

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 28, 2022

Findings Date: September 28, 2022

Project Analyst: Ena Lightbourne

Co-Signer: Lisa Pittman

Project ID #: J-12227-22

Facility: University of North Carolina Medical Center

FID #: 923517

County: Orange

Applicant(s): University of North Carolina Hospitals at Chapel Hill (UNC Hospitals)

Project: Convert a research MRI scanner to a clinical MRI scanner pursuant to Policy AC-3

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.

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University of North Carolina Medical Center (hereinafter referred to as (“the applicant” or “UNC Hospitals”) proposes to convert an existing research MRI scanner to a clinical MRI scanner pursuant to Policy AC-3. The applicant is proposing to initiate the clinical treatment of patients with essential tremor (ET) using a high-intensity focused ultrasound (HIFU) in conjunction with the existing research MRI scanner to perform magnetic resonance-guided HIFU procedures with limited clinical use upon CON approval.

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 2022 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2022 SMFP applicable to this review: *Policy AC-3: Exemption from Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects*

Policy AC-3

Policy AC-3: Exemption from Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects states:

“Projects for which certificates of need are sought by academic medical center teaching hospitals (Appendix F) may qualify for exemption from the need determinations of this document. The Healthcare Planning and Certificate of Need Section shall designate as an academic medical center teaching hospital any facility whose application for such designation demonstrates the following characteristics of the hospital:

- 1. Serves as a primary teaching site for a school of medicine and at least one other health professional school, providing undergraduate, graduate and postgraduate education.*
- 2. Houses extensive basic medical science and clinical research programs, patients and equipment; and*
- 3. Serves the treatment needs of patients from a broad geographic area through multiple medical specialties.*

Exemption from the provisions of need determinations of the North Carolina State Medical Facilities Plan shall be granted to projects submitted by academic medical center teaching hospitals designated prior to January 1, 1990 provided the projects are necessary to meet one of the following unique academic medical needs:

- 1. Necessary to complement a specified and approved expansion of the number or types of students, residents or faculty that are specifically required for an expansion of students or residents, as certified by the head of the relevant associated professional school; the applicant shall provide documentation that the project is consistent with any relevant standards, recommendations or guidance from specialty education accrediting bodies; or*
- 2. With respect to the acquisition of equipment, is necessary to accommodate the recruitment or retention of a full-time faculty member who will devote a majority of their time to the combined activities of teaching (including teaching within the clinical setting), research, administrative or other academic responsibilities within the academic medical center teaching hospital or medical school; or*
- 3. Necessary to accommodate patients, staff or equipment for a specified and approved expansion of research activities, as certified by the head of the entity sponsoring the research; and including, to the extent applicable, documentation*

pertaining to grants, funding, accrediting or other requirements, and any proposed clinical application of the asset; or

4. Necessary to accommodate changes in requirements of specialty education accrediting bodies, as evidenced by copies of documents issued by such bodies.

A project submitted by an academic medical center teaching hospital under this policy that meets one of the above conditions shall demonstrate that the academic medical center teaching hospital's teaching or research need for the proposed project cannot be achieved effectively at any non-academic medical center teaching hospital provider which currently offers and has capacity within the service for which the exemption is requested and which is within 20 miles of the academic medical center teaching hospital.

The academic medical center teaching hospital shall include in its application an analysis of the cost, benefits and feasibility of engaging that provider in a collaborative effort that achieves the academic goals of the project as compared with the certificate of need application proposal. The academic medical center teaching hospital shall also provide a summary of a discussion or documentation of its attempt to engage the provider in discussion regarding its analysis and conclusions.

The academic medical center teaching hospital shall include in its application a discussion of any similar assets within 20 miles that are under the control of the applicant or the associated professional school and the feasibility of using those assets to meet the unique teaching or research needs of the academic medical Center teaching hospital.

For each of the first five years of operation the approved applicant shall submit to Certificate of Need a detailed description of how the project achieves the academic requirements of the appropriate section(s) of Policy AC-3, paragraph 2 [items 1 through 4] as proposed in the certificate of need application.

