ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: January 14, 2019
Findings Date: January 14, 2019

Project Analyst: Celia C. Inman
Team Leader: Gloria C. Hale

Project ID #: J-11617-18
Facility: Duke Health Center Apex
FID #: 180515
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 Health Center Apex (DHCA), at 1545 Orchard Villas Avenue, Apex, Wake County. Duke Orthopaedics of Apex (DOA) is an existing PDC physician clinic in leased medical office building (MOB) space at that location.

DOA operates X-ray and C-arm equipment for use in the evaluation and diagnosis of orthopaedic issues for its patients. The existing medical diagnostic equipment valued at more than $10,000 currently owned by DOA at that location is $362,007.

The applicant plans to move its pediatric cardiology clinic, Duke Pediatric Cardiology of Cary (DPCC), currently located in Cary and co-locate the clinic with DOA at the existing MOB at 1545 Orchard Villas Avenue in Apex. DPCC operates an existing echocardiogram in the evaluation

and diagnosis of cardiac issues for pediatric patients. The cost of the proposed relocated cardiology medical diagnostic equipment is $243,230 (Exhibit 4) and the cost to renovate and upfit the space necessary to support the medical diagnostic equipment is $105,000. The space upfit incurred by the lessor will be passed along to PDC via the facility lease, as documented in Exhibit 2.

The combined costs of all the medical diagnostic equipment, plus the upfit cost and fees, exceeds the statutory threshold of $500,000 ($362,007 + $243,230 + $105,000 + $50,000 = $760,237; therefore, it qualifies as a diagnostic center, which is a new institutional health service, which requires a Certificate of Need (CON).

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.”*

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 SMFP, or
- offer a new institutional health service for which there are any applicable policies in the 2018 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 co-locate two existing PDC physician clinics, DOA and DPCC, in common leased MOB space. Combining the medical diagnostic equipment necessary to operate the two clinics will establish a new diagnostic center, DHCA, in Apex, Wake County.

In Section C.1, pages 16-19, the applicant describes the proposed project and discusses the medical diagnostic equipment used at DOA for the evaluation and diagnosis of orthopaedic patient issues (digital X-ray and C-arm equipment) and at DPCC for the evaluation and diagnosis of cardiac issues for pediatric patients (echocardiogram/ultrasound equipment).

Designation as a Diagnostic Center

In Exhibit 4, the applicant provides a listing of the cost/values of the existing x-ray, C-arm and echocardiogram equipment which will develop the proposed diagnostic center. The combined costs of the existing equipment costing $10,000 or more and the cost of the necessary upfit exceeds the $500,000 threshold for a diagnostic center; thus the applicant filed a CON application.

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 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.4, page 27, the applicant defines the service area for the proposed diagnostic center as Wake County, though the center will serve patients from outside the designated service area.

In Section C, pages 20 and 22, the applicant provides DOA's historical and projected patient origin, respectively, as summarized in the table below.

DUKE ORTHOPAEDICS OF APEX
HISTORICAL AND PROJECTED PATIENT ORIGIN
MEDICAL DIAGNOSTIC EQUIPMENT (X-RAY AND C-ARM)

COUNTY	HISTORICAL PATIENT ORIGIN CY2017	PROJECTED PATIENT ORIGIN CY2020-2022
	% OF TOTAL	% OF TOTAL
Wake	48.3%	48.3%
Durham	8.3%	8.3%
Pitt	8.3%	8.3%
Beaufort	3.6%	3.6%
Wayne	3.2%	3.2%
Craven	2.3%	2.3%
Lenoir	2.0%	2.0%
Orange	1.8%	1.8%
Chatham	1.8%	1.8%
Wilson	1.6%	1.6%
Guilford	1.3%	1.3%
Lee	1.2%	1.2%
Carteret	1.2%	1.2%
Onslow	1.0%	1.0%
Other*	14.2%	14.2%
Total	**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, pages 21 and 23, the applicant provides DPCC's historical and projected patient origin, respectively, as summarized in the table below.

