ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: May 11, 2012

PROJECT ANALYST: Tanya S. Rupp
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: J-8781-12 / Private Diagnostic Clinic, PLLC d/b/a Duke Medicine Specialty Care Croasdaile Commons / Develop a diagnostic center by acquiring one X-ray machine and one Body Plethysmograph / Durham 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

Private Diagnostic Clinic, PLLC (PDC) currently operates two physician practices: Triangle Heart Associates (THA) and Asthma, Allergy and Airway Center (AAAC), both located approximately one mile apart in Durham. THA operates one nuclear camera and two echocardiogram machines on which it provides both preventive and diagnostic cardiology services. AAAC operates two body plethysmograph ("Body Box") machines, which measure the compressible gas in lungs. The Body Box performs diagnostic pulmonary function tests that are designed to measure air flow and obstructions. According to the applicant in Section II.1, pages 15 – 16, the diagnostic tests performed by the Body Box are more thorough than standard pulmonary function tests. PDC intends to consolidate THA and AAAC and locate them in a new facility (Private Diagnostic Clinic, PLLC d/b/a Duke Medicine Specialty Care Croasdaile Commons) in Croasdaile Commons in Durham. The consolidation of the two physician practices at a new location is not subject to review. In addition, PDC proposes to acquire one digital x-ray machine and one additional Body Box. The acquisition of the additional 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 $224,545. 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 II.1(a), page 17, and in Section XI, pages 123 - 125, the applicant reports it will incur costs for the upfit of 5,432 square feet of leased space for the diagnostic center. The following table illustrates the capital cost of the existing diagnostic equipment, the proposed building upfit and the proposed equipment.

COST OF EXISTING EQUIPMENT	COST
Nuclear Camera	$231,002
Body Box	$ 40,441
Body Box	$ 38,000
Echocardiogram	$ 94,553
Echocardiogram	$ 94,553
Sub Total Existing Equipment	$498,549
PROJECTED CAPITAL COSTS	
Building Costs (Cost for upfit of leased space)	
THA	$308,000
AAAC	$235,000
Body Box (new)	$ 63,095
Digital X-ray (new)	$161,450
Sub Total Projected Costs	$767,545
Grand Total	**$1,226,094**

*See Section II, page 28, Section VIII, page102, and Exhibit 13 for equipment lists and valuation assumptions.

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

Private Diagnostic Clinic, PLLC (PDC) began in 1931 as a private physician practice in rented space within the Duke Hospital complex, and in 1997 became a professional limited liability corporation, eventually growing to 1,224 physicians covering 15 specialty areas of

practice. Two of the physician practices, Triangle Heart Associates (THA) and Asthma, Allergy and Airway Center (AAAC), operate in Durham approximately one mile apart. THA is a community based cardiology practice that joined PDC in 2011. THA operates a nuclear camera, which is used to identify and measure the extent of coronary artery disease. THA also operates two echocardiogram machines, which are used to evaluate and diagnose cardiovascular conditions. AAAC is a clinic that diagnoses and treats pulmonary diseases such as asthma and other allergy and lung illnesses. AAAC operates two Body Boxes, which are designed to evaluate and diagnose various pulmonary conditions by placing the patient in a "cabinet" and then using a computer to measure lung volume, air resistance, and other conditions. The applicant states, on page 22, that *"…cardiovascular and pulmonary specialties are closely related. Patients with cardiovascular conditions often need pulmonary evaluation and vice versa. Co-locating* [these two services] *in one facility will afford opportunities to … reduce the cost of providing care while, at the same time, providing a high level of service."* In this application, PDC proposes to acquire one additional Body Box and one digital x-ray machine, which results in the development of a new diagnostic center as that term in defined in G.S. 131E-176(7a).

Population to be Served

In Section III.5, pages 65 - 66, the applicant provides the projected patient origin for the proposed services, which it states is based on historical patient origin for both THA and AAAC. The table below illustrates projected patient origin for CY 2014 – 2015, as reported by the applicant on page 66.

COUNTY	PATIENT ORIGIN % OF TOTAL
Durham	57.5%
Orange	11.7%
Granville	8.3%
Person	6.9%
Virginia	5.4%
Wake	4.3%
Alamance	3.2%
Vance	1.5%
Franklin	1.1%
Total	100.0%

In Section III.5, pages 66 – 67, the applicant states that historically, the two specialties treated patients from other North Carolina Counties and from other states. In its patient projections, it has incorporated that percentage into those counties from which it has historically served a greater percentage of patients. The applicant adequately identified the population it proposes to serve.

