

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 10, 2020

Findings Date: July 10, 2020

Project Analyst: Julie M. Faenza

Team Leader: Gloria C. Hale

Project ID #: F-11891-20

Facility: Novant Health Mint Hill Medical Center

FID #: 060857

County: Mecklenburg

Applicant: Novant Health Mint Hill Medical Center, LLC

Project: Acquire equipment required for MRI-guided focused ultrasound

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Novant Health Mint Hill Medical Center, LLC (hereinafter referred to as “Novant” or “the applicant”) proposes to acquire and install specialized equipment necessary to provide MRI-guided focused ultrasound (MRgFUS) at Novant Health Mint Hill Medical Center (NH Mint Hill).

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 2020 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There is one policy in the 2020 SMFP which is applicable to this review. *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 31 of the 2020 SMFP, states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, page 15, the applicant includes a written statement describing the applicant’s plans to assure improved energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the applicant’s plans to assure improved energy efficiency and water conservation.

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 because the application is consistent with Policy GEN-4.

- (2) Repealed effective July 1, 1987.

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

C

The applicant proposes to acquire and install specialized equipment to provide MRgFUS services at NH Mint Hill.

The parent company of the applicant is Novant Health, Inc. All references to Novant in this application refer to the applicant, and not Novant Health, Inc., unless otherwise specified.

In Section C, pages 16-17, the applicant states it will partner with INSIGHTEC, the company which developed the specialized equipment, to provide MRgFUS for appropriate patients. The applicant states INSIGHTEC developed the first FDA-approved therapeutic device used to treat patients with essential tremors and tremor-dominant Parkinson's Disease without surgical incisions. The applicant states that, if the proposed services are approved, it will be the first facility in North Carolina to offer this service.

Patient Origin

N.C. Gen. Stat. §131E-176(24a) defines "service area" as: "... *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 2020 SMFP does not specifically 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. Thus, the service area for this review is as defined by the applicant.

In Section C, page 25, the applicant states its primary service area for its proposed services is HSA II and HSA III, comprised of the following counties: Alamance, Cabarrus, Caswell, Davidson, Davie, Forsyth, Gaston, Guilford, Iredell, Lincoln, Mecklenburg, Randolph, Rockingham, Rowan, Stanly, Stokes, Surry, Union, and Yadkin. Facilities may also serve residents of counties not included in the service area.

In Section C, page 20, the applicant states it has no historical patient origin because the proposed project is a new service. The applicant projects the following patient origin for the proposed services for the first three full fiscal years (FYs) following project completion, as shown in the table below:

NH Mint Hill MRgFUS Projected Patient Origin – FYs 1-3 (FFYs 2021-2023)						
County	FY 1 (FFY 2021)		FY 2 (FFY 2022)		FY 3 (FFY 2023)	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
HSA III	75	42.7%	82	42.7%	91	42.7%
Mecklenburg	37	21.1%	41	21.1%	45	21.1%
Union	8	4.5%	9	4.5%	10	4.5%
Gaston	7	4.2%	8	4.2%	9	4.2%
Cabarrus	7	4.0%	8	4.0%	9	4.0%
Iredell	6	3.4%	7	3.4%	7	3.4%
Rowan	5	2.7%	5	2.7%	6	2.7%
Lincoln	3	1.6%	3	1.6%	3	1.6%
Stanly	2	1.2%	2	1.2%	3	1.2%
HSA II	57	32.3%	62	32.3%	68	32.3%
Guilford	18	10.1%	20	10.1%	22	10.1%
Forsyth	12	7.1%	14	7.1%	15	7.1%
Alamance	6	3.2%	6	3.2%	7	3.2%
Davidson	6	3.2%	6	3.2%	7	3.2%
Randolph	5	2.7%	5	2.7%	6	2.7%
Rockingham	3	1.7%	3	1.7%	4	1.7%
Surry	2	1.4%	3	1.4%	3	1.4%
Stokes	2	0.9%	2	0.9%	2	0.9%
Davie	1	0.8%	2	0.8%	2	0.8%
Yadkin	1	0.7%	1	0.7%	2	0.7%
Caswell	1	0.4%	1	0.4%	1	0.4%
Other NC Counties	26	15.0%	29	15.0%	32	15.0%
Other States	18	10.0%	19	10.0%	21	10.0%
Total	176	100.0%	192	100.0%	212	100.0%

Source: Section C, page 20

Note: Table may not foot due to rounding.

