

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: July 27, 2012
FINDINGS DATE: July 27, 2012
PROJECT ANALYST: Fatimah Wilson
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: F-8830-13 / Carolinas Imaging Services, LLC / Develop a diagnostic center by replacing an existing CT scanner / Mecklenburg 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

Carolinas Imaging Services (CIS) was established as a joint venture in January 2002 between Charlotte Radiology, P.A. (CR) and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System (CHS). CIS proposes to purchase a replacement CT scanner at its Carolinas Imaging Services—Matthews (CIS-Matthews) freestanding outpatient imaging Center. CIS-Matthews is located at 1401 Matthews Township Parkway, Suite 310-B in Matthews. The acquisition of the replacement diagnostic equipment results in the development of a diagnostic center as that term is defined in G.S. 131E-176(7a). It is the development of a new diagnostic center that is subject to review.

The total cost or fair market value of the proposed equipment is \$604,584. However, when combined with the existing medical diagnostic equipment utilized by the facility which costs \$10,000 or more, the total capital cost 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. In Section XI.4, page 100, the applicant states that there will be no new construction or renovation of existing space at CIS-Matthews for the proposed project. The following table illustrates the capital cost of the existing diagnostic equipment and the proposed equipment.

COST OF EXISTING EQUIPMENT	COST
Existing Ultrasound & X-ray Equipment*	\$30,933
COST OF PROPOSED EQUIPMENT	
Fixed Equipment Purchase**	\$ 604,584
Consultant Fees (CON Application)	\$40,000
Total Projected Capital Costs	\$644,584

*CIS already owns and operates this equipment (sunk cost)

**Includes sales tax.

There are no need determinations in the 2012 State Medical Facilities Plan (2012 SMFP) that are applicable to the acquisition of the type of equipment proposed in this application or to the establishment of a diagnostic center. Furthermore, there are no policies in the 2012 SMFP that are applicable to this proposal. 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.

C

Carolinas Imaging Services (CIS) was established as a joint venture in January 2002 between Charlotte Radiology, P.A. (CR) and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System (CHS). CIS proposes to purchase a replacement CT scanner at its Carolinas Imaging Services—Matthews (CIS-Matthews) freestanding outpatient imaging Center. CIS-Matthews is located at 1401 Matthews Township Parkway, Suite 310-B in Matthews. CIS-Matthews has an existing ultrasound machine, X-ray machine and a 4-slice CT scanner. In this application, CIS-Matthews proposes to purchase a 16-slice CT scanner to replace its existing 4-slice CT scanner, 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

In Section II.1, page 18, the applicant lists existing diagnostic equipment. In Section VIII.2, page 87, the applicant lists the proposed equipment with costs and in Exhibit 12, provides the manufacturer’s quote and specifications for the proposed diagnostic equipment:

No:	Type	Initial Cost	Condition	Date Acquired	Useful Life	Annual Depreciation	Accumulated Depreciation	FMV
1	CT Scanner*	\$172,800	Good	2006	5 Years	NA	\$172,800	\$0
1	Ultrasound	\$22,233	Good	2012	5 Years	\$4,447	\$1,482	\$22,230
1	X-ray	\$8,700	Good	2005	5 Years	NA	\$8,700	\$0

**Will be traded in for acquisition of the replacement CT scanner.*

The total capital cost for the new 16-slice CT scanner and associated components are \$604,584 (including sales tax). The proposed new equipment plus the equipment currently in use at the CIS-Matthews exceeds the \$500,000 threshold.

In Section II.1, page 13, the applicant states,

“The combined value of the existing medical diagnostic equipment and proposed replacement equipment at CIS-Matthews exceeds the statutory threshold of \$500,000, and thus requires a certificate of need for a diagnostic center.”

Population to be Served

In Section III, pages 43-44, the applicant discusses its service area population and projects utilization at CIS-Matthews.

“The primary service area for the proposed diagnostic center includes the following zip codes: 28079, 28104, 28105, 28227 and 28270. The rationale for establishing this service area is based on the historical patient origin for CT patients at CIS-Matthews. The following table provides projected population growth for the proposed service area.”

