

## 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-11616-18

Facility: Duke Health Holly Springs

FID #: 180516

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 Holly Springs (DukeHHS), at 401 Irving Parkway, Holly Springs, Wake County. The diagnostic center will be in leased space in a medical office building (MOB) owned by Duke University Health System (DUHS). PDC, the applicant, is the Duke Health physician practice, but is not owned or operated by DUHS.

The applicant plans to co-locate the existing Carolina Family Practice and Sports Medicine (CFPSM) clinic, which is located in Holly Springs; and a new ophthalmology clinic, Duke Eye Center Holly Springs (DECHS), which will be part of the Duke Eye Center network, in leased space in an existing MOB.

CFPSM operates an existing x-ray machine and the new ophthalmology clinic, DECHS, will require additional medical diagnostic equipment as listed on page 17 of the application. The

applicant states that the existing and new medical diagnostic equipment is needed to support both the existing clinic to be relocated and the proposed new physician clinic. The combined cost of the existing and proposed new medical diagnostic equipment 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).

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 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 the existing CFPSM clinic and a new ophthalmology clinic, DECHS, in leased space in an existing MOB. Combining the medical diagnostic equipment necessary to operate the two clinics will establish a new diagnostic center, DukeHHS, in Holly Springs, Wake County.

In Section C.1, pages 16-22, the applicant describes the proposed project and discusses the medical diagnostic equipment. The existing CFPSM clinic is a primary care clinic offering family medicine and sports medicine services in Holly Springs. The new ophthalmology clinic, DECHS, will offer ophthalmic services, including general eye exams and diagnosis/management of cataracts, corneal diseases, and glaucoma.

#### Designation as a Diagnostic Center

In Exhibit 4, the applicant provides a listing of the cost of the existing x-ray equipment and the proposed new medical diagnostic equipment which will establish the proposed diagnostic center. 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 CON.

#### Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 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 29, 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 23 and 24, the applicant provides CFPSM’s historical and projected patient origin for CFPSM, respectively, as summarized in the table below.

**CAROLINA FAMILY PRACTICE AND SPORTS MEDICINE  
 HISTORICAL AND PROJECTED PATIENT ORIGIN  
 X-RAY EQUIPMENT**

COUNTY	HISTORICAL PATIENT ORIGIN CY2017	PROJECTED PATIENT ORIGIN CY2020-2022
	% OF TOTAL	% OF TOTAL
Wake	93.1%	93.1%
Harnett	1.6%	1.6%
Chatham	1.2%	1.2%
Johnston	0.9%	0.9%
Lee	0.5%	0.5%
Durham	0.5%	0.5%
Orange	0.4%	0.4%
Other*	1.7%	1.7%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

\*Other includes <2% patient origin from the remaining counties in NC and other states.  
 Totals may not foot due to rounding.

In Section C, page 25, the applicant provides the projected patient origin for the proposed new DECHS facility.

**DUKE EYE CENTER OF HOLLY SPRINGS  
 PROJECTED PATIENT ORIGIN  
 OPHTHALMIC DIAGNOSTIC EQUIPMENT**

COUNTY	% OF TOTAL
Wake	70.7%
Durham	3.9%
Johnston	3.0%
Orange	2.3%
Chatham	1.5%
Harnett	1.4%
Lee	1.0%
Other*	16.4%
<b>Total</b>	<b>100.0%</b>

\*Other includes <17% patient origin from the remaining counties in NC and other states.  
 Totals may not foot due to rounding.

In Section C.3(c), page 26, the applicant states that assumptions regarding projected patient origin for CFPSM are based on CFPSM's patient origin for clinic visits during CY2017. The applicant states that clinic patients are the same patients who will utilize the existing x-ray; therefore, PDC determined the recent clinic patient origin is a reasonable proxy for projecting patient origin for CFPSM because it does not anticipate a significant change in patient origin as a result of the proposed project.

In Section C.3(c), page 26, the applicant states that assumptions regarding projected patient origin for the proposed DECHS are based on the patient origin of Duke Eye Center Cary, which is also located in southern Wake County and provides similar outpatient ophthalmic services.

