

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 16, 2019

Findings Date: September 16, 2019

Project Analyst: Ena Lightbourne

Team Leader: Gloria C. Hale

Project ID #: J-11718-19

Facility: Duke Health Arrington Radiology

FID #: 190274

County: Durham

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

Project: Develop a diagnostic center with new CT, mammography, ultrasound, x-ray, and DEXA equipment, relocation of existing extremity scanner, and replacement and relocation of existing MRI scanner.

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.

C

Duke University Health System, Inc. (referred to as “DUHS or “the applicant”) proposes to develop a new diagnostic center, Duke Health Arrington Radiology at 5601 Arrington Park Drive, Durham County. The combined value of the medical diagnostic equipment costing \$10,000 or more exceeds the statutory threshold of \$500,000 and therefore qualifies as a diagnostic center, which is a new institutional health service, and which requires a certificate of need.

The applicant proposes to develop a diagnostic imaging center with new CT, mammography, ultrasound, X-ray, and DEXA equipment, relocation of existing extremity scanner, and replacement and relocation of existing MRI scanner.

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 2019 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities (page 31 of the 2019 SMFP) is applicable to this review. *Policy GEN-4* states:

“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 for this project is greater than \$5 million. In Section B, page 13, the applicant provides a written statement describing its plan to assure improved energy efficiency and water conservation. On page 13, the applicant states:

“DUHS will ensure the proposed facility will be designed and developed in compliance with all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption, including 2019 SMFP Policy GEN-4. Water conservation design standards include the use of low-flow toilets. Upfit of the space in the medical office building will be pursued to ensure energy efficiency and cost-effective utilities, including water conservation. DUHS will closely monitor its utility usage and costs (including water utilization) in order to maintain efficient and environmentally responsible energy operations, and will submit a written statement as required.”

The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the application is consistent with Policy GEN-4.

- (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.

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Patient Origin

N.C.G.S. §131E-176(24a) states: "*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*" The 2019 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section Q, the applicant defines the service area as geographical by zip codes. Facilities may also serve residents of counties not included in their service area.

In Section C, pages 16-22, the applicant provides the projected patient origin by geographical area for each service component. On page 23, the applicant provides the projected patient origin by geographical area for the entire facility, as show in the table below.

		FY 2021 7/1/20-6/30/21		FY 2022* 7/1/21-6/30/22		FY 2023* 7/1/22-6/30/23	
Sub-Region	Zip Code	# of Patients	% of Patients	# of Patients	% of Patients	# of Patients	% of Patients
Apex	27526	52	1%	89	1%	111	1%
Cary	27511	160	2%	257	2%	307	2%
Cary	27513	452	6%	728	6%	915	6%
Cary	27519	568	8%	988	8%	1291	9%
Central Raleigh	27605	31	0%	50	0%	60	0%
Central Raleigh	27608	54	1%	88	1%	105	1%
Chapel Hill-Carrboro	27514	84	1%	155	1%	201	1%
Downtown Durham	27701	268	4%	515	4%	704	5%
Duke University	27710	1	0%	3	0%	4	0%
North Wake	27560	366	5%	600	5%	764	5%
North Wake	27613	556	7%	886	7%	1110	7%
North Wake	27617	260	3%	432	4%	553	4%
Page Road Area	27703	687	9%	1,355	11%	1834	12%
Page Road Area	27709	7	0%	14	0%	19	0%
Southpoint	27707	537	7%	1,027	8%	1363	9%
Southpoint	27713	582	8%	1,090	9%	1441	9%
Wakefield	27615	251	3%	414	3%	495	3%
West Durham	27708	8	0%	16	0%	21	0%
West Raleigh	27607	196	3%	303	2%	375	2%
West Raleigh	27612	480	6%	753	6%	927	6%
West Raleigh	27695	0	0%	0	0%	0	0%
All other Geographies	Average	1,862	25%	2,388	20%	2526	17%
Total		7,461	100%	12,150	100%	15126	100%

Source: Section C.3, page 23

*The applicant used the same projected year for each column, therefore the Analyst has corrected these.

In Section C.3, page 23 and Section Q, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 24-32, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

Incremental Services

The applicant states that CT, Ultrasound, Mammography, X-ray, and DEXA have been identified by DUHS as the most needed new outpatient imaging services needed at the proposed location to ensure access to patients and maximize coordination of care with the

providers in the same building. These services can detect other medical issues as well as support a variety of primary and specialty services. [pages 24-26].