Demonstration of Need

In Section III.1, pages 43 – 61, the applicant describes the need for both the consolidation of the two physician practices, which is not subject to review; and the acquisition of one additional Body Box and one digital x-ray machine, which is subject to review. On page 43, the applicant states the need for the project is based on qualitative and quantitative factors, including projected population growth, particularly of older age cohorts in the service area, and the need for cardiovascular and pulmonary services in the service area.

In Section III.1, page 44, the applicant states:

> *"Triangle Heart Associates*
>
> *The existing nuclear camera and echocardiogram machines involved in this project support THA's clinical practice. … THA provides state-of-the-art cardiac care to help heart patients lead longer, healthier lives. The experienced team of cardiologists at THA delivers high-quality, comprehensive evaluation and treatment services to patients with a broad range of cardiovascular conditions. THA provides evaluation and management of cardiovascular conditions, including:*
>
> - *Acute and chronic coronary artery disease*
> - *Congestive heart failure*
> - *Valvular heart disease*
> - *Cardiac rhythm and conduction disturbances*
> - *Peripheral vascular disease Peripheral artery disease*
> - *Heart disease in women*
>
> *The existing diagnostic equipment is integral to THA's continuum of consultative, preventive and interventional cardiology services. …*
>
> *Asthma, Allergy and Airway Center*
>
> *… AAAC is a state-of-the-art clinic for patients with asthma and other lung and allergic problems. The two existing Body Boxes are used daily for the evaluation and diagnosis of various pulmonary conditions and are an essential modality for AAAC's practice. Body plethysmography or 'Body Box' for short, is a very sensitive lung measurement used to detect lung pathology that might be missed with conventional pulmonary function tests. This method of obtaining the absolute volume of air within one's lungs may also be used in situations where several repeated trials are required or where the patient is unable to perform the multibreath tests. The technique requires moderately complex coaching and instruction for the subject. Using body plethysmography, AAAC physicians can examine the lungs' resistance to airflow, distinguish between restrictive and obstructive lung diseases, determine the response to bronchodilators, and determine bronchial hyper reactivity in response to methacholine, histamine, or isocapnic hyperventilation.*
>
> *As body plethysmography is used for the daily evaluation and diagnosis of AAAC's patients, the two existing Body Boxes are currently utilized above their practical*

capacity. Thus, PDC seeks to acquire one additional Body Box as part of the proposed project. The additional equipment will increase access to this highly sensitive and effective medical diagnostic service and reduce capacity constraints on AAAC's existing equipment.

PDC also seeks to acquire a digital X-ray machine for the proposed diagnostic center to support AAAC's clinical practice. The proposed digital X-ray machine will provide chest X-rays for AAAC patients. The chest X-ray is the most commonly performed diagnostic X-ray examination. A chest X-ray makes images of the heart, lungs, airways, blood vessels and the bones of the spine and chest. AAAC physicians will use the proposed digital X-ray for the evaluation and diagnosis of pulmonary conditions and diseases. Currently, AAAC physicians refer patients for chest X-rays to other (non-PDC) providers. This creates an inconvenience for patients because they must travel to another physician clinic and potentially pay an additional co-pay for the visit. Additionally, not having chest X-ray available onsite can delay a patient's evaluation and diagnosis. Therefore, the proposed project will increase access and to diagnostic imaging services for AAAC patients by making digital X-ray services available on-site."

In Section III.1, pages 46 – 47, the applicant describes how co-locating the two practices will optimally serve PDC patients:

"Co-locating THA and AAAC in the proposed diagnostic center will improve access to cardiovascular and pulmonary services for local residents. Currently, THA and AAAC physicians are located at two separate sites. …

The existing AAAC clinic was not designed to contemporary standards and, thus, is not favorable for the longevity of the program, and the existing THA clinic is not optimally designed for its services. The proposed diagnostic center project will relocate THA and AAAC's clinics to newly up-fitted medical office space at Croasdaile Commons in Durham.… Additionally, PDC will relocate one individual Pulmonologist from PDC's North Duke Street clinic to practice with AAAC in the new diagnostic center. The modern clinical practice facility will be designed to improve patient convenience and increase patient satisfaction. The proposed project will also promote efficiency via economies of scale.