Applicants who are approved for Policy AC-3 projects after January 1, 2012 shall report those Policy AC-3 assets (including beds, operating rooms and equipment) on the appropriate annual license renewal application or registration form for the asset. The information to be reported for the Policy AC-3 assets shall include: (a) inventory or number of units of AC-3 Certificate of Need-approved assets (including all beds, operating rooms and equipment); (b) the annual volume of days, cases or procedures performed for the reporting year on the Policy AC-3 approved asset; and (c) the patient origin by county. Except for operating rooms, neither the assets under (a) above nor the utilization from (b) above shall be used in the annual State Medical Facilities Plan need determination formulas, but both the assets and the utilization will be available for informational purposes to users of the State Medical Facilities Plan. Operating rooms approved under Policy AC-3 and their utilization shall be reported on the license renewal application and included in the inventory, regardless of the date of Certificate of Need approval.

This policy does not apply to a proposed project or the portion thereof that is based solely upon the inability of the State Medical Facilities Plan methodology to accurately project need for the proposed service(s), due to documented differences in patient treatment times that are attributed to education or research components in the delivery of patient care or to differences in patient acuity or case mix that are related to the applicant's academic mission. However, the applicant may submit a petition pursuant to the State Medical Facilities Plan Petitions for Adjustments to Need Determinations process to meet that need or portion thereof (see Chapter 2).

Policy AC-3 projects are required to materially comply with representations made in the certificate of need application regarding academic based need. If an asset originally developed or acquired pursuant to Policy AC-3 is no longer used for research and/or teaching, the academic medical center teaching hospital shall surrender the certificate of need."

The Division of Health Service Regulation designated UNC Hospitals as an academic medical center teaching hospital prior to January 1, 1990. In Section B, pages 28-30, and Exhibits B.3-1 and B.3-2, the applicant provides documentation that using HIFU services in conjunction with the research MRI scanner is necessary to accommodate the recruitment and retention of full-time faculty members that devote a majority of their time to the combined activities of teaching (including teaching within the clinical setting), research, administrative or other academic responsibilities within UNC Hospitals, that the proposed project is necessary to accommodate the expansion of research activities using HIFU services in conjunction with the research MRI scanner to treat patients with ET, and that there are no non-academic medical center teaching hospital providers within 20 miles that offer HIFU services to treat patients with ET. The applicant adequately demonstrates that the proposed project is consistent with the requirements of Policy AC-3.

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 demonstrates that the proposal is consistent with Policy AC-3 for the following reasons:
 - The applicant adequately documents that the using HIFU services in conjunction with the research MRI scanner is necessary to accommodate the recruitment and retention of full-time faculty members that devote a majority of their time

- to the combined activities of teaching (including teaching within the clinical setting), research, administrative or other academic responsibilities within UNC Hospitals;
- The applicant adequately documents that the proposed project is necessary to accommodate the expansion of research activities using HIFU services in conjunction with the research MRI scanner to treat patients with ET; and
 - The applicant adequately documents there are no non-academic medical center teaching hospital providers within 20 miles that offer HIFU services.
- (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 convert an existing research MRI scanner to a clinical MRI scanner pursuant to Policy AC-3.

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 a research MRI scanner or HIFU services, nor are there any applicable rules adopted by the Department that define the service area for a research MRI scanner or HIFU services. In Section G, page 74, the applicant defines the service area for the proposed project as Orange County. Facilities may also serve residents of counties not included in the service area.

In Section G, page 74, the applicant describes the service area as follows:

“As such, based on the proposed location of the equipment and the source of the largest percentage of patients expected to utilize the proposed equipment, UNC Hospitals has defined the service area as Orange County, though it expects to serve patients from other areas as well. Upon completion of the proposed project, UNC Hospitals will be the only provider to clinically treat patients with ET using magnetic resonance-guided HIFU services in Orange County, which is the service area for the proposed project.”

On page 37, the applicant states that magnetic resonance-guided HIFU is not an existing service; therefore, there is no historical patient origin to report. The applicant states that projected patient origin does not consider any potential future projects or initiatives that may impact patient origin of future patients. The following table illustrates projected patient origin.

