

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 22, 2022

Findings Date: November 29, 2022

Project Analyst: Donna Donihi

Assistant Chief: Lisa Pittman

Project ID #: O-12228-22

Facility: Novant Health New Hanover Regional Medical Center

FID #: 943372

County: New Hanover

Applicant(s): Novant Health New Hanover Regional Medical Center, LLC, Novant Health Inc.

Project: Add no more than one electrophysiology (EP) lab for a total of no more than four EP labs upon project completion.

REVIEW CRITERIA

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

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

C

The applicants Novant Health New Hanover Regional Medical Center, LLC, and Novant Health Inc., (referred to hereinafter as “the applicant” or “NH NH RMC”), propose to add no more than one electrophysiology (EP) lab for a total of no more than four EP labs upon project completion.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2022 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There is one policy in the 2022 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities on pages 30-31 of the 2022 SMFP states:

“Any person proposing a capital expenditure greater than \$4 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

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

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

In Section B, pages 27-28, the applicant explains why it believes its application is conforming to Policy GEN-4. On page 27, the applicant states:

- *“The capital expenditure for this project is more than \$4 million. NH New Hanover is committed to the environmental responsibility to its team members, patients, visitors, and communities it serves.*
- *General lighting in the rooms will be designed to meet IESNA recommendations with energy efficient LED luminaries designed specifically for use in operating rooms to reduce light pollution.*
- *LED lighting will be utilized in all but specialized task lighting and decorative lighting fixtures.*
- *Lighting control systems exceeding energy code standards will be employed where applicable, incorporating dual switching, occupancy sensing, daylight harvesting with dimming where feasible and programmable lighting controls as the project requires. These strategies provide energy saving and lower maintenance costs.*
- *Premium efficient motors and variable frequencies drives will be utilized.*

- *Utilizing low VOC emitting materials - adhesives, sealants, paint, flooring, casework*
- *Building reuse-maintaining existing walls, flows*
- *Utilizing regional materials were possible as well as utilizing construction recycling*

In all projects Novant Health considers energy efficiency and water conservation opportunities consistent with the Novant Health Sustainable Energy Management Plan (SEMP) The “written statement” reference in paragraph 1 of Policy Gen-4 in the 2022-State Medical Facilities Plan is articulated in the broader framework of the 2022 SEMP.

Novant Health is sustainably managing energy and water consumption by:

- *Assigning oversight to a Corporate Energy Manager.*
- *Actively managing utility purchases and agreements*
- *Benchmarking portfolio efficiency by performing utility assessments*
- *Progressively converting to more efficient equipment, environmentally preferable products and practices.*
- *Applying retro-commissioning strategies to Building Automation Systems and HVAC equipment”*

The applicant’s 2022 Sustainable Energy Management Plan is in Exhibit 8.2.

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 the following:

- The project is not based on a need determination in the 2022 SMFP.
- The applicant adequately demonstrates that the proposed is consistent with policy Gen4 because the application includes a written statement describing the projects plan to assure improved energy efficiency and water conservation.

- (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 add no more than one electrophysiology (EP) lab for a total of no more than four EP labs upon project completion.

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.” The 2022 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C, pages 36-38, the applicant defines the service area for the proposed project. The applicant states they serves patients from a 5-county area as shown on page 36. Facilities may also serve residents of counties not included in the service area.

The following table illustrates current and projected patient origin.

Novant Health New Hanover RMC

| Electrophysiology | Last Full FY 2021 | | 3 rd Full FY 2026 | |
|-------------------------|----------------------|---------------|---------------------------------|---------------|
| | # of Patients | % of Total | # of Patients | % of Total |
| New Hanover | 765 | 38.0% | 926 | 38.0% |
| Brunswick | 617 | 30.6% | 746 | 30.6% |
| Pender | 208 | 10.3% | 251 | 10.3% |
| Onslow | 135 | 6.7% | 163 | 6.7% |
| Columbus | 3123 | 6.1% | 149 | 6.1% |
| NC Counties & States | 165 | 8.3% | 202 | 8.3% |
| Total | 2,013 | 100.0% | 2,437 | 100.0% |

Source: Section C.3, pages 36-37

The applicant states: “NH New Hanover assumes that its 5-county service area will remain consistent in the future. The 5- county service area represents 91.7 percent of the EP cases.”

