

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 26, 2023

Findings Date: May 26, 2023

Project Analyst: Terris Riley

Co-signer: Mike McKillip

Project ID #: J-12329-23

Facility: Duke Raleigh Hospital

FID #: 923421

County: Wake

Applicant: Duke University Health System, Inc.

Project: Acquire no more than one CT scanner for a total of no more than five 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 Raleigh Hospital (“DRAH”) for a total of no more than five 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 2023 SMFP. Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2023 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.11, 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 five 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 Raleigh Hospital (“DRAH”). DRAH currently operates a total of 4 fixed CT scanners, two in the main hospital building, one in an outpatient clinic in a medical office building on the main hospital campus, and one at an off-campus location, Duke Women’s Cancer Care Raleigh (on Macon Pond Road). With this project, the complement of CT scanners within the main hospital building will increase to three.”

Patient Origin

The 2023 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, 2021 - June 30, 2022), as shown below.

**Historical CT Scanner Patient Origin
 Duke Raleigh Hospital**

County	Number of Patients	Percent of Total
Wake	14,408	72.46%
Franklin	933	4.69%
Johnston	740	3.72%
Harnett	333	1.68%
Durham	320	1.61%
Nash	316	1.59%
Cumberland	223	1.12%
Virginia	152	0.76%
Wilson	148	0.74%
Vance	127	0.64%
Granville	122	0.61%
Wayne	117	0.59%
Other	1489	7.49%
Total	19,884	100.00%

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 Raleigh Hospital**

Entire Facility or Campus	[1 st] Full Fiscal Year 7/1/2024-6/30/2025		[2 nd] Full Fiscal Year 7/1/2025-6/30/2026		3 rd Full Fiscal Year 7/1/2026-6/30/2027	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Patients
Wake	15,705	72.46%	16,162	72.46%	16,633	72.46%
Franklin	1017	4.69%	1047	4.69%	1077	4.69%
Johnston	807	3.72%	830	3.72%	854	3.72%
Other	495	2.28%	509	2.28%	524	2.28%
Harnett	363	1.68%	374	1.68%	385	1.68%
Durham	349	1.61%	359	1.61%	370	1.61%
Nash	345	1.59%	355	1.59%	365	1.59%
Cumberland	243	1.12%	250	1.12%	258	1.12%
Virginia	166	0.76%	171	0.76%	176	0.76%
Wilson	161	0.74%	166	0.74%	171	0.74%
Vance	138	0.64%	143	0.64%	147	0.64%
Granville	133	0.61%	137	0.61%	141	0.61%
Wayne	128	0.59%	131	0.59%	135	0.59%
Other	1,624	7.49%	1,671	7.49%	1,719	7.49%
Total	19,884	100.00%	21,764	100%	21,954	100.00%

Source: Application Section C, page 29-30

In Section 3, page 29, the applicant states:

“DUHS projects that patient origin for CT procedures by percentage will remain constant with FY 2022 utilization patters. 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 33-34, 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
- DUHS projects the patient population for several counties within the following service areas to grow extensively over the next seven years, including: Franklin (33.5%); Johnston (30.1%); Harnett (18.7%); Chatham (16.5%); and Wake (20.7%)
- DRH projects that volume in other counties that comprise its secondary service area will remain consistent with their historical volume.
- Volume is high and growing on DRAH’s existing CT scanners.

In Section C, page 34, the applicant states:

“Wake County’s population is projected to grow 20% over the course of this decade, with almost a quarter million new residents, further driving need for hospital services including CT imaging. While DRAH needs additional capacity to meet existing demand, that need will increase in the future.”

