

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 25, 2021

Findings Date: May 25, 2021

Project Analyst: Mike McKillip

Acting Chief: Lisa Pittman

Project ID #: J-12018-21

Facility: Duke Health Specialty Care Page Road

FID #: 210088

County: Durham

Applicant: Private Diagnostic Clinic, PLLC

Project: Develop a new diagnostic center to include echocardiogram, electrocardiogram, electroencephalogram, pulmonary function test and x-ray

### REVIEW CRITERIA

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, hereinafter referred to as PDC or “the applicant”, proposes to develop a new diagnostic center to include echocardiogram, electrocardiogram, electroencephalogram, pulmonary function test and x-ray.

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP).
- Acquire any medical equipment for which there is a need determination in the 2021 SMFP.
- Offer a new institutional health service for which there are any applicable policies in the 2021 SMFP.

Therefore Criterion (1) 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- (2) Repealed effective July 1, 1987.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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, PDC, proposes to develop a new diagnostic center to include echocardiogram, electrocardiogram, electroencephalogram, pulmonary function test and x-ray. The applicant proposes to develop the new diagnostic center, Duke Health Specialty Care Page Road, by relocating several units of existing diagnostic equipment that are currently located in medical offices and acquiring one new unit of equipment. Specifically, the applicant proposes relocate two units of echocardiogram (echo) equipment, one unit of electrocardiogram (EKG) equipment, one unit of electroencephalogram (EEG) equipment, and one unit of pulmonary function testing (PFT) equipment from existing PDC clinics that will be relocated and consolidated into the new location of the proposed diagnostic center at 4709 Creekstone Drive in Durham. Also, the applicant proposes to purchase one new unit of x-ray equipment to be located at the proposed diagnostic center. In Section C.1, page 27, the applicant describes the project as follow:

*“The proposed project intends to relocate and consolidate existing PDC specialty clinics in leased medical office space at 4709 Creekstone Drive. The name of the proposed diagnostic center is Duke Health Specialty Care Page Road. Duke Health Specialty Care Page Road will be home to several PDC physician clinics providing a wide variety of services. Pediatric specialty services will include endocrinology, neurology, cardiology, infectious disease, pulmonology, rheumatology, gastroenterology, nephrology, mental health, and physical therapy. In particular, the following existing PDC specialty clinics will relocate to 4709 Creekstone Drive:*

- *Duke Children's Specialty Services of Brier Creek, 10211 Alm St, Suite 212, Raleigh, NC 27617*
- *Duke Children's Specialty Services at Brier Creek, 10207 Cerny Street, Suite 110 Raleigh, NC 27617*
- *Duke Children's Specialty Services of Raleigh, 23 Sunnybrook Rd #200, Raleigh, NC 27610*

*Also, PDC will develop an additional clinic for adult endocrinology services. As discussed further in Section C.4, the proposed diagnostic center will serve to optimize PDC's ability to provide patient-centered care in a cost-effective manner. The proposed project involves the combination of existing and proposed medical*

*diagnostic equipment valued at \$10,000 or more that, when aggregated, exceeds the \$500,000 threshold, thus triggering diagnostic center designation.”*

### Designation as a Diagnostic Center

N.C. Gen. Stat. 131E-176(7a) states:

*“Diagnostic center’ means a freestanding facility, program, or provider, including but not limited to, physicians’ offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.”*

In Section C, page 28, the applicant states the total cost of all the proposed medical diagnostic equipment which costs \$10,000 or more is \$677,421, which will exceed the statutory threshold of \$500,000. Therefore, Duke Health Specialty Care Page Road qualifies as a diagnostic center, which is a new institutional health service, and which requires a Certificate of Need (CON).

### Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2021 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C.3, pages 40-41, the applicant defines the service area for the proposed diagnostic center as Wake, Durham and Cumberland counties. Facilities may also serve residents not included in their service area.