Novant Health New Hanover

| Entire Facility | Last Full FY 2021 | | 3 rd Full FY 2026 | |
|-------------------------|----------------------|---------------|---------------------------------|---------------|
| | # of Patients | % of Total | # of Patients | % of Total |
| New Hanover | 312,474 | 50.7% | 324,397 | 50.70% |
| Brunswick | 113,370 | 18.4% | 117,730 | 18.40% |
| Pender | 85,762 | 13.9% | 88,937 | 13.90% |
| Onslow | 36,697 | 6.0% | 38,390 | 6.00% |
| Columbus | 17,627 | 2.9% | 18,555 | 2.90% |
| NC Counties & States | 50,311 | 8.2% | 52,467 | 8.20% |
| Total | 616,241 | 100.0% | 639,837 | 100.0% |

Source: Section C.3, pages 36 & 38

In Section C, page 38, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states:

“Number of Patients Total is multiplied by the FY2016 - FY2021 5-Year CAGR [(616,241/593,862) ^ (1/5)-1 =0.75%] through 2025.”

The applicant assumes its five-county service area will remain consistent in the future.

The applicant’s assumptions are reasonable and adequately supported because projected patient origin is based on historical patient origin.

Analysis of Need

In Section C, pages 39 and 41, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

The applicant states that the need for the project is based on the following factors:

Population Growth in New Hanover County

The applicant used data from the North Carolina Office of State Budget and Management (NCOSBM) to demonstrate the need based on the population growth in the service area.

Novant Health New Hanover Regional Medical Center

Project ID # O-12228-22

Page 6

| Projected Population New Hanover County | 2017 | 2022 | 2027 (Projected) | 2017-2022 Percent Growth | 2022-2027 Percent Growth |
|--|----------------|----------------|-------------------------|---------------------------------|---------------------------------|
| < 18 | 41,889 | 41,147 | 41,138 | -1.8% | 0.0% |
| 18-44 | 88,257 | 91,356 | 96,800 | 3.5% | 6.0% |
| 45-64 | 55,228 | 54,969 | 58,802 | -0.5% | 7.0% |
| 65+ | 37,595 | 43,115 | 48,974 | 14.7% | 13.6% |
| Total Population | 222,969 | 230,587 | 245,714 | 3.4% | 6.6% |
| Percent < 18 | 18.8% | 17.8 | 16.7% | | |
| Percent 18-44 | 39.6% | 39.6 | 39.4% | | |
| Percent 45-64 | 24.8% | 23.8 | 23.9% | | |
| Percent 65+ | 16.9% | 18.7 | 19.9% | | |

Source: Page 40 of the application

- From 2017 to 2022 the population in New Hanover County grew by 3.4% according to the NCOSBM and is expected to grow by an additional 6.6% from 2022 to 2027.
- NCOSBM projects 45-64 population will increase by 7.0 % from 2022 to 2027.
- The 65 + group grew by 14.7% from 2017-2022.
- The 65+ population will be the fastest growing population from 2022 to 2027.

Population Growth in EP Service Area

On page 41, the applicant states that the population in NH NH RMC’s EP Service Area is projected to grow 6.3 percent from 2022 to 2027. The applicant states that 91.7 percent of EP cases originate from the five-county service area, which includes, New Hanover, Brunswick, Pender, Onslow, and Columbus counties. (Section C., Page 41)

| Projected population Growth Electrophysiology Service Area | 2017 | 2027 (Projected) | 2017-2022 Percent Growth | 2022-2027 Percent Growth |
|---|----------------|-------------------------|---------------------------------|---------------------------------|
| < 18 | 143,552 | 151,741 | 4.1% | 1.6% |
| 18-44 | 245,502 | 267,332 | 3.7% | 5.0% |
| 45-64 | 153,006 | 165,123 | 1.9% | 5.9% |
| 65+ | 113,014 | 152,840 | 18.0% | 14.6% |
| Total Population | 655,074 | 737,036 | 5.9% | 6.3% |
| Percent < 18 | 21.9% | 20.6% | | |
| Percent 18-44 | 37.5% | 36.3% | | |
| Percent 45-64 | 23.4% | 22.4% | | |
| Percent 65+ | 17.3% | 20.7% | | |

Source: Section C, page 41

The applicant states that the 65+ population is showing the highest growth projections which is significant due to their higher use of health care resources, including cardiovascular procedures and services. The applicant states that in 2017, 17.3% of the population in the EP service area were 65 years of age or older. Based on data from the NCOSBM, the table below demonstrates additional life expectancy in New Hanover County.