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 88, 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
Hospital Scanners – Diagnostic CT	28,569	29,426	30,309	31,218	32,155
Hospital Scanners – Interventional CT	1,415	1,429	1,443	1,458	1,472
Hospital Scanners – Total CT Procedures	29,984	30,855	31,752	32,676	33,627

In Section Q, pages 87-88, the applicant describes its assumptions as follow:

- The applicant calculated the historical growth rates in diagnostic and interventional CT scanner volumes from FY2019 to FY2022 as 4.4% and 2.7%, respectively.
- The applicant applied projected growth rates in diagnostic and interventional CT scanner volumes for FY2023 through FY2027 as 3.0% and 1.0%, 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, pages 39-40, 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.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	17.6%
Racial and ethnic minorities	38.2%
Women	62.2%
Persons with Disabilities	(Not tracked by DUHS)
The elderly	43.5%
Medicare beneficiaries	49.0%
Medicaid recipients	10.2%

On page 39, the applicant states:

“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 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 five CT scanners.

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:

- Add CT capacity at another location. The applicant states,

“Duke Raleigh Hospital has a CT scanner at an off-campus location (Duke Women’s Cancer Care Raleigh at Macon Pond). DUHS also provides CT services at IDTFs in Wake County and other locations. DUHS could increase CT capacity at a location

other than the main hospital campus with the hope of decanting hospital volume to those locations. This alternative might further 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 and additional staffing that is already available at the main hospital campus.”

- Increase mobile CT services. The applicant states:

“It may be possible to try to increase those services. However, such services require additional operational expenses to pay the mobile provider, they are limited to scheduled outpatient procedures, and they are not available 24/7 to meet patient needs. A fixed scanner in the hospital that can be operated 24/7 if needed is more efficient.”

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 five fixed CT scanners, including three fixed CT scanners to be located at Duke Raleigh Hospital, and two fixed CT scanners located at outpatient clinics.**
- 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, 2023.
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. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder 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. 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 five 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	\$1,260,460
Architect/Engineering Fees	\$118,000
Equipment Costs	\$1,950,460
Non Medical Equipment & IT	\$100,000
Furniture	\$30,000
Miscellaneous Costs*	\$692,540
Total	\$4,151,000

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 50-51, the applicant projects start-up costs or initial operating expenses for the proposed project as \$63,448 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 FY2024)	\$15,925
Staff Benefits (1 month)	\$3,615
ACR Accreditation	\$2,320
Equipment Training (based on vendor information)	\$38,584
Contingency/Miscellaneous (Assumes 5% for owned building in newly constructed space)	\$3,003
Total Start-up Costs	\$63,448

Availability of Funds

In Section F, page 52, 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 *	\$63,448	\$63,448
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing **	\$63,448	\$63,448

* OE = Owner's Equity

In a letter dated February 13, 2023 (Exhibit F.2(a)), the Executive Vice President and Chief Operating Officer for Duke University Health System certifies that the DUHS has committed as much as \$5,000,000 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.

	1st Full Fiscal Year 2025	2nd Full Fiscal Year 2026	3rd Full Fiscal Year 2022
Total Gross Revenues (Charges)	\$111,452,501	\$116,988,639	\$122,801,785
Total Net Revenue	\$31,259,925	\$33,265,583	\$35,402,369
Average Net Revenue per procedure	\$985	\$1018	\$1053
Total Expenses (Costs)	\$6,485,886	\$6,758,279	\$7,408,130
Average Operating Expense per procedure	\$204	\$207	\$220
Net Income	\$24,774,039	\$26,507,304	\$27,994,239

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 five CT scanners.

The 2023 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. In Section G, page 35, the applicant states that its primary service area is Wake County. Facilities may also serve residents of counties not included in their service area.

On pages 57-60, the applicant provides a list of all existing health service facilities that offer the service components proposed in this application.

In Section G, page 60, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved CT scanner services in Wake County. The applicant states:

“As set forth in Section C, additional capacity is needed to accommodate the high existing utilization at Duke Raleigh 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 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
- 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 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 five 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 6/30/2022	1 st Full Fiscal Year 2025	2 nd Full Fiscal Year 2026	3 rd Full Fiscal Year 2027
Director Hospital Supply Chain	0.09	0.09	0.09	0.09
CT Technologists	14.74	16.98	16.98	16.98
Couriers	0.03	0.03	0.03	0.03
Supply Chain Associate	3.41	3.41	3.41	3.41
Supply Chain Team Lead	0.47	0.47	0.47	0.47
Supply Chain Product Analyst	0.09	0.09	0.09	0.09
Sterile Processing Tech Certified	0.04	0.04	0.04	0.04
Administrator Coordinator	0.09	0.09	0.09	0.09
Imaging Manager	1.08	1.08	1.08	1.08
Supply Chain Manager	0.28	0.28	0.28	0.28
Temp Agency	0.25	0.25	0.25	0.25
TOTAL	20.58	20.58	20.58	20.58

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, page 62-63 the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. On page 60, the applicant further states,

“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 five CT scanners.

