

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 29, 2015

Findings Date: October 29, 2015

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Assistant Chief: Martha J. Frisone

Project ID #: J-11059-15

Facility: Duke Sports Science Institute

FID #: 150393

County: Durham

Applicant: Private Diagnostic Clinic, PLLC

Project: Develop a diagnostic center by acquiring two digital radiography machines

### 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), also referred to throughout these Findings as “the applicant”, proposes to acquire two existing digital radiography systems and operate them at Duke Sports Science Institute (DSSI). The value of the digital x-ray equipment (\$558,500) exceeds the statutory threshold for a diagnostic center of \$500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

### **Need Determination**

There are no need determinations in the 2015 State Medical Facilities Plan (2015 SMFP) which are applicable to the acquisition of the type of equipment proposed in this application or to the establishment of a diagnostic center.

## **Policies**

There are no policies in the 2015 SMFP which are applicable to this review.

## **Conclusion**

In summary, the applicant does not propose to develop any beds, operating rooms, or other services or acquire equipment for which there is a need determination in the 2015 SMFP. There are no policies in the 2015 SMFP that are applicable to this review. Therefore, this criterion is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

## C

The applicant proposes to acquire two existing digital radiography systems currently owned and operated by Duke University Health System (DUHS) at DSSI on the Duke Center for Living Campus in Durham. The value of the digital x-ray equipment (\$558,500) exceeds the statutory threshold for a diagnostic center of \$500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

DSSI, formerly Duke Sports Medicine and located at the Finch Yeager building, is an integrated, multi-specialty sports medicine practice owned and operated by the applicant. Sports medicine services offered at DSSI include:

- Clinical and surgical treatments
- Injury prevention and sports performance
- Pediatric sports medicine
- Sports psychology
- Women's sports medicine
- Michael W. Krzyzewski Human Performance Laboratory (K-Lab)

In Section I.12(e), page 11, the applicant states there are currently two digital x-ray machines, owned and operated by DUHS at DSSI. The applicant further states:

*“At the new location, it is more efficient and cost-effective for the PDC to provide onsite access to the same services by purchasing the equipment and providing the services directly.”*

*The value of the digital x-ray equipment costs exceeds the statutory threshold of \$500,000, and thus requires a certificate of need for a diagnostic center. Therefore, PDC submits this CON application seeking approval to acquire the two existing digital x-ray machines from DUHS, each of which will remain located in its current space on the Duke Center for Living Campus on Erwin Road in Durham.”*

### **Population to be Served**

The 2015 SMFP does not provide a need methodology for the establishment of diagnostic centers in North Carolina. Nor does the SMFP specify a service area relative to diagnostic centers. 10A NCAC 14C .1802 (3) defines the service area for diagnostic centers as “*the geographic area, as defined by the applicant, for which the proposed diagnostic center will provide services.*”

In Section III.1, page 38, the applicant states that the primary service area for the DSSI diagnostic center is Durham County and the secondary service area is Wake and Orange counties. The applicant further states that the rationale for the proposed service area is based on the historical patient origin for patients at DSSI. In Section III.4(b), page 45, the applicant provides the current patient origin by percentage by county of residence for its existing x-ray services, as follows.

#### **DSSI X-ray Services Patient Origin FY2015**

<b>COUNTY</b>	<b>PERCENT OF TOTAL</b>
Durham	40.3%
Wake	14.4%
Orange	11.2%
Alamance	4.1%
Person	2.4%
Granville	1.9%
Cumberland	1.2%
Halifax	1.1%
Other*	23.4%
Total	100.0%

\*Other includes <1% patient origin from any one of the remaining counties in North Carolina and other states (including but not limited to South Carolina, Georgia, Virginia, Tennessee, and West Virginia).

In Section III.5(b), page 46, the applicant provides a map illustrating the proposed service area. In Section III.5(c), page 47, the applicant provides the projected patient origin by percentage by county of residence for the first two years of operation following completion of the project, as follows.

**Projected DSSI X-ray Services  
CY2016 and CY2017**

COUNTY	PERCENT OF TOTAL
Durham	40.3%
Wake	14.4%
Orange	11.2%
Alamance	4.1%
Person	2.4%
Granville	1.9%
Cumberland	1.2%
Halifax	1.1%
Other*	23.4%
Total	100.0%

\*Other includes <1% patient origin from any one of the remaining counties in North Carolina and other states (including but not limited to South Carolina, Georgia, Virginia, Tennessee, and West Virginia).

The table above illustrates the projected patient origin is consistent with the historical patient origin at DSSI. The applicant states, “*PDC does not anticipate a significant change in patient origin as a result of the proposed project.*”

The applicant adequately identified the population to be served.

**Analysis of Need**

The applicant proposes to acquire and operate two existing digital radiography systems owned by DUHS, which will result in DSSI becoming a diagnostic center as defined by G.S. 131E-176(7a).

