

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 12, 2019

Findings Date: July 12, 2019

Project Analyst: Mike McKillip

Team Leader: Gloria Hale

Project ID #: F-11691-19

Facility: Novant Health Presbyterian Medical Center

FID #: 943501

County: Mecklenburg

Applicants: The Presbyterian Hospital

Novant Health, Inc.

Project: Develop an endovascular lab with one interventional angiography system that will not perform cardiac catheterization procedures

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

The Presbyterian Hospital (TPH) and Novant Health, Inc. (Novant), collectively referred to as Novant Health Presbyterian Medical Center (NHPMC) or “the applicant,” proposes to develop an endovascular lab with one interventional angiography system that will not perform cardiac catheterization procedures.

Need Determination

There are no need determinations in the 2019 State Medical Facilities Plan (SMFP) applicable to the acquisition of an interventional angiography system that will not perform cardiac catheterization procedures.

Policies

There is one policy in the 2019 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

Policy GEN-4

Policy GEN-4, on page 31 of the 2019 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.11, page 15, and Exhibit B-11, the applicant describes its plan to ensure energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project’s plans to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

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 applicant includes a written statement describing the project's 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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, NHPMC, proposes to develop an endovascular lab with one interventional angiography system that will not perform cardiac catheterization procedures. In Section C.1, pages 16-20, the applicant describes the project as follows:

“The Applicants propose to purchase a GE Discovery IGS 740 interventional angiography system and ancillary equipment to develop an EV [endovascular] Lab. The EV Lab will be part of NHPMC’s Heart and Vascular Institute(‘HVI’). ... The equipment will be located on the fifth floor of NHPMC in a room that previously contained fixed cardiac catheterization equipment. ... Minor renovations of the room are needed and the cost is included in the project budget and schedule. ... The EV Lab will focus on vascular diseases affecting arteries and veins outside of the heart. ... NHPMC will not use the proposed EV Lab to perform cardiac catheterization procedures as defined in 10 NCAC 14C .1601.(4).”

Patient Origin

The 2019 SMFP does not define a service area for interventional angiography equipment. 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 2019 SMFP does not define a service area for interventional angiography equipment, nor are there any applicable rules adopted by the Department that define the service area for interventional angiography equipment. Thus, the service area is defined by the applicant. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 20, the applicant states that NHPMC does not currently operate an endovascular (EV) lab. In Section C.3, page 22, the applicant provides the projected patient origin for the proposed EV lab in the first three full fiscal operating years (CY2021-CY2023) following project completion, as shown in the table below.

Projected Patient Origin for NHPMC Endovascular Lab Visits

County	Percent of Total Patients CY2021-CY2023	PY 1 CY2021 Patients	PY 2 CY2022 Patients	PY 3 CY2023 Patients
Mecklenburg	60.2%	308	338	368
Union	7.8%	40	44	48
Rowan	7.0%	36	40	43
Gaston	6.8%	35	38	42
Other NC counties*	11.7%	60	65	71
Other States**	6.6%	34	37	40
TOTAL	100.0%	512	562	612

Source: Table on page 22 of the application.

*The applicant lists the counties included in the “Other NC Counties” category on page 22 of the application.

**Other States include South Carolina, Kentucky and West Virginia.

In Section C.3, page 23, the applicants state, “Future patient origin is expected to be the same as the most recent year of patient origin (CY 2018) for NHPMC EV Lab Appropriate Visits.” The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 23-30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, including:

- The high utilization of the hospital’s existing cardiac catheterization equipment results in difficulty scheduling and accommodating non-coronary patients (pages 24-26).
- The recent addition of physicians that specialize in cardiovascular, peripheral vascular and endovascular procedures to the medical staff at NHPMC has resulted in growth in the number of patient visits by patients who would be appropriate for an EV lab (pages 26-27).
- The projected population growth in the service area (page 28).
- The projected growth in EV lab procedures that will result from planned additions to the medical staff (pages 28-29).

The information provided by the applicant in the pages referenced above is reasonable and adequately supported for the following reasons:

- The applicant provides historical utilization data for the hospital’s existing cardiac catheterization equipment.
- The applicant provides historical utilization data for the hospital’s endovascular patients.
- The applicant provides information regarding the current and projected population by county for its proposed service area from the North Carolina Office of State Budget and Management (NCOSBM).

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization for the proposed EV lab equipment through the first three full operating years of the proposed project (CY2021-CY2023) following project completion, as summarized in the following table. The EV procedures are projected to be performed on the existing cardiac catheterization equipment until the proposed EV lab system becomes operational in July 2020.

