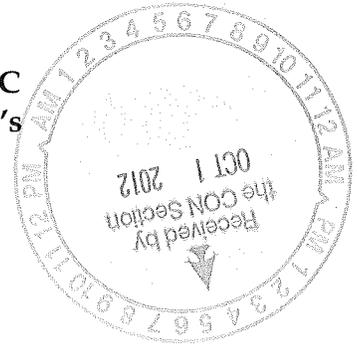


**Comments on Durham Diagnostic Imaging, LLC  
d/b/a/ North Carolina Diagnostic Imaging-Cary's  
Diagnostic Center Application**

*submitted by*

**Wake Radiology**



In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Wake Radiology submits the following comments related to Durham Diagnostic Imaging, LLC d/b/a/ North Carolina Diagnostic Imaging-Cary's application to acquire a mammography unit and ultrasound unit at its existing outpatient imaging facility which will require approval as a diagnostic center. Wake Radiology's comments 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). In order to facilitate the Agency's ease in reviewing the comments, Wake Radiology has organized its discussion by issue, specifically noting the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity relative to each issue:

Failure to identify the population to be served

NCDI-Cary's application provides contradictory information about the population it proposes to serve. On page 25, NCDI-Cary provides its projected patient origin as shown below:

**NCDI-Cary –Patient Origin for Ultrasound and Mammography for  
Project Years 1-3**

County	US	MA
Wake	95%	95%
Other	5%	5%
Total	100%	100%

Other includes: Alamance, Brunswick, Chatham, Carteret, Cumberland, Duplin, Durham, Forsyth, Franklin, Guilford, Halifax, Harnett, Iredell, Johnston, Lee, Macon, Moore, New Hanover, Onslow, Orange, Person, Pitt, Sampson, Surry, Vance, Warren, Wayne and Wilson, SC, VA and other states.

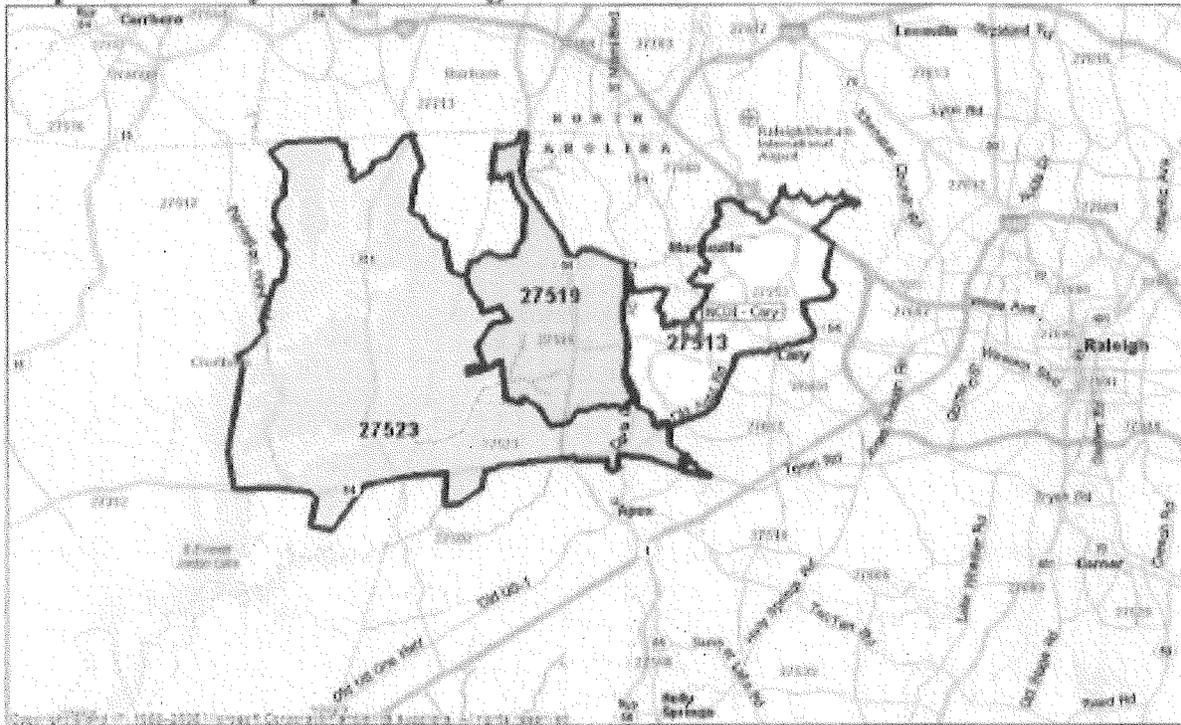
The discussion following this table states, in part, *"[g]iven NCDI-Cary's historical operating experience, it is reasonable to assume that some patients from outside of Wake County will utilize that proposed services. Note: NCDI-Cary will serve any patient in need of imaging services regardless of county of origin"* (page 26).

It is clear from this information that NCDI-Cary expects to serve patients from outside of Wake County. However, this is in complete contradiction with its utilization methodology which assumes that 100 percent of NCDI-Cary's patients will originate

from the three ZIP codes, all within Wake County, that comprise its assumed service area.

On page 36, NCDI-Cary states that the “proposed service area for the diagnostic center is confined to a small area in southwestern Wake County consisting of three zip codes, which currently utilize NCDI-Cary’s CT and MRI services. The 27513 zip code is the location of NCDI-Cary’s facility and the 27519 and 27523 zip codes area contiguous to it” and provides the following map:

**Map - NCDI-Cary’s Proposed Diagnostic Center Service Area**



NCDI-Cary provides its estimate of the projected population of the service area on the same page:

**NCDI-Cary Service Area Population**

Zip Code	2010	2011	2012	2013	2014	2015	2016
27513	40,755	41,570	42,402	43,250	44,115	44,997	45,897
27519	39,178	39,962	40,761	41,576	42,408	43,256	44,121
27523	9,552	9,743	9,938	10,137	10,339	10,546	10,757
Service Area Total	89,485	91,275	93,100	94,962	96,861	98,799	100,775

As part of its utilization methodology, NCDI-Cary provides the service area population by age group:

**NCDI-Cary Diagnostic Center Service Area – Population by Age Group**

	2010	2011	2012	2013	2014	2015	2016
Pop. +65 yrs	5,987	6,106	6,228	6,353	6,480	6,610	6,742
Pop < 65 yrs	83,498	83,060	84,721	86,416	88,144	92,189	94,033
Totals	89,485	89,166	90,950	92,769	94,624	98,799	100,775

See page 37

While there are discrepancies between the total population in the tables above for 2011 through 2014 (which, in itself also demonstrates the unreasonableness of the applicant's population definition), the consistency of the other years and the language in the application makes it clear that NCDI-Cary's service area is confined to the three ZIP codes identified.

NCDI-Cary's methodology clearly shows in the table on page 38, reproduced below, that 100 percent of its ultrasound patients are projected to originate from these three ZIP codes.

Ultrasound

NCDI-Cary proposes to offer ultrasound services at its diagnostic center. The following chart details the projections for this modality.