New Hanover County

| Additional Life Expectancy in Years | | |
|--|------------------|------------------|
| | 1990-1992 | 2018-2020 |
| 65 - 69 | 17.3 | 20.2 |
| 70 - 74 | 14.2 | 16.5 |
| 75 - 79 | 11.4 | 12.9 |
| 80 - 84 | 8.8 | 9.8 |
| 85+ | 6.8 | 7.1 |

Source: Section C, page 42

New Hanover County

| Change Life Expectancy in Years | | |
|--|--------------|-----------------|
| | Years | % Change |
| 65-69 | 2.9 | 16.8% |
| 70-74 | 2.3 | 16.2% |
| 75-79 | 1.5 | 13.2% |
| 80-84 | 1.0 | 11.4% |
| 85+ | 0.3 | 4.4% |

Source: Section C, page 42

Increased Life Expectancy (pages 42-43)

The applicant states, “a 75-year-old African American, New Hanover County resident in 1992 was expected to live an additional 10.9 years or until the age of 85.9 years, however, a 75-year-old African American, New Hanover County resident in 2020 is now expected to live an additional 11.9 years or until the age of 86.9 years. This increase in life expectancy increases the chance of health conditions requiring an EP procedure...

- The number of electrophysiologists will increase from 6.5 providers to 8.5 providers by end of 2022.
- Sg2, a health industry analytic consultancy firm, anticipates EP ablations will grow by 54 percent and device implants will grow by 20 percent by 2029 due to aging population with chronic heart conditions and innovations increasing the number of treatable conditions.

- *Over the past several years, the EP service has experienced an increase in the acuity level of cardiovascular patients, elective cardiovascular procedures are typically more urgent than elective procedures in other service lines because appropriate cardiovascular interventions can delay disease progression...*

Projected Utilization

The applicant states, “NH has experienced growth in utilization of virtually all outpatient and inpatient services, as summarized below:

- Total inpatient days of care have grown from 107,358 in FY2016 to 207,824 in the global pandemic affected FY 2021, a 22.0 percent increase over five years, outpatient visits increase of 49.2 percent...
- The population in New Hanover County and NH New Hanover’s EP service area is projected by the NCOSBM to increase 6.6 percent and 6.3 percent over the 5-year period from 2022 to 2027.
- Key age groups are projected by NCOSBM to increase over the 5-year period from 2022-2027.
- From FY2016 to FY2021, NH New Hanover experienced a 22.6 percent growth in EP procedures from 1,642 procedures to 2,013 procedures.
- Increase capacity to perform more complex procedures which average 3.5 or more hours per case.

The utilization methodology described in Section Q results in NH New Hanover EP Cases through FY 2026, as shown below:

EP Lab Utilization Trend FY 2021 to FY 2026

| | FY 2021 | FY 2022 | FY 2023 | FY 2024 | FY 2025 | FY2026 |
|---------------------------|---------|---------|---------|---------|---------|--------|
| # of Units | 3 | 3 | 3 | 4 | 4 | 4 |
| EP Cases | 2,013 | 2,091 | 2,173 | 2,258 | 2,346 | 2,437 |
| EP Lab Utilization | 89.5% | 92.9% | 96.6% | 75.3% | 78.2% | 81.2% |

Source: Section C, page 44

The table above shows that NH Medical Center’s EP labs are currently operating at 89.5 of capacity and the EP lab will be operating at 96.6 % of capacity by FY 2023.

In Section C, pages 40-44, and Section Q the applicant provides the assumptions and methodology used to project utilization, which are based on the historical utilization of the existing three EP labs at NH Medical Center.

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

- The applicant’s utilization projections are supported by the historical utilization of the existing EP labs.

- Projected population and life expectancy increases in the service area support an increase in the utilization of EP services.

