

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 28, 2024

Findings Date: May 28, 2024

Project Analyst: Cynthia Bradford

Co-signer: Lisa Pittman

Project ID #: J-12484-24

Facility: Duke Regional Hospital

FID #: 923142

County: Durham

Applicant: Duke University Health System, Inc.

Project: Acquire no more than one CT scanner for a total of no more than 4 CT scanners

### 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. (hereinafter referred to as “applicant” or “DUHS”) proposes to acquire one CT scanner to be located in renovated space in the main building of Duke Regional Hospital (“DRH”) for a total of no more than four CT scanners upon project completion.

#### **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 2024 SMFP. Therefore, there are no need determinations applicable to this review.

#### **Policies**

There is one policy in the 2024 SMFP that is applicable to this review: Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

**Policy GEN-4 states:**

*“Any person proposing a capital expenditure greater than \$4 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 \$4 million, but less than \$5 million. In Section B.21, page 26, the applicant describes the project’s plan to assure improved energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

**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 reason stated above.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which

all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to acquire no more than one CT scanner for a total of no more than four CT scanners.

In Section C.1, page 27, the applicant describes the project as follows:

*“Duke University Health System (“DUHS”) proposes to acquire one additional CT scanner to be developed in the main hospital building of Duke Regional Hospital (“DRH”), for a total of 4 fixed CT scanners.”*

**Patient Origin**

The 2024 SMFP does not define a service area for CT scanners. The Criteria and Standards for Computed Tomography Equipment, 10A NCAC 14C .2300, were repealed effective January 1, 2022. The applicant defines its service area based on its historical patient origin for CT scanner services as shown in the tables below. Facilities may also serve residents of counties not included in their service area.

*Historical Patient Origin*

In Section C, pages 27-28, the applicant provides the historical patient origin for its existing CT scanners for the last full fiscal year (July 1, 2022 - June 30, 2023), as shown below.

<b>Historical CT Scanner Patient Origin Duke Regional Hospital</b>		
<b>County</b>	<b>Number of Patients</b>	<b>Percent of Total</b>
Durham	14,761	54%
Granville	2,641	10%
Person	2,021	7%
Orange	1,470	5%
Wake	1,211	4%
Alamance	794	3%
Vance	338	1%
Guilford	223	1%
Franklin	188	1%
Chatham	165	1%
Caswell	157	1%
Cumberland	157	1%
Halifax	138	1%
Mecklenburg	101	<1%
Johnston	100	<1%
Other	2,678	10%
<b>Total</b>	<b>27,143</b>	<b>100%</b>

*Projected Patient Origin*

In Section C, page 29, the applicant provides the projected patient origin for the first three years of the proposed service, as illustrated below.

Projected CT Scanner Patient Origin Duke Regional Hospital						
Fixed CT Procedures	[1 <sup>st</sup> ] Full Fiscal Year 7/1/2025-6/30/2026		[2 <sup>nd</sup> ] Full Fiscal Year 7/1/2026-6/30/2027		3 <sup>rd</sup> Full Fiscal Year 7/1/2027-6/30/2028	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Patients
Durham	16,110	54%	16,422	54%	16,930	54%
Granville	2,882	10%	2,942	10%	3,029	10%
Person	2,206	7%	2,251	7%	2,318	7%
Orange	1,604	5%	1,637	5%	1,686	5%
Wake	1,322	4%	1,349	4%	1,389	4%
Alamance	867	3%	884	3%	911	3%
Vance	369	1%	376	1%	388	1%
Guilford	243	1%	248	1%	256	1%
Franklin	205	1%	209	1%	216	1%
Chatham	180	1%	184	1%	189	1%
Caswell	171	1%	175	1%	180	1%
Cumberland	171	1%	175	1%	180	1%
Halifax	151	1%	154	1%	158	1%
Mecklenburg	110	0%	113	0%	116	0%
Johnston	109	0%	111	0%	115	0%
Other	2,923	10%	2,983	10%	3,071	10%
<b>Total</b>	<b>29,623</b>	<b>100%</b>	<b>30,234</b>	<b>100%</b>	<b>31,131</b>	<b>100%</b>

Source: Application Section C, page 29

In Section 3, page 29, the applicant states:

*“DUHS projects that geographic patient origin for CT procedures by percentage and for the facility as a whole will remain constant with FY 2023 utilization patterns. This project is designed to expand capacity of an existing service to meet current and future projected patient needs, and DUHS has no reason to anticipate a material change in utilization trends by geography.”*

The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C, pages 31-33, the applicant describes the factors which it states support the need for the proposed project, including:

- DUHS anticipates that the demand for hospital services will continue to grow as the patient population grows. (page 32)
- DUHS projects the patient population for several counties within the following service areas to grow extensively over the next seven years, including: Durham (+13.5%); Granville (+11.2%); Person (+2.5%); Orange (+8.3%); and Wake (20.7%). (page 33)

- DRH projects that volume in other counties that comprise its secondary service area will remain consistent with their historical volume. (page 32)
- Volume is high and growing on DRH’s existing CT scanners. (page 31)

In Section C, page 33, the applicant states:

*“Durham County’s population is projected to grow 13.5% over the course of this decade, further driving need for acute care services including CT imaging. While Duke Regional Hospital needs additional capacity to meet its existing demand, it anticipates that the need will increase in the future to meet the demands of the growing population.”*

The information provided by the applicant in the pages referenced above is reasonable and adequately supported for the following reasons:

- The applicant provides information regarding the historical utilization of its existing CT scanners.
- The applicant provides data supporting its utilization projections and projected population growth in the primary and secondary service areas.

**Projected Utilization**

In Section Q, page 79, the applicant provides the projected CT procedures for the three fixed CT scanners in the main hospital building in the table below. The applicant states that it also operates two other fixed CT scanners in outpatient clinics, and that utilization of those two scanners is assumed to be held constant.

	FY23	FY24	FY25	FY26	FY27	FY28
Hospital Scanners – Diagnostic CT	37,583	38,710	39,872	41,068	42,300	43,569
Hospital Scanners – Interventional CT	761	769	776	784	792	800
Hospital Scanners – Total CT Procedures	38,344	39,479	40,648	41,852	43,092	44,369

In Section Q, pages 79-80, the applicant describes its assumptions as follows:

- The applicant calculated the historical growth rates in diagnostic and interventional CT scanner volumes from FY2019 to FY2023 as 7.1% and 1.9% respectively.
- The applicant applied projected growth rates in diagnostic and interventional CT scanner volumes for FY2023 through FY2027 as 3.0% and 1% respectively.

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

- The applicant’s utilization projections are supported by the projected population growth rates for the proposed primary and secondary service area.
- The applicant’s utilization projections for the CT scanner supported by its historical CT scanner utilization.

The applicant adequately demonstrates the need to acquire one CT scanner.

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

In Section C, page 38, the applicant states that its services are open to all area and non-area residents. The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	19%
Racial and ethnic minorities	47%
Women	62%
Persons with Disabilities	(Not tracked by DUHS)
Persons 65 and older	40%
Medicare beneficiaries	45%
Medicaid recipients	14%

On page 38, the applicant states:

*“The services of Duke University Health System facilities, including Duke Regional Hospital, are open to all area and non-area residents. There is no discrimination on the basis of race, ethnicity, age, gender, or disability. Policies to provide access to services by low income, medically indigent, uninsured, or underinsured patients are described and provided elsewhere in this application. The hospital meets ADA requirements for accessibility to disabled persons.”*

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

- The applicant provides estimated percentages of patients from underserved groups.
- The applicant provides written statements about offering access to all residents of the service area, including underserved groups.

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

NA

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

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

C

The applicant proposes to acquire no more than one CT scanner for a total of no more than four CT scanners.

