

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 3, 2024

Findings Date: September 3, 2024

Project Analyst: Crystal Kearney

Co-Signer: Lisa Pittman

Project ID #: J-12525-24

Facility: Duke Raleigh Hospital

FID #: 923421

County: Wake

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

Project: Acquire no more than two additional CT scanners for a total of no more than six CT scanners upon project completion

REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Duke University Health Systems, Inc. (hereinafter referred to as “applicant” or “DUHS”) proposes to acquire no more than two CT scanners at Duke Raleigh Hospital for a total of no more than six 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 State Medical

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

Policies

There is one policy in the 2024 SMFP, on page 25, 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 \$5 million. In Section B, pages 25-26, the applicant describes the project’s plan to ensure improved energy efficiency and water conservation. The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 based on the following:

- The applicant adequately describes how the project will be in compliance with all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption, including 2024 SMFP Policy GEN-4.
- The applicant states that the upfit of the space will be pursued to ensure energy efficient and cost-effective utilities, including water conservation, consistent with patient needs.

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.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to acquire no more than two additional CT scanners to be developed in a building on the campus of Duke Raleigh Hospital (“DRAH”), a licensed hospital that operates as a remote campus of Duke University Hospital for a total of no more than six CT scanners upon project completion.

DRAH currently operates a total of 4 fixed CT scanners on the hospital campus, three in the main hospital building, one in an outpatient clinic in a medical office building on the main hospital campus. With this project, the complement of CT scanners operated on the hospital campus will increase to 6 (3 in the main hospital building, one in a different outpatient setting on the hospital campus and 2 developed pursuant to this project in a building on the hospital campus). The “service component” for this project is CT services provided on the CT scanners on the hospital campus (4 existing and 2 proposed).

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 2024 SMFP does not define the service area for CT scanners, nor are there any applicable rules adopted by the Department that define the service area for CT scanners. In Section G, page 61, the applicant defines the primary service area as Wake County. Providers may serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin for CT scans at Duke Raleigh Hospital.

Duke Raleigh Hospital CT scans				
County	Historical CY 2023		Third Full Year 7/1/2028-6/30/2029	
	# of Patients	% of Total	# of Patients	% of Total
Cumberland	348	1.25%	484	1.2%
Durham	514	1.85%	694	1.8%
Franklin	1,205	4.34%	1,606	4.1%
Harnett	390	1.40%	619	1.6%
Johnston	1,121	4.03%	1,418	3.7%
Nash	532	1.91%	792	2.0%
Wake	19,595	70.53%	26,454	68.2%
Remaining Counties*	3,082	11.11%	4,626	11.9%
Out of State	995	3.58%	2,122	5.5%
Total	27,782	100.00%	38,815	100.0%

Source: Section C, pages 27-30 and 31-33

*Remaining Counties are listed on pages 27-30 and 31-33

In Section C, page 31, the applicant provides the assumptions and methodology used to project its patient origin. The applicant projects patient origin based on its existing patient origin at Duke Raleigh Hospital. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

The applicant states that the hospital proposes to operate the proposed new equipment 50 hours per week in an on-campus hospital department (7am-5pm M-F). The new equipment will be used primarily for routine outpatient scans, which will create capacity on the existing scanners in the hospital building for interventional procedures, ablations, and procedures for inpatients and emergency department patients.

In Section C, pages 35-38, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The need for additional CT capacity is supported by the historical growth in CT imaging at DRAH and across the Duke Health system, as well as population growth in Wake County and surrounding areas and growth in DUHS’s patient base.
- Even though DRAH was approved to develop one incremental scanner in 2023, its continued growth since the filing of the application supports the development of additional capacity with this project.
- Growth in procedures means there could be lag time in scheduling non-emergent procedures, which could delay patients’ treatment.
- Developing additional fixed capacity may allow the hospital to reduce or eliminate its reliance on an outside vendor for mobile scanning, which will be more convenient and comfortable for patients and more cost-effective for the hospital.