Relocation/Replacement of Existing Imaging Services

The applicant states the relocation/replacement of the much-needed existing MRI and extremity scanner in one location will increase operational efficiency and patient conveniences. For example, patients seeking orthopedics and other specialty services can benefit from having the extremity scanner and MRI at the same location. [pages 26-27].

DUHS Historical Growth and Need for non-Hospital-based Option

The applicant states that imaging volumes at all locations have been increasing steadily in recent years, as illustrated in the table below.

Modality	2016	2018	2018	FY16-18 % Change
CT	145,432	158,621	157,635	8%
DEXA	7,322	7,022	7,789	6%
Mammography	37,034	47,545	47,339	28%
MRI	59,204	64,122	66,310	12%
X-ray	295,350	318,494	316,457	7%
Ultrasound	72,794	74,912	76,035	4%

Source: Section C.3, page 27

The applicant states, as a result of this growth, DUHS' existing hospital imaging locations often experience a backlog in scheduling procedures. The applicant states that this growth would be more effectively met with an additional outpatient service location that both expands geographic access and offers a non-hospital-based service model that can offer a lower cost option for some patients and payors. [pages 27-28].

Service Area and Utilization Growth

The applicant states that based on a projected utilization report from Sg2 (DUHS contractor), the geographical service area will experience a significant growth in specific modalities from 2018-2025. [pages 28-31].

DUHS Provider Network Growth (Primary and Specialty Physician Recruitment)

The applicant states that in order to be able to continue to meet the need of the growing population in the service area, DUHS is pursuing growth in both primary care and specialty services. The increased number of primary and specialty providers not only in the service area but specifically in the same medical office building will increase the demand for the diagnostic services essential to these practices and their patients. [pages 31-32].

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

- Reliable data sources are used to support assertions about population growth and medical need for the proposed services.

- The applicant uses the data to make reasonable and adequately supported assumptions about service area residents’ future need for the proposed services.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization, as illustrated in the following table.

Duke Radiology at Arrington Diagnostic Center Form C: Utilizations			
Each Service Component	1st Full FY 7/1/2020- 6/30/2021	2nd Full FY 7/1/2021- 6/30/2022	3rd Full FY 7/1/2022- 6/30/2023
CT Scanner			
# of Units	1	1	1
# of Scans	1,495	2,889	4,269
# of HECT Units*	2,541	4,911	7,257
MRI Scanner			
# of Units	1	1	1
# of Procedures	2,491	3,584	4,009
# of Weighted Procedures	2,515	3,619	4,048
Fixed X-ray			
# of Units	1	1	1
# of Procedures	2,268	3,457	4,596
Mammography			
# of Units	1	1	1
# of Procedures	1,196	2,280	3,349
Ultrasound			
# of Units	1	1	1
# of Procedures	1,388	2,407	3,337
CT Extremity			
# of Units	1	1	1
# of Procedures	437	443	450
Dexa			
# of Units	1	1	1
# of Procedures	463	778	1,084

Source: Section Q, Form C

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

- The applicant identifies the zip codes that are within a 20-minute drive time from the Arrington location. With the exception of the extremity CT scanner, the applicant assumes the primary service areas for the other services will be those zip codes within a 20-minute ride.
- The applicant calculated the FY2018 outpatient volumes for each service at all existing hospital and Independent Diagnostic Testing Facility (IDTF) locations, excluding interventional procedures and cancer volumes.
- The applicant projects a shift of the outpatient volumes from the existing sites to the new location. The applicant projects this shift based on factors described in Section C, pages 24-32.
- The applicant projects a shift in specific modalities volumes based on outpatient zip codes and existing service sites. The applicant assumes the following:
 - Originating zip codes closest to Arrington (10-minute drive time) will shift for geographic convenience.
 - Higher volume shifts for originating zip codes that are not close to other DUHS imaging sites.
 - Higher shifts due to back log or limited capacity at existing locations.
 - The applicant assumes modality-specific factors such as higher costs or driving distance for specific modalities.
- Using the Sg2's forecasting tool, the applicant projects that the new site will serve an additional incremental share of the service area procedure volume based on population growth, provider network growth, geographical access and patient convenience, for patients identified within the 20-minute drive time and costs benefits from an IDTF structure.
- Based on DUHS' historical experience at existing imaging sites, it is assumed that a percentage of the utilization will include patients from outside of the identified zip codes.
- The applicant capped the projected utilization at 80% capacity of a 10-hour day.

