

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 30, 2019

Findings Date: August 30, 2019

Project Analyst: Mike McKillip

Assistant Chief: Lisa Pittman

Project ID #: J-11716-19

Facility: Duke Imaging Services at Cary Parkway

FID #: 190273

County: Wake

Applicant: Duke University Health System, Inc.

Project: Develop a diagnostic center by adding mammography to an existing diagnostic testing facility

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

Duke University Health System, Inc. (referred to as “DUHS” or “the applicant”) proposes to develop a new diagnostic center, Duke Imaging Services at Cary Parkway (Duke Cary Parkway), at 3700 Northwest Cary Parkway in Cary (Wake County) by adding mammography equipment at the existing independent diagnostic testing facility (IDTF).

Duke Cary Parkway currently operates a CT scanner and mobile MRI scanner at the IDTF. The existing medical diagnostic equipment valued at more than \$10,000 currently owned by DUHS at that location costs less than \$500,000. The applicant plans to acquire a mammography unit to be located at the Duke Cary Parkway facility. In Section Q, Form F.1a, the applicant indicates the cost to acquire the proposed mammography equipment and install it at the Duke Cary Parkway facility is \$590,000. Following acquisition of the proposed mammography equipment, the combined costs of all the medical diagnostic equipment at the Duke Cary Parkway facility will

exceed the statutory threshold of \$500,000. Therefore, Duke Cary Parkway qualifies as a diagnostic center, which is a new institutional health service, and 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 2019 State Medical Facilities Plan (SMFP),
- acquire any medical equipment for which there is a need determination in the 2019 SMFP, or
- offer a new institutional health service for which there are any applicable policies in the 2019 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, DUHS, proposes to develop a new diagnostic center, Duke Imaging Services at Cary Parkway (Duke Cary Parkway), at 3700 Northwest Cary Parkway in Cary (Wake County) by adding mammography equipment at the existing independent diagnostic testing facility (IDTF).

Designation as a Diagnostic Center

Duke Cary Parkway currently operates a CT scanner and mobile MRI scanner at the IDTF. The existing medical diagnostic equipment valued at more than \$10,000 currently owned by DUHS at that location costs less than \$500,000. The applicant plans to acquire a mammography unit to be located at the Duke Cary Parkway facility. In Section Q, Form F.1a, the applicant indicates the cost to acquire the proposed mammography equipment and install it at the Duke Cary Parkway facility is \$590,000. Following acquisition of the proposed mammography equipment, the combined costs of all the medical diagnostic equipment at the Duke Cary Parkway facility will exceed the statutory threshold of \$500,000. Therefore, Duke Cary Parkway qualifies as a diagnostic center, which is a new institutional health service, and 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 2019 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.3, page 16, the applicant defines the primary service area for the proposed diagnostic center as the Zip Code areas within ten minutes driving time of the facility.

In Section C, page 15, the applicant provides projected patient origin for the proposed mammography equipment, as summarized in the table below.

SUB-REGION	ZIP CODE	FY2021	FY2022	FY2023
		% OF TOTAL	% OF TOTAL	% OF TOTAL
Apex	27523	3.3%	3.3%	3.4%
Apex	27502	10.4%	10.2%	10.2%
Cary	27511	10.8%	9.7%	9.3%
Cary	27513	14.1%	13.9%	13.9%
Cary	27519	20.4%	23.5%	24.8%
North Wake	27560	12.4%	13.6%	14.2%
West Raleigh	27607	6.1%	5.6%	5.4%
West Raleigh	27606	12.5%	11.2%	10.8%
All Other		10.1%	9.1%	8.1%
Total		100.0%	100.0%	100.0%

Totals may not foot due to rounding.

In Section C.3(c), page 16, the applicant states that assumptions regarding projected patient origin for mammography at Duke Cary Parkway are based on DUHS’s experience at other imaging locations. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 16-20, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below:

- Mammography is an essential and foundational diagnostic service, especially for women over the age of 40, for whom the service is recommended on annual basis (page 16).
- The historical growth in mammography utilization for DUHS facilities in Wake and Durham counties from 2016 to 2018 (page 17).
- The projected growth of the service area population from 2018 through 2023 (pages 17-19).
- DUHS’s planned growth in both primary and specialty physician recruitment in the proposed service area (page 19).
- The cost and convenience benefits of an IDTF, particularly for patients with high-deductible health plans (page 19-20).

