

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 27, 2021

Findings Date: May 27, 2021

Project Analyst: Julie M. Faenza

Team Leader: Gloria C. Hale

Project ID #: G-12031-21

Facility: Novant Health Kernersville Medical Center

FID #: 923174

County: Forsyth

Applicants: Forsyth Memorial Hospital, Inc.

Novant Health, Inc.

Project: Replace and relocate no more than 1 unit of cardiac cath equipment from Novant Health Forsyth Medical Center to Novant Health Kernersville Medical Center and initiate cardiac cath services

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

Forsyth Memorial Hospital, Inc. and Novant Health, Inc. (hereinafter referred to as “Novant” or “the applicant”) propose to replace and relocate an existing unit of cardiac catheterization (cardiac cath) equipment from Novant Health Forsyth Medical Center (NH Forsyth) to its satellite campus, Novant Health Kernersville Medical Center (NH Kernersville), and to begin offering cardiac cath services at the NH Kernersville campus.

Need Determination

The applicant does not propose to develop any beds or services or acquire any medical equipment for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2021 SMFP applicable to this review. Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 29 of the 2021 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 is greater than \$2 million. In Section B, pages 26-27, the applicant provides a written statement describing the project’s plan to assure improved energy efficiency and water conservation. The applicant states it considers energy efficiency and water conservation in every project consistent with its Sustainable Energy Management Plan. The applicant provides a copy of that plan in Exhibit B-21.

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 adequately demonstrates that the application contains 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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to replace and relocate an existing unit of cardiac cath equipment from NH Forsyth to its satellite campus, NH Kernersville, and to begin offering cardiac cath services at the NH Kernersville campus.

Patient Origin

On page 314, the 2021 SMFP defines the cardiac catheterization equipment service areas as “...the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.” Figure 5.1 on page 36 shows Forsyth County as a single county Acute Care Bed Service Area. Thus, the service area for this proposal is Forsyth County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate current and projected patient origin.

NH Forsyth Cardiac Cath Current Patient Origin – CY 2020		
County	Number of Patients	Percent of Total
Forsyth	1,659	38%
Surry	460	11%
Davidson	405	9%
Stokes	324	8%
Yadkin	234	5%
Davie	210	5%
Other*	1,027	24%
Total	4,319	100%

Source: Section C, page 32

*Other includes Alamance, Alexander, Alleghany, Ashe, Avery, Brunswick, Burke, Cabarrus, Caldwell, Carteret, Catawba, Cleveland, Currituck, Gaston, Guilford, Harnett, Iredell, Jackson, Johnston, McDowell, Mecklenburg, Moore, Nash, New Hanover, Pender, Person, Randolph, Rockingham, Rowan, Stanly, Union, Vance, Wake, Warren, Watauga, Wayne, and Wilkes counties in NC, as well as cities and counties in other states.

NH Kernersville Cardiac Cath Projected Patient Origin – FYs 1-3						
County	FY 1 – CY 2025		FY 2 – CY 2026		FY 3 – CY 2027	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Forsyth	317	65.4%	382	65.4%	386	65.4%
Guilford	90	18.5%	108	18.5%	109	18.5%
Stokes	29	5.9%	34	5.9%	35	5.9%
Other*	49	10.2%	60	10.2%	60	10.2%
Total	485	100.0%	584	100.0%	590	100.0%

Source: Section C, page 34

*Other counties in NC as well as the following states: Florida, Georgia, Kentucky, Maryland, New Hampshire, Ohio, Pennsylvania, South Carolina, Utah, Vermont, Virginia, and West Virginia

In Section C, page 33, the applicant provides the assumptions and methodology used to project patient origin. The applicant states it projects patient origin will be consistent with NH Kernersville’s historical patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant relies on historical patient origin to project future patient origin.
- The applicant states it assumes it will draw from the same types of patients it currently serves at NH Kernersville and more complex patients will continue to receive services at NH Forsyth.

Analysis of Need

In Section C, pages 35-38, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, which is summarized below.

- The applicant opened a new Heart and Vascular Institute (HVI) clinic in High Point in January 2021. The applicant states the lead physician had previously spent 27 years practicing interventional cardiology and electrophysiology in the area before leaving for a short time and returning. The applicant is recruiting an additional interventional cardiologist to work with the doctor and the applicant states both doctors will move all clinically appropriate patients needing cardiac cath services to NH Kernersville when the relocated equipment is operational.
- The applicant has a number of other cardiology and vascular clinics in the area. The applicant states patients at these clinics would prefer to receive care, if appropriate, at a location closer to home rather than traveling to NH Forsyth.
- The applicant states it has recruited five cardiologists from outside the area and three cardiologists from other local health systems in the last 18 months and plans to recruit a number of other cardiovascular and vascular physicians. The applicant states that while these cardiologists and other physicians will not perform cardiac cath procedures, it will increase the number of patients in the applicant’s system who may need cardiac cath services. The applicant states patient satisfaction and quality of care will improve if patients

are able to receive services closer to their homes. The applicant provides letters of support from physicians who plan to utilize the relocated cardiac cath equipment in Exhibit C-4.1.

