

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 5, 2023

Findings Date: May 5, 2023

Project Analyst: Cynthia Bradford

Acting Chief: Mike McKillip

Project ID #: J-12328-23

Facility: Duke Imaging Garner

FID #: 230129

County: Wake

Applicant: Duke University Health System, Inc.

Project: Develop a diagnostic center with mammography and ultrasound

### REVIEW CRITERIA

G.S. 131E-183(a): The Department 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, hereinafter referred to as DUHS or “the applicant”, proposes to develop a diagnostic center with mammography and ultrasound.

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2023 State Medical Facilities Plan (SMFP).
- Acquire any medical equipment for which there is a need determination in the 2023 SMFP.
- Offer a new institutional health service for which there are any applicable policies in the 2023 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- (2) Repealed effective July 1, 1987.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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

## C

The applicant proposes to develop a diagnostic center with mammography and ultrasound.

### Designation as a Diagnostic Center

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 one million five hundred thousand dollars (\$1,500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than one million five hundred thousand dollars (\$1,500,000), 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.”*

In Section A, page 17, the applicant states the total cost of the proposed project is \$2,422,000, which will exceed the (adjusted) statutory threshold of \$1,581,000. Therefore, Duke Imaging Garner qualifies as a diagnostic center, which is a new institutional health service, and which requires a Certificate of Need (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 2023 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.3, page 27, the applicant defines the service area for the proposed diagnostic center as Wake County. The facility may also serve residents not included in their service area.

The proposed diagnostic center has no historical patient origin. The following table shows the projected Duke Imaging Garner patient origin for FY2025 – FY2027, as provided in Section C.3, pages 27-28 of the application.

Entire Facility	Duke Imaging Garner					
	1 <sup>st</sup> Full FY		2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY	
	2024-2025		2025-2026		2026-2027	
Zip Code	Number of Patients	% of Total	Number of Patients	% of Total	Number of Patients	% of Total
Garner (27529)	354	23%	561	24%	738	23%
Raleigh (27603)	551	36%	778	33%	1149	36%
Raleigh (27610)	526	34%	834	36%	1091	34%
Other/In-migration	115	7%	174	7%	238	7%
<b>Total</b>	<b>1542</b>	<b>100%</b>	<b>2346</b>	<b>100%</b>	<b>3215</b>	<b>100%</b>

Totals may not sum due to rounding.

In Section Q, page 83, the applicant describes the assumptions and methodology used to project its patient origin, stating:

*“DUHS identified the zip codes within a 10–15-minute drive time of the proposed imaging center. Based on its analysis of existing drive times for imaging services, DUHS anticipates that the primary service area for these services will be zip codes 27529, 27603, and 27610... ...In FY 2022, DUHS served 4.6% of the estimated total utilization from these zip codes. DUHS assumes that without any additional service location its share of the service utilization would remain constant. It therefore applied that percentage to the projected utilization for future years to calculate baseline DUHS volume from these identified zip codes... ...DUHS anticipates that the shift will be greatest for the patients from the same zip codes as the proposed facility due to the greatest geographic proximity.”*

The applicant’s assumptions are reasonable and adequately supported because they are based on the applicant’s historical (FY2022) patient origin experience for each of the diagnostic modalities that will be included in the proposed diagnostic center.

**Analysis of Need**

In Section C.4, pages 28-32, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below:

- The applicant states the proposed project will support other healthcare services planned for the proposed facility and is integral to DUHS’s continuum of specialty services and is necessary for the clinicians to properly diagnose and treat patients. (Page 28)
- The applicant states the proposed project enables DUHS to provide cost-effective services to meet patient expectations and ensure quality care. (Page 32)
- The projected growth of the service area population supports projected increases in demand for healthcare. (Pages 30-31)

The information is reasonable and adequately supported based on the following:

- The applicant documents the proposed project is needed for cost effective delivery of quality care for Duke Imaging Garner patients.
- The projected growth of the service area population is based on information from the North Carolina Office of State Budget and Management.
- The applicant provides supporting information to document the need for the proposed imaging services.

Projected Utilization

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

<b>Duke Imaging Garner Projected Utilization</b>			
	<b>1<sup>st</sup> Full FY FY 2025</b>	<b>2<sup>nd</sup> Full FY FY 2026</b>	<b>3<sup>rd</sup> Full FY FY 2027</b>
<b>Mammogram</b>			
# Units	1	1	1
# Procedures	467	709	975
<b>Ultrasound</b>			
# Units	1	1	1
# Procedures	1,075	1,637	2,240

In Section Q, pages 83-89, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant identifies the service area for the proposed project as Wake County ZIP Code areas within a 10 to 15-minute driving time from the facility.
- The applicant uses projections from Sg2 for total projected utilization in the identified ZIP codes for the two modalities.
- The applicant projects the percentage shift of outpatient, non-emergent mammography and ultrasound patients from existing DUHS sites of service to the proposed site, based on geographic location, preferences of payers and patients for independent diagnostic testing facility (IDTF) over hospital-based services, growth in the referral network, and the backlog and capacity constraints of the existing sites.
- The applicant projects 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. The new shares were estimated by ZIP code reflecting proximity to the proposed site, with the ZIP code

of the proposed facility anticipated to have the greatest increase in share. These projections were calculated based on volumes projected by Sg2 in Step 2.