DUKE PEDIATRIC CARDIOLOGY OF CARY
HISTORICAL AND PROJECTED PATIENT ORIGIN
MEDICAL DIAGNOSTIC EQUIPMENT
(ECHOCARDIOLOGY/ULTRASOUND)

COUNTY	HISTORICAL PATIENT ORIGIN CY2017	PROJECTED PATIENT ORIGIN CY2020-2022
	% OF TOTAL	% OF TOTAL
Wake	32.1%	32.1%
Cumberland	23.9%	23.9%
Harnett	9.6%	9.6%
Durham	6.0%	6.0%
Robeson	4.5%	4.5%
Hoke	2.6%	2.6%
Sampson	2.5%	2.5%
Johston	2.1%	2.1%
Moore	1.5%	1.5%
Onslow	1.2%	1.2%
Orange	1.1%	1.1%
Lee	1.1%	1.1%
Other*	11.7%	11.7%
Total	**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 24, the applicant states that assumptions regarding projected patient origin for DOA and DPCC are based on actual clinic visits during CY2017. The applicant states that clinic patients are the same patients who will utilize the existing diagnostic modalities; therefore, PDC determined the recent clinic patient origin is a reasonable proxy for projecting patient origin because it does not anticipate a significant change in patient origin as a result of the proposed project.

The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 24-28, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

On page 24, the applicant states that the need for the proposed project is based on numerous qualitative and quantitative factors, including:

- The existing diagnostic equipment is integral to the applicant's continuum of orthopaedic and pediatric cardiology services and is necessary for the clinicians to properly diagnose patients. (pages 24-25)
- The proposed project will enable the applicant to provide cost effective services to meet patient expectations and to ensure quality care. (pages 25-26)

- The projected growth of the service area population presumes continued increases in demand for healthcare. (pages 26-28)

Continuum of Care - Access and Quality

In Section C.1, pages 17-19, the applicant discusses each piece of diagnostic equipment to be located at the facility and its function and benefits. On pages 24-25, the applicant states that the identified medical diagnostic equipment is required to aid the physician in diagnosing a patient's condition, illness, or disease. The applicant states that the existing digital x-ray and C-arm support the DOA practice and are integral to its continuum of orthopaedic services. The applicant states that the existing echocardiography equipment is an integral part of diagnosis and determining appropriate treatment for various cardiac conditions and diseases at DPCC. Furthermore, the applicant believes the co-location of the clinics and the diagnostic center equipment will facilitate expanded services via recruitment of incremental physicians for several specialty practices.

Cost Effectiveness

On page 26, the applicant states:

> *"The co-location of Duke Health practices to the new Duke Health Center Apex site 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. Because PDC will bill globally for the proposed services, the patient will only be subject to a physician's office co-pay, rather than deductible and coinsurance payments.*

The applicant lists additional benefits of office-based diagnostic testing, including fewer diagnostic procedures, less time, patient familiarity, and a comprehensive approach. The applicant further states:

> *Given the current state of economic uncertainty, it is particularly important to consider cost effective alternatives and the benefits that cost savings will have for health care recipients."*

Service Area Demographics

On pages 26-27, the applicant defines the service area for the proposed diagnostic center as Wake County. The applicant states that according to the North Carolina Office of State Budget & Management (NCOSBM), Wake County hosts over one million residents and will grow by approximately 2.1% per year, or 91,000 additional residents from 2018 to 2022. The applicant states that DOA provides orthopaedic services to patients of all age groups, while DPCC specializes in serving patients age 0-17. All age groups are projected to grow during the next four years.

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

- The applicant documents the existing medical diagnostic equipment is essential for cost effective delivery of quality care for DOA and DPCC patients.
- The co-location of Duke Health practices to the new DHCA site is expected to optimize synergies and promote resource-sharing.
- The projected growth of the service area population presumes continued increases in demand for healthcare, including the need for diagnostic imaging services specific to the PDC specialty clinics.

Projected Utilization

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

Duke Health Center Apex
Diagnostic Center
Form C: Utilizations

Each Service Component	Prior Full Fiscal Year CY2017*	Interim Full Fiscal Year CY2018	Interim Full Fiscal Year CY2019	First Full Fiscal Year CY2020	Second Full Fiscal Year CY2021	Third Full Fiscal Year CY2022
X-ray						
# Units	NA	1	1	1	1	1
# Procedures	NA	1,482	1,512	1,544	1,576	1,609
C-arm (Fluoroscopy)						
# Units	NA	1	1	1	1	1
# Procedures	NA	358	366	373	381	389
Echocardiogram						
# Units	1	1	1	1	1	1
# Procedures	2,021	2,063	2,106	2,150	2,194	2,240

*In Section Q, pages 98-99, the applicant states that PDC has limited historical utilization data for X-ray and C-arm procedures.