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

- Utilization is projected for each specific diagnostic service type, applying assumptions based on a shift in volumes due to population growth, change in geographical location and historical data.
- The applicant used conservative projected growth rates.

Access

In Section C, pages 37-38, 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. Imaging services are generally provided by physician referral, including from the adjacent urgent care center that will accept patients on a walk-in basis. There is no discrimination on the basis of race, ethnicity, age, gender, or disability.”

In Section L, page 70, the applicant states:

“DUHS does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay. DUHS will continue to have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as undeserved.”

In Section L, page 72, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Duke Radiology at Arrington FY 2022 (7/1/2021-6/30/2022)							
Payor Source	MRI	CT	Extremity Scanner	X-ray	Ultrasound	Mammo	DEXA
Self-Pay	0.13%	1.00%	0.63%	0.00%	0.57%	0.00%	0.05%
Charity Care	1.25%	2.59%	0.47%	4.21%	3.00%	0.95%	0.33%
Medicare*	24.20%	49.44%	48.42%	39.42%	28.78%	32.03%	69.69%
Medicaid *	3.56%	6.74%	0.70%	12.59%	11.40%	2.18%	0.88%
Insurance*	66.77%	37.82%	36.39%	40.61%	53.79%	63.48%	27.74%
Workers Compensation	1.01%	0.06%	0.71%	0.50%	0.03%	0.00%	0.00%
TRICARE	0.95%	0.34%	2.01%	0.70%	0.45%	0.40%	0.22%
Other	2.14%	2.01%	10.67%	1.99%	1.98%	0.96%	1.10%
TOTAL	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

*Includes managed care plans.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately identifies the population to be served.
 - The applicant adequately explains why the population to be served needs the services proposed in this application.
 - Projected utilization is reasonable and adequately supported.
 - The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to develop a new diagnostic center, Duke Health Arrington Radiology at 5601 Arrington Park Drive, Durham County. The combined value of the medical diagnostic equipment costing \$10,000 or more exceeds the statutory threshold of \$500,000 and therefore qualifies as a diagnostic center, which is a new institutional health service, and which requires a certificate of need.

As part of the proposed project, the applicant proposes to relocate an extremity CT scanner and replace and relocate an MRI scanner from Duke Radiology at Page Road, to the new Arrington IDTF at Arrington Park Drive.

In Section D, page 43, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated or relocated will be adequately met following completion of the project. On page 43, the applicant states:

- The new nearby location is equivalently accessible to patients in terms of geography and provides additional convenience in co-locating this equipment with all of the primary, specialty, and ambulatory surgery services in the same office building.
- The same nondiscrimination and financial assistance policies will apply at the new location.
- DUHS has several other MRI service locations in Durham County and will remain able to treat patients at other locations.

In Section Q, Form D, the applicant provides historical utilization of the equipment currently located at Page Road that will be relocated to Arrington. In Section D, page 45, the applicant states:

“Please note that Form D shows MRI volumes provided at Page Road, where DUHS previously provided MRI services on an Alliance mobile scanner, until its own scanner was relocated to that location last year. Volumes on the Duke-owned scanner at its previously location are provided on Duke University Hospital’s license renewal application. There will be no MRI or extremity scanner volumes at Page Road after relocation.”

In Section D, page 46, the applicant states:

“DUHS does not anticipate any material effect on the relocation of equipment to any of the identified groups. The new location [sic] approximately one mile from the existing location and is equivalently accessible to patients in term of geography. The same nondiscrimination and financial assistance policies will apply at the new location.”

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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.

C

The applicant proposes to develop a new diagnostic center, Duke Health Arrington Radiology at 5601 Arrington Park Drive, Durham County. The combined value of the medical diagnostic equipment costing \$10,000 or more exceeds the statutory threshold of \$500,000 and therefore qualifies as a diagnostic center, which is a new institutional health service, and which requires a certificate of need.

