

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 28, 2017

Findings Date: September 28, 2017

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: J-11359-17

Facility: Duke Health Center South Durham

FID #: 170278

County: Durham

Applicant(s): Private Diagnostic Clinic, PLLC

Project: Develop a new diagnostic center by relocating existing equipment and acquiring new equipment

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 (**PDC**) (“the applicant”) proposes to develop a new diagnostic center in Durham County by relocating existing equipment and acquiring new equipment to be located in the Duke Health Center South Durham (DHCS). The combined value of the existing and the proposed new equipment exceeds the statutory threshold for a diagnostic center of \$500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

Need Determination

There are no need determinations in the 2017 State Medical Facilities Plan (2017 SMFP) which are applicable to the acquisition of existing equipment or to the establishment of a diagnostic center.

Policies

There are no policies in the 2017 SMFP which are applicable to this review.

Conclusion

In summary, the applicant does not propose to develop any beds, operating rooms, or other services or acquire equipment for which there is a need determination in the 2017 SMFP. There are no policies in the 2017 SMFP that are applicable to this review. Therefore, this criterion is not applicable to this review.

- (2) Repealed effective July 1, 1987.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

C

The applicant proposes to develop a new diagnostic center in Durham County by relocating existing equipment and acquiring new equipment to be located in the Duke Health Center South Durham (DHCSO). The applicant proposes to relocate several existing medical specialty physician practices to the medical office building and to develop new clinics for pulmonology and neurology services. Construction of the medical office building is exempt from certificate of need (CON) review.

The combined value of the existing and the proposed new equipment exceeds the statutory threshold for a diagnostic center of \$500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

The new diagnostic center, DHCSO, will be located in a newly developed medical office building at 234 Crooked Creek Parkway in Durham. PDC will lease approximately 125,000 square feet of space from PDC Crooked Creek, LLC to develop the proposed facility. See Exhibit 2 for a copy of the proposed lease agreement between PDC and PDC Crooked Creek, LLC.

The applicant provides the following table on page 29 and Exhibits 4 and 5, in regards to the existing and the proposed diagnostic equipment.

	EXISTING TO BE RELOCATED	PROPOSED	NEW EQUIPMENT COST
PULMONOLOGY			
• PFT/ Body Box	-	1	\$55,701
NEUROLOGY			
• Ultrasound	-	1	\$56,925
• EMG	-	1	\$39,842
OPHTHALMONGY			
• Slit Lamps	6	19	\$348,745
• Humphrey field analyzer w/ table	2	1	\$31,798
• Lenstar/Varion Upgrade	1	-	-
• Ophthalmic Ultrasound	-	1	\$50,735
• Topcoon autorefactor & supporting equipment	1	1	\$13,995
• Atlas corneal topography	1	-	-
• Spectralis 6-mode	-	1	\$193,000
• Spectralis 3-mode	1	-	-
• Slit lamp w/ Nikon Camera	-	1	\$37,495
Durham OB/GYN			
• Ultrasound	1	-	-
Imaging			
• Flat film radiology	-	1	\$152,500
Total	13	28	\$980,736

As illustrated above, the applicant projects to relocate thirteen units of diagnostic equipment and to add twenty-eight units of diagnostic equipment for a total of forty-one units of diagnostic equipment at DHCS. The applicant states that the existing diagnostic equipment is valued at \$250,606. The applicant states on page 29 and Exhibits 4 and 5 that the total combined value of the existing and the proposed diagnostic equipment will be \$1,231,242 (\$250,606 value of existing equipment + \$980,736 for the proposed equipment = \$1,231,242).

On page 34, the applicant states that the proposed new x-ray machine will support the clinic practices located at DHCS, specifically, the pulmonology, rheumatology, and endocrinology services. The applicant also states on pages 34-35, that the proposed new Duke Neurology clinic and the Pulmonology clinic, will increase access to neurology and pulmonology services, respectively, in South Durham.

Patient Origin

§131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.” The 2017 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.

OB/GYN

In Section C.2(a), page 37 and Section C.4, page 39, the applicant provides the historical patient origin for calendar year (CY) 2016 and the projected patient origin for the first three years of the proposed project CY2018-CY2020, respectively, for OB/GYN ultrasound patients, as illustrated below:

**Durham OB/GYN Historical and Projected
Patient Origin**

COUNTY	HISTORICAL PATIENT ORIGIN CY2016	PROJECTED PATIENT ORIGIN CY2018-CY2020
Durham	59.6%	59.6%
Wake	20.7%	20.7%
Orange	7.8%	7.8%
Alamance	3.0%	3.0%
Person	2.7%	2.7%
Granville	1.2%	1.2%
Other*	5.0%	5.0%
Total	100.0%	100.0%

*Other includes <1% patient origin from the remaining counties in North Carolina and other states

The applicant states on page 39, that the patient origin for the ultrasound equipment is representative of the overall patient origin for Durham OB/GYN.

Duke Eye Center

On page 37, the applicant provides a list of the existing equipment projected to be relocated from the Duke Eye at Southpoint to the proposed new diagnostic center. In Section C.2(a), page 38 and Section C.4, page 40, the applicant provides the historical patient origin for calendar year (CY) 2016 and the projected patient origin for the first three years of the proposed project CY2018-CY2020, respectively, for the existing equipment at Duke Eye Center at Southpoint, as illustrated below:

**Duke Eye Center at Southpoint
 Historical and Projected Patient Origin**

COUNTY	HISTORICAL PATIENT ORIGIN CY2016	PROJECTED PATIENT ORIGIN CY2018-CY2020
Durham	46.6%	46.6%
Wake	17.4%	17.4%
Orange	15.2%	15.2%
Chatham	3.3%	3.3%
Alamance	3.1%	3.1%
Person	1.4%	1.4%
Granville	1.2%	1.2%
Other*	11.9%	11.9%
Total	100.0%	100.0%

*Other includes <1% patient origin from the remaining counties in North Carolina and other states

The applicant states on page 39, that the patient origin for the ophthalmic equipment is representative of the overall patient origin for Duke Eye at Southpoint.