In Section C, page 21, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 22-32, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- MRgFUS is approved by the FDA to treat essential tremor and tremor-dominant Parkinson’s disease, two conditions which feature tremors that can significantly interfere with activities of daily living and can be disabling. Currently, the only two treatment options for patients are medication and surgery. Medication is effective for approximately half of patients, with the other half showing no improvement, but the medications can have significant side effects that can make treatment worse than the original condition. Surgery requires invasive brain surgery under general anesthesia and has higher risks of complications commonly associated with surgery, such as infection. Surgical treatment also involves implantation of a device in the brain that will need additional treatment and follow-up.

MRgFUS is non-invasive and thus reduces risks of complications associated with surgery. Because it is non-invasive, it is also an option for patients who have underlying conditions that make them poor candidates for surgery. Unlike surgical treatment, it does not involve any implantation, and thus is a one-time procedure instead of requiring additional treatment and follow-up. The applicant states physicians can determine if the treatment is working as they are doing the procedure and can adjust or stop treatment if necessary. (pages 22-24)

- The prevalence of tremor increases with age, and the applicant states the incidence rate of tremor for people age 60 and older is estimated at 6.3 percent to 9 percent. According to the North Carolina Office of State Budget and Management (NC OSBM), between 2020 and 2025, the population in the applicant's primary service area (the counties comprising HSAs II and III) is projected to increase at a compound annual growth rate (CAGR) of 1.31 percent, and the statewide population is projected to grow at a CAGR of 1.11 percent. The applicant further states the population age 65 and older is projected to grow at a higher rate than all other age groups in every county in the applicant's primary service area. The applicant states that, between 2020 and 2025, the population age 65 and older is projected to grow at a CAGR of 3.46 percent for its primary service area and 3.14 percent statewide. (pages 25-29)
- The applicant provides data from Truven showing the historical essential tremor market in the greater Charlotte area and the greater Winston-Salem area for the calendar years 2016-2018. The applicant states the number of essential tremor patients for both markets grew at a combined CAGR of 4.5 percent between 2016 and 2018. (page 29)
- Currently, the closest provider of MRgFUS services for essential tremors and tremor-dominant Parkinson's disease is located at Virginia Tech, with the second closest provider of these services located at the University of Virginia. There are currently no providers of this service in North Carolina or any other adjacent state. INSIGHTEC reports that 34 percent of its inquiries and potential referrals originate from the southeastern US, even though there are only six providers of the service in the southeastern US. (pages 29-31)
- Patients who have traveled hundreds of miles to get the treatment and had positive results have written letters of support for the project, and patients who cannot easily access the treatment have expressed support for receiving services in North Carolina. Additionally, referring physicians support bringing the services to North Carolina. (page 32, Exhibit C-4)

The information is reasonable and adequately supported for the following reasons:

- Patients with essential tremor and tremor-dominant Parkinson's disease have limited existing treatment options and the existing treatment options have risks and undesirable side effects.
- MRgFUS services are a new treatment option for patients who don't respond to existing treatment options or who cannot be treated with existing options due to other health issues.

- There are not currently any providers in North Carolina who offer MRgFUS services for essential tremors or tremor-dominant Parkinson’s disease.
- There is growth in the number of essential tremor patients in various parts of the state.
- The population of patients most affected by tremor, people age 65 and older, is projected to increase at a higher growth rate than any other age group in the applicant’s primary service area.
- There is support for the proposed project from patients who have received MRgFUS services out of state, patients who wish to receive MRgFUS services in North Carolina, and North Carolina physicians.