The applicant's assumptions are reasonable and adequately supported.

### **Analysis of Need**

In Section C.4, pages 26-30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

On page 26, the applicant states that the need for the proposed project is based on numerous qualitative and quantitative factors, including:

- The existing and proposed diagnostic equipment is integral to the applicant's continuum of primary care, sports medicine and ophthalmic services. (pages 27-28)
- The proposed project will enable the applicant to provide cost effective services to meet patient expectations and to ensure quality care. (page 28)
- The projected growth of the service area population presumes continued increases in demand for healthcare. (pages 29-30)

### **Continuum of Care - Access and Quality**

In Section C.1, pages 17-22, the applicant discusses each piece of diagnostic equipment to be located at the facility and its function and benefits, including the x-ray equipment and the proposed ophthalmic equipment. On pages 27-28, the applicant states that the identified medical diagnostic equipment is required to aid physicians in diagnosing a patient's condition, illness, or disease. The applicant states that the existing digital x-ray machine supports the existing CFPSM practice and is integral to its continuum of orthopaedic services. The applicant states that the proposed new DECHS facility will enhance geographic access to Duke Eye Center services and may also relieve some of the backlog at existing clinic sites. The applicant further states that the proposed ophthalmic equipment is essential in the evaluation and diagnosis of ophthalmic conditions and diseases. Furthermore, the applicant believes the co-location of the clinics with the diagnostic center at the new Duke Health Holly Springs site will facilitate expanded services via recruitment of incremental physicians for several specialty practices.

### **Cost Effectiveness**

On page 28, the applicant states:

*"The co-location of Duke Health practices to the new Duke Health Holly Springs 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.*

...

*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 page 29, 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. In addition, the aging population in Wake County is projected to increase at rates more than two times the overall population growth rates. On page 30, the applicant states that this is relevant to the need for the proposed new diagnostic services given the correlation between aging and disease incidence. The applicant further states:

*"In summary, the projected population supports the ongoing need for the existing diagnostic equipment to be located in the proposed diagnostic center. The proposed diagnostic center is needed to ensure timely access to cost effective physician-based services for service area residents."*

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

- The applicant documents the existing and proposed medical diagnostic equipment is essential for cost effective delivery of quality care for the applicant's facilities' patients.
- The co-location of Duke Health practices to the new DukeHHS diagnostic center is expected to optimize synergies and promote resource-sharing.
- The projected growth and aging 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 Holly Springs  
 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 C 2022
<b>X-ray</b>						
# Units	1	1	1	1	1	1
# Procedures	430	439	448	457	467	477
<b>Slit Lamp</b>						
# Units	NA	NA	NA	21	21	21
# Procedures	NA	NA	NA	12,397	13,947	15,497
<b>Visual Field Units</b>						
# Units	NA	NA	NA	2	2	2
# Procedures	NA	NA	NA	456	513	570
<b>Optical Biometry</b>						
# Units	NA	NA	NA	2	2	2
# Procedures	NA	NA	NA	490	552	613
<b>Optical Coherence Tomography</b>						
# Units	NA	NA	NA	2	2	2
# Procedures	NA	NA	NA	2,451	2,757	3,064
<b>Corneal Topography</b>						
# Units	NA	NA	NA	2	2	2
# Procedures	NA	NA	NA	58	65	72
<b>Topcon Autorefractor</b>						
# Units	NA	NA	NA	3	3	3
# Procedures	NA	NA	NA	6,199	6,973	7,748
<b>Topcon Fundus Camera</b>						
# Units	NA	NA	NA	1	1	1
# Procedures	NA	NA	NA	68	77	85
<b>Ophthalmic Ultrasound</b>						
# Units	NA	NA	NA	1	1	1
# Procedures	NA	NA	NA	29	32	36
<b>Lipiview</b>						
# Units	NA	NA	NA	1	1	1
# Procedures	NA	NA	NA	620	697	775

In Section Q, pages 100-111, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

CFPSM X-ray

- The applicant projects CFPSM clinic visits will increase in proportion to the Wake County population growth rate of 2.1%.
- The applicant projects X-ray procedures will be 4% of the total clinic visits at CFPSM.