In Section III.1, beginning on page 36, the applicant states:

*“PDC demonstrates the need for the proposed project based on numerous qualitative and quantitative factors, including:*

- The existing diagnostic equipment is integral to DSSI’s continuum of orthopaedic and sports medicine services.*
- The proposed project will enable PDC to provide cost effective services to meet patient expectations and to ensure quality care.*
- The projected growth of the service area population presumes continued increases in demand for healthcare.*
- The methodologies and assumptions for projecting future utilization are reasonable and conservative, and will meet or exceed the Diagnostic Center performance standards.”*

The applicant states that the digital x-ray machines currently operated by DUHS at DSSI and the subject of this review support DSSI’s clinical practice: a practice described by the

applicant as providing “*world-class orthopaedic services to care for the overall health of athletes of all ages and levels*”. The applicant further states (page 37) that the existing diagnostic equipment is integral to DSSI’s continuum of orthopaedic and sports medicine services, which according to the applicant, includes an extraordinary collection of orthopaedic surgeons and physical therapists and offers the highest quality services for women’s sports medicine, pediatric sports medicine, sports psychology, primary care/non-orthopaedic related medical care and rheumatology care. Therefore, states the applicant, “*it is essential that PDC receive approval for this project to ensure that local residents continue to have access to quality diagnostic services.*”

On page 37, the applicant states that it is more efficient and cost-effective for it to purchase the DUHS’s equipment and provide the services directly. The applicant states it is more operationally efficient and convenient from the patient’s perspective for PDC to operate the equipment directly as part of its own outpatient clinic.

The applicant provides data from the North Carolina Office of State Budget & Management (NCOSBM) on page 38, demonstrating the projected growth in the primary and secondary service area counties of Durham, Wake and Orange as shown in the following table.

**Duke Sports Science Institute  
Proposed Service Area  
Projected Population**

<b>County</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>5-Yr CAGR</b>
Durham	297,811	303,422	309,030	314,629	1.1%
Wake	1,005,385	1,025,465	1,045,542	1,065,621	1.2%
Orange	141,596	143,260	144,924	146,588	0.7%
<b>Total Service Area</b>	<b>1,444,792</b>	<b>1,472,147</b>	<b>1,499,496</b>	<b>1,526,838</b>	<b>1.1%</b>

Source: NCOSBM

In the table above, the applicant calculates a 5-year compound annual growth rate (CAGR) for the service area of 1.1%. The analyst is unsure of how the applicant calculated a 5-year CAGR based on the information provided in the application and shown above. A 5-year CAGR cannot be calculated from the data above and the applicant provides no other information relative to the projection. In clarifying data requested by the Project Analyst in the expedited review of this project, the applicant provides corrected information, providing a 3-year CAGR of 1.9% for the service area. The data shows the service area is projected to increase by more than 82,000 residents from 2015 to 2018.

On page 39, the applicant discusses “sports medicine” and says it is not just for competitive athletes, but is best defined as a medical specialty that serves all individuals with musculoskeletal injury or pain who seek to be more active than their medical condition allows. The applicant further states:

*“This large and growing population supports the need for PDC to acquire the existing digital x-ray equipment from DUHS for continued patient access and convenience. Furthermore, the existing digital x-ray equipment is needed to ensure the continuation of PDC’s state-of-the-art sports medicine program.”*

On page 40, the applicant states that the need for the proposed project is primarily qualitative: acquiring the equipment will facilitate lower out-of-pocket costs for patients and ownership of the existing machines will streamline the DSSI operations as a physician outpatient clinic.

Projected Utilization

The applicant states that its methodology for projecting utilization is based on calendar year projections using the projected population growth rate, as discussed above.

In Section III.1, page 40, the applicant provides historical utilization of patients and x-ray procedures performed at DSSI on the two existing digital x-ray machines currently owned by DUHS and the subject of this review, as follows:

<b>X-ray Services</b>	<b>FY2013</b>	<b>FY2014</b>	<b>FY2015</b>
X-ray Procedures	6,702	6,634	7,010
X-ray Patients	4,603	4,662	4,870

In Section III.1, page 40, the applicant provides the number of projected x-ray procedures and patients at DSSI for fiscal years (July 1 through June 30) 2016 - 2019, as follows:

<b>X-ray Services</b>	<b>FY2016</b>	<b>FY2017</b>	<b>FY2018</b>	<b>FY2019</b>
X-ray Procedures	7,088	7,167	7,246	7,327
X-ray Patients	4,924	4,979	5,034	5,090

The applicant expects the project to be complete and operational by January 2016; therefore the first full year of operation will be CY2016. The following table converts PDC’s fiscal year projections to calendar year projections.

<b>X-ray Services</b>	<b>CY2016</b>	<b>CY2017</b>	<b>CY2018</b>
X-ray Procedures	7,127	7,206	7,286
X-ray Patients	4,951	5,006	5,062

The applicant uses the following assumptions in the above methodology for projecting utilization:

- The x-ray procedures and patients will increase annually at the rate of 1.1%, the applicant's calculated 5-year CAGR for the service area population.
- The conversion of fiscal year to calendar year assumes a constant monthly utilization such that the fiscal year utilization is divided by 12, with the final six months of FY2016 (January 1 – June 30, 2016) being added to the first six months of FY2017 (July 1 – December 31, 2016) to arrive at the utilization for CY2016 (January 1 – December 31, 2016).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. Thus the applicant adequately demonstrates the need for the development of a diagnostic center by acquiring the two existing digital radiography machines.

### Access

In Section VI, pages 60-61, the applicant states that PDC is fully committed to the health and well-being of all patients, historically offering services to medically underserved populations, including the elderly and low-income persons. The applicant further states:

*“... PDC does not discriminate based on income, race, ethnicity, creed, color, age, religion, national origin, gender, physical or mental handicap, sexual orientation, ability to pay or any other factor that would classify a patient as underserved. PDC 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. Diagnostic services at PDC's DSSI diagnostic center will be available to and accessible by any patient having a clinical need for those services.*

...

