

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: July 26, 2022

Findings Date: July 26, 2022

Project Analyst: Donna Donihi

Co-Signer: Mike McKillip

Project ID #: J-12213-22

Facility: Duke University Hospital

FID #: 943138

County: Durham

Applicant: Duke University Health System, Inc.

Project: Acquire no more than one high intensity ultrasound (HIFU) for use with existing MRI scanner.

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.

NA

Duke University Health System, Inc., doing business as Duke University Hospital, (DUH), referred to hereinafter as “the applicant” or “DUHS”, proposes acquire no more than one high intensity focused ultrasound (HIFU) for use with an existing MRI Scanner.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2022 SMFP.
- acquire any medical equipment for which there is a need determination in the 2022 SMFP.
- offer a new institutional health service for which there are any policies in the 2022 SMFP.

Therefore, Criterion (1) is not applicable.

- (2) Repealed effective July 1, 1987.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

Acquire no more than one high intensity focused ultrasound (HIFU) for use with an existing MRI scanner.

The proposed equipment will be located in existing space at Duke University Hospital main campus. In Section C.1, page 26, the applicant describes the project as follows:

“DUHS proposes to acquire a high-intensity focused ultrasound for use on the main campus of Duke University Hospital in Durham, North Carolina. Specifically, the proposed equipment is INSIGHTEC's Exablate, transcranial Magnetic Resonance-guided Focused Ultrasound (MRgFUS) machine, which provides an advanced treatment option for certain neurology patients.

The equipment (sometimes referred to in literature or in this application as HIFU for “high intensity focused ultrasound”) provides an incisionless treatment option for essential tremor and tremordominant Parkinson's disease patients, with up to 1024 ultrasound waves precisely heat and ablate a deep brain target with no surgical incisions. This equipment will be installed in connection with an existing MRI scanner as MR imaging is used to guide treatment by providing high-resolution imaging, real-time thermal feedback.”

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 2022 SMFP does not define a service area for the proposed equipment. In section C.2. page 29, the applicant identifies counties and states in the proposed service area. Facilities may also service residents of counties not included in this service area. In section C.2, pages 27-28, the applicant provides the following table.

Historical Patient Origin
 Duke University Hospital

COUNTY	Last Full FY 07/01/2020-06/30/2021	
	# Patients	% of Total
Alamance	59,983	4.2%
Caswell	4,893	0.3%
Chatham	13,055	0.9%
Cumberland	23,191	1.6%
Durham	510,529	36.0%
Franklin	15,298	1.1%
Granville	42,642	3.0%
Guilford	21,230	1.5%
Harnett	8,578	0.6%
Johnston	13,323	0.9%
Lee	6,945	0.5%
Nash	7,570	0.5%
Orange	107,754	7.6%
Person	39,197	2.8%
Roberson	8,675	0.6%
Vance	19,898	1.4%
Wake	244,672	17.3%
Warren	6,475	0.5%
Wilson	5,297	0.4%
Other NC Counties	143,800	10.2%
Virginia	54,434	3.8%
Other States	59,083	4.2%
International	151	0.0%
Total	1,416,675	100%

In Section C, page 28, the applicant states, “*The patient origin for the service line HIFU procedures is projected to reflect the patient origin for DUH’s existing patients (from FY 2021) with an essential tremor diagnosis of DRG 25.0. Given that this is one of the primary diagnosis for patients who will benefit from this treatment option, DUHS anticipates that it is reasonable proxy for the geographic origin for HIFU patients going forward.*”

**Projected Patient Origin
 DUH HIFU**

COUNTY/STATE	3 rd Full FY 07/01/2025 06/30/2026	
	# Pts	% of Total
Durham	19	19%
Wake	19	19%
Orange	8	8%
Virginia	6	6%
Alamance	5	5%
Harnett	4	4%
Person	4	4%
New Hanover	3	3%
Cumberland	2	2%
Franklin	2	2%
Granville	2	2%
Lee	2	2%
Pitt	2	2%
South Carolina	2	2%
Other Counties	20	20%
Total	100	100%

The applicant’s assumptions are reasonable and adequate because the projected patient origin is consistent with the historical patient origin for patients at DUH that are appropriate for these procedures.

