

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 28, 2013
FINDINGS DATE: February 4, 2013
PROJECT ANALYST: Celia C. Inman
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: J-10025-12 / Durham Diagnostic Imaging, LLC d/b/a North Carolina Diagnostic Imaging-Cary / Develop new diagnostic center by acquiring one ultrasound unit for existing outpatient imaging center / Wake County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall 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.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

Durham Diagnostic Imaging, LLC d/b/a North Carolina Diagnostic Imaging-Cary (NCDI-Cary) proposes to acquire an ultrasound system at NCDI-Cary and obtain designation as a diagnostic center. The parent companies of NCDI-Cary are Novant Health, Inc. (Novant) and Foundation Health Systems Corp. (Foundation). Foundation is a North Carolina nonprofit corporation, the sole member of which is Novant. The management company of NCDI-Cary is MedQuest Associates, Inc. (MedQuest). NCDI-Cary is located at 3700 NW Cary Parkway in Cary.

In Section II.1(a), page 15, the applicant states NCDI-Cary currently offers CT services and mobile MRI services and provides the following chart to identify the original costs of the development of NCDI-Cary.

Item Description	Expense
Construction	\$44,287
Computers	\$12,271
Furniture	\$9,785
PACs(computer software)	\$30,147
CT Scanner & related equipment	\$332,538
Total Expenses	\$429,028

Original development of the imaging center with the CT, valued at \$332,538 being the only medical equipment, did not reach the \$500,000 threshold to trigger development of a diagnostic center. Acquisition of the proposed ultrasound equipment with a total capital cost of \$158,959 in addition to the costs necessary to make the original CT service operational exceeds \$500,000, therefore, pursuant to G.S. 131E-176(7a), acquisition of the proposed equipment results in the development of a diagnostic center, which requires a certificate of need.

The applicant does not propose to develop any beds, operating rooms, or other services or acquire equipment for which there is a need determination in the 2012 State Medical Facilities Plan (2012 SMFP). There are no policies in the 2012 SMFP that are applicable to this review. Therefore, this criterion is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (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.

NC

NCDI-Cary currently provides CT and mobile MRI services. The applicant proposes to acquire an ultrasound system at its existing NCDI-Cary location, which results in the development of a new diagnostic center as that term is defined in G.S. 131E-176(7a).

Project Component(s)

On August 15, 2012, the applicant submitted a Certificate of Need (CON) application to acquire mammography and ultrasound equipment resulting in the development of a new diagnostic center. Wake Radiology and WakeMed Health & Hospitals each submitted comments during the public comment period challenging the proposed service area population and the need the population has for the proposed services. However, neither commenter requested a public hearing. The CON Section did not request/schedule a public hearing; therefore, the expedited review requested by the applicant upon submission of its CON was approved. Per G.S. §131E-185(a2) “*When an expedited review has been approved by the Department, no public hearing shall be held. The Department may contact the*

applicant and request additional or clarifying information, amendments to, or substitutions for portions of the application. The Department may negotiate conditions to be imposed on the certificate of need with the applicant.”

During the expedited review, the analyst requested additional information. Among the information requested was clarifying information related to the proposed service area, the projected patient origin, and the projected need and utilization for the additional proposed services.

The applicant responded to the analyst’s request for additional information with a change in the proposed service area and changes in the need projection and utilization of the ultrasound and mammography services. The analyst reviewed the supplemental information and requested further clarifying information, upon which the applicant responded by eliminating the proposed acquisition of the mammography equipment and expanding the proposed service area for the ultrasound services. The following outlines the flow of information during the review:

- Applicant submits application August 15, 2012 for September 1, 2012 Review
 - Acquire mammography and ultrasound equipment and designation as a diagnostic center
 - Projected patient origin for mammography and ultrasound services
 - 95% Wake County
 - 5% Other
 - Proposed service area consisting of three Wake County zip codes
 - 27513
 - 27519
 - 27523.
 - Total capital expenditure of \$745,108.
- Applicant’s response (supplemental data) to analyst’s first request for additional information
 - Acquire mammography and ultrasound equipment and designation as a diagnostic center
 - Projected patient origin for mammography and ultrasound services
 - 89% Wake County
 - 11% Other
 - Proposed service area consisting of four Wake County zip codes
 - 27513
 - 27519
 - 27523
 - 27560
 - Total capital expenditure of \$745,108.
- Applicant’s response (final supplemental data) to analyst’s second request for additional clarifying information
 - Acquire only ultrasound equipment and designation as a diagnostic center
 - Projected patient origin for ultrasound services
 - 89% Wake County

- 11% Other
- Proposed service area consisting of 21 zip codes originating in Wake County and extending into Chatham, Durham and Johnston Counties
 - 27502
 - 27511
 - 27513
 - 27519
 - 27523
 - 27529
 - 27545
 - 27560
 - 27603
 - 27604
 - 27606
 - 27607
 - 27609
 - 27610
 - 27612
 - 27613
 - 27614
 - 27615
 - 27616
 - 27617
 - 27703
- Total capital expenditure of \$333,503.

Designation as a Diagnostic Center

In Section II.1, page 15, the applicant lists existing medical diagnostic equipment; in Section VIII.2, page 77 of the final supplemental data, the applicant lists the proposed equipment and costs; and in Exhibit F, the applicant provides the manufacturer’s quote and specifications for the proposed medical diagnostic equipment. The following table is a summary.

NCDI-Cary Existing Value and Proposed Equipment

Description	Cost/Value
Existing	
CT Scanner & related equipment	\$332,538
Construction	\$44,287
PACs and Computer	\$42,418
Original Cost of Imaging Center	\$419,243
Proposed	
Ultrasound Unit*	\$158,959
Total proposed equipment	\$158,959
Total Medical Equipment at Proposed Diagnostic Center	\$578,202

*Proposed new equipment, including shipping and tax

The total capital cost for the new ultrasound is \$158,959. The total cost/value of the medical diagnostic equipment at NCDI-Cary upon acquisition of the proposed ultrasound equipment will be \$578,202.

In Section II.1, page 15 of the final supplemental data, the applicant states:

“The acquisition of the ultrasound equipment will exceed the \$500,000 threshold as defined by NC Gen. Stat. 131E-176(7a). As such, NCDI-Cary is filing this certificate of need to obtain a diagnostic center certificate of need.”

Population to be Served

In the final supplemental data provided during the expedited review, Section II.8, page 25 and Section III.4, page 45, the applicant provides historic patient origin. The following table illustrates historical patient origin as reported on page 25.

NCDI-Cary Historic Patient Origin 2011		
County	MRI (mobile)*	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	0.3%	1.1%
Other	3.6%	3.2%
Total	100%	100%

*The MRI scanner is provided by a mobile MRI vendor.

In the final supplemental data, Section II.8, page 26, the applicant provides projected patient origin for the proposed ultrasound services by percentage by county of residence, as shown in the following table.

NCDI-Cary Patient Origin for Project Years 1-3	
County	Ultrasound
Wake	89%
Other	11%
Total	100%

On page 26, the applicant states, *“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.”*

In the final supplemental data, page 26, the applicant states the following supports the proposed service area:

“NCDI-Cary is an existing outpatient imaging facility, which predominately serves Wake County residents as indicated by its existing patient origin (89% - combined Wake County patient origin all services). The letters of support are from physicians

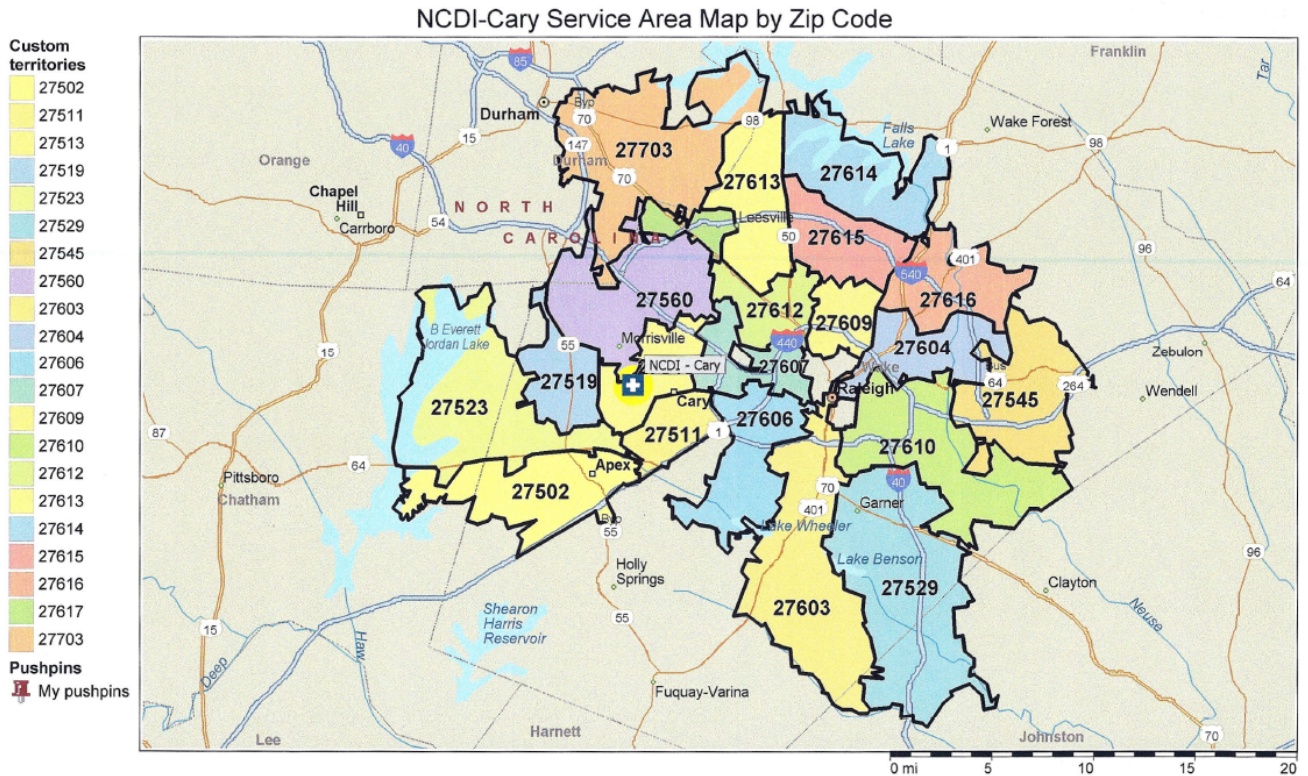
located in Wake County. However, NCDI-Cary assumes that its referring physicians would see patients from various zip codes and as such has assumed that 11% of its patients would originate from other areas outside of the proposed diagnostic center service area. This percentage of “other” patients is consistent with NCDI-Cary’s historical operating experience.”