*Specifically, with approval of this DSSI diagnostic center CON application, PDC will perform outpatient diagnostic imaging procedures for the registered uninsured and underserved population of Durham County.”*

The applicant further addresses access to its services in Section VI.14-15, pages 70-71 and provides the following payor mix for the second full fiscal year of the proposed project.

**Duke Sports Science Institute  
Entire Facility  
CY 2017**

<b>Payor Category</b>	<b>Percent of Total Utilization</b>
Self Pay/ Indigent/ Charity	1.1%
Medicare	24.1%
Medicaid	3.9%
Managed Care/Commercial/SEHP	37.7%
Blue Cross Blue Shield	29.4%
Other (includes Worker's Comp)	3.7%
<b>Total</b>	<b>100.0%</b>

Totals may not sum due to rounding.

**Duke Sports Science Institute  
PDC Diagnostic Center  
CY 2017**

<b>Payor Category</b>	<b>Percent of Total Utilization</b>
Self Pay/ Indigent/ Charity	1.7%
Medicare	18.5%
Medicaid	4.7%
Managed Care/Commercial/SEHP	36.3%
Blue Cross Blue Shield	35.2%
Other (includes Worker's Comp)	3.5%
<b>Total</b>	<b>100.0%</b>

Totals may not sum due to rounding.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

**Conclusion**

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project and adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, 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 43-44, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – the applicant states that this alternative is not cost efficient or the most effective alternative at this time because operating the two digital x-ray machines under PDC ownership streamlines the current DSSI operations as a physician outpatient clinic. PDC can provide onsite access to the same services and provide the services directly, eliminating hospital outpatient department services for the patient.
- 2) Utilize Radiologic Services in Another PDC Location- the applicant states that it would be burdensome to require sports medicine patients to travel to another clinic location to receive routine radiographic services; therefore, this alternative is not the most effective.

The applicant states that radiology is central to the diagnosis, treatment and recovery from sports related injuries. In Section III.1, page 41, the applicant states:

*“Each year, DSSI encounters over 21, 000 clinic visits; therefore, the two digital X-ray machines are essential to support ongoing clinical services.”*

In Section II.5, page 15, the applicant states, *“The existing diagnostic equipment is integral to DSSI’s continuum of orthopaedic and sports medicine services.”* For these reasons, the applicant states that acquiring the existing two digital x-ray machines already located at DSSI is the least costly and most effective alternative.

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

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Private Diagnostic Clinic, PLLC shall materially comply with the representations made in the certificate of need application.**

2. **Private Diagnostic Clinic, PLLC shall acquire no more than two digital diagnostic radiography systems.**
  3. **Private Diagnostic Clinic, PLLC 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 and that would otherwise require a certificate of need.**
  4. **Private Diagnostic Clinic, PLLC 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

PDC proposes to acquire two digital radiography systems and operate them at DSSI. The value of the digital x-ray equipment (\$558,500) exceeds the statutory threshold for a diagnostic center of \$500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

**Capital and Working Capital Costs**

In Section VIII.1, page 80, the applicant projects that the total capital cost of the project will be \$638,388, consisting of \$600,388 equipment purchase/lease of the two radiography systems and \$38,000 consultant fees. The project requires no construction or renovation.

Exhibit 2 contains a letter from PDC's Chief Financial Officer documenting PDC's intention to acquire the DUHC radiography systems currently located in the DSSI building on the Duke Center for Living Campus in Durham. The letter also documents a lease agreement allowing PDC to lease the equipment space (1,033 square feet) from DUHS. Exhibit 5 contains a letter from DUHS Chief Financial Officer and Treasurer documenting its intentions to make the radiography systems available for acquisition by PDC at fair market value, pursuant to PDC's operating lease with First Citizens Bank. The proposed operating lease with First Citizens Bank is provided in Exhibit 13.

In Section IX.1, page 87, the applicant states no start-up or initial operating expenses are required for the proposed project.

**Availability of Funds**

Exhibit 13 contains a letter dated July 27, 2015 from the Chief Financial Officer of PDC which states:

*“The project does not involve any facility construction or up fit. PDC will lease the spaces from Duke University Health System, with the lease 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 \$40,000 associated with the consultant and application fees through its cash reserves. The Statement of Revenue Collected and Expenses from our most recent audited financial statements shows that PDC has these funds currently available. Please accept this letter as confirmation of PDC’s intention to use the funds for the proposed CON project.”*

Exhibit 13 contains PDC’s financial statements for the years ending December 31, 2013 and 2012. As of December 31, 2013, PDC had revenues collected above expenses incurred of \$265,541,462.

**Financial Feasibility**

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

<b>Digital Radiography</b>	<b>Project Year 1 CY2016</b>	<b>Project Year 2 CY2017</b>	<b>Project Year 3 CY2018</b>
Projected Procedures	7,127	7,206	7,286
Projected Average Charge (Gross Patient Revenue / Projected Proc)	\$ 160	\$ 164	\$ 168
Gross Patient Revenue	\$ 1,141,105	\$ 1,182,625	\$ 1,225,656
Deductions from Gross Patient Revenue	\$ 582,331	\$ 603,519	\$ 625,479
Net Patient Revenue	\$ 558,774	\$ 579,106	\$ 600,177
Total Expenses	\$ 472,060	\$ 480,391	\$ 488,986
Net Income	\$ 86,715	\$ 98,715	\$ 111,191