The proposed diagnostic center has no historical patient origin. The following table shows the projected Duke Health Specialty Care Page Road patient origin for FY2024, the third year of operation, as provided in the table on page 34 of the application.

**Projected Patient Origin  
 Third Full Fiscal Year of Operation - CY2024**

County	Entire Facility (All Modalities)	
	Patients	% of Total
Wake	3,440	26.3%
Durham	1,566	11.9%
Cumberland	1,435	10.9%
Robeson	605	4.6%
Johnston	503	3.8%
Harnett	414	3.2%
Alamance	317	2.4%
Granville	270	2.1%
Vance	267	2.0%
Orange	251	1.9%
Sampson	233	1.8%
Franklin	230	1.8%
Person	223	1.7%
Guilford	215	1.6%
Hoke	207	1.6%
Nash	175	1.3%
Moore	173	1.3%
Wilson	165	1.3%
Onslow	160	1.2%
Wayne	152	1.2%
Other	2,105	16.1%
<b>Totals</b>	<b>13,103</b>	<b>100.0%</b>

Totals may not sum due to rounding  
 Source: Section C.3, page 34

In Section C.3, page 30, the applicant describes the assumptions and methodology used to project its patient origin, stating:

*“As described in Section C, Question 1, PDC intends to relocate and consolidate existing PDC specialty clinics in leased medical office space at 4709 Creekstone Drive. The project involves the following existing modalities: echocardiogram (echo), electrocardiogram (EKG), treadmill, electroencephalogram (EEG), and pulmonary function test (PFT). These existing modalities will support the clinics that will be relocated to the diagnostic center. The clinics have an established referral base and PDC does not anticipate a material change in patient origin patterns upon completion of the proposed project. Therefore, projected patient origin by county for the existing modalities is based on the CY2020 patient origin for each respective service. ... The proposed project involves acquisition of a new X-ray; thus, this modality does not have historical patient origin. The X-ray machine will support all the physician clinics located in the new diagnostic center. Thus, PDC reasonably expects patient origin for the X-ray machine will be representative of the CY2020 weighted average patient origin for all existing modalities.”*

The applicant's assumptions are reasonable and adequately supported because they are based on the applicant's historical (CY2020) patient origin experience for the each of the diagnostic modalities that will be included in the proposed diagnostic center.

### **Analysis of Need**

In Section C.4, pages 20-25, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below:

- The applicant states the existing and proposed diagnostic equipment is integral to PDC's continuum of specialty services and is necessary for the clinicians to properly diagnose patients.
- The applicant states the existing and proposed diagnostic equipment enables PDC to provide cost-effective services to meet patient expectations and ensure quality care.
- The projected growth of the service area population supports projected increases in demand for healthcare

The information is reasonable and adequately supported based on the following:

- The applicant documents the proposed medical diagnostic equipment is essential for cost effective delivery of quality care for Duke Health Specialty Care Page Road patients.
- The projected growth of the service area population is based on credible information from the North Carolina Office of State Budget and Management.
- The applicant provides supporting information to document the need for the proposed imaging services in Exhibit I.2.

### **Projected Utilization**

In Section Q, Form C Utilization, the applicant provides the projected utilization for the medical diagnostic equipment for the first three years of operation following completion of the project, as summarized in the following table.

**Duke Health Specialty Care Page Road Projected Utilization**

	<b>1<sup>st</sup> Full FY CY2022</b>	<b>2<sup>nd</sup> Full FY CY2023</b>	<b>3<sup>rd</sup> Full FY CY2024</b>
<b>Echocardiography</b>			
# Units	2	2	2
# Procedures	14,220	14,285	14,352
<b>EEG</b>			
# Units	1	1	1
# Procedures	1,370	1,377	1,383
<b>EKG</b>			
# Units	1	1	1
# Procedures	4,006	4,025	4,044
<b>Pulmonary Function Test</b>			
# Units	1	1	1
# Procedures	405	540	675
<b>X-ray</b>			
# Units	1	1	1
# Procedures	2,523	3,028	3,532

In Section Q, pages 96-103, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

**Echocardiography, EEG and EKG:** The applicant states the interim year (CY2021) utilization for echocardiography, EKG and EEG is based on the historical utilization of the equipment at the existing PDC clinics, which is projected to increase based on the weighted pediatric population growth rate for the identified service area (Wake, Durham and Cumberland counties) of 0.5%, as calculated and shown in the tables on page 97 of the application.