**Projected X-ray Utilization**

Assumptions		CY2018	CY2019	CY2020	CY2021	C 2022
Clinic Visits Base Year CY2017	10,500					
Projected Increase for Total Clinic Visits	2.1%	10,718	10,941	11,168	11,400	11,637
Ratio of X-ray to Clinic Visits, Resulting in Total Projected X-rays	4%	439	448	457	467	477

Totals may not sum due to rounding

Slit Lamps

- The project includes the acquisition of 21 slit lamps.
- Every DECHS clinic visit includes a slit lamp exam, which may be done for multiple reasons.
- Based on experience, the applicant projects that each of the four physicians at DECHS will perform 3,874 slit lamp procedures at full utilization ( $30,993 / 8 = 3,874$ ).
- The applicant adjusts the projected annual slit lamp procedures for a ramp up of 80%, 90% and 100% for the first three years, respectively.

**Projected Slit Lamp Utilization**

Assumptions		CY2020	CY2021	C 2022
# of Procedures at Duke Eye Center of Cary CY2017	30,993			
# of Duke Eye Center Cary Physicians	8			
Slit Lamp Procedures per Physician	3,874			
# of Duke Eye Center Holly Springs Physicians, Resulting in Total Potential Procedures	4	15,497	15,497	15,497
Ramp Up CY2020	80%	12,397		
Ramp Up CY2021	90%		13,947	
Ramp Up CY2022	100%			15,497

Totals may not sum due to rounding

Visual Fields- Humphrey Field Analyzer and Octopus

- The project includes the acquisition of two Humphrey Field Analyzers and two Octopus machines – utilization is not differentiated by visual field exam type.
- Based on experience, the applicant projects that each of the four physicians at DECHS will perform 142 visual field procedures at full utilization ( $1,139 / 8 = 142$ ).



- The applicant adjusts the projected annual visual field procedures for a ramp up of 80%, 90% and 100% for the first three years, respectively.

**Projected Visual Field Utilization (HFA & Octopus)**

Assumptions		CY2020	CY2021	C 2022
# of Procedures at Duke Eye Center of Cary CY2017	1,139			
# of Duke Eye Center Cary Physicians	8			
Visual Field Procedures per Physician	142			
# of Duke Eye Center Holly Springs Physicians, Resulting in Total Potential Procedures	4	570	570	570
Ramp Up CY2020	80%	456		
Ramp Up CY2021	90%		513	
Ramp Up CY2022	100%			570

Totals may not sum due to rounding

Optical Biometry

- The project includes the acquisition of two optical biometry units: one Lenstar and one IOLMaster – utilization is not differentiated optical biometry type.
- Based on experience, the applicant projects that each of the four physicians at DECHS will perform 153 optical biometry procedures at full utilization ( $1,226 / 8 = 153$ ).
- The applicant adjusts the projected annual procedures for a ramp up of 80%, 90% and 100% for the first three years, respectively.

**Projected Optical Biometry Utilization**

Assumptions		CY2020	CY2021	C 2022
# of Procedures at Duke Eye Center of Cary CY2017	1,226			
# of Duke Eye Center Cary Physicians	8			
Optical Biometry Procedures per Physician	153			
# of Duke Eye Center Holly Springs Physicians, Resulting in Total Potential Procedures	4	613	613	613
Ramp Up CY2020	80%	490		
Ramp Up CY2021	90%		552	
Ramp Up CY2022	100%			613

Totals may not sum due to rounding

Optical Coherence Tomography

- The project includes the acquisition of two spectralis units: one 3-Mode and one 6-Mode – utilization is not differentiated by type.
- Based on experience, the applicant projects that each of the four physicians at DECHS will perform 766 optical coherence tomography procedures at full utilization ( $6,127 / 8 = 766$ ).
- The applicant adjusts the projected annual procedures for a ramp up of 80%, 90% and 100% for the first three years, respectively.