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See applicant’s Tab 13 for the assumptions regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges, and 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

The applicant proposes to acquire two existing digital radiography systems currently owned and operated by DUHS at DSSI. The value of the digital x-ray equipment exceeds the statutory threshold for a diagnostic center of \$500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

The 2015 SMFP does not provide a need methodology for the establishment of diagnostic centers in North Carolina. Nor does the SMFP specify a service area relative to diagnostic centers. 10A NCAC 14C .1802 (3) defines the service area for diagnostic centers as *“the geographic area, as defined by the applicant, for which the proposed diagnostic center will provide services.”*

In Section III.1, page 38, the applicant states that the primary service area for the DSSI diagnostic center is Durham County and the secondary service area is Wake and Orange counties. PDC’s acquisition of the existing equipment does not increase the inventory of radiography equipment in the service area. The equipment is already in use by the applicant but is currently owned by the hospital.

In Section I.12, pages 7-8, the applicant discusses the other health care facilities that it owns and operates and PDC’s existing medical equipment which is similar to the x-ray equipment in this application. The following tables reflect the information provided by the applicant.

**Health Care Facilities Owned by PDC**

<b>Facility</b>	<b>Type</b>	<b>County</b>
Brier Creek Imaging	Dx Center	Wake
Duke Medicine Specialty Care Knightdale	Dx Center	Wake
Duke Medicine Specialty Care Croasdaile Commons	Dx Center	Durham
Duke GI at Brier Creek	GI Endo	Wake

**Similar Equipment Owned by PDC**

<b>PDC Medical Offices</b>	<b>Type</b>	<b>Quantity</b>	<b>County</b>
Duke Medical Center Page Road	Digital x-ray	4	Durham
Duke Executive Health	Digital x-ray	1	Durham
North Carolina Orthopaedic Center	Digital x-ray	3	Durham

In Section II.8, pages 23-24 and Section III.6, pages 48-49, the applicant discusses providers of x-ray equipment in the identified service area. Exhibit 6 contains a printout from the North Carolina Radiation Protection Section listing x-ray equipment located in the applicant’s proposed service area of Durham, Orange and Wake counties. The applicant states, *“To PDC’s knowledge, annual utilization data for x-ray equipment located in diagnostic centers is not collected by any state agency or regulatory body.”* The applicant further states, *“The following information is available for hospital-based providers and diagnostic centers.”*

Health Service Facility	Type	County	Fixed x-ray^	FY2015 Procedures
Duke University Hospital <sup>1</sup>	Hospital	Durham	49	128,762
Duke Regional Hospital <sup>2</sup>	Hospital	Durham	4	48,979
NC Specialty Hospital	Hospital	Durham	1	111
Triangle Orthopaedic Associates	Dx Center	Durham	5	*
Durham Diagnostic Imaging	Dx Center	Durham	2	*
Duke Medical Plaza Page Road	Dx Center	Durham	4	32,903
UNC Hospitals	Hospital	Orange	37	171,131
Wake Radiology Chapel Hill	Dx Center	Orange	1	*
WakeMed Hospital (all sites)	Hospital	Wake	14	138,810
WakeMed Cary Hospital	Hospital	Wake	4	36,536
Duke Raleigh Hospital	Hospital	Wake	3	40,333
Rex Hospital	Hospital	Wake	11	79,765
Raleigh Radiology Cedarhurst	Dx Center	Wake	2	*
Raleigh Radiology Blue Ridge	Dx Center	Wake	2	*
Wake Radiology	Dx Center	Wake	3	*
Wake Radiology-Raleigh	Dx Center	Wake	3	*
Wake Radiology-Garner	Dx Center	Wake	1	*
Raleigh Orthopaedic Clinic	Dx Center	Wake	4	*

Source: FY2015 x-ray utilization obtained from 2016 Hospital LRAs; NC Radiation Protection Section

^Excludes Fluoroscopy equipment

\*Data not publicly available

<sup>1</sup>Per Duke University Hospital's 2016 License Renewal Application (LRA), fixed x-ray equipment includes the following: bone, chest, GU, mammography, portable and OR.

<sup>2</sup>Per Duke Regional Hospital's 2016 LRA, the two fixed x-ray units and procedure volumes performed located at Lincoln Community Health Center are not included.

In clarifying information requested by the Project Analyst, the applicant confirms that the x-ray utilization data provided on pages 48-49 of the application and shown above is FY2014 data submitted on 2015 LRAs. The references citing 2016 LRAs and FY2015 procedures on pages 24, 48 and 49 are inadvertent typographical errors.

In Section V.7, pages 58-59, the applicant states that the digital x-ray equipment involved in this project already exists at DSSI, supports its diagnostic services and is integral to DSSI's continuum of orthopaedic and sports medicine services.

In Section III.6(b), page 50, the applicant states:

*"..., the identified need is internal to PDC, as it involves an existing specialty clinic and the medical diagnostic equipment necessary to support that clinic. No other provider can or should provide for the internal clinical diagnostic needs at PDC."*

The information provided by the applicant in the application is reasonable and adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the proposed service area. 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.1, pages 72-73, the applicant provides the projected staffing and average annual salary during Project Year 2 for the proposed diagnostic center at DSSI, as shown in the following table.

