

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 29, 2013
FINDINGS DATE: February 4, 2013
PROJECT ANALYST: Celia C. Inman
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: F-10056-12 / Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center-Mooresville / Develop a new diagnostic center by acquiring a mammography unit for an existing imaging center / Iredell 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

Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center-Mooresville (PIC-Mooresville) proposes to acquire a digital mammography unit at PIC-Mooresville and obtain designation as a diagnostic center. The parent companies of PIC-Mooresville 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. MedQuest Associates, Inc. (MedQuest) manages PIC-Mooresville. PIC-Mooresville is located at 118 Gateway Boulevard, Mooresville, North Carolina 28117.

In Section II.1(a), page 15, the applicant states PIC-Mooresville currently offers CT services and mobile MRI services. The applicant further states original development of the imaging center including acquisition of equipment and construction totaled \$478,413 and thus did not reach the \$500,000 threshold to trigger development of a diagnostic center. Acquisition of the proposed digital mammography equipment with a total capital cost of \$527,683 exceeds \$500,000 and 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

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

Designation as a Diagnostic Center

The total capital cost for the new digital mammography is \$527,683, including minor renovations to the existing facility.

In Section II.1, page 15, the applicant states:

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

Population to be Served

In Section II.8, page 24, the applicant provides historic patient origin of its existing diagnostic services by county of residence, as follows:

2011 Historical Patient Origin

COUNTY	MOBILE MRI*	CT
Iredell	58.1%	55.1%
Mecklenburg	19.8%	13.8%
Catawba	6.4%	9.8%
Lincoln	4.2%	9.4%
Gaston	1.3%	4.9%
Rowan	4.6%	3.4%
Alexander	1.1%	0.3%
Other	4.5%	3.3%
Total	100%	100%

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

The applicant states, “Other includes: Davie, Forsyth, Wilkes, Burke, Caldwell, Union, Ashe, Davidson, Watauga, Stanly, McDowell, Cleveland, Surry, Transylvania, Rutherford, Yadkin, and other states.”

In Section II.8, page 25, the applicant states PIC-Mooresville predominately serves Iredell and northern Mecklenburg county residents as indicated by its historical patient origin (73.9% in CY 2011). The following excerpt from the table above for CY 2011 illustrates Iredell and Mecklenburg county patient origin of 77.9% and 68.9% for existing MRI and CT services, respectively; and supports the applicant’s statement of historical patient origin from Iredell and Mecklenburg averaging 73.9%.

COUNTY	MRI	CT
Iredell	58.1%	55.1%
Mecklenburg	19.8%	13.8%
Total	77.9%	68.9%

In Section II.8, page 25, the applicant provides projected patient origin for the proposed mammography services by percentage by county of residence as shown in the following table.

Projected Patient Origin

COUNTY	MAMMOGRAPHY
Iredell (28117, 28115, 28166)	83.7%
Mecklenburg (28031, 28036)	16.2%
Total	100.0%

In Section III, page 35, the applicant states PIC-Mooresville's proposed service area for mammography services is a small area in Iredell and Mecklenburg counties consisting of five zip codes, residents of which currently utilize PIC-Mooresville's imaging services. The applicant states:

"The 28117 zip code is the location of PIC-Mooresville's facility and the zip codes of 28166, 28115, 28036 and 28031 are contiguous to it."

In Section II, page 25, the applicant states:

"A review of the current patient origin for the proposed diagnostic center service area indicates that 83.7% of the patients from the five zip code area are Iredell County residents and 16.2% originate from the Mecklenburg County zip codes included in the proposed diagnostic center service area. PIC-Mooresville has applied these percentages for the proposed mammography service. In order to be conservative, PIC-Mooresville has projected patient origin from Iredell and Mecklenburg Counties in order to be consistent with the need projections for the five zip code service area."

In Section III, page 35, the applicant further states, *"The proposed diagnostic center service area accounts for 58.1% of PIC-Mooresville's CY 2011 patient origin for its existing services."* Thus, 42% of the applicant's current CT and MRI patients come from outside the applicant's proposed service area for mammography. The applicant does not adequately demonstrate that it is reasonable to assume that future mammography patient origin will differ significantly from the patient origin for its existing CT and MRI services. Furthermore, rather than supporting the applicant's proposed service area, the support letters provided in Exhibit Z of the application, tend to show that the proposed mammography service area is not reasonable based on expected physician referrals. Only 34.4% of the referrals are from physicians located in one of the five zip codes in the proposed mammography service area. Therefore, 65.6% of the referrals are from physicians located outside the proposed mammography service area, with 46.06% of the total referrals coming from physicians located in zip code 28078 and 19.52% from physicians in 28037. While all of a physician's patients may not live in the same zip code where their physician's office is located, it is reasonable to assume that some of them do live in the same zip code or reasonably near the office. The applicant fails to adequately explain why only five zip codes were included in the proposed mammography service area, given the historical patient origin for the CT and MRI services currently provided at the facility.

In summary, the applicant does not adequately identify the population it proposes to serve because it does not provide adequate information to demonstrate the reasonableness of limiting its proposed mammography service area to a population significantly different from the population it currently serves.

Demonstration of Need

On page 15, the applicant states the proposed Hologic Selenia Digital Mammography unit meets its demand for high quality digital images. The applicant further states:

“According to a study by the National Cancer Institute, the findings indicate:

- *Digital mammography was significantly better than film mammography in screening women who were under age 50, or women of any age who had very dense breasts.*
- *Digital mammography allows improvement in image storage and transmission because images can be stored and sent electronically.*
- *Radiologists can use software to assist in the interpretation of the digital mammograms.”*

In Section II.5, page 17, the applicant states the availability of a mammography unit at its outpatient imaging facility will improve access for patients by *“increasing the availability of these important imaging services for Iredell County.”* In Section III.1, page 34, the applicant states mammography screening is a valuable tool in the early detection of breast cancer and the availability of the service will enhance healthcare options in the proposed diagnostic center service area. In its 2008 studies, The Centers for Disease Control and Prevention (CDC) lists breast cancer as the most common cancer among females with a rate of 122.7 per 100,000 for North Carolina females. The applicant further states the National Cancer Institute projects North Carolina will have 89,900 cases of breast cancer in 2012, increasing to 101,300 by 2015. The Incidence Rate Report for North Carolina by County shows Iredell and Mecklenburg counties have annual incidence rates of 119.5 and 133.9 per 100,000, respectively. The applicant states, according to the American Cancer Society, early detection tests for breast cancer saves thousands of lives each year.