Carolinas Imaging Services-Matthews
 Proposed CT Scanner Service Area
 Projected Population

Zip Code	Area	2012	2017	5-Yr CAGR
28079	Indian Trail	34,868	41,721	3.7%
28104	Matthews	29,008	33,818	3.1%
28105	Matthews	41,819	46,370	2.1%
28227	Charlotte	52,193	56,385	1.6%
27270	Charlotte	31,554	33,767	1.4%
Total		189,442	212,061	2.3%

Source: Claritas

The applicant states that according to Claritas population projections, the proposed service area will grow at an average rate of 2.3% per year, or 22,619 residents, from 2012 to 2017. Thus, the need for the proposed project is supported by the steady projected population growth of the service area. On page 44, the applicant demonstrates growth among the 65 and older segment of the population as shown in the following table.

*Carolinas Imaging Services-Matthews
 Proposed CT Scanner Service Area
 Projected Population Age 65+*

Zip Code	Area	2012	2017	5-Yr CAGR
28079	Indian Trail	2,700	3,899	7.6%
28104	Matthews	2,601	3,871	8.3%
28105	Matthews	3,583	4,800	6.0%
28227	Charlotte	4,547	6,009	5.7%
27270	Charlotte	2,618	3,493	5.9%
Total		16,049	22,072	6.6%

The applicant states that approximately one-third (32.8%) of CIS-Matthews’ CT scanner patients are age 65 and over. As shown in the table above, the service area population age 65 and older is projected to increase over two and a half times faster as compared to the overall service area population. The increase in the aging population in the service area is indicative that the demand for diagnostic imaging services will also continue to increase.

In Section III.5, page 53, the applicant provides the projected patient origin for the proposed services, which it states is based on historical patient origin for the facility. The table below illustrates projected patient origin for CY 2013 – 2014, as reported by the applicant on page 53.

COUNTY	PATIENT ORIGIN % OF TOTAL
Mecklenburg	63.4%
Union	29.5%
Stanly	2.1%
Cabarrus	1.5%
York (SC)	1.1%
Anson	0.6%
Orangeburg (SC)	0.3%
Other SC	0.3%
Horry (SC)	0.2%
Gaston	0.2%
Scotland	0.1%
Richmond	0.1%
Cleveland	0.1%
Chesterfield (SC)	0.1%
Alexander	0.1%
Chester (SC)	0.1%
Iredell	0.1%
Greenville (SC)	0.1%
Watauga	0.1%
Lee	0.1%

Totals may not foot due to rounding.

In Section III.5, page 51, the applicant demonstrates that historically, the facility treated residents from Mecklenburg County and surrounding communities. In its patient projections, it has incorporated that percentage into those counties from which it has historically served residents. The applicant adequately identified the population it proposes to serve.

Demonstration of Need

In Section III.1, page 40, the applicant states that the need for the proposed project is based on the following qualitative and quantitative factors:

- *“The 4-slice CT scanner at CIS-Matthews is not current technology, and is limited in its capabilities.*
- *The proposed replacement 16-slice CT scanner represents the current standard of care for local patients. More specifically, a replacement 16-slice CT scanner will enable CIS-Matthews to offer an expanded scope of diagnostic imaging services.*
- *Due to enhanced software capabilities, the proposed replacement 16-slice CT scanner will reduce the radiation exposure of patients receiving CT scans.*
- *The proposed project will enable CIS to provide more cost effective and timely service to meet patient expectations and to ensure quality care.*
- *The projected growth of the service area population presumes continued increases in demand for healthcare, including the need for diagnostic imaging services.”*

In Section III.1, page 41, the applicant states:

“CIS seeks to continue its mission of providing state-of-the art radiological services to residents of Mecklenburg and surrounding communities. CIS has continuously responded to changes and innovations in radiological applications. Therefore, the goal of the proposed project is to expand the scope of CIS-Matthews CT services, while at the same time enhancing technological capability, comfort and convenience.