In Section III.5(b), final supplemental data, page 47, the applicant provides the projected number of patients to be served in the first two project years by county of residence. The percentages are consistent with the information provided in Section II.8, page 26 of the final supplemental data, as shown in the table below.

NCDI-Cary Patient Origin for Project Years 1 and 2				
County	Number of Patients Yr 1	Percentage of Total Yr 1	Number of Patients Yr 2	Percentage of Total Yr 2
Wake	2,446	89%	2,488	89%
Other	302	11%	307	11%
Total	2,748	100%	2,795	100%

In Section III.1, final supplemental data, page 32, the applicant states, “*NCDI-Cary is proposing a diagnostic center service area that is consistent with its current patient utilization trends for CT and Mobile MR services. The following map outlines the proposed diagnostic center service area, which represents 69% of NCDI-Cary’s current patient origin.*”

The map provided by the applicant in the final supplemental data, Section III.1, page 32 and Section III.5, page 46, has been reproduced below.



In Section III.5, final supplemental data, page 45, the applicant describes its proposed service area as follows:

“The proposed service area represents the central core of Wake County, which has easy accessibility to NCDI-Cary’s location due to the close proximity of the facility to the I-440 and I-540 beltlines.”

Thus, in Section III.1, page 32, and Section III.5, page 46, the applicant proposes a zip code service area which is not consistent with the proposed service area reported in Section II.8, page 26, and Section III.5, page 47.

The applicant does not provide adequate explanation to show how the proposed zip code service area on pages 32 and 46 relates to the projected patient origin on pages 26 and 47 where the applicant states that 89% of all patients are projected to be Wake County residents.

Furthermore, the applicant states on page 47 of the final supplemental data, “NCDI-Cary assumes that its referring physicians would see patients from various zip codes and as such has assumed that 11% of its patients would originate from other areas outside of the proposed diagnostic center service area.” The applicant states that 11% of the patients are expected to be residents of zip codes not included in the proposed zip code service area. But on pages 32 and 46, the applicant does not include an “other”. Most of the zip codes lie entirely in Wake County. Only three of the 21 zip codes extend into other counties. Moreover, it is not likely that the percentage for “other” would be 11% for both the projected “Wake County and other” patient origin reported on pages 26 and 47 and the proposed zip

code service area (21 zip codes originating in Wake County and extending into Chatham, Durham and Johnston counties) reported on pages 32 and 46. Particularly, since there are more counties included in “other” as described on pages 26 and 47 than are included in “other” when looking at the map of the proposed zip code service area on pages 32 and 46. In addition, parts of Wake County are not included in the proposed zip code service area but presumably all of Wake County is included in the proposed service area as reported on page 47, where the applicant does not state that “Wake County” does not include all of Wake County.

Furthermore, the applicant does not adequately explain why the contiguous zip codes 27518, 27539 and 27540, located in the center of the proposed zip code service area, were not included in the proposed zip code service area. See the map above. The applicant includes the southern region of the Garner zip code 27529 which is located much farther from the facility than zip code 27518. Zip code 27518 is a contiguous zip code in the center of the proposed zip code service area, within 10 miles driving distance of the facility. Moreover, the applicant received a significant number of referrals from physicians located in zip code 27518. Attachment Z contains physician support letters from 5 physicians located in one of the omitted zip codes (27518) estimating 480 referrals.

Moreover, in comments submitted during the public comment period, Wake Radiology provided utilization for the ultrasound at Wake Radiology-Cary (located in zip code 27518) and indicated that the ultrasound operates far below 80% of capacity, as defined by Wake Radiology (43% of capacity for CY2011 and 44% for CY2012). Novant Health owned, MedQuest managed North Carolina Diagnostic Imaging-Holly Springs (NCDI-Holly Springs) received a certificate of need (Project ID #J-8537-10) in June 2011 to develop a diagnostic center with an ultrasound unit to be located in the Holly Springs zip code of 27540. That zip code also includes two hospital-based ultrasound providers. By not including those zip codes, the applicant would not be required to demonstrate that existing ultrasound equipment located in those zip codes operated at 80% of capacity during the 12 months before submitting the application, as required by 10A NCAC 14C .1804(1). Moreover, the applicant would not be required to demonstrate that existing and approved ultrasound equipment would be operating at 80% of capacity by the fourth quarter of Project Year 3 as required by 10A NCAC 14C .1804(2). Based on historical patient origin for MRI and CT services, it would appear that the excluded zip codes should have been included in the proposed zip code service area. In particular, the approved ultrasound to be located at NCDI-Holly Springs will be managed by the same legal entity. The applicant should be able to determine the annual capacity and to project utilization for that unit since it will be owned ultimately by Novant and managed by MedQuest which is owned by Novant.

In summary, the applicant does not adequately identify the population it proposes to serve. The discrepancy between the projected patient origin on pages 26 and 47 of the final supplemental data (89% Wake, 11% Other) and the proposed zip code service area described on pages 32 and 46 was not adequately explained. In addition, the applicant did not adequately demonstrate the reasonableness of the proposed zip code service area given the historical patient origin for MRI and CT services, estimated physician referrals and the proximity of the excluded zip codes.

Demonstration of Need

The applicant states it reviewed epidemiological studies, capabilities of the proposed equipment, national and state utilization rates and internal data in the development of its need methodology for additional ultrasound services in the proposed zip code service area.

In Section III, final supplemental data, page 34, the applicant explains ultrasound technology is a widely utilized imaging service that involves exposing part of the body to high-frequency sound waves to produce pictures of the inside of the body. By beaming high-frequency sound waves into the body, the echoes that bounce off body tissues and organs are captured by sensitive transducers and then translated into visual images utilizing powerful computers that provide valuable medical information. Ultrasound is used to detect changes in the appearance of organs, tissue and vessels or to detect abnormal masses, such as tumors. Ultrasound is a tool used to examine many of the body's internal organs and can be used to help detect heart disease, the leading cause of death for both men and women; stroke; abnormalities in the abdomen or reproductive system; prostate cancer; musculoskeletal issues; and breast cancer among other diseases.

In Section II.1, pages 15-16, the applicant proposes to acquire an ultrasound system and states:

“The Acuson S1000 system supports multiple transducers and exam types to scan any organ or body type. This ultrasound system has ability to support a broad range of specialties from obstetrics and gynecology to cardiology, using innovations such as:

- *Clarify™ vascular enhancement (VE) technology – Allows clinicians to clearly differentiate vascular anatomy from acoustic artifacts and surrounding tissue.*
- *Amnioscopic Rendering – Improves the visualization of fetal anatomy and provides the most photo realistic fetal ultrasound images ever produced by shining a unique user-movable light into the imaged structures.*
- *Syngo® Velocity Vector Imaging (VVI) – Enables clinicians to examine mechanical myocardial functions to determine possible dyssynchrony and fetal heart dysfunction.”*

In Section III.1, final supplemental data, page 37, NCDI-Cary provides the following information which it states demonstrates a need for the proposed ultrasound service:

“According to the American College of Radiology’s website, the following utilization rates for imaging services were estimated for 2008.

<i>Estimated Country Level Utilization by Modality 2008</i>	
<i>Modality</i>	<i>Per 1000 Persons</i>
<i>CT</i>	<i>287</i>
<i>MRI</i>	<i>86</i>
<i>Ultrasound</i>	<i>522</i>
<i>Xray (total including mammography)</i>	<i>1,091</i>
<i>All Diagnostic Radiology</i>	<i>2,259</i>

Based on procedure counts for Part B, nonmanaged care Medicare enrollees.

NCDI-Cary recognizes that this information focuses on the Medicare population. However, non-hospital based outpatient imaging centers are not required to report ultrasound procedure data in North Carolina. This makes it difficult, if not impossible, to determine a reliable ultrasound utilization rate based on publicly available information for all providers (hospitals and non-hospital based facilities).”

In Section III, pages 32-41 of the final supplemental data, the applicant provides the following table showing population estimates for its proposed zip code service area from 2010-2016.