In Section E, page 47, 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:

No New Imaging Center-The applicant states that this alternative would not meet the need for additional access to imaging services. The applicant states that providing services in a medical office building with primary, urgent, specialty, and ambulatory surgery services will enhance patient convenience and coordination of care.

Imaging Center Without Relocation of Existing MRI and Extremity CT-The applicant states that creating two imaging locations less than a mile apart with only some of the equipment at each location, would require duplication of staff and support services. The applicant states it would be less convenient especially to patients seeking orthopedics care, which will be relocated to Arrington.

Relocating Existing MRI Without Replacement-The applicant states that the existing MRI machine is more than 10 years old and would require downtime for maintenance. Relocating and replacing the equipment would avoid gaps in access to service.

Relocating Existing Equipment (other than MRI and extremity CT) to new IDTF rather than Developing New Equipment-The applicant states existing CT scanners are already well-utilized and do not have significant excess capacity. The applicant states that other imaging equipment is also well-utilized and necessary to support hospital services at existing locations.

In Section D, page 43, the applicant states that its proposal is the most effective alternative because a new imaging center would meet the need for additional access to imaging services. The applicant states that the new nearby location is equivalently accessible to patients in terms of geography and provides additional convenience in co-locating this equipment with all of the primary, specialty, and ambulatory surgery services in the same office building.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Duke University Health System, Inc. shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the**

- event that representations conflict, Duke University Health System, Inc. shall materially comply with the last made representation.
2. Duke University Health System, Inc. shall develop a diagnostic imaging center with new CT, mammography, ultrasound, X-ray, and DEXA equipment, relocation of existing extremity scanner, and replacement and relocation of existing MRI scanner.
 3. Duke University Health System, Inc., as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section Q of the application or that would otherwise require a certificate of need.
 4. 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.
 5. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, 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.
 6. 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 insurance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

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Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the project as shown in the table below.

Duke Health Arrington Radiology	
Construction Costs	\$3,000,000
Architect/engineering fees	\$300,000
Medical Equipment	\$5,600,000
Miscellaneous Costs	\$410,000
Total	\$9,310,000

In Section Q, Form F.1a, F.1. and Exhibit F.1a, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 50-51, the applicant states that there are no start-up costs or initial operating expenses associated with this project.

Availability of Funds

In Section F, page 49, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing	
Type	Duke University Health System, Inc.
Loans	\$0
Accumulated reserves or OE *	\$9,310,000
Bonds	\$0
Other (Specify)	\$ 0
Total Financing	\$ 9,310,000

* OE = Owner's Equity

In Section F, page 52, the applicant states that the accumulated reserves of DUHS and revenue projections are sufficient to cover any operating costs until revenues exceed expenses. Exhibit F.2 (a) contains a letter from the Chief Financial Officer of Duke University Health Systems, Inc., dated June 10, 2019, committing to funding the proposed project. Exhibit F.2 (b) contains financial statements for Duke University Health Systems, Inc. and Affiliates, for the years ending June 30, 2018 and 2017. As of June 30, 2018, Duke University Health Systems, Inc. and Affiliates, had adequate cash and cash equivalents to fund the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F.2, the applicant projects that operating expenses will exceed revenues in the first two operating years, and that revenues will exceed operating expenses in the third operating year of the project, as shown in the table below.

Duke Health Arrington Radiology	1st Full FY 7/1/2020- 6/30/2021	2nd Full FY 7/1/2021- 6/30/2022	3rd Full FY 7/1/2022- 6/30/2023
Total Procedures	9,738	15,838	21,094
Total Gross Revenues (Charges)	\$3,841,735	\$6,184,411	\$7,994,451
Total Net Revenue	\$1,874,880	\$2,962,434	\$3,737,052
Average Net Revenue per procedure	\$192.53	\$187.04	\$177.16
Total Operating Expenses (Costs)	\$2,544,758	\$2,972,551	\$3,165,960
Average Operating Expense per procedure	\$261.32	\$187.68	\$150.08
Net Income	(\$669,878)	(\$10,117)	\$571,092

*Total Procedures include CT, MRI, x-ray, mammography, ultrasound, CT extremity and DEXA

Source: Section Q, Form F.2

Although their net income was negative for the first three years of operation, In Section Q, DUHS demonstrates that net revenue exceeds operating costs.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

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N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” The 2019 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section Q, the applicant defines the service area as geographical by zip codes. Facilities may also serve residents of counties not included in their service area.

