ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: September 28, 2018
Findings Date: October 5, 2018

Project Analyst: Jane Rhoe-Jones
Team Leader: Fatimah Wilson

Project ID #: J-11532-18
Facility: Duke Vascular Specialists of Raleigh
FID #: 180318
County: Wake
Applicant: Private Diagnostic Clinic, PLLC
Project: Develop a new diagnostic center

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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 (referred to as "PDC") or "the applicant" proposes to develop a new diagnostic center, Duke Vascular Specialists of Raleigh (DVSR), in a medical office building (MOB) on the campus of Duke Raleigh Hospital (DRAH), Raleigh, Wake County.

The combined value of the existing and proposed new medical diagnostic equipment, costing $10,000 or more exceeds the statutory threshold of $500,000; therefore, the equipment qualifies as a diagnostic center, which is a new institutional health service, which requires a Certificate of Need (CON).

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2018 State Medical Facilities Plan (SMFP)
- acquire any medical equipment for which there is a need determination in the 2018 State Medical Facilities Plan (SMFP)
- offer a new institutional health service for which there are any policies in the 2018 State Medical Facilities Plan (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(2) Repealed effective July 1, 1987.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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a new diagnostic center on the campus of Duke Raleigh Hospital, Raleigh, Wake County.

The combined value of the existing and proposed new medical diagnostic equipment, costing $10,000 or more exceeds the statutory threshold of $500,000; therefore, the equipment qualifies as a diagnostic center, which is a new institutional health service, which requires a Certificate of Need (CON).

In Section C.1, pages 16-19, the applicant describes the proposed project. The existing clinic has been operating since April 1, 2018 in MOB #7 on the campus of Duke Raleigh Hospital, but will move to MOB #9, the new location, once it is renovated. DVSR is a private diagnostic clinic (PDC) physician clinic. Duke University Health System (lessor) is currently renovating the MOB in which the diagnostic center will be located. The existing clinic currently provides ultrasound services and is proposing to add new C-Arm equipment for fluoroscopy services.

Designation as a Diagnostic Center

In Section C.1, page 17, the applicant states that the three existing ultrasound machines are not included in the equipment cost to develop the proposed diagnostic center per N.C. Gen. Stat. §131E-176(7a) because each unit is valued at less than $10,000. The cost of the existing Flo-Lab equipment is $46,483; therefore the value of the existing diagnostic equipment does not meet the threshold to develop a diagnostic center. The cost of the new C-Arm equipment is $313,580 (see Exhibit 4 for vendor quote). It is projected to cost $410,000 to renovate and upfit the space needed to support the proposed diagnostic equipment which will be paid by Duke University Health System (see Exhibit 6). The combined costs of the existing and proposed equipment plus up-fit cost exceeds the $500,000 threshold for a diagnostic center; thus the applicant filed a CON application.

Patient Origin

N.C.G.S. §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 2018 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. Facilities may also serve residents not included in their service area.

In Section C, page 33, the applicant defines its service area as Wake, Johnston, Harnett, Franklin, Granville and Wilson counties. The applicant states that less than 1.0% of its patient origin is comprised of patients from the remaining 94 North Carolina counties and out of state.

On pages 20 and 21, the applicant provides the historical and projected patient origin for the proposed facility as illustrated in the table below:

DUKE VASCULAR SPECIALISTS OF RALEIGH
Historical and Projected Patient Origin
MEDICAL DIAGNOSTIC EQUIPMENT

COUNTY	HISTORICAL PATIENT ORIGIN APRIL 1, 2018 – MAY 31, 2018		PROJECTED PATIENT ORIGIN CY2019-CY2021
	PATIENTS	% OF TOTAL	% OF TOTAL
Wake	182	55.0%	55.0%
Johnston	25	7.6%	7.6%
Harnett	12	3.6%	3.6%
Franklin	11	3.3%	3.3%
Granville	10	3.0%	3.0%
Wilson	9	2.7%	2.7%
Other*	82	24.8%	24.8%
Total	**331**	**100.0%**	**100.0%**

Other includes <1% patient origin from the remaining counties in NC and other states.
Totals may not foot due to rounding.