Projections:

Ultrasound Capacity	250 days x 8 procedures per day = 2,000 procedures annually 80% of capacity = 1,600		
	<b>YR 1- 2014</b>	<b>YR 2- 2015</b>	<b>YR 3- 2016</b>
Population - 65+	6480	6610	6742
Utilization Rate/1000	522	522	522
Est. Volume for 65+ Population	<b>3316</b>	<b>3383</b>	<b>3450</b>
Population < 65	88,144	92,189	94,033
Utilization Rate/1000	261	261	261
Est. Volume for Under 65 years	<b>22112</b>	<b>22554</b>	<b>23006</b>
Service Area Total (Under 65 & 65+)	<b>25428</b>	<b>25937</b>	<b>26456</b>
Estimated Mkt Share	5%	6%	7%
<b>NCDI - Ultrasound Volume</b>	<b>1271</b>	<b>1556</b>	<b>1852</b>

As the table above shows, NCDI-Cary applies ultrasound utilization rates to the projected population of the service area in order to estimate the "Service Area Total". Finally, NCDI-Cary applies a market share estimate to that service area total to determine the facility's projected volume. As shown on page 50 and page 6 of the pro forma financial statements, the volumes shown in the table above are the total projected ultrasound volumes for the facility. Thus, it is clear that according to the utilization methodology that 100 percent of the ultrasound volumes will originate from the three service area ZIP codes, each of which is entirely within Wake County. The methodology for mammography utilization is similarly presented on pages 39-40 showing that 100 percent of utilization will originate from the service area.

These methodologies are directly in contradiction with NCDI-Cary's projected patient origin which states that five percent of patients will originate from areas other than Wake County. In summary, NCDI-Cary cannot state on one page of its application that 100 percent of patients will originate from Wake County and then state on another page that 95 percent of patients will originate from Wake County. NCDI-Cary clearly fails to identify the population to be served. As explained in detail below, this issue is of particular importance in this review, given the requirement for the applicant to address other providers in its service area.

**As a result of this issue, NCDI-Cary's application should be found non-conforming with Criterion 3 as well as with the Criteria and Standards for Diagnostic Centers at 10A NCAC 14C .1803(7) and (8)(e).**

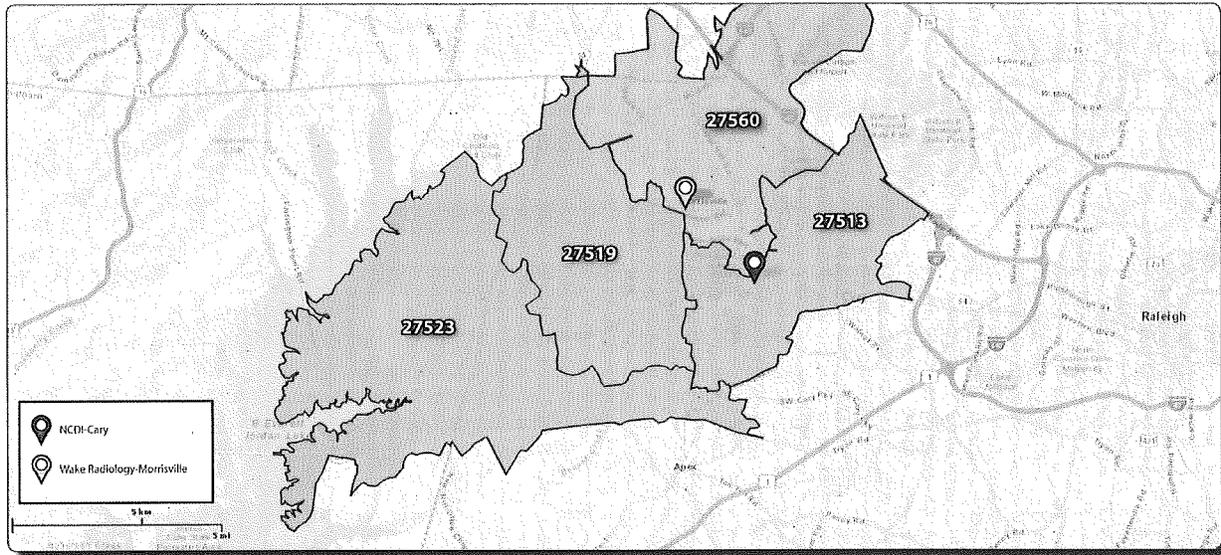
Failure to justify the rationale for the proposed service area

NCDI-Cary provides no data or analysis to support its assumed three-ZIP code service area, only vague, generalized statements. Furthermore, the proposed service area is unreasonable based on the location of its facility, NCDI-Cary's historic patient origin, and NCDI-Cary's own letters of support. Instead of being based on the applicant's actual historical experience at the facility, which clearly includes patients from outside these ZIP codes, as discussed above, NCDI-Cary's service area appears to be contrived specifically to mislead the Agency in an effort to circumvent the diagnostic center performance standards requiring NCDI-Cary to demonstrate that other providers will be appropriately utilized in the future [see 10A NCAC 14C.1804 (2)].

NCDI-Cary identifies its service area as three ZIP codes (27513, 27519, and 27523) but provides no demonstration of the reasonableness of that assumption. NCDI-Cary provides no data to suggest what portion of its existing patients originate from those three ZIP codes. Instead, NCDI-Cary offers a vague statement, "[a] significant number of NCDI-Cary's existing patients originate from [the service area] zip codes" (page 45). Note, NCDI-Cary does not say that a majority of its patients (and certainly not all) originate from the service area or provide any quantification of how many or what percentage of

its patients. A “significant number” in this context could mean virtually anything and provides too little detail for the Agency to find the applicant’s assumptions to be reasonable.

Moreover, the proposed service area is unreasonable based on the location of the facility. As shown in the map below, the facility is located within ZIP code 27513.