Access to Medically Underserved

In Section C, page 51, the applicant provides the estimated percentage for each medically underserved group to be served at NH NH RMC as shown in the following table.

| NH Medical Center Hospital Projected Payor Mix Third Full Fiscal Year | |
|--|--|
| Group | Estimated Percent of Total Patients during the Third Full Fiscal Year |
| Low Income | 4.2% |
| Racial and ethnic minorities | 13.3% |
| Woman | 39.3% |
| Person with disability | NH New Hanover does not track. |
| Persons 65 and older | 74.5% |
| Medicare beneficiaries | 75.6% |
| Medicaid recipients | 2.5% |

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based in part on the following:

- The applicant states its commitment to providing care for each group listed in the table above on pages 50-51 of the application.
- NH New Hanover conforms to all requirements of the Americans with Disability Act.
- The applicant states on pages 50-52 Novant Health will not discriminate based on income, race, ethnicity, color, age, religion, national origin, gender, physical or mental handicap, sexual orientation, ability to pay, or any other factor that would classify a patient as underserved.
- The Novant Health Charity Care and related policies (“Charity Care, Uninsured Discount, Catastrophic Settlement”), which apply to all existing Novant Health affiliates, on page 51 of the application.

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 of the reasons describe 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, 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 add no more than one electrophysiology (EP) lab for a total of no more than four EP labs upon project completion.

In Section E, page 61-62, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo - The applicant states that maintaining the status quo will not meet patient demand. Therefore, the applicant determined that this alternative was not the most effective.

Joint Venture – The applicant states that it considered developing a joint venture with a physician practice but determined this alternative to be both unreasonable and unsuitable option because of federal Stark regulations and facility needs.

Extending the Hours of Operation - The applicant states that it considered extending the hours of operation but determined that the extended hours required would not meet the EP's volumes are not feasible.

Performing EP Studies in Cardiac Catheterization Suite -The applicant states that this is not a viable alternative due to continued growth of EP and cardiac catheterization services.

Add a Dedicated EP Lab -The applicant states that this was the most effective alternative because it would accommodate the additional demand for patients it generated by adding new EP physicians to its medical staff.

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

- The applicant provides reasonable information to 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. Novant Health New Hanover Regional Medical Center, LLLP and Novant Health Inc., (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall add no more than one Electrophysiology Lab for a total of no more than four Electrophysiology Labs at Novant Health New Hanover Regional Medical Center upon project completion.**
- 3. Upon completion of the project, Novant Health New Hanover Regional Medical Center shall be licensed for no more than four Electrophysiology Labs.**
- 4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 5. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 6. Progress Reports:**

- a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
 - b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on January 2, 2023.
7. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holders 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.
8. The certificate holders 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 it-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 add no more than one electrophysiology (EP) lab for a total of no more than four EP labs upon project completion.

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 following table:

| Capital Costs | |
|-----------------------------------|--------------------|
| Construction/Renovation Contract | \$2,870,000 |
| Architect/Engineer | \$229,600 |
| Medical Equipment | \$2,091,866 |
| Non-Medical Equipment | \$393,000 |
| Furniture | \$524,000 |
| Consulting Fees (CON Preparation) | \$50,000 |
| Contingency | \$143,500 |
| Total | \$6,301,966 |

In Section Q, Form F.1a Assumptions, and Exhibit F-1, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the project capital cost is based on reasonable and adequately supported assumptions based on the following:

- Architectural estimate based on current construction cost for similar projects
- Proposed purchase agreement

In Section F, page 65, the applicant states that there are no start-up or initial operating expenses, because it is not proposing a new service.

Availability of Funds

In Section F, page 63, the applicant states that the capital cost will be funded, as shown in the table below.

| Sources of Capital Cost Financing | | |
|--|---------------------------|--------------------|
| Type | Novant Health Inc. | Total |
| Accumulated reserves | \$6,301,966 | \$6,301,966 |
| Total Financing | \$6,301,966 | \$6,301,966 |

Exhibit F-2 contains a letter dated June 10, 2022, from the SVP, Operational Finance, and Revenue Cycle states that the capital cost will be funded by accumulated reserves.

In Exhibit F.2, page 134, the 2021 consolidated balance sheet for Novant Health Inc. and Affiliates shows Cash and Cash Equivalents of \$795,602,000 and Current Portion of Assets Limited As To Use of \$40,627,000.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the letter referenced above.