**Projected Optical Coherence Tomography Utilization**

Assumptions		CY2020	CY2021	C 2022
# of Procedures at Duke Eye Center of Cary CY2017	6,127			
# of Duke Eye Center Cary Physicians	8			
Optical Coherence Procedures per Physician	766			
# of Duke Eye Center Holly Springs Physicians, Resulting in Total Potential Procedures	4	3,064	3,064	3,064
Ramp Up CY2020	80%	2,451		
Ramp Up CY2021	90%		2,757	
Ramp Up CY2022	100%			3,064

Totals may not sum due to rounding

Corneal Topography

- The project includes the acquisition of two corneal topography units: one atlas and one pentacam – utilization is not differentiated by type.
- Based on experience, the applicant projects that each of the four physicians at DECHS will perform 18 corneal topography procedures at full utilization (144 / 8 = 18).
- The applicant adjusts the projected annual procedures for a ramp up of 80%, 90% and 100% for the first three years, respectively.

**Projected Corneal Topography Utilization**

Assumptions		CY2020	CY2021	C 2022
# of Procedures at Duke Eye Center of Cary CY2017	144			
# of Duke Eye Center Cary Physicians	8			
Corneal Topography Procedures per Physician	18			
# of Duke Eye Center Holly Springs Physicians, Resulting in Total Potential Procedures	4	72	72	72
Ramp Up CY2020	80%	58		
Ramp Up CY2021	90%		65	
Ramp Up CY2022	100%			72

Totals may not sum due to rounding

Topcon Autorefractor

- The project includes the acquisition of three Topcon autorefractors.
- Based on experience, the applicant projects utilization of the autorefractors at one-half of the procedures for the slit lamps with no ramp up.

**Projected Topcon Autorefractor Utilization**

Assumptions	CY2020	CY2021	C 2022
# of Slit Lamp Projected Procedures at DECHS	12,397	13,947	15,497
Ratio of Topcon Autorefractor Procedures to Slit Lamp Procedures	50%	50%	50%
# of Topcon Autorefractor Projected Procedures	6,199	6,973	7,748

Totals may not sum due to rounding

Topcon Fundus Camera

- The project includes the acquisition of one Topcon fundus camera.
- Based on experience, the applicant projects that each of the four physicians at DECHS will perform 21 Topcon fundus camera procedures at full utilization ( $170 / 8 = 21$ ).
- The applicant adjusts the projected annual procedures for a ramp up of 80%, 90% and 100% for the first three years, respectively.

**Projected Topcon Fundus Camera Utilization**

Assumptions	CY2020	CY2021	C 2022
# of Procedures at Duke Eye Center of Cary CY2017	170		
# of Duke Eye Center Cary Physicians	8		
Topcon Fundus Camera Procedures per Physician	21		
# of Duke Eye Center Holly Springs Physicians, Resulting in Total Potential Procedures	4	85	85
Ramp Up CY2020	80%	68	
Ramp Up CY2021	90%		77
Ramp Up CY2022	100%		85

Totals may not sum due to rounding

Ophthalmic Ultrasound (B-scan)

- The project includes the acquisition of one B-scan machine (ophthalmic ultrasound).
- Based on experience, the applicant projects that each of the four physicians at DECHS will perform 9 ultrasound procedures at full utilization ( $72 / 8 = 9$ ).
- The applicant adjusts the projected annual procedures for a ramp up of 80%, 90% and 100% for the first three years, respectively.

**Projected Ultrasound (B-scan) Utilization**

<b>Assumptions</b>		<b>CY2020</b>	<b>CY2021</b>	<b>C 2022</b>
# of Procedures at Duke Eye Center of Cary CY2017	72			
# of Duke Eye Center Cary Physicians	8			
B-scan Utrasound Procedures per Physician	9			
# of Duke Eye Center Holly Springs Physicians, Resulting in Total Potential Procedures	4	36	36	36
Ramp Up CY2020	80%	29		
Ramp Up CY2021	90%		32	
Ramp Up CY2022	100%			36

Totals may not sum due to rounding

Lipiview

- The project includes the acquisition of one lipiview machine.
- Based on experience, the applicant projects utilization of the lipiview at 5% of the procedures for the slit lamps with no ramp up.

