

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 20, 2017

Findings Date: October 20, 2017

Project Analyst: Gregory F. Yakaboski

Team Leader: Lisa Pittman

Project ID #: J-11353-17

Facility: Duke Radiology at Heritage

FID #: 170274

County: Wake

Applicant(s): Duke University Health System, Inc.

Project: Develop a diagnostic center with 2 x-ray units, one CT scanner, one mammography unit and one ultrasound unit

### 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.

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Duke University Health System, Inc. (DUHS) proposes to develop a diagnostic center with 2 x-ray units, one CT scanner, one mammography unit and one ultrasound unit. The diagnostic center will be known as Duke Radiology at Heritage and will be located on the first floor of a medical office building (MOB) to be built at 3000 Rodgers Road in Wake Forest.

#### **Need Determination**

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2017 State Medical Facilities Plan (2017 SMFP).

## **Policies**

The following policy is applicable to this review:

- **Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities**

### **Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities**

*Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN 4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy-GEN 4. The plan shall not adversely affect patient or resident health, safety, or infection control.*

The proposed capital expenditure is greater than \$5 million. In Section B, pages 19-20, and in Exhibit K.5, the applicants provide a written statement describing the proposed project's plan to assure improved energy efficiency and water conservation including compliance with all applicable federal, state and local building codes and requirements for energy efficiency and consumption, water conserving plumbing fixtures, LED lamps for energy efficiency and to reduce heat loads, roof top mechanical equipment with a 10.2 EER rating and an Energy Recovery Ventilator designed with the system. The application is consistent with Policy GEN-4.

## **Conclusion**

In summary, the applicants demonstrate that the proposal is conforming to all applicable policies in the 2017 SMFP. Therefore, the application is conforming to this criterion.

- (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

DUHS proposes to develop a diagnostic center with 2 x-ray units, one CT scanner, one mammography unit and one ultrasound unit. The diagnostic center will be known as Duke Radiology at Heritage and will be located on the first floor of a MOB to be built at 3000 Rodgers Road in Wake Forest.

The 2017 SMFP does not provide a need methodology for the establishment of diagnostic centers in North Carolina. Nor does the SMFP specify a service area relative to diagnostic centers.

In Section C, pages 23-27, and in Section Q, Form C, the applicant defines the proposed service area by zip codes set forth in the table below.

#### **Patient Origin**

Duke Radiology at Heritage is a proposed new facility. No historical patient origin data is available.

In Section C, page 27, the applicant provides the projected patient origin for Duke Radiology at Heritage during the first three full fiscal years (FFY) of operation following completion of the project as shown in the table below.

Zip Codes	OY1 7/1/18-6/30/19		OY1 7/1/19-6/30/20		OY1 7/1/20-6/30/21	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
27508	62	0.7%	80	0.7%	95	0.6%
27525	657	7.9%	851	7.0%	1,000	6.4%
27549	746	9.0%	978	8.1%	1,154	7.4%
27596	508	6.1%	671	5.5%	798	5.1%
27544	187	2.3%	241	2.0%	278	1.8%
27571	97	1.2%	135	1.1%	166	1.1%
27587	1,154	13.9%	1,624	13.4%	2,007	12.8%
27614	713	8.6%	1,005	8.3%	1,246	7.9%
27615	1,033	12.5%	1,459	12.0%	1,795	11.4%
27604	626	7.5%	976	8.1%	1,302	8.3%
27609	590	7.1%	917	7.6%	1,224	7.8%
27613	759	9.1%	1,142	9.4%	1,490	9.5%
27616	580	7.0%	908	7.5%	1,218	7.8%
Other Zip Codes within HSA	584	7.0%	1,135	9.4%	1,912	12.2%
<b>Total</b>	<b>8,296</b>	<b>100.0%</b>	<b>12,122</b>	<b>100.0%</b>	<b>15,685</b>	<b>100.0%</b>

On page 27 of the application, the applicant identifies the assumptions and methodology used to determine projected patient origin which includes utilizing unique DUHS patients from the proposed service area from FY16 and applying procedure-to-patient ratios. In Section Q, Form C, the applicant states *“These zip codes were identified first by taking those zip codes within a 20-minute drive time from the proposed Heritage service location. A 20-minute drive time was selected based on an analysis of current patient origin data for existing CT and other outpatient imaging services... DUHS also evaluated the location of other service providers in adjacent areas to determine what service area this site would serve. Because there were no existing CT providers in the adjacent Franklin and Vance zip codes, DUHS also included those zip codes in the proposed service area, reflecting an assumption that patients in those areas can and will drive somewhat longer to obtain medical services given the lack of more proximate services.”*

The applicant adequately identified the population to be served.