In Section C.3(c), page 22, the applicant states that assumptions regarding projected patient origin for each service are based on utilization in DVSRs recently established physician practice.

> "*There is limited historical patient origin data available to PDC because the DVSR clinic in North Raleigh was recently established and is still ramping up as a new site for PDC. Historical patient origin is not available for DVSR physicians prior to joining PDC on April 1, 2018. Therefore, PDC projects patient origin based on DVSRs patient origin for clinic visits during April 1, 2018 – May 31, 2018. DVSR clinic patients ae the same patients who will utilize the proposed diagnostic modalities; therefore, PDC determined the recent clinic patient origin is a proxy for projecting patient origin for the proposed project*."

The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 22-33, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

On pages 23-24, the applicant states:

> "*The proposed diagnostic capabilities and capacity on site at DVSR are intended to enable physicians to provide more integrated, efficient, and effective care for their patients. The proposed diagnostic equipment on site at DVSR enable the convenience of one-stop-shopping for patients and will enhance their continuity of care and the efficiency of the acquisition of necessary diagnostic information to support the care of these ambulatory patients. The proposed medical diagnostic equipment will also facilitate the early diagnosis and treatment of complex diseases that would otherwise go undetected.*
>
> *As medical diagnostic technology improves and becomes more cost efficient, physician practices are increasingly leveraging the technology to incorporate office-based testing into their diagnostic and treatment regimens…"*

On page 24, the applicant states the following benefits of in-office diagnostic center testing:

- Treatment plans developed earlier due to faster diagnoses and immediate results
- Patient compliance improvement
- Health outcomes improved
- Invasive diagnostic techniques reduced
- Office visits more productive due to fewer duplicated visits
- Fewer more costly and higher risk diagnostic procedures
- Less time required for procedures
- Physicians become more familiar with their patients
- Physicians can take a comprehensive approach in treating their patients

In Section C.1, pages 24-27, the applicant discusses each piece of diagnostic equipment to be located at the facility and its function and benefits, including the proposed and existing equipment.

Fluoroscopy (Mobile C-arm) Services (proposed new equipment)

Based on the applicant's representations on pages 24-25, mobile C-arm fluoroscopy is a routine diagnostic procedure to see inside the arteries. The applicant states that for vascular services, fluoroscopy is commonly used in the following procedures:

- diagnostic lower extremity angiography
- diagnostic cerebrovascular angiography
- renal / mesenteric angiography
- diagnostic upper extremity angiography
- angiography / stenting for all the above except cerebrovascular

- diagnostic aortagram

On page 25, the applicant further states:

> "*An angiogram is considered the gold standard for evaluating blockages in the arterial system.*
>
> …
>
> *The proposed diagnostic equipment is needed to ensure timely access to cost effective outpatient diagnostic services for DVSR's patients*."

Exhibit 11 includes support letters from vascular surgeons who state that angiography, fluoroscopy and ultrasound are essential in the evaluation and diagnosis of vascular disease or issues. Exhibit 11 also includes letters from referring physicians who state that they often refer patients to PDC clinics, including DVSR.

Vascular Ultrasound (existing medical diagnostic equipment)

As discussed on pages 25-26 of the application, vascular ultrasound is a routine diagnostic procedure and is commonly performed to:

- help monitor the blood flow throughout the body to organs and tissues
- locate and identify stenosis and abnormalities
- detect blood clots in the major veins of the arms or legs
- determine if patients are good candidates for procedures such as angioplasty
- evaluate the success of grafts or bypasses to blood vessels
- diagnose enlarged aneurysms
- evaluate varicose veins

On pages 25-26, the applicant states,

> "*Advantages of vascular ultrasound include non-invasiveness, portability, avoidance of ionizing radiation, cost and price as well as its ability to image dynamically (e.g., to obtain real-time data about blood flow directionality).*
>
> *… vascular ultrasound is a common and growing diagnostic imaging modality that is appropriately performed in outpatient settings. … The diagnostic equipment is needed to ensure timely access to cost-effective outpatient diagnostic services …*"

Vascular Studies (Parks Flo-Lab) (existing medical diagnostic equipment)

As discussed on pages 26-27 of the application, vascular studies use a doppler ultrasound system to check the blood flow in arteries and veins.