**Projected Lipiview Utilization**

<b>Assumptions</b>	<b>CY2020</b>	<b>CY2021</b>	<b>C 2022</b>
# of Slit Lamp Procedures at DECHS	12,397	13,947	15,497
Ratio of Lipiview Procedures to Slit Lamp Procedures	5%	5%	5%
# of Lipiview Projected Procedures	620	697	775

Totals may not sum due to rounding

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 36, 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 80-81, the applicant states 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), pages 82-83, the applicant provides the projected payor mix for the proposed diagnostic center for the X-ray and ophthalmology service components for the second full fiscal year of operation following completion of the project, CY2021, as summarized in the following table.

**DUKE HEALTH HOLLY SPRINGS  
DIAGNOSTIC CENTER  
FY2021**

<b>Payor Source</b>	<b>Entire Facility</b>	<b>X-ray</b>	<b>Ophthalmology</b>
Self-Pay/Charity Care	NA	0.43%	11.66%
Medicare*	NA	13.76%	46.61%
Medicaid *	NA	0.18%	1.79%
Insurance*	NA	77.71%	38.33%
Other (Government)	NA	7.91%	1.59%
<b>TOTAL</b>	<b>NA</b>	<b>100.00%</b>	<b>100.00%</b>

\* 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 83. 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 co-locate the existing CFPSM clinic and a new ophthalmology clinic, DECHS, in common leased MOB space. Combining the medical diagnostic equipment necessary to operate the two clinics will establish a new diagnostic center, DukeHHS, in Holly Springs, Wake County.

In Section E.2, pages 46-48, 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 and proposed medical diagnostic equipment is typically found in specialty practices and is used for the evaluation and diagnosis of diseases and illnesses; and for PDC to provide the standard of care at the proposed DukeHHS site, the existing and proposed medical diagnostic equipment is necessary. 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 could hinder access for the existing patient population at CFPSM in Holly Springs. Additionally, locating the new ophthalmology clinic at DukeHHS alongside CFPSM 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 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 DukeHHS. 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 PDC, a joint venture would not be an effective alternative.

On pages 46-47, the applicant states that its proposal is the most effective alternative because in order to provide the standard of care required at the proposed DukeHHS site, the existing and proposed diagnostic equipment is necessary. The applicant further states that 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 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 X-ray and ophthalmology 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, DukeHHS, in Holly Springs, Wake County by co-locating the existing CFPSM clinic and a new ophthalmology clinic, DECHS, 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 Holly Springs  
Capital Cost**

Construction Costs/Renovation	\$536,000
Medical Equipment	\$1,311,746
Consultant Fees/Other	\$55,000
<b>Total</b>	<b>\$1,902,746</b>



In Section F.1(b), page 49, and Section Q, the applicant provides the assumptions used to project the capital cost. PDC will lease space within the new MOB. PDC will incur the tenant improvement costs via the facility lease agreement. Thus, the facility lease costs are operational. The equipment will also be leased. The applicant states that although PDC leases both the facility and all the medical diagnostic equipment, the project capital cost table reflects all of those project costs. 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 51-52, the applicant projects that start-up costs will be \$50,000 and initial operating expenses will be \$40,000 for a total working capital of \$90,000. 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 50, 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 *	\$45,000	\$45,000
Bonds	\$0	\$0
Other (Equipment Leases)	\$1,321,746	\$1,321,746
Other (Facility Lease)	\$536,000	\$536,000
<b>Total Financing **</b>	<b>\$1,902,746</b>	<b>\$1,902,746</b>

\* OE = Owner's Equity.

\*\*Total financing should equal line 14 in Form F.1a Capital Cost.