In Section G.1, pages 55-57, the applicant identifies the providers of similar hospital and outpatient imaging services within the applicant’s defined service area. There are over 20 facilities identified in the service area with one or more of the diagnostic modalities to be offered by the applicant.

In Section G, page 58, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved imaging services in the service area. The applicant states:

“The population in southern Durham County and surrounding areas is growing quickly and the demand for imaging services is growing with it, as set forth in response to Section C. Reflecting the growing demand for imaging services in this part of the county, DUHS volumes have grown significantly in recent years and its equipment is highly utilized across all modalities.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed diagnostic center is needed in addition to the existing or approved diagnostic center services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

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

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Duke Health Arrington Radiology		
Position	Current FTE Staff	Projected FTE Staff
	As of 6/30/2019	2nd Full Fiscal Year 7/1/2021-6/30/2022
Radiology* Technologists	0	9.09
Clinical Test Equipment	0	1.62
Financial Care Counselor	0	1.62
TOTAL		12.33

*Includes Mammography Techs and Sonographers

The assumptions and methodology used to project staffing are provided in Section Q, Form H. 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.2 and H.3, pages 60 and 61, respectively, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I.3, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

In Section I, page 62, the applicant states that the following ancillary and support services are necessary for the proposed diagnostic center:

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

On page 62, the applicant adequately explains how each ancillary and support service will be made available.

In Section I, pages 62-63, the applicant describes its efforts to develop relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (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

In Section K, page 66, the applicant states that the project involves renovating 7,125 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 66, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit F.1(a).

On page 67, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services and provides supporting documentation in Exhibit F.1(a).

On page 67, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On page 68, 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.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 70, the applicant provides the historical payor mix during the last full fiscal year (7/1/2017-6/30/2018) for services provided at the Page Road hospital clinic locations from which the existing extremity scanner and the MRI to be replaced will be relocated, as shown in the table below.

Duke Radiology at Page Road			
Payor Source	Page Road	MRI	CT Extremity
Self-Pay	0.44%	0.46%	0.30%
Charity Care	1.37%	1.42%	0.89%
Medicare*	24.79%	22.00%	37.98%
Medicaid *	2.74%	3.06%	0.74%
Insurance*	66.52%	69.34%	53.11%
Workers Compensation	0.74%	0.63%	1.19%
TRICARE	1.44%	1.42%	1.34%
Other	1.97%	1.68%	4.46%
Total	100.00%	100.00%	100.00%

*Including any managed care plans

In Section L, page 69, the applicant provides the following comparison.

DUHS Page Road Imaging HOPD	Las full Fiscal Year (7/1/2017-6/30/2018)	
	% of total patients served	% of Population of the Service Area* Durham
Female	56.5%	52.2%
Male	43.4%	47.8%
Unknown	0.1%	
64 and Younger	77.3%	87.3%
65 and Older	22.7%	12.7%
American Indian	0.2%	0.9%
Asian	3.5%	5.2%
Black or African-American	14.7%	37.8%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	73.5%	53.5%
Other Race	4.9%	2.5%
Decline/Unavailable	4.1%	

*Source: US Census Bureau QuickFacts, <https://www.census.gov/quickfacts/facts/table/us/PST045218>

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 70, the applicant states:

“DUHS does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay. DUHS will continue to have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

In Section L, page 71, the applicant states that during the last five years five patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina. The applicant states that four of the five complaints have been dismissed without further investigation. One complaint is still under investigation.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L, page 72, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Duke Radiology at Arrington FY 2022 (7/1/2021-6/30/2022)							
Payor Source	MRI	CT	Extremity Scanner	X-ray	Ultrasound	Mammo	DEXA
Self-Pay	0.13%	1.00%	0.63%	0.00%	0.57%	0.00%	0.05%
Charity Care	1.25%	2.59%	0.47%	4.21%	3.00%	0.95%	0.33%
Medicare*	24.20%	49.44%	48.42%	39.42%	28.78%	32.03%	69.69%
Medicaid *	3.56%	6.74%	0.70%	12.59%	11.40%	2.18%	0.88%
Insurance*	66.77%	37.82%	36.39%	40.61%	53.79%	63.48%	27.74%
Workers Compensation	1.01%	0.06%	0.71%	0.50%	0.03%	0.00%	0.00%
TRICARE	0.95%	0.34%	2.01%	0.70%	0.45%	0.40%	0.22%
Other	2.14%	2.01%	10.67%	1.99%	1.98%	0.96%	1.10%
TOTAL	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