A vascular study may be done to:

- check signs and symptoms that may indicate decreased blood flow in arteries or veins in the neck, legs or arms
- assess procedures patients have had before to restore blood flow to an area
- assess a vascular dialysis device (such as an A-V fistula in the arm)

On pages 26-27, the applicant states,

> "*Doppler ultrasound is a common diagnostic imaging modality that is appropriately used to perform vascular studies in outpatient office settings. … The diagnostic equipment is needed to ensure timely access to cost effective outpatient diagnostic services for … patients*."

In Section C, pages 27-32, the applicant states that the unmet need in the proposed market area is based on the following factors:

- Prevalence of peripheral artery disease (PAD) according to the CDC. (Page 27)
- High blood pressure being the most common form of vascular disease in America according to Johns Hopkins. (Page 27)
- Other common cardiovascular diseases (CVD) that comprise the second and fourth leading causes of death in NC according to the 2012 NC Justus-Warren Heart Disease & Stroke Prevention Task Force. (Page 28)
- Wake County having had the second highest number of heart disease-related deaths in NC and Johnston County also making the top of the list according to the NC State Center for Health Statistics. (Pages 28- 29)
- Population aging, size and projected growth. (Pages 30-32)

The information provided by the applicant is reasonable and adequately supported for the following reasons:

- The applicant documents the incidence and prevalence of cardiovascular diseases in the proposed service
- Disease incidence and prevalence data that are from reliable and respected sources
- The proposed project will improve patient access to diagnostic testing of cardiovascular diseases
- The projected continued growth of population in the service area will increase the demand for healthcare

Projected Utilization

In Section Q, pages 99-118, the applicant provides the historical and projected utilization for the first three years of operation following completion of the project, as shown on in the table on page 103.

DVSR Projected Utilization CY2018-CY2021				
Each Service Component	**Interim Full Fiscal Year CY2018**	**Interim Full Fiscal Year CY2019**	**Interim Full Fiscal Year CY2020**	**Interim Full Fiscal Year C 2021**
Mobile C-arm (Fluoroscopy)*				
# Units	NA	1	1	1
# Procedures	NA	792	871	958
Ultrasound				
# Units	3	3	3	3
# Procedures	1252	1,836	2,019	2,221
Flo-Lab (Doppler Ultrasound)				
# Units	1	1	1	1
# Procedures	675	990	1,089	1,198
The DVSR clinic was established April 1, 2018; thus there is no prior years' utilization.				

*The mobile C-arm is a new unit of equipment.

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

DVSR Clinic Visits

- The DVSR received its first clinic visit on April 1, 2018.
- During April 1 – May 31, 2018, 466 office visits occurred or an average of 233 visits per month. Feedback from the three DVSR physicians indicates that, combined, in their former patient clinic they averaged 300 clinic visits per month. Based on an annualized clinic visit rate, the physicians project 300 clinic visits per month. The applicant projects an annualized 2,700 clinic visits during the first nine months of operation, April – December 2018, in the diagnostic facility.
- The physicians project that clinic visits will increase 10% due to the move to a larger facility (MOB #9), larger referral network, demographic factors, increased physician productivity, and successful recruitment of an incremental vascular surgeon.

Ultrasound Procedures

- Three existing ultrasound machines will be relocated to the new MOB with no new machines planned.
- 216 diagnostic ultrasound procedures were performed between April – May 2018 with a total of 466 office visits for a ratio of 0.46 projected ultrasound procedures per office visit or 1,252 ultrasound procedures over an annualized nine month period, April through December 2018.