Analysis of Need

In Section C, pages 32-43 the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The primary patient populations who may be eligible for this new technology are those with Parkinson’s or Essential Tremor disorders. The applicant states, “*Essential Tremor is the most widespread neurological condition in the United States. Patients of any age can develop Essential Tremor, although the disease progresses at a substantially faster rate after the age of 40.*- *Parkinson's disease is a progressive, chronic disease caused by the dysfunction and/or death of brain cells essential for movement and coordination. It is anticipated that about one million persons in the United States have PD. Tremor is the primary debilitating symptom in around 26% of patients with Parkinson's disease. Essential tremor affects an estimated 2.2% of the population. Of that patient population, up to 70% may have symptoms well managed by medication, leaving 30% or more who do not respond effectively to medical management There are 25-55% of patients which show no response to pharmacotherapy). Many of these individuals may be candidates for deep brain stimulation but are averse to invasive surgery and the associated risk.*- *The technology proposed in this application provided a promising treatment option for tremor symptoms that is an outpatient treatment.*

- *Population growth and aging trends for Durham County and the extended service area demonstrate an increase for the population most likely to use the services being proposed.”*

Projected Utilization

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

HISTORICAL AND INTERIM MEDICAL EQUIPMENT UTILIZATION	PARTIAL FY 01/01/2023 06/30/2023	FIRST FY 07/01/2023 06/30/2024	SECOND FULL FY 07/01/2024 06/30/2025	THIRD FULL FY 07/01/2025 06/30/2026
High Intensity Focused Ultrasound				
# of units	1	1	1	1
# of Procedures	40	100	100	100

In Section Q, C.1., the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- *The applicant states, the MRI used to guide the HIFU equipment cannot be used for diagnostic imaging utilization while dedicated to these interventional procedures.*
- *DUH is able to allocate one MRI four hours per week for this purpose and will schedule HIFU procedures during a single four-hour block.*
- *DUHS projects that for the first 10 weeks, it will perform 1 procedure during each four-hour block to allow for ramp up in training and scheduling.*
- *After the 10-week ramp-up period, DUH will schedule two procedures per four-hour weekly block. This leads to a utilization of 100 patients per year.*
- *Based on current patient interest in this technology and the current wait times at other facilities outside of the Triangle to schedule procedures, DUH anticipates that the schedule will be fully utilized, and that capacity will be the limiting factor in utilization.*
- *DUH anticipates that there are more than 10,000 people in the 10-county area that comprises the hospital’s primary service area who could benefit from this treatment option.*
- *Currently, there are no providers of this treatment within this 10-county area.*
- *100 patients per year reflects less than 1% of this potential patient population who might benefit from this population and is generally consistent with DUH’s experience and utilization of Deep Brain Stimulator, the existing surgical treatment option for these patients.”*

Project utilization is reasonable and adequately supported based on the following reasons:

- The applicant documents projected population growth in the population groups most likely to need HIFU procedures.
- Projected utilization is based on the applicant’s historical treating patients who could benefit from this treatment option.

The applicant provides reasonable and adequately supported information to justify the need for the HIFU equipment.

Access to Medically Underserved Groups

In Section C, page 40, the applicant states,

“All individuals including low income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients and other underserved groups, will have access to DUH, as clinically appropriate. DUHS does not discriminate based on 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 in Exhibit C.6. As set forth in the pro forma, a significant proportion of DUH’s proposed services will be provided to Medicare, Medicaid, and uninsured patients.”

In Section C.6, page 40, the applicant provides the following table:

GROUP	ESTIMATED PERCENTAGE OF TOTAL PATIENTS DURING THE THIRD FULL FISCAL YEAR
Low income persons	18.0%
Racial and ethnic minorities	39.0%
Women	59.0%
Persons with disabilities	*
Persons 65 and older	34.0%
Medicare beneficiaries	38%
Medicaid recipients	12.0%

*The applicant states, “low income persons is not defined; this estimate is based on projected Medicaid beneficiaries and charity/reduced cost recipients in Section L.”

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
- 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 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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce or 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.

CA

The applicant proposes to acquire no more than one HIFU for use with an existing MRI scanner.

In Section E. page 48, the applicant states there are no alternative methods of meeting the needs for the proposed project. On page 48, the applicant states that DUHS does not currently have the technology to offer this treatment.

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 reasonable information to explained why the project is the most effective alternative.
- The applicant is conforming to all other statutory review criteria.

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 to acquire no more than one high intensity focused ultrasound (HIFU) for use with an existing MRI scanner at Duke University Hospital.**
 - 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on December 1, 2022.**
 - 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 Healthcare Planning and Certificate of Need Section 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 HIFU for use with an existing MRI scanner.

Capital and Working Capital Costs

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

DUKE UNIVERSITY HOSPITAL CAPITAL COSTS	
Construction/Renovation Contract	\$477,100
Architect/Engineering Fees	\$71,000
Medical Equipment	\$2,040,000
Non-Medical Equipment	\$25,000
Furniture	\$20,000
Other	266,900
Total	\$2,900,000

In Exhibit F.1(b), 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:

- In Exhibit F.1, the applicant provides documentation from the manufacturer regarding prices for all items associated with the the delivery and installation of the proposed equipment and these costs are included in the projected capital cost.
- In Exhibit F.1, the applicant provides documentation from an architect projecting construction plans and capital costs which are included in the projected capital cost.