- The applicant states the area population is growing significantly and states that more than 13,000 new housing units either were built or are under construction within a 10-mile radius of NH Kernersville in recent years. The applicant states that patients age 65 and older are the largest users of cardiac cath and angiography procedures and states that, based on data from ESRI, the population age 65 and older in the Kernersville ZIP code (27284), Forsyth County, and Guilford County will grow at higher rates than the overall population of those areas. The applicant further states that, based on data from ESRI, the total population as well as the population age 65 and older in the 27284 ZIP code is projected to grow at higher rates than both of those groupings for Forsyth and Guilford counties.

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

- The applicant discusses the number of clinics and physicians in the area of NH Kernersville who may have patients in need of cardiac cath services at NH Kernersville.
- The applicant provides letters of support from physicians who state they plan to utilize the relocated cardiac cath equipment for their patients.
- The applicant relies on publicly sourced data about population growth in the area.

Projected Utilization

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

NH Kernersville Projected Utilization – Cardiac Cath Lab				
	Partial FY – Apr-Dec 2024	FY 1 – CY 2025	FY 2 – CY 2026	FY 3 – CY 2027
# of Units	1	1	1	1
# Diagnostic Procedures	190	256	258	261
# Therapeutic Procedures	0	0	94	95
# Diagnostic-Equivalent Procedures	190.00	256.00	422.50	427.25
# Angiography Procedures	170	229	232	234

In the Form C.2b Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

Cardiac Cath Procedures

- The first three full fiscal years of the project are CYs 2025-2027.
- The Novant System Vice President for HVI estimated that between 350-400 patients would receive cardiac cath procedures in CY 2027, based on historical data at NH Forsyth, the opening of a new HVI clinic in High Point, expanded staffing, and physician recruitment.

The applicant provides a letter from the Novant System Vice President for HVI in Exhibit C-4.1.

- HVI leadership reviewed 2019 cardiac cath lab volume and excluded any procedures that would not be appropriate for treatment at NH Kernersville based on the scope of services offered at NH Kernersville.
- The applicant identified the number of cardiac cath lab encounters for patients who were clinically appropriate for NH Kernersville and who were residents of NH Kernersville's "home" ZIP code (27284). The applicant used data for CY 2019 rather than CY 2020 due to the potential impact of COVID-19 on volume in CY 2020. The applicant states that there was a bigger discrepancy between CY 2019 and CY 2020 for angiography procedures than for cardiac cath procedures.
- Based on analysis of patients with the same MS-DRG codes who were treated at NH Forsyth and NH Kernersville and the proportion served at each facility, the applicant determined 63.2 percent of the clinically appropriate cardiac cath lab patients from ZIP code 27284 would shift from NH Forsyth to NH Kernersville.
- The applicant assumed that the patient origin for cardiac cath services would be the same as for all acute care services at NH Kernersville. The applicant states that 36.1 percent of NH Kernersville patients originate from ZIP code 27284 and the remaining 64 percent from outside of that ZIP code. The applicant calculated how many additional cardiac cath patients would be served at NH Kernersville by applying those percentages to the patients already projected to shift to NH Kernersville.
- After obtaining the baseline number of patients the applicant projected would be served at NH Kernersville based on CY 2019 utilization, the applicant projected growth between CYs 2019-2024 at an annual rate of 1.1 percent. The applicant states this is the projected 2019-2024 Compound Annual Growth Rate (CAGR) for adults in Davidson, Davie, Forsyth, Guilford, Stokes, Surry, and Yadkin counties, where 85.9 percent of NH Forsyth's CY 2019 acute care discharges originated from. For CYs 2024-2027, the applicant projected growth at a rate of 1.0 percent, which is the 2024-2027 CAGR for the same seven counties as above. The applicant states 93.7 percent of NH Kernersville's CY 2019 acute care discharges originated from these seven counties.
- The applicant projects patients will start to shift from NH Forsyth to NH Kernersville in April 2024. The applicant also projects that between April 2024 and December 2025, the cardiac cath lab at NH Kernersville will only perform diagnostic cardiac cath procedures and will not start performing interventional cardiac cath procedures until CY 2026.

Angiography Procedures

- The first three full fiscal years of the project are CYs 2025-2027.