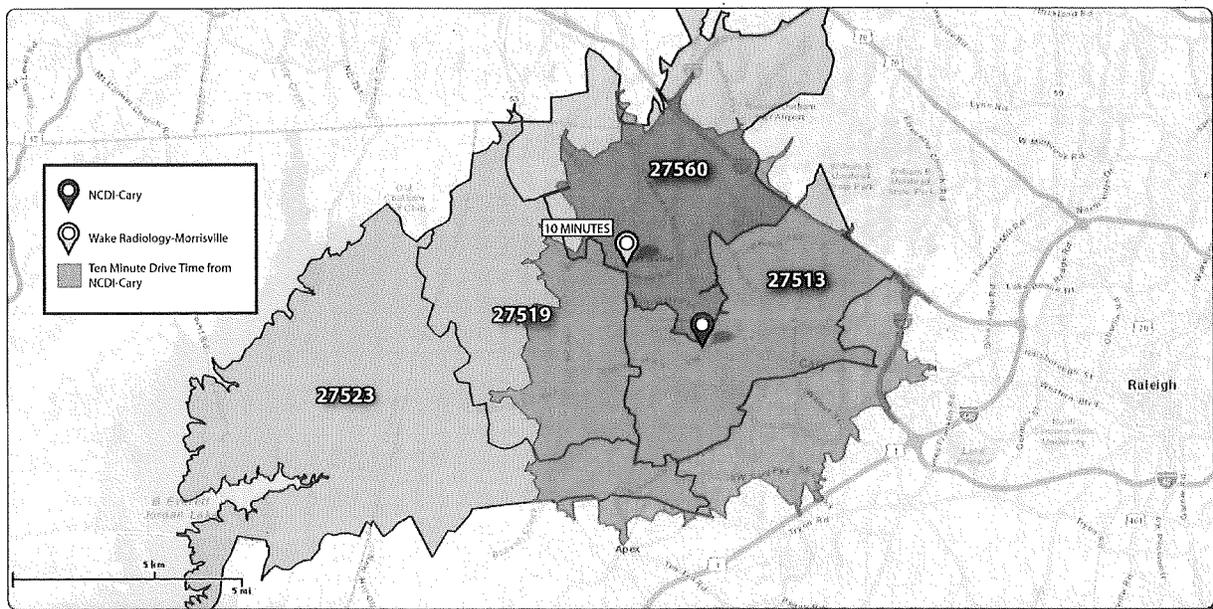


The nearest contiguous ZIP code to the facility’s site, 27560, is not included in the service area, and no rationale is provided as to the applicant’s failure to include the ZIP code. In fact, NCDI-Cary has provided letters of support from providers in ZIP code 27560 which account for 14 percent and 27 percent of the ultrasound and mammography referrals cited in the letters of support.<sup>1</sup> There are no geographic, road/highway or other barriers that would prevent patients from 27560 from accessing the proposed facility, and most of the ZIP code is closer to the facility than other ZIP codes included in the service area. In fact, a neighborhood located off NW Cary Parkway, less than one mile from the proposed facility, is in ZIP 27560. For the Agency’s reference, that neighborhood (as well as many others in close proximity), known as Preston Grande as shown in the map below, is on the same side of Cary Parkway as the proposed diagnostic center, less than one mile way, before crossing any major street.

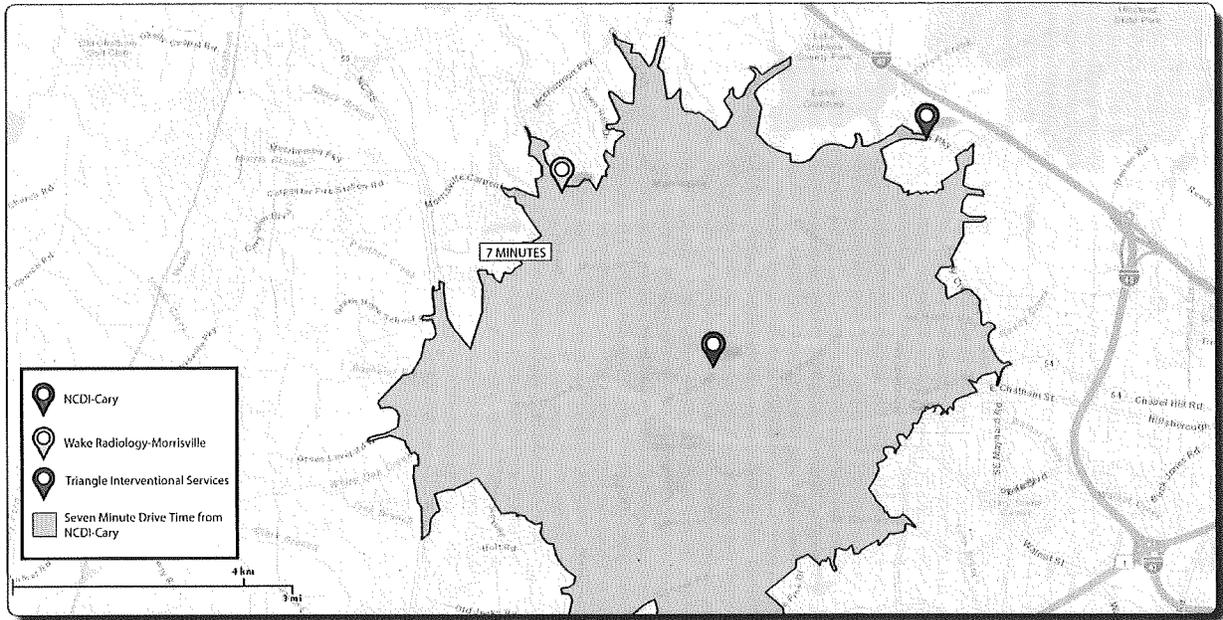
<sup>1</sup> Please see Letters of Support in Attachment Z from Avance Care providers Vaikunth, Adeyina, and Husman.



Clearly the assumption that its service area would not include patients from this ZIP code is unreasonable. Even though these nearby patients are excluded from the service area, NCDI-Cary projects that its service area will include ZIP codes 27519 and 27523. As the map demonstrates, ZIP code 27523 stretches into Chatham County, and contains many areas that are much more distant than ZIP code 27560. In fact, as the map below demonstrates the area within a ten minute drive time of NCDI-Cary's facility includes the majority of ZIP code 27560 but only a small portion of ZIP code 27523.



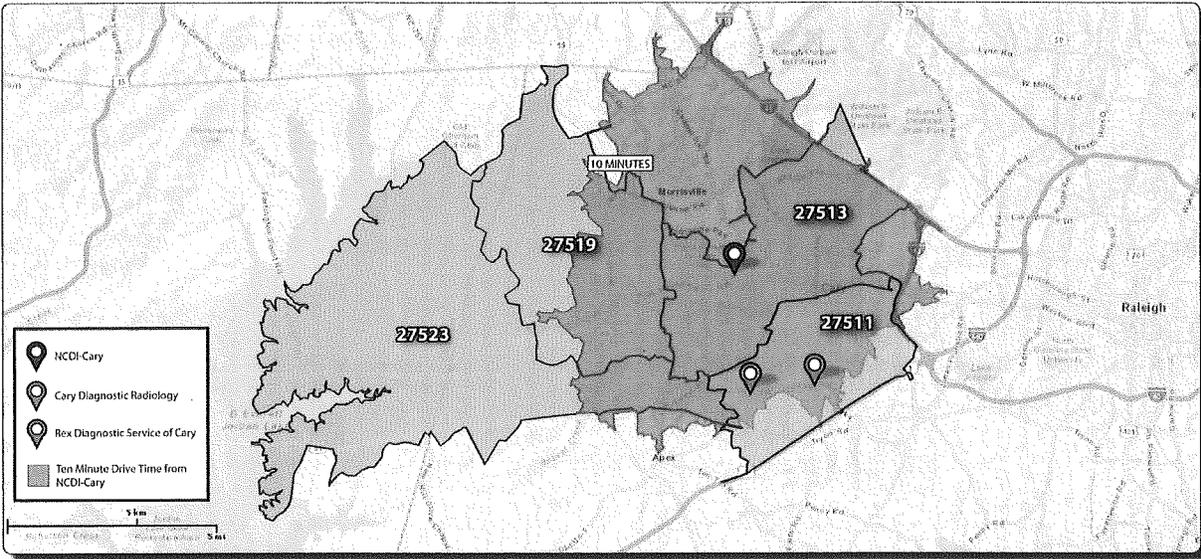
More significantly, Wake Radiology-Morrisville is in ZIP code 27560 and is within a *seven minute* drive time of NCDI-Cary. Wake Radiology-Morrisville began operation in December 2011 and its mammography unit is not yet fully utilized (please see the discussion below for more information about Wake Radiology-Morrisville). Triangle Interventional Services is the only provider of imaging services discussed by NCDI-Cary; it, too is within a seven minute drive time of the NCDI-Cary as shown in the map below.