In Section F, pages 52-53, 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	\$90,000
(c)	Lines of credit	\$0
(d)	Bonds	\$0
(e)	<b>Total *</b>	<b>\$90,000</b>

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

See Exhibits 2, 3, and 4 for documentation of the lease agreements and Exhibit 7 for 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 Holly Springs  
 Diagnostic Center**

	<b>1<sup>st</sup> Full FY CY2020</b>	<b>2<sup>nd</sup> Full FY CY2021</b>	<b>3<sup>rd</sup> Full FY CY2022</b>
Total Procedures	23,224	26,080	28,936
Total Gross Revenues (Charges)	\$ 2,991,119	\$ 3,458,783	\$ 3,951,846
Total Net Revenue	\$ 1,294,303	\$ 1,497,808	\$ 1,712,452
Average Net Revenue per Procedure	\$ 56	\$ 57	\$ 59
Total Operating Expenses (Costs)	\$ 1,188,088	\$ 1,233,368	\$ 1,280,581
Average Operating Expense per Procedure	\$ 51	\$ 47	\$ 44
<b>Net Income</b>	<b>\$ 106,214</b>	<b>\$ 264,440</b>	<b>\$ 431,871</b>

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, DukeHHS, in Holly Springs, Wake County by co-locating the existing CFPSM clinic and a new ophthalmology clinic, DECHS, 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 29, 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 58-60, 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 58, 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, i.e. X-ray machines:”*

The following table summarizes the information provided by the applicant on pages 59-60 regarding existing and approved X-ray services in Wake County.

**Approved and Existing Health Service Facilities Offering X-ray in Wake County**

Facility	Type	County	X-ray	
			Inventory	FY2017 Procedures
WakeMed Hospital	Hospital	Wake	13	151,255
WakeMed Cary Hospital (All sites)	Hospital	Wake	4	39,633
Duke Raleigh Hospital	Hospital	Wake	3	39,649
UNC Rex Hospital	Hospital	Wake	12	89,993
Raleigh Radiology Cedarhurst	Diagnostic Center	Wake	*	*
Raleigh Radiology Blue Ridge	Diagnostic Center	Wake	*	*
Wake Radiology	Diagnostic Center	Wake	*	*
Wake Radiology-Raleigh	Diagnostic Center	Wake	*	*
Wake Radiology-Garner	Diagnostic Center	Wake	*	*
Raleigh Orthopaedic Clinic	Diagnostic Center	Wake	*	*

Applicant’s source: 2018 Hospital License Renewal Applications (LRAs).

\*Not available

In Section G, page 59, 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 ophthalmic diagnostic 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 60, 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 medical diagnostic equipment will result in the establishment of a new diagnostic center. 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 them. 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 ophthalmic providers who will practice at Duke Health Holly Springs, 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 in for the proposed services for the first three operating years, as shown in the table below.

**Duke Health Holly Springs  
Proposed Diagnostic Center Staffing**

<b>Position</b>	<b>FY2020 FTE</b>	<b>FY2021 FTE</b>	<b>FY2022 FTE</b>
Ophthalmology Technician	5.00	5.00	5.00
X-ray Radiology Technologist	0.10	0.10	0.10
X-ray Supervisor	0.03	0.03	0.03
CFPSM Administrator	0.33	0.33	0.33
Eye Administrator	0.03	0.03	0.03
Patient Service Associate - Eye	1.00	1.00	1.00
Patient Service Associate - CFPSM	0.05	0.05	0.05
<b>TOTAL</b>	<b>6.54</b>	<b>6.54</b>	<b>6.54</b>

In Section H.1, page 62, 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 62-64, 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 64-65, 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 64, 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 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, 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 67, 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 68, the applicant discusses PDC's relationships with the referring physician community in Wake and surrounding counties and its ongoing relationship with DUHS. Exhibit 11 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, DukeHHS, in Holly Springs, Wake County by co-locating the existing CFPSM clinic and a new ophthalmology clinic, DECHS, including their medical diagnostic equipment, in common leased MOB space.

In Section K.2, page 71, the applicant states that the project involves the upfit of 3,575 square feet (SF) of space within the existing MOB (3,368 SF for ophthalmology diagnostic equipment and 207 SF for CFPSM X-ray equipment). Exhibit 6 contains line drawings. The applicant states that the space noted above represents only what is necessary to house or make operational the medical diagnostic equipment, and not all the physician clinic space.