**Projected Staffing CY2017**

<b>EMPLOYEE CATEGORY</b>	<b>ANNUAL SALARY</b>	<b>Staff FTEs</b>
Health Care Administrator	\$94,557	0.23
Radiology Technologist	\$73,544	2.30
Patient Services Associate	\$31,519	0.23
Total Staffed FTEs		2.76

The applicant projects 2.3 full time equivalent (FTE) radiology technologist positions. In Section VII.1, page 72, the applicant states that the above staffing represents dedicated diagnostic center clinical staffing only, and does not include the overall medical clinic (non-diagnostic center) staffing at DSSI. The applicant also states that DUH will continue to supply the radiology technologists and patient services associate and will lease those employees to PDC. In Section VII.3(b), page 74, the applicant states:

*“PDC will lease any additional employees (as needed) from Duke University to staff the DSSI diagnostic center. Substantially all of the non-physician staff of the PDC is provided through an arrangement with Duke University under which the PDC leases the services of a substantial number of Duke University employees (on both a full-time and part-time basis, as appropriate). All of these individuals are compensated by Duke University, and are considered employees solely of Duke University. The PDC bears the salary and benefit expense of all time spent by such leased employees in the service of the PDC.”*

The applicant further states that Duke University is one of the largest employers in the Triangle area, offers competitive salaries and benefits; and PDC does not expect any difficulty in filling the positions required by the diagnostic center.

In Section VII.7, page 76, the applicant states that PDC will continue to have David Attarian, MD serve as Chief Medical Officer. Exhibit 11 includes a letter documenting Dr. Attarian’s intent to continue in his capacity at PDC and DSSI, along with his curriculum vitae. The

applicant further states there are approximately 28 physicians who will utilize the DSSI diagnostic center and that all current physicians at PDC have active privileges and are in good standing at Durham County hospitals.

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

Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section V.3, page 56, the applicant describes PDC as an established, physician-owned local healthcare provider with long-standing positive working relationships with the referring physician community in Durham and surrounding counties. The applicant also states PDC has an ongoing working relationship with Duke University Health System and Duke Primary Care and that its physicians will continue to have privileges at Duke University Hospital and Duke Regional Hospital. Exhibit 14 contains support letters from numerous area physicians.

The applicant adequately demonstrates the availability of necessary ancillary and support services, and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
  - (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;

- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

NA

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

C

In clarifying information requested by the Project Analyst during the expedited review of this project, the applicant provides DSSI's fiscal year 2015 payor mix as shown below.



<b>Duke Sports Science Institute Percent of Total Utilization FFY2015</b>		
	<b>Entire Facility</b>	<b>Service Component</b>
Self Pay/ Indigent/ Charity	1.1%	1.7%
Medicare	24.1%	18.5%
Medicaid	3.9%	4.7%
Managed Care/Commercial/SEHP	37.7%	36.3%
Blue Cross Blue Shield	29.4%	35.2%
Other (includes Worker's Comp)	3.7%	3.5%
<b>TOTAL</b>	<b>100.0%</b>	<b>100.0%</b>

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available. The following table illustrates those percentages for Durham, Orange, and Wake counties and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Durham County	15.6%	5.7%	20.1%
Orange County	8.6%	3.5%	18.9%
Wake County	9.8%	3.3%	18.4%
Statewide	16.5%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services proposed in this application.

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

The applicant demonstrates that medically underserved populations currently have adequate access to the services offered at DSSI. 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.11, page 67, the applicant states, "*PDC is not obligated under public regulations to provide uncompensated care, community service, or access by minorities and handicapped persons.*" The applicant further states that PDC does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay.

In Section VI.10, page 67, the applicant states that it is not aware of any documented civil rights equal access complaints or violations filed against PDC in the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section VI.6, page 64, the applicant states, "*PDC will continue to provide services without regard to race, color, religion, sex, age, national origin, handicap, or ability to pay.*" Exhibit 9 contains PDC's patient financial policies.

In Sections VI.14 (a) and (b) and VI.15 (a) and (b), pages 70-71, the applicant provides the projected payor mix for the entire DSSI facility and the diagnostic center services for CY2017, the second full operating year following completion of the project, as illustrated in the table below:

**DSSI Projected CY2017 Payor Mix  
Procedures as a Percent of Total Utilization**

	<b>Entire Facility</b>	<b>Service Component</b>
Self-Pay / Indigent / Charity	1.1%	1.7%
Medicare	24.1%	18.5%
Medicaid	3.9%	4.7%
Managed Care /Commercial /SEHP	37.7%	36.3%
Blue Cross Blue Shield	29.4%	35.2%
Other (includes Worker's Comp)	3.7%	3.5%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Totals may not sum due to rounding.

On page 70, the applicant states that its payor mix is based on the actual historical DSSI payor mix during 2014.

The applicant adequately demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.9, page 66, the applicant states that access to PDC's diagnostic services will continue to be by physician referral or self-referral (patients who present directly at PDC specialty clinics). Therefore, 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 55, the applicant states,

*"PDC recognizes the importance and value that local health training programs add to the medical community. As an existing provider of healthcare series, PDC has established affiliation agreements with Durham Technical Community College and Miller-Motte College. "*

Exhibit 10 contains copies of the professional training agreements. The applicant states that PDC functions as the faculty practice plan for Duke University, and PDC physicians hold

academic appointments at Duke University School of Medicine; therefore, all PDC practice sites and services provide opportunities for training medical students and residents. The information provided is reasonable and adequately supports a determination that 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

The applicant proposes to acquire two digital radiography systems currently owned and operated by DUHS at DSSI. The value of the digital x-ray equipment exceeds the statutory threshold for a diagnostic center of \$500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

The 2015 SMFP does not provide a need methodology for the establishment of diagnostic centers in North Carolina. Nor does the SMFP specify a service area relative to diagnostic centers. 10A NCAC 14C .1802 (3) defines the service area for diagnostic centers as *“the geographic area, as defined by the applicant, for which the proposed diagnostic center will provide services.”*

In Section III.1, page 38, the applicant states that the primary service area for the DSSI diagnostic center is Durham County and the secondary service area is Wake and Orange counties. PDC’s acquisition of the existing equipment does not increase the inventory of radiography equipment in the service area. The equipment is already in use by the applicant but is currently owned by the hospital.