UNC Medical Center Magnetic Resonance-Guided HIFU Projected Patient Origin						
County	1st Full FY		2nd Full FY		3rd Full FY	
	FY2024		FY2025		FY2026	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Orange	6	24.2%	10	24.2%	12	24.2%
Wake	4	17.3%	7	17.3%	9	17.3%
Chatham	2	7.1%	3	7.1%	4	7.1%
Durham	2	6.0%	2	6.0%	3	6.0%
Other^	11	45.4%	18	45.4%	22	45.4%
Total	25	100.0%	40	100.0%	50	100.0%

Source: Section C, page 38

^Includes 82 other counties and other states.

In Section C, page 37, the applicant provides the assumptions and methodology used to project patient origin. The applicant states the proposed service is not expected to have any impact on patient origin. The applicant projects patient origin based on the SFY 2021 patient origin of UNC Medical Center patients diagnosed with ET applied to the projected number of patients that will be clinically treated using magnetic resonance-guided HIFU. The applicant assumes that the total number of patients will grow at 0.9 percent per year consistent with ESRI’s (a geographic information systems provider) projected population growth from 2020 to 2026 in Orange County.

Analysis of Need

In Section C, pages 40-44, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- Using Magnetic Resonance-Guided HIFU to clinically treat ET patients will lead to less-invasive and more effective treatments that can improved the quality of life for ET patients (41-42).
- Optimize magnetic resonance-guided HIFU techniques and advance research (page 42-44).
- The projected population growth in the “service area”, particularly among the 65+ age cohort, the group mostly impacted, supports the need to advance clinical research for treatment of ET (page 44).

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

- The applicant provides reasonable and adequately supported information to support its assertions regarding the clinical advantages of magnetic resonance-guided HIFU treatment.
- The applicant provides projected population growth data to support its assumptions regarding the projected utilization.

Projected Utilization

In Section Q, Form, C.2b, the applicant provides projected utilization, as illustrated in the following table.

UNC Medical Center Magnetic Resonance-Guided HIFU Projected Utilization				
	Partial FY 2/1/2023- 06/30/2023	1st Full FY FY2024	2nd Full FY FY 2025	3rd Full FY FY 2026
Units	1	1	1	1
Procedures	20	50	80	100
MR-Guided HIFU Treatments	10	25	40	50

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

- The applicant is proposing to initiate the clinical treatment of patients with ET using a HIFU in conjunction with the existing research MRI scanner. The proposed project is scheduled to be operational on February 1, 2023. The applicant projects that the first operating year of the project will be FY 2024 (July 1, 2023 – June 30, 2024), the second operating year will be FY 2025 (July 1, 2024 – June 30, 2025), and the third operating year will be FY 2026 (July 1, 2025 – June 30, 2026).
- The HIFU in conjunction with the existing research MRI scanner will be used to perform reimbursable magnetic resonance-guided HIFU procedures consisting of one pre-treatment CT scan, two MRI scans (one during and one following the treatment) and the HIFU treatment itself. There are no performance standards associated with this project.
- The medical team identified the patients that would be appropriate for treatment through the first three full project years. The applicant states that the projections for the number of patients are reasonable and conservative based on the size of the existing patient panel, the medical team’s reputation, and the availability of the research grant to support the project.

UNC Hospitals Projected Number of Magnetic Resonance-Guided HIFU Patients				
	Partial FY 2/1/2023- 06/30/2023	1st Full FY FY2024	2nd Full FY FY 2025	3rd Full FY FY 2026
MR-Guided HIFU Patients	10	25	40	50

Source: Section Q, Form C, page 2

- The applicant assumes that one HIFU treatment will be performed on each patient. The applicant projects the number of treatments to be performed during the first three years of the project.

- As part of treatment, two MRI scans will be performed on each patient. The applicant projects number of scans to be performed during the first three years of the project by multiplying the number of patients by the number of treatments proposed in the project.