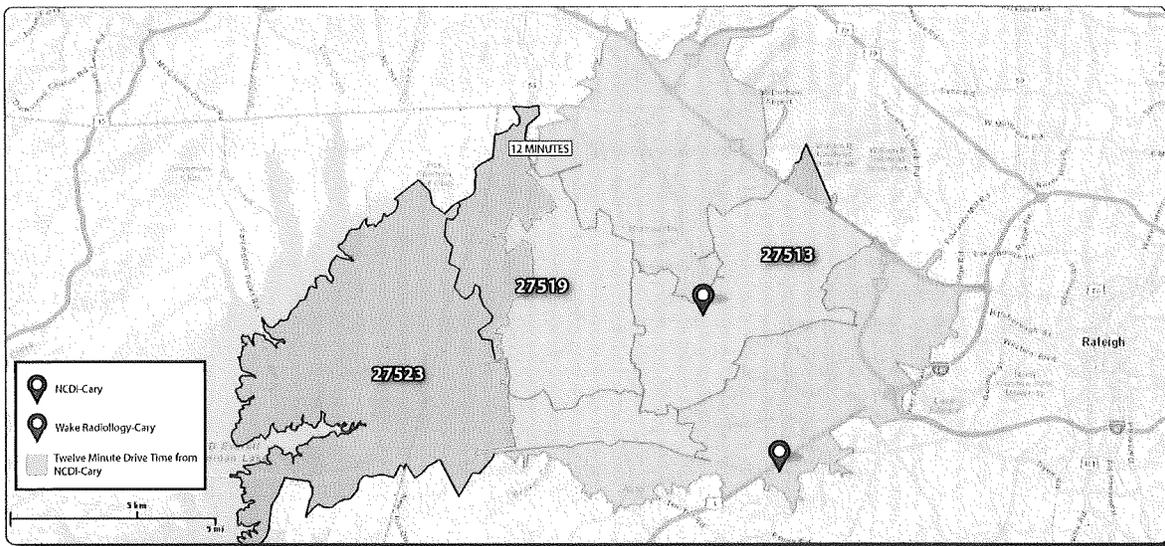
It is unreasonable for NCDI-Cary to address Triangle Interventional Services in its application (though NCDI-Cary ultimately does not provide any utilization information for Triangle Interventional Services) and not address Wake Radiology-Morrisville given that these two existing providers are with the same drive time from NCDI-Cary.

Similarly, ZIP code 27511 is also contiguous with the ZIP code of NCDI-Cary. As the map below shows Cary Diagnostic Radiology and Rex Diagnostic Services<sup>2</sup> which both offer ultrasound and mammography services are also within a ten minute drive time of NCDI-Cary, and neither of these facilities were considered in the application.

<sup>2</sup> These providers were identified using a ZIP code search of accredited providers using the American College of Radiology's website, the same tool used by NCDI-Cary, as shown by the search results in Exhibit 2.



Additionally, Wake Radiology's Cary site is within a 12 minute drive time of the proposed site as shown in the map below.



In fact, as the map demonstrates, Wake Radiology's Cary site is closer to NCDI-Cary in terms of drive time than several areas of the proposed service area, including areas within NCDI-Cary's home ZIP code (27513).

Given the proximity of these ZIP codes to NCDI-Cary (as shown by the areas within a ten minute drive time) and the presence of other ultrasound and mammography providers, the failure of NCDI-Cary's application to provide any basis by which to

determine the reasonableness of its proposed service area appears designed to circumvent the performance standards in the diagnostic center rules requiring NCDI-Cary to demonstrate that other providers will be appropriately utilized in the future [see 10A NCAC 14C.1804 (2)].

Finally, while NCDI-Cary fails to provide ZIP code patient origin data to support its assumed service area, it does provide historical patient origin data by county. However, this patient origin data further demonstrates that the proposed service area is unreasonable. As shown on page 25 of its application and reproduced below, Wake County patients account for 88.8 percent and 90.1 percent of NCDI-Cary's existing MRI and CT patients, respectively.

**NCDI-Cary –Patient Origin by Diagnostic Service CY 2011**

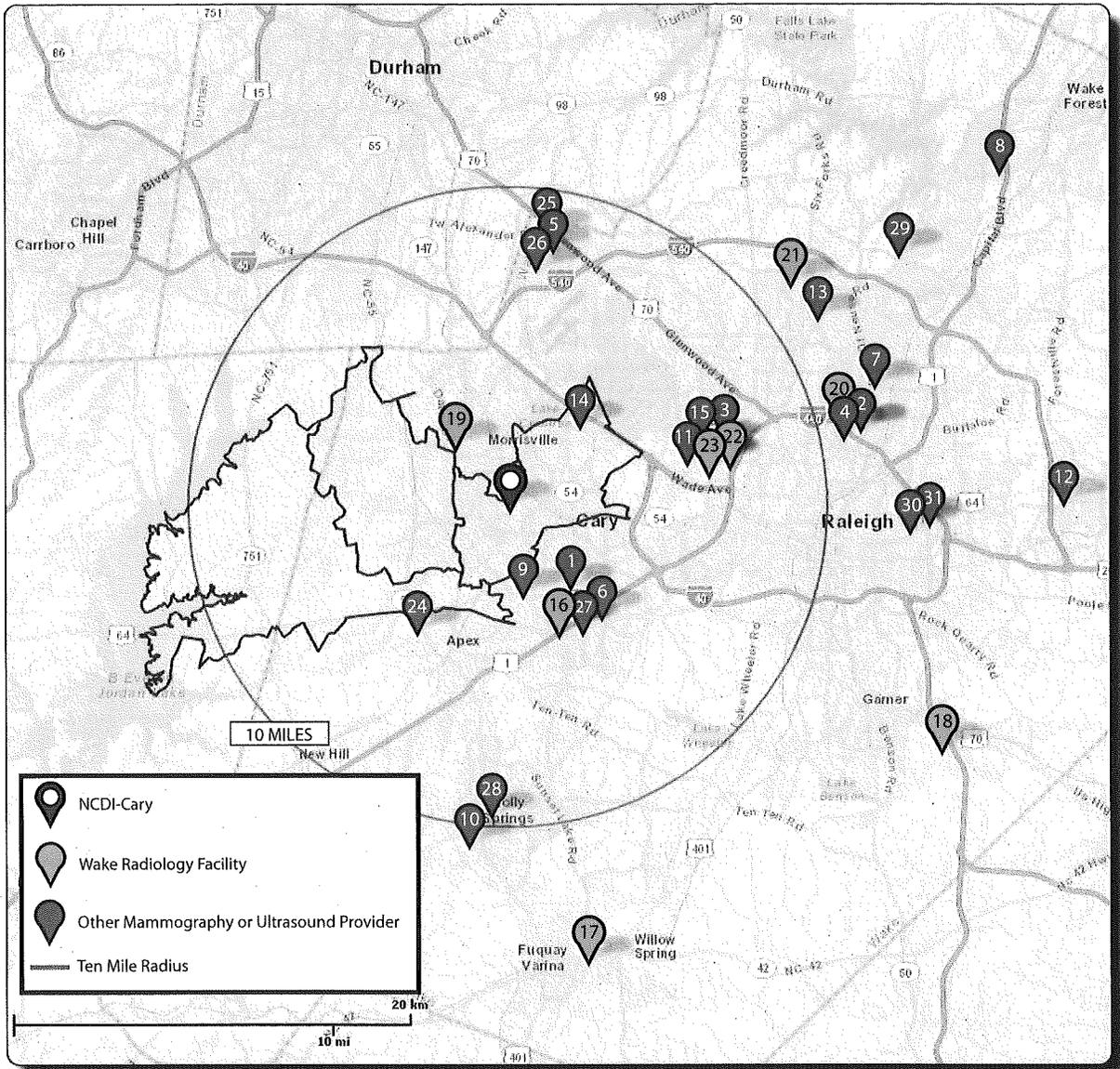
County	MRI	CT
Wake	88.8%	90.1%
Johnston	2.5%	2.0%
Lee	1.4%	0.9%
Harnett	1.0%	0.9%
Durham	1.2%	0.7%
Orange	1.0%	1.1%
Chatham	0.5%	1.1%
Other	3.6%	3.2%
Total	100%	100%