NCDI-Cary Proposed Service Area Population							
Zip Code	2010	2011	2012	2013	2014	2015	2016
27513	40,755	41,448	42,152	42,869	43,598	44,339	45,093
27519	39,178	39,844	40,521	41,210	41,911	42,623	43,348
27523	9,552	9,714	9,880	10,047	10,218	10,392	10,569
27560	22,623	23,008	23,399	23,796	24,201	24,612	25,031
27502	30,831	31,355	31,888	32,430	32,982	33,542	34,112
27511	32,029	32,573	33,127	33,690	34,263	34,846	35,438
27529	42,148	42,865	43,593	44,334	45,088	45,854	46,634
27545	23,006	23,397	23,795	24,199	24,611	25,029	25,455
27606	43,210	43,945	44,692	45,451	46,224	47,010	47,809
27603	47,033	47,833	48,646	49,473	50,314	51,169	52,039
27604	42,204	42,921	43,651	44,393	45,148	45,915	46,696
27607	25,188	25,616	26,052	26,495	26,945	27,403	27,869
27609	32,964	33,524	34,094	34,674	35,263	35,863	36,473
27610	65,648	66,764	67,899	69,053	70,227	71,421	72,635
27612	35,028	35,623	36,229	36,845	37,471	38,108	38,756
27613	42,690	43,416	44,154	44,904	45,668	46,444	47,234
27614	31,516	32,052	32,597	33,151	33,714	34,288	34,870
27615	42,166	42,883	43,612	44,353	45,107	45,874	46,654
27616	42,294	43,013	43,744	44,488	45,244	46,013	46,796
27617	15,199	15,457	15,720	15,987	16,259	16,536	16,817
27703	41,937	42,650	43,375	44,112	44,862	45,625	46,401
Total	747,199	759,901	772,820	785,958	799,319	812,907	826,727

Source:www.zip-codes.com (based on 2010 US Census Data); 2010 data increased by the CAGR for Wake County of 1.7% based on data from the NC OBSM 2010-2016.

In Section III.1, final supplemental data, pages 38-41, the applicant discusses the proposed service area in terms of the use of the proposed services by the population age 65 and older. On page 38, the applicant includes the following information on projected population age 65 and older for the proposed zip code service area.

NCDI-Cary Proposed Service Area Population 65+							
Zip Code	2010	2011	2012	2013	2014	2015	2016
27513	2,658	2,703	2,749	2,796	2,843	2,892	2,941
27519	2,551	2,594	2,638	2,683	2,729	2,775	2,823
27523	778	791	805	818	832	846	861
27560	946	962	978	995	1,012	1,029	1,047
27502	2,007	2,041	2,076	2,111	2,147	2,183	2,221
27511	4,612	4,690	4,770	4,851	4,934	5,018	5,103
27529	5,591	5,686	5,783	5,881	5,981	6,083	6,186
27545	1,754	1,784	1,814	1,845	1,876	1,908	1,941
27606	2,339	2,379	2,419	2,460	2,502	2,545	2,588
27603	3,634	3,696	3,759	3,823	3,887	3,954	4,021
27604	3,678	3,741	3,804	3,869	3,935	4,001	4,069
27607	1,896	1,928	1,961	1,994	2,028	2,063	2,098
27609	4,912	4,996	5,080	5,167	5,255	5,344	5,435
27610	4,671	4,750	4,831	4,913	4,997	5,082	5,168
27612	4,458	4,534	4,611	4,689	4,769	4,850	4,932
27613	2,976	3,027	3,078	3,130	3,184	3,238	3,293
27614	2,663	2,708	2,754	2,801	2,849	2,897	2,946
27615	5,674	5,770	5,869	5,968	6,070	6,173	6,278
27616	1,990	2,024	2,058	2,093	2,129	2,165	2,202
27617	793	806	820	834	848	863	877
27703	3,013	3,064	3,116	3,169	3,223	3,278	3,334
Total	63,594	64,675	65,775	66,893	68,030	69,186	70,363

Source:www.zip-codes.com based on 2010 US Census Data; subsequent years - 2010 data increased by the CAGR for Wake County of 1.7% based on data from the NC OBSM 2010-2016.

The applicant’s methodology for projecting population by zip code starts with base 2010 zip code population from 2010 US Census data for the total population and the selected age group populations and increases the 2010 population by a 1.7% compound annual growth rate (CAGR). This CAGR is relatively low. According to the projected population data obtained by the analyst from The North Carolina Office of State Budget and Management (NC OSBM), the CAGR for Wake County total population from 2010 to 2016 is 1.99%. The CAGR for the population 65 and older is 5.87%.

NCDI-Cary applied the ACR utilization rate of 522 procedures per 1,000 residents to the 65 and older population to estimate the number of ultrasounds to be performed. In Section III.1, pages 37-38 of the final supplemental data, the applicant states:

“This estimate would not be a complete indication of the actual full demand in the proposed diagnostic center service area since it does not project for those under 65 years of age, which represent over 91.5% of the population.”

Applicant's Projected Ultrasound Service Area Need Age 65+			
	Yr 1 - 2014	Yr 2 - 2015	Yr 3 - 2016
Population 65+	68,030	69,186	70,363
Utilization Rate/1000	522	522	522
Estimated SA Scans 65+	35,512	36,115	36,729

The projection above for ultrasound services for the population age 65 and older appears to be based on reasonable assumptions for that age group and calculated using conservative 2010 US Census population estimates. If the applicant had applied the NC OSBM CAGR for the population age 65 and older (5.87%), that portion of the population in the proposed zip code service area would be projected to increase by 2,885 to 73,248 in 2016 and the number of ultrasound scans needed by residents age 65 and older in the proposed zip code service area would have increased by more than 1,500 scans in 2016.

The applicant states the age group 65 and older represented 8.5% of the total population of the proposed diagnostic center zip code service area in 2010. The North Carolina Office of State Budget and Management (NC OSBM) provides data estimating the population age 65 and older will comprise 11% in 2016. As stated above, the population age 65 and older reflects only a small proportion of the proposed zip code service area. The applicant does not attempt to project ultrasound need for the population under age 65. The other 89% (91.5 % per the applicant) of the 2016 population will utilize ultrasound services at some rate, but the applicant did not attempt to project utilization for the population under age 65.

Projected Utilization

In Section III, page 36 of the final supplemental data, the applicant states:

“NCDI-Cary reviewed the national utilization rates for ultrasound, reviewed internal data for other Novant/MedQuest outpatient facilities offering similar services and projected population estimates for the service area to assist with the projected demand for these services at NCDI-Cary. Ultimately, NCDI-Cary utilized its referring physician estimates as the basis for its projections. The use of physician estimates is reasonable based on the following factors:

- *Physicians are the direct care providers and are responsible for ordering necessary medical diagnostic procedures for their patients.*
- *Physicians are familiar with the needs of the patients seen in their practices.*
- *Physicians are aware of the availability (and subsequent need) for medical imaging services in their community.*
- *Physicians are willing to refer patients to outpatient imaging providers that provide their patients with thigh quality services at affordable rates.”*

The applicant states the estimated number of procedures in Project Year 1 is based on the physician referral estimates included in Attachment Z and provides a chart on page 39 of the final supplemental data detailing the referrals per month by zip code. The zip code service area annual total excludes the physician referrals originating from zip code 27518, which is not included in the proposed zip code service area. Therefore, as shown in the following table, the applicant included only 85% (2,748/3,228) of the estimated physician referrals shown in Attachment Z in its projected utilization.

Physician Office Location and Annual Referrals		
Zip Code	Number of Physicians	Ultrasound Referrals
27513	10	1,980
27519	3	324
27560	3	444
27523	0	0
Total Referrals in Proposed SA	21	2,748
Referrals from Zip Code 27518	5	480
Total Referrals in Attachment Z		3,228

On page 40 of the final supplemental data, the applicant provides the annual capacity for the proposed ultrasound unit as follows: 250 days x 14 procedures per day = 3,500 procedures annually, with 80% of capacity being 2,800 procedures. The following table illustrates the applicant’s projected demand for ultrasound services at NCDI-Cary based on its physician referral estimates, excluding those for zip code 27518.

NCDI-Cary Projected Ultrasound Utilization			
	Yr 1 - 2014	Yr 2 - 2015	Yr 3 - 2016
Ultrasound Patients 65+	2,748		
% Increase		1.7%	1.7%
NCDI-Cary Ultrasound Volume	2,748	2,795	2,843
% of Capacity	78.5%	79.8%	81.2%

Note: The applicant uses its CAGR calculation of 1.7%: NC OSBM CAGR for the population 65 and older = 5.87%

As the table above shows, the applicant’s total projected utilization is based on the 2,748 physician referrals originating from the proposed zip code service area. However, the proposed zip code service area, representing only 69% of historical patient origin for MRI and CT services, is projected to represent 100% of projected utilization. This is not consistent with the projected patient origin provided in the final supplemental data, Section II.8, page 26, where 89% of the patients are projected to be residents of Wake County and 11% are projected to live outside Wake County. Most of the 21 zip codes are entirely in Wake County. Only three of the 21 zip codes extend into other counties. The applicant does not adequately explain how it determined the ratio would be 89% Wake and 11% Other. It is not likely that it would be the same ratio as the historical patient origin for MRI and CT services.

NCDI-Cary projects the zip code service area residents age 65 and older will have a need for more than 36,000 ultrasounds in 2016. The projection assumes one procedure per patient, and does not include a projection for individuals under age 65.

On page 34 of the final supplemental data, the applicant states, “...the proposed diagnostic center service area has nearly 750,000 residents and can support the addition of an ultrasound unit at NCDI-Cary’s existing facility.”