**Pulmonary Function Test:** The applicant states the utilization of the pulmonary function test equipment was projected based on data available from a proprietary model that benchmarks outpatient ancillary utilization per physician specialty for pulmonary medicine specialists, as shown in the tables on pages 98-99 of the application.

**X-ray:** The applicant states the utilization of the pulmonary function test equipment was projected based on data available from a proprietary model that benchmarks outpatient ancillary utilization per physician specialty for the specialist physicians projected to practice at the clinic, as shown in the tables on pages 100-101 of the application.

Projected utilization is reasonable and adequately supported based on the following:

- Projected utilization is based on historical experience of PDC for the medical diagnostic equipment at its existing clinic sites of service in the proposed service area, and on proprietary models for utilization of the proposed medical diagnostic equipment by physician specialty.

- Exhibit I.2 contains copies of letters from physicians expressing support for the proposed project and their intention to refer patients.
- Projected population increases in the service area support increases in the utilization of diagnostic imaging services.

### **Access to Medically Underserved Groups**

In Section, C.6, page 47, the applicant states,

*“PDC is fully committed to the health and well-being of all patients. PDC has historically provided care and services to medically underserved populations. As a certified provider under Title XVIII (Medicare), PDC offers its services to the elderly. Also, PDC provides services to low-income persons as a certified provider under Title XIX (Medicaid). Further, 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. Please see Exhibit L.4. 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 the proposed diagnostic center will be available to and accessible by any patient having a clinical need for those services.”*

On page 48, the applicant provides the estimated percentage for the following medically underserved groups at the proposed diagnostic center, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Estimated Percentage of Total Services in Year 3</b>
Low income persons	32.0%
Racial and ethnic minorities	49.0%
Women	51.0%
Persons with disabilities	Not available
Persons 65 and over	0.3%
Medicare	0.3%
Medicaid	32.0%

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services.

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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, PDC, proposes to develop a new diagnostic center to include echocardiogram, electrocardiogram, electroencephalogram, pulmonary function test and x-ray.

In Section E, pages 55-56, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicant states this alternative would be less effective because the existing medical diagnostic equipment is typically found in specialty practices and is used for the daily evaluation and diagnosis of patient diseases and illnesses. Therefore, in order for PDC clinicians to provide the standard of care at the proposed site, the medical diagnostic equipment is necessary.
- Develop the imaging services at a different location – The applicant states that this alternative would not allow PDC to achieve the operating efficiencies and savings achieved by developing the diagnostic center in the medical office space to be vacated at 4709 Creekstone Drive in Durham.
- Manage the specialty clinic with medical diagnostic equipment – The applicant states that managing the specialty clinic with medical diagnostic equipment is not an effective



alternative because the lack of onsite diagnostic services would result in additional burdens on patients due to the need to travel elsewhere for services and would cause delays in treatment, which may cause more negative treatment outcomes.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all statutory and regulatory review criteria.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Private Diagnostic Clinic, PLLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a new diagnostic center by relocating two units of echocardiogram equipment, one unit of electrocardiogram (EKG) equipment, one unit of electroencephalogram (EEG) equipment, one unit of pulmonary function testing equipment, and acquiring one unit of x-ray equipment, as designated in the application.**
- 3. Progress Reports:**
  - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
  - b. The certificate holder shall complete all sections of the Progress Report form.**
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**



**Duke Health Specialty Care Page Road Capital Cost**

Construction/Renovation Costs	\$115,000
Medical Equipment	\$119,750
Consultant Fees	\$50,000
<b>Total</b>	<b>\$284,750</b>

In Section Q, following the pro forma financial statements, the applicant provides the assumptions used to project the capital cost. Exhibit F contains supporting documentation. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Building renovation costs are based on the letter from the architect in Exhibit K.3.
- Medical equipment costs are based on an equipment lease arrangement which is included in Exhibit F.2.