On page 73, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix of the existing DUHS diagnostic services originating

from the identified zip codes for the proposed project, diagnostic services used at the Page Road location, and the anticipated payor shift due to the aging population.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L, page 73, 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

In Section M, page 74, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
 - (16) Repealed effective July 1, 1987.
 - (17) Repealed effective July 1, 1987.
 - (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to develop a new diagnostic center, Duke Health Arrington Radiology at 5601 Arrington Park Drive, Durham County. The combined value of the medical diagnostic equipment costing \$10,000 or more exceeds the statutory threshold of \$500,000 and therefore qualifies as a diagnostic center, which is a new institutional health service, and which requires a certificate of need.

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” The 2019 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section Q, the applicant defines the service area as geographical by zip codes. Facilities may also serve residents of counties not included in their service area.

In Section G.1, pages 55-57, the applicant identifies the providers of similar hospital and outpatient imaging services within the applicant’s defined service area. There are over 20 facilities identified in the service area with one or more of the diagnostic modalities to be offered by the applicant.

In Section N, page 75, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 75, the applicant states:

“This project will create a new, non-hospital-based imaging site, DUHS’s first in Durham County. The proposed IDTF structure typically has lower reimbursement than hospital facilities and is more cost effective for many payors and patients depending on their plan terms.”

...

Patients will have access to all of the highly specialized services for which Duke is known; with the PACS system, images can be accessed by radiologists throughout the system, and therefore patients will have access to high-quality state-of-the-art services in a new location and with a different reimbursement structure.

...

As previously stated, DUHS will continue to have a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved."

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F, K, N and Q of the application and any exhibits)
- Quality services will be provided (see Sections N and O of the application and any exhibits)
- Access will be provided to underserved groups (see Sections C, L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section Q, Form A, the applicant identifies the diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of one of this type of facility located in North Carolina.

In Section O, page 78, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care have not occurred in any of these facilities. After reviewing and considering information provided by the applicant, 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 applicant proposes to develop a diagnostic image center with new CT, mammography, ultrasound, X-ray, and DEXA equipment, relocation of existing extremity scanner, and replacement and relocation of existing MRI scanner.

The Criteria and Standards for Diagnostic Centers promulgated in 10A NCAC 14C .1800 were repealed. The Criteria and Standards for Major Medical Equipment promulgated in 10A NCAC 14C .3100 were repealed. However, the Criteria and Standards for Computed Tomography Equipment promulgated in 10A NCAC 14C .2300 are applicable to this review. The specific criteria are discussed below.

SECTION .2300 – CRITERIA AND STANDARDS FOR COMPUTED TOOGRAPHY EQUIPMENT

10A NCAC 14C .2300 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- In Section Q, Form H, the applicant projects that the CT scanner will perform 7,257 HECT units in the third year of operation (FY2023). This exceeds the minimum of 5,100 HECT units annually in the third year of operations as required by 10A NCAC 14C .2303. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (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- In Section C.12, page 40, the applicant states that DUHS currently owns and operates 29 CT scanners located in the service area. The applicant states that the scanners performed at least 5,100 HECT units, as show in the table below.

Facility	Scanners	Volumes in FY 18
DUHS IDTFs (Cary and Heritage)	2	1316 (unweighted; assume 1316 HECT units)
DUH campus and clinical sites	23	160751.25 HECT units
Duke Regional Hospital	3	44989.75 HECT units
Duke Raleigh Hospital	4	54627.25 HECT units
Total	32	261,684.25

*Source: Section C, page 40

The applicant demonstrates that DUHS met the required standard by performing an average of 8178 HECT units on its 32 fixed CT scanners in the last 12 months ($261,684.25/32 = 8177.63$). This exceeds the minimum of 5,100 HECT units per scanner in the 12-month period prior to the application submittal, as required by 10A NCAC 14C .2303.

- (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.*

- NA- In Section C.12, page 40, the applicant states that the total inventory for CT scanners will increase by 1. Based on the current performance measures, the average volume with 33 scanners would be 7929.82 or 7930 HECT units per scanner.