As illustrated in the tables above, projected patient origin at Durham OB/GYN and Duke Eye Center at Southpoint are consistent with the historical patient origin at those facilities.

The applicant also proposes to acquire new X-ray equipment to be used at the new diagnostic center in its Neurology and Pulmonology Clinics. The applicant provides the projected patient origin for the proposed X-ray equipment on page 40, as illustrated below.

**Projected Patient Origin for X-ray
 Neurology & Pulmonology Services
 CY2018 - CY2020**

COUNTY	PERCENT OF TOTAL
Durham	47.0%
Wake	18.0%
Orange	15.0%
Other*	20.0%
Total	100.0%

*Other includes counties in North Carolina and other states

On page 41, the applicant states that projected patient origin for the existing equipment and services is based on the applicant's historical experience in providing the relevant service. The applicant also states that the existing clinics for Durham OB/GYN and Duke Eye Center at Southpoint are located in close proximity to the proposed new DHCS location, therefore they do not project a significant change in patient origin as a result of the proposed project.

In regards to the new equipment and services, the applicant states the following, also on page 41,

"PDC will be expanding services by establishing new clinic locations for neurology and pulmonology. Utilizing historical experience, PDC projects that 80% of the service's [sic] visits will originate from within Durham, Orange and Wake counties during the initial three project years. Because PDC physicians receive referrals from across the state, PDC projects that 20 percent of its patients will originate from outside of Durham Orange, and Wake counties."

Based on the applicant's historical patient origin for other services as shown in the tables above, the 80 percent projected patient origin for the new services seems reasonable.

The applicant adequately identified the population to be served.

Analysis of Need

The applicant proposes to develop a new diagnostic center by relocating existing equipment and acquiring new equipment to be located in the Duke Health Center South Durham (DHCS). The applicant proposes to relocate existing diagnostic equipment and to acquire new diagnostic equipment through lease agreements. The applicant provides a table in Section C, page 29 and Exhibit 5 that summarizes the twenty-eight units of medical diagnostic equipment proposed in this new diagnostic center. See Exhibit 8 for lease agreement documentation. Below is a list of the new equipment the applicant proposes to lease for its specialty clinics:

- Pulmonology PFT/ Body Box
- Neurology Ultrasound Room (Machine & Bed) and EMG
- Ophthalmology one B-Scan (Ophthalmic Ultrasound), Spectrails 6- mode, 19 slit lamps, one Humphrey field analyzer with table, one Topcon Autorefractor and supporting equipment, one slit lamp with Nikon Camera
- Imaging Flat Film Radiology

In Section C.4, page 42, the applicant describes the factors which they state support the need for the proposed project based on numerous qualitative and quantitative factors, including:

- The proposed project is consistent with PDC's mission to improve geographic access, promote cost-effective care and maintain high quality care delivery;

- The existing and proposed medical diagnostic equipment is essential for cost effective care delivery;
- The proposed project will improve patient access for PDC patients;
- The projected growth of the service area population presumes continued increases in demand for healthcare, including for diagnostic imaging services specific to PDC specialty clinics; and
- The proposed project will enable PDC to provide more cost-effective and timely service to meet patient expectations and to ensure quality care.

On pages 42-50, the applicant describes the factors above.

The applicant adequately demonstrates the need to develop a new diagnostic center in Durham County.

Projected Utilization

Durham OB/GYN

Ultrasound Equipment

In Section Q, page 119, the applicant provides the historical and projected utilization for the ultrasound diagnostic equipment at Durham OB/GYN, as illustrated below.

**Durham OB/GYN
 Historical and Projected Utilization for
 Ultrasound Equipment**

	Historical			Interim	Projected		
	CY2014	CY2015	CY2016	CY2017	Project Year 1 CY2018	Project Year 2 CY2019	Project Year 3 CY2020
# of Units	1	1	1	1	1	1	1
# of Procedures	1,022	1,241	1,234	1,295	1,359	1,426	1,497

The applicant provides its assumptions and methodology for projecting utilization for its ultrasound equipment in Section Q, pages 119-120. The applicant states that projected utilization is based on the applicant’s historical experience in providing the service. On page 119, the applicant states the 2-year compound annual growth rate (CAGR) for ultra sound services at Durham OB/GYN from CY2014-CY2016 was 9.9 percent. The applicant projects utilization forward using 4.9 percent for its ultrasound equipment which is one half of the 2-year CAGR ($9.9 \div 2 = 4.95$).

Durham Eye Center

Slit Lamps

In Section Q, pages 120-121, the applicant provides the historical and projected utilization for the slit lamp diagnostic equipment at Duke Eye Center at Southpoint, as illustrated below.