- The applicant based its projected ultrasound procedures on the actual procedures performed April – May 2018.

Flo-Lab

- One existing Flo-Lab machine will be relocated to the new MOB with no new machines planned.
- 64 Flo-Lab procedures were performed between April – May 2018 with a total of 466 office visits for a ratio of 0.25 projected ultrasound procedures per office visit or 675 Flo-Lab procedures over an annualized nine month period, April through December 2018.
- The applicant based its projected Flo-Lab procedures on the actual procedures performed April – May 2018.

Mobile C-Arm/Fluoroscopy

- One proposed C-Arm machine will be acquired for the proposed diagnostic facility. There is no existing C-Arm machine in the DVSR practice.
- In the physician's former practice, 20% of the clinic visits were C-Arm procedures. The DVSR physicians are basing their projected C-Arm procedures on their former practice experience. Therefore, the applicant is projecting 20% of the projected 3,960 clinic visits or 792 C-Arm procedures during the first CY of the proposed diagnostic facility, January 2019 – December 2019.

Projected utilization is reasonable and adequately supported for the following reasons:

- Projected utilization is based on historical data
- Proposed expansion of the physician referral network
- Active ongoing recruitment including recruitment for an incremental vascular surgeon, thus increased clinic visits is an expected result
- Increased physician productivity due to expanded clinic space.

Access

In Section C.11, page 38, the applicant discusses access to the proposed services.

The applicant states:

> " *... 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 classify a patient as underserved.*"

In Section L.1(a), page 80, the applicant states that 53.5% and 61.9% of PDC existing services between April 1 and May 31, 2018 were provided to women and persons 65 and older, respectively. The applicant states that it does not track racial and ethnic minority data on its patients.

The applicant includes the assumptions for the proposed payor mix by service in Exhibit L.3(b). Exhibit 9 includes PDC's non-discrimination, charity, and financial assistance policies.

In Exhibit L.3(a), page 82, the applicant provides the projected payor mix (since it is not an existing diagnostic center and the practice has only been offering services since April 2018) for each of the proposed service components for the second full year of operation, CY2020, as shown below in the table.

DVSR DIAGNOSTIC CENTER CY2020			
Payor Source	**C-arm**	**Ultrasound**	**Flo-Lab**
Self-Pay	0.00%	0.97%	1.63%
Medicare*	93.10%	66.68%	77.29%
Medicaid *	4.46%	0.98%	5.17%
Insurance*	2.44%	28.96%	16.01%
Workers Compensation	0.00%	0.00%	0.00%
TRICARE	0.00%	0.00%	0.00%
Other (Government)	0.00%	2.41%	0.00%
TOTAL	**100.0%**	**100.0%**	**100.0%**

*Medicare, Medicaid and insurance includes any managed care plans included in those payor sources

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application,
- Exhibits to the application, and
- Written comments
- Response to written comments
- Information publicly available during the review and used by the Agency

Based on the 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 projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce or eliminate a service or relocate a facility or service. The applicant proposes to move the facility from MOB #7 to MOB #9, both on the Duke Raleigh Hospital campus. 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

PDC proposes to develop a new diagnostic center in a MOB on the campus of Duke Raleigh Hospital, Raleigh, Wake County.

In Section E.2, pages 48-49, the applicant describes the alternatives 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:

1. Maintain Status Quo – the applicant states that the proposed medical diagnostic equipment is typically found in practices such as DVSR and is used for the evaluation and diagnosis of diseases and illnesses. The project is also expected to improve access and increase cost efficiencies. Therefore, maintaining status quo is not an effective alternative.

2. Locate the Proposed Diagnostic Center in Another Location – the applicant states that to move the proposed diagnostic center to a different location could hinder access for the existing patient population. Therefore, moving the proposed diagnostic center is not an effective alternative.