**Analysis of Need**

In Section C.4, pages 27-30, the applicant describes the need for the proposed project as follows:

- Wake County is one of the fastest growing counties in North Carolina and, over the next five years, the Wakefield region of Wake County is projected to grow by 9.4% while Wake County is projected to grow by 8.7%. Within the Wake County population the 65+ age groups are expected to grow by 30.0% with the 45-64 age group expected to grow by 13.0%.

- Duke University Hospital System has identified the Wakefield region of Wake County as in need of greater access to local medical services and is developing “*primary care, urgent care and specialty care*” in a new medical office building on Rogers Road in the Wakefield region of Wake County.
- DUHS is proposing to develop a diagnostic imaging center, Duke Radiology at Heritage, in the first floor
- A key component of diagnosing patients for primary, urgent and specialty care is imaging services. On-site imaging services permit ease of scheduling, particularly with respect to urgent care situations, and avoids the need for multiple appointments at various locations throughout the health system.
- DUHS has imaging available to Duke Raleigh Hospital, however, development of Duke Radiology at Heritage will permit patients the option of a non-hospital setting for imaging services. Freestanding services are priced at a lower fee rate by Medicaid and managed care payors and the proposed project will ease capacity constraints on the existing imaging equipment at Duke Raleigh Hospital.

Based on the information provided the need for the proposed project is reasonably supported.

Projected Utilization

In Section Q, Form C, the applicants provide the projected utilization for each service component of the proposed diagnostic center for the first three OYs (FY2019-FY2021) of the project, as illustrated in the tables below:

<b>Fixed X-Ray (Non Urgent)</b>	<b>OY1</b>	<b>OY2</b>	<b>OY3</b>
# of Units	1	1	1
# of Procedures	2,687	4,053	5,664
Capacity Per Unit	6,450	6,450	6,450
% of Capacity (Procedures/Capacity)	41.7%	62.8%	87.8%

Source: Form C in Section Q and Table in Section C, page 31. Note-the table in the beginning of Form C entitled *Form C Utilization* combines the projected utilization for the non-urgent and the urgent care x-ray units. The “*Methodology & Assumptions for Projecting Utilization Urgent Care Diagnostic/X-ray*” section of Form C provides the projected utilization of the urgent care x-ray unit which permits the projected utilization of the non-urgent x-ray unit to be determined.

<b>Fixed X-Ray (Urgent)</b>	<b>OY1</b>	<b>OY2</b>	<b>OY3</b>
# of Units	1	1	1
# of Procedures	3,142	4,189	4,189
Capacity Per Unit	13,661	13,661	13,661
% of Capacity (Procedures/Capacity)	23.0%	30.7%	30.7%

Source: Form C in Section Q and Table in Section C, page 31. Note-the table in the beginning of Form C entitled *Form C Utilization* combines the projected utilization for the non-urgent and the urgent care x-ray units. The “*Methodology & Assumptions for Projecting Utilization Urgent Care*”

*Diagnostic/X-ray*” section of Form C provides the projected utilization of the urgent care x-ray unit which permits the projected utilization of the non-urgent x-ray unit to be determined.

<b>Mammography Unit</b>	<b>OY1</b>	<b>OY2</b>	<b>OY3</b>
# of Units	1	1	1
# of Procedures	2,357	3,415	4,606
Capacity Per Unit	5,080	5,080	5,080
% of Capacity (Procedures/Capacity)	46.4%	67.2%	90.7%

Source: Form C in Section Q and Table in Section C, page 31.

<b>Ultrasound Unit</b>	<b>OY1</b>	<b>OY2</b>	<b>OY3</b>
# of Units	1	1	1
# of Procedures	1,410	2,178	3,025
Capacity Per Unit	3,333	3,333	3,333
% of Capacity (Procedures/Capacity)	42.3%	65.4%	90.8%

Source: Form C in Section Q and Table in Section C, page 31.