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

- The applicant documents the medical diagnostic equipment is essential for cost effective delivery of quality care for Duke Cary Parkway patients.
- The projected growth of the service area population is based on U.S. Census data and data from Truven Analytics.

Projected Utilization

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

**Duke Cary Parkway
Mammography Utilization**

Mammography	Interim Full Fiscal Year FY2020	First Full Fiscal Year FY2021	Second Full Fiscal Year FY2022	Third Full Fiscal Year FY2023
# Units	1	1	1	1
# Procedures	103	616	1,085	1,552

In Section Q, pages 1-3, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

Step 1: The applicant identified the service area for the proposed equipment as the Wake County Zip Code areas within a ten-minute driving time from the facility.

Step 2: The applicant totaled its mammography utilization across all the DUHS’s existing mammography sites of service (six locations) for FY2018.

Step 3: The applicant projected the percentage shift of patients from existing DUHS mammography sites of service to the proposed mammography equipment based on geographic location, preferences of payers and patients for IDTF over hospital-based services, growth in the referral network, Medicaid reimbursement changes, and the backlog and capacity constraints of the existing sites.

Step 4: The applicant projected additional patient volume based on increases in the service area population, physician recruitment, increased geographic access and patient convenience, and the cost-savings associated with the IDTF setting.

Step 5: The applicant projected additional patient volume based on in-migration from areas outside the Zip Code areas identified as the primary services, which is consistent with DUHS experience at other mammography sites of service.

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

- Projected utilization is based on historical utilization of DUHS mammography equipment at six existing sites of service in Wake and Durham counties.
- Exhibit C.4(a) contains copies of letters from physicians expressing support for the proposed project and their intention to refer patients.
- Projected population increases in the service area are expected to support increase in the utilization of diagnostic imaging services such as mammography.

Access

In Section C.11, page 24, the applicant discusses access to the proposed services. The applicant states,

“The services of Duke University Health System facilities, including the proposed diagnostic center, are open to all area and non-area residents. ... There is no discrimination on the basis of race, ethnicity, age, gender or disability.”

In Section L.6, page 53, the applicant projects the following payor mix for Duke Cary Parkway’s mammography services during the second year of operation (FY2022) following completion of the project, as shown in the following table.

Payment Source	Mammography Services Percent of Total Procedures
Charity Care	0.6%
Medicare	26.3%
Medicaid	1.7%
Insurance	69.5%
TRICARE	0.8%
Other	1.1%
Total*	100.0%

Source: Table on page 53 of the application.

*Totals may not foot due to rounding.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

NA

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

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

CA

The applicant proposes to develop a new diagnostic center, Duke Cary Parkway, by adding mammography equipment at the existing independent diagnostic testing facility (IDTF).

In Section E.2, page 31, 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 maintaining the status quo would not meet the need for diagnostic imaging services in the service area population. Therefore, maintaining status quo is not an effective alternative.
2. Relocate Existing Equipment from Another Location – The applicant states that developing the proposed diagnostic center by relocating equipment from another facility would not be effective given that the existing equipment is already well-utilized. Therefore, developing

the proposed diagnostic center by relocating equipment from another location is not an effective alternative.

In Section C.1, the applicant states that its proposal is the most effective alternative because today's standard of care requires the proposed medical diagnostic equipment. The project is also expected to improve access and increase cost efficiencies.

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

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

Conclusion

The Agency reviewed the:

- Application
- 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. Duke University Health System, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Duke University Health System, Inc. shall develop a new diagnostic imaging center by acquiring one unit of mammography equipment.**
- 3. Duke University Health System, Inc. 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, Duke University Health System, Inc. 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. **Duke University Health System, Inc. 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, Duke Cary Parkway, by adding mammography equipment at the existing independent diagnostic testing facility (IDTF).