- The applicant projects 7% additional patient volume based on in-migration from areas outside the Zip code areas identified as the primary service area, which the applicant states is consistent with DUHS experience at other imaging sites of service.

Projected utilization is reasonable and adequately supported based on the following:

- Projected utilization is based on outpatient, non-emergent historical experience of DUHS mammography and ultrasound equipment at its 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 and ultrasound.

### **Access to Medically Underserved Groups**

In Section, C.6, page 37, 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. Ultrasound services are generally provided by physician referral. Screening mammography services do not require a referral. There is no discrimination on the basis of race, ethnicity, age, gender, or disability. Policies to provide access to services by low income, medically indigent, uninsured, or underinsured patients are described and provided elsewhere in this application. The facility will meet all ADA requirements for physical accessibility. Please see Exhibit C.11 for Duke’s notice of nondiscrimination.”*

On pages 37-38, the applicant provides the estimated percentage for the following medically underserved groups at the proposed diagnostic center, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Estimated Percentage of Total Services in FY 2027</b>
Low income persons	7.2%
Racial and ethnic minorities	24.2%
Women	65.5%
Persons with disabilities	DUHS does not track
Persons 65 and over	29.2%
Medicare	29.2%
Medicaid	5.9%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to 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 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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services.

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. 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 diagnostic center with mammography and ultrasound.

In Section E, pages 45-46, the applicant describes the alternatives it 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:

- Increase imaging capacity at existing locations – The applicant states that the average travel time to these sites from the proposed project location is 30 minutes or more. Accordingly, increasing capacity at other locations would not increase geographic access to the growing population in the Garner area and would not meet the identified need as effectively.

- Relocate existing imaging equipment to proposed location - The applicant states that its other imaging equipment is well-utilized and necessary to support services at the existing locations. Also, the expense of moving used equipment is not necessarily cost-effective.
- Select alternate location – The applicant states they could have selected an alternative location in Garner. The applicant identified the proposed location as a site where it can develop a range of ambulatory services, including primary and specialty physician clinics as well as ambulatory surgery services. Co-locating imaging at this site will enhance patient convenience and coordination of care. In addition, the applicant identified Garner as a location with relatively few imaging services available to the population.

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

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

### 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. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall develop a new diagnostic center with mammography and ultrasound imaging equipment in a medical office building to be developed in Garner.**
3. **Progress Reports:**
  - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare**





<b>Duke Imaging Garner Capital Cost</b>	
Construction Contracts	\$1,255,000
Architect/ Engineering Fees	\$145,000
Medical Equipment	\$550,000
Non-Medical Equipment & IT	\$110,000
Furniture	\$60,000
Other (contingency)	\$302,000
<b>Total Capital Cost</b>	<b>\$2,422,000</b>

In Section Q, following the pro forma financial statements, the applicant provides the assumptions used to project the capital cost. Exhibit F.1 contains supporting documentation. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Building renovation costs are based on the letter from the architect in Exhibit F.1(a).
- Medical equipment costs are based on an equipment lease arrangement which is included in Exhibit F.1(b).

In Section F, pages 48-49, the applicant projects \$37,949 in start-up expenses and \$1,438,609 in initial operating expenses for total working capital expenses of \$1,476,558. On page 49, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the information regarding projected start-up costs and initial operating expenses.

**Availability of Funds**

In Section F, pages 47 and 50, the applicant states that the capital and working capital cost, respectively, will be funded by the cash reserves of DUHS, as shown in the tables below.

<b>Sources of Capital Financing</b>	
<b>Type</b>	<b>Duke University Health System, Inc.</b>
Loans	
Accumulated reserves or OE *	\$ 2,422,000
Bonds	
Other (Specify)	
<b>Total Financing</b>	<b>\$ 2,422,000</b>

\* OE = Owner's Equity

Sources of Working Capital Financing	
Type	Duke University Health System, Inc.
Loans	
Accumulated reserves or OE *	\$1,476,558
Bonds	
Other (Specify)	
<b>Total Financing</b>	<b>\$1,476,558</b>

\* OE = Owner's Equity

In Exhibit F.2(a), the applicant provides a letter dated February 13, 2023, from the Chief Operating Officer for DUHS documenting its commitment to fund the capital and working capital costs of the project. Exhibit F.2(b) also contains a copy of Consolidated Financial Statements and Supplementary Schedules for FY2020 and FY2021 showing that the applicant has adequate accumulated reserves to fund the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the documentation provided in Section F and Exhibits F.2(a) and F.2(b), as described above.