Projected Utilization

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

NH Mint Hill MRgFUS Projected Utilization			
	FFY 2021	FFY 2022	FFY 2023
# Units	1	1	1
# Procedures	175	193	212

In Section C, page 33, the applicant provides the assumptions and methodology used to project utilization. The applicant states that, since MRgFUS services are not currently offered in North Carolina, it prepared the projected utilization based on input from INSIGHTEC, the company that developed the technology, and based on feedback from its physicians. The applicant projects to serve 175 patients in the first full fiscal year and utilization will grow each subsequent year by 10 percent. On page 33, the applicant states the following assumptions were used in projecting utilization:

- NH Mint Hill will offer MRgFUS services one weekday per week and on 10 additional weekend days per year.
- Other MRgFUS programs similar in size to NH Mint Hill have performed similar volumes during the first years of operation.
- There is growth in the area population, the area population age 65 and older, and in the number of essential tremor patients.
- There are no other providers of MRgFUS services in North Carolina. The only other providers in the southeast are in Virginia, West Virginia, Maryland, and southern Florida, for a total of six providers in the entire southeast region of the US.
- NH Mint Hill will be the exclusive provider of MRgFUS services in North Carolina during its first full fiscal year and will be the exclusive provider for referrals in specific ZIP codes

during its second full fiscal year. There are nine additional Novant Health hospitals in the applicant's primary service area that will refer patients to NH Mint Hill.

- INSIGHTEC has received thousands of patient inquiries and potential referrals and will refer eligible patients to NH Mint Hill.

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

- The applicant relies on historical experience from the company providing the technology as well as feedback from its own physicians.
- The applicant relies on population data from Truven and NC OSBM in projecting utilization.
- The applicant will be the exclusive provider of MRgFUS services in North Carolina for the first full fiscal year and will have exclusive referrals for some ZIP codes during the second full fiscal year.
- The applicant documents demand for the proposed services through letters from patients who have had the procedure, patients who want the procedure, and physicians in Exhibit C-4.

Access

In Section C, page 38, the applicant states:

“NHMHMC and all Novant Health facilities in North Carolina continue to comply with the community service obligation, and there is no denial, restriction, or limitation of access to minorities or [persons with disabilities]. NHMHMC does not discriminate against any class of patient based on age, sex, religion, race, [disability], ethnicity, or ability to pay. NHMHMC actively participates in both the Medicaid and Medicare programs.”

In Section L, page 67, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

NH Mint Hill Projected Payor Mix – FY 3 (FFY 2023)		
Payor Category	Entire Facility	MRgFUS
Self-Pay*	9.54%	0.00%
Medicare**	26.72%	75.00%
Medicaid**	14.39%	0.00%
Insurance**	45.34%	25.00%
Workers Compensation	0.47%	0.00%
TRICARE	1.35%	0.00%
Other (specify)	2.19%	0.00%
Total	100.00%	100.00%

Source: NH Mint Hill internal data

*Includes charity care

**Including any managed care plans.

The projected payor mix is reasonable and adequately supported.

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 (payor mix) and adequately supports its assumptions.

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

NA

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

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

CA

The applicant proposes to acquire and install specialized equipment to provide MRgFUS services at NH Mint Hill.

In Section E, pages 45-46, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need.

The applicant considered the alternative of maintaining the status quo. The applicant states there are no providers currently offering MRgFUS anywhere in North Carolina, and the only other option for treatment of essential tremor that does not respond to medication is invasive brain surgery, which may not be possible for some patients. The applicant states maintaining the status quo would continue to leave some patients with no options for treatment that could improve their condition or force patients to travel out of state to receive MRgFUS services; therefore, this was not an effective alternative.

On page 46, the applicant states its proposal is the most effective alternative because it provides an innovative and effective treatment option for patients in North Carolina while requiring only minimal upfit and adaptation of existing space in NH Mint Hill's radiology department.