The applicant does not use a market share analysis to project ultrasound utilization at NCDI-Cary. The analyst determined that the applicant is essentially projecting a 7.7% market share for the zip code service area ultrasound patients age 65 and older in 2016. Per the data provided by the applicant in Section III.6, page 48 of its final supplemental data, there are 18 existing ultrasound providers in the proposed zip code service area. If market share is distributed equally based on the number of providers (19, including the applicant) market share per provider would be only 5.26%. However, if market share is distributed equally based on the number of ultrasound units in the zip code service area (54 according to the applicant’s chart on page 48 and including the applicant’s unit) market share per ultrasound unit would be only 1.85%. The only support for the applicant’s projected market share for the population age 65 and older are the referral estimates included in the physicians’ letters provided in Attachment Z.

Pursuant to 10A NCAC 14C .1804(1), the applicant is required to demonstrate that all existing ultrasound units located in the proposed service area operated at 80% of capacity during the 12 months immediately preceding submission of the application. In Section II.8, pages 28-29 of the final supplemental data, the applicant provides information on the existing ACR-accredited ultrasound providers in the proposed zip code service area. The following table shows the hospital-based ultrasound providers identified by the applicant.

Hospital-Based Ultrasound Utilization

Hospital-based Provider	Ultrasound Units	Total Procedures	Procedures per Unit
WakeMed Apex HealthPlex	2	1,704	852
Rex Healthcare	23	18,101	787
Duke Raleigh Hospital	6	8,299	1383
WakeMed Apex HealthPlex	7	14,394	2056
WakeMed North HealthPlex	1	3,980	3980
WakeMed Brier Creek HealthPlex*	1	131	131

Source: Pages 48-49 of the final supplemental data. The applicant relied on the 2012 Hospital License Renewal Applications.

*Volume does not represent a full year of operation.

On page 28, the applicant states, “NCDI-Cary is unable to accurately determine capacity levels due to the lack of information regarding hours of operation, staffing average procedure times, equipment capabilities, etc.”

However, based on the applicant’s own assumptions regarding the capacity of an ultrasound unit located in a diagnostic center (3,500 annual procedures), the analyst determined which of the existing hospital-based providers’ ultrasound services are not utilized at 80% of capacity (as defined by the applicant). Note: a hospital could easily operate longer hours than a diagnostic center, resulting in a lower percentage of capacity than what is shown in the table below.

Hospital-Based Ultrasound Utilization

Hospital-based Provider	Ultrasound Units	Capacity @ 3,500 per unit	Total Procedures Reported	Percent of Capacity
WakeMed Apex HealthPlex	2	7,000	1,704	24.3%
Rex Healthcare	23	80,500	18,101	22.5%
Duke Raleigh Hospital	6	21,000	8,299	39.5%
WakeMed Apex HealthPlex	7	24,500	14,394	58.8%
WakeMed North HealthPlex	1	3,500	3,980	113.7%
WakeMed Brier Creek HealthPlex*	1	3,500	131	3.7%

*Volume does not represent a full year of operation

As the table above shows, the only facility that operated at 80% of capacity or greater, as defined by the applicant, is WakeMed North HealthPlex, which operated at 113.7% of capacity. Moreover, if the omitted zip codes were included in the proposed service area, there would be other ultrasound units that operated at less than 80% of capacity, including the one at Wake Radiology-Cary.

The applicant does not attempt to provide projected utilization for existing and approved ultrasound units located in the proposed zip code service area to demonstrate that these units will be operating at 80% of capacity in the fourth quarter of Project Year 3 as required by 10A NCAC 14C .1804(2).

In summary, the applicant did not adequately identify the population it proposes to serve because it provides inconsistent information regarding the population to be served and the proposed zip code service area is not based on reasonable, credible and supported assumptions. Furthermore, the applicant does not adequately demonstrate the need for the proposed ultrasound unit. Consequently, the application is not conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

NC

In Section III.3, final supplemental data, page 44, the applicant describes the alternatives considered prior to submission of this application, which include:

1. Maintain the Status Quo – the applicant states that the “numerous letters of support” received for the project demonstrates the need for ultrasound services at its facility. Not acquiring the equipment would not meet the need.
2. Joint Venture – the applicant states this is not a viable option as NCDI-Cary requires the equipment to be onsite each day to provide the most efficient services for referring physicians and patients.
3. Mobile Vendor - the applicant states this is not a viable option as NCDI-Cary requires the equipment to be onsite each day to provide the most efficient services for referring physicians and patients.
4. File certificate of need to acquire an ultrasound unit and obtain a diagnostic center designation.

The applicant explains why it chose the selected alternative over the other alternatives. However, the applicant did not adequately demonstrate there is an unmet need for an additional ultrasound unit in the proposed zip code service area. Furthermore, the application is not conforming to all other statutory and regulatory review criteria, and thus, is not approvable. A project that cannot be approved cannot be an effective alternative. The applicant did not adequately demonstrate that its proposal is the least costly or most effective alternative to meet the need it says exists. Consequently, the application is not conforming to this criterion and can not be approved.

- (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.

NC

In Section VIII.1, pages 77-79, the applicant projects the total capital cost for the acquisition and installation of the proposed equipment will be \$333,503; which includes \$158,959 for the proposed equipment, \$104,544 for renovations and \$70,000 for furniture, architect/engineering fees, consultant fees and contingency. In Section IX, page 87, the applicant states the project does not require any start-up or initial operating expenses. In Section VIII.3, page 80, the applicant states the project will be funded through accumulated reserves of “*MedQuest/Novant, Inc.*” Attachment S contains a letter dated August 6, 2012 from a MedQuest Vice President, which states:

“This letter confirms the availability of funds for Durham Diagnostic Imaging, LLC d/b/a North Carolina Diagnostic Imaging – Cary (“NCDI-Cary”) to support the capital expenditure required for the acquisition of ultrasound and mammography equipment as proposed in NCDI-Cary’s CON application. The total capital expenditure required for the proposed project is \$745,108, which includes the total cost of the imaging equipment and other related equipment, construction, expenses and common consulting fees. The project does not require any start-up and initial operating expenses as it is an existing outpatient imaging facility.

MedQuest, Inc., an affiliate of NCDI-Cary, will make available all funds necessary to finance the proposed project and required working capital, as well [sic] any unforeseen expenses related to the CON application, through its accumulated reserves and through MedQuest Inc.’s \$425 million Revolving Line of Credit with Novant Health, Inc.”

The letter states in a footnote, “As of June 30, 2012, MedQuest, Inc. had in excess of \$100 Million of availability under this Revolving Line of Credit.” The analyst notes the letter was submitted with the application and states adequate funding for the original proposal to acquire both ultrasound and mammography equipment; therefore it states adequate funding for the project as now proposed in the final supplemental data submitted during the expedited review. However, the applicant does not provide financial statements for MedQuest, Inc. to document MedQuest has sufficient funds for the capital needs of the project.

Attachment T contains audited financial statements for Novant, which shows that, as of December 31, 2011, Novant had total cash and cash equivalents of \$301,708,000; total assets of \$4,481,951,000 and excess of revenues over expenses of \$890,000. However, the applicant does not provide a letter from a fiscally responsible officer of Novant committing to provide Novant’s funds for the capital needs of the project.

In summary, the applicant provides a letter committing funding from MedQuest, but does not provide financial statements to document availability of funds from that entity. The applicant then provides financial statements for Novant showing availability of funds, but does not provide a letter from that entity to commit to funding the project. Therefore, the applicant does not adequately demonstrate the availability of funds for the capital needs of the project.

In Form D of the final supplemental data ProFormas, the applicant provides projected average charges for the proposed ultrasound services. The charges remain unchanged for the first three years of operation, as shown in the table below.

	ULTRASOUND
FY 2014	\$319
FY 2015	\$319
FY 2016	\$319

In Form B of the final supplemental data ProFormas, the applicant projects revenues (total charges) will exceed expenses (costs) in all three project years for the proposed service and the entire facility. The applicant adequately demonstrates that the projected costs and charges are based on reasonable assumptions.

The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges, but did not adequately demonstrate the availability of funds for the capital needs of the project. Therefore, the application is not conforming to this 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.

NC

The applicant proposes to acquire an ultrasound system at NCDI-Cary and obtain designation as a new diagnostic center. The applicant's proposed zip code service area consists of multiple zip codes which originate in Wake County and extend into contiguous counties. The facility is located in zip code 27513. The remaining zip codes are located to the north, south, east and west of 27513. In Section III.5(a), final supplemental data, page 45, the applicant states,

“NCDI-Cary has designated a zip code-based service area, which represents 69% of NCDI-Cary’s current patient origin for CT and mobile MRI services. The proposed service area represents the central core of Wake County, which has easy accessibility to NCDI-Cary’s location due to the close proximity of the facility to the I-440 and I-540 beltlines. The proposed diagnostic center service area is reflective of anticipated patient origin patterns for NCDI-Cary.”

In Section III.6, pages 48-49, the applicant provides a listing of the ACR-accredited ultrasound facilities in the proposed zip code service area. The applicant also lists the number of units and corresponding number of procedures performed by the hospital-based providers on the list. The applicant notes the unavailability of volume data for the freestanding facilities.

However, based on the applicant's assumptions regarding the capacity of an ultrasound unit located in a diagnostic center (3,500 annual procedures), the analyst determined which of the existing hospital-based providers' ultrasound services are not utilized at 80% of capacity (as defined by the applicant). Note: a hospital could easily operate longer hours than a diagnostic center, resulting in a lower percentage of capacity than what is shown in the table below.