According to NCDI, “population data shows that the number of residents in the [service] area represent approximately 10% of the population of Wake County” (page 36). Given these data from NCDI-Cary, it is unreasonable to believe that the service area for NCDI-Cary is accurately represented by only these three ZIP codes. It cannot be assumed that all of NCDI-Cary's Wake County patients originate from these three service area ZIP codes, as they comprise only 10 percent of the county's total population. Moreover, given that patients from neighboring counties utilize NCDI-Cary, it is even more likely that patients from Wake County ZIP codes outside of the service area utilize the facility, particularly 27560 and other ZIP codes as discussed above. Additionally, NCDI-Cary's inclusion of ZIP code 27523 in its service area is unsupported by its county patient origin data. ZIP code 27523 includes portions of Chatham County. However, as the table above shows, Chatham County is the 6<sup>th</sup> ranked county aside from Wake County for MRI services and the 2<sup>nd</sup> or 3<sup>rd</sup> ranked county for CT services. As noted above, NCDI-Cary does not provide any data or discussion beyond vague statements nor does it offer any statements as to why it has not chosen a broader service area, such as the entirety of Wake County, which would have been much more strongly supported by the data provided in its application.

NCDI-Cary clearly fails to justify the rationale for the proposed service area and thus has not identified the population to be served. **As a result of this issue, NCDI-Cary's application should be found non-conforming with Criterion 3 as well as with Rules .1803(7) and (8)(e).**

Failure to demonstrate the reasonableness of its market share and utilization rate assumptions

In the application, NCDI-Cary assumes that it will achieve a five to seven percent market share of ultrasound services and seven to nine percent share of mammography services. In its justification of these market share assumptions, NCDI-Cary states that they "*take into account the extremely limited availability of [imaging] services in the proposed service area*" (pages 29-30). However, as Wake Radiology has shown in the prior section, there are numerous imaging providers near NCDI-Cary, but they are not discussed as NCDI-Cary's service area appears to be designed in order to exclude them. In fact, the area around NCDI-Cary's site contains numerous existing or approved diagnostic facilities which offer ultrasound and mammography services as shown in the map and table below.



<i>Legend</i>	<i>Facility</i>	<i>Address</i>	<i>City</i>	<i>ZIP Code</i>	<i>Mammo</i>	<i>US</i>
1	Cary Diagnostic Radiology	101 SW Cary Pkwy, Ste 40	Cary	27511	Yes	Yes
2	Duke Raleigh	3480 Wake Forest Rd., Ste 100	Raleigh	27609	Yes	Yes
3	Raleigh Radiology Blue Ridge	3200 Blue Ridge Rd. Ste 100	Raleigh	27612	Yes	Yes
4	Raleigh Radiology Breast Cancer	3900 Barrett Dr., Ste 100	Raleigh	27609	Yes	
5	Raleigh Radiology Brier Creek	8851 Ellstree Ln, Ste 100	Raleigh	27617	Yes	Yes
6	Raleigh Radiology Cary	150 Parkway Office Court, Suite 100	Cary	27518	Yes	Yes
7	Raleigh Radiology Cedarhurst	1212 Cedarhurst Drive	Raleigh	27609	Yes	Yes
8	Rex Diagnostic Imaging of Wakefield	11200 Governor Manly Way, Ste 106	Raleigh	27614	Yes	Yes
9	Rex Diagnostic Services of Cary/Primary Care	1515 S.W. Cary Parkway, Suite 120	Cary	27511	Yes	Yes
10	Rex Healthcare of Holly Springs	781 Avent Ferry Rd.	Holly Springs	27540	Yes	Yes
11	Rex Hospital	4420 Lake Boone Trail	Raleigh	27607	Yes	Yes
12	Rex Radiology of Knightdale	6602 Knightdale Blvd.	Knightdale	27545	Yes	Yes
13	Richard D. Adelman, M.D.	7320 Six Forks Rd., Ste 260	Raleigh	27615	Yes	
14	Triangle Interventional Services	2501 Weston Parkway	Cary	27513		Yes
15	Wake Internal Medicine Consultants	3100 Blue Ridge Road. Suite 100	Raleigh	27612	Yes	Yes
16	Wake Radiology-Cary	300 Ashville Avenue	Cary	27518	Yes	Yes
17	Wake Radiology-Fuquay Varina	7636 Purfoy Rd., Ste 200	Fuquay-Varina	27526	Yes	Yes
18	Wake Radiology-Garner	300 Health Park Dr., Suite 100	Garner	27529	Yes	Yes
19	Wake Radiology-Morrisville	1101 Grace Park Dr.	Morrisville	27560	Yes	
20	Wake Radiology-North Hills	3821 Merton Dr.	Raleigh	27609	Yes	Yes
21	Wake Radiology-Northwest Raleigh	8300 Health Park, Ste 221	Raleigh	27615	Yes	Yes
22	Wake Radiology-West Raleigh	4301 Lake Boone Tr., Ste 104	Raleigh	27607	Yes	Yes
23	Wake Radiology-Breast Center West	2301 Rexwoods Dr., Ste 116 B	Raleigh	27607	Yes	Yes
24	WakeMed Apex Healthplex	120 Healthplex Way	Apex	27502	Yes	Yes
25	WakeMed Brier Creek Healthplex ED	8001 T.W. Alexander Drive	Raleigh	27617	Yes	Yes
26	WakeMed Brier Creek Medical Park	10208 Cerny St., Ste 101	Raleigh	27617	Yes	
27	WakeMed Cary Hospital	1900 Kildaire Farm Rd.	Cary	27518	Yes	Yes
28	WakeMed Holly Springs	500 Holly Springs Rd., Ste 106	Holly Springs	27540	Yes	Yes
29	WakeMed North Healthplex	10000 Falls of Neuse, Ste 101	Raleigh	27614	Yes	Yes
30	WakeMed Raleigh	3000 New Bern Avenue	Raleigh	27610	Yes	Yes
31	WakeMed Raleigh Medical Park	23 Sunnybrook Rd. Ste 110	Raleigh	27610	Yes	Yes

Source: American College of Radiology Accredited Facility Search.

As the map and table show, there are at least 17 providers of ultrasound or mammography services within a ten mile radius of NCDI-Cary (indicated in table by purple). All of these facilities are closer to NCDI-Cary than some areas of its service area as shown on the map. Furthermore, there are numerous other facilities further than ten miles within Wake County, such as Wake Radiology-Fuquay-Varina that offer mammography or ultrasound services, many of which have available capacity.

Given the significant presence of other providers in the market, it is unreasonable for NCDI-Cary to provide market share assumptions which have no justification. While NCDI-Cary does not provide the methodology or assumptions used to project market share, Wake Radiology has conducted its own analyses which suggest that NCDI-Cary has grossly overstated its projected share.

On page five of its pro forma financial statements, NCDI-Cary presents projected volumes for its existing CT scanner: 628, 647, and 666 during the three project years, respectively. Wake Radiology used the methodology presented in NCDI-Cary's application for ultrasound services (see page 38) and the CT utilization rates shown on page 37 in order to project market CT volume, as shown below.