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.

Construction Costs/Renovation	\$125,000
Medical Equipment	\$342,030
Consultant Fees/Contingency	\$122,970
Total	\$590,000

In Section Q, the applicant provides the assumptions used to project the capital cost. In Section F, pages 33-34, the applicant projects no start-up or initial operating expenses.

Availability of Funds

In Section F, page 32, the applicant states that the capital cost will be funded as shown below in the table.

Type	DUHS	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$590,000	\$590,000
Bonds	\$0	\$0
Other (Equipment Leases)	\$0	\$0
Other (Facility Lease)	\$0	\$0
Total Financing	\$590,000	\$590,000

* OE = Owner's Equity.

Exhibit F.2(a) contains a copy of a letter dated June 10, 2019 from the Senior Vice President and Chief Financial Officer for DUHS expressing its intention to fund the capital costs of the project with accumulated reserves. Exhibit F.2(b) contains a copy of the audited financial statements for DUHS which indicate it had cash and cash equivalents of \$278 million as of June 30, 2018.

Financial Feasibility

The applicant provided pro forma financial statements for mammography services at Duke Cary Parkway for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses for mammography services in the third full fiscal year of operation following completion of the proposed project, as shown in the table below.

Duke Cary Parkway Mammography Services			
	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Gross Revenues (Charges)	\$205,527	\$362,007	\$517,821
Total Net Revenue	\$101,347	\$177,644	\$252,829
Total Operating Expenses (Costs)	\$165,809	\$200,427	\$209,425
Net Income	(\$64,462)	(\$22,783)	\$43,404

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the 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, Duke Cary Parkway, by acquiring mammography equipment at the existing independent diagnostic testing facility.

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 2019 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 15, the applicant defines the service area for the proposed diagnostic center as Wake County.

In Section G.1, page 38, the applicant states, “*There is no listing of existing and approved diagnostic centers that provide mammography services maintained by the state.*” In Section G.3, pages 39-40, 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 population in Cary and surrounding areas is growing quickly and the demand for imaging services is growing with it, as set forth in response to Section C. DUHS does not currently have any mammography services in this part of Wake County, and operates only one other IDTF providing mammography services located in Wake Forest (not in the proposed service area). As the population grows and ages, and as that population also faces insurance network limitations, providing access to cost-effective services and choice of providers will be essential. This project will therefore not unnecessarily duplicate and existing imaging services in the service area.”

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 2019 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

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

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

C

In Section Q, Form H, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services for the first three operating years, as shown in the table below.

**Duke Cary Parkway
Proposed Diagnostic Center Staffing**

Position	FY2021 FTE	FY2022 FTE	FY2023 FTE
RNs	1.02	1.02	1.02
Radiology Technologist	2.99	2.99	2.99
Financial Care Counselor	1.62	1.62	1.62
TOTAL	5.63	5.63	5.63

In Section H.1, page 41, 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 41-42, the applicant describes DUHS's experience and process for recruiting and retaining staff and its proposed training and continuing education programs. Exhibit I.3 contains a letter from the existing medical director for Duke Cary Parkway expressing support and willingness to continue to serve as medical director for the proposed services. The applicant provides additional letters of support documentation in Exhibit C.4(b).

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 43, 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:

- Business office/registration
- Medical records
- Administration
- Material management
- Quality control
- Clinical engineering
- Laundry/housekeeping

In Section I.3, pages 44-45, the applicant discusses its relationships with the referring physician community. Exhibit C.4(b) 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
- 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, Duke Cary Parkway, by acquiring mammography equipment to be located in renovated space in the applicant's existing imaging center.

In Section K.2, page 47, the applicant states that the project involves the renovation of 500 square feet of space within the existing imaging center. Exhibit K.2 contains line drawings.

In Section K.3(a), page 47, 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 F.1(a).

On pages 47-48, 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(a).

On page 48, 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
- 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 51, the applicant provides the historical payor mix for Duke Cary Parkway for FY2018, as shown below.