Endovascular (EV) Lab Procedures Utilization			
YEAR	EV Lab Units	EV Procedures	Percent Change
CY2016 (Actual)	0	130	---
CY2017 (Actual)	0	290	123.1%
CY2018 (Actual)	0	412	42.1%
CY2019 (Projected)	0	412	0.0%
CY2020 (Partial)*	1	462	12.1%
CY2021 Year 1	1	512	10.8%
CY2022 Year 2	1	562	9.8%
CY2023 Year 3	1	612	8.9%

Source: Form C, Section Q of the application.

*Applicant projects the proposed EV lab will become operational on July 1, 2020.

The applicant provides its assumptions and methodology for projecting utilization for its proposed services in Section Q, Form C, pages 90-92, which is summarized as follows:

Step 1: Identify the Physicians to Utilize the EV Lab – The applicant identified the ten current interventional cardiologists and vascular surgeons on the NHPMC medical staff that could move cases to the proposed EV lab.

Step 2: Historical Utilization - The applicant identified all the inpatients and outpatients who received procedures in the cardiac catheterization labs or hybrid operating rooms, excluding patients who received cardiac catheterizations, from CY2016 to CY2018.

Step 3: Project EV Lab Appropriate Visits in CY2019 – The applicant assumed no growth in EV lab-appropriate visits from CY2018 to CY2019.

Step 4: Project EV Lab Appropriate Visits from CY2019 to CY2023 – The applicant assumed an annual growth of 50 EV lab-appropriate visits at NHPMC from CY2019 through CY2023, as shown in the following table.

NHPMC Projected EV Lab Appropriate Visits					
	CY2019	CY2020	CY2021	CY2022	CY2023
EV Lab Appropriate Visits	412	462	512	562	612
Annual Visit Growth	0	50	50	50	50

Source: Section Q, page 92

On page 92, the applicant states,

“Beginning in CY2020 through CY2023, the 3rd project year, we project an additional 50 patient visits to the EV Lab each year. An additional 50 visits per year is only about one-third of the average growth in visits, 141, for the last two years.”

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

- The applicant’s utilization projections are supported by the historical utilization of the existing cardiac catheterization labs and hybrid operating rooms at NHPMC, excluding cardiac catheterizations.
- The applicant provides letters from physicians and surgeons expressing support for the proposed project and their intention to treat patients in the proposed EV lab at NHPMC in Exhibit H-4.1 of the application.

Access

In Section C.11, page 34, the applicant states NHPMC will continue to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental condition, age, ability to pay, or any other factor. In Section L.3, page 73, the applicant projects the following payor mix for NHPMC’s EV lab services during the second year of operation (CY2022) following completion of the project, as shown in the following table.

Payment Source	EV Lab Services Percent of Total Procedures
Medicare*	75%
Medicaid*	3%
Insurance*	16%
TRICARE	1%
Other Government	5%
Total	100%

Source: Table on page 73 of the application.

*Including any managed care plans.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.

- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (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 the reduction or elimination of a service. Therefore, Criterion (3a) is not applicable to this review

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

CA

The applicant, NHPMC, proposes to develop an endovascular lab with one interventional angiography system that will not perform cardiac catheterization procedures.

In Section E.2, pages 44-45, 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 this was not an effective alternative due to the fact that the existing cardiac catheterization equipment is already fully utilized and, therefore, is not available for non-coronary procedures that would be appropriate for an EV lab.
- Transfer patients to another hospital – The applicant states this was not an effective alternative because transferring patients would require unnecessary costs and duplicative services, and providing the services at another hospital would be inconvenient for both the medical staff and patients.

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 alternative will meet the need for additional capacity to perform non-coronary vascular procedures at NHPMC.
- The alternative is more cost-effective and convenient for patients and medical staff.

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. The Presbyterian Hospital and Novant Health, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. The Presbyterian Hospital and Novant Health, Inc. shall acquire no more than one interventional angiography system that will not perform cardiac catheterization procedures.**
 - 3. The Presbyterian Hospital and Novant Health, Inc., as part of this project, shall not acquire 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 years of operation following initiation of the services authorized by this certificate of need, The Presbyterian Hospital and Novant Health, Inc. 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. The Presbyterian Hospital and Novant Health, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance 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.

NHPMC proposes to develop an endovascular lab with one interventional angiography system that will not perform cardiac catheterization procedures. The applicant proposes minor renovations to existing space on the fifth floor of the hospital to accommodate the proposed EV lab.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 94, the applicant projects the total capital cost of the project as shown in the table below.

Construction Costs	\$895,024
Equipment	\$1,068,456
Miscellaneous Costs	\$272,666
Total	\$2,236,146

In Section Q, page 95, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 48, the applicant states the project does not involve a new service and there will be no start-up costs or initial operating expenses required.