Hospital-Based Ultrasound Utilization

Hospital-based Provider	Ultrasound Units	Capacity @ 3,500 per unit	Total Procedures Reported	Percent of Capacity
WakeMed Apex HealthPlex	2	7,000	1,704	24.3%
Rex Healthcare	23	80,500	18,101	22.5%
Duke Raleigh Hospital	6	21,000	8,299	39.5%
WakeMed Apex HealthPlex	7	24,500	14,394	58.8%
WakeMed North HealthPlex	1	3,500	3,980	113.7%
WakeMed Brier Creek HealthPlex*	1	3,500	131	3.7%

*Volume does not represent a full year of operation

As the table above shows, the only facility that operated at 80% of capacity or greater, as defined by the applicant, is WakeMed North HealthPlex, which operated at 113.7% of capacity.

The applicant did not adequately demonstrate the need for an additional ultrasound unit in the proposed zip code service area. One, the applicant did not adequately demonstrate that the proposed zip code service area is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding the population to be served (i.e., patient origin) which is incorporated hereby as if set forth fully herein. Two, there are existing ultrasound units in the proposed zip code service area that are not operating at 80% of capacity as required by 10A NCAC 14C .1803(1). See Criterion (3) for additional discussion which is incorporated hereby as if set forth fully herein. Therefore, the applicant did not adequately demonstrate the proposal will not result in the unnecessary duplication of existing or approved ultrasound units in the proposed zip code service area. Thus the application is not conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section II.4, final supplemental data, page 17, the applicant states the proposed ultrasound services will be available 8:30 am to 5:00 pm, Monday through Friday.

In Section VII.1, pages 71-72 of the final supplement data, the applicant projects staffing and average annual salary during Project Year 2, as shown in the following table.

Projected Staffing Year 2

POSITION TITLE	# OF FTEs	ANNUAL SALARY	Expense
Administrator	0.20	\$80,474	\$16,095
Radiology Technologist	2.00	\$67,691	\$135,382
Clerical	1.00	\$36,965	\$36,965
Total Staffed FTEs	3.2		\$188,442

The applicant projects one additional full time equivalent (FTE) radiology technologist position. In Section VII.5, page 74, the applicant states, *“The proposed staff at NCDI-Cary will be sufficient for the operation of the proposed project. 2.0 FTE Technologists on staff will provide more than sufficient coverage for all modalities during the facility’s hours of operation.”* In Section V.3, page 55, the applicant states, *“Dr. Christopher Cepeda will serve as Medical Director for NCDI-Cary following approval of the proposed project.”* Attachment K includes a letter documenting Dr. Cepeda’s willingness to serve as Medical Director. In Section II.7(a), page 19, the applicant states Dr. Cepeda and his associates at Durham Radiology will provide interpretive services.

It is noted that the applicant appears to provide contradictory information regarding the proposed number of FTE administrator and technologist positions. In Section II, page 32 of the final supplemental data, the applicant identifies the number of staff by type projected to provide services, as shown in the following table.

Staff	FTE
Administrator / Center Manager	0.5
Technologists	3.0
Clerical	1.0
Total Staffed FTEs	4.5

As shown in the table above, instead of 0.2 of a FTE administrator/center manager position, the table in Section II, page 32 shows 0.5 of a FTE position. On page 32, the applicant shows 3 FTE technologist positions, not 2.

In the ProFormas provided in the final supplemental data, the applicant projects \$188,442 as the total salary expense in Project Year 2, which is consistent with the representations in Section VII. In Section VII.3, page 74 of the final supplemental data, the applicant states it will add 1.0 FTE for the facility. In Section VII.5, page 74, the applicant states,

“The proposed staff at NCDI-Cary will be sufficient for the operation of the proposed project. 2.0 FTE Technologists on staff will provide more than sufficient coverage for all modalities during the facility’s hours of operation.”

Therefore, it appears the application contains an error in the response in Section II. However, the number of FTE positions proposed in Section VII is sufficient for the ultrasound services proposed in this application. Therefore, the applicant adequately

demonstrates the availability of sufficient health manpower and management personnel for the provision of the proposed services.

Therefore, the application is conforming to this 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.

C

In Section II.2, page 16 of the final supplemental data, the applicant states that MedQuest will provide the necessary ancillary and support services. Attachment B contains the proposed management agreement with MedQuest.

In Section V.2, page 54, the applicant states NCDI-Cary will establish working relationships to provide acute care services as needed for NCDI-Cary's patients. The applicant also states NCDI-Cary will accept referrals from hospitals where physicians utilizing the facility have practice privileges. In Section II.3, page 17, the applicant states,

“NCDI-Cary will work with the closest appropriate provider to transfer a patient who develops an emergent problem while undergoing a diagnostic procedure at NCDI-Cary. NCDI-Cary also adheres to the facility's Emergency Policy which explains the procedures to follow in case of an emergency situation in the facility. Please refer to Attachment H for a copy of NCDI-Cary's Emergency Policy.”

In Section V.3, pages 54-55, the applicant describes NCDI-Cary's routine practice for technologists to call referring physicians to ask questions, clarify orders and suggest techniques to enhance the diagnostic capability of the requested scan for the benefit of the patient.

The applicant provides letters of support for the proposal from Wake County physicians in Attachment Z. The applicant adequately demonstrates the availability of necessary ancillary and support services, and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the

project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section III.2, final supplemental data, page 43, the applicant states NCDI-Cary provides equal access to all patients in need of imaging services without regard for the patient's ability to pay for the services. In Section VI.2, page 59, the applicant states NCDI-Cary will not discriminate based on race, creed, color, sex, age, religion, national origin, mental or physical handicap, or ability to pay. In the final

supplemental data, Section VI.12, page 66, the applicant provides the facility payor mix for the last full fiscal year.

NCDI-Cary Percent of Total Utilization 1/1/2011-12/31/2011	
Self Pay/Indigent/Charity	9.6%
Medicare/Medicare Managed Care	8.1%
Medicaid	0.7%
Commercial Insurance	55.5%
Managed Care	22.9%
Other (Champus)	3.2%
TOTAL	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Wake County and statewide.

County	2010 Total # of Medicaid Eligibles as % of Total Population	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2008-09 (Estimate by Cecil G. Sheps Center)
Wake	10.0%	3.4%	18.4%
Statewide	17.0%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the proposed services at the same rate as older segments of the population, particularly the services offered by NCDI-Cary.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage was 45.9% for those age 20 and younger and 30.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina.

In addition, data is available by age, race and gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates it provides adequate access to medically underserved groups. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.11, page 65, the applicant states NCDI-Cary has no current obligation or any prior obligation under any Federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. In Section VI.4, page 60, the applicant states NCDI-Cary provides equal access to all patients in need of imaging services without regard for the patient's ability to pay for the services. In Section VI.11, page 65, the applicant states NCDI-Cary does not and will not discriminate on the basis of race, creed, color, sex, age, religion, national origin, mental or physical handicap, or ability to pay. See Attachment O for MedQuest's admission policy. In Section VI.10, page 65, the applicant states, "*There have been no civil rights equal access complaints filed against any facility or services owned by MQ Associates, Inc. or Novant Healthcare in North Carolina in the last five years.*" The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.6, page 62, the applicant states NCDI-Cary's policy is to accept all patients regardless of payment source, and without distinction due to race, color, national origin, disability, age, religion, or ability to pay. See Attachment O for MedQuest's admission policy.

In Section VI.14 and VI.15, final supplemental data, page 67, the applicant projects the following payor mix during the second full fiscal year for the entire facility and for the proposed ultrasound services, based on historical payor mix for MedQuest sites in the region.

NCDI-Cary Percent of Total Utilization Entire Facility and Each Service Component 1/1/2013-12/31/2013	
Self Pay/Indigent/Charity	9.6%
Medicare/Medicare Managed Care	8.1%
Medicaid	0.7%
Commercial Insurance	55.5%
Managed Care	22.9%
Other (Champus, Workers Compensation, Third Party Admin)	3.2%
TOTAL	100.0%

However, in the final supplemental data ProFormas, the applicant provides the following payor mix for both the ultrasound services and the entire facility for each year.

NCDI-Cary Percent of Total Utilization Forms C and D Projected Year 1-3	
Self Pay/Indigent/Charity	9.6%
Medicare/Medicare Managed Care	8.1%
Medicaid	0.7%
Commercial Insurance	12.7%
Managed Care	38.7%
Other	30.2%
TOTAL	100.0%

In the first set of supplemental data, the applicant corrected the payor mix in Sections VI.14 and VI.15 to agree with the payor mix in the ProFormas. It appears the applicant forgot to make the corrections in Section VI in the final supplemental data.

In Section VI.6, page 62 of the final supplemental data, the applicant states NCDI has a generous charity policy to increase accessibility to diagnostic services for patients who might otherwise be unable to afford services. On page 64, the applicant states that for uninsured patients, NCDI-Cary reduces the charge to the 2012 Medicare Allowable Fee Schedule for that service.

In Section III.2, page 43, the applicant states NCDI-Cary will adopt a generous charity care policy consistent with requirements of its ultimate parent company, Novant Health, Inc. The Novant Health charity care policy has been recognized by the North Carolina Health Access Coalition as being one of the most generous policies in the State of North Carolina. See Attachment N.

The application includes conflicting projections of payor mix in Section VI and the ProForma financial statements; however, it appears to be only an oversight in the submission of the final supplemental data. Furthermore, because the gross revenue and net revenue for the payors in question was the same for each category, the percentage breakdown does not affect total gross or total net revenue. Moreover, the percent of total utilization projected for medically underserved groups, specifically, Self-pay/Indigent/Charity, Medicare and Medicaid are not impacted at all. The applicant demonstrates that it will provide adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9, page 64, the applicant states a referral from a licensed physician is required for access to NCDI-Cary's proposed imaging services. Payors do not permit patients to self-refer for imaging scans. NCDI-Cary referrals will come from a variety of local physicians and physician groups. In Section VI.9(c), page 65, the applicant states NCDI-Cary does not have any formal working agreements with other existing health care facilities or agencies because a patient's care is directed by his or her attending physician. In Section V.2, pages 53-54, the applicant states NCDI-Cary works with the closest appropriate provider to transfer a patient who is in need of emergent medical care. The application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1 of the application, page 53, the applicant states,

“Durham Diagnostic Imaging, LLC currently has a clinical training agreement with Wake Technical Community College. NCDI-Cary will offer its facility as a clinical training site for any health training programs that are interested in providing educational opportunities for their students.”