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 operating years of the project, as shown in the table below.

| Novant Health New Hanover RMC | 1st Full FY 2024 | 2ND Full FY 2025 | 3RD Full FY 2026 |
|--------------------------------------|------------------------------------|------------------------------------|------------------------------------|
| Total Cases | 2,258 | 2,346 | 2,437 |
| Total Gross Revenues | \$187,660,873 | \$200,835,827 | \$214,943,145 |
| Total Net Revenue | \$49,429,874 | \$52,900,157 | \$56,616,024 |
| Average Net Revenue per Case | \$21,891 | \$22,549 | \$23,232 |
| Total Operating Expenses (Costs) | \$21,733,569 | \$23,114,152 | \$24,563,954 |
| Average Operating Exp. per Case | \$9,625 | \$9,865 | \$10,080 |
| Net Income | \$27,696,305 | \$29,786,005 | \$32,052,070 |

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

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 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 add no more than one electrophysiology (EP) lab for a total of no more than four EP labs upon project completion.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area. - The area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2022 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C.4, page 41, the applicant defines the service area for the proposed project, as the 5-county area including, Brunswick, Columbus, New Hanover, Onslow and Pender counties. Facilities may also serve residents of counties not included in the service area.

In Section G, page 72, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved electrophysiology services in the 5-county service area. The applicant states that there are no other providers of EP lab services in the service area. The closest provider of EP services is Cape Fear Valley Medical Center (93 miles northwest of Wilmington in Fayetteville), as reported in the 2022 HLRA.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that NH Medical Center is the only provider of EP lab services in the service area and that the EP lab services are needed in addition to the existing or approved 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 based on the reasons stated above.

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

C

The applicant proposes to add no more than one electrophysiology (EP) lab for a total of no more than four EP labs upon project completion.

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

| Position | Current as of 2/28/2022 | Projected Third FFY |
|----------------------------|------------------------------------|--------------------------------|
| Admin. Coordinator Nursing | 1.00 | 1.00 |
| Staff Nurse | 4.73 | 7.23 |
| Cardiac Cath Technologist | 0.79 | 0.79 |
| Cardiovascular Tech-C | 4.10 | 7.60 |
| Total | 10.62 | 16.62 |

The assumptions and methodology used to project staffing are based on historical experience as provided in Section Q. The applicant adequately demonstrates the 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.2 and H.3, pages 74 and 75, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than one electrophysiology (EP) lab for a total of no more than four EP labs upon project completion.

Ancillary and Support Services

In Section I, pages 78-80 the applicant identifies the necessary ancillary and support services for the proposed services. On pages 79-80, 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.

Coordination

In Section I, page 80, 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 based on the following.

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.

- (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

The applicant proposes to add no more than one electrophysiology (EP) lab for a total of no more than four EP labs upon project completion.

In Section K, page 84, the applicant states that the project involves renovating 932 square feet of existing space. Line drawings are provided in, Exhibit K-2.

On page 84, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the project architect's review of the project.

On pages 84-85, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on locating the new EP Lab adjacent to EP Labs 1-3.

On page 85, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic

minorities, women, and 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 proposes to add no more than one electrophysiology (EP) lab for a total of no more than four EP labs upon project completion.

In Section L, page 88, the applicant provides the historical payor mix during the last full fiscal year before submission of this application for the proposed services, as shown in the table below.

| NH Medical Center Hospital Historical Payor Mix FY2021 | |
|---|--|
| Payor Source | EP Lab Services as Percent of Total |
| Self-Pay | 7.1% |
| Charity Care | 2.5% |
| Medicare | 40.2% |
| Medicaid | 15.4% |
| Insurance | 29.4% |
| Governmental | 5.4% |
| Total | 100.0% |

In Section L, page 89, the applicant provides the following comparison.

| NH New Hanover Regional Medical Center EP Lab Services | Last Full Fiscal Year | |
|--|-------------------------------------|--|
| | Percentage of Total Patients Served | Percentage of the Population of the Service Area * |
| Female | 60.4% | 52.4% |
| Male | 39.6% | 47.6% |
| Unknown | 0.00% | 0.0% |
| 64 and Younger | 63.6% | 81.6% |
| 65 and Older | 36.4% | 18.4% |
| American Indian | 0.7% | 0.6% |
| Asian | 0.3% | 1.6% |
| Black or African American | 12.3% | 13.4% |
| Native Hawaiian or Pacific Islander | 0.0% | 0.1% |
| White or Caucasian | 83.4% | 82.2% |
| Other Race | 1.7% | 2.1% |
| Declined / Unavailable | 1.6% | 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>.