…

PDC's plan to co-locate THA and AAAC (including the existing medical diagnostic equipment) is cost effective. Generally speaking, cardiovascular and pulmonary specialties are closely related. Patients with cardiovascular conditions often need pulmonary evaluation and vice versa. Co-locating cardiovascular and pulmonary services in one facility will afford opportunities to utilize economies of scale to reduce the cost of providing care while, at the same time, providing a high level of service. Relocating THA and AAAC from their existing locations to one new location will also reduce PDC's overhead for these services, which is also cost effective.

> *PDC's proposal is consistent with the SMFP Basic Principle of promoting cost effective healthcare approaches. Given the current state of economic uncertainty, it is particularly important to consider low-cost alternatives and the benefits that cost savings will have for health care recipients."*

The applicant examined the historical utilization of services at both THA and AAAC, and population growth projections for the proposed service area. On page 48, the applicant provides population data from Claritas that shows the population for the 13 ZIP codes that comprise the proposed service area is projected to grow at a compound annual growth rate (CAGR) of 1.3% from 2011 to 2016. On page 49, the applicant states the population cohort most likely to use pulmonary and cardiovascular diagnostic services, based on historical information, is the over 65 age group. The applicant states:

> *"As described previously, the proposed project involves diagnostic imaging modalities that support cardiovascular and pulmonary services. Generally speaking, cardiovascular and pulmonary diseases are a legitimate cause for concern in older individuals. For example, in the United States, cardiovascular disease, e.g., atherosclerosis and hypertension, which lead to heart failure and stroke, is the leading cause of mortality, accounting for over 40 percent of deaths in those aged 65 years and above. Over 80 percent of all cardio-vascular deaths occur in the same age group. Similarly, respiratory symptoms are common in older individuals. For example, in 2008, an estimated 9.8 million Americans reported a physician diagnosis of chronic bronchitis. Chronic bronchitis affects people of all ages, although people aged 65 years or more have the highest rate at 56.3 per 1,000 persons."*

Following are two tables that contrast projected population growth of the general population and of the 65+ age cohort in the proposed service area, as reported by the applicant on pages 48 and 50:

Service Area Population Growth Projections
Entire Population

ZIP CODE	CITY	2011	2016	2011- 16 CAGR
Primary Service Area				

27701	Durham	27,080	28,279	0.9%
27704	Durham	33,343	36,272	1.7%
27705	Durham	46,565	50,048	1.5%
27707	Durham	48,942	50,030	1.6%
27710	DUMC	NA	NA	NA
27712	Durham	19,779	21,065	1.3%
Primary Service Area Total		**175,709**	**188,694**	**1.4%**
Secondary Service Area				
27278	Hillsborough	22,274	23,762	0.9%
27503	Bahama	3,346	3,509	1.0%
27509	Butner	11,047	11,848	1.4%
27522	Creedmoor	10,683	11,806	2.0%
27565	Oxford	25,852	26,875	0.8%
27572	Rougemont	6,900	7,217	0.9%
27581	Stern	2,949	3,207	1.7%
Secondary Service Area Total		**83,501**	**88,224**	**1.1%**
Total Service Area		**259,210**	**276,918**	**1.3%**

Service Area Population Growth Projections
Over Age 65 Population

ZIP CODE	CITY	2011	2016	2011- 16 CAGR
Primary Service Area				
27701	Durham	1,989	2,229	4.1%
27704	Durham	3,682	4,516	4.2%
27705	Durham	5,447	6,494	3.6%
27710	DUMC	NA	NA	NA
27707	Durham	4,796	5,803	3.9%
27712	Durham	2,889	3,556	4.2%
Primary Service Area Total		**18,803**	**22,798**	**3.9%**
Secondary Service Area				
27278	Hillsborough	3,028	3,717	4.2%
27503	Bahama	469	580	4.3%
27509	Butner	732	868	3.5%
27522	Creedmoor	1,274	1,654	5.4%
27565	Oxford	3,945	4,663	3.4%
27572	Rougemont	887	1,123	4.8%
27581	Stern	295	404	6.5%
Secondary Service Area Total		**10,630**	**13,009**	**4.1%**
Total Service Area		**29,433**	**35,807**	**4.0%**

Thus, it is evident that the over age 65 population cohort is projected to grow at a CAGR that is three times faster than the total population of the proposed service area.