### **Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of this project. In Section Q, Form F.2(b), the applicant projects that revenues will not exceed operating expenses in the first three operating years of the project, as summarized in the table below.

Duke Imaging Garner (Mammogram & Ultrasound)			
	1 <sup>st</sup> Full FY FY2025	2 <sup>nd</sup> Full FY CY2026	3 <sup>rd</sup> Full FY CY2027
Total Procedures <sup>^</sup>	2,009	3,055	4,190
Total Gross Revenues (Charges)	\$476,406	\$739,051	\$1,033,196
Total Net Revenue	\$232,914	\$367,474	\$522,703
Average Net Revenue per Procedure <sup>^^</sup>	\$116	\$120	\$125
Total Operating Expenses (Costs)	\$631,912	\$693,006	\$715,891
Average Operating Expense per Procedure <sup>^^</sup>	\$315	\$227	\$171
<b>Net Income</b>	<b>(\$398,998)</b>	<b>(\$325,532)</b>	<b>(\$193,188)</b>

<sup>^</sup> Combined projected utilization of mammogram (page 86), and projected ultrasound (page 89) procedures.

<sup>^^</sup> Totals may not sum due to rounding.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. In Section F.4, page 51, the applicant states,

*“As set forth in the documentation of availability of funds, DUHS is committed to supporting any operating losses with available reserves, which are well in excess of any amount necessary to make this project financially feasible for DUHS.”*

The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 and working capital costs are based on reasonable and adequately supported assumptions.
  - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

### C

The applicant proposes to develop a diagnostic center with mammography and ultrasound.

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 2023 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.3, page 27, the applicant defines the service area for the proposed diagnostic center as Wake County. The facility may also serve residents not included in their service area.

In Section G.1, page 55, the applicant states,

*“Mammography and ultrasound services are not subject to required equipment registration (except for those operated by hospitals). The following provider is listed as the only facility accredited by the American College of Radiology for mammography and/or ultrasound within any of the three zip codes identified as the primary service area for these services: 27529, 27603, and 27610.”*

- Wake Radiology Diagnostic Imaging (27529)

Outside of those 3 zip codes, the following Wake County hospitals report ultrasounds and mammography services on their annual license renewal applications:

- Duke Raleigh Hospital
- Wake Med
- Wake Med Cary
- Rex Hospital

In addition, for information purposes, the applicant identified the following facilities accredited by ACR within 10 miles of the identified zip codes:

- Cardinal Points Imaging Clayton (27520)
- Johnston Medical Center (27520)
- Raleigh Radiology Cary (27518)
- Wake Radiology – Fuquay (27526)
- Cary OB/GYN (27518)
- Triangle Physicians for Women (27518)
- Wake Med Raleigh Medical Park (27610)
- North Carolina Correctional Institute for Women HCF (27610)
- Cardinal Points Imaging Clayton (27520)
- Triangle Vein Clinic (27518)
- Raleigh Radiology Knightdale (27545)
- Duke Raleigh Hospital Ultrasound Center (27609)
- Wake Radiology – North Hills (27609)
- American Diagnostic Services (27609)
- Raleigh Radiation Clayton (27520)

In Section G.3, pages 57-58, the applicant explains why it believes its proposal would not result in an unnecessary duplication of existing or approved diagnostic centers in Wake County. The applicant states:

*“This project is designed to increase geographic access and address capacity constraints at existing Duke imaging locations. DUHS imaging utilization has*

*increased significantly across the system in recent years, reflecting a growing demand for these services. Rather than expanding its capacity to meet this growing need at an existing site, DUHS is developing those services in an underserved area. Duke is aware of only one accredited facility within the identified service area. This project will therefore increase patient choice and access within that 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 2023 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 to meet the identified need.

### **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

The applicant proposes to develop a diagnostic center with mammography and ultrasound.

In Section Q, Form H, the applicant provides the projected full-time equivalent (FTE) positions for the proposed diagnostic services at Duke Imaging Garner, as shown in the table below.

<b>Position</b>	<b>Projected FTE Positions 3rd FFY 2027</b>
Radiology Technologists	1.12
Sonographer	1.12
Imaging Manager	0.28
Imaging Supervisor - Mammography	0.28
Financial Care Counselor	1.12
Patient Service Associate	0.28
<b>TOTAL</b>	<b>4.20</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 59-60, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Exhibit H.3, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the information provided in Section H, pages 59-60, and in Section Q, Form H, as described above.