On page 34, the applicant states:

“Despite a recommendation by the U.S. Preventive Services Task Force in 2009 that screening should start at age 50, the American Medical Association, American College of Radiology and the American Cancer Society all concur that screening should begin at age 40.”

On page 35, the applicant quotes Dr. Paul Ellenbogen, Chair of the American College of Radiology (ACR) Board of Chancellors, *“The ACR urges women ages 40 and over to receive annual mammograms.”*

In Section II.5, page 17, the applicant states referring physicians have requested the proposed services at PIC-Mooresville indicating a need in the community for the service. In Section III.1, page 34, the applicant states:

“The proposed project has significant support from referring physicians as indicated by over 40 letters of support, which estimate between 458 to 495 monthly referrals to PIC-Mooresville for mammography services, which represents an annual estimate of 5,496 to 5,940 mammography procedures.”

The applicant states it relied upon the operating experience of MedQuest and Novant along with population data and statistical data from a variety of sources, including the ACR and the Centers of Medicare and Medicaid Services (CMS), to project the need for mammography services in its proposed service area.

In Section III, pages 35-38, the applicant discusses the PIC-Mooresville proposed mammography service area population by zip code and age, and projects demand for mammography services. The applicant provides the following table on page 36 of its application to illustrate the population estimates for its proposed service area from 2010-2016.

PIC-Mooresville Proposed Service Area Population								
Zip Code	County	2010	2011	2012	2013	2014	2015	2016
28117	Iredell	35,454	35,809	36,167	36,528	36,894	37,263	37,635
28115	Iredell	34,339	34,682	35,029	35,380	35,733	36,091	36,452
28166	Iredell	8,619	8,705	8,792	8,880	8,969	9,059	9,149
28031	Mecklenburg	24,390	24,805	25,226	25,655	26,091	26,535	26,986
28036	Mecklenburg	14,654	14,903	15,156	15,414	15,676	15,943	16,214
Total Service Area		117,456	118,904	120,370	121,857	123,363	124,891	126,436

Source: US Census Data for 2010 population; Years 2011-2016 were projected based on the 2010 population increased by the estimated county growth rate percentage from the Office of State Budget and Management data. Zip codes 29117, 28115 and 28166 are located in Iredell County (1.0% growth) and zip codes 28031 and 28036 are located in northern Mecklenburg County (1.7%).

In Section III.1, page 37, the applicant provides the following table as the projected need for mammography services in the proposed service area, based on the population of women aged 40 and over and the assumption that all women aged 40 and over will have an annual mammogram.

PIC-Mooresville Women Over 40 in Proposed Service Area								
	Percent	2010	2011	2012	2013	2014	2015	2016
28117	38.7%	13,746	13,883	14,022	14,162	14,304	14,447	14,591
28115	24.1%	8,296	8,379	8,463	8,548	8,633	8,719	8,806
28031	23.5%	5,734	5,831	5,930	6,031	6,134	6,238	6,344
28166	25.6%	2,210	2,232	2,254	2,277	2,300	2,323	2,346
28036	24.0%	3,523	3,583	3,644	3,706	3,769	3,833	3,898
Totals		33,509	33,908	34,313	34,724	35,140	35,560	35,985

Source: US Census Data for 2010 population; Years 2011-2016 were projected based on the 2010 population increased by the estimated county growth rate percentage from the Office of State Budget and Management data. Zip codes 29117, 28115 and 28166 are located in Iredell County (1.0% growth) and zip codes 28031 and 28036 are located in northern Mecklenburg County (1.7%).

Note the applicant reversed the order of zip codes 28166 and 28031 in the previous two tables and applied inaccurate percentages. Analyzing the applicant’s US Census population raw data supplied in Attachment M and recalculating the “Women aged 40 and over” for each zip code provides the following percentages.

Percent of Women Aged 40 and Over											
Zip Code	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85+	Percent 40+
28117	4.8%	5.0%	3.9%	2.9%	2.7%	2.0%	1.3%	0.9%	0.7%	0.5%	24.7%
28115	4.0%	4.0%	3.6%	2.8%	2.7%	2.0%	1.6%	1.3%	1.1%	1.1%	24.2%
28166	3.7%	4.3%	3.9%	3.3%	3.5%	2.1%	1.7%	1.4%	1.1%	0.7%	25.7%
28031	4.2%	4.2%	3.7%	3.2%	3.0%	2.2%	1.3%	0.9%	0.6%	0.5%	23.8%
28036	4.2%	4.2%	3.4%	2.7%	2.8%	1.9%	1.5%	1.2%	1.1%	1.0%	24.0%

The following table illustrates the difference in the percentages presented by the applicant and the recalculated percentages.

Percent of Women Over 40			
	Application	Calculations	Difference
28117	38.7%	24.7%	14.0%
28115	24.1%	24.2%	-0.1%
28166	25.6%	25.7%	-0.1%
28031	23.5%	23.8%	-0.3%
28036	24.0%	24.0%	0.0%

The only notable variation is in zip code 28117. However, that difference has a significant impact on the total number of women over 40 in the proposed service area. Applying the recalculated percentages for women over 40 and correcting the order of the zip codes and calculations in the applicant’s population table on page 37 provides the following projected need for mammograms in the proposed service area, **assuming all women over 40 have an annual mammogram** [emphasis added].