On pages 51 – 55, the applicant describes the incidence and impact of cardiovascular and respiratory diseases in the proposed service area. Citing information from the North Carolina Center for Health Statistics, the applicant states on page 51:

"According to the State Center for Health Statistics, chronic diseases, including heart

disease and chronic lung disease, account for 60 percent of all deaths in North Carolina.

…

In 2009, cardiovascular diseases (heart disease, stroke, and atherosclerosis) accounted for almost one-third of all deaths in the state (29 percent). Pulmonary diseases, including chronic lower respiratory diseases, pneumonia and influenza, were also among the top ten leading causes of death. In order to effectively diagnose and subsequently treat these chronic diseases, the population must have ready access to appropriate medical diagnostic services. This supports the need for the proposed diagnostic center and medical diagnostic equipment.

Every 10 years since 1990, North Carolina has set decennial health objectives with the goal of making North Carolina a healthier state. One of the primary aims of this objective-setting process is to mobilize the state to achieve a common set of health objectives. …

…

The existing nuclear camera and echocardiogram machines involved in this project support THA's cardiovascular services. The diagnostic medical equipment performs procedures that aid THA physicians in the evaluation, diagnosis and treatment of various cardiovascular conditions. As described previously, THA's existing medical diagnostic equipment is critical to the continuation of cardiovascular services at PDC. This mortality data, combined with projected population growth and aging, indicates that THA's nuclear cardiology and echocardiogram services have and will continue to be well-utilized in the future.

…

Asthma and chronic obstructive pulmonary disease (COPD) are severe and under-recognized diseases in Durham County. While COPD is the fourth leading cause of death nationally, it is the second leading cause of death in Durham County from 2001-2005…. … An important risk factor for COPD is cigarette smoking; in Durham County, the prevalence of any smoking is 36 percent and 21 percent of respondents consider themselves current smokers.

Asthma prevalence in Durham County middle schools is 15.4 percent overall and 27.5 percent among African-American students, two to three times higher than national averages. According to [the National Center for Chronic Disease Prevention, Behavior Risk Surveillance System]*, among adults (>18 years), asthma was diagnosed in 56 percent during childhood, and 44 percent during adulthood. These statistics contrast from the national average, where 10-20 percent of asthma is diagnosed in adulthood. Of note, a diagnosis of asthma in adults was also present in 35 percent of patients with COPD, suggesting an overlap between these two diseases in the adult population in*

North Carolina. Of the adults with asthma, 20 percent experienced at least one exacerbation requiring an urgent care/Emergency Department visit, and 15 percent lost between one and seven days of work. …

In response to these astounding statistics, Durham Health Innovations (DHI) sought to develop an innovative model of care that builds upon programs existing in Durham County for patients with asthma and COPD. DHI is a partnership between Duke Medicine (including PDC) and the Durham community that seeks to improve the health status of Durham County residents. In 2009, DHI funded 10 planning teams to find ways to reduce death or disability from specific diseases or disorders prevalent in the community. One of the teams that was established was The Duke-Durham Respiratory Partnership (also known as the Breathe Easy Team), co-chaired by Monica Kraft, MD, Director of AAAC.

The Breathe Easy Team was tasked with the objective of developing a strategy to identify and care for children and adults with asthma, and adults with COPD who represent this high-risk cohort. The team developed a model that can be expanded to the greater asthma and COPD populations and potentially other chronic conditions. One of the technology components of the model included measurement of lung function. Regular assessment of lung function is considered standard of care for patients with asthma and COPD. At AAAC, the vast majority of patients evaluated undergo pulmonary function testing via spirometry and body plethysmography (Body Box).”