- DUHS anticipates that the demand for these hospital services will only continue to grow as the population the hospital serves grows.

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

- The applicant adequately demonstrates that the addition of two CT scanners will help meet the growing demand for CT imaging services at DUHS locations in Wake County.
- The applicant adequately demonstrates that the addition of two CT scanners will ensure continued capacity to meet needs of patients at Duke Raleigh Hospital.
- The applicant adequately states the addition of two CT scanners will reduce reliance on mobile services.

Projected Utilization

In Section Q, pages 91, the applicant provides the FY 24 volumes for the existing fixed, mobile and outpatient hospital campus scanners, as illustrated in the following table below.

Duke Raleigh Hospital CT Procedures		
DRAH CT procedures (2 hospital scanners, 1 mobile, 1 outpatient)	FY 2024 (FP 1-8) *	FY 2024 (Annualized)
Diagnostic Procedures	28,647	42,971
Interventional Procedures	1,019	1,529
Total	29,666	44,500

*FP= Fiscal Period. 1st 8 months of applicants' fiscal year July-February

In Section Q, pages 91-92, the applicant provided historical growth rates for diagnostic and interventional procedures, as illustrated in the following table below.

	FY 2019	FY 2024 (Annualized)	CAGR*
Diagnostic Procedures	31,332	42,971	5.4% [6.5%]
Interventional Procedures	1,292	1,529	2.8% [3.4%]

*Compound Annual Growth Rate

** Agency calculation based on 5 year's growth in brackets

In Section Q, page 92, the applicant provided projected volumes for diagnostic and interventional procedures, as illustrated in the following table below.

	FY24 (Annualized)	FY 25	FY 26	FY 27	FY 28
Diagnostic Procedures	42,971	45,334	47,827	50,458	53,223
Interventional Procedures	1,529	1,559	1,590	1,622	1,654
Hospital Scanners-Total CT Procedures	44,500	49,417	49,417	52,080	54,887
Total Fixed Scanners	4	4	6	6	6

In Section Q, pages 91-92, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The Compound Annual Growth Rate (CAGR) of diagnostic procedures from FY 2019 – FY 2024 is 5.4%.
- The two additional fixed scanners are projected to grow at a CAGR of 5.5%.
- The Compound Annual Growth Rate (CAGR) of intervention procedures from FY2019 – FY2024 is 2.8%. The procedures are projected to grow a more a conservative CAGR of 2% annually.
- The total number of diagnostic and interventional CT scanner procedures performed at DRAH in FY 2024 will be 44,500 and FY 2025 will be 49,417 with three fixed scanners and one mobile scanner.
- Beginning in FY 2026, DUHS projects that all procedures will be accommodated on the six existing and proposed fixed scanners.

	Duke Raleigh Hospital CT Scanner Projected Utilization Upon Project Completion				
	Partial FY CY2024	1 st Full FY CY2025	2 nd Full FY CY 2026	2 nd Full FY CY2027	3 rd Full FY CY2028
Fixed CT Scanners Procedures	40,414	42,583	49,417	52,080	10,291
Mobile Scanners Procedures	4,086	6,834			
Total Fixed Scanners	4	4	6	6	6

Source: Section Q, page 92

Projected utilization is reasonable and adequately supported because the projected growth rate is conservative and based on the historical growth of CT procedures at Durham Raleigh Hospital.

Access to Medically Underserved Groups

In Section C, page 43, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients during the Third Full FY
Low income persons	14.4% (charity care and Medicaid)
Racial and ethnic minorities	37.4%
Women	63.5%
Persons with Disabilities	NA (not tracked by DUHS)
Persons 65 and older	43.5%
Medicare beneficiaries	52.3%
Medicaid recipients	11.3%

Source: Section C, page 43

On page 43, the applicant states:

“The services of Duke University Health System facilities, including Duke Raleigh 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. Please see Exhibit C.6 for DUHS’s Notice of Nondiscrimination.”