The 4-slice CT scanner at CIS-Matthews is not current technology, and is limited in its capabilities. Currently, CIS-Matthews is unable to offer many types of CT scans because of the limited capabilities of the 4-slice CT scanner. Therefore many local patients must be referred to another CIS outpatient imaging center or to another provider. This is an inconvenience for patients and inconsistent with CIS’s mission of providing timely access to state-of-the-art diagnostic imaging services.

Due to the age of the 4-slice CT scanner (12 years), CIS-Matthews is more likely to experience unexpected downtime associated with equipment maintenance. For example, during CY 2011, the 4-slice CT scanner was down for three days for unscheduled maintenance. As the equipment continues to age, the risk of equipment malfunction or failure increases. Additionally, it is becoming increasingly difficult to locate replacement parts for the equipment when such needs arise.

The proposed replacement 16-slice CT scanner represents the current standard of care for local patients. More specifically, the proposed GE BrightSpeed Elite 16-

slice CT scanner will enable CIS-Matthews to offer an expanded scope of diagnostic imaging services. For example:

- *Diagnostic oncology protocols are written for 16-slice CT scanners or higher; thus, the proposed project will enable CIS-Matthews to serve patients needing CT cancer screening.*
- *Orthopedic exams with metal implants are more accurate on a 16-slice CT scanner; thus, the proposed project will improve the quality of diagnostic imaging for referring orthopedic physicians and their patients.*
- *Pulmonary embolism exams should only be performed on a 16-slice CT scanner; thus, the proposed project is consistent with contemporary healthcare standards and practices and will expand access to pulmonary patients.*
- *Urograms/Stone surveys are more accurate on a 16-slice CT scanner; thus the proposed project will improve the quality of diagnostic imaging for referring urologists and their patients.*
- *CT colonography and non-coronary CTAs should be performed on a minimum of a 16-slice CT scanner; thus, the proposed project is consistent with contemporary healthcare standards and practices and will expand access to gastrointestinal and coronary patients.*
- *Due to speed, pediatric studies are easier to perform on a 16-slice CT scanner; thus, the proposed project will improve the quality of diagnostic imaging and patient experience for pediatric patients.”*

In summary, the applicant states that the technological advances of the 16-slice CT scanner will expose patients to less radiation than with the current 4-slice CT scanner. This is an important benefit based on recommendations from the American College of Radiology. The 4-slice CT scanner is now 12 years old and it will become increasingly difficult to find parts to maintain and upgrade the existing equipment. The new 16-slice CT scanner will standardize CIS’s CT inventory and will facilitate operational economies of scale with regard to staff training, supplies, maintenance and operating procedures. This will lead to more efficient and cost effective delivery of care at CIS-Matthews. Patients will no longer have to be referred to other CIS imaging facilities or providers as a result of downtime due to the aging and maintenance of the existing equipment. In Section III.1, page 43, the applicant states, *“Therefore, the proposed replacement equipment will enhance the quality of care delivered at CIS-Matthews via an expanded range of CT services, reduce radiation dose and standardized equipment inventory.”*

Projected Utilization

In Section III, pages 45 – 46, the applicant presents its methodologies and assumptions used to project CT scanner utilization at CIS-Matthews. The applicant states:

“Step 1: Identify Historical CT Scanner Utilization

	<i>CY 2009</i>	<i>CY 2010</i>	<i>CY 2011</i>	<i>CY 2012*</i>
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<i>CT Scans</i>	<i>2,090</i>	<i>1,925</i>	<i>1,831</i>	<i>2,010</i>
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*Source: Application page 45

CIS experienced a slight decrease in CT scans during CY2010 and CY2011. This decrease was the direct result of a key physician practice and referral source purchasing their own CT scanner. Additionally, in 2009 the State of North Carolina Division of Medical Assistance (DMA) clarified that Medicaid would not pay for CT and routine x-ray services provided by an independent diagnostic testing facility (IDTF) (which includes CIS-Matthews). This also contributed to the decrease in CT scans during CY2010 and CY2011. However, CIS-Matthews has since established new and additional referral sources, and CT utilization has stabilized. In fact, based on year-to-date utilization (Jan-Apr CY2012), CT scans at CIS-Matthews are projected to increase 9.8 percent compared to CY2011. Additionally, CIS-Matthews has learned that DMA has recently reassessed its position regarding IDTFs, and it appears that it will pay for CT services when rendered by CIS-Matthews in the latter part of 2012. This will further stimulate future CT scan growth at CIS-Matthews.