In Section F, page 59, the applicant projects \$9,000 in start-up expenses and \$15,000 in initial operating expenses for total working capital expenses of \$24,000. On page 59, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the information regarding projected start-up costs and initial operating expenses provided on page 59 of the application.

**Availability of Funds**

In Section F, pages 57 and 60, the applicant states that the capital and working capital cost, respectively, will be funded by the cash reserves of PDC, as shown in the tables below.

**Sources of Capital Financing**

Type	Private Diagnostic Clinic, PLLC
Loans	
Accumulated reserves or OE *	\$284,750
Bonds	
Other (Specify)	
<b>Total Financing</b>	<b>\$284,750</b>

\* OE = Owner's Equity

**Sources of Working Capital Financing**

Type	Private Diagnostic Clinic, PLLC
Loans	
Accumulated reserves or OE *	\$24,000
Bonds	
Other (Specify)	
<b>Total Financing</b>	<b>\$24,000</b>

\* OE = Owner's Equity

In Exhibit F.2, the applicant provides a letter dated February 5, 2021, from the Chief Financial Officer for PDC documenting its commitment to fund the capital and working capital costs of the project. Exhibit F.2 also contains a copy of a February 5, 2021 letter from a Senior Vice President of First Citizens Bank stating that the applicant has adequate deposits at the bank to fund the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the documentation provided in Section F and Exhibit F.2, as described above.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of this project. In Section Q, Form F.2, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as summarized in the table below.

**Duke Health Specialty Care Page Road**

	1 <sup>st</sup> Full FY CY2022	2 <sup>nd</sup> Full FY CY2023	3 <sup>rd</sup> Full FY CY2024
Total Procedures	22,583	23,313	24,044
Total Gross Revenues (Charges)	\$15,632,007	\$16,296,001	\$16,986,109
Total Net Revenue	\$1,326,205	\$1,406,485	\$1,490,415
Average Net Revenue per Procedure	\$59	\$60	\$62
Total Operating Expenses (Costs)	\$1,031,227	\$1,057,588	\$1,084,867
Average Operating Expense per Procedure	\$46	\$45	\$45
Net Income	\$294,978	\$348,897	\$405,548

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
  - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (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, PDC, proposes to develop a new diagnostic center to include echocardiogram, electrocardiogram, electroencephalogram, pulmonary function test and x-ray.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2021 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C.3, pages 40-41, the applicant defines the service area for the proposed diagnostic center as Wake, Durham and Cumberland counties. Facilities may also serve residents not included in their service area.

In Section G.1, page 65, the applicant states, “*PDC is not aware of a public data source that provides an inventory of all existing and approved non-hospital facilities located in the service area that provide the services proposed in this project.*” On page 65, the applicant provides the x-ray utilization data reported by the acute care hospitals in the proposed service area on their respective 2020 Hospital License Renewal Applications (HLRA) forms.