Payor Category	Entire Facility	CT Services	Mobile MRI Services
Self-Pay	0.2%	0.3%	0.1%
Charity Care	0.5%	0.5%	0.5%
Medicare*	31.9%	40.2%	26.0%
Medicaid*	1.3%	1.3%	1.3%
Insurance*	61.1%	51.8%	67.8%
Workers Compensation	0.1%	0.0%	0.2%
TRICARE	2.1%	1.9%	2.2%
Other (Gov't)	2.8%	4.0%	2.0%
Total	100.00%	100.00%	100.00%

Totals may not sum due to rounding

*Including any managed care plans

In Section L.1(a), page 50, the applicant provides the demographics of Wake County patients who currently use Duke Cary Parkway services compared to the demographics of the Wake County service area, as summarized below.

	Percentage of Total Patients Served by Duke Cary Parkway during the Last Full FY	Percentage of the Population of the Service Area (Wake County)
Female	56.5%	51.3%
Male	43.4%	48.7%
Unknown	0.1%	0.0%
64 and Younger	73.2%	88.8%
65 and Older	26.8%	11.2%
American Indian	0.5%	0.8%
Asian	7.2%	7.2%
Black or African-American	8.3%	21.1%
Native Hawaiian or Pacific Islander	0.3%	0.1%
White or Caucasian	77.6%	68.4%
Other Race	3.0%	2.5%
Declined / Unavailable	3.1%	0.0%

Source: Duke Cary Parkway and US Census Bureau

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically 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 51, the applicant states that the Duke Cary Parkway 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 Duke Cary Parkway does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay.

In Section L.2(c-d), page 52, the applicant states that there have been four patient civil rights equal access complaints filed against DUHS facilities in the past five years. The applicant states that three of the complaint investigations have since been closed, and one is still pending.

The Agency reviewed the:

- Application

- 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 53, 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 Cary Parkway
 Proposed Payor Mix FY2022**

Payor Category	Entire Facility	CT Scanner	MRI Scanner	Mammography
Self-Pay	0.27%	0.4%	0.3%	0.0%
Charity Care	0.38%	0.4%	0.3%	0.6%
Medicare*	31.04%	40.3%	27.6%	26.3%
Medicaid*	0.66%	0.4%	0.6%	1.7%
Insurance*	63.24%	53.3%	66.6%	69.5%
Workers Compensation	1.71%	0.1%	2.9%	0.0%
TRICARE	0.65%	1.6%	0.1%	0.8%
Other (Gov't)	2.05%	3.5%	1.6%	1.1%
Total	100.00%	100.0%	100.0%	100.0%

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 0.65 percent of total diagnostic services will be provided to self-pay and charity care patients, 31.04 percent provided to Medicare patients and 0.66 percent of diagnostic services will be provided to Medicaid patients.

In Section L.3(b), page 53, 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. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical experience providing diagnostic imaging services at Duke Cary Parkway.

The Agency reviewed the:

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

The Agency reviewed the:

- Application
- Exhibits to the application

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 55, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes.

The Agency reviewed the:

- Application
- 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, Duke Cary Parkway, by acquiring mammography equipment at the existing independent diagnostic testing facility.

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 2019 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 15, the applicant defines the service area for the proposed diagnostic center as Wake County.

In Section G.1, page 38, the applicant states, “*There is no listing of existing and approved diagnostic centers that provide mammography services maintained by the state.*”

In Section N, pages 56-57, 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 56, the applicant states:

“The project will benefit competition by creating a new outpatient/non-hospital based mammography provider in Cary. DUHS currently offers mammography at three locations in the county, including two hospital-based location and one IDTF in Wake Forest, but does not currently have mammography services in Cary. The new center will expand provider choice for patients, particularly those in Cary and surrounding areas.”

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

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 Form A, the applicant identifies one other diagnostic center, Duke Health Heritage Radiology, operated by DUHS. On page 59, the applicant states that no DUHS facility has had licensure or certification issues during the 18-month period immediately preceding submission of the application. After reviewing and considering information provided by the applicant regarding the quality of care provided at DUHS 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, Duke Cary Parkway, by acquiring mammography equipment at the existing independent diagnostic testing facility.

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.