The following step describes the method for projecting CT scans at CIS-Matthews

Step 2: Project Future CT Scanner Utilization

To project utilization for the proposed replacement CT scanner, CIS-Matthews applied the projected population growth rate for the proposed service area (2.3 percent)."

	<i>CY2013</i>	<i>CY2014</i>	<i>CY2015</i>
<i>CT Scans</i>	<i>2,056</i>	<i>2,103</i>	<i>2,151</i>

Source: Application page 46

The applicant states on page 46 that CIS-Matthews' projected CT scanner utilization is reasonable and conservative. The projected population growth rate (2.3 percent) for the service area is much lower compared to its annualized CY2012 growth rate of 9.8 percent. The CY2012 growth rate of 9.8 percent was calculated by subtracting CY2011 CT scans (1,831) from CY2012 CT scans (2,010). The difference (179) was then divided by the CY2011 CT scans (179 / 1,831 = 0.0977 or 9.8 %).

The applicant states on page 46 that because the replacement 16-slice CT scanner will expand the scope of diagnostic imaging services offered at CIS-Matthews, incremental growth as a result of the expanded capabilities is expected in addition to increases in physician referrals and equitable access to Medicaid CT scanner patients based on expanded reimbursement for IDTFs. In Exhibit 14, the applicant provides letters of support from local physicians documenting their support and intent to refer patients to the facility as a result of the proposed project.

The applicant's CT utilization is based on the population of its proposed service area; in particular, the projected growth of the population cohort projected to use the diagnostic services offered by the applicant. The applicant's projections are also based on historical utilization growth. Projected utilization is adequately based on reasonable, credible and

supported assumptions. Therefore, CIS-Matthews adequately demonstrates the need to replace one 4-slice CT scanner and to be designated as a diagnostic center.

In summary, the applicant adequately identifies the population it proposes to serve and adequately demonstrates the need the population has for the replacement CT scanner and designation as a diagnostic center. Consequently, the application is 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.

CA

In Section III.3, pages 48-50, the applicant describes the alternatives it considered, including maintaining the status quo, acquiring a different replacement CT scanner and pursuit of a joint venture. The applicant adequately explains why it chose the selected alternative over the other alternatives. Furthermore, the application is conforming to all other applicable statutory review criteria. See Criteria (1), (3), (3a), (5), (6), (7), (8), (12), (13), (14), (18a), (20) and *Section .1800 Criteria and Standards for Diagnostic Centers* for additional discussion. Therefore, the applicant adequately demonstrates that the selected proposal is its least costly or most effective alternative to meet the need for a replacement CT scanner and designation as a diagnostic center. Consequently, the application is conforming to this criterion and is approved subject to the following conditions:

- 1. Carolinas Imaging Services, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Carolinas Imaging Services, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**
- 3. Carolinas Imaging Services, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**

- (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.

C

In Section VIII.1, pages 85 - 86, the applicant projects the total capital cost for the CT scanner will be \$644,584; which includes \$604,584 for the proposed equipment, and \$40,000 in consultant fees. In Section VIII.4, page 89, the applicant states that CIS-Matthews will not use a loan to fund this project, but will fund the project using accumulated reserves. In Exhibit 15 the applicant provides an April 30, 2012 letter from the Chief Financial Officer of Charlotte Radiology, which states in part:

“Carolinas Imaging Services, LLC (CIS) is seeking to replace its existing CT scanner with a newer CT scanner, and thus will exceed the \$500,000 diagnostic center threshold at the CIS-Matthews facility. ...

CIS is planning to fund the project with accumulated reserves. As shown on the accompanying financial statements, CIS has sufficient financial resources to fund the project cost. ...”

In Section IX, page 93, the applicant states there are no start-up or initial operating expenses associated with this project.

Exhibit 16 contains the audited financial statements for CIS, which show that as of December 31, 2011, CIS had total income in the amount of \$12,247,683, total expenses in the amount of \$10,824,951 and net income in the amount of \$1,422,731. The applicant adequately demonstrates the availability of funds for the capital needs of the project.