3. Acquire Different Quantities of Medical Diagnostic Equipment – the applicant states that clinical and administrative leadership have decided that the proposed mix of medical diagnostic equipment will adequately meet the qualitative and quantitative needs of the specialty clinics that will be located at DVSR. Therefore, a different mix or quantity of diagnostic equipment is not an effective alternative.

4. Pursue a Joint Venture – the applicant states that this proposed project is an internal PDC matter. Thus, to meet the needs of the DVSR, a joint venture is not an effective alternative.

On page 48, the applicant states that its proposal is the most effective alternative because in order to provide the standard of care required for a vascular center, the proposed equipment is necessary. The project is also proposed to improve access and increased cost efficiencies.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Information which was publicly available during the review and used by the Agency.

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 shall materially comply with all representations made in the certificate of need application.

2. Private Diagnostic Clinic, PLLC shall develop a new diagnostic imaging center with mobile C-arm fluoroscopy, vascular ultrasound and Doppler ultrasound equipment.

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 expenditures in Section Q of the application and that would otherwise require a certificate of need.

4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Private Diagnostic Clinic, PLLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:

a. Payor mix for the services authorized in this certificate of need.
b. Utilization of the services authorized in this certificate of need.
c. Revenues and operating costs for the services authorized in this certificate of need.
d. Average gross revenue per unit of service.
e. Average net revenue per unit of service.
f. Average operating cost per unit of service.

5. Private Diagnostic Clinic, PLLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency 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 develop a new diagnostic center in a MOB on the campus of Duke Raleigh Hospital, Raleigh, Wake County.

Capital and Working Capital Costs

In Section Q, on Form F.1a, the applicant projects the total capital cost of the project as shown below in the table.

DVSR Capital Cost	
Construction Costs/Renovation	$410,000
Medical Equipment	$360,063
Consultant Fees	$45,000
Total	**$815,063**

In Section F.1(b), page 50, and Section Q, the applicant provides the assumptions used to project the capital cost. Supporting documentation can be found in Exhibits 2, 4 and 7.

In Section F, pages 52-53, the applicant projects that start-up costs will be $40,000 and initial operating expenses will be $50,000 for a total working capital of $90,000. In Section Q, Assumption (10), the applicant provides the assumptions used to project the working capital needs of the project.

Availability of Funds

In Section F, page 51, the applicant states that the capital cost will be funded as shown below in the table.

DVSR Sources of Capital Cost Financing		
Type	**PDC**	**Total**
Loans	$0	$0
Accumulated reserves or OE *	$45,000	$45,000
Bonds	$0	$0
Other (Equipment Leases)	$360,063	$360,063
Other (Facility Lease)	$410,000	$410,000
**Total Financing ** **	**$815,063**	**$815,063**

* OE = Owner's Equity. **Total financing should equal line 14 in Form F.1a Capital Cost.

In Section F, page 53, the applicant states that the working capital needs of the project will be funded as shown below in the table. See Exhibit 7 for First Citizens Bank documentation of funding for the proposed project working capital cost.

	DVSR Sources of Financing for Working Capital	Amount
(a)	Loans	$0
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	$90,000
(c)	Lines of credit	$0
(d)	Bonds	$0
(e)	**Total ***	**$90,000**

*Total sources of financing for working capital should equal the amount listed in Question F.3(c) above.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown below in the table.

DVSR Financial Feasibility C-Arm, Ultrasound and Flo-lab Procedures			
	1st Full CY	**2nd Full CY**	**3rd Full CY**
Total Procedures*	3,618	3,979	4,377
Total Gross Revenues (Charges)	$3,214,546	$3,642,080	$4,126,477
Total Net Revenue	$867,990	$983,433	$1,114,229
Average Net Revenue per Procedure	$240	$247	$255
Total Operating Expenses (Costs)	$856,236	$942,015	$1,033,059
Average Operating Expense per Procedure	$237	$237	$236
Net Income	**$11,754**	**$41,418**	**$81,170**

*Pro forma Form C. Note: Total procedures includes C-Arm, Ultrasound and Flo-Lab procedures.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Information publicly available during the review and used by the Agency

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

PDC proposes to develop a diagnostic center in a MOB on the campus of Duke Raleigh Hospital, Raleigh, Wake County.