**Duke Eye Center at Southpoint
 Historical and Projected Utilization for
 Slit Lamp Equipment**

	Historical			Interim	Projected		
	CY2014	CY2015	CY2016	CY2017	PY 1 CY 2018	PY 2 CY 2019	PY 3 CY 2020
# of Units	6	6	6	6	26	26	26
# of Procedures	8,131	8,248	8,770	9,108	15,946	17,402	18,948

PY= Project Year

The applicant provides its assumptions and methodology for projected utilization for Durham Eye Center’s ophthalmic diagnostic equipment on pages 120-122. The applicant states that projected utilization is based on the applicant’s historical experience in providing the service. Durham Eye Center at Southpoint currently has six slit lamps and performed 8,770 procedures in CY2016. The applicant proposes to acquire 20 additional slit lamps as part of the proposed project for a total of 26 slit lamps upon project completion, including one with a Nikon camera. The applicant states that PDC’s operational model equates one physician to two exam rooms. Duke Eye Center will be staffed by thirteen physicians with a total of 26 exam rooms (13 x 2 = 26 exam rooms). The applicant proposes the addition of six new physicians at the Duke Eye Center including a physician who specializes in glaucoma and one who specializes in retinal disease. The applicant assumes the ramp up in utilization during the initial three project years will be 80 percent, 90 percent, and 100 percent, respectively. The applicants state that from CY 2014 to CY 2016, the compound annual growth rate for procedures using the slit lamps increased by 3.9%. The applicant further states that slit lamp exams are performed on every Duke Eye Center clinic visit.

There are no applicable criteria and standards for diagnostic centers. Therefore, there are no performance standards applicable to this review for any of the existing or proposed equipment.

Humphrey Field Analyzers

In Section Q, pages 122-124, the applicant provides the historical and projected utilization for the Humphrey Field Analyzer diagnostic equipment at Duke Eye Center at Southpoint, as illustrated below.

**Duke Eye Center at Southpoint
 Historical and Projected Utilization for
 Humphrey Field Analyzer Equipment**

	Historical			Interim	Projected		
	CY2014	CY2015	CY2016	CY2017	PY 1 CY2018	PY2 CY2019	PY3 CY2020
# of Units	2	2	2	2	3	3	3
# of Procedures	1,126	1,125	1,086	1,086	1,831	1,924	2,017

PY= Project Year

The applicant provides its assumptions and methodology for projecting utilization for its Humphrey Field Analyzer equipment in Section Q, pages 122-124. The applicant states on page 123, that the projected utilization for the Humphrey Field Analyzer equipment is based on the projected number of procedures divided by seven physicians. PDC projects to increase the number of physicians from seven to thirteen physicians. One new physician was recruited effective July 1, 2017 and the other physicians will be recruited incrementally. Several existing physicians propose to increase their clinical time or shift a portion of their existing practice to DHCS. PDC assumes a ramp up in utilization for the Humphrey Field Analyzer equipment of 80%, 90% and 100%, respectively, in the initial first three years of the project. (page 123)

Lenstar

In Section Q, pages 124-125, the applicant provides the projected utilization for the Lenstar diagnostic equipment at Duke Eye Center at Southpoint, as illustrated below.

**Duke Eye Center at Southpoint
 Historical and Projected Utilization for
 Lenstar Equipment**

	PY1 CY2018	PY2 CY2019	PY3 CY2020
# of Units	1	1	1
# of Procedures	1,500	1,528	1,557

PY= Project Year

The applicant provides its assumptions and methodology for projecting utilization for its Lenstar equipment in Section Q, pages 124-125. The proposed project will include the relocation of one existing Lenstar from Duke Eye Clinic to the proposed DHCS site. The applicant states the Lenstar was purchased, but never used at the current site due to a lack of space. The applicant reviewed the utilization of similar equipment located at the Page Road clinic. In CY2016 the equipment at Page Road performed 1,530 procedures.

The relocation of the Duke Eye Center will facilitate the expansion of its ophthalmic services thereby allowing it to function more like the facility on Page Road.

Spectralis

In Section Q, pages 126, the applicant provides the historical and projected utilization for the Spectralis diagnostic equipment at Duke Eye Center at Southpoint, as illustrated below.

**Duke Eye Center at Southpoint
 Historical and Projected Utilization for
 Spectralis Equipment**

	Historical			Interim	Projected		
	CY2014	CY2015	CY2016	CY2017	PY1 CY2018	PY2 CY2019	PY3 CY2020
# of Units	1	1	1	1	2	2	2
# of Procedures	687	1,066	1,185	1,278	2,323	2,632	2,976

PY= Project Year

The applicant provides its assumptions and methodology for projecting utilization for its spectralis equipment in Section Q, pages 125-127. The applicant also proposes to relocate one existing Spectralis from the existing location to the new DHCS site. The applicant states on page 125 that the Spectralis equipment performed 1,185 procedures in CY2016 with a 2-year CAGR of 31.3 percent increase in utilization from CY2014 - CY2016. The applicants propose the addition of one new Spectralis and projects an increase 7.8 percent increase utilization on page 125, which is one-fourth the 2-year CAGR ($31.3 \div 4 = 7.8$) for the proposed and existing equipment.

Corneal Topography

In Section Q, page 127, the applicant provides historical and projected utilization for the corneal topography diagnostic equipment at Duke Eye Center at Southpoint, as illustrated below.

**Duke Eye Center at Southpoint
 Historical and Projected Utilization for
 Corneal Topography Equipment**

	CY2017	PY1 CY2018	PY2 CY2019	PY2 CY2020
# of Units	1	1	1	1
# of Procedures	100	102	104	106

PY= Project Year

The applicant provides its assumptions and methodology for projecting utilization for its corneal topography equipment in Section Q, page 127. On page 127, the applicant discusses the relocation of one corneal topography unit that was purchased in December 2016 and became operational in January 2017. The applicant states that projected utilization of the corneal topography unit is based on the historical utilization of a similar unit at Page Road. The applicant projects to do 100 procedures in CY2017, 102 in CY2018, 104 in CY2019 and 106 procedures in CY2020. The applicant does not propose to increase the number of corneal topography units to be located at the DHCS site.