Ancillary and Support Services

In Section I, page 64, the applicant states that the following ancillary and support services are necessary for the proposed services. On page 64, the applicant adequately explains how each ancillary and support service is to be made available.

Coordination

In Section I, page 65, 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 one additional CT scanner to be located in 2,500 square feet of renovated space in the main hospital building.

On pages 68-69 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.”

- 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 69, 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 69, 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 71, the applicant provides the historical (FY2022) payor mix at DRAH illustrated in the following table.

**Duke Raleigh Hospital
 Payor Mix FY2022**

Payor Source	Percentage of Total Patients Served
Self-Pay	0.9%
Charity Care	3.0%
Medicare*	46.6%
Medicaid*	8.3%
Insurance*	38.7%
TRICARE	1.4%
Workers Compensation	0.2%
Other (Specify)	0.8%
Total	100.0%

*Including any managed care plans

In Section L, page 75, the applicant provides the following comparison.

	% of Total Patients	% of the Population of the Service Area*
Female	62.2%	51.1%
Male	37.8%	48.9%
64 and Younger	56.5%	87.4%
65 and Older	43.5%	12.6%
American Indian	0.4%	0.8%
Asian	3.1%	8.3%
Black or African-American	26.5%	21.0%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	62.6%	67.1%
Other Race	3.3%	2.8%
Declined/Unavailable	4.0%	n/a

* 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 73, the applicant states,

“Duke University Health hospitals have satisfied the requirements of applicable federal regulations to provide, on an annual basis, a certain amount of uncompensated care in return for Hill Burton funds previously received. ... DUHS have 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 which participate in the Medicare, Medicaid, and Title V programs.”

In Section L, page 78, the applicant states there have been no patient civil rights access complaints have been filed against DUHS in the 18 months immediately preceding the submission of its application.

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 75, the applicant projects the following payor mix during 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)
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Self-Pay	1.0%	0.8%
Charity Care	3.1%	7.4%
Medicare*	48.8%	50.3%
Medicaid*	10.2%	10.2%
Insurance*	34.4%	28.9%
Workers Compensation	0.2%	0.4%
TRICARE	1.5%	0.8%
Other	0.9%	1.2%
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 0.8% of total CT services will be provided to self-pay patients, 50.3% to Medicare patients and 10.2% to Medicaid patients.

In Section L, page 75, the applicant provides the methodology and assumptions used to calculate these projections:

“The payor mix remains consistent with DRAH FY22 inpatient experience with the exception of a onetime adjustment of 3.2% in FY 2023 from the insurance volume to Medicare to reflect the anticipated aging of the population based on an age analysis of the existing DUHS patient population. The payor mix also reflects the effect of a projected 3% annual growth in all patient encounters beginning in FY 24.

Payor Mix for the CT service component utilizes baseline patient data from FY2022 DRAH On-Campus CT cost center, with a one-time 2.7% aging adjustment from insurance to Medicare in FY 2023.”

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, pages 73-74, 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 similarly 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 78, 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 five CT scanners.

The 2023 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. In Section G, page 35, the applicant states that its primary service area is Wake County. Facilities may also serve residents of counties not included in their service area.

In Section N, page 79, 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. 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 three existing hospitals located in North Carolina owned, operated or managed by the applicant, including Duke University Hospital, Duke Regional Hospital and Duke Raleigh Hospital.

In Section O, page 82, the applicant states that, during the 18 months immediately preceding the submittal of the application, no 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. 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.