In Section Q, pages 98-101, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

X-ray Procedures

- The applicant projects DOA clinic visits will increase in proportion to the Wake County population growth rate of 2.1%.
- The applicant projects the X-ray procedure ratio will be 0.62 X-ray procedures per office/clinic visit, or 62% of visits.

Projected X-ray Utilization

Assumptions		CY2018	CY2019	CY2020	CY2021	CY2022
Clinic Visits Base Year CY2017	2,341					
Projected Annual Increase	2.1%	2,390	2,439	2,492	2,542	2,594
Ratio of X-ray to Clinic Visits	62%	1,482	1,512	1,544	1,576	1,609

Mobile C-arm/Fluoroscopy Procedures

- The applicant projects DOA clinic visits will increase in proportion to the Wake County population growth rate of 2.1%.
- The applicant projects the C-arm procedure ratio will be 0.15 C-arm procedures per office/clinic visit, or 15% of visits.

Projected C-arm/Fluoroscopy Utilization

Assumptions		CY2018	CY2019	CY2020	CY2021	CY2022
Clinic Visits Base Year CY2017	2,341					
Projected Annual Increase	2.1%	2,390	2,439	2,492	2,542	2,594
Ratio of C-arm to Clinic Visits	15%	358	366	373	381	389

Pediatric Echocardiography Procedures

- The applicant projects DOA clinic visits will increase in proportion to the Wake County population growth rate of 2.1%.
- The applicant projects the echocardiography procedure ratio will be 0.9047 echocardiogram procedures per office/clinic visit, or 90.47% of visits.

Projected Echocardiography/Ultrasound Utilization

Assumptions		CY2018	CY2019	CY2020	CY2021	CY2022
Clinic Visits Base Year CY2017	2,234					
Projected Annual Increase	2.1%	2,280	2,328	2,376	2,425	2,476
Ratio of Echos to Clinic Visits	90.47%	2,063	2,106	2,150	2,194	2,240

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

- Projected utilization is based on historical utilization for each specific diagnostic procedure type, applying assumptions based on PDC practice experience.
- Proposed additional access to services is expected to support ongoing diagnostic services.
- Projected population increase and aging in the service area is expected to support ongoing diagnostic services.

Access

In Section C.11, page 34, the applicant discusses access to the proposed services.

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 classify a patient as underserved."

In Section L.1(a), pages 78-79, the applicant indicates that 53.5% and 61.9% of PDC current services 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.

In Section L.3(a), page 81, the applicant provides the projected payor mix for the proposed diagnostic center for the X-ray, C-arm and Echocardiography(Ultrasound) service components for the second full fiscal year of operation following completion of the project, CY2021, as summarized in the following table.

DUKE HEALTH CENTER APEX
DIAGNOSTIC CENTER
FY2021

Payor Source	X-ray (Orthopaedics)	C-arm (Orthopaedics)	Echocardiography/ Ultrasound (Cardiology)
Self-Pay/Charity Care	2.55%	2.55%	0.67%
Medicare*	28.03%	28.03%	0.00%
Medicaid *	0.00%	0.00%	27.82%
Insurance*	67.97%	67.97%	59.28%
Other (Government)	1.45%	1.45%	12.23%
TOTAL	**100.00%**	**100.00%**	**100.00%**

* Includes any managed care plans
Totals may not sum due to rounding

The applicant includes the assumptions for the proposed payor mix by service in Section L.3(b), page 81. Exhibit 9 includes PDC's non-discrimination, charity, and financial assistance policies.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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 health service facility or health service. The applicant proposes to establish a new diagnostic center. 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 proposes to develop a new diagnostic center, DHCA, in Apex, Wake County, by co-locating two existing PDC physician clinics, DOA and DPCC, including their medical diagnostic equipment, in common leased MOB space.

In Section E.2, pages 44-45, 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 existing medical diagnostic equipment is typically found in specialty practices and is used for the evaluation and diagnosis of diseases and illnesses. For PDC to provide the standard of care for its physician clinics at the proposed DHCA site, the existing medical diagnostic equipment is necessary. The applicant states that the project is also expected to improve access and increase cost efficiencies. Therefore, maintaining status quo is not an effective alternative.