PIC-Mooresville Women Over 40 in Proposed Service Area Recalculated								
	Percent	2010	2011	2012	2013	2014	2015	2016
28117	24.7%	8,757	8,845	8,933	9,022	9,113	9,204	9,296
28115	24.2%	8,310	8,393	8,477	8,562	8,647	8,734	8,821
28166	25.7%	2,215	2,237	2,260	2,282	2,305	2,328	2,351
28031	23.8%	5,805	5,904	6,004	6,106	6,210	6,315	6,423
28036	24.0%	3,517	3,577	3,638	3,699	3,762	3,826	3,891
Totals		28,604	28,955	29,311	29,672	30,037	30,407	30,782

The recalculated percentages reduce the projected need in the proposed service area by more than 5,000 mammograms in each of the first three project years, as shown in the following table.

	Yr 1-2014	Yr 2 - 2015	Yr 3 - 2016
Application's Women over 40 / Need	35,140	35,560	35,985
Recalculated Women over 40 / Need	30,037	30,407	30,782
Reduction in Need	5,103	5,153	5,203

In Section III.1, page 37, the applicant states the above need is based on the recommendation of The American Cancer Society (ACS) that women over the age of 40 should have a mammogram every year. However, The National Cancer Institute recommends women age 40 or older have screening mammograms every 1 to 2 years¹. The Centers for Disease Control and Prevention recommend women from age 50 to 74 should have mammograms every two years.² The applicant's projection incorporating an annual mammogram for all women over 40 may be over-aggressive: according to the North Carolina Division of Public Health, the 2010 mammography screening rate for North Carolina female residents aged 40 and over was 76.5%.³

The applicant's mammography service area need projection is based upon unreasonable assumptions and incorrect calculations; therefore the applicant fails to adequately demonstrate the need the proposed population has for the proposed services.

Projected Utilization

In Section III, pages 38-39, the applicant provides the following assumptions for PIC-Mooresville projected mammography utilization at PIC-Mooresville.

¹ <http://www.cancer.gov/cancertopics/factsheet/detection/mammograms>
² [Http://www.cdc.gov/cancer/breast/basic_info/mammograms.htm](http://www.cdc.gov/cancer/breast/basic_info/mammograms.htm)
³ http://www.schs.state.nc.us/schs/pdf/2010_Trends_Report_20120814.pdf

“Assumptions:

1. *The percentage of females over the age of 40 was determined by using population data for each zip code.*
2. *The estimated market share of 6% in Year 1, 7.1% in Year 2, and 8.2% in year 3 take into account the extremely limited availability of mammography services in the PIC-Mooresville diagnostic center service area, the size of the population to be served, physician support for the project and the American Cancer Society’s recommendations for mammography services.*
3. *PIC-Mooresville reviewed its market share for MRI services in Iredell County as a benchmark for the proposed service. It should be noted that there are multiple providers of MRI services in Iredell County. Over the last three years, PIC-Mooresville has averaged 12.0% of the unweighted MRI volume in market share for Iredell County. In an effort to be conservative, PIC-Mooresville used half of this percentage, 6.0%, to estimate its market share for the first year of operation of its mammography service. For the second and third years of operation, PIC-Mooresville increased the market share by the combined service area growth rate for the defined service area (1.1%). See page 37.*

<i>Year</i>	<i>Iredell County Unweighted MRI Total Volume</i>	<i>PIC-Mooresville Unweighted MRI Volume</i>	<i>% of Total Unweighted MRI Volume</i>
<i>FY 2010-11</i>	<i>16,569</i>	<i>2,025</i>	<i>12.2%</i>
<i>FY 2009-10</i>	<i>14,946</i>	<i>1,743</i>	<i>11.7%</i>
<i>FY 2008-09</i>	<i>17,031</i>	<i>2,100</i>	<i>12.3%</i>
		<i>Average</i>	<i>12.0%</i>

4. *Physician support for this project indicates monthly referrals of approximately 458 to 495 patients. Assuming one patient has one mammography procedure, PIC-Mooresville can project an annual referral estimate of 5,496 to 5,940 patients based on the physician support letters. In Year 1, PIC-Mooresville has projected less than half of this number in order to be conservative. The strong physician support for this project demonstrates the demand for the proposed services at PIC-Mooresville.*
5. *PIC-Mooresville assumes one procedure per patient.”*

In Section III.1, page 38, the applicant provides PIC-Mooresville’s annual capacity for providing mammography as follows: 250 days x 14 procedures per day = 3,500 procedures annually, with 80 % of capacity being 2,800 procedures. The following table from page 38 illustrates PIC-Mooresville’s projected utilization based on its proposed mammography service area total need calculations.

PIC-Mooresville Projected Mammography Utilization			
	YR 1- 2014	YR 2 - 2015	YR 3 - 2016
Females 40+ years – potential scans	35,140	35,560	35,985
Estimated Market Share	6%	7.1%	8.2%
NCDI Mammography Volume	2,108	2,525	2,951
% of Capacity	60.2%	72.1%	84.3%

As shown in the table above, the applicant projects the proposed mammography unit will operate at 84.3% of capacity (as defined by the applicant) in Project Year 3, which exceeds the 80% required by 10A NCAC 14C .1804(2).

However, as the following table shows, the applicant fails to reach 80% capacity when using the correct percentages for women over 40, as recalculated above.

PIC-Mooresville Recalculated Projected Mammography Utilization			
	YR 1- 2014	YR 2 - 2015	YR 3 - 2016
Females 40+ years – potential scans	30,037	30,407	30,782
Estimated Market Share	6%	7.1%	8.2%
NCDI Mammography Volume	1,802	2,159	2,524
% of Capacity	51.49%	61.68%	72.12%

As shown in the table above, based on the correct population percentages for women over 40, the proposed mammography unit would operate at only 72.12% of capacity (as defined by the applicant), which is less than the 80% required by 10A NCAC 14C .1804(2). The applicant does not adequately demonstrate the need to acquire the proposed mammography unit since the applicant does not adequately demonstrate that the proposed mammography unit is reasonably expected to operate at 80% of capacity by Project Year 3.

Moreover, Lake Norman Regional Medical Center (LNRMC) reported 3 units of mammography equipment and 10,643 mammography procedures (100% outpatient) on its 2012 License Renewal Application, which is an average of 3,548 annual procedures per unit of equipment per year [10,643 / 3 = 3,548]. LNRMC is located less than one mile from PIC-Mooresville.