Topcon Autorefractor

In Section Q, page 128, the applicant provides historical and projected utilization for the topcon autorefractor diagnostic equipment at Duke Eye Center at Southpoint, as illustrated below.

**Duke Eye Center at Southpoint
 Historical and Projected Utilization for
 Topcon Autorefractor Equipment**

	Historical			Interim	Projected		
	CY2014	CY2015	CY2016	CY2017	PY1 CY2018	PY2 FY2019	PY3 CY2020
# of Units	1	1	1	1	2	2	2
# of Procedures	4,066	4,124	4,385	4,554	7,973	8,701	9,474

PY= Project Year

The applicant provides its assumptions and methodology for projecting utilization for its Topcon autorefractor equipment in Section Q, page 128. On page 128, the applicant discusses the relocation of one existing Topcon autorefractor unit and the need to purchase a second unit to support the addition of six new physicians at the proposed new DHCS site. The applicant states that there is no historical utilization for the Topcon autorefractor equipment because procedures are not billable. The applicant states that utilization is based on similar equipment at Page Road. The applicant states that utilization of the existing and the proposed equipment is based on one-half of the procedures for the slit lamps. (page 128)

B-Scan (Ophthalmic Ultrasound)

In Section Q, page 128, the applicant provides projected utilization for the B-Scan (Ophthalmic Ultrasound) diagnostic equipment at Duke Eye Center at Southpoint, as illustrated below.

**Duke Eye Center at Southpoint
 Historical and Projected Utilization for
 B-Scan (Ophthalmic Ultrasound) Equipment**

	PY1 CY2018	PY2 CY2019	PY3 CY2020
# of Units	1	1	1
# of Procedures	67	68	70

PY= Project Year

The applicant provides its assumptions and methodology for projecting utilization for its B-Scan (Ophthalmic Ultrasound) equipment in Section Q, pages 128-129. The applicant proposes to purchase one B-scan ophthalmic ultrasound to be used at the Duke Eye Center. The applicant states that the addition of the B-scan ophthalmic ultrasound will ensure a full continuum of outpatient ophthalmic services for patients at the DHCS site. The applicant based the projected utilization of the B-scan ophthalmic ultrasound on B-scan utilization at Page Road.

Pulmonology

In Section Q, pages 130-131, the applicant provides projected utilization for pulmonology equipment, the body box diagnostic equipment at DHCS, as illustrated below.

**Duke Health Center South Durham
 Projected Body Box Utilization**

	PY1 CY2018	PY2 FY2019	PY3 CY2020
# of Units	1	1	1
# of Procedures	2,026	2,078	2,130

PY= Project Year

The applicant provides its assumptions and methodology for projecting utilization for its body box equipment in Section Q, pages 129-131. On page 129, the applicant states PDC proposes to improve access to pulmonology services in South Durham by including a clinic location at the proposed DHCS site. The clinic will be staffed by two pulmonologists, one of which was hired effective July 1, 2017. The second pulmonologist is projected to start in CY2018. The applicant assumes a gradual ramp up of procedure referrals during the first three project years. The applicant provides a table on page 130 that illustrates the ratio of procedures for the proposed equipment. The applicant also states that the proposed equipment will be used by Duke cardiologists who will refer patients to the proposed body box. The applicant states that Duke Cardiology has 46 cardiologists and is located .25 miles away on Herndon Road. The applicant assumes 70 percent of the projected referrals will utilize the body box at DHCS which is based on the presence of the 46 cardiologists located at Duke Cardiology.

Neurology

In Section Q, page 133, the applicant provides projected utilization for EMG and neurological ultrasound diagnostic equipment at DHCS, as illustrated below.

**Duke Health Center South Durham
 Projected EMG Utilization**

	PY1 CY2018	PY2 CY2019	PY3 CY2020
# of Units	1	1	1
# of Neurologists	2	3	4
Yield Rate: Procedures/Neurologist	320	320	320
Potential EMG Procedures	639	959	1,279
EMG Referral Ramp up	80%	90%	100%
# of Procedures	511	863	1,279

PY= Project Year

**Duke Health Center South Durham
 Projected Neurological Ultrasound Procedures**

	CY2018	FY2019	CY2020
# of Units	1	1	1
# of Neurologists	2	3	4
Yield Rate: Procedures/Neurologist	240	240	240
Potential Ultrasound Procedures	480	720	960
Ultrasound Referral Ramp up	80%	90%	100%
# of Procedures	384	648	960

PY= Project Year

The applicant provides its assumptions and methodology for projecting utilization for its neurology diagnostic equipment in Section Q, pages 132-134. On page 132, the applicant states the new DHCS D site will offer expanded neurology services to improve access to patients in South Durham. The neurology clinic will operate with four neurologists with two of those neurologists being recruited as of July and August 2017. To support the new neurology clinic, PDC proposes to purchase one new ultrasound and one electromyography (EMG) machine. The applicant states that it used the historical utilization for similar existing equipment at PDC's North Duke Street clinic, which is not a diagnostic center, to project utilization for the proposed new ultrasound and EMG equipment.

Radiology

In Section Q, page 135, the applicant provides projected utilization by procedure for the X-ray equipment at DHCS D, as illustrated below.