The applicant states NCDI-Cary will participate with Novant in providing clinical training opportunities to educational programs throughout North Carolina. See Attachment P for a list of Novant's extensive training/educational relationships. The applicant adequately demonstrates that it will accommodate the clinical needs of area health professional training programs. Therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.

- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (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.

NC

NCDI-Cary proposes to acquire an ultrasound system at NCDI-Cary and obtain designation as a diagnostic center. In Section III.1, page 32 of the final supplemental data, the applicant states,

“Based on NCDI-Cary’s operating experience, it has determined that a need exists at its facility to offer the additional imaging service proposed in this application, which is further supported by NCDI-Cary’s referring physician estimates for the proposed services.”

The applicant further states that the proposed zip code service area represents 69% of NCDI-Cary’s current patient origin. Thus, 31% of NCDI-Cary’s current patients reside in other Wake County zip codes and other counties. In Section III.1, page 34 of the final supplemental data, the applicant further states:

“As the population data for the service area will demonstrate, the proposed diagnostic center service area has nearly 750,000 residents and can support the addition of an ultrasound unit at NCDI-Cary’s existing facility. As documented by the physician support letters, the proposed service is in demand and will be well utilized based on the referring physician estimates.”

However, the applicant does not adequately demonstrate the expected effects on competition in the proposed zip code service area include a positive effect on the cost-effectiveness of the proposed ultrasound services.

The applicant does not adequately demonstrate that the population proposed to be served is based on reasonable, credible and supported assumptions. Specifically, the applicant omits zip codes located within 10 miles of its facility but includes others located much farther from its facility. It appears this was done to avoid including underutilized ultrasound units in the proposed zip code service area. See Criterion (3) for additional discussion regarding the population to be served which is incorporated hereby as if set forth fully herein.

The applicant does not adequately demonstrate that the proposed ultrasound is needed in addition to existing and approved ultrasound units in the proposed zip code service area. See the discussion in Criteria (3) and (6) which is incorporated hereby as if set forth fully herein.

Therefore, the application is not conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

NA

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NC

The application is not conforming to all applicable Criteria and Standards for Diagnostic Centers promulgated in 10A NCAC 14C .1800. The specific criteria are discussed below.

SECTION .1800 CRITERIA AND STANDARDS FOR DIAGNOSTIC CENTERS

10A NCAC 14C .1803 INFORMATION REQUIRED OF APPLICANTS

(a) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall use the Acute Care Facility/Medical Equipment application form.

-C- The applicant used the correct application form.

(b) An applicant shall also provide the following additional information:

(1) the number, type, cost, condition, useful life and depreciation schedule of all medical diagnostic equipment that either is proposed to be acquired or is currently owned or operated by the applicants, and will be part of the diagnostic center following completion of the project;

- C- In Section II.8 of the final supplemental data, page 23, the applicant identifies the existing medical diagnostic equipment at NCDI-Cary, the proposed ultrasound unit to be located at the diagnostic center and the number, type, cost, condition, useful life, and depreciation schedule for each piece of equipment.
 - (2) *other than the equipment listed in Subparagraph (b) (1) of this Rule, a list of all equipment and related components which are necessary to perform the proposed procedures and services;*
- C- In Section II.8 of the final supplemental data, page 23, the applicant refers to the equipment quotes in Attachment F, which contains a quote for the Acuson S1000 Ultrasound. The quote identifies all equipment and related components necessary to perform ultrasound scans.
 - (3) *the maximum number of procedures that each piece of medical diagnostic equipment in the diagnostic center is capable of performing and the assumptions used to project capacity;*
- C- In Section II.8, page 23 of the final supplemental data, the applicant provides the projections and the assumptions it used to project capacity for the ultrasound services, as shown below.

EQUIPMENT	DAYS / YEAR	PROCEDURES / DAY	MAXIMUM PROCEDURE CAPACITY	80% OF CAPACITY
Ultrasound	250	14	3,500	2,800

Assumptions:

1. Days of service: 250 days annually (50 weeks x 5 days per week) to allow for holidays and inclement weather.
 2. Procedures per day: based on MedQuest’s experience, allows for set-up, patient preparation, exam time, and clean up.
 3. Maximum capacity: days of operation per year x procedures per day
- (4) *a list of all existing and approved health service facilities that operate or have been approved to operate medical diagnostic equipment and diagnostic suites by type and location in the proposed medical diagnostic equipment service area;*
- C- In Section III.1, page 32 of the final supplemental data, the applicant identifies NCDI-Cary’s proposed zip code service area, consisting of 21 Wake County zip codes. Some of the service area zip codes extend into Chatham, Durham and Johnston counties.

In Section II, page 24 and Section III, page 33 of the final supplemental data, the applicant provides a listing compiled from the American College of Radiology’s website, showing 18 accredited ultrasound providers in NCDI-Cary’s proposed zip code service area.

(5) *the hours of operation of the proposed diagnostic center and each proposed diagnostic service;*

-C- In Section II.8, page 25 of the final supplemental data, the applicant states the diagnostic services will be offered from 8:30 AM to 5:00 PM Monday-Friday.

(6) *the patient origin by percentage by county of residence for each diagnostic service provided by the applicants in the 12 month period immediately preceding the submittal of the application;*

-C- In Section II.8, page 25 of the final supplemental data, the applicant provides the patient origin by county for services provided by NCDI-Cary during CY 2011.

COUNTY	MRI (MOBILE)*	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	0.3%	1.1%
Other	3.6%	3.2%
Total	100%	100%

*MRI scanner provided by mobile MRI vendor.

(7) *the projected patient origin by percentage by county of residence for each service proposed, and all the assumptions and data supporting the methodology used for the projections;*

-NC- In Section II.8, page 26 of the final supplemental data, the applicant provides projected patient origin by percentage by county of residence for the proposed ultrasound services as well as the assumptions upon which the applicant projected the patient origin. However, the data provided by the applicant does not support the proposed projected patient origin. As shown in the table found in 10A NCAC 14C .1803(b)(6) which is incorporated hereby as if set forth fully herein, 88.8% of the MRI scans and 90.1% of the CT scans performed at NCDI-Cary during CY2011 were performed on residents of Wake County.

In Section II.8, page 26 of the final supplemental data, the applicant projects that 89% of the proposed diagnostic center's patients will be residents of Wake County, as shown in the following table.

COUNTY	ULTRASOUND
Wake	89%
Other	11%
Total	100%

On page 26, the applicant states that “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 in NC, SC, VA and other states.

In Section II.8, page 26 of the final supplemental data, the applicant states the following supports the projected patient origin.

“NCDI-Cary is an existing outpatient imaging facility, which predominately serves Wake County residents as indicated by its existing patient origin (89%-combined Wake county patient origin all services). The letters of support are from physicians located in Wake County. However, NCDI-Cary assumes that its referring physicians would see patients from various zip codes and as such has assumed that 11% of its patients would originate from other areas outside of the proposed diagnostic center service area. This percentage of “other” patients is consistent with NCDI-Cary’s historical operating experience.

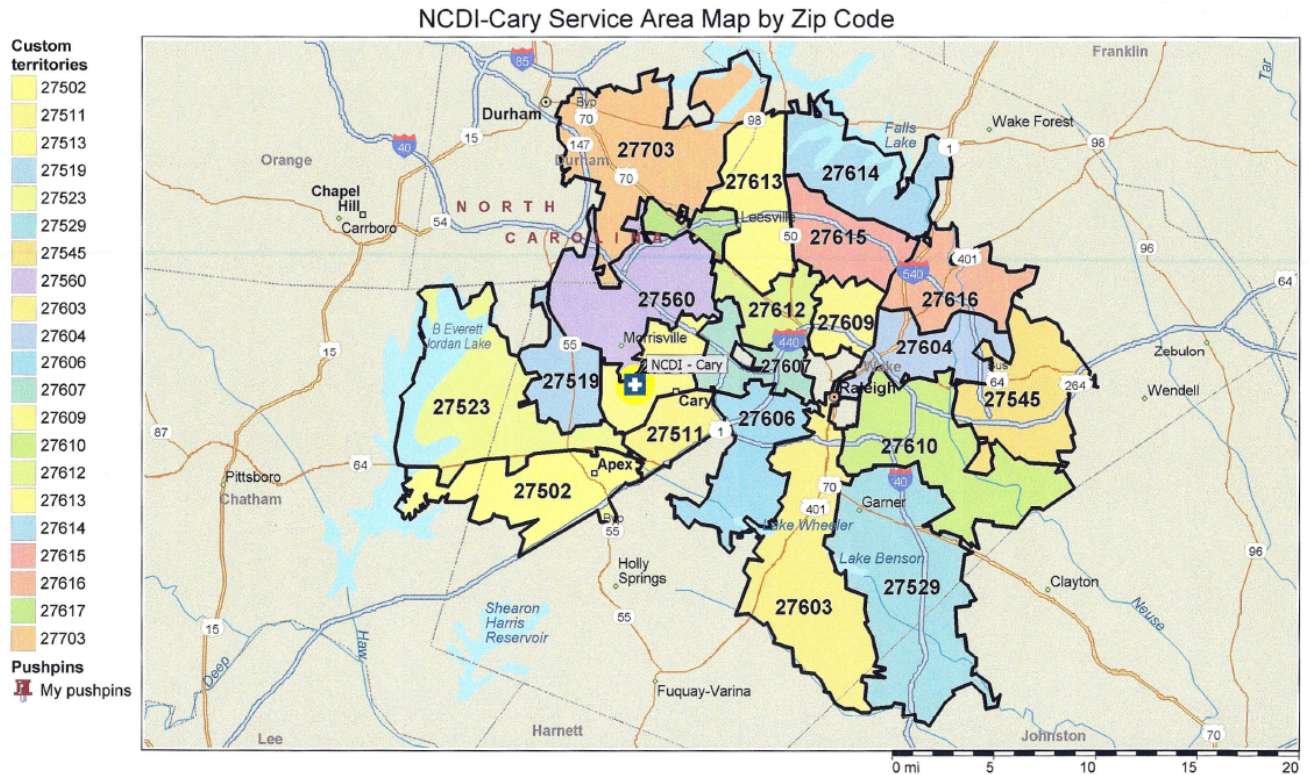
Note: NCDI-Cary will serve any patient in need of imaging services regardless of county of origin.”