<b>CT Scanner</b>	<b>OY1</b>	<b>OY2</b>	<b>OY3</b>
# of Units	1	1	1
# of Scans	2,143	3,348	4,712
# of HECT Units	3,624	5,661	7,966
Capacity Per Unit	5,100	5,100	5,100
% of Capacity (HECT Units/Capacity)	71.1%	111.0%	156.2%

Source: Form C in Section Q and Table in Section C, page 31.

In Section Q, Form C, the applicant provided the assumptions and methodology used to project utilization for each service component of the proposed project, which are summarized below.

**X-ray (Urgent Care)** (See Section Q, Form C, Tab C)

Projected utilization is based on historic experience of other DUHS urgent care centers with a similar number of providers and which serve a similar market as the proposed Heritage service area.

**X-Ray (Non Urgent Care)/ Mammography/ Ultrasound and CT** (See Section Q, Form C, Tab C)

1<sup>st</sup>: *Population Projections* by Zip Code- identified the projected service area based on 20 minute driving time from the proposed location of Duke Radiology at Heritage.

2<sup>nd</sup>: *Projected Market Modality Volumes* based on Sg2, a company nationally recognized for its expertise in analytics, with which DUHS contracts with for its strategic planning needs. Factors considered by Sg2 included: “*demographic, economic, epidemiologic, technological and policy change factors.*” and projected utilization by modality of population in Heritage Service Area.

3<sup>rd</sup>) *Projected Growth Rate for Existing Sites*

- 4<sup>th</sup>) *Project Shift of DUHS Outpatient Procedure Volume*
- 5<sup>th</sup>) *Project Incremental Market Share for Duke Radiology at Heritage*
- 6<sup>th</sup>) *Total Projected DUHS Procedures and Share of Heritage Service Area*
- 7<sup>th</sup>) *In-Migration*
- 8<sup>th</sup>) *Project Weighted CT Scans*

Projected utilization is based on reasonable and adequately supported assumptions.

**Access**

In Exhibit L.4, page 8, that applicant states DUHS “complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Duke Health does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.” (See also Section C, pages 32-33.)

Exhibit L.2 contains a letter from the Program Manager of Project Access, which connects low-income, uninsured people to donated care across Wake County, stating that DUHS had reaffirmed its commitment to Project Access and that each year DUHS provides healthcare services, including imaging, to Project Access enrollees. The Program Manager also states “*Outpatient imaging services operated by DUHS in Wake Forest would improve geographic access, and also provide more expedient diagnosis for needy residents in our community.*”

In Section L, page, page 64, the applicants project the following payor mix during the second full FFY (7/1/2019 – 6/30/2020):

**Overall facility**

<b>Payor Source</b>	<b>Duke Radiology at Heritage</b>
Medicare	46.9%
NC Medicaid	5.0%
Private Payor/Managed Care	43.2%
Tricare	0.5%
Workers Compensation	0.2%
Self-Pay	1.8%
Other*	2.3%
Total	100.0%

\*Other: Includes Out of State Medicaid, VA, International, Other Government & Other Non-Specified Payors. Note that Charity and Other Self-Pay patients are not distinguished.

As shown in the table above, the applicants project that Medicare and Medicaid will be the payor source for 51.9% of the patients for the entire facility.

The applicant adequately demonstrates the extent to which all residents of the service area, including medically underserved populations would have access to the proposed diagnostic services.

## Conclusion

In summary, the applicant identified the population to be served, demonstrated the need that this population has for the proposed project and adequately demonstrated the extent to which all residents, including underserved groups, will 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.

NA

- (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-1, page 40, the applicant states that there are no other alternatives to the proposed project that would meet the identified needs.

On page 40, the applicant states that the identified area is in need of imaging services, the imaging assets operated by Duke Raleigh Hospital are highly utilized and DUHS has no other freestanding imaging equipment in the proposed area. The applicant identified that developing new imaging equipment in the same building as urgent, primary and specialty care would be more efficient and effective in providing coordinated care than developing the new imaging equipment in a stand-alone imaging center.