**Duke Health Center South Durham
 Projected X-ray Utilization**

	CY2018	FY2019	CY2020
Pulmonary Procedures	720	720	720
Cardiology Procedures	4,140	4,140	4,140
Rheumatology Procedures	4,160	4,160	4,160
Endocrinology Procedures	2,592	3,024	3,456
Total X-ray Referrals	11,612	12,044	12,476
Percent of Potential Referrals	40%	50%	60%
# of Procedures	4,645	6,022	7,486

The applicant provides its assumptions and methodology for projecting utilization for its radiology diagnostic equipment in Section Q, pages 134-135. The applicant proposes to provide radiology services at the DHCS D site and acquire one X-ray machine to support clinical practices that include pulmonology, rheumatology, and endocrinology. The proposed X-ray machine will also provide chest X-rays for Duke Cardiology patients. The applicant

projects utilization for the proposed X-ray machine based on the data available from the Hammes Company. The Hammes Company provides market-based and financially sound solutions for national healthcare systems, regional and community hospitals and physician groups.

The Criteria and Standards for Diagnostic Centers were repealed. Therefore, there are no performance standards required.

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

The applicant adequately demonstrates the need to develop a new diagnostic center by relocating existing equipment and acquiring new equipment.

Access

In Section C.10, page 61, the applicant states that PDC is fully committed to the health and well-being of all patients, and has historically provided services to medically underserved populations, including the elderly and low-income persons. The applicant further states:

“... PDC does not discriminate based on income, race, ethnicity, creed, color, age, religion, national origin, gender, physical or mental handicap, sexual orientation, ability to pay or any other factor that would classify a patient as underserved. PDC will continue to have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved. Diagnostic services at PDC’s DHCS diagnostic center will be available to and accessible by any patient having a clinical need for those services.”

In Section L, page 105, the applicant provides the projected payor mix for the second full fiscal year (2019) of the proposed project by service component, as illustrated below.

**Duke Health Center South Durham
 Service Components CY 2019**

Payor Source	X-ray Radiology	Ultrasound Neurology	EMG Neurology	Ultrasound Obstetrics
Self Pay	1.2%	0.0%	0.0%	0.5%
Medicare*	33.3%	31.0%	35.3%	3.8%
Medicaid*	4.4%	4.7%	3.2%	2.0%
Insurance*	57.7%	60.5%	58.0%	92.5%
Worker’s Compensation	1.5%	1.3%	0.7%	0.0%
Other/Government	1.8%	2.5%	2.8%	1.2%
Total	100.0%	100.0%	100.0%	100.0%

*Includes managed care plans

Payor Source	Body Box Pulmonology	Ophthalmology
Self Pay	1.1%	0.1%
Medicare*	48.1%	55.7%
Medicaid*	4.4%	1.6%
Insurance*	44.0%	42.0%
Worker's Compensation	0.1%	0.2%
Other/Government	2.3%	0.5%
Total	100.0%	100.0%

*Includes managed care plans

The applicant states that the proposed project will not change the existing physician referral process. PDC projects the diagnostic center payor mix based on its historical FY2016 payor mix for each of the various diagnostic modalities. (page 105)

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed project and adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to develop a new diagnostic center in Durham County by relocating existing equipment and acquiring new equipment to be located in the Duke Health Center South Durham. The combined value of the existing and the proposed new equipment exceeds the statutory threshold for a diagnostic center of \$500,000; therefore, the acquisition of the proposed equipment requires a certificate of need. In Section D, page 66, the applicant states it does not propose the elimination of any services, but rather the relocation of existing specialty clinics within one mile of those specialty clinics existing practices. The applicant states that the project will allow for improved patient access due to expanded clinic space and covered parking spaces. In Section L, page 105, the applicant states that the proposed project will not change the existing physician referral process, therefore, patients will still have access to the same physician specialty clinics.

The applicant adequately demonstrates that low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly will continue to have access to its services.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section E, pages 69-70, the applicant discusses the four alternatives considered for meeting the needs for the proposed project, as briefly discussed below:

- Maintain the Status Quo – the applicant states that maintaining the status quo is not an effective alternative because PDC plans to relocate its existing services and develop new specialty clinics that will improve access and increase cost efficiencies for patients residing in South Durham
- Develop the Proposed Diagnostic Center in Another Location – the applicant state that there is no reason to locate the proposed diagnostic center to another location because the DHCS site will be located within one mile of the existing clinics. Relocation and development of the facility to another site could hinder access for the existing patients.
- Acquire Different Quantities of Medical Diagnostic Equipment – the applicant states through discussion with clinical and administrative leadership, PDC determined that the proposed complement of medical diagnostic equipment would be adequate to meet the needs of the specialty clinics located at the DHCS site.
- Pursue a Joint Venture – the applicant states that the need for the proposed project is internal to PDC and it involves the relocation of physician clinics and the development of new clinics to improve geographic access in southern Durham, thus, the applicant concluded that a joint venture was not realistic.

The applicant concluded that development of the project as proposed in this application was its most cost-effective alternative to meet the need of residents in southern Durham.

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

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

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

2. **Private Diagnostic Clinic, PLLC shall acquire no more than one PFT/body plethysmography (Body Box), one ultrasound machine, one EMG, nineteen LED slit lamps, one Humphrey Field Analyzer, one B-Scan ultrasound machine, one Topcon Autorefractor and supporting equipment, one Spectrails 6-mode unit, one slit lamp with imaging system Nikon Camera, and one flat film radiology unit to be located at Duke Health Center South Durham.**
 3. **Private Diagnostic Clinic, PLLC shall not relocate any existing services or equipment other than those services and equipment that are outlined in Section C of the application to Duke Health Center South.**
 4. **Private Diagnostic Clinic, PLLC, as part of this project, shall acquire not acquire any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.**
 5. **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.**
 6. **Private Diagnostic Clinic, PLLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance 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 by relocating existing equipment and acquiring new equipment.