#### CT Market Volume for NCDI-Cary Service Area

	<i>Source</i>	<i>PY1</i>	<i>PY2</i>	<i>PY3</i>
Population 65+	Pg. 38	6,480	6,610	6,742
Utilization Rate/1000	Pg. 37	287	287	287
<b>Est. Volume for 65+ Population</b>	Calculation	<b>1,860</b>	<b>1,897</b>	<b>1,935</b>
Population under 65	Pg. 38	88,144	92,189	94,033
Utilization Rate/1000	50% of 65+ Rate per Page 38	144	144	144
<b>Est. Volume for under 65 Population</b>	Calculation	<b>12,649</b>	<b>13,229</b>	<b>13,494</b>
<i>Service Area Total</i>	Sum	<b>14,508</b>	<b>15,126</b>	<b>15,429</b>

Based on NCDI-Cary's approach for estimated imaging volume, Wake Radiology calculates that the proposed service area will need approximately 15,000 CT scans annually. It should be noted that NCDI-Cary's approach utilizes national use rates but fails to demonstrate that they can be appropriately applied to the proposed service area. In addition, the national use rates are for all imaging services including services provided in all care settings, not just diagnostic imaging centers, which would include acute care hospitals, physician offices, etc. Finally, NCDI-Cary's assumption that all women over 40 years of age in the service area will seek mammography services is unreasonable. In 2009, the U.S. Preventative Services Task Force recommended against routine screening for women 40 to 49 and the mammography rate declined by almost 8 percent in response (see Exhibit 1 for an article on this topic).

However, even assuming the validity of NCDI-Cary's approach, Wake Radiology calculates that NCDI-Cary's projected CT market share for its service will be 4.3 percent, well below its projected share for the proposed services.

**Estimated CT Market Share for NCDI-Cary**

	<i>Source</i>	<i>PY1</i>	<i>PY2</i>	<i>PY3</i>
Service Area Total	Calculated in prior table	14,508	15,126	15,429
NCDI-Cary CT Procedures per Financial Statements	Pg. 5 of Pro Formas	628	647	666
<b>Estimated Market Share</b>	Calculation	<b>4.3%</b>	<b>4.3%</b>	<b>4.3%</b>

NCDI-Cary also cites the number of referrals projected by providers in its letters of support as justification for its market share assumptions. However, several of these letters are from providers outside of the service area as shown below:

**Letters of Support from Providers Outside of Projected Service Area**

<i>Provider</i>	<i>Office Address</i>	<i>Monthly Ultrasound Referrals</i>	<i>Monthly Mammo Referrals</i>
Corey Musselman, MD*	1110 SE Cary Pkwy, Ste 203, Cary 27518	5	5
H. Paul Singh, MD	1120 SW Cary Pkwy, Ste 204, Cary 27518	Varies	--
Raj Makam, MD	1120 SW Cary Pkwy, Ste 204, Cary 27518	Varies	--
David Adams, MD	218 Ashville Ave, Ste 20, Cary 27518	30	40
Aparna Vaikunth, MD	6402 McCrimmon Pkwy, Ste 100, Morrisville, 27560	15	35
Festino Adeyina, MD	6402 McCrimmon Pkwy, Ste 100, Morrisville, 27560	20	40
Kari Husman, MD	6402 McCrimmon Pkwy, Ste 100, Morrisville, 27560	2	0
Robert Resnik, MD	930 SE Cary Pkwy, Cary, 27518	5	10
<b>Total from Providers Outside Service Area</b>		<b>77</b>	<b>130</b>

\*NCDI-Cary's application contains a typo and refers to Dr. Mufelman in the summary table in Letters of Support Attachment Z.

The referrals from providers with offices outside of NCDI-Cary's service area represent 29 percent and 47 percent of the total monthly referrals contained in the letters of support.

**Percentage of Support from Providers Outside of Service Area**

	<i>Monthly Ultrasound Referrals</i>	<i>% of Ultrasound Total</i>	<i>Monthly Mammo Referrals</i>	<i>% of Mammo Total</i>
Providers Outside Service Area	77	29%	130	47%
Providers in Service Area	187	71%	148	53%
Total for NCDI-Cary	264		278	

NCDI-Cary’s representation that providers outside of their service area will refer significant percentage of its volumes further indicate that its service area is contrived and not based on reasonable assumptions. In addition, the referrals from these providers are an unreliable justification for NCDI-Cary’s market share assumptions within its service area as these providers are not in the service area. In fact, if NCDI-Cary were to only consider referrals from these providers in its service area its letters of support would indicate insufficient volume to appropriately utilize its proposed mammography equipment.

**Equipment Utilization based on Referrals  
from Providers in Service Area Only**

	<i>Monthly Mammo Referrals</i>	<i>Annual Mammo Referrals</i>
Providers in Service Area	148	1,776
Annual Capacity		2,500
Percent Utilization		71%

Finally, NCDI-Cary’s letters of support contain six providers at urgent care centers.

**Mammography Referrals from Urgent Care Providers**

<i>Provider</i>	<i>Urgent Care Center</i>	<i>Monthly Mammo Referrals</i>
Aparna Vaikunth, MD	Avance Care	35
Festino Adeyina, MD	Avance Care	40
Kari Husman, MD	Avance Care	0
Sue Hoslick, MD	FastMed of Cary	10
Todd Wallace, PA-C	FastMed of Cary	8
Ameilia Craver, PA-C	FastMed of Cary	0
<b>Total for Urgent Care Providers</b>		<b>93</b>

Wake Radiology does not believe that NCDI-Cary has provided information in its application to demonstrate that it is reasonable to expect that any urgent care patients would be referred for screening mammography services from an urgent care center. NCDI-Cary expects its mammography patients to be seeking annual screenings as the "American Cancer Society recommends that women over the age of 40 should have a mammogram every year" (pages 33 and 39). Women seeking annual mammography screenings are more likely to see their personal physician for referral to an annual mammography screening than a walk-in urgent care center. This is yet another example of the multiple and inconsistent assumptions provided by NCDI-Cary and is yet another piece of evidence of the unreasonableness of their methodology and projections.

**As a result of this issue, NCDI-Cary's application should be found non-conforming with Criterion 3 as well as Rules .1803(8)(e), .1804(2), and .1804(3).**

Failure to demonstrate the utilization of other providers

In 2009, Wake Radiology's application to acquire a digital mammography unit to replace its existing unit at its Northwest Raleigh Office (NWRO) was denied by the Agency (Project ID # J-8248-08). In its findings, the Agency stated "*there is no information in the application with regard to the projected utilization of the other digital mammography units in the proposed service area. 10A NCAC 14C .1804(2) also requires the applicant to document that 'all existing and approved medical diagnostic equipment and services of the type proposed in this CON application' are projected to be utilized at 80% of the maximum capacity of the equipment [emphasis added]. The applicant projected the utilization of its own equipment at the NWRO location, but failed to take into account the projected utilization of the other digital mammography units in the service area*" (page 18).

Similarly, NCDI-Cary's application projects its own utilization but failed to take into account the projected utilization of other mammography units in its service area. NCDI-Cary discusses Triangle Interventional Services (TIS) which operates an ultrasound unit in its service area but states "*NCDI-Cary has made several efforts to contact TIS to identify the amount of volume and its maximum annual capacity but have been unable obtain [sic] this volume information prior to the application filing. Based on NCDI-Cary's volume projections for the service area, NCDI-Cary has utilized a very small portion, only 5% in Year 1, of market share for its proposed project. There is more than sufficient demand for both providers to operate in the service area*" (page 28). As noted previously, NCDI-Cary provides no information in its application to support its market share assumptions or to support the assertion that five percent is a small portion that would allow sufficient volume for other providers.