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

The applicants adequately demonstrate that the proposed alternative is the most effective or least costly alternative to meet the identified need. Therefore, the application is conforming to this criterion and 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 diagnostic center with 2 x-ray units, one CT scanner, one mammography unit and one ultrasound unit.**



- 3. Upon completion of the project, Duke Radiology at Heritage shall be licensed for no more than 2 x-ray units, one CT scanner, one mammography unit and one ultrasound unit.**
  - 4. 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, Form F.1a of the application and that would otherwise require a certificate of need.**
  - 5. Duke University Health System, Inc. shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
  - 6. 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.**
  - 7. 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

DUHS proposes to develop a diagnostic center with 2 x-ray units, one CT scanner, one mammography unit and one ultrasound unit. The diagnostic center will be known as Duke Radiology at Heritage and will be located on the first floor of a MOB to be built at 3000 Rodgers Road in Wake Forest.

### **Capital and Working Capital Costs**

In Section F, page 41, and Form F.1a in Section Q, the applicant projects the total capital cost of the proposed project will be:

Purchase Price of Land	\$175,131
Site Preparation	\$174,000
Construction/Renovation Contract	\$3,764,450
Landscaping	\$8,700
Architect/Engineering Fees	\$290,500
Medical Equipment	\$3,300,000
Non-Medical Equipment	\$205,000
Furniture	\$150,000
Other (CON Filing Fee)	\$30,000
Total Capital Cost	\$8,097,781

In Section F, page 43, the applicant states that there are no working capital needs for the proposed project since Duke Radiology at Heritage will be operated as part of the Duke University Health System, DUHS does not generally allocate working capital for new sites within the system and the accounting is done at the system level.

### **Availability of Funds**

In Section F, page 41, the applicant states that the proposed project will be financed through the accumulated reserves of Duke University Health System, Inc.

In Exhibit F.2, the applicant provides a letter from Kenneth C. Morris, Senior Vice President, Chief Financial Officer & Treasurer of Duke University Health System, which states that that \$10,000,000 is available for the capital cost and any working capital for the proposed project from existing accumulated cash reserves of Duke University Health System. The letter refers to the audited consolidated balance sheets of Duke University Health Systems, Inc. and Affiliates in Exhibit F.2 and specifically the line "Net assets: unrestricted" which line has \$2,337,076,000 as of June 30, 2016. (See page 6 of Exhibit F.2). Duke University Health System, Inc. had total net assets of \$2,770,033,000 as of June 30, 2016.

The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the proposed project.

### **Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In the pro forma financial statement (Form F.3), the applicant projects that revenues will not exceed operating expenses in the first three operating years of the project, as shown in the table below.

**Duke Radiology at Heritage**

	<b>1<sup>st</sup> Full Fiscal Year (FFY 2019)</b>	<b>2<sup>nd</sup> Full Fiscal Year (FFY 2020)</b>	<b>3<sup>rd</sup> Full Fiscal Year (FFY 2021)</b>
Total Procedures	11,739	17,183	22,196
Total Gross Revenues (Charges)	\$3,132,992	\$4,729,565	\$6,405,984
Total Net Revenue	\$1,164,302	\$1,729,177	\$2,315,885
Average Net Revenue per Procedure	\$99.18	\$100.63	\$104.34
Total Operating Expenses (Costs)	\$1,908,734	\$2,309,561	\$2,546,517
Average Operating Expense per Procedure	\$162.60	\$134.41	\$114.73
Net Income	(\$744,433)	(\$580,384)	(\$230,631)

The proposed Duke Radiology at Heritage facility will be part of the Duke University Health System.