In Section F.3, page 51, the applicant projects there will be no start-up costs or initial operating expenses associated with the proposed project because DUH is an existing facility.

Availability of Funds

In Section F.2, page 49, the applicant states that the capital cost will be funded as shown in the table below.

Type	Duke University Health System, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$2,900,000	\$2,900,000
Bonds	\$0	\$0
Other (Tenant Allowance)	\$0	\$0
Total Financing	\$2,900,000	\$2,900,000

* OE = Owner's Equity

In Exhibit F.2, the applicant provides a letter dated April 7, 2022 from the Senior Vice President, Chief Financial Officer and Treasurer for Duke University Health System, Inc. documenting its intention to provide accumulated reserves to finance the proposed project. Exhibit F.2-2 contains the Consolidated Financial Statements for Duke University Health System and affiliates for June 30, 2021 and 2020. As of June 30, 2021, DUHS had adequate cash and assets available to fund the proposed project.

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

- The applicant provides a letter from an appropriate individual confirming the availability of the type of funding proposed for the capital needs of the project and the commitment to using that funding for the capital needs of the project.
- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital and working capital needs of the project.

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 in Section Q, the applicant projects revenues will exceed operating expenses in the first three full fiscal years following completion of the project, and provided the calculations shown in the table below.

DUH HIFU Projected Revenue & Expenses			
	FY 1	FY 2	FY 3
	7/1/2023	7/1/2024	7/1/2025
	6/30/2024	6/30/2025	6/30/2026
Total # HIFU procedures	100	100	100
Total Gross Revenue (Charges)	\$6,363,622	\$6,490,894	\$6,620,712
Total Net Revenue	\$1,685,882	\$1,713,277	\$1,741,140
Average Net Revenue per procedure	\$16,858	\$17,132	\$17,411
Total Operating Expenses (Costs)	\$1,200,661	\$1,306,491	\$1,332,192
Average Operating Expense per procedure	\$12,006	\$13,064	\$13,321
Net Income	\$485,221	\$406,786	\$408,948

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

- The applicant accounts for projected operating expenses, such as salaries, consistent with projections elsewhere in the application.
- 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 based on the following:

- 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 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.

The applicant proposes to acquire no more than one HIFU for use with an existing MRI scanner.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2022 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C, page 29, the applicant defines the service area for the proposed project. Facilities may also serve residents of counties not included in the service area.

In Section G, page 57, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved services. The applicant states there are no other providers of these services in the proposed service area.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The applicant adequately demonstrates that acquiring a HIFU is necessary to accommodate the projected utilization by DUH patients who could benefit from HIFU treatment option.
- The applicant states there are no other providers of these services in the proposed service area.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion based on 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 HIFU for use with an existing MRI scanner.

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

DUH HIFU Current and Projected Staff			
Position	FY 1 (SFY2024)	FY 2 (SFY2025)	FY 3 (SFY2026)
Registered Nurse	0.1	0.1	0.1
Radiation Technologist	0.2	0.2	0.2
Financial Care Counselor	0.1	0.1	0.1
Patient Navigator	0.1	0.1	0.1
Total	0.5	0.5	0.5

The assumptions and methodology used to project staffing costs are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 59-60, the applicant describes its existing training and continuing education programs. In Section I, page 61, the applicant identifies the current medical director. In Exhibit H.3., the applicant provides supporting documentation.

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

- The applicant adequately documents the number of FTEs it needs to offer the proposed services.
- The applicant accounts for projected salaries and other costs of employment in its projected operating expenses found on Form F.3 in Section Q.
- The applicant provides adequate documentation of staff and its existing training and continuing education programs.

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 one HIFU for use with an existing MRI scanner.

Ancillary and Support Services

In Section I, page 61-62, the applicant identifies the necessary ancillary and support services for the proposed services. On page 62, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant identifies the existing ancillary and support services provided at DUH to the patients for the proposed services.
- The applicant states the existing providers will continue to provide the necessary ancillary and support services will continue to be available to the DUH patients.

Coordination

DUH is an existing facility. In Section I, page 62, the applicant describes its existing and proposed relationships with other local health care and social service providers. On page 61, the applicant states that DUH is part of the Duke University Health System. DUH maintains established relationships with local health care and social service providers in the area. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because the applicant provides documentation that it has existing relationships with other local health care and social service 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 for all the reasons described above.

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

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

NA

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

C

The applicant proposes to acquire no more than one HIFU for use with an existing MRI scanner.

In Section K, page 65, the applicant states the project involves renovating 971 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 65, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the fact that the applicant will utilize an existing MRI scanner and the project will require minimal renovation costs.

On pages 65-66, 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 of the proposed project is in compliance with all requirements for energy efficiency and consumption.

- The applicant states it is using existing space without developing any new square footage, which the applicant states will keep the capital cost to develop the project lower than it would be if it constructed additional space.