UNC Hospitals Projected Number of MRI Scans Performed as part of HIFU Treatments				
	Partial FY 2/1/2023- 06/30/2023	1st Full FY FY2024	2nd Full FY FY 2025	3rd Full FY FY 2026
MRI Scans Performed	20	50	80	100

Source: Section Q, Form C, page 2

Projected utilization is reasonable and adequately supported based on the following:

- Projected utilization is based on the need to expand research to include clinical treatment with the existing research MRI scanner to treat patients with ET.
- The applicant provides reasonable and adequately supported information to justify the need to use the existing research MRI scanner for clinical treatment.

Access to Medically Underserved Groups

In Section C, page 51, the applicant states:

“As North Carolina’s only state-owned, comprehensive, full service hospital system, UNC Health has the obligation to accept any North Carolina citizen requiring medically necessary treatment. UNC Hospitals is quaternary academic medical center, trauma center, and provider of specialty care of complex diseases for patients from all 100 North Carolina counties, including for HIFU services. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status, or lack of medical insurance.”

In Section C, page 52, the applicant provides the estimated percentage for each medically underserved group for the third full fiscal year, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	
Racial and ethnic minorities	35.1%
Women	58.5%
Persons with Disabilities	
Persons 65 and older	29.0%
Medicare beneficiaries	33.7%
Medicaid recipients	13.5%

On page 52, the applicant states that UNC Health does not maintain data that includes the number of low income or disabled persons; therefore, the applicant is unable to estimate a percentage for these groups. 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.

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.

- (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 the reduction or elimination of a 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 convert an existing research MRI scanner to a clinical MRI scanner pursuant to Policy AC-3.

In Section E, page 62, the applicant describes why there is no alternative method available to meet the need for the proposal. On page 62, the applicant states:

“...the need for the project is based on the need to optimize magnetic resonance-guided HIFU services to provide safe, effective, high-quality care using revolutionary treatment methods.”

On page 62, the applicant states that its proposal is the most effective alternative because it would allow the facility to continue its research to optimize magnetic resonance-guided HIFU treatment for ET patients.

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 proposed project will allow the facility to continue its research to develop innovative ways to treat patients with ET.
- The applicant provides reasonable 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. University of North Carolina Hospitals at Chapel Hill (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall convert an existing research MRI scanner to a clinical MRI scanner pursuant to Policy AC-3.**
- 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>.**

The applicant proposes to convert an existing research MRI scanner to a clinical MRI scanner pursuant to Policy AC-3.

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.

Capital Costs	
Other (Contingency)	\$200,000
Total	\$200,000

In Section F, page 63, 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 which are based on possible unforeseen costs. The existing HIFU is CON-exempt and all costs to develop the HIFU for research purposes will incur prior to the approval of this application.

On page 65, the applicant states that the proposed project does not require start-up or initial operating costs because the existing research MRI scanner is already installed and operational.

Availability of Funds

In Section F, page 64, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing		
Type	UNC Hospitals	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$200,000	\$200,000
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$200,000	\$200,000

*OE = Owner's Equity

In Exhibit F.2-1, the applicant provides a letter from the chief financial officer of UNC Hospitals, authorizing the use of accumulated reserves for the capital needs of the project. The applicant provides the 2021 consolidated balance sheets for UNC Hospitals, which states over \$100 million in cash and cash equivalents and over \$700 million in assets available to fund the capital cost of the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for 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. In Form F.2b, 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.

Magnetic Resonance-Guided HIFU	1st Full FY FY 2024	2nd Full FY FY 2025	3rd Full FY FY 2026
Total MRI Procedures	50	80	100
Total Gross Revenues (Charges)	\$1,261,159	\$2,145,951	\$2,762,912
Total Net Revenue	\$376,029	\$632,593	\$811,885
Average Net Revenue per Procedure	\$7,521	\$7,907	\$8,119
Total Operating Expenses (Costs)	\$346,128	\$551,904	\$702,363
Average Operating Expense per Procedure	\$6,923	\$6,899	\$7,024
Net Income	\$29,901	\$80,689	\$109,522

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions 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.

C

The applicant proposes to convert an existing research MRI scanner to a clinical MRI scanner pursuant to Policy AC-3.

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 a research MRI scanner or HIFU services, nor are there any applicable rules adopted by the Department that define the service area for a research MRI scanner or HIFU services. In Section G, page 74, the applicant defines the service area for the proposed project as Orange County. Facilities may also serve residents of counties not included in the service area.