Capital and Working Capital Costs

In Form F.1a in Section Q, the applicant projects the total capital cost of the proposed project to be \$45,000, which reflects the consultant fees, because the medical diagnostic equipment and the medical office space will be leased. PDC proposes to lease the medical office space from PDC Crooked Creek, LLC (lessor).

In Section F.3(a) and (b), pages 74-75, the applicant projects a start-up cost of \$30,00 with no initial operating expenses for a total working capital of \$30,000. The applicant provides a copy of its lease agreement with PDC Cooked Creek, LLC in Exhibit 2.

Availability of Funds

In Section F.2, page 73, the applicant states the capital cost of the project will be funded with accumulated reserves or owner’s equity. Exhibit 13 contains a letter dated April 10, 2017 from the Chief Financial Officer of Private Diagnostic Clinic, PLLC committing up to \$75,000 in cash reserves for the capital and working capital cost of the proposed project. Exhibit 12 also contains a letter dated June 12, 2017 from the Senior Vice President of First Citizens Bank verifying that PDC has significant money to cover the anticipated capital and working capital costs of the proposed project. On page 77, the applicant states that PDC operates on a cash basis. The applicant further states that projected operating expenses are based on PDC’s historical experience offering medical diagnostic services.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project for PDC’s Duke Health Center South Durham on Form F.3. The applicant projects that revenues will exceed operating expenses in each of the first three years for the entire medical office building, as illustrated below.

Duke Health Center South Durham			
	OY 1 – FY 2018	OY 2 – FY 2019	OY 3 – FY 2020
Total Gross Revenues (Charges)	\$5,688,058	\$6,482,942	\$7,366,699
Total Net Revenue	\$1,402,910	\$1,609,846	\$1,841,357
Total Operating Expenses (Costs)	\$1,153,536	\$1,339,394	\$1,404,143
Net Income	\$249,375	\$270,452	\$437,214

As PDC will operate several specialty clinics at the proposed Duke Health Center South Durham site, the applicant provides information on the individual specialty clinics in Section Q, Form F.4, which includes the total number of procedures, projected average charge per procedure and the operating expense per procedure.

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 analysis of need and projected utilization found in Criterion (3) is incorporated herein by reference. 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.

Conclusion

In summary, the applicant adequately demonstrates the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop a new diagnostic center by relocating existing equipment and acquiring new equipment.

§131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.” The 2017 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant.

In Section Q, page 80, the applicant provides a list of existing and approved diagnostic centers in the identified service area owned by PDC, as summarized below;

Health Care Facilities Owned by PDC

Facility	Type	Equipment	County
Duke Health Specialty Care Page Road	Dx Center	Similar equipment (i.e. X-ray & ophthalmic)	Durham
Duke Medicine Specialty Care Knightdale	Dx Center	Does not operate similar equipment	Wake
Duke Medicine Specialty Care Croasdaile Commons	Dx Center	Similar equipment (body box)	Durham
Duke Sports Science Institute	Dx Center	Similar equipment (i.e. X-ray)	Durham

On page 82, the applicant provides a detailed list of the similar equipment operated at Duke Health Specialty Page Road, Duke Health Specialty Care Croasdaile Commons and Duke Sports Science Institute and the number of procedures performed on the equipment.

On pages 81 and 83, the applicant provides a list of other health service facilities that operate similar medical diagnostic equipment, as summarized in the table below:

Health Service Facility	Type	County	Fixed x-ray**	FY2016* Procedures	Ultrasound	FY2016* Procedures
Duke University Hospital	Hospital	Durham	49	114,017	18	41,840
Duke Regional Hospital	Hospital	Durham	4	49,598	5	19,596
NC Specialty Hospital	Hospital	Durham	Data not reported on LRA			
Triangle Orthopaedic Associates	Dx Center	Durham	Data not publicly available			
Durham Diagnostic Imaging	Dx Center	Durham	2			
UNC Hospitals	Hospital	Orange	27	179,455	15	31,776
Wake Radiology Chapel Hill	Dx Center	Orange	Data not publicly available			
WakeMed Cary (all sites)	Hospital	Wake	14	149,239	9	24,230
WakeMed Cary Hospital	Hospital	Wake	4	37,725	7	7,797
Duke Raleigh Hospital	Hospital	Wake	3	36,614	3	10,366
Rex Hospital	Hospital	Wake	12	84,012	26	20,806
Raleigh Radiology Cedarhurst	Dx Center	Wake	Data not publicly available			
Raleigh Radiology Blue Ridge	Dx Center	Wake	Data not publicly available			
Wake Radiology	Dx Center	Wake	Data not publicly available			
Wake Radiology-Raleigh	Dx Center	Wake	Data not publicly available			
Wake Radiology-Garner	Dx Center	Wake	Data not publicly available			
Raleigh Orthopaedic Clinic	Dx Center	Wake	Data not publicly available			

Source: *2017 License Renewal Application (LRA)

**Excludes fluoroscopy X-rays

In Section Q, page 84, the applicant states that the proposed relocation of existing specialty clinics and the acquisition of leased equipment will not result in the unnecessary duplication of services because PDC is the sole provider group to Duke University Health System. The identified need is internal to PDC, as it involves specialty clinics and medical diagnostic equipment necessary to support those clinics. As such, PDC's continued growth depends on the consolidation, relocation, and expansion of existing PDC specialty physicians who will practice at the proposed new DHCS site. The applicant further states that the cost to both the patient and the insurer will be less than if the patient received the procedure in a facility not attached to a physician's office. (See page 84)

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in its proposed service area. Therefore, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