In Section II, page 28, the applicant determined that the maximum capacity of LNRMC’s mammography units is 3,952 mammography procedures per machine based on “*information and belief*” and the following assumptions: 7.75 hours per day, 255 days

per year, and 2 procedures per hour = 3,952 procedures per unit. Based on PIC-Mooresville's assumptions, LNRMC would be operating above 80% of its maximum capacity ($3,547 / 3,952 = 89.7\%$).

However, according to comments submitted by LNRMC during the written comment period, the applicant underestimated LNRMC's capacity based on faulty assumptions. LNRMC states it offers mammography services from 8 AM to 5 PM, Monday through Friday and can serve as many as four patients per hour. Therefore LNRMC's capacity is 9,180 procedures per unit (9 hours per day x 255 days x 4 patients per hour = 9,180) and it operated at only 39% of capacity ($3,548 / 9,180 = 38.64\%$) during FFY 2011. Thus, the applicant does not adequately demonstrate the need to acquire the proposed mammography unit given that the existing mammography units at LNRMC did not operate at 80% of capacity during the 12 months immediately preceding submittal of the application.

In Section II.8, pages 28-29, the applicant states PIC-Mooresville does not have access to the internal data and/or future plans for LNRMC's mammography service, but it anticipates LNRMC will continue to perform at or above its current mammography utilization. The applicant further states LNRMC experienced a 6.5% increase in mammography volume from FY 2009-10 through FY 2010-11 ($10,643 / 9,987 - 1 = 6.5\%$). On page 29, PIC-Mooresville provides its projections for LNRMC's mammography service for the first three years of PIC-Mooresville's proposed project. PIC-Mooresville projects LNRMC will be operating above 90% capacity based on Iredell County's expected population growth rate of 1.0% annually.

However, based on comments submitted by LNRMC during the comment period, it is operating at only 39% of capacity. LNRMC cannot reach 80% of capacity by following the applicant's methodology and applying the annual growth rate of 1.0% to its 2011 volume.

	Actual	Projected	Projected	Projected	Projected	Projected
	2011	2012	2012	2012	2012	2012
Volume	10,643	10,749	10,857	10,965	11,075	11,186
% Growth		1.0%	1.0%	1.0%	1.0%	1.0%
# of Units	3	3	3	3	3	3
LNRMC Capacity*	27,540	27,540	27,540	27,540	27,540	27,540
% Capacity	38.6%	39.0%	39.4%	39.8%	40.2%	40.6%

*Per LNRMC, Capacity = 255 days x 9 hours per day x 4 patients per hour x 3 units

In summary, the applicant did not adequately identify the population to be served. Furthermore, the applicant did not adequately demonstrate the need the population to be served has for the proposed mammography services. 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, page 42, the applicant states the alternatives available to PIC-Mooresville are limited in light of the need for mammography services at its facility and include the following:

1. Maintain the Status Quo – the applicant states that the “numerous letters of support” received for the project demonstrates the need for mammography 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 PIC-Mooresville 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 PIC-Mooresville 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 a mammography 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 mammography unit in the proposed service area.

Furthermore, the application is not conforming to all other applicable statutory review criteria, and thus, is not approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant does not adequately demonstrate that its proposal is the least costly or most effective alternative to meet the need it states exists. Therefore, 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 76-78, the applicant projects the total capital cost for the acquisition and installation of the proposed equipment as follows:

PROPOSED CAPITAL COST

ITEM	COST
Equipment, including shipping and tax	\$412,683
Renovations	\$60,000
Furniture, Fees, Contingency	\$55,000
Total	\$527,683

In Section VIII.3, page 79, the applicant states the project will be funded through accumulated reserves of “*MedQuest/Novant Health, Inc.*” In Section IX, page 86, the applicant states the project does not require any start-up or initial operating expenses.

Attachment S contains a letter dated October 10, 2012 from a MedQuest Vice President, which states:

“This letter confirms the availability of funds for Mecklenburg Diagnostic Imaging, LLC d/b/a Presbyterian Imaging Center-Mooresville (“PIC-Mooresville”) to support the capital expenditure required for the acquisition of the mammography equipment as proposed in PIC-Mooresville’s CON application. The total capital expenditure required for the proposed project is \$527,683, 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 PIC-Mooresville, 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 July 31, 2012, MedQuest, Inc. had in excess of \$100 Million of availability under this Revolving Line of Credit.*” The applicant does not provide financial statements for MedQuest, Inc. that document MedQuest has sufficient funds for the capital needs of the project.

Attachment T contains audited financial statements for Novant, which show 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 Novant’s funds for 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 (the parent) showing availability of funds, but does not provide a letter from a fiscally responsible officer of that entity which documents a commitment to fund the project. Therefore, the applicant does not adequately demonstrate the availability of funds for the capital needs of the project.

The applicant provides ProForma financial statements for the first three years of the project. The applicant projects revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below.

Mammography Service	Project Year 1	Project Year 2	Project Year 3
Projected # of Procedures	2,108	2,525	2,951
Projected Average Charge(Gross Patient Revenue / Projected # of Procedures)	\$ 282	\$ 282	\$ 282
Gross Patient Revenue	\$ 594,456	\$ 712,050	\$ 832,182
Deductions from Gross Patient Revenue	\$ 273,297	\$ 327,360	\$ 382,589
Net Patient Revenue	\$ 321,159	\$ 384,690	\$ 449,593
Total Expenses	\$ 247,496	\$ 288,648	\$ 300,171
Net Income	\$ 73,664	\$ 96,043	\$ 149,422

The applicant also projects a positive net income for the entire facility in each of the first three operating years of the project. The assumptions used by the applicant in preparation of the ProFormas appear reasonable; however, the projected mammography utilization, which is based on erroneous assumptions and inaccurate calculations, is not reasonable; therefore costs and charges for mammography services which are based on projected utilization are not reliable. See Section X, pages 87-89 and the ProFormas for the assumptions regarding costs and charges. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein.