2. Develop the Proposed Diagnostic Center in Another Location – the applicant states that developing the proposed diagnostic center in a different location would not be effective

given the location of DOA. Additionally, co-locating DPCC alongside DOA, and establishing the proposed DHCA diagnostic center will optimize synergies and promote resource-sharing opportunities for more cost-effective care delivery. Furthermore, managing the specialty ambulatory care center without diagnostic and treatment services is not an effective alternative because the lack of onsite diagnostic services could result in additional burdens on patients due to the need to travel elsewhere for services and would cause delays in treatment, which may cause negative treatment outcomes. Therefore, developing the proposed diagnostic center in another location is not an effective alternative.

3. Acquire Different Quantities of Medical Diagnostic Equipment – the applicant did not discuss this alternative; however, the medical diagnostic equipment is existing equipment owned by the two physician groups that will be co-located at the proposed facility. Therefore, the quantities of equipment are already set.

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

On pages 44-45, the applicant states that its proposal is the most effective alternative because in order to provide the standard of care required for the physician clinics at the proposed DHCA site, the existing medical diagnostic equipment is necessary. The project is also expected to improve access and increase cost efficiencies.

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

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

Conclusion

The Agency reviewed the:

- application, and
- 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 shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Private Diagnostic Clinic, PLLC shall materially comply with the last made representation.

2. Private Diagnostic Clinic, PLLC shall develop a new diagnostic imaging center with existing X-ray, C-arm and Echocardiography medical diagnostic 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

The applicant proposes to develop a new diagnostic center, DHCA, in Apex, Wake County, by co-locating two existing PDC physician clinics, DOA and DPCC, including their medical diagnostic equipment, in common leased MOB space.

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.

Duke Health Center Apex
Capital Cost

Construction Costs/Renovation	$105,000
Medical Equipment	$605,237
Consultant Fees/Other	$50,000
Total	**$760,237**

In Section F.1(b), page 46, and Section Q, the applicant provides the assumptions used to project the capital cost. PDC will upfit leased space within the existing MOB. PDC will incur the tenant improvement costs via the facility lease agreement. Thus, the facility lease costs are operational. The applicant states:

> *"PDC leases the digital radiology system, mobile C-arm, and ultrasound system via an equipment lease with First Citizens Band. Although PDC leases both the facility and all the medical diagnostic equipment, the project capital cost table on the following page reflects all of these project costs, plus the CON consultant and application fees."*

The applicant further states that the lessor will not own or operate the diagnostic center and thus is not a co-applicant for the CON project. Supporting documentation can be found in Exhibits 2, 3, 4 and 7.

In Section F, pages 48-49, the applicant projects that start-up costs will be $25,000 and initial operating expenses will be $25,000 for a total working capital of $50,000. In Section Q, Financial Assumptions, Assumption (10), the applicant provides the assumptions used to project the working capital needs of the project.

Availability of Funds

In Section F, page 47, the applicant states that the capital cost will be funded as shown below in the table.

Sources of Capital Cost Financing

Type	PDC	Total
Loans	$0	$0
Accumulated reserves or OE *	$50,000	$50,000
Bonds	$0	$0
Other (Equipment Leases)	$605,237	$605,237
Other (Facility Lease)	$105,000	$105,000
**Total Financing ** **	**$760,237**	**$760,237**

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

In Section F, page 49, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital

	Type	Amount
(a)	Loans	$0
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	$50,000
(c)	Lines of credit	$0
(d)	Bonds	$0
(e)	**Total ***	**$50,000**

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

See Exhibits 2, 3, 4, and 7 for documentation of the lease agreements, PDC's commitment to fund the project, and First Citizen Bank's documentation of available funding for the proposed project working capital cost.

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 full fiscal years of the project, as shown below in the table.

Duke Health Center Apex
Diagnostic Center

	1st Full FY CY2020	2nd Full FY CY2021	3rd Full FY CY2022
Total Procedures	4,067	4,151	4,238
Total Gross Revenues (Charges)	$ 2,141,280	$ 2,251,335	$ 2,367,046
Total Net Revenue	$ 541,002	$ 568,808	$ 598,043
Average Net Revenue per Procedure	$ 133	$ 137	$ 141
Total Operating Expenses (Costs)	$ 535,294	$ 546,979	$ 559,061
Average Operating Expense per Procedure	$ 132	$ 132	$ 132
Net Income	**$ 5,709**	**$ 21,829**	**$ 38,982**

Totals may not sum due to rounding
Source: Pro forma Form Cs
Note: Total procedures, revenues and expenses are the sum for all X-ray and Ophthalmic services

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, and
- 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 proposes to develop a new diagnostic center, DHCA, in Apex, Wake County, by co-locating two existing PDC physician clinics, DOA and DPCC, including their medical diagnostic equipment, in common leased MOB space.