Projected Utilization

In Section III, pages 56 – 61, in a series of steps, the applicant presents its methodologies and assumptions used to project utilization of the new body box and the digital x-ray machine in the proposed diagnostic center. The applicant states:

“Step 1: Identify Historical AAAC Body Box Utilization

…

	FY 2008	***FY 2009***	***FY 2010***	***FY 2011***
Body Box Procedures	*2,884*	*3,252*	*3,466*	*3,752*

**Source: Application page 56*

AAAC’s Body Box utilization has experienced a three-year compound annual growth rate of 9.7 percent from FY2008 to FY2011. AAAC experienced a slight decrease in Body Box procedures in FY2010; however, this decrease was not due to a decrease in demand for diagnostic services at AAAC. PDC attributes this slight decrease to the challenging economic climate experienced both locally and across the State. PDC anticipates that as the local economy continues to stabilize, Body Box utilization will return to historical growth patterns. Indeed, utilization increased 8.3 percent from FY2010 to FY2011 and the first six months of FY2012 (July 2011-December 2011) have

experienced an annualized increase of 8.4 percent."

Even taking into account the decrease in utilization from FY 2009 to FY 2010, as explained by the applicant, there has been an overall increase in body box utilization from FY 2008 to FY 2011 of 31.9%, and an increase of 8.25% from FY 2010 to FY 2011. On page 56, the applicant states:

"AAAC's two existing Body Boxes are currently utilized above their practical capacity. Based on the historical and projected growth of these procedures, and to alleviate capacity constraints, AAAC demonstrates the need for an additional Body Box. …

Step 2: Project Future Body Box Utilization

To project utilization for the existing and proposed Body Boxes, PDC applied one half of the three-year compound annual growth rate from FY2008 to FY2011 (9.7 percent / 2 = 4.8 percent).

	FY 2012*	***FY 2013***	***FY 2014***	***FY 2015***	***FY 2016***
Body Box Procedures	*4,066*	*4,263*	*4,469*	*4,685*	*4,912*

**Annualized based on six months data, as reported by the applicant on page 57.*

The applicant states on page 57 it captures historical utilization data based on a fiscal year that runs from July to June. However, to project utilization, the applicant converted the data to calendar year projections, as follows:

"PDC's historical procedure data is captured annually from July-June. PDC projects to initiate the proposed project by January 1, 2013 (CY2013). Therefore, PDC converted its July-June utilization projections to calendar year utilization projections (January-December). For example, PDC utilized the following formula to convert projection utilization to CY2013: [(50% x FY2013) + (50% x FY2014)]; [(50% x 4,263) + (50% x 4,469) 4,366]. …

Duke Medicine Specialty Care Croasdaile Commons
Athsma, Allergy & Airway Center
Projected Body Box Utilization

	CU 2013	***CY 2014***	***CY 2015***
Body Box Procedures	*4,366*	*4,577*	*4,798*

On page 58, the applicant projects that the body boxes at the PDC will be utilized at 84.2% capacity during the third project year.

On pages 58 – 60, the applicant projects utilization for the digital x-ray machine. The applicant states:

"As described previously, PDC seeks to acquire a digital X-ray machine for the proposed diagnostic center to support AAAC's clinical practice. The proposed digital X-ray machine will provide chest X-rays for AAAC patients. The chest X-ray is the most

commonly performed diagnostic X-ray examination. A chest X-ray makes images of the heart, lungs, airways, blood vessels and the bones of the spine and chest. …

To project the number of X-ray procedures for the proposed diagnostic center, PDC used data available from the Hammes Company. Hammes Company is a provider of market-based and financially sound solutions for national healthcare systems, regional and community hospitals as well as physician groups. PDC utilized a proprietary model developed by Hammes Company that benchmarks outpatient ancillary utilization per physician specialty. The following table shows the provider to ancillary procedure ratio for pulmonary medicine specialists to X-ray procedures.

Number of Procedures per Specialty (per 1.0 Clinical FTE)	
Specialty	***X-ray Procedures***
Pulmonary Medicine	*360.0*

AAAC currently has a total of 17 providers (15 physicians and 2 nurse practitioners) on staff who will utilize the proposed digital X-ray. … Not all of the 17 identified providers are full-time clinical providers at AAAC due to their academic and research responsibilities. PDC estimates the total clinical effort of all 17 providers is anticipated to be 12.0 FTE. PDC utilized the Hammes Company ancillary procedure rate to project the number of X-ray procedures for the proposed diagnostic center. …

	CY2013	***CY2014***	***CY2015***
X-ray Procedures	*4,320*	*4,320*	*4,320*

PDC's methodology for projecting X-ray procedures is reasonable and conservative. PDC utilized a projection model specific to pulmonary medicine physicians based on the Hammes Company's national experience providing consulting services for healthcare organizations. Furthermore, AAAC is an existing physician clinic that utilizes X-ray for the diagnosis and evaluation of its patients every day."