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 projections for CT services specifically; patients over 65 are assumed to be the same as Medicare beneficiaries, and racial and gender percentages are assumed to reflect the facility as a whole.
- The applicant states that the percentages for payor categories for the facility as a whole are reflected in information provided in Section L of the 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 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 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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

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

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

C

The applicant proposes to acquire no more than two additional CT scanners to be developed in a building on the campus of Duke Raleigh Hospital (“DRAH”), a licensed hospital that operates as a remote campus of Duke University Hospital for a total of no more than six CT scanners upon project completion.

In Section E, page 51, 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 that another new location would also require developing a variety of support services and additional staffing that is already available at the main hospital campus. Current and projected utilization supports the addition of capacity at the hospital campus. DUHS does not have space available at the other campus location where CT services are provided for the additional equipment. The building identified for this project has empty shell space that can be efficiently developed for imaging services without disruption to other patient care.
- **Increase mobile CT services** - The applicant states that DUHS already contracts with Alliance Imaging for mobile CT services at Duke Raleigh Hospital and is increasing hours of operation in July to 12 hours/day. However, such services require additional operational expenses to pay the mobile provider and have limited availability to further increase capacity. Fixed scanners are more cost-effective and provide more flexibility to expand hours of service as needed to meet demand

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

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all 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 two CT scanners for a total of no more than six CT scanners at Duke Raleigh Hospital upon project completion.**
 - 3. The certificate holder 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.**
 - 4. 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 February 1, 2025.**
 - 6. 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.**
 - 7. 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 two additional CT scanners to be developed in a building on the campus of Duke Raleigh Hospital (“DRAH”), a licensed hospital that operates as a remote campus of Duke University Hospital for a total of no more than six CT scanners upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 106, the applicant projects the total capital cost of the project, as shown in the table below.

Duke Raleigh Hospital CT Scanner Projected Capital Cost	
Construction/Renovation Contract(s)	\$2,182,625
Architect /Engineering Fees	\$590,000
Medical Equipment	\$5,250,000
Non-Medical Equipment and IT	\$195,000
Furniture	\$110,000
Other (Contingency, misc.-see assumptions)	\$1,666,375
Total	\$9,994,000

Section Q, Form F.1a page 106

In Section Q, page 93, the applicant provides the assumptions used to project the capital cost.

The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant projects construction costs and architect and engineering costs based on the experience of the project architect with similar projects.
- The costs of the medical equipment, non-medical equipment, and furniture are based on the vendor estimates and the experience of DUHS with similar projects.
- All other costs are based on DUHS’s experience with similar projects.
- The applicant provides supporting documentation in Exhibit F.1.(a) and F.1(b).

In Section F, page 54, the applicant states that there will be start-up costs of \$87,600, however, there will be no initial operating expenses. The applicant states that DRAH already offers CT services at its main hospital campus. The applicant states that this service component is projected to have a positive net income throughout all interim and project years.

Availability of Funds

In Section F, page 54, the applicant states that Duke University Health System intends to use accumulated reserves to fund this project. Exhibit F.2(a) contains a letter dated June 3, 2024, from the Senior Vice President and Chief Financial Officer, Treasurer of DUHS stating their commitment to fund this project from existing accumulated cash reserves. In Exhibit F.2(b), the applicant provides the most recent audited financial statements for DUHS, demonstrating sufficient cash and cash equivalents and assets limited as to use to fund the project.

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

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, page 110, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

Duke Raleigh Hospital Fixed CT Services	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
	7/1/25-6/30/26	7/1/26-6/30/27	7/1/27-6/30/28
Total CT Procedures	49,417	52,080	54,887
Total Gross Revenues	\$167,827,092	\$176,868,346	\$186,403,084
Total Net Revenue	\$40,021,196	\$43,455,442	\$47,191,548
Average Net Revenue Per Procedure	810	834	860
Total Operating Costs	\$10,243,529	\$10,879,156	\$11,320,842
Average Operating Expense Per Procedure	\$207	\$209	\$206
Net Income	\$29,777,667	\$32,576,286	\$35,870,705

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 99-100. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant explains how it accounts for projected operating expenses and explains its revenue projections.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
 - 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 revenues and operating expenses for all the reasons described above.
- (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 two additional CT scanners to be developed in a building on the campus of Duke Raleigh Hospital (“DRAH”), a licensed hospital that operates as a remote campus of Duke University Hospital for a total of no more than six CT scanners upon project completion.