- Five Novant physicians projected that they would perform between 200 and 250 angiography procedures in 2027 and they expect to move approximately half of their clinically appropriate patients to NH Kernersville. The applicant provides a letter from the Novant physicians in Exhibit C-4.1.
- HVI leadership reviewed 2019 cardiac cath lab volume and excluded any patients who had a cardiac cath procedure that was not clinically appropriate for NH Kernersville in addition to the angiography procedure.
- The applicant identified the number of angiography patients the five physicians treated in CY 2019. The applicant used data for CY 2019 rather than CY 2020 due to the potential impact of COVID-19 on volume in CY 2020.
- Based on the projections of the physicians, the applicant projected half of the clinically appropriate encounters from these five physicians would shift to NH Kernersville.
- After obtaining the baseline number of patients the applicant projected would be served at NH Kernersville based on CY 2019 utilization, the applicant projected growth between CYs 2019-2024 at an annual rate of 1.1 percent. The applicant states this is the projected 2019-2024 CAGR for adults in Davidson, Davie, Forsyth, Guilford, Stokes, Surry, and Yadkin counties, where 85.9 percent of NH Forsyth’s CY 2019 acute care discharges originated from. For CYs 2024-2027, the applicant projected growth at a rate of 1.0 percent, which is the 2024-2027 CAGR for the same seven counties as above. The applicant states 93.7 percent of NH Kernersville’s CY 2019 acute care discharges originated from these seven counties.
- The applicant projects patients will start to shift from NH Forsyth to NH Kernersville in April 2024.

A summary of the applicant’s assumptions, methodology, and projected utilization are shown in the tables below.

CY 2019 Baseline Cardiac Cath Patients			
	Diagnostic	Interventional	Total
Clinically appropriate patients from NH Forsyth residing in ZIP code 27284			
Inpatient	48	32	80
Outpatient	89	18	107
Baseline shift of patients in ZIP code 27284 to NH Kernersville based on 63.2% historical volume			
Inpatient	30.3	20.2	50.6
Outpatient	56.2	11.4	67.6
Total projected baseline patients based on 64% of NH Kernersville discharges outside ZIP code 27284			
Inpatient	84.1	56.0	140.1
Outpatient	155.8	31.5	187.3
Total	239.9	87.5	327.4

CY 2019 Baseline Angiography Patients				
Physician	Outpatient	Inpatient	½ Outpatient	½ Inpatient
Dr. Moore	71	9	35.5	4.5
Dr. Thomason	13	7	6.5	3.5
Dr. Deonanan	87	19	43.5	9.5
Dr. Fleming	129	23	64.5	11.5
Dr. Rickey	53	18	26.5	9.0
Total	353	76	176.5	38.0

NH Kernersville Cardiac Cath Lab Projected Utilization										
	Patients Still at NH Forsyth						Shift	FY 1	FY 2	FY 3
	2019	2020	2021	2022	2023	Jan-Mar 2024*	Apr-Dec 2024*	2025	2026	2027
Cardiac Cath Procedures										
Diagnostic	240	242	245	248	251	63	190	256	258	261
Interventional	88	88	89	90	91	23	0	0	94	95
Total	327	331	335	338	342	86	190	256	353	356
Angiography Procedures										
Inpatient	38	38	39	39	40	10	30	41	41	41
Outpatient	177	179	181	183	185	47	140	189	191	193
Total	215	217	220	222	225	57	170	229	232	234

Note: Table may not foot due to rounding

*January-March 2024 is CY 2024's total multiplied by 1/4th; April-December 2024 is CY 2024's total multiplied by 3/4th

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

- The applicant uses historical utilization and historical patient origin patterns to project utilization.
- The applicant excludes patients who are not clinically appropriate for care at NH Kernersville.
- The applicant documents the basis for projections which are not based entirely on historical utilization.

Access

In Section C, pages 43-44, the applicant states:

“Services are available to all persons including: (a) low income persons, (b) racial and ethnic minorities, (c) women, (d) [disabled] persons, (e) elderly, (f) Medicare beneficiaries, and (g) Medicaid recipients, including the medically indigent referred by their attending physicians. These policies are currently in place at NH Kernersville and will apply to the transferred asset applied for under this CON application.”

In Section C, page 44, the applicant provides the estimated percentage for each medically underserved group it proposes to serve during the third full fiscal year, as shown in the following table.

Medically Underserved Groups	% of Total Patients
Racial and ethnic minorities	28%
Women	64%
Persons age 65 and older	31%
Medicare beneficiaries	35%
Medicaid recipients	10%

In Section C, page 44, the applicant states it does not collect data on low income persons and people with disabilities.