In Section H, page 86, the applicant states as some of the diagnostic equipment is relocating from existing clinics to the proposed new site, many of the staff will simply shift to the new facility. The applicant states on page 87, that substantially all the staff (excluding physicians) are provided through an arrangement with Duke University under which PDC leases the services of both full-time and part-time staff. All of the staff leased through the agreement with Duke University are solely employees of Duke University and therefore compensated by Duke University. However, PDC bears the salary and the benefit expenses of all the time those employees are in service at PDC. The applicant states, as one of the largest employers in the Triangle-area, Duke University does not anticipate any problems with recruitment for any positions. Additionally, the applicant states that training for new employees will be managed by Duke University. (See page 87)

In Section Q, the applicant provides a table which illustrates the current and projected staff for PDC's DHCSO site. The applicant projects to add 0.75 full time equivalents (FTEs) for an eye center technician and 0.25 FTEs for an eye center scheduler. The applicant projects to have 7.725 FTE positions in OY1 and to increase that number to 8.725 FTE positions in OY2. On page 88, the applicant states that approximately 100 physicians from nine medical specialties will utilize the DHCSO site. The applicant further states that Dr. David Attarian will continue to serve as the Chief Medical Officer of PDC. (See page 88)

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

Therefore, the application is conforming to this criterion.

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

C

In Section I, pages 90-91, the applicant states that although DHCSO is a proposed new site, PDC already offers medical diagnostic services in Durham County. The applicant states on page 90, that all support services will be performed by PDC staff except for billing which is contracted to the Patient Revenue Management Organization (PRMO). The proposed new site would allow PDC to coordinate many of those services into one convenient, physical location. The applicant states on page 91, that PDC is an established, physician-owned local healthcare provider with long-standing positive working relationships with the referring physician community in Durham and surrounding counties. The applicant also states PDC has an ongoing working relationship with Duke University Health System and Duke Primary Care and that its physicians will continue to have privileges at Duke University Hospital and Duke Regional Hospital. (See page 91)

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

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

C

The applicant proposes to develop a new diagnostic center in Durham County by relocating existing equipment and acquiring new equipment to be located in the Duke Health Center South Durham (DHCS). The new diagnostic center, DHCS, will be located in a newly developed medical office building at 234 Crooked Creek Parkway in Durham. PDC will lease approximately 125,000 square feet of space from PDC Crooked Creek, LLC to develop the proposed facility. See Exhibit 2 for a copy of the proposed lease agreement between PDC and PDC Crooked Creek, LLC. Construction of the medical office building is exempt from certificate of need (CON) review.

- (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

The proposed DHCS diagnostic center is not an existing health service facility. However, PDC proposes to relocate existing specialty clinics to the new site. On page 102, the applicant provides a table which illustrates the percentage of the medically underserved population served, including women, those age 65 and older and racial minorities served at the existing facilities and throughout Durham County, as illustrated below.

	% Served by Entire Facility FY2016	% Served in Durham County**
Women	46.7%	52.1%
65+	61.2%	11.5%
Racial Minorities*	NA	46.9%

*The applicant reports on page 102, that PDC does not track racial and ethnic minority data on its patients.

**Percentage of all patients served at PDC facilities in Durham County

On pages 102-103, the applicant provides the payor mix for PDC by modality for CY2016, as illustrated in the table below.

Payor Source	X-ray Radiology	Ultrasound Neurology	EMG Neurology	Ultrasound Obstetrics
Self Pay	1.2%	0.0%	0.0%	0.5%
Medicare*	33.3%	31.0%	35.3%	3.8%
Medicaid*	4.4%	4.7%	3.2%	2.0%
Insurance*	57.7%	60.5%	58.0%	92.5%
Worker's Compensation	1.5%	1.3%	0.7%	0.0%
Other/Government	1.8%	2.5%	2.8%	1.2%
Total	100.0%	100.0%	100.0%	100.0%

*Includes managed care plans

Payor Source	Body Box Pulmonology	Ophthalmology
Self Pay	1.1%	0.1%
Medicare*	48.1%	55.7%
Medicaid*	4.4%	1.6%
Insurance*	44.0%	42.0%
Worker's Compensation	0.1%	0.2%
Other/Government	2.3%	0.5%
Total	100.0%	100.0%

*Includes managed care plans

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Durham	12%	52%	58%	17%	7%	14%
Wake	11%	51%	40%	11%	6%	10%
Orange	12%	52%	31%	14%	6%	10%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

*Excludes "White alone" who are "not Hispanic or Latino"

***This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

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

The applicant adequately demonstrates that it currently provides access to medically underserved populations. 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;

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section L.2(b), page 103, the applicant states, “PDC has no obligation under federal regulations to provide uncompensated care or community service, or access by minorities and handicapped persons.” The applicant further states that PDC does not discriminate based on income, racial/ethnic origin, physical or mental conditions, ability to pay or any other factor that would classify a patient as underserved.

In Section L.2, page 104, the applicant states no one has filed any court actions against PDC alleging patient civil rights equal access violations at any similar facilities in the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.3, page 105, the applicant projects its payor mix for the second operating year following project completion (FY2019) for the proposed Duke Health Center South Durham, as shown below.