In Section 13, Form D, the applicant provides projected average charges for each piece of equipment for the first three project years. In addition, the applicant projects revenues will exceed expenses in all three project years. Projected revenues and expenses are reasonable, credible and supported. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Therefore, the application is 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.

C

CIS-Matthews proposes to acquire one replacement CT scanner, which results in the development of a new diagnostic center. The patients to be served will be the same as the patients currently served in the existing location. No new services will be offered. CIS-Matthews' patients are currently referred to other facilities for certain types of CT scans not

offered at the facility and as a result of downtime during maintenance of the existing unit. CIS-Matthews adequately demonstrates it is more cost effective to replace the 4-slice CT scanner with a 16-slice CT scanner because the patients will not incur additional co-pays and delays in diagnoses that result from referral to other locations. The applicant adequately demonstrates the need to replace the existing CT scanner, and thus to develop a diagnostic center. Projected utilization is based on reasonable, credible, and supported assumptions. See Criterion (3) for a description of the methodologies used to project utilization. The discussion in Criterion (3) regarding projected utilization is incorporated as if fully set forth herein. Utilization of existing and approved CT scanners is not publically available such that it is possible to determine if excess capacity exists in the service area. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities, and therefore the application is 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 V.5, page 82, the applicant states,

“Due to the nature of outpatient services, CIS-Matthews will continue to operate on a scheduled basis, rather than an emergent basis. Normal business hours are weekdays from 8:00 am to 5:00 pm. CIS-Matthews requires one staffing shift to accommodate the weekly medical diagnostic equipment schedule (Monday – Friday from 8:00 am to 5:00 pm, 40 hours/week).”

In Section VII.3, page 80, the applicant states that the proposal does not involve the addition of any new FTE positions.

In Section VII.1, page 79, the applicant projects staffing for the second project year, CY 2014, for CIS-Matthews, as shown in the following table.

**Carolinas Imaging Services-Matthews
 Projected CT Staffing, CY 2014**

POSITION TITLE	# OF FTES	SALARY
Administrative		
HC Administrator	0.20	\$58,055
Clinical		
CT Technologist	1.40	\$56,299
Subtotal	1.60	\$114,354
Support		
Receptionist	1.40	\$44,829
Subtotal	1.40	\$44,829
Subtotal		
Total Diagnostic Center	3.00	\$159,183

In Section V.3, page 62 and Section VII.7, page 83, the applicant states Dr. James Oliver currently serves as the Medical Director for CIS-Matthews, and will continue to do so following project completion. In Exhibit 6, the applicant provides an April 25, 2012 letter signed by Dr. Oliver affirming his commitment to serve in that capacity. In addition, in Section VII.3, page 81, the applicant states that Charlotte Radiology will continue to be available to staff the diagnostic center.

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, pages 16 - 18, the applicant states that the necessary ancillary and support services are currently available at CIS-Matthews. In Section II.3, page 17, the applicant states,

“In case of an emergency, including those requiring blood or blood product, transfusion or transfer to an acute care hospital, patients will be transported by local EMS to Presbyterian Hospital Matthews or another appropriate facility.”

The applicant provides letters of support for the proposal from area physicians in Exhibit 14. The applicant adequately demonstrated 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 VI.2(a-f), pages 66-67, the applicant states,

“CIS will continue to have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

In Section VI.13, page 74, the applicant provides the current (January-December 2011) payor mix for CIS-Matthews CT services.

**Carolinas Imaging Services-Matthews
 CY2011 (January-December 2011)
 CT Service**

Service Component Last Full Fiscal Year Current Patient Days / Procedures as Percent of Total Utilization	
Self Pay	0.9%
Medicare	44.1%
Medicaid	0.1%
Managed Care / Commercial	27.8%
Blue Cross Blue Shield	27.2%
TOTAL	100.0%

Totals may not exactly add up due to rounding.