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 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 90, the applicant states that the facility is not obligated under any applicable federal law to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 90, the applicant states: “NH New Hanover has had no patient civil rights equal access complaint filed in the 18 months immediately preceding the application deadline.”

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 91, 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.

| NH NH RMC Electrophysiology Services Projected Payor Mix 3rd FFY, 2026 | |
|--|--|
| Payor Source | EP Lab Services as Percent of Total |
| Self-Pay | 1.7% |
| Medicare | 75.6% |
| Medicaid | 2.5% |
| Insurance | 16.2% |
| Other (Workers Comp, TRICARE) | 4.0% |
| Total | 100.0% |

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.7% of total services will be provided to self-pay and charity care patients, 75.6% to Medicare patients and 2.5% to Medicaid patients.

On page 91, 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 projected payor mix is reasonable and adequately supported based on the following:

- Payor mix is based on the most recent actual experience at NH NH Regional Medical Center.

- The projected payor source for EP lab services is based on the historical payor mix.

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, NH Medical Center by house staff, and NH Medical Center by personal physicians.

C

In Section L, page 93, 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 add no more than one electrophysiology (EP) lab for a total of no more than four EP labs upon project completion.

In Section M, page 95, and Exhibit M.1., 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. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes, based on their current established clinical education agreements.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add no more than one electrophysiology (EP) lab for a total of no more than four EP labs upon project completion.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area - The area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2022 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C.4, page 41, the applicant defines the service area for the proposed project as a 5-county area including Brunswick, Columbus, New Hanover, Onslow, and Pender Counties.

In Section G page, 72, the applicant states that NH NH Regional Medical Center is the only provider of EP lab services in the service area. The applicant states “*the closest hospital that offers EP procedures is Cape Fear Valley Medical Center (93 miles northwest of Wilmington in Fayetteville).*”

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 97, the applicant states:

“The applicant expects the additional EP lab will have a positive effect on competition in the service area because it will increase the current capacity of EP services in the service area. The EP lab will also allow more complex EP procedures to be performed in the Service Area.”

Regarding the expected effects of the proposal on quality in the service area, in Section N, page 99, the applicant states:

“NH New Hanover is committed to continuing to carry out its performance improvement program. Including the development of the proposed project. The objective of the performance improvement program is to make certain a mechanism is in place which ensures the occurrence of ongoing evaluation of various aspects of NH New Hanover’s operation, both medical and non-medical. The program provides a methodology to monitor, analyze, and improve performance. It is critical that both NH New Hanover personnel and attending medical staff understand the program.”

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

“Novant Health is collaborating with payors and partners to identify payment models that match Novant Health’s value-based care delivery. Getting the right care in the right setting at the right price is the future of healthcare. It is what makes healthcare affordable and more sustainable.

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

Regarding the impact of the proposal on quality, in Section N, page 97 the applicant states:

“NH New Hanover is committed to continuing to carry out its performance improvement program, including the development of the proposed project. The objective of the performance improvement program is to make certain a mechanism is in place which ensures the occurrence of ongoing evaluation of various aspects of the NH New Hanover’s operations, both medical and non-medical. The program provides a methodology to monitor, analyze, and improve performance. It is critical that both NH New Hanover personnel and attending medical staff understand the 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, page 100, the applicant states:

“NH New Hanover is a comprehensive provider to all patients without regard to race, color, religion, creed, national origin, sex, sexual orientation, disability, age, or ability to pay.”

See also Section 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

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

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

C

The applicant proposes to add no more than one electrophysiology (EP) lab for a total of no more than four EP labs upon project completion.

In Section Q, Form O, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 18 of this type of facility located in North Carolina.

In Section O, page 106., the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents of immediate jeopardy occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHR, during the 18 months immediately preceding NH Medical Center of the application through the date of this decision, incidents were noted, and plan of corrections are pending. 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 18 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

NA

The applicant proposes to add no more than one electrophysiology (EP) lab for a total of no more than four EP labs upon project completion.

There are no administrative rules that are applicable to this proposal.