In Section III.5(b), final supplemental data, page 47, the applicant provides the projected number of patients to be served in each of the first two project years by county of residence. The percentages are consistent with the information provided in Section II.8, page 26 of the final supplemental data, as shown in the table below.

NCDI-Cary Patient Origin for Project Years 1 and 2				
County	Number of Patients Yr 1	Percentage of Total Yr 1	Number of Patients Yr 2	Percentage of Total Yr 2
Wake	2,446	89%	2,488	89%
Other	302	11%	307	11%
Total	2,748	100%	2,795	100%

In Section III.1, final supplemental data, page 32, the applicant states, “NCDI-Cary is proposing a diagnostic center service area that is consistent with its current patient utilization trends for CT and Mobile MR services. The following map outlines the proposed diagnostic center service area, which represents 69% of NCDI-Cary’s current patient origin.”

The map provided by the applicant in the final supplemental data, Section III.1, page 32 and Section III.5, page 46, has been reproduced below.



In Section III.5, final supplemental data, page 45, the applicant describes its proposed service area as follows:

“The proposed service area represents the central core of Wake County, which has easy accessibility to NCDI-Cary’s location due to the close proximity of the facility to the I-440 and I-540 beltlines.”

Thus, in Section III.1, page 32, and Section III.5, page 46, the applicant proposes a zip code service area which is not consistent with the proposed service area reported in Section II.8, page 26, and Section III.5, page 47. The applicant does not provide adequate explanation to show how the proposed zip code service area on pages 32 and 46 relates to the projected patient origin on pages 26 and 47 where the applicant states that 89% of all patients are projected to be Wake County residents.

Furthermore, the applicant states on page 47 of the final supplemental data, “NCDI-Cary assumes that its referring physicians would see patients from various zip codes and as such has assumed that 11% of its patients would originate from other areas outside of the proposed diagnostic center service area.” The applicant states that 11% of the patients are expected to be residents of zip codes not included in the proposed zip code service area. But on pages 32 and 46, the applicant does not include an “other”. Most of the zip codes lie entirely in Wake County. Only 3 of the 21 zip codes extend into other counties. Moreover, it is not likely that the percentage for “other” would be 11% for both the projected “Wake County and other” patient origin reported on pages

26 and 47 and the proposed zip code service area (21 zip codes originating in Wake County and extending into Chatham, Durham and Johnston counties) reported on pages 32 and 46. Particularly, since there are more counties included in “other” as described on pages 26 and 47 than are included in “other” when looking at the map of the proposed zip code service area on pages 32 and 46. In addition, parts of Wake County are not included in the proposed zip code service area but presumably all of Wake County is included in the proposed service area as reported on page 47, where the applicant does not state that “Wake County” does not include all of Wake County.

Furthermore, the applicant does not adequately explain why the contiguous zip codes 27518, 27539 and 27540, located in the center of the proposed zip code service area, were not included in the proposed zip code service area. See the map above. The applicant includes the southern region of the Garner zip code 27529 which is located much farther from the facility than zip code 27518. Zip code 27518 is a contiguous zip code in the center of the proposed zip code service area, within 10 miles driving distance of the facility. Moreover, the applicant received a significant number of referrals from physicians located in zip code 27518. Attachment Z contains physician support letters from 5 physicians located in one of the omitted zip codes (27518) estimating 480 referrals.

Moreover, in comments submitted during the public comment period, Wake Radiology provided utilization for the ultrasound at Wake Radiology-Cary (located in zip code 27518) and stated that the ultrasound operates far below 80% of capacity, as defined by Wake Radiology (43% of capacity for CY2011 and 44% for CY2012). Novant Health owned, MedQuest managed North Carolina Diagnostic Imaging-Holly Springs (NCDI-Holly Springs) received a certificate of need (Project ID #J-8537-10) in June 2011 to develop a diagnostic center with an ultrasound unit to be located in the Holly Springs zip code of 27540. That zip code also includes two hospital-based ultrasound providers. By not including those zip codes, the applicant would not be required to demonstrate that existing ultrasound equipment located in those zip codes operated at 80% of capacity during the 12 months before submitting the application, as required by 10A NCAC 14C .1804(1). Moreover, the applicant would not be required to demonstrate that existing and approved ultrasound equipment would be operating at 80% of capacity by the fourth quarter of Project Year 3 as required by 10A NCAC 14C .1804(2). Based on historical patient origin for MRI and CT services, it would appear that the excluded zip codes should have been included in the proposed zip code service area. In particular, the approved ultrasound to be located at NCDI-Holly Springs will be managed by the same legal entity. The applicant should be able to determine the annual capacity and to project utilization for that unit since it will be owned ultimately by Novant and managed by MedQuest which is owned by Novant.

Therefore, the application is not conforming to this Rule.

- (8) *drawings or schematics of the proposed diagnostic center that identifies a distinct, identifiable area for each of the proposed services; and*

-C- In Attachment X, the applicant provides line drawings of the proposed diagnostic center that identifies a distinct, identifiable area for the proposed ultrasound services.

(9) a three year capital budget.

-NC- In Section II.8, page 26 of the final supplemental data, the applicant states, “*See the NCDI-Cary’s [sic] financial pro formas.*” However, the applicant does not reference any specific line item(s) that reflect a “three year capital budget”. Therefore, the application is not conforming to this Rule.

(c) An applicant proposing to establish a new mobile diagnostic program shall also provide the following information:

(1) the number, type and cost of all proposed mobile medical diagnostic equipment including the cost of the transporting equipment;

(2) other than the equipment listed in Subparagraph (b)(1) of this Rule, a list of all equipment and related components which are necessary to perform the proposed procedures and services;

(3) the number and type of all existing and approved mobile diagnostic equipment in the proposed mobile diagnostic center service area;

(4) the maximum number of procedures that each proposed piece of medical diagnostic equipment is capable of performing and the assumptions used to project capacity;

(5) the name, address and hours of service at each host facility that is proposed to be served by the mobile diagnostic program; and

(6) copies of letters of intent from, and proposed contracts with, all of the proposed host facilities of the mobile diagnostic program.

-NA- The applicant does not propose to establish a mobile diagnostic program.

(d) An applicant shall demonstrate that all equipment, supplies and pharmaceuticals proposed for the diagnostic center have been certified for clinical use by the U.S. Food and Drug Administration or will be operated or used under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services' regulations.

-C- On page 27 of the final supplemental data, the applicant states all proposed equipment has been certified for clinical use by the U.S. Food and Drug Administration. The applicant further states all equipment produced and offered for use to perform human diagnostic testing must be approved by the FDA prior to sale.

(e) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall provide:

(1) the projected number of patients to be served, classified by diagnosis for each of the first twelve calendar quarters following completion of the project; and

- C- In Attachment V of the final supplemental data, the applicant provides the projected number of scans (patients), classified by diagnosis, for each of the first twelve calendar quarters following project completion.

(2) the projected number of patients to be served by county of residence for each of the first twelve calendar quarters following completion of the project; and

- C- In Attachment V of the final supplemental data, the applicant provides the projected number of patients to be served by county of residence for each of the first twelve calendar quarters following project completion. However, the applicant does not adequately demonstrate the projected patient origin for ultrasound services is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion.

(3) the projected number and type of diagnostic procedures proposed to be provided by CPT code or ICD-9-CM procedure code for each of the first twelve calendar quarters following completion of the project.

- C- In Attachment V of the final supplemental data, the applicant provides the projected number and type of diagnostic procedures proposed to be provided, by CPT code, for each of the first twelve calendar quarters following project completion.

10A NCAC 14C .1804 PERFORMANCE STANDARDS

An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall provide:

- (1) documentation that all existing health service facilities providing similar medical diagnostic equipment and services as proposed in the CON application in the defined diagnostic center service area were operating at 80% of the maximum number of procedures that the equipment is capable of performing for the twelve month period immediately preceding the submittal of the application;*

- NC- In Section II, pages 28 and 29 of the final supplemental data, the applicant provides a chart listing the facilities which provide ultrasound services in the proposed zip code service area. The following table illustrates the FFY 2011 ultrasound volumes reported by hospitals located in the proposed zip code service area on their 2012 Hospital License Renewal Applications.