Availability of Funds

In Section F, page 46, 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
Loans	\$0	\$ 0
Accumulated reserves or OE *	\$2,236,146	\$2,236,146
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$2,236,146	\$2,236,146

* OE = Owner's Equity

Exhibit F-2.1 contains a letter dated April 15, 2019 from the Senior Vice President, Operational Finance, for Novant Health documenting its intention to provide accumulated reserves for the capital needs of the proposed project. Exhibit F-2.2 contains the audited financial statements of Novant Health, Inc. which show that as of December 31, 2017, the applicant had \$409 million in cash and cash equivalents, \$6.5 billion in total assets, and \$3.9 billion in net assets (total assets less total liabilities).

Financial Feasibility

The applicant provided pro forma financial statements for NHPMC for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicant

projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

NHPMC EV Lab Services

	1st Fiscal Year	2nd Fiscal Year	3rd Fiscal Year
Total Procedures	512	562	612
Total Gross Revenues (Charges)	\$37,117,432	\$41,972,994	\$47,069,896
Total Net Revenue	\$8,553,112	\$9,674,396	\$10,846,003
Net Revenue per Procedure	\$16,705	\$17,214	\$17,722
Total Operating Expenses (Costs)	\$4,271,904	\$4,867,442	\$5,385,157
Operating Expense per Patient	\$8,344	\$8,661	\$8,799
Net Income	\$4,281,208	\$4,806,954	\$5,460,845

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the 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, NHPMC, proposes to develop an endovascular lab with one interventional angiography system that will not perform cardiac catheterization procedures. 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 2019 SMFP does not define a service area for interventional

angiography equipment, nor are there any applicable rules adopted by the Department that define the service area for interventional angiography equipment. Thus, the service area is defined by the applicant. Facilities may also serve residents of counties not included in their service area.

In Section C.3, page 22, the applicant provides the projected patient origin for the proposed EV lab in the first three full fiscal operating years (CY2021-CY2023) following project completion, as shown in the table below.

Projected Patient Origin for NHPMC Endovascular Lab Visits

County	Percent of Total Patients CY2021-CY2023	PY 1 CY2021 Patients	PY 2 CY2022 Patients	PY 3 CY2023 Patients
Mecklenburg	60.2%	308	338	368
Union	7.8%	40	44	48
Rowan	7.0%	36	40	43
Gaston	6.8%	35	38	42
Other NC counties*	11.7%	60	65	71
Other States**	6.6%	34	37	40
TOTAL	100.0%	512	562	612

Source: Table on page 22 of the application.

*The applicant lists the counties included in the “Other NC Counties” category on page 22 of the application.

**Other States include South Carolina, Kentucky and West Virginia.

In Section C.2, page 20, the applicant states that NHPMC does not currently operate an endovascular (EV) lab. However, in Section C.1, page 16, the applicant states that it currently does procedures appropriate for an EV lab in its cardiac catheterization lab or in its hybrid operating room. The applicant further states in Section G.1, page 53, that the service to be provided in the proposed EV lab “*could possibly be provided on the type of x-ray angiography equipment found in Cath Labs, EV Labs, and Electrophysiology Labs (‘EP Labs’), or Hybrid ORs.*” In Section G.1, page 54, the applicant provides a table showing the hospitals in the service area that currently operate cardiac catheterization (Cath) equipment and electrophysiology (EP) equipment, as shown below.

Hospital	Cath Labs	EP Labs
NH Presbyterian Medical Center	X	X
NH Matthews Medical Center	X	
NH Huntersville Medical Center	X	X
Carolinas Medical Center	X	X
Carolinas HealthCare System Pineville	X	X
CaroMont Regional Medical Center	X	X
NH Rowan Medical Center	X	
Carolinas HealthCare System Union	X	

In Section G.3, page 54, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved endovascular services in the service area. The applicant states:

“This application is not proposing a new service. Instead, it proposes additional equipment to more efficiently schedule and perform peripheral cardiac procedures. This equipment will reduce the time patients must wait to have procedures performed. By moving peripheral procedures out of the Cath Lab, patients receiving both types of procedures will experience reduced delays.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed EV lab is 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 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

In Section Q, Form H, page 114, the applicant provides projected full-time equivalent (FTE) staffing in the first three full fiscal years (CY2021-CY2023) for the proposed EV lab. Current staffing and projected staffing for the second full fiscal year is summarized below.

Full-Time Equivalent (FTE) Staffing

Position	Current (1/31/2018)	Year 2 (CY2022)
Registered Nurses	2.16	5.00
Clerical	0.15	0.15
Nurse Manager	0.18	0.18
Nurse Supervisor	0.18	0.18
Scheduler	0.18	0.18
Total	2.86	5.70

The assumptions and methodology used to project staffing are provided in Section Q, pages 115-116. 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 Sections H.2 and H.3, pages 56-59, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section H.4, page

59, the applicant identifies the medical director and provides supporting documentation in Exhibit H-4.1.