On page 60, the applicant projects that the digital x-ray machine at the PDC will be utilized at 94.7% capacity during the third project year.

The applicant projects body box and digital x-ray utilization based on the population of its proposed service area; in particular, the projected growth of the population cohort projected to use the pulmonary and cardiovascular 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, PDC adequately demonstrates the need to acquire one additional body box and one digital x-ray machine and to establish 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 proposed 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

The applicant does not operate a diagnostic center at either physician practice (THA or AAAC). Thus, the relocation of those physician offices is not the relocation of a health service facility. Moreover, the relocation will take place regardless of the outcome of this review. In other words, it is not part of the project that is subject to review, which is the acquisition of a body box and an x-ray unit that results in the development of a diagnostic center at the new location.

(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

The applicant proposes to lease and upfit approximately 5,432 square feet of existing space in this proposal to acquire additional medical diagnostic equipment and develop a diagnostic center. The applicant states in Section III.3, pages 62 – 63, that it considered several alternatives before proposing this project, which include maintaining the status quo, locating the facility in another location, and pursuing a joint venture with another provider. 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) and (20) 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 an additional body box and a digital x-ray unit. Consequently, the application is conforming to this criterion and is approved subject to the following conditions:

1. **Private Diagnostic Clinic, PLLC d/b/a Duke Medicine Specialty Care Croasdaile Commons shall materially comply with all representations made in the certificate of need application.**

2. **Private Diagnostic Clinic, PLLC d/b/a Duke Medicine Specialty Care Croasdaile Commons 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. **Private Diagnostic Clinic, PLLC d/b/a Duke Medicine Specialty Care Croasdaile Commons 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 102 - 106, the applicant projects the total capital cost for the building upfit and additional diagnostic equipment will be $818,263; which includes $543,000 for facility upfit, $240,263 for the proposed equipment, and $35,000 in consultant fees. In Section VIII.1, pages 102 – 103, the applicant states that an unrelated company, Glenwood Hillandale Company, LLC, owns the building and will incur the facility upfit costs. PDC will lease the space and the lease payments include reimbursing the lessor for the upfit costs. In addition, the proposed medical diagnostic equipment will be funded with a capital lease from First Citizens Bank. In Exhibit 16 the applicant provides a February 8, 2012 letter from the Chief Financial Officer of PDC, which states in part:

> *"PDC is planning to fund the facility up fit (including square footage directly related to the diagnostic center), through a lease with Glenwood Hillandale Company, LLC. All of this cost is covered in the lease with the lessor. The lease will be paid through patient revenues and recorded as an operating expense.*
>
> *PDC is planning to fund the medical diagnostic equipment acquisition through an operating lease with First Citizens Bank. The operating lease will be paid through patient revenues and recorded as an operating expense.*
>
> *PDC will fund the $35,000 associated with the consultant and application fees through the PDC global patient revenue, as identified on the PDC audited financial statements…. As shown on the audited financial statements, PDC has sufficient financial resources to fund the project costs. … Please accept this letter as confirmation of PDC's intention to use the funds for the proposed CON."*

In Exhibit 16, the applicant provides a copy of a lease commitment dated February 8, 2012 from First Citizens Bank which confirms a lease line of credit has been approved for PDC in the amount of $240,263 for the proposed diagnostic equipment.

In Section IX, page 111, the applicant states there are no start-up or initial operating expenses associated with this project.

Exhibit 17 contains the audited financial statements for PDC, which show that as of December 31, 2010, PDC had total revenue in the amount of $494,346,709, total expenses in the amount of $274,214,642 and net revenue in the amount of $220,132,067. 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

PDC proposes to acquire one new body box and one new digital x-ray unit, which results in the development of a new diagnostic center. In addition, the applicant proposes to relocate two existing physician practices, THA and AAAC, and consolidate them into one practice, As a result, PDC will have one location where it will offer both pulmonary and cardiac diagnostic and interventional services. The patients to be served will be the same as the patients currently served in the separate locations. No new services will be offered. PDC already has 2 body boxes and adequately demonstrates the need for a third body box. PDC's patients are currently referred to other facilities for x-rays. PDC adequately demonstrates it is more cost effective to have the x-ray unit on site 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 acquire the proposed third body box and x-ray unit, 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 body boxes and x-ray units 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 VII.3, page 96, the applicant states:

"…PDC intends to hire minimal additional clinical staff in job positions already existing; PDC already offers medical diagnostic services and employs sufficient administrative and support staff for the service. PDC will relocate the existing medical diagnostic equipment and all associated staff to Croasdaile Commons when the facility becomes operational."