Consequently, the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Furthermore, the applicant does not adequately demonstrate the availability of funds for the capital needs of the project. Therefore, the application is nonconforming 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 a mammography unit at PIC-Mooresville and obtain designation as a new diagnostic center. The applicant's proposed mammography service area is an area consisting of five contiguous zip codes in Iredell and Mecklenburg counties. In Section III.5(a), page 43, the applicant states market research indicates there is one existing mammography provider, Lake Norman Regional Medical Center (LNRMC), operating three units in the proposed service area. LNRMC is located less than one mile from PIC-Mooresville.

Information on utilization of existing mammography equipment is not publicly available such that it is possible to determine if excess capacity exists in the proposed service area. The exception is when the mammography equipment is owned and operated by a hospital, in which case, the utilization is reported on its hospital license renewal application. LNRMC reported performing 10,643 procedures (3,548 per unit) on three mammography units during FFY 2011. In Section II, pages 27-28, the applicant provided the assumptions it used to determine that LNRMC's mammography units operated at 89.7% of capacity. Those assumptions are: 7.75 hours per day x 255 days x 2 patients per hour = 3,952 procedures per unit [3,548 / 3,952 = 89.7%].

However, according to comments submitted by LNRMC during the written comment period, the applicant underestimated LNRMC's capacity based on faulty assumptions. LNRMC states it offers mammography services from 8 AM to 5 PM, Monday through Friday and can serve as many as four patients per hour. Therefore LNRMC's capacity is 9,180 procedures per unit (9 hours per day x 255 days x 4 patients per hour = 9,180) and it operated at only 39% of capacity [3,548 / 9,180 = 38.64%] during FFY 2011.

The applicant does not adequately demonstrate the need for additional mammography services in its proposed mammography service area. The discussion in Criterion (3) regarding the proposed mammography service area, need and projected utilization is incorporated hereby as if fully set forth herein. The applicant does not adequately demonstrate that its proposal would not result in the unnecessary duplication of existing or approved mammography equipment in the proposed mammography service area. Therefore 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.8, page 24, the applicant states its mammography service will be offered Monday-Friday from 8:30 AM to 4:00 PM.

In Section VII.1, pages 70-71, the applicant projects staffing and average annual salary for the second year following completion of the project as shown in the following table.

Projected Staffing Year 2

POSITION TITLE	# OF FTES	SALARY
Administrator	0.50	\$81,157
Radiology Technologist	3.00	\$66,803
Clerical	1.00	\$30,521

The applicant is projecting one additional full time equivalent (FTE) radiology technologist position. In Section VII.5, page 73, the applicant states, *“The proposed staff at PIC-Mooresville will be sufficient for the operation of the proposed project. 3.0 FTE Technologists on staff will provide more than sufficient coverage for all modalities during the facility’s hours of operation.”*

Project Year Three’s projected utilization of 2,951 mammograms at the applicant’s average of 2 procedures per hour will require 1,476 hours of technologist staffing. The applicant’s ProFormas show one FTE (2,080 hours) for the mammography service. Therefore, one additional FTE is more than adequate to provide the proposed mammography service and allow adequate employee leave time (2,080 – 1,476 = 604).

The applicant states MedQuest and Novant have extensive resources to recruit the necessary additional personnel. In Section II.2, page 16, the applicant states MedQuest, the management company, will provide any additional support and ancillary services on site, per the management agreement in Attachment B.

In Section V.3(c), page 54, the applicant states, *“Dr. Jay Patti will continue to serve as Medical Director for PIC-Mooresville following approval of the proposed project.”* See Attachment J for a letter documenting Dr. Patti’s willingness to serve as Medical Director. Attachment J also includes Dr. Patti’s curriculum vitae. In Section II.7(a), page 19, the applicant states Dr.Patti and his associates at Mecklenburg Radiology Associates will provide interpretive services for PIC-Mooresville.

The applicant demonstrates the availability of adequate 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, 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, page 53-54, the applicant states PIC-Mooresville will establish working relationships to provide acute care services as needed for PIC-Mooresville patients. The applicant also states PIC-Mooresville will accept referrals from hospitals where physicians utilizing the facility have practice privileges. In Section II.3, page 17, the applicant states:

“PIC-Mooresville will work with the closest appropriate provider to transfer a patient who develops an emergent problem while undergoing a diagnostic procedure at PIC-Mooresville.

...

PIC-Mooresville 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 PIC-Mooresville’s Emergency Policy.”

In Section V.3, page 53, the applicant describes PIC-Mooresville’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.

Attachment Z contains letters of support for the proposal from referring physicians.

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, page 41, the applicant states PIC-Mooresville currently 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 58, the applicant states PIC-Mooresville will not discriminate based on race, creed, color, sex, age, religion, national origin, mental or physical handicap, or ability to pay. In Section VI.12, page 65, the applicant provides the facility payor mix for the last full fiscal year.

PIC-Mooresville Percent of Total Utilization 1/1/2011-12/31/2011	
Self Pay/Indigent/Charity	2.4%
Medicare/Medicare Managed Care	21.4%
Medicaid	1.6%
Commercial Insurance	65.6%
Managed Care	7.9%
Other (Champus)	1.1%
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 Iredell and Mecklenburg counties and statewide.

County	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2008-09 (Estimate by Cecil G. Sheps Center)
Iredell	14.0%	5.5%	18.3%
Mecklenburg	15.0%	5.1%	20.1%
Statewide	17.0%	6.7%	19.7%

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

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 of persons eligible to receive dental services who actually received dental services 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, population data is available by age, race and gender. However, a direct comparison to the applicants' 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 that it provides adequate access to medically underserved populations. 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 64, the applicant states PIC-Mooresville 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 59, the applicant states it is the policy of PIC-Mooresville to accept all patients regardless of payment source, and without distinction due to race, color, national origin, disability, age, religion, or ability to pay. In Section VI.11, pages 64-65, the applicant states PIC-Mooresville 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 64, the applicant states that it is not aware of any documented civil rights equal access complaints or violations filed against PIC-Mooresville 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 61, the applicant states PIC-Mooresville'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. PIC-Mooresville's Charity Care policy is in Attachment N.