N.C.G.S. §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 2018 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. Facilities may also serve residents not included in their service area. The applicant defines its service area from the origin of patients who used the existing diagnostic equipment between April 2018 and May 2018.

In Section C, page 33, the applicant defines its service area as Wake, Johnston, Harnett, Franklin, Granville and Wilson counties. The applicant states that less than 1.0% of its patient origin is comprised of patients from the remaining 94 North Carolina counties and out of state.

In Section G.1, page 59, the applicant identifies a diagnostic center in Knightdale, Wake County for which it was approved in CON Project ID# J-8167-08. The applicant states that the Knightdale facility does not operate similar diagnostic equipment. On pages 59 and 60, the applicant identifies the existing and approved services in the service area in a table. The applicant states,

"*Separate from its own health service facilities, PDC is aware of the following existing and approved health service facilities that operate similar medical diagnostic equipment in the proposed service area*:"

Approved and Existing Diagnostic Centers in Wake County				
Facility	**Type**	**County**	**Ultrasound**	
			Inventory	FY2017 Procedures
WakeMed Hospital*	Hospital	Wake	9	22,602
WakeMed Cary Hospital	Hospital	Wake	5	6,033
Duke Raleigh Hospital	Hospital	Wake	9	15,484
UNC Rex Hospital	Hospital	Wake	26	21,993

Applicant's source: 2018 Hospital License Renewal Applications (LRAs). *All sites.

In Section G, page 61, the applicant explains why it believes its proposal would not result in an unnecessary duplication of existing or approved diagnostic centers in Wake County. The applicant states:

"*… The identified need is internal to PDC, as it involves a PDC specialty clinics* [sic] *and the medical diagnostic equipment necessary to support it. No other provider can or should provide for the internal clinical diagnostic need at PDC.*

… The proposed diagnostic center is needed by the vascular surgeons who will practice at the DVSR to aid them in diagnosing their patients' illnesses or conditions.

Further, because the diagnostic center will be located within the respective specialty clinic, the cost to both the PDC patient and the insurer will be less than if the patient received the procedure in a facility not attached to a physician's office."

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 2018 SMFP for diagnostic centers.
- The applicant adequately demonstrates that the proposed diagnostic center is needed in addition to the existing or approved diagnostic centers in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Information which was publicly available during the review and used by the Agency.

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.

C

In Section Q, Form H, the applicant provides projected staffing for the proposed services for the first three operating years, as shown in the table below.

DVSR Proposed Diagnostic Center Staffing			
Position	**FY2019 FTE**	**FY2020 FTE**	**FY2021 FTE**
Nursing			
Nurse Manager	0.50	0.50	0.50
RN	1.00	1.00	1.00
Other			
Vascular Technologist	1.50	1.75	2.00
Interventional Radiology Technologist	1.20	1.45	1.70
CMA/RMA	1.20	1.45	1.70
Administration			
Administrator	.25	.25	.25
Staff Assistant	.75	.75	.75
Financial Care Counselor	.50	.50	.50
Patient Service Associate	1.5	1.5	1.5
TOTAL	**8.40**	**9.15**	**9.90**

Note: FTE = full-time equivalent positions

In Section H.1, page 63, and in Section Q, the applicant discusses the assumptions and methodology used to determine staffing needs. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Forms F.4 and H which are found in Section Q. In Section H.2 and H.3, pages 63-64, the applicant describes Duke University's experience and process for recruiting and retaining staff and its proposed training and continuing education programs. In Section H.4, pages 65-66, the applicant discusses physician coverage needed for the project and states that its physician recruitment plan ensures adequate and appropriate physician staffing in all specialties to meet patient care demand. On page 65, the applicant identifies David Attarian, M.D. as the existing Medical Director of the PDC. Dr. Attarian's letter expressing support and willingness to continue to serve as Medical Director for the proposed services at the PDC and the proposed diagnostic center are included in Exhibit 5. The applicant provides additional letters of support documentation in Exhibit 11.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Information which was publicly available during the review and used by the Agency

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

In Section I.1, page 67, the applicant states that the following ancillary and support services are necessary for the proposed services:

- environmental
- business office
- registration
- scheduling
- billing
- medical records

In Section I.1(b), page 67, the applicant explains how the necessary services will be made available.