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.

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 provides 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 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 80, the applicant discusses payor mix and states that the proposed DukeHHS 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 provided the following payor mix information for CY2017 for X-ray services at CFPSM and ophthalmology services at Duke Eye Center of Cary.

<b>Payor Category</b>	<b>Entire Facility</b>	<b>X-ray</b>	<b>Ophthalmology</b>
Self-Pay	NA	0.43%	11.66%
Medicare*	NA	13.76%	46.61%
Medicaid*	NA	0.18%	1.79%
Insurance*	NA	77.71%	38.33%
Other (Gov't)	NA	7.91%	1.59%
<b>Total</b>	NA	<b>100.00%</b>	<b>100.00%</b>

Totals may not sum due to rounding.

\*Including any managed care plans

Section L.1(a), page 81, 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.

	<b>Percentage of Total Patients Served by PDC during the Last Full FY</b>	<b>Percentage of the Population of the Service Area (Wake County)</b>
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 82, 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-d), page 82, 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 83, 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 Holly Springs  
Proposed Payor Mix  
CY2021**

<b>Payor Category</b>	<b>Entire Facility</b>	<b>X-ray</b>	<b>Ophthalmology</b>
Self-Pay/Charity Care	NA	0.43%	11.66%
Medicare*	NA	13.76%	46.61%
Medicaid*	NA	0.18%	1.79%
Insurance*	NA	77.71%	38.33%
Other (Gov't)	NA	7.91%	1.59%
<b>Total</b>	<b>NA</b>	<b>100.00%</b>	<b>100.00%</b>

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 0.43% and 11.66% of total services will be provided to self-pay and charity care patients for X-ray and Ophthalmology, respectively. Also, the applicant projects that 13.76% and 46.61% of total services will be provided to Medicare patients for X-ray and Ophthalmology, respectively; and 0.18% and 1.79% of X-ray and Ophthalmology, respectively to Medicaid patients.

In Section L.3(b), page 83, 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 is based on the historical payor mix for the services at CFPSM and Duke Eye Center of Cary during CY2017, 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 84, 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 86, 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, DukeHHS, in Holly Springs, Wake County by co-locating the existing CFPSM clinic and a new ophthalmology clinic, DECHS, 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 29, 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 58-60, 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 pages 59, the applicant identifies the other existing and approved X-ray services provided in the Wake County service area. 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, i.e. X-ray machines:”*

The following table summarizes the information provided by the applicant on pages 59-60 regarding existing and approved X-ray services in Wake County.

**Approved and Existing Health Service Facilities Offering X-ray in Wake County**

Facility	Type	County	X-ray	
			Inventory	FY2017 Procedures
WakeMed Hospital	Hospital	Wake	13	151,255
WakeMed Cary Hospital (All sites)	Hospital	Wake	4	39,633
Duke Raleigh Hospital	Hospital	Wake	3	39,649
UNC Rex Hospital	Hospital	Wake	12	89,993
Raleigh Radiology Cedarhurst	Diagnostic Center	Wake	*	*
Raleigh Radiology Blue Ridge	Diagnostic Center	Wake	*	*
Wake Radiology	Diagnostic Center	Wake	*	*
Wake Radiology-Raleigh	Diagnostic Center	Wake	*	*
Wake Radiology-Garner	Diagnostic Center	Wake	*	*
Raleigh Orthopaedic Clinic	Diagnostic Center	Wake	*	*

Applicant’s source: 2018 Hospital License Renewal Applications (LRAs).

\*Not available

In Section G, page 59, 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 ophthalmic diagnostic 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 87-91, 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 87, the applicant states,

*“With this proposed project, PDC is offering medical diagnostic imaging services at a convenient location in Holly Springs in order to improve patient access to quality, cost-effective diagnostic care. As a new diagnostic imaging site, DHHS 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, page 96, 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 97 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, DukeHHS, in Holly Springs, Wake County by co-locating the existing CFPSM clinic and a new ophthalmology clinic, DECHS, 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.