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

- The applicant provides projected utilization by each medically underserved group it tracks.
- The applicant provides copies of policies related to access for medically underserved groups in Exhibits C-6.1, C-6.2, C-6.4, and L-4.1.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to replace and relocate an existing unit of cardiac cath equipment from NH Forsyth to its satellite campus, NH Kernersville, and to begin offering cardiac cath services at the NH Kernersville campus.

NH Forsyth currently has eight units of cardiac cath equipment. After the replacement and relocation of one unit of cardiac cath equipment, NH Forsyth will have seven remaining units of cardiac cath equipment.

In Section D, page 50, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 50, the applicant states:

“The cath labs at NH Forsyth are not fully utilized, and the Winston-Salem campus can accommodate the demand for cardiac catheterization services with seven (7) cath labs. NH Forsyth reported 4,890 diagnostic equivalent cardiac catheterization procedures on its 2020 LRA, or 611.25 equivalent procedures per laboratory. The performance standard for cardiac catheterization equipment states that the capacity for cardiac cath procedures is 1,500 diagnostic equivalent procedures per year. With seven cath labs at NH Forsyth, each cath lab would have performed an average of 698.57 equivalent procedures, and the combined cath labs on the campus would have been at 46.6 percent utilization. The cath lab capacity on the NH Forsyth Winston-Salem campus will be sufficient for the foreseeable future.”

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

- Publicly available information confirms the applicant’s statement about its current utilization of cardiac cath labs and the capacity that exists.
- In Exhibit D-2, the applicant provides a letter from the President of NH Forsyth and Novant Health’s Greater Winston-Salem Market, stating that there will still be sufficient capacity at NH Forsyth for cardiac cath procedures even with the relocation of one unit of cardiac cath equipment to NH Kernersville.

On Form D.2 in Section Q, the applicant provides projected utilization of cardiac cath labs at NH Forsyth through CY 2025, the first full fiscal year following project completion, as shown in the table below.

NH Forsyth Cardiac Cath Lab Projected Utilization							
	2020*	2021	2022	2023	Jan-Mar 2024**	Apr-Dec 2024**	2025
# of Units	8	8	8	8	8	7	7
# Diagnostic Procedures	2,599	2,628	2,657	2,686	679	1,847	2,487
# Therapeutic Procedures	1,088	1,100	1,112	1,124	284	852	1,148
# Diagnostic-Equivalent Procedures	4,503	4,553	4,603	4,653	1,176	3,338	4,496
# Angiography Procedures	989	1,000	1,011	1,022	258	604	813

***Note:** Based on information in other sections of the application, the data for CY 2020 in Form D.2 appears to be incorrect. The Project Analyst has substituted the correct information based on other areas of the application.

**January-March 2024 is CY 2024’s total multiplied by 1/4th; April-December 2024 is CY 2024’s total multiplied by 3/4th

In the Form D.2 Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, as summarized below.

- The applicant identified the number of cardiac cath procedures and angiography procedures for CY 2019. The applicant used data for CY 2019 rather than CY 2020 due to the potential impact of COVID-19 on volume in CY 2020. The applicant states that there was a bigger discrepancy between CY 2019 and CY 2020 for angiography procedures than for cardiac cath procedures.
- The applicant projected growth in cardiac cath lab utilization between CYs 2019-2024 at a rate of 1.1 percent. The applicant states this is the projected 2019-2024 CAGR for adults in Davidson, Davie, Forsyth, Guilford, Stokes, Surry, and Yadkin counties, where 85.9 percent of NH Forsyth’s CY 2019 acute care discharges originated from. For CYs 2024-2027, the applicant projected growth at a rate of 1.0 percent, which is the 2024-2027 CAGR for the same seven counties as above.
- The applicant projects patients will start to shift from NH Forsyth to NH Kernersville in April 2024 and subtracts the projected shifts from the projected utilization.

A summary of the applicant’s assumptions, methodology, and projected utilization are shown in the tables below.

NH Forsyth Cardiac Cath Lab Projected Utilization								
							Patients Shift	
	2019	2020	2021	2022	2023	Jan-Mar 2024*	Apr-Dec 2024*	2025
Cardiac Cath Procedures								
Diagnostic	2,571	2,599	2,628	2,657	2,686	679	1,847 (-190)	2,487 (-256)
Interventional	1,076	1,088	1,100	1,112	1,124	284	852	1,148
Total	3,647	3,687	3,728	3,769	3,810	963	2,699	3,635
Angiography Procedures								
Procedures	978	989	1,000	1,011	1,022	258	604 (-170)	814 (-229)

Note: Numbers in parentheses indicate the number of patients projected to shift from NH Forsyth to NH Kernersville.