The 2024 SMFP does not define a service area for CT scanners. In Section G, page 61, the applicant defines its service area as Wake County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 64, the applicant states that only hospitals are required to report CT utilization. The applicant states that the following volumes were reported by Wake Med and Rex Hospitals in their 2024 LRAs for 2023.

Facilities	Total # of procedures
WakeMed (all locations)	79,429 procedures
WakeMed Cary	27,219 procedures
Rex Hospital (all locations)	60,051 procedures
DRAH*	29,666 procedures (8 months)

*Page 41, FY 2024 CT Volumes for all Wake County DRAH facilities.

In Section G, page 65, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved CT 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. 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. Moreover, it appears from hospital license renewal applications that utilization is increasing steadily at other facilities also, reflecting a need for increased capacity to these services.”

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 scanners are 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 all the reasons described 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 two additional CT scanners to be developed in a building on the campus of Duke Raleigh Hospital (“DRAH”), a licensed hospital that operates as a remote campus of Duke University Hospital for a total of no more than six CT scanners upon project completion.

In Section Q, Form H, page 116, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current Staff SFY 24	SFY 25 1st Full FY	SFY 26 2nd Full FY	SFY27 3rd Full FY
Clinical Nurse	0.00	1.68	1.68	1.68
CT Technologists	19.04	23.64	23.64	23.64
Radiology Techs	0.14	0.00	0.00	0.00
Imaging Manager	1.00	1.00	1.00	1.00
Radiology Supervisor	0.01	0.00	0.00	0.00
Financial Care Counselor	0.00	1.68	1.68	1.68
Orientees	0.01	0.01	0.01	0.01
Total	20.20	28.01	28.01	28.01

Section Q, Form H, page 116
 SFY= 7/1 – 6/30

The assumptions and methodology used to project staffing are provided in Section Q, page 101. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 66-67, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- Duke University Health System Nurse Recruitment is responsible for the recruitment of nursing and nursing support personnel for Duke Regional Hospital and the entire health system.
- Duke has a human resource department and uses multiple strategies to attract and recruit talent.
- DUHS offers competitive pay and attractive benefits to recruit qualified staff and the human resource department regularly conducts salary surveys and adjusts to market demands as necessary to facilitate recruitment and retention of high-quality staff.
- DUHS works closely with these programs to serve as a clinical training site, and benefits from interacting with potential new hires.
- The applicant states that in addition to position specific training, DUHS offers an array of programs and resources to support employees in learning new skills and advancing their careers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 two additional CT scanners to be developed in a building on the campus of Duke Raleigh Hospital (“DRAH”), a licensed hospital that operates as a remote campus of Duke University Hospital for a total of no more than six CT scanners upon project completion.

Ancillary and Support Services

In Section I, page 68, the applicant identifies the necessary ancillary and support services for the proposed services. On page 68, the applicant states that DRAH already provides CT scanning procedures and has identified those ancillary and support services used in connection with the existing CT service lines. The existing arrangements will be used to support the additional equipment at the new location on campus as needed.

Coordination

In Section I, page 69, 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 based on the following:

- DUHS works within the communities it serves to promote wellness and access to care.
- The applicant states that DUHS cooperates with public health departments in Wake and Durham counties and numerous community organizations to better understand the needs of the people who live here.
- The applicant states that Duke physicians donate emergency, primary and specialty care services to eligible, uninsured patients through Project Access, a program in Durham and Wake counties.
- The applicant states that DUHS and its local partners continue collaborative efforts to eliminate healthcare disparities and to improve access to high-quality medical care.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which

the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

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

NA

- (11) Repealed effective July 1, 1987.