In Section VII.1, pages 94 – 95, the applicant projects staffing for the second project year, CY 2014, for THA and AAAC, as shown in the following table prepared by the project analyst:

THA and AAAC Projected Staffing
CY 2014

POSITION	# OF FTES
Triangle Heart Associates	
Nurse Manager	0.03
Supervisor, Clinical Services	0.17
Clinical Operations Supervisor	0.17
Nurse Practitioner	0.35
Nuclear Medicine Technologist	0.12
Clinical Technician I	0.11
Cardiology Technician II	1.29
Echocardiography Technologist I	2.47
Echocardiography Technologist II	6.73
Ambulatory Care Nurse II	0.72
Total THA	**12.16**
Allergy, Asthma, & Airway Center	
Nurse Manager	0.09
Radiology Technician	1.50
Respiratory Care Practitioner	1.58
Patient Care Technician	0.06
Total AAAC	**3.24**
Total Diagnostic Center	**15.40**

In Section VII.1, page 93, the applicant states the staff necessary for the project are currently in place and will relocate to the diagnostic center when the services are relocated. Furthermore, the only additional staffing required for the project is the addition of 1.5 full-time equivalent (FTE) radiology technician positions for AAAC.

In Section V.3, page 75 and Section VII.7, page 99, the applicant states Dr. David Zaas currently serves as Chief Medical Officer for PDC, and will continue to do so following project completion. In Exhibit 14, the applicant provides a January 20, 2012 letter signed by Dr. Zaas affirming his commitment to serve in that capacity. In addition, in Section VII.3, page 96, the applicant states PDC will continue to lease employees from Duke University 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 18 - 19, the applicant identifies the necessary ancillary and support services currently provided by PDC. In Section II.1(c), page 19, the applicant states those services will continue to be made available following completion of the project. In Exhibit 5, the applicant provides copies of existing transfer agreements with Duke University Medical Center and states those agreements will continue following project completion. The applicant provides letters of support for the proposal from area physicians in Exhibit 15. 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, page 81, the applicant states that, during 2011, combined Medicare and Medicaid patients represented 55.7 percent of all patients at THA. Furthermore, during 2011, combined Medicare and Medicaid patients represented 39.8 percent of all patients at the AAAC.

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 May 2, 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)
Durham	16.0%	5.7%	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 pulmonary and cardiac diagnostic and interventional services offered by PDC.

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 82, the applicant states low income and any other medically underserved group will continue to have access to all services at PDC following project completion. In Section VI.10, page 88, the applicant states that PDC has not had any civil rights equal access complaints or violations filed against either THA or AAAC in the last five years. In Section VI.11, page 89, 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 90 - 91, the applicant projects the following payor mix during CY 2014 for the entire facility and for each component:

Total Facility CY 2014

Source of Payment	Percent
Self Pay/Indigent/Charity	2.1%
Medicare	44.8%
Medicaid	3.5%
Managed Care/Commercial	19.7%
Blue Cross Blue Shield	28.9%
Other*	1.0%
Total	**100.0%**

*The applicant defines “other” as contract programs such as VA, Worker’s Comp, and Victim’s Assistance.

AAAC CY 2014

Source of Payment	Percent
Self Pay/Indigent/Charity	2.3%
Medicare	33.6%
Medicaid	6.2%
Managed Care/Commercial	24.0%
Blue Cross Blue Shield	32.0%
Other	1.9%
Total	**100.0%**

*The applicant defines “other” as contract programs such as VA, Worker’s Comp, and Victim’s Assistance.

THA CY 2014

Source of Payment	Percent
Self Pay/Indigent/Charity	1.9%
Medicare	54.5%
Medicaid	1.2%
Managed Care/Commercial	16.0%
Blue Cross Blue Shield	26.2%
Other	0.2%
Total	**100.0%**

*The applicant defines "other" as contract programs such as VA, Worker's Comp, and Victim's Assistance.