Hospital-Based Ultrasound Utilization

Hospital-based Provider	Ultrasound Units	Total Procedures	Procedures per Unit
WakeMed Apex HealthPlex	2	1,704	852
Rex Healthcare	23	18,101	787
Duke Raleigh Hospital	6	8,299	1383
WakeMed Apex HealthPlex	7	14,394	2,056
WakeMed North HealthPlex	1	3,980	3,980
WakeMed Brier Creek HealthPlex*	1	131	131

Source: Pages 48-49 of the final supplemental data. The applicant relied on the 2012 Hospital License Renewal Application.

*Volume does not represent a full year of operation

On page 28, the applicant states,

“NCDI-Cary is unable to accurately determine capacity levels due to the lack of information regarding hours of operation, staffing, average procedure times, equipment capabilities, etc.”

In Section II, page 30 of the final supplemental data, the applicant states,

“There is no statutory requirement for diagnostic centers to submit utilization data on an annual basis nor are there any requirements mandating that diagnostic centers make public any utilization data. NCDI-Cary can not reasonably estimate the equipment capacity of any existing health service provider in the service area. Each diagnostic center provider has different imaging systems, hours of operation, staffing patterns, and internal policies and procedures that are utilized in each facility in determining capacity.”

However, based on the applicant’s own assumptions regarding the capacity of an ultrasound unit located in a diagnostic center (3,500 annual procedures), the analyst determined which of the existing hospital-based providers’ ultrasound services are not utilized at 80% of capacity (as defined by the applicant). Note: a hospital could easily operate longer hours than a diagnostic center, resulting in a lower percentage of capacity than what is shown in the table below.

Hospital-Based Ultrasound Utilization

Hospital-based Provider	Ultrasound Units	Capacity @ 3,500 per unit	Total Procedures Reported	Percent of Capacity
WakeMed Apex HealthPlex	2	7,000	1,704	24.3%
Rex Healthcare	23	80,500	18,101	22.5%
Duke Raleigh Hospital	6	21,000	8,299	39.5%
WakeMed Apex HealthPlex	7	24,500	14,394	58.8%
WakeMed North HealthPlex	1	3,500	3,980	113.7%
WakeMed Brier Creek HealthPlex*	1	3,500	131	3.7%

*Volume does not represent a full year of operation

As the table above shows, the only facility that operated at 80% of capacity or greater, as defined by the applicant, is WakeMed North HealthPlex, which operated at 113.7% of capacity.

The applicant does not adequately demonstrate that all existing ultrasound units located in the proposed zip code service area for which utilization data is publicly available operated at 80% of the maximum number of procedures that the equipment is capable of performing during the 12 months immediately preceding submittal of the application.

Consequently, the application is not conforming to this Rule.

- (2) *documentation 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 number of procedures that the equipment is capable of performing by the fourth quarter of the third year of operation following initiation of diagnostic services;*

-NC- The applicant states, “NCDI-Cary projects it will exceed 80% of capacity in Year 3 of operation” and provides the following table on page 30 of the supplemental data.

	Year 1	Year 2	Year 3
Ultrasound Volume	2,748	2,795	2,843
% of Capacity	78.50%	79.80%	81.20%

The applicant adequately demonstrates the proposed ultrasound equipment will be utilized above 80% of capacity (as defined by the applicant) by the fourth quarter of the third year of operation.

Regarding existing ultrasound units located in the proposed zip code service area, in Section II, pages 30-31 of the final supplemental data, the applicant states:

“NCDI-Cary does not have access to ultrasound provider’s operating information, which would be necessary to project volume for their services and

capacity for the equipment operated by each provider. This information is not publicly available.”

The applicant obtained and provided the FFY 2011 ultrasound volumes reported by hospitals located in the proposed zip code service area on their 2012 Hospital License Renewal Applications. However, the applicant did not attempt to provide the projected utilization for those hospitals located in the proposed zip code service area. Therefore, the application is not conforming to this Rule.

(3) documentation that the applicants utilization projections are based on the experience of the provider and on epidemiological studies; and

-C- In Section III.1, pages 34-36 of the final supplemental data, the applicant adequately demonstrates it reviewed epidemiological studies, national utilization rates, NCDI-Cary and Novant/MedQuest experience, physician referral patterns, and service area demographic data to project utilization. On page 36 of the final supplemental data, the applicant states, *“Ultimately, NCDI-Cary utilized its referring physician estimates as the basis for its projections.”*

(4) all the assumptions and data supporting the methodologies used for the projections in this Rule.

-NC- In Section III, pages 36-41 of the final supplemental data, the applicant provides the assumptions and data which it states supports the methodologies used to project its utilization. However, the applicant does not provide data supporting the proposed zip code service area. See Criterion (3) for discussion regarding the proposed service area which is incorporated hereby as if set forth fully herein. Therefore, the application is not conforming to this Rule.

10A NCAC 14C .1805 REQUIRED SUPPORT SERVICES

An applicant shall provide documentation showing the proximity of the proposed diagnostic center to the following services:

(1) emergency services;

-C- In Section II, page 31 of the final supplemental data, the applicant states emergency services are provided through the Emergency Medical Services of Wake County and local hospitals. WakeMed Cary is 6 miles from NCDI-Cary and Rex is 10 miles away. In Section II.8, page 32 of the final supplemental data, the applicant states it will require all clinical staff to acquire and maintain certification in cardiopulmonary resuscitation and basic cardiac life support and will ensure opportunity to obtain such training is made available to all staff. In Section II.3, page 17 of the final supplemental data, the applicant states NCDI-Cary adheres to the facility’s Emergency Policy which

explains the procedures to follow in case of an emergency situation in the facility. See Attachment H for a copy of NCDI-Cary's Emergency Policy.

(2) *support services;*

-C- In Section II, page 31 of the final supplemental data, the applicant states support services are provided onsite.

(3) *ancillary services; and*

-C- In Section II, page 31 of the final supplemental data, the applicant states ancillary services are provided onsite.

(4) *public transportation.*

-C- In Section II, page 31 of the final supplemental data, the applicant states public transportation is available through the Town of Cary (C-Tran) with Route 3 servicing Cary Parkway. Cary residents who are disabled or at least 60 years of age have the option of registering for door-to-door services. Attachment G contains the C-Tran schedules and routes.

10A NCAC 14C .1806 STAFFING AND STAFF TRAINING

(a) *An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall identify the number of radiologists, radiation physicists, other physicians, laboratory staff, radiologic technologists and support staff that are projected to be involved in providing each of the proposed diagnostic services.*

-C- In Section II, page 32 of the final supplemental data, the applicant states Dr. Christopher Cepeda will serve as Medical Director for NCDI-Cary with Durham Radiology's 23 physicians providing radiology services. Also on page 32, the applicant identifies the number of staff by type projected to provide services, as shown in the table below.

Position	# of FTEs
Administrator / Center Manager	0.5
Technologists	3.0
Clerical	1.0
Total Staffed FTEs	4.5

However, in Section VII.1(b), pages 71-72 of the final supplemental data, the applicant provides the following proposed staffing during Project Year 2, as shown in the table below.

Position	# of FTEs	Annual Salary	Expense
Administrator/Center Mgr	0.2	\$80,474	\$16,095
Technologists	2.0	\$67,691	\$135,382
Clerical	1.0	\$36,965	\$36,965
Total Staffed FTEs	3.2		\$188,442

As shown in the tables above, instead of 0.2 of a FTE administrator/center manager position, the table in Section II, page 32 shows 0.5 of a FTE position. On page 32, the applicant shows 3 FTE technologist positions, not 2.

In the ProFormas provided in the final supplemental data, the applicant projects \$188,442 as the total salary expense in Project Year 2, which is consistent with the representations in Section VII. In Section VII.3, page 74 of the final supplemental data, the applicant states it will add 1.0 FTE position. In Section VII.5, page 74, the applicant states,

“The proposed staff at NCDI-Cary will be sufficient for the operation of the proposed project. 2.0 FTE Technologists on staff will provide more than sufficient coverage for all modalities during the facility’s hours of operation.”

Therefore, although the applicant provided inconsistent information regarding projected staffing in response to this Rule, the information regarding projected staffing provided in response to Section VII is consistent with the ProFormas and projected staffing levels provided in Section VII are sufficient for the level of services to be provided. Thus, the application is conforming to this Rule.

- (b) *An applicant proposing to provide ionizing and nonionizing radiation procedures shall demonstrate that a physician, licensed to practice medicine in North Carolina shall be available to perform and supervise all radiation procedures and shall document the qualifications of this physician to perform radiation procedures.*
- C- In Section II, page 32 of the final supplemental data, the applicant states Dr. Christopher Cepeda will serve as Medical Director for NCDI-Cary with Durham Radiology’s 23 physicians providing radiology services. On page 32, the applicant refers to Attachment J for Dr. Christopher Cepeda’s information. Attachment J documents Dr. Cepeda is board-certified in diagnostic radiology and has worked with Durham Radiology Associates, Inc. since July 2007.
- (c) *An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall document that a program of continuing education shall be available for technologists and medical staff.*
- C- In Section II.8, page 32 of the final supplemental data, the applicant states it will require all clinical staff to acquire and maintain certification in cardiopulmonary resuscitation and basic cardiac life support and will ensure opportunity to obtain such training is made available to all staff. The applicant further states all training/education

will be provided by MedQuest. Attachment L contains a letter dated August 13, 2012 from the NCDI-Cary Center Manager documenting a program of continuing education shall be available for NCDI-Cary technologists and medical staff. The letter further states all imaging services operated by NCDI-Cary and MedQuest in North Carolina presently have a continuing education program in place.