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 as of June 2010 and Calendar Year 2008 – 2009 respectively. The data in the table was obtained on July 10, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

COUNTY	TOTAL # MEDICAID ELIGIBLES AS % OF TOTAL POPULATION JUNE 2010	TOTAL # MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION JUNE 2010	% UNINSURED CY 2008 - 09 (ESTIMATE BY CECIL G. SHEPS CENTER)
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 CT services offered by CIS-Matthews. 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 48.6% for those age 20 and younger and 31.6% 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 or 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; particularly, diagnostic 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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.II, page 66, the applicant states low income and any other medically underserved group will continue to be available at CIS-Matthews. In Section VI.10, page 72, the applicant states that CIS-Matthews has not had any civil rights equal access complaints or violations filed against it the last five years. In Section VI.11, page 72, the applicant states it is under no obligation to provide uncompensated care, community service, or access by minorities or handicapped persons, but that it will continue to do so. 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.14 and VI.15, pages 75 - 76, the applicant projects the following payor mix during CY 2014 for the entire facility and for the service component:

**Carolinas Imaging Services-Matthews
 CY2014 (January-December 2014)**

ENTIRE FACILITY SECOND FULL FISCAL YEAR CURRENT PATIENT DAYS / PROCEDURES A PERCENT OF TOTAL UTILIZATION	
Self Pay	1.2%
Medicare	39.4%
Medicaid	0.1%
Managed Care/Commercial	29.8%
Blue Cross Blue Shield	29.6%
Total	100.0%

Totals may not exactly add due to rounding.

**Carolinas Imaging Services-Matthews
 CT Scanner
 CY2014 (January-December 2014)**

SOURCE OF PAYMENT	PERCENT
Self Pay	0.9%
Medicare	44.1%
Medicaid	0.1%
Managed Care/Commercial	27.8%
Blue Cross Blue Shield	27.2%
Total	100.0%

Totals may not exactly add due to rounding.

In Section VI.6, page 69, the applicant states “*All services offered by CIS-Matthews will continue to be available to all persons who present themselves for services ... without regard to race, color, religion, sex, age, national origin, handicap, or ability to pay.*” Exhibit 7 contains the relevant CIS patient financial policy which describes how the facility plans to ensure access to its services by indigent and other medically underserved persons, and confirms the same provision of services will continue following project completion. The applicant demonstrates it will provide adequate access to medically underserved groups. 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(a), page 72 of the application, the applicant states that all patients will have access to the diagnostic services through physician referrals, with services provided on a scheduled and non-emergent basis. In Section VI.0(c), page 72, the applicant states that CIS-Matthews does not have any formal working agreements with other existing health care facilities or agencies because the attending physicians will direct the patients’ care. The applicant states that in case of an emergency,

patients will be transported by local EMS to Presbyterian Hospital Matthews or another appropriate facility. 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 60, the applicant states

“CIS is currently available and will continue to be available to students in any training program, as needed. CIS has established relationships with area clinical training programs through its members, CHS and CR, as documented in Exhibit 9. CIS-Matthews will be able to provide additional training capacity for the clinical programs currently being served.”

In Exhibit 9, the applicant provides a list of facilities and a copy of a sample agreement by CHS to offer the facility as a clinical training site. The applicant adequately demonstrates that it will continue to 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.

C

See Sections II, III, V, VI and VII. In particular, see Section V.7, pages 63 - 64, in which CIS-Matthews discusses how the project will foster competition by promoting cost-effectiveness, quality and access to CT and cardiac diagnostic services. The information provided by the applicant in those sections is reasonable and credible. Furthermore, the information provided by the applicant adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to CT and diagnostic services in Mecklenburg County. This determination is based on the information in the application, and the following:

- ◆ The applicant adequately demonstrates the need to replace the existing 4-slice CT scanner and develop a diagnostic center, and that the proposal is a cost-effective alternative;
- ◆ The applicant has and will continue to provide quality services; and
- ◆ The applicant has and will continue to provide adequate access to medically underserved populations.

Therefore, the application is 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.

C

The application is conforming to all applicable Criteria and Standards for Diagnostic Centers. 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 24, the applicant identifies the existing medical diagnostic equipment at CIS-Matthews, the proposed medical diagnostic 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 24, the applicant states that there is no additional equipment or related components which are necessary to perform the proposed procedures and services.