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.4, page 27, the applicant defines the service area for the proposed diagnostic center as Wake County, though the center will serve patients from outside the designated service area.

In Section G.1, pages 55-56, the applicant identifies two PDC diagnostic centers in Wake County, approved through: CON Project ID #J-8167-08, Duke Orthopaedics-Knightdale, which PDC states acquired an X-ray machine in July 2018 and performed 795 procedures from July 1 through September 30, 2018; and Project ID #J-11532-18 in Raleigh, for which the certificate was issued in October 2018.

On page 55, 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*:"

The following table summarizes the information provided by the applicant on pages 56-57 regarding existing and approved X-ray and C-arm (Fluoroscopy) services in Wake County.

Approved and Existing Health Service Facilities Offering Medical Diagnostic Services in Wake County

Facility	Type	X-ray		Fluoroscopy	
		Inventory	FY2017 Procedures	Inventory	FY2017 Procedures
WakeMed Hospital	Hospital	13	151,255	5	2,106
WakeMed Cary Hospital	Hospital	4	39,633	4	2,613
Duke Raleigh Hospital	Hospital	3	39,649	2	3,782
UNC Rex Hospital	Hospital	12	89,993	3	5,396
Raleigh Radiology Cedarhurst	Diagnostic Center	*	*	*	*
Raleigh Radiology Blue Ridge	Diagnostic Center	*	*	*	*
Wake Radiology	Diagnostic Center	*	*	*	*
Wake Radiology-Raleigh	Diagnostic Center	*	*	*	*
Wake Radiology-Garner	Diagnostic Center	*	*	*	*
Raleigh Orthopaedic Clinic	Diagnostic Center	*	*	*	*

Applicant's source: 2018 Hospital License Renewal Applications (LRAs).
*Not available

In Section G, page 56, the applicant states:

> *"To PDC's knowledge, utilization data for medical diagnostic equipment located in diagnostic centers is not collected by any state agency or regulatory body.*
>
> *To PDC's knowledge, utilization data for pediatric echocardiology equipment is not collected by any state agency or regulatory body, nor is it reported on the annual hospital license renewal applications."*

In Section G.3, page 58, 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 relocation of the identified PDC medical diagnostic equipment will result in the establishment of a new diagnostic center in Apex. PDC's proposal will not result in unnecessary duplication of existing or approved health service capabilities. PDC adequately demonstrates the need to maintain and relocate the identified medical diagnostic equipment. See Section C, Criterion (3) for discussion. The identified need is internal to PDC, as it involves PDC specialty clinics and the medical diagnostic equipment necessary to support the clinicians in their care of patients. No other provider can or should provide for the internal clinical diagnostic needs at PDC.*
>
> *PDC is the sole provider group to Duke University Health System. PDC's continued growth depends on the development and expansion of PDC specialty practices to serve Wake County and surrounding communities. The proposed diagnostic center is needed by the orthopaedic and cardiology providers who will practice at Duke Health Center Apex, to aid them in diagnosing their patients' illnesses or conditions.*

Further, because the diagnostic center will be located within the respective specialty clinics, 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, and
- 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 full-time equivalent (FTE) staffing for the proposed services for the first three operating years, as shown in the table below.

Duke Health Center Apex
Proposed Diagnostic Center Staffing

Position	FY2020 FTE	FY2021 FTE	FY2022 FTE
RNs (ACN II)	0.1	0.1	0.1
LPNs	0.1	0.1	0.1
X-ray Radiology Technologist	1.5	1.5	1.5
Sonographer	1.0	1.0	1.0
Othopaedic Administrator	0.1	0.1	0.1
Pediatrics Administrator	0.1	0.1	0.1
Financial Care Counselor	0.1	0.1	0.1
Patient Service Associate	0.3	0.3	0.3
TOTAL	**3.30**	**3.30**	**3.30**

In Section H.1, page 60, 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 Form F.4 and Form H, which are found in Section Q. In Section H.2 and H.3, pages 60-62, 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 62-63, 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 62, the applicant identifies David Attarian, M.D. as the existing Medical Director of PDC. Dr. Attarian's letter expressing support and willingness to continue to serve as Medical Director for the proposed services at PDC and the proposed diagnostic center is included in Exhibit 5. The applicant provides additional letters of support documentation in Exhibit 12.