On page 66, the applicant states, *“This project is not anticipated to require construction. However, DUHS undertakes all construction efforts to follow all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption.”* Supporting documentation from the architect indicates this is the most cost-effective way to design this project in Exhibit F.1.

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.

- (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

The applicant proposes to acquire no more than one HIFU for use with an existing MRI scanner. In Section L, page 68, the applicant provides the historical payor mix during FY2021 for DUH as shown in the table below.

DUH Historical Payor Mix 07/01/2020 to 06/30/2021	
Payor Source	Entire Facility
Self-Pay	2.2%
Charity Care	2.6%
Medicare *	37.8%
Medicaid *	10.9%
Insurance *	43.3%
Workers Comp.	0.2%
TRICARE	1.4%
Other	1.5%
Total	100.0%

Source: Page 68 of the application.

* Including any managed care plans

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

Duke University Hospital	Percentage of Total Patients Served	Percentage of the Population in the Service Area * Durham County
Female	58.7%	52.3%
Male	41.3%	47.7%
Unknown	0.0%	0.0%
64 and Younger	65.3%	84.4%
65 and Older	34.7%	13.6%
American Indian	0.5%	0.9%
Asian	3.3%	5.5%
Black or African American	26.4%	36.9%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	61.5%	54.0%
Other Race	3.9%	0.0%
Declined / Unavailable	4.1%	0.0%

Sources: Page 69 of the application.

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

The applicant proposes to acquire no more than one HIFU for use with an existing MRI scanner.

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 71, the applicant states, “*DUHS does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap or ability to pay.*”

In Section L, page 71, the applicant states that during the last 18 months no patient civil rights access complaints have been filed against DUHS facilities located in North Carolina.

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 72, the applicant projects the following payor mix for the entire hospital and the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

Duke University Hospital Projected Payor Mix – FY 3 (FY 2026)		
Payor Source	Percent of Total Patients Served	HIFU Procedures
Self-Pay	1.9%	3.0%
Charity Care	2.4%	0.0%
Medicare *	38.2%	72.0 %
Medicaid *	12.3%	3.0%
Insurance *	41.8%	20.0%
Workers Compensation	0.2%	0.0%
TRICARE	1.4%	0.0%
Other	1.7%	2.0%
Total	100.0%	100.0%

Source: Page 72 of the application

As shown in the table above, during the third full fiscal year of operation, the applicant projects 1.9 percent and 3.0 percent of total facility services and HIFU procedures, respectively, will be provided to self-pay patients; 2.4 percent and 0.0 percent of total facility services and HIFU procedures, respectively, will be provided to charity care patients; 38.2 percent and 72.0 percent of total facility services and HIFU procedure services, respectively, will be provided to Medicare patients; and 12.2 percent and 3.0 percent of total facility services and HIFU procedure services, respectively, will be provided to Medicaid patients.

On page 72, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on DUH’s historical payer 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 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 74, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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

The applicant proposes to acquire no more than one HIFU for use with an existing MRI scanner.

In Section M, page 75, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant provides documentation of existing health professional training programs in the area for which it already provides access at DUH and other DUHS facilities.
- The applicant states it will continue to provide access to DUHS as it has in the past.

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.

(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 HIFU for use with an existing MRI scanner.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the department, which receives services from a health service facility.*” The 2022 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the department that define the service area for major medical equipment. In Section C, page 29, the applicant defines the service area for the proposed project. Facilities may also serve residents of counties not included in the service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 76, the applicant states: “*This project would create a second provider of this specialized neurology treatment in the state and the first in the county, providing patients a choice of provider and a greater range of treatment options.*”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 76, the applicant states, “*The project will not affect the cost to patients or payors for the services provided by DUH because reimbursement rates are set by the federal government and commercial insurers.*”

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

Regarding the impact of the proposal on quality, in Section N, page 76, the applicant states, “*The capital expenditure for this project is necessary to ensure that DUHS will continue to provide high quality services that are accessible to patients. DUHS received a 98.88% quality score from the ACO.*”

See also Sections B, C, and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 77, the applicant states DUHS will continue to have a policy to provide services to all persons regardless of race, sex, age, religion, creed, disability, national origin or ability to pay.

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:

- 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 which was publicly available during the review and used by the Agency

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

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

C

The applicant proposes to acquire no more than one HIFU for use with an existing MRI scanner.

On form O in Section Q, the applicant identifies the hospitals located in North Carolina which are owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of three facilities located in North Carolina.

In Section O, page 80, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that 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, the facilities owned, operated, or managed by the applicant are in compliance with all CMS Conditions of Participation. After reviewing and considering information provided by the applicant and considering the quality of care provided at three 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.

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.

The applicant proposes to acquire no more than one HIFU for use with an existing MRI scanner. There are no administrative rules that are applicable to their proposal.