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

C

The applicant proposes to acquire no more than two additional CT scanners to be developed in a building on the campus of Duke Raleigh Hospital (“DRAH”), a licensed hospital that operates as a remote campus of Duke University Hospital for a total of no more than six CT scanners upon project completion.

In Section K, page 71, the applicant states that the project involves the renovation of 4,012 square feet of existing space. Line drawings of the project are provided in Exhibit K.2.

On page 71, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The design minimizes cost of the project by renovating existing space rather than constructing new space.

- 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.

In Section K, page 72, the applicant adequately explains why the proposal will not unduly increase the cost to the applicant of providing the proposed services or the cost and charges to the public for the proposed services. The applicant states:

“This project will not increase the charges or projected reimbursement for these services, which are established by Medicare, Medicaid, and/or existing private payor contracts. DUHS has concluded that any costs incurred by it to develop and operate this facility are necessary and appropriate to provide critical screening and diagnostic services for patients in the area.”

In Section B, page 26, the applicant identifies any applicable energy saving features that will be incorporated into the construction plan.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on the 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 ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 75, the applicant provides the historical payor mix during FY2023 illustrated in the following table.

Payor Source	Percentage of Total Patients Served
Self-Pay	1.4%
Charity Care	2.1%
Medicare*	48.0%
Medicaid*	7.9%
Insurance*	37.6%
Workers Compensation	<1%
TRICARE	<1%
Other (workers comp; Tricare, other government payors)	<1%
Total	100.0%

* Including any managed care plans

In Section L, page 76, the applicant provides the following comparison.

Duke Raleigh Hospital	Last Full FY Before Submission of the Application	
	% of Total Patients	% of the Population of the Service Area*
Female	62.2%	50.9%
Male	37.8%	49.1%
Unknown	0.0%	0.0%
64 and Younger	54.9%	87.0%
65 and Older	45.1%	13.0%
American Indian	0.5%	0.8%
Asian	3.1%	8.9%
Black or African-American	26.3%	20.8%
Native Hawaiian or Pacific Islander	0.2%	0.1%
White or Caucasian	62.3%	58.3%
Other Race	3.4%	2.8% (two or more races)
Declined/Unavailable	4.3%	0.0%

* 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

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 persons with disabilities 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 77, the applicant states it has no such obligation.

In Section L, page 78, the applicant states there have been no patient civil rights access complaints have been filed against Duke Raleigh Hospital 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 group is expected to utilize the proposed services; and

C

In Section L, page 79, 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.

Projected Payor Mix 3rd Full FY	
Payor Source	Percentage of Total Patient Served
Self-Pay	1.4%
Charity Care [^]	2.1%
Medicare*	47.6%
Medicaid*	8.5%
Insurance*	39.5%
Workers Compensation ^{^^}	<1%
TRICARE ^{^^}	<1%
Other (Other Payor) ^{^^}	<1%
Total	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 1.4% of total services will be provided to self-pay patients, 47.6% to Medicare patients, and 8.5% to Medicaid patients.

DRAH Fixed CT Scanners Main Hospital Building

Payor Source	Percentage of Total Patient Served
Self-Pay	0.7%
Charity Care^	3.9%
Medicare*	49.1%
Medicaid*	10.8%
Insurance*	32.6%
Workers Compensation	0.4%
TRICARE	1.0%
Other (Other Payor)	1.5%
Total	100.0%

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.7% of total CT scanner services will be provided to self-pay patients, 49.1% to Medicare patients, and 10.8% to Medicaid patients.