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.1, page 62, the applicant states NHPMC is an existing full-service hospital, as such, the hospital currently has all necessary ancillary and support services in place. In Section I.2, pages 62-63, the applicant states it has established relationships with other local health care and social service providers which will continue following completion of the proposed project. The applicant provides supporting documentation in Exhibits I-1 and I-2.

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 HSA IV where 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.2, page 66, the applicant states that the project requires renovations to 1,019 square feet of space in the existing cardiac catheterization department of the hospital. Line drawings are provided in Exhibit K-2.

In Section K.4, page 66, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

In Section K.4. page 67, 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.

In Section K.4, page 67, 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.

(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

In Section L.1, page 72, the applicant provides the historical payor mix during CY2018 for the EV lab-appropriate patients at NHPMC, as shown in the table below.

Payment Source	EV Lab Services Percent of Total Procedures
Medicare	75%
Medicaid	3%
Insurance	16%
TRICARE	1%
Other Government	5%
Total*	100%

Source: Table on page 72 of the application.

*Totals may not foot due to rounding.

In Section L.1, page 71, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the CY2018	Percentage of the Population of the Service Area
Female	63.7%	51.6%
Male	36.3%	48.4%
Unknown	NA	NA
64 and Younger	72.3%	87.1%
65 and Older	27.7%	12.9%
American Indian	0.2%	0.4%
Asian	1.8%	4.8%
Black or African-American	40.2%	26.0%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	47.8%	59.9%
Other Race	5.9%	8.8%
Declined / Unavailable	4.0%	0.0%

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.2, page 72, the applicant states NHPMC complies with all the relevant regulatory requirements with regard to uncompensated care, community benefits and access to care by all persons, regardless of ability to pay or other factors.

In Section L.2, page 73, the applicant states that during the last five years, no patient civil rights access complaints have been filed against Novant Health facilities or a related entity and located in North Carolina.

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.3, page 73, the applicant provides the projected payor mix for the second full fiscal year (CY2022) for the proposed project, as shown in the table below.

Payment Source	EV Lab Services Percent of Total Procedures
Medicare	75%
Medicaid	3%
Insurance	16%
TRICARE	1%
Other Government	5%
Total*	100%

Source: Table on page 73 of the application.

*Totals may not foot due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 75 percent of EV lab services will be provided to Medicare patients, and 3 percent to Medicaid patients.

In Section L.3, page 73, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical experience.

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.5, page 76, 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

In Section M.1, page 77, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit H-2.1.

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, NHPMC, proposes to develop an endovascular lab with one interventional angiography system that will not perform cardiac catheterization procedures. 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 2019 SMFP does not define a service area for interventional angiography equipment, nor are there any applicable rules adopted by the Department that define the service area for interventional angiography equipment. Thus, the service area is defined by the applicant. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 20, the applicant states that NHPMC does not currently operate an endovascular (EV) lab. In Section G.1, page 54, the applicant provides a table showing the hospitals in the service area that currently operate cardiac catheterization (Cath) equipment and electrophysiology (EP) equipment, which it states, on page 53, could provide the services proposed to be provided in an EV lab, as shown below.

Hospital	Cath Labs	EP Labs
NH Presbyterian Medical Center	X	X
NH Matthews Medical Center	X	
NH Huntersville Medical Center	X	X
Carolinas Medical Center	X	X
Carolinas HealthCare System Pineville	X	X
CaroMont Regional Medical Center	X	X
NH Rowan Medical Center	X	
Carolinas HealthCare System Union	X	

In Section N.2, pages 79-81, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 79, the applicant states,

“The proposed project will expand NHPMC’s capacity to provide endovascular procedures and cardiac catheterization procedures. Having separate laboratories for each category of procedure will improve efficiency and patient outcomes. The proposed project will reduce scheduling inefficiencies and delays, which will improve patient satisfaction and physician productivity and efficiency. The EV Lab will improve NHPMC’s competitive position in Mecklenburg County.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

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.

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

C

In Section O.3, page 84, the applicant states Novant Health owns or manages 14 hospitals in North Carolina, including NHPMC.

In Section O, pages 84, the applicant states that, during the 18 months immediately preceding the submittal of the application, none of its hospitals operated out of compliance with the Medicare Conditions of Participation. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, all of the facilities are in compliance with all Medicare Conditions of Participation. 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 14 facilities, the applicant provides 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 develop an endovascular lab with one interventional angiography system that will not perform cardiac catheterization procedures. There are no administrative

rules that are applicable to proposals to develop an endovascular lab with one interventional angiography system that will not perform cardiac catheterization procedures.