In Section E, page 45, 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:

- Add CT capacity at another location. The applicant states,  
*“DUHS could increase CT capacity at a location other than the Duke Regional Hospital campus with the hope of decanting hospital volume to those locations. This alternative might alleviate capacity constraints to a limited extent for scheduled outpatient procedures. DUHS has already created two new IDTFs with CT scanning in the past five years (Heritage and Arrington) to accommodate scheduled outpatient diagnostic procedures in a more geographically disbursed model. At this point, adding additional capacity outside the hospital would not provide capacity for emergency or inpatient procedures, nor for most interventional procedures which are performed in the hospital itself. A new location would also require developing a variety of support services that are already available at the main hospital campus.”*
- Contract for mobile CT services. The applicant states:  
*“DUHS could attempt to contract for mobile CT services. However, such services*

*require additional operational expenses to pay a third-party mobile provider, the services are not conducive to inpatient procedures, and they are not typically available 24/7 to meet emergent patient needs. A fixed scanner in the hospital that can be operated 24/7 is more efficient and cost-effective.”*

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Duke University Health System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall acquire no more than one fixed CT scanner for a total of no more than four fixed CT scanners located at Duke Regional Hospital.**
- 3. Progress Reports:**
  - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
  - b. The certificate holder shall complete all sections of the Progress Report form.**
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
  - d. The first progress report shall be due on December 1, 2024.**



4. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
  
  5. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to acquire no more than one CT scanner for a total of no more than four CT scanners.

**Capital and Working Capital Costs**

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

Construction/Renovation Costs	\$1,000,000
Architect/Engineering Fees	\$264,000
Equipment Costs	\$2,364,079
Non Medical Equipment & IT	\$60,000
Furniture	\$20,000
Miscellaneous Costs^	\$586,921
<b>Total</b>	<b>\$4,295,000</b>

^ Includes permits and contingency costs

In Section Q, the applicant states that the Duke Facilities Planning Design and Construction provided the assumptions used to project the capital cost.

In Section F, pages 47-48, the applicant projects start-up costs or initial operating expenses for the proposed project as \$115,855 for the primary purpose of training staff. These start-up projections were calculated as follows:

Description	Cost
Staff Wages/salaries (1 month salary for the incremental CT Techs in FY2026)	\$81,694
Staff Benefits (1 month)	\$18,126
ACR Accreditation	\$2,100
Equipment Training (based on vendor information)	\$8,436
Contingency/Miscellaneous (Assumes 5% for owned building in newly constructed space)	\$5,499
<b>Total Start-up Costs</b>	<b>\$115,855</b>

**Availability of Funds**

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

Sources of Working Capital Cost Financing		
Type	Duke University Health System, Inc.	Total
Loans	\$	\$
Accumulated reserves or OE *	\$115,855	\$115,855
Bonds	\$	\$
Other (Specify)	\$	\$
<b>Total Financing **</b>	<b>\$115,855</b>	<b>\$115,855</b>

\* OE = Owner’s Equity

In a letter dated February 6, 2024 (Exhibit F.2(a)), the Executive Vice President of Finance, and Interim Chief Financial Officer for Duke University Health System certifies that the DUHS has committed as much as \$6,000,000 in accumulated reserves for the capital costs of the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The assumptions for calculating working capital costs are reasonably adequate and supported by sufficient documentation
- The source and availability of funding for the proposed project is reasonable and adequate

**Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. On Form F.2, the applicant states that keeping with its historical practice, DUHS provided the balance sheet for the health system as a whole. DUH fiscal year operates from July 1-June 30 each year. In Form F.4, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project for its CT services, as shown in the table that follows.

	1 <sup>st</sup> Full Fiscal Year 2026	2 <sup>nd</sup> Full Fiscal Year 2027	3 <sup>rd</sup> Full Fiscal Year 2028
Number of Procedures <sup>^</sup>	46,983	48,375	49,809
Total Gross Revenues (Charges)	\$144,444,970	\$148,724,705	\$153,132,295
Total Net Revenue	\$31,914,527	\$33,810,596	\$35,824,111
Average Net Revenue per procedure	\$679	\$699	\$719
Total Operating Expenses (Costs)	\$11,596,024	\$12,096,388	\$12,546,303
Average Operating Expense per procedure	\$247	\$250	\$252
Net Income	\$20,318,503	\$21,714,208	\$23,277,808

Source: Section Q, Form C.2a

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 that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

**C**

The applicant proposes to acquire no more than one CT scanner for a total of no more than four CT scanners.

The 2024 SMFP does not define a service area for CT scanners. In Section G, page 54, the applicant states that its primary service area is Durham County. Facilities may also serve residents of counties not included in their service area.

On page 54, the applicant provides a list of all existing health service facilities in Durham County that offer the service components proposed in this application.