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

Conclusion

The Agency reviewed the:

- application, and
- 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

In Section I.1(b), page 65, the applicant states that the following ancillary and support services are necessary for the proposed services and explains how the necessary services will be made available:

- patient scheduling,
- accounting and billing,
- medical records,
- human resources/payroll,
- staff education,
- infection control,
- quality and performance improvement,
- information technology, and
- housekeeping/linens.

Although the applicant proposes a new diagnostic center, PDC is not a new provider. In Section I.2(b), page 66, the applicant discusses PDC's relationships with the referring physician community in Wake and surrounding counties and its ongoing relationship with DUHS. Exhibit 12 of the application contains support letters from physicians expressing support for the proposed project. The applicant adequately demonstrates that the necessary ancillary and support services will be made available and that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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 an 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

The applicant proposes to develop a new diagnostic center, DHCA, in Apex, Wake County, by co-locating two existing PDC physician clinics, DOA and DPCC, including their medical diagnostic equipment, in common leased MOB space.

In Section K.3, page 69, the applicant states that the project involves the upfit of 511 square feet(SF) of space within an existing MOB (325 SF for orthopaedic diagnostic equipment and186 SF for pediatric cardiology diagnostic equipment). Exhibit 6 contains line drawings. The applicant states that the space noted above represents only what is necessary to house and make operational the medical diagnostic equipment, and not all the physician clinic space.

In Section K.4(a), page 70, 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.

Also on page 70, 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 provides supporting documentation in Section Q and Exhibit F.1.

On page 71, the applicant identifies applicable energy saving features that will be incorporated into the upfit/renovation 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, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

(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.1(a), page 78, the applicant discusses payor mix and states that the proposed diagnostic center is not an existing health service facility. In supplemental information requested by the Agency during the expedited review of this application, the applicant provides the payor mix for CY2017 for PDC Wake County orthopaedic diagnostic X-ray and C-arm services and for the existing pediatric cardiology (Echocardiography/Ultrasound) services being relocated from Cary, as shown below.

Payor Category	Entire Facility	X-ray (Orthopaedics)	C-arm (Orthopaedics)	Ultrasound (Cardiology)
Self-Pay	NA	2.55%	2.55%	0.67%
Medicare*	NA	28.03%	28.03%	0.00%
Medicaid*	NA	0.00%	0.00%	27.82%
Insurance*	NA	67.97%	67.97%	59.28%
Other (Gov't)	NA	1.45%	1.45%	12.23%
Total	NA	**100.00%**	**100.00%**	**100.00%**

Totals may not sum due to rounding
*Including any managed care plans

In Section L.1(a), page 79, the applicant provides the demographics of Wake County patients who currently use PDC services compared to the demographics of the Wake County service area, as summarized below.

	Percentage of Total Patients Served by PDC during the Last Full FY	Percentage of the Population of the Service Area (Wake County)
Female	53.5%	51.3%
Male	46.5%	48.7%
Unknown	0.0%	0.0%
64 and Younger	38.1%	88.8%
65 and Older	61.9%	11.2%
American Indian	*	0.8%
Asian	*	7.2%
Black or African-American	*	21.1%
Native Hawaiian or Pacific Islander	*	0.1%
White or Caucasian	*	60.6%
Other Race	*	10.2%
Declined / Unavailable	*	0.0%

Sources: PDC and US Census Bureau
*PDC does not track racial and ethnic minority data on its patients

The Agency reviewed the:

- application,
- exhibits to the application, and
- supplemental information requested by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medical underserved population 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. Therefore, the application is conforming to this criterion.

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

C

In Section L.2(b), 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 81-82 and includes its patient financial assistance policies in Exhibit 9.

In Section L.2(c-d), page 80, the applicant states that there have been no patient civil rights equal access complaints filed against similar PDC facilities in the past five years.

The Agency reviewed the:

- application, and
- exhibits to the application.

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 81, 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.