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

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

Conclusion

The Agency reviewed the:

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

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

1. **Novant Health Mint Hill Medical Center, LLC shall materially comply with all representations made in the certificate of need application.**
 2. **Novant Health Mint Hill Medical Center, LLC shall acquire no more than one ExAblate Neuro System to be located at Novant Health Mint Hill Medical Center.**
 3. **Novant Health Mint Hill Medical Center, LLC 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.**
 4. **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, Novant Health Mint Hill Medical Center, LLC 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.**
 5. **Novant Health Mint Hill Medical Center, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to acquire and install specialized equipment to provide MRgFUS services at NH Mint Hill.

Capital and Working Capital Costs

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

Construction Costs	\$148,125
Medical Equipment	\$2,305,300
A&E/Consultant Fees	\$60,000
Other Costs	\$45,035
Total	\$2,558,460

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

In Section F, pages 48-49, the applicant projects that start-up costs will be \$35,000, to lease a mobile MRI while renovations are taking place, and states there are no initial operating expenses since NH Mint Hill is already an operational facility. On page 49, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, pages 47-50, the applicant states it will fund the capital and working capital costs of the proposed project with accumulated reserves from Novant Health, Inc., its parent company. Exhibit F-2.1 contains a letter from the Senior Vice President of Operational Finance for Novant Health, Inc., authorizing the use of accumulated reserves for the capital and working capital needs of the project. Exhibit F-2.2 contains the audited financial statements for Novant Health, Inc. and Affiliates which show that as of as of December 31, 2019, Novant Health, Inc. had adequate cash and assets to fund the capital and working capital costs of the proposed project.

Financial Feasibility

In Section Q, the applicant provides pro forma financial statements for the applicant’s MRgFUS services for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years of operation following project completion, as shown in the table below.

NH Mint Hill Revenues/Operating Expenses – FYs 1-3 (FFYs 2021-2023)			
	FY 1 (FFY 2021)	FY 2 (FFY 2022)	FY 3 (FFY 2023)
Total Procedures	175	193	212
Total Gross Revenues (Charges)	\$12,793,794	\$14,073,174	\$15,480,491
Total Net Revenue	\$2,861,381	\$3,147,519	\$3,462,271
Average Net Revenue per Procedure	\$16,351	\$16,308	\$16,331
Total Operating Expenses (Costs)	\$2,283,905	\$2,649,652	\$2,824,166
Average Operating Expense per Procedure	\$13,051	\$13,729	\$13,322
Net Income/(Loss)	\$577,477	\$497,867	\$638,105

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 and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
 - 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 costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to acquire and install specialized equipment to provide MRgFUS services at NH Mint Hill.

N.C. Gen. Stat. §131E-176(24a) defines “service area” as: “... *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 2020 SMFP does not specifically 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. Thus, the service area for this review is as defined by the applicant.

In Section C, page 25, the applicant states its primary service area for its proposed services is HSA II and HSA III, comprised of the following counties: Alamance, Cabarrus, Caswell, Davidson, Davie, Forsyth, Gaston, Guilford, Iredell, Lincoln, Mecklenburg, Randolph, Rockingham, Rowan, Stanly, Stokes, Surry, Union, and Yadkin. Facilities may also serve residents of counties not included in the service area.

Currently, there are no providers of MRgFUS services for essential tremors or tremor-dominant Parkinson’s disease anywhere in North Carolina.

In Section G, page 53, the applicant states it believes its proposal would not result in the unnecessary duplication of existing or approved MRgFUS services in the service area because there are no existing or approved MRgFUS services anywhere in North Carolina.

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:

- There are no existing or approved MRgFUS services or service providers in North Carolina.
- The applicant demonstrates there is a need for MRgFUS services in North Carolina. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

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

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

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

C

On Form H in Section Q, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table. In clarifying information, the applicant states the current staffing represents the staffing for the MRI machine to be used for MRgFUS based on the projected hours of operation.

NH Mint Hill Current/Projected Staffing for MRgFUS Services		
Position	Number of FTEs	
	Current	FYs 1-3
Registered Nurse	0.00	0.36
Clerical Staff	0.36	0.36
Radiology Technologists	0.36	0.36
Clinical Services Navigator	0.36	0.36
Total	1.08	1.44

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are

budgeted in Form F.3, which is found in Section Q. In Section H, pages 54-56, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 59, the applicant identifies the proposed medical director. In Exhibit I-3, the applicant provides a letter from the proposed medical director which states he intends to serve as medical director for the proposed services.