As discussed above, Wake Radiology-Morrisville, which operates one mammography unit, is within a seven minute drive time of NCDI-Cary's location. Wake Radiology-Morrisville began operation in December 2011. Wake Radiology's Cary office, which

operates two mammography units and four ultrasound units, is within a 12 minute drive time of NCDI-Cary. Finally, Wake Radiology's Fuquay-Varina office opened on August 3, 2012 and operates one ultrasound and one mammography unit. In addition to other fixed mammography providers, the applicant failed to recognize that mobile mammography is also available nearly every day within Wake County, including sites near the proposed diagnostic center, as shown on the internet.<sup>3</sup> The tables below present the historical volume and utilization for these two Wake Radiology facilities.

**Wake Radiology-Cary  
Mammography & Ultrasound Utilization**

	<i>Mammography</i>				<i>Ultrasound</i>			
	<i>CY 2009</i>	<i>CY 2010</i>	<i>CY 2011</i>	<i>Last 12 Months*</i>	<i>CY 2009</i>	<i>CY 2010</i>	<i>CY 2011</i>	<i>Last 12 Months*</i>
Procedures	14,933	14,040	14,549	13,801	5,300	5,287	5,486	5,625
Capacity <sup>^</sup>	19,656	19,656	19,656	19,656	12,740	12,740	12,740	12,740
<b>% Utilization</b>	<b>76%</b>	<b>71%</b>	<b>74%</b>	<b>70%</b>	<b>42%</b>	<b>41%</b>	<b>43%</b>	<b>44%</b>

\*Last 12 months includes September 2011 to August 2012.

<sup>^</sup>Capacity based on Wake Radiology-Cary's days of operation per year, hours per day, and procedures per hour.

**Wake Radiology-Morrisville  
Mammography Utilization**

	<i>December 2011</i>	<i>December 2011 to August 2012</i>
Procedures	93	656
Capacity <sup>^</sup>	628	5,655
<b>% Utilization</b>	<b>15%</b>	<b>12%</b>

<sup>^</sup>Capacity based on Wake Radiology-Morrisville's days of operation per year, hours per day, and procedures per hour *adjusted for the months of actual operation*.

**Wake Radiology-Fuquay-Varina  
Mammography & Ultrasound Utilization**

	<i>Mammography August 2012</i>	<i>Ultrasound August 2012</i>
Procedures	48	31
Capacity <sup>^</sup>	607	195
<b>% Utilization</b>	<b>8%</b>	<b>16%</b>

<sup>^</sup>Capacity based on Wake Radiology-Fuquay-Varina's days of operation per year, hours per day, and procedures per hour *adjusted for the months of actual operation*.

<sup>3</sup> <http://www.rexhealth.com/mobile-mammography-schedule>

As shown, Wake Radiology's three nearby facilities do not currently operate above 80 percent of capacity. NCDI-Cary is required, by 10A NCAC 14C .1804(2) to demonstrate that other providers were and will be utilized at 80 percent of capacity. While the rule specifies that the applicant should consider facilities within its defined diagnostic center service area, it is clear from the discussion above that NCDI-Cary has proposed a service area in order to attempt to avoid considering other providers such as Wake Radiology. Thus, Wake Radiology's facilities should be considered in an analysis of the NCDI-Cary site. In particular, Wake Radiology-Morrisville is within a seven minute drive time of NCDI-Cary which is equivalent to the distance to Triangle Interventional Services, which was identified by NCDI-Cary as appropriate for consideration. While Wake Radiology does not have access to Triangle Interventional Services' utilization, it is within the Agency's prerogative to request that data to determine whether it is effectively utilized.

Please note that the capacity figures utilized in the table above are based on Wake Radiology's own determination of capacity based on hours of operation, procedures per hour, and annual days of operation, which Wake Radiology believes is the most appropriate definition of its own capacity. Wake Radiology's capacity estimates exceed those of NCDI-Cary due to all of these factors. Notably, Wake Radiology's Cary office offers evening and weekend hours and has higher estimates of procedures per hour. However, if NCDI-Cary's capacity assumptions are used, Wake Radiology-Morrisville's mammography equipment, Wake Radiology-Fuquay-Varina's mammography and ultrasound equipment, and Wake Radiology-Cary's ultrasound equipment would all remain below 80 percent utilization.

**Wake Radiology-Cary  
Mammography & Ultrasound Utilization at NCDI-Cary Capacity**

	<i>Mammography</i>				<i>Ultrasound</i>			
	<i>CY 2009</i>	<i>CY 2010</i>	<i>CY 2011</i>	<i>Last 12 Months*</i>	<i>CY 2009</i>	<i>CY 2010</i>	<i>CY 2011</i>	<i>Last 12 Months*</i>
Procedures	14,933	14,040	14,549	13,801	5,300	5,287	5,486	5,625
Capacity^	5,000	5,000	5,000	5,000	8,000	8,000	8,000	8,000
<b>% Utilization</b>	<b>299%</b>	<b>281%</b>	<b>291%</b>	<b>276%</b>	<b>66%</b>	<b>66%</b>	<b>69%</b>	<b>70%</b>

\*Last 12 months includes September 2011 to August 2012.

^Based on NCDI-Cary's capacity assumptions: mammography capacity assumed to be 2,500 procedures annually per unit x two units; ultrasound capacity assumed to be 2,000 procedures annually per unit x four units.

**Wake Radiology-Morrisville  
Mammography Utilization**

	<i>December 2011</i>	<i>December 2011 to August 2012</i>

Procedures	93	656
Capacity^	208	1,875
<b>% Utilization</b>	<b>45%</b>	<b>35%</b>

^Based on NCDI-Cary's capacity assumptions: mammography capacity assumed to be 2,500 procedures annually per unit x one unit, or 208 procedures per month and 1,875 procedures per nine months (December 2011 to August 2012).

**Wake Radiology-Fuquay-Varina  
Mammography & Ultrasound Utilization**

	<i>Mammography August 2012</i>	<i>Ultrasound August 2012</i>
Procedures	48	31
Capacity^	208	167
<b>% Utilization</b>	<b>23%</b>	<b>19%</b>

^Capacity based on NCDI-Cary's capacity assumptions: mammography capacity assumed to be 2,500 procedures annually per unit or 208 procedures per month; ultrasound capacity assumed to be 2,000 procedures annually per unit or 167 per month.

Please note, Wake Radiology has only provided utilization data for three facilities, but can provide similar information for its other Wake County facilities if the Agency would find such information helpful in this review.

Wake Radiology believes that the Agency can utilize the historical utilization data for its facilities provided above to evaluate NCDI-Cary's application in a manner consistent with the Agency's review and denial of Scotland Memorial Hospital's application to acquire a new CT scanner (Project ID # N-7772-06). In that review, the Agency utilized data provided during the public comment period to determine that another unit of similar equipment has not historically been utilized at 80 percent of capacity:

[I]n 10A NCAC 14C .2300 – *Criteria and Standards for Computed Tomography Equipment*, the applicants failed to demonstrate that each existing CT scanner in the project's CT service area shall have performed at least 5,100 HECT units over the past 12 months prior to submittal of the application. Although the applicants identified a CT scanner operated by Scotland Imaging, LLC, and located across from the hospital at 507 Lauchwood Drive, Laurinburg, the applicants state they were unable to obtain the number of HECT units performed on that scanner during the previous year.