In Section VI.6, page 85, the applicant states *"All services offered by PDC 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."* The applicant also describes its charity care policies for homeless and otherwise indigent patients on page 85, 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 87 of the application, the applicant states that all patients will have access to the diagnostic services through referrals by PDC physicians or self referral. In Exhibit 15, the applicant provides a copy of PDC's transfer policy with Duke University Medical Center. 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 74, the applicant states

> *"PDC functions as the faculty practice plan for Duke University, and PDC physicians hold academic appointments at the Duke University School of Medicine; as a result, all PDC practice sites and services provide opportunities for training medical students and residents.*
>
> *PDC is currently available and will continue to be available to students in any training program, as needed."*

In Exhibit 8, the applicant provides copies of correspondence committing to offer the facility as a clinical training site for Duke University Medical School students. 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 77 - 80, in which PDC discusses how the project will foster competition by promoting cost-effectiveness, quality and access to pulmonary 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 pulmonary and cardiac diagnostic services in Durham County. This determination is based on the information in the application, and the following:

- The applicant adequately demonstrates the need to acquire the third body box and a digital x-ray unit 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 28, the applicant identifies the existing medical diagnostic equipment at both THA and AAAC. On page 29, the applicant identifies the proposed medical diagnostic equipment to be located at the diagnostic center. In addition, the applicant provides the number, type, cost, condition, useful life, and depreciation schedule for each piece of equipment on page 28.

(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 29, the applicant states the only piece of medical equipment not listed in subparagraph (b) (1) of this rule which is necessary to perform the proposed procedures and services is a treadmill.

(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 IV.2, pages 29 - 30, the applicant provides the assumptions it used to project capacity for the proposed diagnostic equipment, and the projections, as shown below.

EQUIPMENT	DAYS / WEEK	HOURS / WEEK	MACHINE DOWN TIME	PROCEDURES / HOUR	TOTAL CAPACITY
Body Box	5	40	5%	1.0	1,900
Digital X-ray	5	40	5%	2.4	4,560

In Section VI.2, page 30, the applicant states the projections for the digital x-ray are based on approximately 25 minutes per case; and the projections for the body box are based on approximately one hour per case, with the facility operating 8 hours per day, five days per week, 50 weeks per year.

(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 31, 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 32, 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 64, the applicant provides the patient origin by county for services provided by THA and AAAC during FY 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 66 - 67, 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 THA and AAAC.

(9) a three year capital budget.

-NA-In section II, page 33, the applicant states PDC acquires its medical equipment through capital leases, which is paid for with operating revenues.

(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 10, 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 35, 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, pages 36 and 37, 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 body box and the digital x-ray machine.

(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, page 35, 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 38, the applicant states there is no publicly available data which identifies the number and utilization of body box machines or digital x-ray machines in the applicant's service area. On page 39, and in Section IV, the applicant states that the existing body box at AAAC performed above 80% of the maximum number of cases the equipment is capable of performing in the 12-month period preceding submittal of this application.

(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 40, the applicant projects that utilization for the existing and proposed body box equipment will be 84.2% of capacity in the third operating year. Furthermore, the applicant projects that utilization for the digital x-ray machine will be 94.7% of capacity in the third operating year.

(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 40, the applicant states the projected utilization is based upon the most recent utilization data for PDC, physician standards, and service area demographic information.

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

-C- In Section III.1, pages 43 - 60, 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 41, the applicant states that the nearest hospital emergency room is at Duke University Hospital, located less than two miles from the proposed facility.

(2) support services;

-C- In Section II, page 41, the applicant states that staff from PDC has and will continue to provide administrative support services and physician services.

(3) ancillary services; and

-C- In Section II, page 41, the applicant states the necessary ancillary and support services are currently in place in PDC. In addition, the applicant states laboratory and other diagnostic services are and will be available from Duke University Health System *"or other qualified providers."*

(4) public transportation.

-C- In Section II, page 41, the applicant states the facility is located on a Durham Area Transportation Authority (DATA) bus route.

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 42, and in Section VII.1, pages 94 - 95, 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 42, the applicant states all of the physicians associated with AAAC are licensed to practice in North Carolina and have the credentials required by this rule.

(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 7, the applicant provides PDC's policy regarding continuing education.