In Section VI.6, page 61, the applicant states PIC-Mooresville has a generous charity policy to increase accessibility to diagnostic services for patients who might otherwise be unable to afford services.

In Section III.2, page 41, the applicant states PIC-Mooresville will adopt a generous charity care policy consistent with requirements of its ultimate parent company, Novant. The applicant further states the Novant 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.

In Section VI.14 and VI.15, page 66, the applicant projects the following payor mix during the second full fiscal year for the entire facility and for the proposed mammography services.

NCDI-Cary Percent of Total Utilization Entire Facility and Each Service Component 1/1/2015-12/31/2015	
Self Pay/Indigent/Charity	2.40%
Medicare/Medicare Managed Care	21.40%
Medicaid	1.60%
Commercial Insurance	65.60%
Managed Care	7.90%
Other (Champus)	1.10%
TOTAL	100.0%

Percent allocation for each payor is based on PIC-Mooresville's historical payor mix.

However, the payor mix reported by the applicant on page 66 is not consistent with the projected payor mix in the ProFormas, as illustrated in the following table. Specifically, the percentages for the payors in the Commercial Insurance, Managed Care and Other categories total the same cumulative percentage, but in differing individual percents. The applicant provides no explanation for the differences.

NCDI-Cary ProForma Percent of Total Utilization and Gross Revenue Entire Facility and Each Service Component 1/1/2015-12/31/2015	
Self Pay/Indigent/Charity	2.40%
Medicare/Medicare Managed Care	21.40%
Medicaid	1.60%
Commercial Insurance	7.5%
Managed Care	49.6%
Other (Champus)	17.4%
TOTAL	100.0%

However, the ProFormas show that average gross revenue and average net revenue are the same for the Commercial Insurance, Managed Care and Other categories, so the percentage breakdown within those categories has no effect on total gross revenue or total net revenue.

Moreover, the percentages for medically underserved populations are consistent. Therefore, the applicant demonstrates it will provide adequate access to medically underserved groups. Consequently, 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, pages 63-64, the applicant states a referral from a licensed physician is required for access to PIC-Mooresville's proposed imaging services. Payors do not permit patients to self-refer for imaging scans. PIC-Mooresville referrals will come from a variety of local physicians and physician groups. In Section VI.9(c), page 64, the applicant states PIC-Mooresville 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 52, the applicant states PIC-Mooresville 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 52, the applicant states,

“PIC-Mooresville will offer its facility as a clinical training site for any health training programs that are interested in providing educational opportunities for their students.

...

Novant, the ultimate owner of PIC-Mooresville, and MedQuest, the management company for PIC-Mooresville, have relationships with health professional training programs throughout North Carolina.”

The applicant states PIC-Mooresville will participate with Novant in providing clinical training opportunities to educational programs. 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

The applicant proposes to acquire a digital mammography unit at its existing PIC-Mooresville imaging location and obtain designation as a diagnostic center.

The Iredell County zip codes of 28117, 28115, and 28166 and the Mecklenburg zip codes of 28031 and 28036 comprise the proposed mammography service area. In Section II.8, page 25, the applicant states PIC-Mooresville predominately serves Iredell and northern Mecklenburg county residents. LNRMC also provides mammography services in the proposed service area. In fact, LNRMC is located within one mile of PIC-Mooresville. On page 39, the applicant discusses the impact of the proposed project on competition in the proposed service area:

“Using the American College of Radiology’s accredited facility search, it shows there is one accredited mammography provider (three units) in PIC-

Mooresville’s proposed diagnostic center service area at this time. With a population [sic] over 35,000 female residents over the age of 40, there is a need to provide mammography services in a convenient and affordable outpatient imaging setting as proposed by PIC-Mooresville.”

...

The availability of a mammography unit at PIC-Mooresville’s outpatient imaging facility in Iredell County will improve access for patients [sic] in by increasing the availability of these important imaging services. Additionally, referring physicians have requested the proposed services at PIC-Mooresville indicating a need in the community to add these services.”

However, the correct calculation of female residents over the age of 40 results in just 30,782, 17% less than projected by the applicant. Furthermore, in North Carolina, only 76.5% of females over 40 report having annual mammograms.

In Section V.7, page 56, the applicant discusses the proposed project as it relates to promoting cost-effectiveness, quality and access, stating PIC-Mooresville will offer the proposed service in a cost-effective outpatient setting with competitive charges and global billing. The applicant further states,

“PIC-Mooresville also has access to the extensive management resources of MedQuest, which manages approximately 75 imaging centers in numerous states. This extensive experience and focus on outpatient imaging services result in highly efficient operations.

...

PIC-Mooresville will seek ACR (American College of Radiology) certification for the proposed service. PIC-Mooresville is currently ACR-accredited for CT and mobile MRI services.

...

In addition to being geographically accessible to patients, PIC-Mooresville is also financially accessible to all patients who seek services. PIC-Mooresville and all MedQuest imaging centers are committed to serving all patients, including the medically indigent, and have policies in place to assure that all patients receive the financial assistance they need.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

However, the applicant does not adequately demonstrate the need to acquire the proposed mammography unit and develop a new diagnostic center in Mooresville. Furthermore, the

applicant does not adequately demonstrate that the proposal would not result in unnecessary duplication of existing and approved mammography services in the proposed service area. See Criterion (3) and (6) for additional discussion which is incorporated hereby as if fully set forth herein. Therefore the applicant did not adequately demonstrate how enhanced competition would have a positive impact on cost-effectiveness because it is not cost-effective to develop a new diagnostic center that is not needed in addition to the existing and approved health service facilities providing the same services. Consequently, the application is nonconforming 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, page 22, the applicant identifies the existing CT scanner at PIC-Mooresville, the proposed mammography equipment 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, page 23, the applicant refers to the equipment quote in Attachment F, which contains a quote for the Hologic Selenia Performance Package Mammography System. The quote identifies all equipment and related components necessary to perform mammography procedures.
- (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, the applicant provides the capacity and the assumptions it used to project capacity for the new service component, as shown below.

