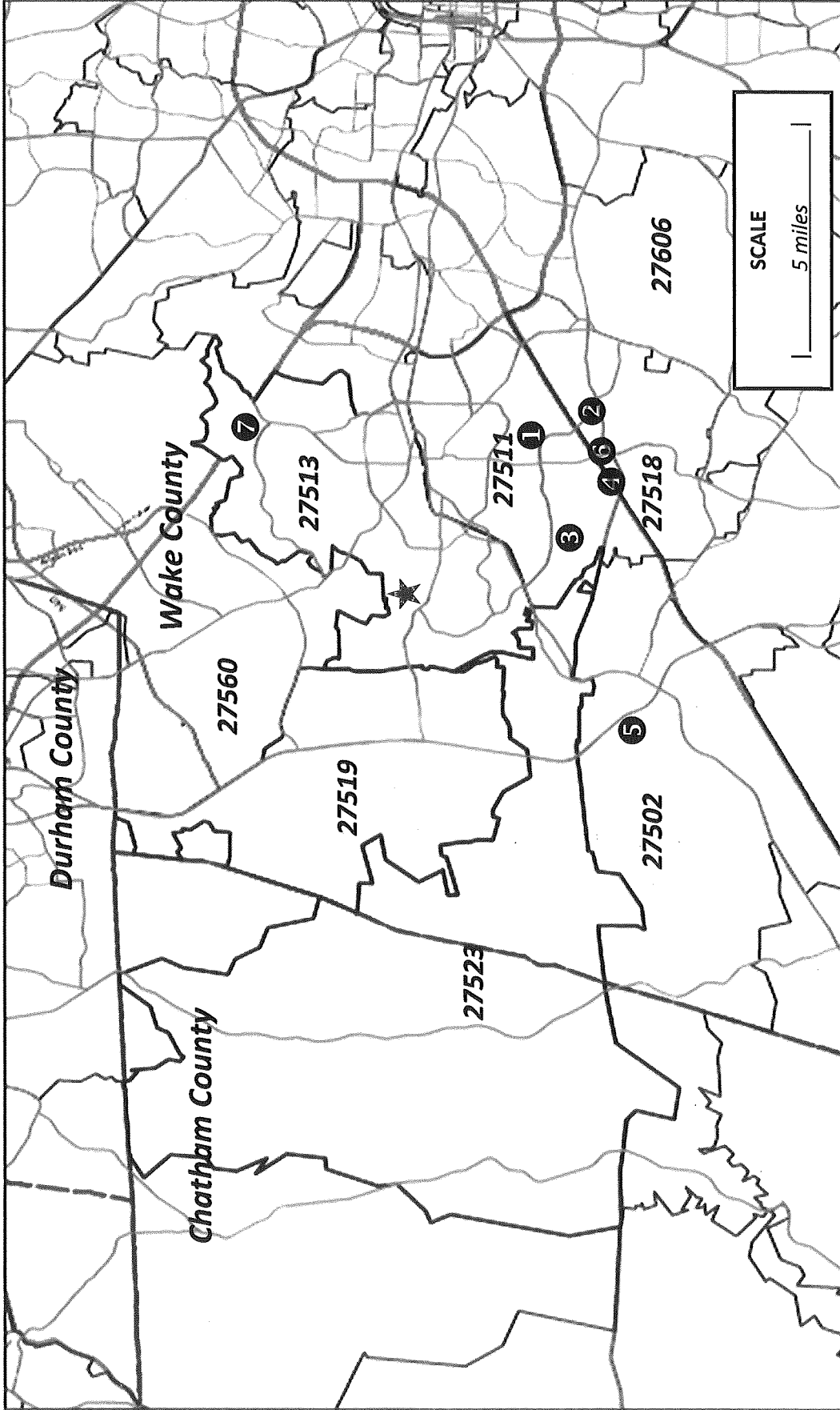
The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for 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.

On pages 56-57, NCDI-Cary describes how its proposal will enhance competition for mammography and ultrasound services in the Cary/Apex area. NCDI-Cary professes to be "more convenient for patients compared to a congested hospital campus", although only one of the diagnostic imaging providers listed in Table 1 above is an acute care hospital; nearly all of the other providers of mammography and ultrasound are freestanding locations. NCDI-Cary's claim that it will increase access to these services falls flat when one considers the locations of existing providers of mammography and ultrasound in the Cary/Apex/Morrisville area, most of which are within a 15-minute drive of NCDI-Cary's site.

Summary

NCDI-Cary's certificate of need application to acquire mammography and ultrasound equipment represents a duplication of imaging services in western Wake County. Its volume projections are based on unreasonable assumptions, and its equipment will operate well below capacity. For these reasons, the NCDI-Cary application should be denied.