In Section G.3, page 66, the applicant explains why it believes its proposal would not result in an unnecessary duplication of existing or approved diagnostic centers in Durham County. The applicant states:

*“Each of PDC’s existing diagnostic centers operates medical diagnostic equipment to support the internal clinical needs of the practice in which it is located. PDC existing diagnostic centers cannot meet the need of the proposed project. The need for the proposed project is based on the need for PDC to provide convenient access to diagnostic services to support the physician clinics to be located at Duke Health Specialty Care Page Road. The proposed diagnostic center will serve to optimize PDC’s ability to provide patient-centered care in a cost-effective manner. No other provider can meet the identified need. Further, though other imaging and diagnostic services may be available in the service area, they are not reasonably available to the patients of the PDC physicians who will practice at Duke Health Specialty Care Page Road. Specifically, use of such equipment would require leaving the physician office building, registering as a patient at another facility, waiting hours, days, or weeks for an available appointment, then having to return to the PDC practice. Compared to the availability of the service within the same building, typically during the same visit, the use of other capacity in the service area is ineffective at providing sufficient access to patients.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is not a need determination in the 2021 SMFP for diagnostic centers.
- The proposal would not result in an increase in any regulated imaging services.
- The applicant adequately demonstrates that the proposed diagnostic center is needed in addition to the existing or approved diagnostic centers in the service area to meet the identified need.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the above stated reasons.

- (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.

The applicant, PDC, proposes to develop a new diagnostic center to include echocardiogram, electrocardiogram, electroencephalogram, pulmonary function test and x-ray.

In Section Q, Form H, the applicant provides the projected full-time equivalent (FTE) positions for the proposed diagnostic services at Duke Health Specialty Care Page Road, as shown in the table below.

<b>Position</b>	<b>Projected FTE Positions 3rd Full FY - CY2024</b>
Operations Manager	0.17
Receptionist	0.20
Nurse Manager	0.17
Echo Tech	2.00
EKG Tech	1.00
EEG Tech	1.00
PFT Tech	0.50
X-ray Tech	1.00
<b>TOTAL</b>	<b>6.04</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 67-68, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Exhibit H.3, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the information provided in Section H, pages 67-68, and in Section Q, Form H, as described above.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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

The applicant, PDC, proposes to develop a new diagnostic center to include echocardiogram, electrocardiogram, electroencephalogram, pulmonary function test and x-ray.

### **Ancillary and Support Services**

In Section I.1, the applicant identifies the necessary ancillary and support services for the proposed services. On page 69, the applicant explains how each ancillary and support service is or will be made available. The applicant states,

*“The proposed project involves developing a diagnostic center, which is itself an ancillary service provided in support of the PDC physician clinics to be located at Duke Health Specialty Care Page Road. The project involves relocation of existing physician clinics. As such, PDC has currently [sic] has all ancillary and support services in place necessary to support the existing medical diagnostic equipment. Each of these services will continue to be provided upon receipt of the CON.”*

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the information provided in Section I.1, as described above.

### **Coordination**

In Section I.2, page 70, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant states,

*“PDC currently offers medical diagnostic services in the service area. As an established, physician-owned local healthcare provider, PDC has long-standing positive working relationships with the referring physician community in the service area. The physicians who will utilize the existing and proposed diagnostic equipment have practiced in Durham and Wake counties for many years and have during that time developed long-standing professional relationships with referring physicians and the broader healthcare provider community. PDC is aware of the medical needs of the community, through its involvement with patients at its current practices and through interactions with referring physicians.”*

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2 and Exhibit I.2, as described above.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application



Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (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.

C

The applicant, PDC, proposes to develop a new diagnostic center to include echocardiogram, electrocardiogram, electroencephalogram, pulmonary function test and x-ray.

In Section K.1, page 73, the applicant states that the project involves renovation of 1,855 square feet of leased medical office space. Line drawings are provided in Exhibit K.2.

On pages 74-75, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K. The site appears to be suitable for the proposed facility based on the applicant's representations and supporting documentation.

In Section K.3, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information and representations made by the applicant on page 73 of the application.

In Section K.3, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the information and representations made by the applicant on page 74 of the application.

On page 74, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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 ... persons [with disabilities], 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;

NA

The proposed diagnostic center will be a new facility and does not have historical payor mix.

- (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 ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NA

The proposed diagnostic center will be a new facility and does not have any past performance.