Projected Mammography Capacity

EQUIPMENT	DAYS / YEAR	PROCEDURES / DAY	MAXIMUM PROCEDURE CAPACITY	80% OF CAPACITY
Mammography	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: 14 – 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 35, the applicant states PIC-Mooresville’s proposed mammography service area is confined to a small area in Iredell and Mecklenburg

counties, consisting of five zip codes: 28117, the location of PIC-Mooresville and contiguous zip codes 28166, 28115, 28036 and 28031.

In Section II.8, page 23, the applicant states the American College of Radiology's (ACR) website lists only one existing provider of mammography in the proposed diagnostic center service area: Lake Norman Regional Medical Center at Lake Norman Imaging Center, 146 Medical Park Drive, Mooresville, NC 28117. Attachment R contains documentation of the applicant's search for mammography services in zip codes 28117, 28115, 28036 and 28031. The applicant did not provide documentation for zip code 28166; however, the analyst found confirmation of no facilities providing accredited mammography services in zip code 28166 on the ACR website.

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

-C- In Section II.8, page 24, the applicant states the mammography service will be offered Monday-Friday from 8:30 AM to 4:00 PM.

(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 24, the applicant provides the patient origin by county for diagnostic services provided by PIC-Mooresville during CY 2011. A summary of the patient origin follows. Other is composed of Catawba, Lincoln, Gaston, Rowan, Alexander, Davie, Forsyth, Wilkes, Burke, Caldwell, Union, Ashe, Davidson, Watauga, Stanly, McDowell, Cleveland, Surry, Transylvania, Rutherford, Yadkin, and other states.

Historical Patient Origin

COUNTY	MRI	CT
Iredell	58.1%	55.1%
Mecklenburg	19.8%	13.8%
Other	22.1%	31.1%
Total	100%	100%

(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 25, the applicant provides projected patient origin by percentage by county of residence for the proposed mammography service as well as the assumptions upon which the applicant projected the patient origin.

Projected Patient Origin

COUNTY	MAMMOGRAPHY
Iredell (28117, 28115, 28166)	83.7%
Mecklenburg (28031, 28036)	16.2%
Total	100.0%

However, projected patient origin does not mirror historical patient origin and the applicant does not provide adequate justification for a departure from historical. In Section III, page 35, the applicant states, “*The proposed diagnostic center service area accounts for 58.1% of PIC-Mooresville’s CY 2011 patient origin for its existing services.*” Thus, 42% of the applicant’s current CT and MRI patients come from outside the applicant’s proposed service area for mammography. The applicant does not adequately demonstrate that it is reasonable to assume that future mammography patient origin will differ significantly from the patient origin for its existing CT and MRI services. Furthermore, rather than supporting the applicant’s proposed service area, the support letters provided in Exhibit Z of the application, tend to show that the proposed mammography service area is not reasonable based on expected physician referrals. Only 34.4% of the referrals are from physicians located in one of the five zip codes in the proposed mammography service area. Therefore, 65.6% of the referrals are from physicians located outside the proposed mammography service area, with 46.06% of the total referrals coming from physicians located in zip code 28078 and 19.52% from physicians in 28037. While all of a physician’s patients may not live in the same zip code where their physician’s office is located, it is reasonable to assume that some of them do live in the same zip code or reasonably near the office. The applicant fails to adequately explain why only five zip codes were included in the proposed mammography service area, given the historical patient origin for the CT and MRI services currently provided at the facility.

In summary, the applicant does not adequately demonstrate the projected patient origin is based on reasonable, credible and supported assumptions. 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 distinct, identifiable areas for the mammography service.

(9) *a three year capital budget.*

-NC- In Section II.8, 10A NCAC 14C .1803 (b)(9), page 26, the applicant states, “*See the PIC-Mooresville’s [sic] financial pro formas.*” However, the applicant did not reference any specific line item(s) that reflect a three year capital budget.

- (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 26, 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, the applicant provides the projected number of patients classified by diagnosis, for each of the first twelve calendar quarters following project completion. PIC-Mooresville assumes one procedure per patient. However, the projected utilization is based upon inaccurate calculations which are discussed in Criterion (3).

(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, 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. The applicant projects serving the following patients.

Quarterly Patient Origin Projection by Year

County	Year 1	Year 2	Year 3
Iredell	441	528	618
Mecklenburg	86	103	120
Quarterly Total	527	631	738
Annual Total	2108	2524	2952

However, the applicant does not adequately demonstrate the projected patient origin for mammography services is based on reasonable, credible and supported assumptions. Additionally, the annual totals are based upon inaccurate calculations. 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, 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. However, projected utilization is based on inaccurate calculations which are discussed in Criterion (3).

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, page 27, the applicant states:

“According to the American College of Radiology website, there is one existing accredited mammography provider, Lake Norman Regional Medical Center, operating in PIC-Mooresville’s proposed diagnostic center service area.”

LNRMC reported 3 units of mammography equipment and 10,643 mammography procedures (100% outpatient) on its 2012 License Renewal Application, which is

an average of 3,548 annual procedures per unit of equipment per year [10,643 / 3 = 3,548].

In Section II, page 28, the applicant determined that the maximum capacity of LNRMC's mammography units is 3,952 mammography procedures per machine based on "*information and belief*" and the following assumptions: 7.75 hours per day, 255 days per year, and 2 procedures per hour = 3,952 procedures per unit. Based on PIC-Mooresville's assumptions, LNRMC would be operating above 80% of its maximum capacity (3,547 / 3,952 = 89.7%).

However, according to comments submitted by LNRMC during the written comment period, the applicant underestimated LNRMC's capacity based on faulty assumptions. LNRMC states it offers mammography services from 8 AM to 5 PM, Monday through Friday and can serve as many as four patients per hour. Therefore LNRMC's capacity is 9,180 procedures per unit (9 hours per day x 255 days x 4 patients per hour = 9,180) and it operated at only 39% of capacity (3,548 / 9,180 = 38.64%) during FFY 2011.