In Section II.8, pages 23-24 and Section III.6, pages 48-49, the applicant discusses providers of x-ray equipment in the identified service area. Exhibit 6 contains a printout from the North Carolina Radiation Protection Section listing x-ray equipment located in the applicant’s proposed service area of Durham, Orange and Wake counties. The applicant states, *“To PDC’s knowledge, annual utilization data for x-ray equipment located in diagnostic centers is not collected by any state agency or regulatory body.”* The applicant further states, *“The following information is available for hospital-based providers and diagnostic centers.”*

Health Service Facility	Type	County	Fixed x-ray <sup>^</sup>	FY2015 Procedures
Duke University Hospital <sup>1</sup>	Hospital	Durham	49	128,762
Duke Regional Hospital <sup>2</sup>	Hospital	Durham	4	48,979
NC Specialty Hospital	Hospital	Durham	1	111
Triangle Orthopaedic Associates	Dx Center	Durham	5	*
Durham Diagnostic Imaging	Dx Center	Durham	2	*
Duke Medical Plaza Page Road	Dx Center	Durham	4	32,903
UNC Hospitals	Hospital	Orange	37	171,131
Wake Radiology Chapel Hill	Dx Center	Orange	1	*
WakeMed Hospital (all sites)	Hospital	Wake	14	138,810
WakeMed Cary Hospital	Hospital	Wake	4	36,536
Duke Raleigh Hospital	Hospital	Wake	3	40,333
Rex Hospital	Hospital	Wake	11	79,765
Raleigh Radiology Cedarhurst	Dx Center	Wake	2	*
Raleigh Radiology Blue Ridge	Dx Center	Wake	2	*
Wake Radiology	Dx Center	Wake	3	*
Wake Radiology-Raleigh	Dx Center	Wake	3	*
Wake Radiology-Garner	Dx Center	Wake	1	*
Raleigh Orthopaedic Clinic	Dx Center	Wake	4	*

Source: FY2015 x-ray utilization obtained from 2016 Hospital LRAs.

<sup>^</sup>Excludes Fluoroscopy equipment

\*Data not publicly available

<sup>1</sup>Per Duke University Hospital's 2016 License Renewal Application (LRA), fixed x-ray equipment includes the following: bone, chest, GU, mammography, portable and OR.

<sup>2</sup>Per Duke Regional Hospital's 2016 LRA, the two fixed x-ray units and procedure volumes performed located at Lincoln Community Health Center are not included.

In clarifying information requested by the Project Analyst, the applicant confirms that the x-ray utilization data provided on pages 48-49 of the application and shown above is FY2014 data submitted on 2015 LRAs. The references citing 2016 LRAs and FY2015 procedures on pages 24, 48 and 49 are inadvertent typographical errors.

In Section V.7, pages 58-59, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states that the digital x-ray equipment involved in this project already exists at DSSI, supports its diagnostic services and is integral to DSSI's continuum of orthopaedic and sports medicine services. The applicant further states:

*“At the new location, it is more efficient and cost effective for the PDC to provide onsite access to the same services by purchasing the equipment and providing the services directly. Additionally, operating the two digital X-ray machines under PDC ownership streamlines the current DSSI operations as a physician outpatient clinic.”*

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

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to acquire the proposed equipment and become a diagnostic center and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that DSSI has and will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant adequately demonstrates DSSI will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

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.

### C

In Section 1.12, page 7, the applicant states that it currently owns, leases, or manages three diagnostic centers (Brier Creek Imaging, Duke Medicine Specialty care Knightdale and Duke Medicine Specialty Care Croasdaile Commons) and a GI Endoscopy center (Duke GI at Brier Creek) in North Carolina. After reviewing and considering information provided by the applicant and considering the quality of care provided at all four facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (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 promulgated in 10A NCAC 14C .1800. The specific criteria are discussed below.

**SECTION .1800 CRITERIA AND STANDARDS FOR DIAGNOSTIC CENTERS**

**10A NCAC 14C .1803 INFORMATION REQUIRED OF APPLICANTS**

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

-C- The applicant used the correct application form.

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

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

-C- In Section II.8, page 21, the applicant identifies the medical diagnostic equipment to be acquired and which will be a part of the diagnostic center, as follows:

Type	# of Units	Cost*	Condition	Useful Life	Depreciation**
Digital x-ray	2	\$279,250	Excellent	5	Leased

\*Cost reflects FMV price for each of the radiography systems to be acquired from DUHS. Cost excludes sales tax.

\*\*Depreciation is not tracked on the leased equipment, nor is it allocable to PDC.

*(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 22, 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 II.8, page 22, the applicant provides the projections and the assumptions it used to project capacity for the proposed radiography services, as shown below.