In Section G, pages 54-55, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved CT scanner services in Durham County. The applicant states:

*“As set forth in Section C, CT scanning is an essential hospital function. Additional capacity is needed to accommodate the high and growing utilization at Duke Regional Hospital, including for inpatients and patients presenting through the emergency department, who cannot readily be transferred to another facility for imaging procedures. Expanding capacity to meet the existing demand for the facility’s patients will, therefore, not unnecessarily duplicate any services provided elsewhere in the county, including services provided by DUHS at its off-campus locations.”*

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 CT scanner is needed in addition to the existing or approved CT scanners.

### **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.

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

### C

The applicant proposes to acquire no more than one CT scanner for a total of no more than four CT scanners.

In Section Q, Form H, the applicant provides current and projected staffing for the proposed services as illustrated in the following table.

Position	Current		Projected	
	As of 6/30/2023	1 <sup>st</sup> Full Fiscal Year 2026	2 <sup>nd</sup> Full Fiscal Year 2027	3 <sup>rd</sup> Full Fiscal Year 2028
CT Technologists	19.69	26.97	27.78	28.61
Clinical Tech Assistant	1.99	3.97	4.09	4.22
Radiology Techs	0.04	0.0	0.0	0.0
Imaging Manager	1.00	1.12	1.12	1.12
Temp Labor	0.18	0.25	0.26	0.26
Orientees	0.53	2.87	2.95	3.04
<b>TOTAL</b>	<b>23.44</b>	<b>35.18</b>	<b>36.20</b>	<b>37.25</b>

Source: Form H in Section Q of the application.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.2, which is found in Section Q. In Section H, pages 56-57, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. On page 56, the applicant further states,

*“DUHS uses a variety of platforms to advertise and recruit for open positions, and conducts targeted online hiring events. DUHS offers competitive pay and attractive benefits to recruit qualified staff. Because high quality healthcare professionals are always in demand, the DUHS Human Resources Department regularly conducts salary surveys and adjusts to market demands as necessary to facilitate recruitment and retention of high quality staff. Also, DUHS is active in the community at large and interacts consistently with area clinical training programs.”*

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services for the following reasons:

- The applicant has provided sufficient evidence of the availability of resources and health manpower and management personnel for the proposed services.
- The applicant is experienced in recruiting and maintaining quality staff and personnel.
- The applicant has a proven training program to meet the needs of the proposed health services.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire no more than one CT scanner for a total of no more than four CT scanners.

### **Ancillary and Support Services**

In Section I, page 58, the applicant states that the following ancillary and support services are necessary for the proposed list. On page 58, the applicant adequately explains how each ancillary and support service is to be made available.

### **Coordination**

In Section I, page 59, the applicant describes its existing and proposed 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. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

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

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

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

C

The applicant proposes to acquire no more than one CT scanner for a total of no more than four CT scanners.

On page 61, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. In Section K, the applicant states:

*“DUHS has conferred with its experienced project managers and architects to determine the most reasonable alternative to develop CT services within the hospital building. DUHS worked with its project architect, as it does with all of its projects, to develop a cost-effective plan that would meet current and anticipated clinical needs and patient satisfaction within the existing medical office building. The architect based the projected design and upfit cost on a review of the project and actual costs of similar projects, published construction costing data, and the architect’s design experience. Based on its extensive experience developing health service projects and as set forth in the architect’s letter attached with Exhibit F.1(a), DUHS accordingly believe the construction plans reflect the most reasonable and cost-effective means of developing this project.”*

- The applicant is proposing to develop a CT scanner in an existing space which is more cost-effective than constructing a new space.

- The proposed equipment will improve quality and access to CT scanner services.

On page 62, 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.

On page 62, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

(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 64, the applicant provides the historical (FY2023) payor mix at DRH illustrated in the following table.

Duke Regional Hospital Payor Mix FY2023	
Payor Source	Percentage of Total Patients Served
Self-Pay	1%
Charity Care	5%
Medicare*	44%
Medicaid*	14%
Insurance*	34%
TRICARE	1%
Workers Compensation	<1%
Other (Specify)	1%
Total	100.0%

\*Including any managed care plans



In Section L, page 65, the applicant provides the following comparison.