*January-March 2024 is CY 2024’s total multiplied by 1/4th; April-December 2024 is CY 2024’s total multiplied by 3/4th

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

- The applicant uses historical utilization and historical patient origin patterns to project utilization.
- The applicant uses assumptions and methodology consistent with its projections for NH Kernersville.

Access to Medically Underserved Groups

In Section D, page 50, the applicant states:

“The proposed project will not affect the ability of any of the above-listed groups to obtain cardiac catheterization or angiography procedures. ..., there will be sufficient

capacity for any patients that wish to continue receiving care in NH Forsyth's cath labs to continue doing so. The proposed project will allow Kernersville area residents, including low income persons, minorities, women, persons with disabilities, persons 65 and older and Medicare and Medicaid beneficiaries to receive care at NH Kernersville, closer to their homes."

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use cardiac cath lab services will be adequately met following completion of the project for the following reasons:

- Publicly available information shows that utilization of cardiac cath lab services at NH Forsyth is low enough that there will still be sufficient capacity for patients, including patients in medically underserved groups.
- In Exhibit D-2, the applicant provides a letter from the President of NH Forsyth and Novant Health's Greater Winston-Salem Market, stating that there will still be sufficient capacity at NH Forsyth for cardiac cath procedures even with the relocation of one unit of cardiac cath equipment to NH Kernersville.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated, or relocated will be adequately met following project completion for all the reasons described above.
 - The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.
- (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 replace and relocate an existing unit of cardiac cath equipment from NH Forsyth to its satellite campus, NH Kernersville, and to begin offering cardiac cath services at the NH Kernersville campus.

In Section E, page 54, the applicant states there are no other alternatives to the proposed project. The applicant states:

“The objective of this application is to establish cardiac catheterization and angiography services at NH Kernersville. The Applicants have determined there are no less costly or more effective alternatives to meet the objective of this application. The Applicants have considered with their architect and contractors alternatives to the proposed construction relative to immediate needs and to the long-term development of the hospital. The Applicants believe the selected option is the least costly and most effective design, materials and construction methods. The Applicants believe they have selected the most cost-effective equipment for the laboratory.”

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 applicant provides credible information to explain why it believes the proposed project is the only 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
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

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

- 1. Forsyth Memorial Hospital, Inc. and Novant Health, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. The certificate holder shall relocate no more than 1 unit of cardiac catheterization equipment from the Novant Health Forsyth Medical Center campus to the Novant Health Kernersville Medical Center campus.**
- 3. Upon completion of the project, the Novant Health Forsyth Medical Center campus shall have no more than 7 units of cardiac catheterization equipment and the Novant Health Kernersville Medical Center campus shall have no more than 1 unit of cardiac**

catheterization equipment. There shall be no change in the total number of units of cardiac catheterization equipment on Novant Health Forsyth Medical Center's license.

- 4. 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.**
- 5. 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. Progress reports shall be due on the first day of every third month. The first progress report shall be due on September 1, 2021. The second progress report shall be due on December 1, 2021 and so forth.**
- 6. 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.**
- 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 holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**

8. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to replace and relocate an existing unit of cardiac cath equipment from NH Forsyth to its satellite campus, NH Kernersville, and to begin offering cardiac cath services at the NH Kernersville campus.

Capital and Working Capital Costs

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

Construction Costs	\$2,977,962
Architect/Engineering Fees	\$256,914
Medical Equipment	\$3,475,212
Furniture	\$52,026
Consultant Fees	\$50,000
Interest During Construction	\$235,397
IT/Low voltage communications	\$466,864
Other (Security, DHSR)	\$28,824
Contingency	\$678,032
Total	\$8,221,231

The applicant provides its assumptions and methodology for projecting capital cost in Section Q and Exhibits F-1.1, F-1.2, and K-2. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Section Q immediately following Form F.1a, the applicant provides information on what costs are included in the calculation of each line item in the projected capital cost.
- In Exhibit F-1.1, the applicant provides a certified cost estimate for construction from an architect.
- In Exhibit F-1.2, the applicant provides an itemized list of equipment it proposes to acquire, and which is included in the projected capital cost.

- In Exhibit K-2, the applicant provides the line drawings it references in its assumptions and methodology.

In Section F, pages 56-57, the applicant states there will be no start-up costs or initial operating expenses because the proposed project is an expansion of existing services already being offered at the NH Kernersville campus.

Availability of Funds

In Section F, pages 55-56, the applicant states the entire projected capital expenditure of \$8,221,231 will be funded by Novant's accumulated reserves.

In Exhibit F-2.1, the applicant provides a letter dated February 5, 2021 from the Senior Vice President of Operational Finance & Revenue Cycle for Novant, stating that Novant has sufficient accumulated reserves to fund all projected capital costs and committing to providing that funding to develop the proposed project.