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 the reasons stated above.

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

C

In Section I, pages 57-58, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Pharmacy
- Surgical Services
- Nursing
- Clinical Equipment Management Program
- Laboratory & Pathology Services
- Respiratory Therapy Services
- Food & Nutrition
- Interpreter Services
- Housekeeping
- Emergency Services
- Strategic Sourcing/Materials Management/Purchasing
- Billing & Finance
- Hospitalist/Inpatient Care Specialist Physicians

On page 57, the applicant adequately explains how each ancillary and support service is or will be made available. The applicant states that NH Mint Hill, an existing acute care hospital with

a radiology department that offers both MRI and ultrasound services, already provides all necessary ancillary and support services.

In Section I, pages 58-60, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits C-4, I-2, and I-3.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

C

In Section K, page 62, the applicant states that the project involves renovating 500 square feet of existing space in NH Mint Hill's Radiology Department. Line drawings are provided in Exhibit K-2.

On page 62, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit K-3.1.

On page 63, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 63, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K-3.2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the

State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

The applicant does not currently provide MRgFUS services. In Section L, page 66, the applicant provides the historical payor mix during the last full fiscal year for all of NH Mint Hill, as shown in the following table:

NH Mint Hill Historical Payor Mix – FFY 2019	
Payor Category	Entire Facility
Self-Pay*	9.54%
Medicare**	26.72%
Medicaid**	14.39%
Insurance**	45.34%
Workers Compensation	0.47%
TRICARE	1.35%
Other (specify)	2.19%
Total	100.00%

Source: NH Mint Hill internal data

*Includes charity care

**Including any managed care plans.

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

	Percentage of Total Patients Served by NH Mint Hill during FFY 2019	Percentage of the Population of HSAs II & III
Female	65.80%	51.29%
Male	34.15%	48.71%
Unknown	0.05%	0.00%
64 and Younger	76.11%	83.08%
65 and Older	23.89%	16.92%
American Indian	0.26%	1.27%
Asian	1.43%	3.18%
Black or African-American	29.92%	21.60%
Native Hawaiian or Pacific Islander	0.09%	0.08%
White or Caucasian	58.52%	65.99%
Other Race	8.36%	7.86%
Declined / Unavailable	1.42%	0.00%

Sources: NH Mint Hill internal data; *Spotlight 2020*

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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 66, the applicant states,

“Existing Novant Health acute care hospitals and the existing NHMHMC Radiology Department do provide and will continue to provide services in a manner that is consistent with:

- *Title VI of the Civil Rights Act of 1963 (and any applicable amendments);*
- *Section 504 of the Rehabilitation Act of 1973 (and any applicable amendments); and*
- *The Age Discrimination Act of 1975 (and any applicable amendments).*

Further, Novant Health hospitals fulfilled their Hill-Burton obligations long ago. NHMHMC and all Novant Health facilities in North Carolina continue to comply with the community service obligation, and there is no denial, restriction, or limitation of access to minorities or [persons with disabilities]. Novant Health's acute care hospitals maintain a commitment to provide care to all persons, regardless of their ability to pay.”

In Section L, page 67, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any related facility 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 67, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

NH Mint Hill Projected Payor Mix – FY 3 (FFY 2023)		
Payor Category	Entire Facility	MRgFUS
Self-Pay*	9.54%	0.00%
Medicare**	26.72%	75.00%
Medicaid**	14.39%	0.00%
Insurance**	45.34%	25.00%
Workers Compensation	0.47%	0.00%
TRICARE	1.35%	0.00%
Other (specify)	2.19%	0.00%
Total	100.00%	100.00%

Source: NH Mint Hill internal data

*Includes charity care

**Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 9.54 percent of total services and none of its MRgFUS services will be provided to self-pay patients, 26.72 percent of total services and 75 percent of MRgFUS services to Medicare patients, and 14.39 percent of total services and none of its MRgFUS services to Medicaid patients. On page 67, the applicant states Medicaid does not currently cover MRgFUS services.