### **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

The applicant proposes to develop a diagnostic center with mammography and ultrasound.

### **Ancillary and Support Services**

In Section I.1, the applicant identifies the necessary ancillary and support services for the proposed services. On page 61, the applicant explains how each ancillary and support service is or will be made available. The applicant states,

*“In addition to the staff positions assigned to the facility reflected in Form H, DUHS provides support services other than housekeeping centrally, with projected costs allocated as set forth in the financial proformas. Housekeeping will be provided pursuant to a third-party contract, the cost of which is included in the financial proformas. Imaging does not typically entail dietary or discharge planning services.”*

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the information provided in Section I.1, as described above.

### **Coordination**

In Section I.2, page 62, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant states,

*“This facility will be part of the Duke University Health System, which includes inpatient acute care, outpatient surgery, psychiatric, and rehabilitation services, primary care, home health and hospice services. DUHS works closely with the Private Diagnostic Clinic, PLLC, the Duke University School of Medicine faculty practice which provides a full range of specialty physician services across the Triangle. Through specialty program affiliations including the Duke Heart Network, the Duke Cancer Network, and the Duke Telestroke Network, Duke Network Services links community-based specialty programs at hospitals throughout the region with Duke Centers of Excellence.”*

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2 as described above.

### **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 all the reasons described above.

- (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.

- (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 diagnostic center with mammography and ultrasound.

In Section K.1, page 64, the applicant states that the project involves construction of 2,295 square feet of new medical office space. Line drawings are provided in Exhibit K.1.

On pages 64-65, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K.1. The site appears to be suitable for the proposed facility based on the applicant's representations and supporting documentation.

In Section K.3, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information and representations made by the applicant on page 64-65 of the application.

In Section K.3, 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 based on the information and representations made by the applicant on page 65-66 of the application.

On page 65-66, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.



## 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 all the reasons described above.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], 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;

NA

The proposed diagnostic center will be a new facility and does not have historical payor mix.

- (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 ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NA

The proposed diagnostic center will be a new facility and does not have any past performance.

- (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 72, the applicant projects the payor mix for the proposed diagnostic center during the third full fiscal year (FY2027) of operation following completion of the project, as shown in the table below.

<b>Duke Imaging Garner Projected Payor Mix During Full FY2027</b>	
<b>Payor Category</b>	<b>Entire Facility</b>
Self-Pay	0.3%
Charity Care	1.3%
Medicare*	29.2%
Medicaid*	5.9%
Insurance*	62.0%
Other government payors	1.4%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.3% of total services will be provided to self-pay patients, 29.2% to Medicare patients and 5.9% to Medicaid patients.

On page 72, the applicant provides the assumptions and methodology used to project payor mix during the first three years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's proposed patient payor mix is based on DUHS's historical experience providing the proposed services at its existing clinics.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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, page 71, the applicant adequately describes the range of means by which patients 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

The applicant proposes to develop a diagnostic center with mammography and ultrasound.

In Section M.1, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides a listing of educational institutions that offer training opportunities for radiology students on page 75. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the information provided in Section M, page 75, as described above.

**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 all the reasons described above.

- (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 diagnostic center with mammography and ultrasound.

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 2023 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.3, page 27, the applicant defines the service area for the proposed diagnostic center as Wake County. The facility may also serve residents not included in their service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 76, the applicant states:

*“By creating a new imaging site, this project will also be more accessible to patients who are medically underserved in that part of the county. It creates a new entry point for patients seeking Duke’s high quality specialized services.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 76, the applicant states:

*“This project will increase cost-effectiveness of the proposed services by creating a new IDTF with a different reimbursement structure than hospital-based services, which may be more favorable financially for some patients.”*

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 76, the applicant states,

*“... the project will increase the quality of available imaging services by creating an access point to Duke’s specialized radiology services in a new accessible location. Professional interpretations will be provided by Duke specialists.”*

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 76, the applicant states:

*“By creating a new imaging site, this project will also be more accessible to patients who are medically underserved in that part of the county. It creates a new entry point for patients seeking Duke’s high quality specialized services.”*

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrates: a) the need the population to be served has for the proposal; b) that the proposal would not result in an

- unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and DUHS's record of providing quality care in the past.
  - 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

### **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 based on the reasons stated above.

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

### C

In Section Q, Form O, the applicant identifies three diagnostic centers located in Wake County that are owned, operated or managed by the applicant or a related entity.

In Section O.4, page 79, the applicant states that, during the 18 months immediately preceding the submittal of the application, it is not aware of any incidents regarding quality care at any of its diagnostic centers. After reviewing and considering information provided by the applicant and considering the quality of care provided at all three 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.

G.S. 131E-183 (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 diagnostic center with mammography and ultrasound. 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.