EQUIPMENT	WEEKS PER YEAR	HOURS PER WEEK	MACHINE DOWNTIME	PROCEDURES / HOUR	TOTAL PROCEDURE CAPACITY
Digital x-ray	50	37.5	5%	2.4	4,275

Note: The applicant states that the above capacity is relevant only to the digital x-ray machines at DSSI and is based specifically on DSSI's hours of operation, clinical staffing levels, and patient turnover time. These variables are not identical for every provider, or for every location at which x-ray services are offered.

Assumptions:

1. Days of service: 250 days annually (50 weeks x 5 days per week) to allow for holidays.
2. Machine downtime is 5%.
3. Procedures per hour: based on DSSI experience, current patient turnover time is 25 minutes (2.4 procedures per hour).
4. Capacity: hours of operation per year x procedures per hour

(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.8, pages 23-24, the applicant states:

*“Health service facilities operating or approved to operate medical diagnostic equipment includes hospitals and diagnostic centers, based on the definition of “health service facility” in NCGS 131E-176(9b).*

...

*PDC is aware of the following existing and approved health service facilities that operate or have been approved to operate similar medical diagnostic equipment in the proposed service area:”*



Health Service Facility	Type	Fixed x-ray (excluding Fluoro)	County Location
Duke University Hospital <sup>1</sup>	Hospital	49	Durham
Duke Regional Hospital <sup>2</sup>	Hospital	4	Durham
NC Specialty Hospital	Hospital	1	Durham
Triangle Orthopaedic Associates	Dx Center	5	Durham
Durham Diagnostic Imaging	Dx Center	2	Durham
Duke Medical Plaza Page Road	Dx Center	4	Durham
UNC Hospitals	Hospital	37	Orange
Wake Radiology Chapel Hill	Dx Center	1	Orange
WakeMed Hospital (all sites)	Hospital	14	Wake
WakeMed Cary Hospital	Hospital	4	Wake
Duke Raleigh Hospital	Hospital	3	Wake
Rex Hospital	Hospital	11	Wake
Raleigh Radiology Cedarhurst	Dx Center	2	Wake
Raleigh Radiology Blue Ridge	Dx Center	2	Wake
Wake Radiology	Dx Center	3	Wake
Wake Radiology-Raleigh	Dx Center	3	Wake
Wake Radiology-Garner	Dx Center	1	Wake
Raleigh Orthopaedic Clinic	Dx Center	4	Wake

Source: FY2015 x-ray utilization obtained from 2016 Hospital LRAs; NC Radiation Protection Section

\*Data not publicly available

<sup>1</sup>Per Duke University Hospital's 2016 License Renewal Application (LRA), fixed x-ray equipment includes the following: bone, chest, GU, mammography, portable and OR

<sup>2</sup>Per Duke Regional Hospital's 2016 LRA, the two fixed x-ray units and procedure volumes performed located at Lincoln Community Health Center are not included

In clarifying information requested by the Project Analyst, the applicant confirms that the x-ray utilization data provided on pages 48-49 of the application and shown above is FY2014 data submitted on 2015 LRAs. The references citing 2016 LRAs and FY2015 procedures on pages 24, 48 and 49 are inadvertent typographical errors.

The applicant further states:

*“PDC has made every reasonable attempt to identify current health service facility providers of similar medical diagnostic equipment and diagnostic services in the identified service area.*

*Please refer to Exhibit 6 for a list provided to PDC by the North Carolina Radiation Protection Section of facilities in the PDC service area that operate X-ray machines. Neither the list nor the Medical Facilities Planning Section has a comprehensive list of existing or approved diagnostic centers. As such, this list is provided as a summary of the providers of radiography equipment in*

*the PDC service area, whether or not the facilities meet the definition of diagnostic center as defined in NCGS 131E-176(9b).”*

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

-C- In Section II.8, page 25, the applicant states the diagnostic services will be offered from 8:30 a.m. to 4:00 p.m. Monday-Friday (37.5 hours per week, 50 weeks per year, accounting for holidays).

(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 45, the applicant provides the patient origin by percentage by county for DSSI x-ray services provided during FY2015.

COUNTY	% OF TOTAL
Durham	40.3%
Wake	14.4%
Orange	11.2%
Alamance	4.1%
Person	2.4%
Granville	1.9%
Cumberland	1.2%
Halifax	1.1%
Other*	23.4%
Total	100.0%

\*Other includes <1% from any of the remaining counties in North Carolina and other states.

(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(c), page 47, the applicant provides projected patient origin by percentage by county of residence for the proposed x-ray services for CY2016 and CY2017, the first two operating years following completion of the proposed project, as follows.

COUNTY	% OF TOTAL
Durham	40.3%
Wake	14.4%
Orange	11.2%
Alamance	4.1%
Person	2.4%
Granville	1.9%
Cumberland	1.2%
Halifax	1.1%
Other*	23.4%
Total	100.0%

\*Other includes <1% from any of the remaining counties in North Carolina and other states.

The applicant assumes that the projected patient origin will be consistent with the historical patient origin at DSSI. A map is provided on page 46, illustrating the proposed primary and secondary service area.

- (8) *drawings or schematics of the proposed diagnostic center that identifies a distinct, identifiable area for each of the proposed services; and*
- C- Exhibit 12 contains line drawings of the PDC facility, which identifies distinct, identifiable areas for the x-ray equipment.
- (9) *a three year capital budget.*
- C- The applicant states (page 26) that the acquisition of the two digital x-ray systems represent the capital budget for PDC for the next three years.
- (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- Exhibit 4 contains documentation that the proposed equipment has 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 Exhibit 15, the applicant provides the projected number of x-ray procedures, classified by diagnosis (CPT code), for each of the first twelve calendar quarters following project completion. In clarifying information requested by the Project Analyst in the expedited review of this project, the applicant submits a revised Exhibit 15, which contains the projected number of patients to be served, classified by diagnosis for each of the initial twelve calendar quarters following completion of the project.