(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 III.1, pages 45-46, the applicant provides the assumptions it used to project capacity for the service component, and the projections, as shown below.

EQUIPMENT	DAYS / WEEK	HOURS / WEEK	MACHINE DOWN TIME	PROCEDURES / HOUR	TOTAL PROCEDURE CAPACITY
CT Scanner	5	40	10%	1.33	2,400

In Section III.1, page 46, the applicant states that the projected utilization for the proposed replacement CT scanner is based on projected population growth rate for the proposed service area (2.3 percent).

(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 II, page 26, the applicant provides a table that lists all existing and approved providers of the types of diagnostic equipment proposed for the facility that are located in the proposed service area.

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

- C- In Section II.8, page 27 the applicant states the diagnostic center will be open from 8:00 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 III.4(b), page 51, the applicant provides the patient origin by county for services provided by CIS-Matthews during CY 2011.
- (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;*
- C- In Section III.5, pages 53-54, the applicant provides projected patient origin by percentage by county of residence for the proposed service as well as the assumptions and data which support the methodology.
- (8) *drawings or schematics of the proposed diagnostic center that identifies a distinct, identifiable area for each of the proposed services; and*
- C- In Exhibit 13 the applicant provides line drawings of the proposed diagnostic center that identifies a distinct, identifiable area for the CT scanner.
- (9) *a three year capital budget.*
- C- In Exhibit 4, the applicant provides a capital equipment budget for CIS-Matthews from 2012-2014.
- (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- In Exhibit 11, the applicant provides documentation that all equipment proposed for the diagnostic center have been certified for clinical use by the U.S. Food and Drug Administration.
- (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 Section II, page 30, the applicant provides the projected number of patients to be served, 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 Section II, page 32, 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, for the CT scanner.
- (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 Section II, pages 33-34, 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;*

- C- In Section II, page 35, the applicant states there is no publicly available data which identifies the number of existing CT scanners located in health service facilities in CIS's proposed service area that also includes the hours of operation for the facility, or the hours that a physician is available to perform interpretations.
 - (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;*
- C- In Section II, page 36, the applicant projects that utilization for the CT scanner will exceed 80 percent (89.6%) of the maximum number of procedures the proposed replacement equipment is capable of performing by the fourth quarter of the third year of operation.
 - (3) *documentation that the applicants utilization projections are based on the experience of the provider and on epidemiological studies; and*
- C- In Section II, page 37, the applicant states that all utilization projections are based on 1) the most recent utilization information available to CIS, 2) physician referral patterns, and 3) service area demographic data..
 - (4) *all the assumptions and data supporting the methodologies used for the projections in this Rule.*
- C- In Section III.1, pages 45-46, the applicant provides the assumptions and data supporting the methodologies used to project utilization.

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 37, the applicant states that emergency services are available at Presbyterian Hospital Matthews, less than one mile from the CIS-Matthews proposed diagnostic center.
 - (2) *support services;*
- C- In Section II, page 38, the applicant states that primary support services, including administration, business office, information technology and medical records are currently provided at CIS-Matthews, and will continue to be provided upon implementation of the diagnostic center project.

(3) *ancillary services; and*

- C- In Section II, page 38, the applicant states as an existing outpatient imaging center which provides medical diagnostic services, necessary ancillary services are currently in place at CIS-Matthews. Lab and other diagnostic services are available from Carolinas Healthcare System or other qualified providers.

(4) *public transportation.*

- C- In Section II, page 38, the applicant states that patients in Mecklenburg County have access to public transportation via Charlotte Area Transit System (CATS). Route 65X Matthews Express travels to Matthews and stops approximately one mile from the proposed diagnostic center.

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 38, and in Section VII.1, page 79, the applicant identifies the number of staff by type projected to provide the proposed services.

(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 39, the applicant states that all CR's physicians are licensed to practice medicine in North Carolina and have the qualifications necessary to perform radiation procedures, and shall be available to perform and supervise all CT scanner procedures.

(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 Exhibit 8, the applicant provides CIS-Matthews' policy regarding continuing education.