Exhibit F-2.2 contains a copy of the audited Annual Financial Report for Novant Health, Inc. and Affiliates for the years ending December 31, 2019 and 2018. According to the audited Annual Financial Report, as of December 31, 2019, Novant had adequate cash and assets to fund all the capital needs of the proposed project.

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

- The applicant provides a letter from the appropriate Novant official confirming the availability of the funding proposed for the capital needs of the project and the commitment to use those funds to develop the proposed project.
- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion. On Form F.2b in Section Q, the applicant projects operating expenses will exceed revenues during the first full fiscal year following project completion, but that revenues will exceed operating expenses in the second and third full fiscal years following project completion, as shown in the table below.

NH Kernersville Cardiac Cath Revenues & Operating Expenses – FYs 1-3			
	FY 1 (CY 2025)	FY 2 (CY 2026)	FY 3 (CY 2027)
Total Procedures (combined)	485	584	590
Total Gross Revenues (Charges)	\$19,080,177	\$26,496,450	\$27,572,797
Total Net Revenue	\$5,630,405	\$8,367,618	\$8,707,714
Average Net Revenue per Procedure	\$11,609	\$14,328	\$14,759
Total Operating Expenses (Costs)	\$5,737,626	\$6,393,798	\$6,564,384
Average Operating Expense per Procedure	\$11,830	\$10,948	\$11,126
Net Income/(Loss)	(\$107,221)	\$1,973,820	\$2,143,330

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Forms F.2b and F.3b in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant clearly details the sources of information it uses to make its projections.
- The applicant based its projections on its historical experience at NH Forsyth.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to replace and relocate an existing unit of cardiac cath equipment from NH Forsyth to its satellite campus, NH Kernersville, and to begin offering cardiac cath services at the NH Kernersville campus.

On page 314, the 2021 SMFP defines the cardiac catheterization equipment service areas as “...the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.” Figure 5.1 on page 36 shows Forsyth County as a single county Acute Care Bed Service Area. Thus, the service area for this proposal is Forsyth County. Facilities may also serve residents of counties not included in their service area.

According to Chapter 17 of the 2021 SMFP, there are two facilities with cardiac cath equipment located in Forsyth County. Information about each facility is shown in the table below.

Cardiac Cath Equipment – Forsyth County					
Facility	# of Units	# of Diagnostic Procedures	# of Interventional Procedures	2019 Weighted Total Procedures	# of Machines Needed (80% util.)
North Carolina Baptist Hospital	5	2,309	1,396	4,784	3.99
NH Forsyth	8	2,568	1,327	4,890	4.08
Total	13	4,877	2,723	9,674	8.07

Source: 2021 SMFP, Table 17A-1, page 316, and Table 17A-3, page 319

In Section G, page 64, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved cardiac cath services in Forsyth County. The applicant states the relocation and replacement of one unit of cardiac cath equipment is necessary to better meet the needs of the population served by NH Kernersville. The applicant further states the proposal does not increase the number of existing or approved cardiac cath labs in Forsyth County.

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

- The proposal would not result in an increase in units of cardiac cath equipment located in Forsyth County.
- The applicant demonstrates the need the population it proposes to serve has for the proposed project. The discussion regarding analysis of need and projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to replace and relocate an existing unit of cardiac cath equipment from NH Forsyth to its satellite campus, NH Kernersville, and to begin offering cardiac cath services at the NH Kernersville campus.

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

NH Kernersville Cardiac Cath Lab Projected Staffing – FYs 1-3			
Position	FY 1 CY 2025	FY 2 CY 2026	FY 3 CY 2027
Registered Nurses	5.17	5.17	5.17
Certified Nurse Aides/Nursing Assistants	0.86	0.86	0.86
Certified Registered Nurse Anesthetists	1.00	1.00	1.00
Counselors/Certified Counselors	0.09	0.09	0.09
Social Workers	0.34	0.34	0.34
Medical Records	0.19	0.19	0.19
Materials Management	0.33	0.33	0.33
Maintenance/Engineering	0.35	0.35	0.35
Clerical	1.98	1.98	1.98
Cardiovascular Tech	6.00	6.00	6.00
Clinical Lead/Manager	2.00	2.00	2.00
Cardiac Sonographer	1.00	1.00	1.00
Public Safety	0.81	0.81	0.81
Total Staffing	20	20	20

Note: Table may not foot due to rounding.

The assumptions and methodology used to project staffing are provided immediately following Form H in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, which is found in Section Q. In Section H, pages 66-68, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-2.1, H-2.2, H-2.3, H-2.4, and H-2.5.