Although the applicant proposes a new diagnostic center, PDC already provides, except for the proposed mobile C-arm, other diagnostic services such as ultrasound and Flo-Lab in Wake County and has established relationships within the existing health care system. Exhibit 11 of the application contains eleven letters from physicians written on behalf of their primary care practices (which include 77 colleagues in their primary care practices) expressing support for the proposed project. The applicant adequately demonstrates that the necessary ancillary and support services are available and that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Response to written comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that 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

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. Therefore, Criterion (9) is not applicable to this review.

(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

The applicant is not HMO. Therefore, Criterion (10) is not applicable to this review.

(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

PDC proposes to develop a diagnostic center in a MOB on the campus of Duke Raleigh Hospital, Raleigh, Wake County.

In Section K.2, page 71, the applicant states that the project involves renovating 1,192 square feet of new space within an existing MOB. Exhibit 6 contains line drawings.

In Section K.4(a), page 72, the applicant adequately explains how the cost, design and means of renovation represents the most reasonable alternative for the proposal and provides supporting documentation in Section Q and Exhibit 6. The applicant provides a photo of the MOB where the proposed diagnostic center will be located, a diagram of the DRAH campus, and a map depicting the diagnostic center on pages 74-76, respectively.

Also on page 72, 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 and provide supporting documentation in Section Q and Exhibit F.1.

On page 73, the applicant identifies applicable energy saving features that will be incorporated into the construction plans. The applicant also states that the proposed project will be in compliance with all applicable federal, state and local requirements for energy efficiency and water consumption.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated 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 handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L(a), page 82, the applicant discusses its payor mix and states,

> "*The DVSR payor mix table … is based on the payor mix for these services during the two-month period (April 1 – May 31, 2018) since the DVSR vascular surgeons joined PDC on April 1, 2018. Please note that the historical payor mix data from the previous physician clinic is not available to PDC*."

DVSR April 1, 2018 – May 31, 2018 Payor Mix			
Payor Category	**C-arm Vascular**	**Ultrasound Vascular**	**Flo-Lab Vascular**
Self-Pay/ Charity Care	0.0%	0.97%	1.63%
Medicare	93.10%	66.68%	77.29%
Medicaid	4.46%	0.98%	5.17%
Insurance	2.44%	28.96%	16.01%
Workers Compensation	0.0%	0.0%	0.0%
TRICARE	0.0%	0.0%	0.0%
Other (Gov't)	0.0%	2.41%	0.0%
Total	**100.00%**	**100.00%**	**100.00%**

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.2(a), page 80, the applicant states that the PDC is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. The applicant states that the PDC does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay. The applicant discusses its charity or reduced cost care on pages 82-83 and includes its patient financial assistance policies in Exhibit 9.

In Section L.2(c), page 81, the applicant states that there have been no patient civil rights equal access complaint filed against PDC in the past five years.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that 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 L, page 82, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown below in the table.

DVSR Proposed Payor Mix CY2020			
Payor Category	**C-arm Vascular**	**Ultrasound Vascular**	**Flo-Lab Vascular**
Self-Pay/ Charity Care	0.0%	0.97%	1.63%
Medicare	93.10%	66.68%	77.29%
Medicaid	4.46%	0.98%	5.17%
Insurance	2.44%	28.96%	16.01%
Workers Compensation	0.0%	0.0%	0.0%
TRICARE	0.0%	0.0%	0.0%
Other (Gov't)	0.0%	2.41%	0.0%
Total	**100.00%**	**100.00%**	**100.00%**

Table may not foot due to rounding.