The applicant provides pro forma financial statements for Duke University Health System for the first three full fiscal years of operation following completion of the project. In the pro forma financial statement (Form F.3), the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

**Duke University Health System**

	<b>1<sup>st</sup> Full Fiscal Year (FFY 2019)</b>	<b>2<sup>nd</sup> Full Fiscal Year (FFY 2020)</b>	<b>3<sup>rd</sup> Full Fiscal Year (FFY 2021)</b>
Total Gross Patient Revenues (Charges)	\$10,372,681,000	\$10,528,479,000	\$10,686,731,000
Net Patient Revenue	\$3,208,145,000	\$3,256,331,000	\$3,305,277,000
Total Net Revenue (Patient & Non-Patient)	\$3,391,857,000	\$3,441,070,000	\$3,491,051,000
Total Operating Expenses (Costs)	\$3,115,194,000	\$3,195,464,000	\$3,242,051,000
Operating Income Before Transfers to University	\$276,663,000	\$245,606,000	\$249,000,000
Excess Revenue over Expenses from Continuing Operations (excl transfers to the University)	\$399,784,000	\$367,000,000	\$375,761,000

Table Source is Form F3

The overall Duke University Health System is financially viable. The proposed project does not negatively impact the financial feasibility of the entire Duke University Health System

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q, Form F.3, 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. 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 demonstrated 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

DUHS proposes to develop a diagnostic center with 2 x-ray units, one CT scanner, one mammography unit and one ultrasound unit. The diagnostic center will be known as Duke Radiology at Heritage and will be located on the first floor of a MOB to be built at 3000 Rodgers Road in Wake Forest.

The 2017 SMFP does not provide a need methodology for the establishment of diagnostic centers in North Carolina. Nor does the SMFP specify a service area relative to diagnostic centers. In Section C, pages 23-27, the applicant defines the proposed service area by certain zip codes.

In Section G, pages 47-48, the applicant identified other providers of CT services, mammography services and ultrasound services in the proposed service area. A comprehensive list of providers of x-ray services and volumes is not publically available. The discussion regarding analysis of need and projected utilization found in Criterion (3), is incorporated herein by reference.

In Section N, page 67, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services and states:

*“The project will create an additional provider of freestanding (non-hospital based) outpatient imaging in Wake Forest. This will provide a potentially lower cost option for many patients, especially those with high deductible plans, and respond to increasing patient and payor interest in freestanding service options. ... freestanding services are often a more attractive option for both patients and their insurers. ... DUHS partners with Project Access and offers care to the medically underserved in Wake County, and this project will provide another outlet for such services, particularly for patients who may have transportation difficulties and other barriers to reaching DUHS services in other geographic locations”.*”

In Section G, page 49, the applicant states *“As the population grows and ages, and as that population also faces insurance network limitation, providing additional services and choices of providers will be essential. This project will not unnecessarily duplicate any existing imaging services in the service area.”*

In Section C, page 28 the applicant states that a key component of diagnosing patients for primary, urgent and specialty care is imaging services. On-site imaging services permit ease of scheduling, particularly with respect to urgent care situations, and avoid the need for multiple appointments at various locations throughout the health system. Further on page 28 the applicant states, DUHS has imaging available to Duke Raleigh Hospital, however, development of Duke Radiology at Heritage will permit patients the option of a non-hospital setting for imaging services. Freestanding services are priced at a lower fee rate by Medicaid and managed care payors and the proposed project will ease capacity constraints on the existing imaging equipment at Duke Raleigh Hospital.

The applicants adequately demonstrate that the proposed project would not result in the unnecessary duplication of imaging services in the identified service area. Consequently, 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.

C

In Section Q, Form H, the applicant states that initially service will be provided as follows: Mammography, Ultrasound and CT [8 hours per day/ M-F] and Diagnostic X-Ray and a financial care counselor [12 hours day/ 7 days week] with coverage increasing in OY3 (FY2021) as volumes increase as shown in the following table.

**Duke Radiology at Heritage- full-time equivalent (FTE) staffing**

	OY1 (FY2019)	OY2 (FY2020)	OY3 (FY2021)
<b>Mammography</b>			
Mammo Tech	1.12	1.12	1.17
<b>Ultrasound</b>			
U/S Tech	1.12	1.12	1.70
<b>CT</b>			
CT Tech	1.12	1.12	1.70
Nurse	1.12	1.12	1.12
<b>Diagnostic</b>			
X-ray Tech	2.80	3.36	3.36
<b>FCC</b>			
Financial Care Counselor	2.80	3.36	3.36
<b>Total</b>	10.08	11.20	12.94

As shown in the table above, the applicants state that by FFY2020 (the second full fiscal year) Duke Radiology will be staffed by 11.20 FTE positions.

Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in the pro forma financial statements. The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide 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.

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In Section I, page 44, the applicant identifies the necessary ancillary and support services and indicates how they will be made available. Exhibit H-4 contains a letter from Tedric Dale Boyse, MD, agreeing to serve as the medical director of the facility and expressing his support for the proposed project. Duke Radiology at Heritage will be part of the Duke University Health System. (See application page 55). The applicant discusses coordination with the existing health care system on pages 54-55 of the application. Exhibit I.2 contains a letter from Project Access detailing DUHS's participation. The applicants adequately demonstrate that the necessary ancillary and support services will be available 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 is proposing develop a diagnostic center on the first floor of a new 6,818 square foot medical office building. To be located at 3000 Rogers Road, Wake Forrest. DUHS already holds title to the property, which is properly zoned and serviced by existing water, sewer and power lines. (See Exhibit K.5) In Section B, pages 19-20, and in Exhibit K.5, the applicant provides a written statement describing the proposed project's plan to assure improved energy efficiency and water conservation including compliance with all applicable federal, state and local building codes and requirements for energy efficiency and consumption, water conserving plumbing fixtures, LED lamps for energy efficiency and to reduce heat loads, roof top mechanical equipment with a 10.2 EER rating and an Energy Recovery Ventilator designed with the system. Exhibit F.1 contains a letter from Marc Christopher, AIA which provides cost estimates relating to site development and construction costs of the proposed new construction for Duke Radiology at Heritage which are consistent with the capital cost estimates in F.1a in Section Q.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative for the proposed construction project. Furthermore, the applicants adequately demonstrate that the proposed construction project would not unduly increase the costs and charges of diagnostic services. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that applicable energy saving features have been incorporated into the construction plans. Therefore, 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;

NA

Duke Radiology at Heritage is not an existing facility.

- (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;

NA

Duke Radiology at Heritage is not an existing facility.

- (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, page 64, the applicants project the following payor mix during the second full FFY (7/1/2019 – 6/30/2020):

**Overall facility**

Payor Source	Duke Radiology at Heritage
Medicare	46.9%
NC Medicaid	5.0%
Private Payor/Managed Care	43.2%
Tricare	0.5%
Workers Compensation	0.2%
Self-Pay	1.8%
Other*	2.3%
Total	100.0%

\*Other: Includes Out of State Medicaid, VA, International, Other Government & Other Non-Specified Payors. Note that Charity and Other Self-Pay patients are not distinguished.

**Individual Service Components**

Payor Source	CT	Mammography	Ultrasound	X-ray
Medicare	55.4%	37.5%	37.4%	50.5%
NC Medicaid	4.0%	2.5%	8.0%	5.8%
Private Payor/Managed Care	36.9%	57.1%	49.6%	38.8%
Tricare	0.4%	0.4%	0.5%	0.7%
Workers Compensation	0.1%	0.0%	0.0%	0.5%
Self-Pay	1.6%	0.9%	1.9%	2.9%
Other*	1.6%	1.6%	2.5%	1.5%
Total	100.0%	100.0%	100.0%	100.0%

\*Other: Includes Out of State Medicaid, VA, International, Other Government & Other Non-Specified Payors. Note that Charity and Other Self-Pay patients are not distinguished.

As shown in the table above, the applicants project that Medicare and Medicaid will be the payor source for 51.9% of the patients for the entire facility. DUHS based projected payor mix on the payor mix for the current outpatient procedures performed at DUHS locations for patients residing in the identified service area. (See application pages 64-



65). Exhibit I.2 contains a letter from the Program Manager of Project Access, which connects low-income, uninsured people to donated care across Wake County, stating that DUHS had reaffirmed its commitment to Project Access and that each year DUHS provides healthcare services, including imaging, to Project Access enrollees. The Program Manager also states “*Outpatient imaging services operated by DUHS in Wake Forest would improve geographic access, and also provide more expedient diagnosis for needy residents in our community.*” In Exhibit L.4, page 8, that applicant states DUHS “complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Duke Health does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.”