In Section G, page 74, the applicant describes the service area as follows:

“As such, based on the proposed location of the equipment and the source of the largest percentage of patients expected to utilize the proposed equipment, UNC Hospitals has defined the service area as Orange County, though it expects to serve patients from other areas as well. Upon completion of the proposed project, UNC Hospitals will be the only provider to clinically treat patients with ET using magnetic resonance-guided HIFU services in Orange County, which is the service area for the proposed project.”

In Section G, page 74, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved magnetic resonance-guided HIFU services in Orange County. The applicant states:

“...UNC Hospitals will be the only provider to clinically treat patients with ET using magnetic resonance-guided HIFU services in Orange County upon completion of the proposed project.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because there are no other providers in Orange County that clinically treats patients with ET using magnetic resonance-guided HIFU.

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 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.

The applicant proposes to convert an existing research MRI scanner to a clinical MRI scanner pursuant to Policy AC-3.

In Section H, pages 76-77, the applicant states that UNC Hospitals will not employ direct staff for the proposed project because staff will be employed by the UNC School of Medicine through a lease agreement. UNC Hospitals is a large hospital system that has well-established methods to recruit and retain staff.

In Section H, page 77, the applicant states that the proposed project does not involve the addition of any new positions and the current staff and staff training standards either meet or exceed all relevant accreditation and certification criteria. Additionally, UNC hospitals provide academic assistance and access to continuing education.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 convert an existing research MRI scanner to a clinical MRI scanner pursuant to Policy AC-3.

Ancillary and Support Services

In Section I, page 78, the applicant identifies the necessary ancillary and support services for the proposed services. On page 78, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because ancillary and support services are already in place at the existing academic medical center to support hospital operations and clinical treatment of patients.

Coordination

In Section I, page 79, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because UNC Hospitals is an existing healthcare system with established relationships with area providers and has support from UNC Medical Center physicians.

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 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. Therefore, Criterion (9) is not applicable to this review.

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

NA

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

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

NA

The applicant does not propose construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (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 86, the applicant provides the historical payor mix during FY 2021 at UNC Medical Center. In supplemental information provided to the Agency, the applicant states that the historical payor mix consists of the entire facility.

UNC Medical Center Historical Payor Mix 07/01/2020-06/30/2021	
Payor Category	Percent of Total
Self-Pay	9.3%
Charity Care^	
Medicare*	33.7%
Medicaid*	13.5%
Insurance*	39.4%
Workers Compensation^^	
TRICARE^^	
Other	4.1%
Total	100.0%

*Including any managed care plans.

^Charity Care is not tracked as a payor source.

^^Workers Compensation and TRICARE are included in other payor categories.

In Section L, page 87, the applicant provides the following comparison.

UNC Medical Center	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	58.5%	52.3%
Male	41.5%	47.7%
Unknown	0.0%	0.0%
64 and Younger	71.0%	85.4%
65 and Older	29.0%	14.6%
American Indian	0.8%	0.6%
Asian	2.1%	8.1%
Black or African-American	22.6%	11.8%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	60.6%	69.5%
Other Race	9.5%	9.9%
Declined / Unavailable	4.3%	0.0%

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

The Agency reviewed the:

- Application
- Exhibits to the application

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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 88, the applicant states:

“While it is no longer under a federal obligation to provide this care, charity care provided by UNC Hospitals for State Fiscal Year 2021 is estimated to be \$253.4 million. UNC Hospitals provides care to all persons based only on their need for care, and without regard to minority status or handicap/disability.”

In Section L, page 89, the applicant states that during the 18 months immediately preceding the application deadline, UNC Hospitals has not been notified of any patient civil rights equal access complaints filed against the facility.

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

Magnetic Resonance-Guided HIFU Projected Payor Mix 3rd Full FY, FY 2026	
Payor Category	Percent of Total
Self-Pay	
Charity Care [^]	
Medicare*	78.6%
Medicaid*	
Insurance*	21.4%
Workers Compensation ^{^^}	
TRICARE ^{^^}	
Other	
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 78.6% of total services will be provided to Medicare patients.