	% of Total Patients	% of the Population of the Service Area*
Female	62%	52%
Male	38%	48%
Unknown	<1%	
64 and Younger	60%	85%
65 and Older	40%	15%
American Indian	<1%	1%
Asian	2%	6%
Black or African-American	38%	35%
Native Hawaiian or Pacific Islander	<1%	<1%
White or Caucasian	53%	44% (excl. Latino), 58% (incl. Latino)
Other Race	4%	
Declined/Unavailable	3%	

\* The percentages can be found online using the United States Census Bureau's QuickFacts located online at: <http://www.census.gov/quickfacts/fact/table/US/PST045218>.

**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 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 66, the applicant states,

*“DUHS has no special obligation under applicable Federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons, other than those obligations which apply to private, not-for-profit, acute care hospitals that participate in the Medicare, Medicaid, VA, TRICARE, and Title V programs.”*

In Section L, page 67, the applicant states there has been one patient civil rights access complaints have been filed against DUHS in the 18 months immediately preceding the submission of its application. The applicant states.

*“A race discrimination complaint was filed with the Office of Civil Rights by a hospital emergency department patient, which complaint was received by Duke on March 7, 2023. After Duke filed its response, OCR closed the complaint, finding insufficient evidence of noncompliance.”*

**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.

- (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 68, the applicant projects the following payor mix in SFY 28, the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Source	Entire Facility or Campus	CT Scanner Services (Service Component)
Self-Pay	1%	0.9%
Charity Care	5%	7.3%
Medicare*	45%	52.1%
Medicaid*	14%	9.4%
Insurance*	33%	26.5%
Workers Compensation	<1%	0.4%
TRICARE	1%	0.4%
Other	1%	3.1%
Total	100.0%	100.0%

\* Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.9% of total CT services will be provided to self-pay patients, 52.1% to Medicare patients and 9.4% to Medicaid patients.

In Section L, page 68, the applicant provides the methodology and assumptions used to calculate these projections:

*“Payor Mix for CT procedures utilizes baseline data from based on FY23 DRH Hospital CT cost center baseline. A one-time 1.16% aging adjustment for the inpatient population and a 1.81% aging adjustment for the outpatient population from insurance to Medicare was applied based on the recommendations provided by DUHS Revenue Management based on the specific aging assumptions applicable to the service line baseline 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 based on the reasons stated above.

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

C

In Section L, page 69, the applicant adequately describes the range of means by which patients will have access to the proposed services. The applicant states:

*“CT procedures are provided by physician referral. Patients presenting with emergent conditions in the emergency department are referred for imaging by emergency department providers.”*

### **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.

- (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, pages 71, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

### C

The applicant proposes to acquire no more than one CT scanner for a total of no more than four CT scanners.

The 2024 SMFP does not define a service area for CT scanners. In Section G, page 54, the applicant states that its primary service area is Durham County. Facilities may also serve residents of counties not included in their service area.

In Section N, page 72, 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 cost-effectiveness, quality and access to the proposed services. The applicant states,

*“This project will have a positive impact on access and quality as a result of increasing the availability capacity for these heavily utilized hospital services. The existing CT equipment is reaching capacity constraints which can affect the scheduling of procedures. Expanding capacity will increase scheduling flexibility and reduce any delays in treatment. The cost to patients and payors is established by government and/or contractual rates and is not projected to change based on the addition of*

*incremental equipment. However, to the extent that this project will reduce any delay in beginning treatment, it could decrease inpatient length of stay.”*

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

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

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 based on all the reasons described above.

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

### C

In Form O, Section Q, the applicant identifies seven existing hospitals located in North Carolina owned, operated or managed by the applicant.

In Section O, page 75, the applicant states that, during the 18 months immediately preceding the submittal of the application, they are not aware of any incidents related to quality of care occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred

in any of these facilities. The applicant also states on page 75, that One North Carolina Duke Life Point Hospital, Wilson Medical Center, faced a finding of immediate jeopardy in 2022, but is currently under compliance. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all other facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The Criteria and Standards for Computed Tomography Equipment promulgated in 10A NCAC 14C .2300 were repealed effective January 1, 2022. Therefore, there are no rules applicable to this review.