**Duke Health Center South Durham
 Service Components CY 2019**

Payor Source	X-ray Radiology	Ultrasound Neurology	EMG Neurology	Ultrasound Obstetrics
Self Pay	1.2%	0.0%	0.0%	0.5%
Medicare*	33.3%	31.0%	35.3%	3.8%
Medicaid*	4.4%	4.7%	3.2%	2.0%
Insurance*	57.7%	60.5%	58.0%	92.5%
Worker's Compensation	1.5%	1.3%	0.7%	0.0%
Other/Government	1.8%	2.5%	2.8%	1.2%
Total	100.0%	100.0%	100.0%	100.0%

*Includes managed care plans

Payor Source	Body Box Pulmonology	Ophthalmology
Self Pay	1.1%	0.1%
Medicare*	48.1%	55.7%
Medicaid*	4.4%	1.6%
Insurance*	44.0%	42.0%
Worker's Compensation	0.1%	0.2%
Other/Government	2.3%	0.5%
Total	100.0%	100.0%

*Includes managed care plans

The applicant projects the following regarding patients who will have all or some of their services paid for by Medicare and/or Medicaid, which includes managed care:

- 37.7% X-ray
- 35.7% Ultrasound (neurology)
- 38.5% EMG (neurology)
- 5.8% Ultrasound (obstetrics)
- 52.5% Body Box (pulmonology)
- 57.3% Ophthalmology

The applicant states on page 105, that PDC does not project a change in its payor mix from its historical payor mix as the existing referring physicians will not change. The applicant demonstrates that medically underserved populations will continue to have adequate access to the services offered at PDC. Concerning charity care, the applicant states on page 106, that PDC has no formal financial assistance policy, but it follows the financial assistance determinations made by DUHS. PDC uses the Federal Poverty Income Guidelines estimated by income, family members, medical expenses, and living expenses to determine eligibility for charity care. Exhibit 9 contains the Dukes' Financial Assistance Policy.

The applicant adequately demonstrates the extent to which the elderly and medically underserved groups will have access to the proposed diagnostic services at DHCS.

Therefore, the application is conforming to this criterion.

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

C

In Section L.5, page 107, the applicant states that patients are referred for services by physicians and self-referrals. The applicant adequately demonstrates that the facility

will offer a range of means by which patients will have access to the proposed services. See Exhibit 14 for physicians' letters of support. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page, page 108, the applicant states as an existing provider of healthcare services, PDC has established agreements with Durham Technical Community College and Miller-Motte College. Exhibit 10 contains service agreements with both schools. Additionally, on page 108, the applicant states PDC functions as the faculty practice plan for Duke University with PDC's physicians holding academic appointments at Duke University School of Medicine. The information provided is reasonable and credible and supports a finding of conformity 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 by relocating existing equipment and acquiring new equipment.

§131E-176(24a) states, "*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*" The 2017 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant.

In Section C, page 27, the applicant defines its service area as Durham, Wake, Orange, Person, and Granville counties. On pages 81 and 83, the applicant provides a list of other health service facilities that operate similar medical diagnostic equipment in the service area, as summarized in the table below:

Health Service Facility	Type	County	Fixed x-ray**	FY2016* Procedures	Ultrasound	FY2016* Procedures
Duke University Hospital	Hospital	Durham	49	114,017	18	41,840
Duke Regional Hospital	Hospital	Durham	4	49,598	5	19,596
NC Specialty Hospital	Hospital	Durham	Data not reported on LRA			
Triangle Orthopaedic Associates	Dx Center	Durham	Data not publicly available			
Durham Diagnostic Imaging	Dx Center	Durham	2			
UNC Hospitals	Hospital	Orange	27	179,455	15	31,776
Wake Radiology Chapel Hill	Dx Center	Orange	Data not publicly available			
WakeMed Cary (all sites)	Hospital	Wake	14	149,239	9	24,230
WakeMed Cary Hospital	Hospital	Wake	4	37,725	7	7,797
Duke Raleigh Hospital	Hospital	Wake	3	36,614	3	10,366
Rex Hospital	Hospital	Wake	12	84,012	26	20,806
Raleigh Radiology Cedarhurst	Dx Center	Wake	Data not publicly available			
Raleigh Radiology Blue Ridge	Dx Center	Wake	Data not publicly available			
Wake Radiology	Dx Center	Wake	Data not publicly available			
Wake Radiology-Raleigh	Dx Center	Wake	Data not publicly available			
Wake Radiology-Garner	Dx Center	Wake	Data not publicly available			
Raleigh Orthopaedic Clinic	Dx Center	Wake	Data not publicly available			

Source: *2017 License Renewal Application (LRA)

**Excludes fluoroscopy x-rays

In Section N, page 109, the applicant states it assumes no adverse effect on current medical diagnostic services in Durham County, as PDC is an existing provider of diagnostic services within the county. The applicant states that the proposed project will increase cost effectiveness, quality and access to the medical underserved by allowing the consolidation of medical clinics and equipment to the proposed new DHCS site which will reduce overhead for those services. On page 110, the applicant states that PDC will continue to utilize its existing policies and procedures to ensure quality management that emphasizes a customer-oriented perspective used to determine the needs of patients, physicians and others who use the diagnostic services. The applicant provides information on its performance improvement programs on pages 110-112 and additional information concerning access by the medically underserved population on pages 112-113.

See also Sections C, E, F, G, H, I, L, and O, where the applicant discusses the impact of the project on cost-effectiveness, quality, and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access

to the proposed services. This determination is based on the information in the application and the following analysis:

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

The application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section O, page 116, the applicant states that it currently owns, leases, or manages four diagnostic centers in North Carolina. As diagnostic centers are not licensed facilities, there are no Division of Health Service Regulations requirements. The applicant states on page 117, that PDC diagnostic centers have provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision at all four facilities and were found to be in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicant and considering the quality of care provided at all four facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion. 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 Criteria and Standards for Diagnostic Centers were repealed. Therefore, there are no performance standards required.