The applicant does not adequately demonstrate that all existing providers of mammography services in the proposed mammography service area were operating at 80% of capacity during the 12 month period immediately preceding submittal of the application. Therefore 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- In Section II.8, pages 28-29, the applicant states PIC-Mooresville does not have access to the internal data and/or future plans for LNRMC's mammography service, but it anticipates LNRMC will continue to perform at or above its current mammography utilization. The applicant further states LNRMC experienced a 6.5% increase in mammography volume from FY 2009-10 through FY 2010-11 (10,643 / 9,987 - 1 = 6.5%). On page 29, PIC-Mooresville provides its projections for LNRMC's mammography service for the first three years of PIC-Mooresville's proposed project. PIC-Mooresville projects LNRMC will be operating above 90% capacity based on Iredell County's expected population growth rate of 1.0% annually.

However, based on comments submitted by LNRMC during the comment period, it is operating at only 39% of capacity. LNRMC cannot reach 80% of capacity by following the applicant's methodology and applying the annual growth rate of 1.0% to its 2011 volume.

	Actual	Projected	Projected	Projected	Projected	Projected
	2011	2012	2012	2012	2012	2012
Volume	10,643	10,749	10,857	10,965	11,075	11,186
% Growth		1.0%	1.0%	1.0%	1.0%	1.0%
# of Units	3	3	3	3	3	3
LNRMC Capacity*	27,540	27,540	27,540	27,540	27,540	27,540
% Capacity	38.6%	39.0%	39.4%	39.8%	40.2%	40.6%

*Per LNRMC, Capacity = 255 days x 9 hours per day x 4 patients per hour x 3 units

PIC-Mooresville projects its proposed mammography service will exceed 84% of capacity in Project Year 3. However, projected utilization is based on incorrect percentages. As the following table shows, using the applicant's methodology with the correct percentages, as calculated by the analyst, the applicant does not demonstrate it will operate at 80% of capacity (as defined by the applicant).

PIC-Mooresville Recalculated Projected Mammography Utilization			
	YR 1- 2014	YR 2 - 2015	YR 3 - 2016
Females 40+ years – potential scans	30,037	30,407	30,782
Estimated Market Share	6%	7.1%	8.2%
NCDI Mammography Volume	1,802	2,159	2,524
% of Capacity	51.49%	61.68%	72.12%

- (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, page 35, the applicant states its utilization projections were developed based on the operating experience of PIC-Mooresville, MedQuest and Novant, utilizing population data and statistical data from the American College of Radiology and the Centers of Medicare and Medicaid Services.
- (4) *all the assumptions and data supporting the methodologies used for the projections in this Rule.*
- NC- In Section II, pages 27-31 and Section III, pages 34-39, the applicant provides assumptions and data which it states support the methodology used to project utilization, as follows:
- Develop PIC-Mooresville mammography capacity based on hours of service and patients per hour;
 - Develop LNRMC mammography capacity based on hours of service and patients per hour;
 - Project proposed service area women age 40 and over;
 - Project PIC-Mooresville proposed market share of 6% in Year 1, increased by 1.1% growth rate to 7.1% in Year 2 and 8.2% in Year 3;
 - PIC-Mooresville referrals of 5,496 patients; and

- One procedure per patient.

However, the applicant did not adequately demonstrate that projected utilization is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

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 32, the applicant states emergency services are provided through the Emergency Medical Services of Iredell County and local hospitals. LNRMC is less than one mile from PIC-Mooresville. Attachment G contains Iredell County EMS information and locations. In Section II.4, page 17, the applicant states,

“PIC-Mooresville will work with the closest appropriate provider to transfer a patient who develops an emergent problem while undergoing a diagnostic procedure at PIC-Mooresville. PIC-Mooresville also 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.”

(2) support services;

- C- In Section II.8, page 32, the applicant states that support services are provided onsite. In Section II.2, page 16, the applicant states the only ancillary and support services needed for the proposed project are staff training, accounting, purchasing, and human resources, all of which will be provided by PIC-Mooresville staff or MedQuest, PIC-Mooresville’s management company. Attachment B contains the management agreement.

(3) ancillary services; and

- C- In Section II.8, page 32, the applicant states ancillary services are provided onsite. In Section II.2, page 16, the applicant states the only ancillary and support services needed for the proposed project are staff training, accounting, purchasing, and human resources, all of which will be provided by PIC-Mooresville staff or MedQuest, PIC-Mooresville’s management company. Attachment B contains the management agreement.

(4) public transportation.

- C- In Attachment G, the applicant provides Iredell County Area Transportation System (ICATS) information, including policies, hours of operation, scheduling telephone numbers, cost 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, the applicant states Dr. Jay Patti will serve as Medical Director for PIC-Mooresville with Mecklenburg Radiology Associates' 39 physicians providing radiology services. Also on page 32, and in Section VII.1, page 70-71, the applicant identifies the number of staff by type projected to provide the proposed services.

PIC-Mooresville Proposed Staff

Staff	FTE
Center Manager/Administrator	0.5
Technologists	3.0
Clerical	1.0

(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, the applicant states Dr. Jay Patti will serve as Medical Director for PIC-Mooresville with Mecklenburg Radiology Associates' 39 physicians providing radiology services. On page 32, the applicant refers to Attachment J for Dr. Patti's information. Attachment J documents Dr. Patti is board-certified in radiology and has worked with Mecklenburg Radiology Associates since July 2008.

(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, pages 32-33, the applicant states it requires all clinical staff to acquire and maintain certification in cardiopulmonary resuscitation and basic cardiac life support and will ensure opportunities to obtain such training are available to all staff. The applicant further states all training/education will be provided by MedQuest. Attachment L contains a letter dated October 13, 2012 from the PIC-Mooresville Center Manager documenting a program of continuing

education shall be available for PIC-Mooresville technologists and medical staff. The letter further states all imaging services operated by PIC-Mooresville and MedQuest in North Carolina presently have the continuing education program in place. In Section I, page 13, the applicant states MedQuest offers in-service and education programs for local physicians and technologists in order to educate them about available imaging techniques and patient benefits.