Nevertheless, on January 2, 2007, the Agency received "Comments regarding Scotland Memorial Hospital Outpatient Imaging Center, Project I.D. # N-7772-06", from Scotland Imaging, LLC indicating it performed 1,148 CT procedures and 2,141.25 HECT units during calendar year 2006. Because SILLC's current volume did not exceed the minimum number of HECTs, SMH's application was found nonconforming with Performance Standards in Rule .2300, and the applicants failed to document the inability of existing providers to meet the CT diagnostic service needs of service area residents.

In addition, SILLC provided data on the utilization of its existing X-ray system during the past twelve months. SILLC stated its X-ray system performed 1,828 procedures and has a capacity of 15,300 procedures per year. Thus, SILLC calculated its X-ray system has been used at only 11.9% capacity.

In summary, the applicants failed to demonstrate the need of the population for the proposed project. Therefore, the application is nonconforming with this criterion.

See Agency Findings for Project ID # N-7772-06.

In its review of NCDI-Cary's application, the Agency should be consistent with the reviews of Scotland CT, as well as Wake Radiology NWRO. The Agency should use the utilization data provided by Wake Radiology to find that existing equipment does not currently exceed the utilization threshold, and therefore **find NCDI-Cary nonconforming with Performance Standards in Rule .1804, and also find that the applicants failed to document the inability of existing providers to meet the mammography and ultrasound needs of service area residents.** Additionally, given that NCDI-Cary's failure to appropriately identify its service area, the Agency should find it **nonconforming with Information Required of Applicant in Rule .1803(4)**

#### Failure to provide adequate financial information

NCDI-Cary's pro forma financial statements do not include any historical or interim financial information. Section X.2 requests that applicants provide balance sheet and income statement information for "*the last full fiscal year immediately prior to submission of the application*" and "*from the last full fiscal year of operation prior to submission of the application through the fiscal year during which the project is completed.*" Without this information, the Agency cannot determine that the financial projections used reasonable and supported assumptions or that the project is financially feasible. Per

N.C. GEN. STAT. § 131E-182 (b), “[a]n application for a certificate of need shall be made on forms provided by the Department. The application forms, which may vary according to the type of proposal, shall require such information as the Department, by its rules deems necessary to conduct the review. An applicant shall be required to furnish only that information necessary to determine whether the proposed new institutional health service is consistent with the review criteria implemented under G.S. 131E-183 and with duly adopted standards, plans and criteria” (emphasis added). As such, the information requested by the Agency in the application form is required in order to conduct a review and NCDI-Cary’s failure to provide the requested information precludes the Agency from conducting its review.

**On the basis of this gross omission, NCDI-Cary should be found non-conforming with Criterion 5.**

# Exhibit 1

## Young Women Skip Mammo After USPSTF Recs

By Charles Bankhead, Staff Writer, MedPage Today

Published: September 15, 2012

Reviewed by Robert Jasmer, MD; Associate Clinical Professor of Medicine, University of California, San Francisco

SAN FRANCISCO -- Rates of screening mammography among women younger than 50 declined within 2 months of a negative recommendation by the U.S. Preventive Services Task Force (USPSTF) and have remained below baseline rates, according to a study reported here.

The mammography rate among women 40 to 49 decreased by almost 8% in the period immediately after the 2009 release of the USPSTF recommendation against routine screening mammography for that age group.

Two years after publication of the screening guideline, the mammography rate among women 40 to 49 remained more than 5% lower than the baseline level.

In contrast, the screening mammography rate did not change among women 50 to 64.

In absolute terms, the decline in mammography rates meant that "more than 90,000 fewer mammograms were performed in women 40 to 49 in this dataset in the 2 years after the USPSTF update," Amy Wang, MD, of the Mayo Clinic in Rochester, Minn., and colleagues concluded in a poster presentation at the Breast Cancer Symposium.

"These findings underscore the need for further research on the benefits and risks of screening mammography, as it is difficult to act on numerous sources of contradictory information," they added.

In November 2009 the USPSTF issued updated recommendations for screening mammography. The recommendations included two key changes: The panel recommended against routine screening mammography for women younger than 50. Additionally, the USPSTF changed the recommended screening interval for women  $\geq 50$  to every 2 years instead of annually.

In recommending against routine mammography for younger women, the USPSTF, perhaps unknowingly, tossed a lighted match into a powder keg of controversy. In particular, opposition to the recommendation reached all the way to Congress, and Health and Human Services Secretary Kathleen Sebelius issued a statement distancing the Obama administration from the USPSTF decision.

The debate has continued to flare periodically almost 3 years after the USPSTF announced the decision.

Despite the widespread publicity and controversy, the recommendation's impact on clinical practice remained unclear. Wang and colleagues sought to inform on the issue by comparing rates of screening mammography before and after the USPSTF update.

Investigators analyzed claims data from more than 100 health plans for the years 2006 to 2011. They selected 2006 as the starting point to account for potential effects of the economic recession. They limited the analysis to women 40 to 64 because the dataset did not include Medicare recipients.

The analysis included 11.4 million women. Baseline mammography rates were 39.3 per 1,000 women in the 40 to 49 age group and 47 per 1,000 women in the 50 to 64 group.

Two months after the USPSTF announced the update, the screening mammography rate was 7.59% lower among women 40 to 49 as compared with rates prior to the announcement. The decline continued as the analysis extended to 2 years after the recommendation was published.

One year after the USPSTF update the mammography rate in younger women remained 5.33% below the baseline rate. At 2 years, 5.02% women ages 40 to 49 underwent screening mammography as compared with the baseline rate.

### Action Points

Note that this study was published as an abstract and presented at a conference. These data and conclusions should be considered to be preliminary until published in a peer-reviewed journal.

Rates of screening mammography among women younger than 50 had declined within 2 months of a negative recommendation by the U.S. Preventive Services Task Force (USPSTF) and have remained below baseline rates.

Point out that in contrast, the screening mammography rate did not change among women 50 to 64.

The screening rate among women 50 to 64 did not change at any point in the period included in the analysis.

Symposium invited discussant Thomas Buchholz, MD, said the study showed that the USPSTF recommendation impacted clinical practice related to screening mammography, but the reasons are not entirely clear.

"For some young women who really did not want to get their first mammogram, did it lead them not to get the mammogram? Perhaps, but we're not sure of that," said Buchholz, of the University of Texas MD Anderson Cancer Center in Houston. "I'm sure it influenced some doctors' recommendations, and that's a contributor. And I'm sure it influenced some third-party payers."

The authors reported no conflicts of interest.

**Primary source:** Breast Cancer Symposium

Source reference:

Wang AT, et al "Impact of the US Preventive Services Task Force update for breast cancer screening" BCS 2012; Abstract 5.

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#### **Related Article(s):**

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Canadian Panel Nixes Mammograms for Women in Their 40s

## Exhibit 2

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Zip/Postal Code

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Facility	Expiration
Cary Diagnostic Radiology 101 SW Cary Parkway Suite 40 Cary, NC 27511 919-467-5900 General Gynecological Vascular Deep Abdominal Vascular Peripheral	10/21/2015

### Facilities under review (1)

Facility	Expiration
Rex Diagnostic Services of Cary 1515 SW Cary Parkway, Suite 120 Cary, NC 27511 919-387-3187	NA

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#### Accredited facilities found (1)

Facility	Expiration
Rex Primary Care and Wellness Center 1515 SW Cary Pkwy, Ste 120 Cary, NC 27511 (919)784-3419	04/05/2015

#### Facilities under review (1)

Facility	Expiration
Cary Diagnostic Radiology 101 SW Cary Pkwy Ste 40 Cary, NC 27511 (919)467-5900	NA

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