The applicants adequately demonstrate that medically underserved populations would have access to the proposed services. 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 65, the applicant states “*Patients will be referred for imaging services by physicians. The facility will accept referrals for procedures from all providers, whether or not affiliated with Duke Medicine. Patients can access the urgent care clinic on a walk-in basis without prior appointments or referrals, and may be referred by urgent care for imaging.*” In Section C, page 32, the applicant states “*Imaging services are generally provided by physician referral, including from the adjacent urgent care center that will accept patients on a walk-in basis.*” The applicant adequately demonstrates that the proposed Duke Radiology at Heritage facility will offer a range of means by which a person can access the services. 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 66, the applicant states that DUHS has long-standing training agreements and relationships with existing training programs in the area, and will extend training opportunities to the new site. The applicant states “*DUHS provides training opportunities for radiology technician students in the area. Students from Wake Tech and Johnston Community College may be rotated through this proposed site pursuant to existing training agreements.*” The information provided in Section M 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

DUHS proposes to develop a diagnostic center with 2 x-ray units, one CT scanner, one mammography unit and one ultrasound unit. The diagnostic center will be known as Duke Radiology at Heritage and will be located on the first floor of a MOB to be built at 3000 Rodgers Road in Wake Forest.

The 2017 SMFP does not provide a need methodology for the establishment of diagnostic centers in North Carolina. Nor does the SMFP specify a service area relative to diagnostic centers.

In Section C, pages 23-27, the applicant defines the proposed service area by certain zip codes.

In Section N, page 67, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services and states:

*“The project will create an additional provider of freestanding (non-hospital based) outpatient imaging in Wake Forest. This will provide a potentially lower cost option for many patients, especially those with high deductible plans, and respond to increasing patient and payor interest in freestanding service options. ... freestanding services are often a more attractive option for both patients and their insurers. ... DUHS partners with Project Access and offers care to the medically underserved in Wake County, and this project will provide another outlet for such services, particularly for patients who may have transportation difficulties and other barriers to reaching DUHS services in other geographic locations”.*”

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

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the 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 Duke Radiology at Heritage will provide quality diagnostic services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant adequately demonstrates that Duke Radiology at Heritage will continue to provide access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, 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, pages 69-70, the applicant states that it currently owns, leases, or manages ten facilities in North Carolina. According to the files in the & Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of the application through the date of the decision no facilities were found to be out of compliance with one or more Medicare conditions of participation. At this time, all facilities are in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicant and by the Licensure and Certification Section and considering the quality of care provided at all 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.

C

The application is conforming with all applicable Criteria and Standards for Computed Tomography Equipment. The specific criteria are discussed below.

## **SECTION .2300 – CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY EQUIPMENT**

### **10A NCAC 14C .2303 PERFORMANCE STANDARDS**

An applicant proposing to acquire a CT scanner shall demonstrate each of the following:

- (1) each fixed or mobile CT scanner to be acquired shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment;
- C- The applicant proposes to develop one fixed CT scanner and projects the proposed CT scanner to perform 7,966 HECT units annually in FY 2021 (7/1/2020 to 6/30/2021) which is the third year of operation following completion of the project.
- (2) each existing fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall have performed at least 5,100 HECT units in the 12 month period prior to submittal of the application; and
- C- DUHS defines the service area for the proposed CT scanner as a multi-zip code area including parts of Wake, Franklin and Vance Counties. In Section C, pages 34-35, the applicant states that DUHS has four CT scanners in the proposed service area all on the Duke Raleigh Hospital License (3 existing CT scanners on the Duke Raleigh Hospital campus and 1 CT scanner operated at Duke Cancer Center Macon Pond). The applicant states that in FY 2017 *“based on 10 months, Duke Raleigh will perform an annualized volume of 47,154 HECT units on its 4 scanners”* which averages 10,937 HECT units per scanner, which exceeds the 5,100 HECT units required by this rule. [Note: the annualized volume of the 4 CT scanners in FY 2017 based on 47,154 HECT units is 11,788.5, not 10,937.] In FY 2016 the 4 CT scanners performed 43,746 HECT units or 10,936.5 HECT units per scanner.
- (3) each existing and approved fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment.
- C- In Section C, page 35, the applicant projects that each existing and approved fixed CT scanner in the proposed projects CT scanner service area shall perform in excess of 5,100 HECT units annually.