As shown in the table above, during the second full calendar year of operation, the applicant projects that 0.97% and 1.63% of total services will be provided to self-pay and charity care patients for ultrasound and Flo-Lab, respectively. Also, the applicant projects that 93.1%, 66.68% and 77.29% of total services will be provided to Medicare patients for C-arm, Ultrasound and Flo-Lab, respectively. And 4.46%, 0.98%, and 5.17% of total service, respectively to Medicaid patients.

In Section L3(b), page 82, the applicant provides the assumptions and methodology used to project payor mix during the second full calendar year of operation following completion of the project. In Exhibit 9, the applicant provides its policies and procedures for patient financial status which includes charity and self-pay patients. The projected payor mix is reasonable and adequately supported for the following reasons:

- the projected payor mix is based on the brief historical payor mix of patients in the applicant's DVSR office, and
- the applicant adequately demonstrates that medically underserved populations will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that 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 L.5, page 83, the applicant describes the range of means by which a person will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Information which was publicly available during the review and used by the Agency

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

In Section M, page 85, 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 10.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

PDC proposes to develop a diagnostic center in a MOB on the campus of Duke Raleigh Hospital, Raleigh, Wake County.

N.C.G.S. §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 2018 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. Facilities may also serve residents not included in their service area. The applicant defines its service area from the origin of patients who used the existing diagnostic equipment between April 2018 and May 2018.

In Section G.1, page 59, the applicant identifies a diagnostic center in Knightdale, Wake County for which it was approved in CON Project ID# J-8167-08. However, the applicant states that the Knightdale facility does not operate similar diagnostic equipment. On pages 59 and 60, the applicant identifies the existing and approved services in the service area in a table. The applicant states,

> "*Separate from its own health service facilities, PDC is aware of the following existing and approved health service facilities that operate similar medical diagnostic equipment in the proposed service area*:"

Approved and Existing Diagnostic Centers in Wake County				
Facility	**Type**	**County**	**Ultrasound**	
			Inventory	FY2017 Procedures
WakeMed Hospital*	Hospital	Wake	9	22,602
WakeMed Cary Hospital	Hospital	Wake	5	6,033
Duke Raleigh Hospital	Hospital	Wake	9	15,484
UNC Rex Hospital	Hospital	Wake	26	21,993

Applicant's source: 2018 Hospital License Renewal Applications (LRAs). *All sites.

In Section N, pages 86-90, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 86, the applicant states,

> "*PDC assumes no adverse effect on current providers of medical diagnostic services in Wake County, as the vascular surgeons of DVSR have been longtime existing providers of these medical diagnostic services in Wake County. With this project, PDC is proposing to offer vascular medical diagnostic services at a convenient location on the DRAH campus, in order to improve patient access to quality, cost-effective diagnostic care*.
>
> … *The project will promote competition in the service area because it will enable PDC to better meet the needs of PDC's existing patient population, and to ensure more timely provision of and convenient access to outpatient medical diagnostic services for all area residents*."

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 O, pages 94-95, the applicant identifies the diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of five of this type of facility located in North Carolina.

On page 95 the applicant states,

> "*PDC has never had its Medicare or Medicaid provider agreement terminated. PDC's operational diagnostic centers have provided quality care during the 18 months immediately preceding submission of the application. Diagnostic centers are not licensed facilities, therefore, there are no Division of Health Service Regulation licensure requirements*."

After reviewing and considering information provided by the applicant regarding the quality of care provided at all five 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.

NA

The applicant proposes to develop a new diagnostic center in a medical office building (MOB) on the campus of Duke Raleigh Hospital, Raleigh, Wake County.

The Criteria and Standards for Diagnostic Centers were repealed, effective March 16, 2017. Therefore, there are no performance standards applicable to this review.