Duke Health Center Apex
Proposed Payor Mix
CY2021

Payor Category	Entire Facility	Flat Film X-ray (Orthopaedics)	C-arm (Orthopaedics)	Echocardiography/ Ultrasound (Cardiology)
Self-Pay/Charity Care	NA	2.55%	2.55%	0.67%
Medicare*	NA	28.03%	28.03%	0.00%
Medicaid*	NA	0.00%	0.00%	27.82%
Insurance*	NA	67.97%	67.97%	59.28%
Other (Gov't)	NA	1.45%	1.45%	12.23%
Total	NA	**100.00%**	**100.00%**	**100.00%**

Totals may not sum due to rounding
*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.55% of total orthopaedic diagnostic services will be provided to self-pay and charity care patients with 28.03% provided to Medicare patients. Also, the applicant projects that 0.67% of total cardiology diagnostic services will be provided to self-pay and charity care patients with 27.82% provided to Medicaid patients.

In Section L.3(b), page 81, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal 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 for orthopaedic diagnostic services is based on the historical payor mix at similar orthopaedic diagnostic imaging services in Wake County during CY2017,
- the projected payor mix for cardiology diagnostic services is based on the existing pediatric cardiology services being relocated from Cary, and
- the applicant adequately demonstrates that medically underserved populations will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

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 82, the applicant describes the range of means by which a person will have access to the proposed services.

The Agency reviewed the:

- application, and
- 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

In Section M, page 84, 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, and
- exhibits to the application.

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

The applicant proposes to develop a new diagnostic center, DHCA, in Apex, Wake County, by co-locating two existing PDC physician clinics, DOA and DPCC, including their medical diagnostic equipment, in common leased MOB space.

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.4, page 27, the applicant defines the service area for the proposed diagnostic center as Wake County, though the center will serve patients from outside the designated service area.

In Section G.1, pages 55-56, the applicant identifies two PDC diagnostic centers in Wake County, approved through: CON Project ID #J-8167-08, Duke Orthopaedics-Knightdale, which PDC states acquired an X-ray machine in July 2018 and performed 795 procedures from July 1 through September 30, 2018; and Project ID #J-11532-18 in Raleigh, for which the certificate was issued in October 2018.

On page 55, 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:*"

The following table summarizes the information provided by the applicant on pages 56-57 regarding existing and approved X-ray and C-arm (Fluoroscopy) services in Wake County.

Approved and Existing Health Service Facilities Offering Medical Diagnostic Services in Wake County

Facility	Type	Flat Film X-ray		Fluoroscopy	
		Inventory	FY2017 Procedures	Inventory	FY2017 Procedures
WakeMed Hospital	Hospital	13	151,255	5	2,106
WakeMed Cary Hospital	Hospital	4	39,633	4	2,613
Duke Raleigh Hospital	Hospital	3	39,649	2	3,782
UNC Rex Hospital	Hospital	12	89,993	3	5,396
Raleigh Radiology Cedarhurst	Diagnostic Center	*	*	*	*
Raleigh Radiology Blue Ridge	Diagnostic Center	*	*	*	*
Wake Radiology	Diagnostic Center	*	*	*	*
Wake Radiology-Raleigh	Diagnostic Center	*	*	*	*
Wake Radiology-Garner	Diagnostic Center	*	*	*	*
Raleigh Orthopaedic Clinic	Diagnostic Center	*	*	*	*

Applicant's source: 2018 Hospital License Renewal Applications (LRAs).
*Not available

In Section G, page 56, the applicant states:

> *"To PDC's knowledge, utilization data for medical diagnostic equipment located in diagnostic centers is not collected by any state agency or regulatory body.*
>
> *To PDC's knowledge, utilization data for pediatric echocardiology equipment is not collected by any state agency or regulatory body, nor is it reported on the annual hospital license renewal applications."*

In Section N, pages 85-89, 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 85, the applicant states:

> "*With this proposed project, PDC is offering medical diagnostic imaging services at a convenient location in Apex in order to improve patient access to quality, cost-effective diagnostic care. As a new diagnostic imaging center, DHCA will have a positive effect on 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 better meet the needs of PDC's existing patient population, and to 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 providers of medical diagnostic services in Wake County, as PDC physicians have been longtime existing providers of these medical diagnostic services in Wake County."*

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, and
- 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.3, pages 94-95, the applicant identifies the diagnostic centers located in Wake and Durham counties in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of five operational facilities and one recently approved facility of this type.

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 and operated in compliance with Medicare Conditions of Participation 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, DHCA, in Apex, Wake County, by co-locating two existing PDC physician clinics, DOA and DPCC, including their medical diagnostic equipment, in common leased MOB space.

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.