On page 90, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The limited number of patients projected to qualify for the grant are projected to have Medicare and commercial insurance as a payor source.
- The applicant assumes that the payor mix will remain constant during the first three years of the project.

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 91, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

The applicant proposes to convert an existing research MRI scanner to a clinical MRI scanner pursuant to Policy AC-3.

In Section M, pages 93-94, 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:

- UNC Hospitals serves as an academic medical center in North Carolina and has a history of supporting health professional training programs in the community.
- UNC Hospitals serve as a clinical teaching site for several healthcare disciplines.
- UNC Hospitals' post-surgical and clinical services provide the required clinical rotations for residents.

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 convert an existing research MRI scanner to a clinical MRI scanner pursuant to Policy AC-3.

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 a research MRI scanner or HIFU services, nor are there any applicable rules adopted by the Department that define the service area for a research MRI scanner or HIFU services. In Section G, page 74, the applicant defines the service area for the proposed project as Orange County. Facilities may also serve residents of counties not included in the service area.

In Section G, page 74, the applicant describes the service area as follows:

“As such, based on the proposed location of the equipment and the source of the largest percentage of patients expected to utilize the proposed equipment, UNC Hospitals has defined the service area as Orange County, though it expects to serve patients from other areas as well. Upon completion of the proposed project, UNC Hospitals will be the only provider to clinically treat patients with ET using magnetic resonance-guided HIFU services in Orange County, which is the service area for the proposed project.”

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 96, the applicant states:

“...the proposed project will enhance competition by establishing and optimizing clinical magnetic resonance-guided HIFU services at UNC Hospitals, which will improve its ability to compete with other providers, nationwide, for patients, faculty, and future funding.”

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 96-97, the applicant states:

“...Although the HIFU and the existing research MRI will be integrated with one another to provide the proposed services, the cost of care for patients with ET that receive clinical treatment as a participant in Dr, Krishna’s research will be covered in part by funds from Dr. Krishna’s NIH grant.

...

Further, there will be no additional capital costs required upon initiation of the clinical treatment of patients with ET using the HIFU in conjunction with the existing research MRI scanner. As such, the cost to develop the proposed project represents a cost effective approach.”

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

Regarding the impact of the proposal on quality, in Section N, pages 98 and 100, the applicant states:

“The proposed project will enable Dr. Krishna and his team to plan, perform, monitor, and evaluate the efficacy of 3D tractography in magnetic resonance-guided HIFU procedures in improving patient outcomes.

...

UNC Hospitals’ commitment to providing quality care is further demonstrated by its Performance, Improvement Program, Utilization Management Plan, and Risk Management Program...”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 100-101, the applicant states:

“...UNC Hospitals has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status, or lack of medical insurance...”

See also Sections L and C of the application and any exhibits.

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

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

Conclusion

The Agency reviewed the:

- Application

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

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

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

C

In Section Q, Form O, the applicant identifies the acute care hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 16 of this type of facility located in North Carolina.

In Section O, page 104, the applicant states that, during the 18 months immediately preceding the submittal of the application, each of the facilities has continually maintained all relevant licensure, certification, and accreditation. The applicant states that UNC health Blue Ridge was cited for a Medicare deficiency effective July 24, 2021. However, after a survey was conducted on November 5, 2021, all deficiencies were resolved and removed. Additionally, Southeastern Regional Medical Center was cited for an Emergency Medical Treatment and Labor Act (EMTALA) violation. However, after a desk review, it was determined that the facility has taken actions to correct the deficiency. The applicant provides supporting documentation in Exhibit O.4. 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, incidents related to quality of care occurred in three of these facilities. One of the facilities was back in compliance as of April 11, 2022. The other two facilities were cited as early as June 2022. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all of the 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.

NA

The applicant is proposing to initiate the clinical treatment of patients with essential tremor (ET) using a high-intensity focused ultrasound (HIFU) in conjunction with the existing research MRI scanner with limited clinical use. There are no administrative rules that are applicable to this proposal. Therefore, this Criterion is not applicable.