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

- The applicant adequately demonstrates it has experience in acquiring sufficient personnel to provide services and the ways it has done so in the past that will be used for the proposed project.
- The applicant adequately documents the number of FTEs it projects will be needed to offer the proposed services.
- The applicant accounts for projected salaries and other costs of employment in its projected operating expenses found on Form F.3b in Section Q.
- The applicant provides adequate documentation of its proposed recruitment, training, and continuing education programs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to replace and relocate an existing unit of cardiac cath equipment from NH Forsyth to its satellite campus, NH Kernersville, and to begin offering cardiac cath services at the NH Kernersville campus.

Ancillary and Support Services

In Section I, page 69, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, page 69, the applicant explains how each ancillary and support service 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 based on the following:

- The applicant already provides the necessary ancillary and support services at NH Kernersville.

- In Exhibit I-1, the applicant provides a letter from the Director of Operations at NH Kernersville confirming the necessary ancillary and support services will be made available.
- In Exhibit I-2, the applicant provides a list of facilities with which Novant has transfer agreements with.

Coordination

In Section I, page 70, the applicant describes Novant's existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits C-4.1 and I-2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant is an established facility with existing relationships and coordination with the existing health system in Forsyth County.
- The applicant provides letters of support from local physicians and healthcare providers documenting their support for the proposed project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

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

NA

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

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

C

The applicant proposes to replace and relocate an existing unit of cardiac cath equipment from NH Forsyth to its satellite campus, NH Kernersville, and to begin offering cardiac cath services at the NH Kernersville campus.

In Section K, page 73, the applicant states that the project involves constructing 7,927 square feet of new space. Line drawings are provided in Exhibit K-2.

On page 73, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states Novant design staff are participating in developing the cost, design, and means of construction.
- The applicant states the design architect and Novant team developed a facility layout that maximizes efficiency.

On pages 73-74, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states no major payor bases payment on the costs of a specific hospital.
- The applicant explains how Medicare and commercial payors calculate payments which are not hospital specific.

On page 74, 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 ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, pages 76-77, the applicant provides the historical payor mix during CY 2020 for patients at NH Forsyth and NH Kernersville, as shown in the table below.

Historical Payor Mix – CY 2020		
Payor Category	NH Forsyth	NH Kernersville
Self-Pay	3.4%	4.1%
Charity Care	6.8%	8.0%
Medicare*	41.1%	34.5%
Medicaid*	14.6%	10.4%
Insurance*	30.7%	38.0%
Workers Compensation	0.4%	0.6%
TRICARE	0.6%	1.2%
Other	2.5%	3.4%
Total	100.0%	100.0%

*Including any managed care plans.

Source: Novant internal data

In Section L, pages 77-78, the applicant provides the following comparison.

% of Total Patients Served During CY 2020	NH Forsyth	NH Kernersville	% of the Population of Forsyth County
Female	58%	64%	52.7%
Male	42%	36%	47.3%
Unknown	0%	0%	0.0%
64 and Younger	64%	69%	83.6%
65 and Older	36%	31%	16.4%
American Indian	0%	0%	0.9%
Asian	1%	1%	2.6%
Black or African-American	23%	22%	27.5%
Native Hawaiian or Pacific Islander	0%	0%	0.1%
White or Caucasian	69%	72%	56.3%
Other Race	5%	5%	12.6%
Declined / Unavailable	2%	0%	0.0%

Source: Novant internal data; US Census Bureau

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

and ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 78, the applicant states it has no such obligation.

In Section L, page 78, the applicant states that during the 18 months immediately preceding the application deadline no patient civil rights access complaints have been filed against any Novant hospital or any affiliated hospitals in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 79, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

NH Kernersville Projected Payor Mix – FY 3 (CY 2027)		
Source	Entire Hospital – % Patients	Cardiac Cath Lab - % of Patients
Self-Pay	4.0%	0.6%
Charity Care	8.0%	4.7%
Medicare*	34.6%	55.9%
Medicaid*	10.3%	4.2%
Insurance*	37.9%	32.4%
Worker’s Compensation	0.6%	0.0%
TRICARE	1.2%	0.5%
Other	3.3%	1.6%
Total	100.0%	100.0%

*Including any managed care plans.

Source: Novant internal data

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.6 percent of cardiac cath lab services will be provided to self-pay patients, 4.7 percent to charity care patients, 55.9 percent to Medicare patients, and 4.2 percent to Medicaid patients.