- (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 L, page 79, the applicant projects the payor mix for the proposed diagnostic center during the third full fiscal year (CY2024) of operation following completion of the project, as shown in the table below.

**Duke Health Specialty Care Page Road  
Payor Mix as a Percent of Total Services**

<b>Payor Category</b>	<b>Entire Facility</b>
Self-Pay	0.7%
Medicare*	0.3%
Medicaid*	32.0%
Insurance*	62.5%
Other government payors	4.6%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.7% of total services will be provided to self-pay patients, 0.3% to Medicare patients and 32.0% to Medicaid patients.

On pages 81-82, the applicant provides the assumptions and methodology used to project payor mix during the first three years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's proposed patient payor mix is based on PDC's historical experience providing the proposed services at its existing clinics.

The Agency reviewed the:

- Application

- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (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 L, page 82, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

The applicant, PDC, proposes to develop a new diagnostic center to include echocardiogram, electrocardiogram, electroencephalogram, pulmonary function test and x-ray.

In Section M.1, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the information provided in Section M, page 83, and Exhibit M.1, as described above.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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, PDC, proposes to develop a new diagnostic center to include echocardiogram, electrocardiogram, electroencephalogram, pulmonary function test and x-ray.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2021 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C.3, pages 40-41, the applicant defines the service area for the proposed diagnostic center as Wake, Durham and Cumberland counties. Facilities may also serve residents not included in their service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 85, the applicant states:

*“The new diagnostic center will positively affect competition in the service area. The proposed project will promote cost-effective, high quality medical diagnostic imaging services that will be broadly accessible by local residents, as described in Section N.2 below. The project will enable PDC to continue meeting its existing patient population's needs and ensure more timely provision of and convenient access to outpatient medical diagnostic imaging services for all area residents. PDC assumes no adverse effect on current medical diagnostic services providers in the service area, as PDC physicians have been longtime existing providers of these medical diagnostic services.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 85, the applicant states:

*“PDC’s plan to relocate and consolidate existing specialty clinics is cost effective. The co-location of Duke Health practices to 4709 Creekstone Drive, Durham is expected to optimize synergies and promote resource-sharing opportunities for more cost-effective care delivery across specialty physician practices. Furthermore, the cost to both the*

*patient and insurer is less when services are provided in an office-based setting compared to hospital based (also referred to as facility-based) services.”*

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 86, the applicant states,

*“PDC is dedicated to ensuring quality and patient safety through compliance with all applicable licensure and certification standards established regarding diagnostic services. PDC will maintain the highest standards and quality of care, consistent with the standards that it has sustained throughout its many years of providing patient care. PDC will continue utilizing its existing quality-related policies and procedures. These quality management programs emphasize a customer-oriented perspective to determine the needs of patients, physicians, and others who utilize medical diagnostic services. Copies of quality-related policies and procedures are included in Exhibit O.2.”*

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 86, the applicant states:

*“The proposed project will improve access to non-hospital based diagnostic services to underserved groups. PDC is a participating Medicare and Medicaid provider serving the elderly and medically indigent populations in the identified service area. As shown in Section L, PDC projects to serve Medicare and Medicaid patients for the proposed diagnostic services and provide charity care.”*

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrates: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and PDC’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (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 Q, Form O, the applicant identifies eight diagnostic centers located in Wake and Durham counties that are owned, operated or managed by the applicant or a related entity.

In Section O.4, page 91, the applicant states that, during the 18 months immediately preceding the submittal of the application, it is not aware of any incidents, regarding quality care at any of its diagnostic centers. 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.

G.S. 131E-183 (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.

### NA

The applicant, PDC, proposes to develop a new diagnostic center to include echocardiogram, electrocardiogram, electroencephalogram, pulmonary function test and x-ray. The Criteria and Standards for Diagnostic Centers were repealed, effective March 16, 2017. The project does not involve any other regulated medical diagnostic equipment for which there are applicable Criteria and Standards. Therefore, there are no performance standards applicable to this review.