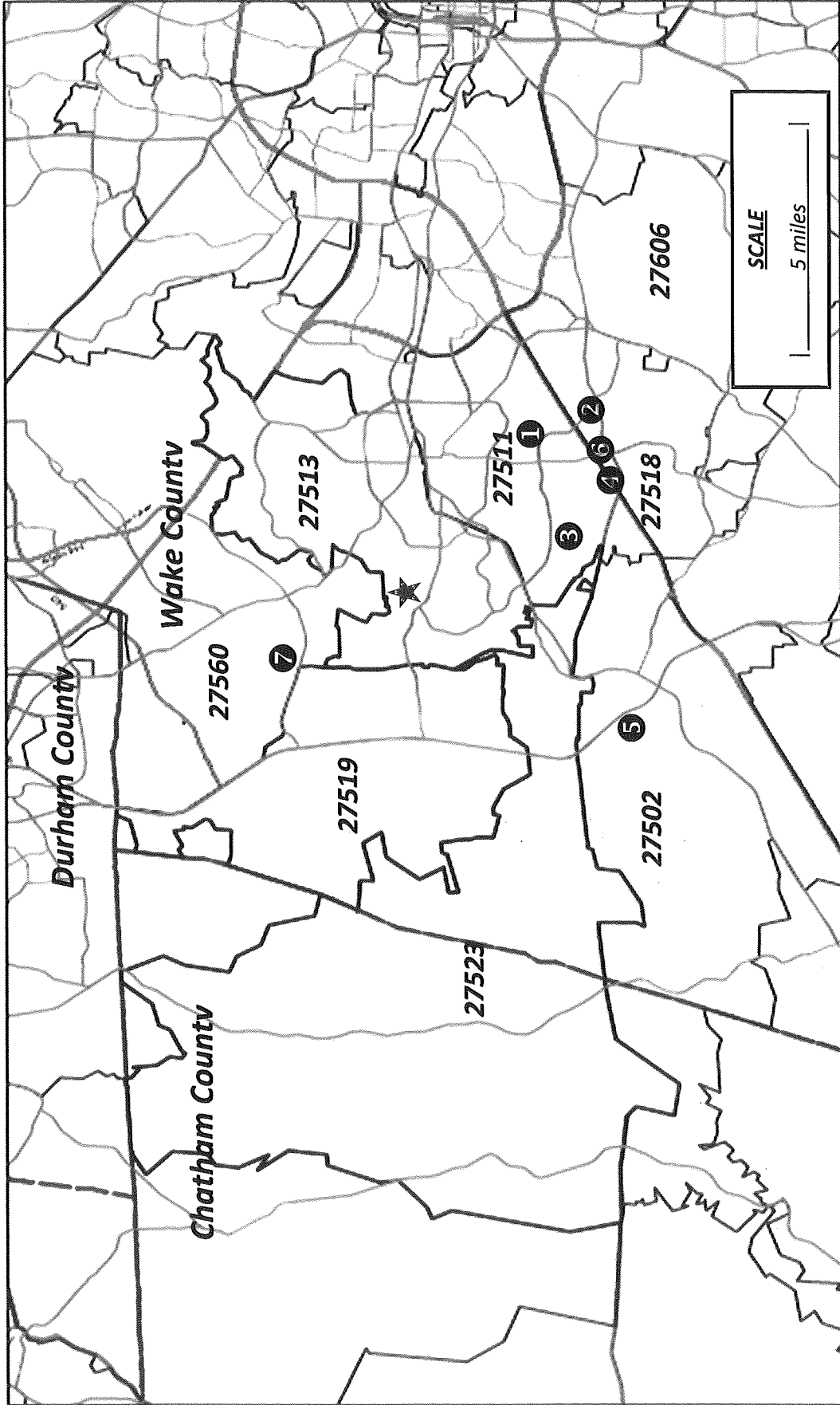
Existing Ultrasound Providers in Cary/Apex Area
Shown in Relationship to NCDI-Cary Site



LEGEND

- 1 Cary Diagnostic Radiology;
- 2 Raleigh Radiology-Cary;
- 3 Rex Diagnostic Services of Cary;
- 4 Wake Radiology Diagnostic Imaging;
- 5 WakeMed Apex Healthplex;
- 6 WakeMed Cary Hospital;
- 7 Triangle Interventional Services;
- ★ NCDI-Cary Site

Existing Mammography Providers in Cary/Apex Area
Shown in Relationship to NCDI-Cary Site



LEGEND

- ① Cary Diagnostic Radiology;
- ② Raleigh Radiology-Cary;
- ③ Rex Diagnostic Services of Cary;
- ④ Wake Radiology Diagnostic Imaging;
- ⑤ WakeMed Apex Healthplex;
- ⑥ WakeMed Cary Hospital;
- ⑦ Wake Radiology-Morrisville;
- ★ NCDI-Cary Site