In Section L, page 79, the applicant provides the methodology and assumptions used to calculate these projections:

Projected payor mix for CT services is based on FY 24 P1-8 actual procedures, with the following adjustments:

- Payor mix for inpatient volumes include a one-time 2.96% aging of population adjustment from Managed Care to Medicare thru FY25 based on evaluation of the age of the existing patient population.
- Payor mix for outpatient volumes include a one-time 1.9% aging of population adjustment from Managed Care to Medicare thru FY 24 based on an evaluation of the age of the existing patient population.
- Payor mix for inpatient and outpatient volumes also reflect a one-time 32.07% shift from self-pay to Medicaid to account for the Medicaid Expansion, effective December 1, 2023. NC DHHS originally projected that half of the 1.2 million uninsured in North Carolina would attain eligibility for Medicaid under the 2023 legislation. Based on this estimate and internal evaluations of the patient population, DUHS conservatively projected that approximately one-third of self-pay patients would convert to Medicaid.

Projected payor mix for the facility as a whole was based on FY 24 P1-4 actual encounters, with a one-time adding adjustment from managed care to Medicare and a one-time 32.0% shift from self -pay to Medicaid.

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 80, the applicant states that patients will have access to the proposed services via a physician referral to obtain CT procedures.

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, page 82, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- DRAH serves as training site for clinical training rotations for DUHS learners. Radiology residents and fellows in DUHS's graduate medical education programs engage in professional interpretations of imaging conducted across the system, including at the DRAH campus.
- In addition to its own nursing and medical student and graduate medical education training activities, DUHS also provides training opportunities for students in the area, including students from UNC, Wake Tech, Johnston Community College, and other local training programs.
- The applicant states that learners will continue to have access to all aspects of clinical care at DRAH upon project completion

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 two additional CT scanners to be developed in a building on the campus of Duke Raleigh Hospital (“DRAH”), a licensed hospital that operates as a remote campus of Duke University Hospital for a total of no more than six CT scanners upon project completion.

The 2024 SMFP does not define a service area for CT scanners. In Section G, page 61, 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 G, page 64, the applicant states that only hospitals are required to report CT utilization. The applicant states that the following volumes were reported by Wake Med and Rex Hospitals in their 2024 LRAs for 2023.

Facilities	Total # Procedures
WakeMed (all locations)	79,429 procedures
WakeMed Cary	27,219 procedures
Rex Hospital (all locations)	60,051 procedures
DRAH*	29,666 procedures (8 months)

*Page 41, FY 2024 CT Volumes for all Wake County DRAH facilities.

In Section N, page 83, 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 expand access and ease capacity constraints for highly utilized services at Duke Raleigh Hospital. Without additional capacity, the ability to timely meet the demand for these services is impeded, limiting patient and provider options for needed clinical care. This project will allow Duke Raleigh Hospital to continue to ensure meaningful patient and provider choice.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 83, the applicant states that 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 overall costs to patients and payors.

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

Regarding the impact of the proposal on quality, in Section N, page 83, the applicant states that 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 subject to capacity constraints which can affect the scheduling of procedures. Expanding capacity will increase scheduling flexibility and reduce any delays in treatment. DUHS is an established provider with a national reputation for high quality care, which will be expanded with this project.

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section C, pages 43, the applicant states,

“The services of Duke University Health System facilities, including Duke Raleigh 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.”

See also Sections C and L 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:

- 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.
- 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.
- Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on 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 Section Q, page 118, the applicant identifies three hospitals, and two diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity. In Section O, page 86, the applicant states that Duke Raleigh Hospital became a campus of Duke University Hospital effective June 1, 2024, and going forward will be certified for participation in Medicare and Medicaid and accredited as part of Duke University Hospital. As a result, DUHS is presenting documentation of Duke University Hospital's accreditation by The Joint Commission. For information purposes, Duke Raleigh Hospital was historically certified for participation in Medicare and Medicaid and accredited by the Joint Commission.

In Section O, page 86, 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. DUHS would note that Wilson Medical Center, which is owned by Duke LifePoint but not operated by DUHS, faced an immediate jeopardy finding in March 2023 but that designation has been remediated and removed. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The 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.