In supplemental information requested by the Agency, 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 for the following reasons:

- The applicant states the projected payor mix for cardiac cath lab patients is based on CY 2019 payors for NH Kernersville-appropriate encounters and were adjusted to account for the delayed start in interventional procedures.
- The applicant states the projected payor mix for all of NH Kernersville is based on the following:
 - The historical payor mix at NH Kernersville;
 - Projected growth of the entire patient population at 5.9 percent, which the applicant states was 75 percent of the historical CY 2016-2019 growth rate; and
 - The addition of cardiac cath lab patients projected to transfer services to NH Kernersville.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 80, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to replace and relocate an existing unit of cardiac cath equipment from NH Forsyth to its satellite campus, NH Kernersville, and to begin offering cardiac cath services at the NH Kernersville campus.

In Section M, page 82, 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. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant provides documentation of existing health professional training programs in the area with which it already has clinical education agreements.
- The applicant describes the steps it takes to manage clinical education training programs and identifies clinical rotations it offers to students at High Point University and Forsyth Tech.

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 replace and relocate an existing unit of cardiac cath equipment from NH Forsyth to its satellite campus, NH Kernersville, and to begin offering cardiac cath services at the NH Kernersville campus.

On page 314, the 2021 SMFP defines the cardiac catheterization equipment service areas as “...the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.” Figure 5.1 on page 36 shows Forsyth County as a single county Acute Care Bed Service Area. Thus, the service area for this proposal is Forsyth County. Facilities may also serve residents of counties not included in their service area.

According to Chapter 17 of the 2021 SMFP, there are two facilities with cardiac cath equipment located in Forsyth County. Information about each facility is shown in the table below.

Cardiac Cath Equipment – Forsyth County					
Facility	# of Units	# of Diagnostic Procedures	# of Interventional Procedures	2019 Weighted Total Procedures	# of Machines Needed (80% util.)
North Carolina Baptist Hospital	5	2,309	1,396	4,784	3.99
NH Forsyth	8	2,568	1,327	4,890	4.08
Total	13	4,877	2,723	9,674	8.07

Source: 2021 SMFP, Table 17A-1, page 316, and Table 17A-3, page 319

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 84, the applicant states:

“To compete with other hospitals for physicians, patients and market share, NH Kernersville must have the comparable services. Cath labs are now an accepted service of community hospitals and not reserved for tertiary hospitals. The relocation of a cardiac catheterization laboratory to NH Kernersville will enable it to better compete with other general acute care hospitals in the Triad.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 84, the applicant states:

“The project also will increase the cost-effectiveness of the cardiac catheterization services NH provides in Forsyth County by reducing travel time and expense for

physicians and patients in eastern Forsyth County and western Guilford County who must now travel to Winston-Salem, High Point, or Greensboro for services.”

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

Regarding the impact of the proposal on quality, in Section N, pages 84-85, the applicant states:

“The project will improve quality of care by using more current hardware and software for cardiac catheterization and angiography procedures. The proposed replacement equipment, the Siemens Artis zee, is a proven and reliable system that delivers optimal image quality at the lowest possible dose, and is equipped with industry-leading imaging technology....

... The relocated cardiac catheterization laboratory will be held to the same quality standards as existing Novant Health cardiology services.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 85, the applicant states:

“The relocated cardiac catheterization laboratory will improve access to non-emergency cardiology services for underserved groups including uninsured patients and patients covered by Medicare and Medicaid. ..., NH Kernersville has a history of providing services to Medicare and Medicaid patients, and will continue to do so if this project is approved.

NH Kernersville and its medical staff operate under NH’s Charity Care and financial assistance policies Having the policies apply to Novant Health cardiologists is essential if patients are to access non-emergency services. The additional location for services and the additional Novant Health cardiologists being recruited...will increase access for all underserved groups, but especially for uninsured and low-income patients.”

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

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

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to replace and relocate an existing unit of cardiac cath equipment from NH Forsyth to its satellite campus, NH Kernersville, and to begin offering cardiac cath services at the NH Kernersville campus.

On Form O in Section Q, the applicant identifies hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity which have cardiac cath equipment. The applicant identified a total of six hospitals in North Carolina with cardiac cath equipment. There are an additional five hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity which do not have cardiac cath equipment.

In Section O, page 91, the applicant states that during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in a finding of immediate jeopardy at any of the 11 hospitals. According to the files in the Acute and Home Care Licensure and Certification Section, DHHS, during the 18 months immediately preceding submission of the application through the date of this decision, there were incidents related to quality of care that occurred in three of the hospitals with cardiac cath equipment. All three hospitals have resolved the issues and are back in compliance. 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 11 hospitals, the applicant provided sufficient

evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The Criteria and Standards for Cardiac Catheterization Equipment and Cardiac Angioplasty Equipment promulgated in 10A NCAC 14C .1600 are not applicable to this review because the applicant is proposing to relocate existing cardiac cath equipment and is not acquiring any additional cardiac cath equipment. There are no other administrative rules which would apply to this proposal.