*(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 II.8, page 28, 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.

*(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 Exhibit 15, the applicant provides the projected number of x-ray procedures, classified 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.8, pages 23-24, the applicant provides a definition of “health service facility” and a list of the health service facilities in the proposed service area. (See 10A NCAC 14C .1803(b)(4) above.)

On page 30, the applicant states that Hospital LRAs include an inventory of x-ray machines in the hospital facility, but do not provide information relevant to hours of operation and availability of staff, which is necessary information to determine equipment capacity. The applicant further states that there is no publicly available data which identifies the number of existing x-ray machines in the service area that also identifies the number of procedures performed on the machine; therefore the applicant is unable to determine utilization or capacity of the machines.

In Section I.12(d), page 8, the applicant lists PDC’s existing medical equipment which is similar to the x-ray equipment in this application, as summarized below.

### Similar Equipment Owned by PDC

PDC Medical Office	Type	Quantity	County
Duke Medical Plaza Page Road	Digital x-ray	4	Durham
Duke Executive Health	Digital x-ray	1	Durham
North Carolina Orthopaedic Center	Digital x-ray	3	Durham

The applicant provides data relative to the similar equipment at health service facilities owned and operated by PDC on page 30. The applicant states that PDC’s Page Road diagnostic center (Duke Medical Plaza Page Road) operates above 80% based on its hours of operation, staffing and procedures performed. The applicant further states that the other digital x-ray equipment it operates at Executive Health and North Carolina Orthopaedic Center is not applicable to this rule because those clinics are not “health service facilities”. Though the applicant states that DSSI is not an existing health service facility, for informational purposes, the applicant provides data demonstrating DSSI operated the two existing x-ray machines that it is proposing to acquire at 82% of capacity in FY2015.

- (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.8, pages 30-33, the applicant provides data demonstrating that the proposed digital x-ray systems at DSSI will operate at 85.2% by the end of the third operating year. The applicant also provides data demonstrating that the x-ray equipment at other PDC clinics (Duke Medical Plaza Page Road, Executive Health and North Carolina Orthopaedic Center) will operate above 80% of capacity based on each clinics' hours of operation, patient turnover and staffing.

The applicant states that based on the absence of publicly available data for x-ray equipment, as discussed above, it is not possible to project the utilization and capacity of other similar equipment which is not owned/operated by PDC.

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

- C- In Section II.8, page 33, the applicant states:

*“All utilization projections are based on 1) the most recent utilization information available to PDC, 2) physician benchmarks, and 3) service area demographic data. Please refer to the assumptions and need methodology in Section III.1.”*

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

- C- In Section II.8, page 33, the applicant states:

*“Please refer to Section III.1 for the specific assumptions and methodology used to project x-ray procedures.”*

The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

#### **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.8, page 34, the applicant states that emergency services are available at Duke University Hospital one mile from DSSI.

(2) *support services;*

- C- In Section II.8, page 34, the applicant states that support services are provided and will continue to be provided onsite. The discussion regarding ancillary and support services found in Criterion (8) is incorporated herein by reference.

(3) *ancillary services; and*

- C- In Section II.8, page 34, the applicant states that ancillary services are provided onsite. Lab and other diagnostic services are available from Duke University Health System or other qualified providers. The discussion regarding ancillary and support services found in Criterion (8) is incorporated herein by reference.

(4) *public transportation.*

- C- In Section II.8, page 34, the applicant states that patients in Durham County have access to public transportation via Durham Area Transportation Authority (DATA), which includes a route along Erwin Road.

#### **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 VII.1, pages 72-73, the applicant provides the projected staffing for the proposed diagnostic center at DSSI, as shown in the following table.

**Projected Staffing CY2017**

<b>EMPLOYEE CATEGORY</b>	<b>Staff FTEs</b>
Health Care Administrator	0.23
Radiology Technologist	2.30
Patient Services Associate	0.23
Total Staffed FTEs	2.76

The applicant projects 2.3 full time equivalent (FTE) radiology technologist positions. In Section VII.1, page 72, the applicant states that the above staffing represents dedicated diagnostic center clinical staffing only, and does not include the overall medical clinic (non-diagnostic center) staffing at DSSI. In Section VII.7, the applicant states that PDC will continue to have David Attarian, MD serve as Chief Medical Officer. In Section II.8, page 34, the applicant states that nine orthopaedists and 19 radiologists will be the medical staff at DSSI.

- (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.8, page 35, the applicant states that all PDC physicians are licensed to practice medicine in North Carolina and will continue to provide physician oversight of the licensed radiologic technologists.
- (c) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall document that a program of continuing education shall be available for technologists and medical staff.*
- C- In Section II.8, page 35, the applicant states that all technologists at the proposed diagnostic center will be American Society of Radiologic Technologists (ASRT) certified, which requires them to maintain current RT and ARRT licenses, CPR and BCLS certification and 24 CME credit hours every two years. The applicant further states that PDC will continue to require staff to attend continuing education programs and annual in-services on HIPAA, Medicare Compliance and OSHA.