On pages 67-68, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The applicant states:

“NHMHMC does not anticipate that the payor mix for the entire campus will change from the historical payor mix. The payor mix for the MRgFUS neurosurgery service is based on feedback from INSIGHTEC. Note that Medicaid does not currently cover MRgFUS services. MRgFUS is an innovative procedure that recently began to be covered under Medicare and some commercial payors. Workers Compensation is not relevant to this service and TRICARE does not currently cover this service. NHMHMC will evaluate charity care and self-pay patients on a case-by-case basis for this new service line.”

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.

- (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 70, 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

In Section M, page 71, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to acquire and install specialized equipment to provide MRgFUS services at NH Mint Hill.

N.C. Gen. Stat. §131E-176(24a) defines “service area” as: “... *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 2020 SMFP does not specifically 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. Thus, the service area for this review is as defined by the applicant.

In Section C, page 25, the applicant states its primary service area for its proposed services is HSA II and HSA III, comprised of the following counties: Alamance, Cabarrus, Caswell, Davidson, Davie, Forsyth, Gaston, Guilford, Iredell, Lincoln, Mecklenburg, Randolph, Rockingham, Rowan, Stanly, Stokes, Surry, Union, and Yadkin. Facilities may also serve residents of counties not included in the service area.

Currently, there are no providers of MRgFUS services for essential tremors or tremor-dominant Parkinson’s disease anywhere in North Carolina.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 72, the applicant states:

“There will be no effect on the competition in the proposed service area, because no other facility in North Carolina offers MRgFUS services for ET and tremor-dominant Parkinson’s disease patients.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 72, the applicant states:

“...there are limited treatment options for ET patients. Medications such as beta-blockers and anti-seizure medication can help reduce the symptoms for only 50 percent of ET patients. Patients who do not respond well to medication treatment can undergo deep brain stimulation which is an invasive and costly procedure. MRgFUS will give these patients a more cost-effective alternative treatment options that does not require overnight hospitalization and is non-invasive. With improved access to MRgFUS services, there will be a positive impact on the cost-effectiveness of treatment for ET patients.”

Regarding the impact of the proposal on quality, in Section N, page 74, the applicant states:

“The provision of MRgFUS services at NHMHMC will improve access to care for ET patients who currently have limited access to treatment options, thereby improving the quality of care provided.

Furthermore, Novant Health has a reputation of providing high quality care. Novant Health has several programs in place to monitor and measure quality on a regular basis.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 75, the applicant states:

“In the US, most regional payment centers for Medicare are covering MRgFUS for ET and tremor-dominant Parkinson’s disease patients. The procedure is currently not covered by Medicaid and is covered by a few commercial insurers depending on the company and region. As such, NHMHMC anticipates that a majority of its patients will be Medicare patients, especially considering that ET is most common in elderly populations, which are often underserved.

NHMHMC serves all patients regardless of race, sex, age, religion, creed, disability, national origin or ability to pay. Novant Health has a comprehensive charity care policy that will apply to all eligible patients, including patients seeking MRgFUS services. With MRgFUS offered at NHMHMC, all ET and tremor-dominant Parkinson’s disease patients residing in North Carolina in particular, including medically underserved groups, will have improved access to care.”

Considering all the information in the application, 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 (see Sections C, F, K, N, and Q of the application and any exhibits)
- Quality (see Sections C, N, and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L, and N of the application and any exhibits)

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 for 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

On Form A in Section Q, the applicant identifies the hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies 11 hospitals in North Carolina. The applicant also has a management agreement with one additional hospital for a total of 12 hospitals in North Carolina.

In Section O, page 82, 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, DHRS, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in one of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 12 hospitals, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

NA

The applicant proposes to acquire and install specialized equipment to provide MRgFUS services for essential tremor patients and tremor-dominant Parkinson's disease patients. There are no administrative rules that are applicable to proposals to acquire the type of equipment proposed in this application.