

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 29, 2016

Findings Date: August 29, 2016

Project Analyst: Jane Rhoe-Jones

Team Leader: Lisa Pittman

Project ID #: F-11183-16

Facility: Novant Health Presbyterian Medical Center

FID #: 943501

County: Mecklenburg

Applicants: Novant Health, Inc.

The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center

Project: Acquire a third cardiac electrophysiology laboratory

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Novant Health, Inc. and The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center (“the applicants”) propose to acquire equipment for a third cardiac electrophysiology (EP) laboratory at Novant Health Presbyterian Medical Center (“NHPMC”) located at 200 Hawthorne Lane in Charlotte, Mecklenburg County.

#### **Need Determination**

The applicants are not proposing to develop or offer a new institutional health service for which there is a need determination in the 2016 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2016 SMFP applicable to this review.

## **Policies**

There is one policy in the 2016 SMFP applicable to the review of the application - Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES, which 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 are required to submit a plan of 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 project is greater than \$2 million but less than \$5 million. In Section III, pages 47-48, the applicants provide a written statement describing NHPMC’s energy efficiency, water conservation and sustainability plan; and provide a copy of the plan in Exhibit 15. Also, in Section XI.7, page 106, the applicants describe the energy savings features to be incorporated into the renovation plans. The applicants also state that plans include compliance with applicable local, state, and federal requirements for energy efficiency and consumption. The application is consistent with Policy GEN-4.

## **Conclusion**

In summary, the application is consistent with Policy GEN-4. Therefore, the application is conforming to this criterion.

- (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 applicants, Novant Health, Inc. and The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center propose to acquire equipment for a third EP laboratory to be located on the fifth floor of the main hospital and adjacent to the two existing EP laboratories, the NHPMC cardiac catheterization laboratories and other cardiac testing services, and are shown in line drawings in Exhibit 4. The new EP laboratory will be located in space formerly occupied by a cardiac catheterization laboratory that in 2015 was relocated to Novant Health Matthews Medical Center (NHMMC) in Charlotte. In Section II.1, page 11, the applicants state:

*“The proximity of the EP lab and the cardiac catheterization lab will assure continuity of care and efficient operation for EP patients, cardiologists and staff.*

*Electrophysiology (EP) studies help identify the cause of an irregular heartbeat. ...*

*NHPMC currently operates two EP laboratories in addition to its cardiac catheterization laboratories. All of the following procedures currently are provided in the NHPMC EP laboratory.”*

- Arrhythmia Management and Treatment
- Atrial Fibrillation (Afib)
- Cardioverter Defibrillator Implantation (ICD)

### **Population to be Served**

The 2016 SMFP does not define the service area for electrophysiology equipment. The Criteria and Standards for Major Medical Equipment (10A NCAC 14C .3100) do not define a service area.

In Sections III.4 and III.5, pages 50-51, the applicants provide the current (Calendar Year 2015) and projected patient origin for EP laboratory services at the hospital, as summarized below in the table.

<b>NHPMC EP PATIENT ORIGIN</b>			
<b>County</b>	<b>Current &amp; Projected % of Total</b>	<b>PY1 7/1/2017- 6/30/2018</b>	<b>PY2 7/1/2018- 6/30/2019</b>
Mecklenburg	52.2%	607	639
Union	13.5%	157	165
Rowan	9.9%	115	121
Gaston	4.2%	49	51
York, SC	3.4%	39	42
Lincoln	2.7%	32	33
Iredell	2.6%	30	32
Cabarrus	2.0%	24	25
All Other	9.5%	111	116
<b>Total</b>	<b>100.0%</b>	<b>1,163</b>	<b>1,225</b>

The applicants state on page 52 that the distribution of patients by county of origin is based on 2015 data and they do not anticipate changes in patient origin as a result of the proposed project. The applicants adequately identify the population to be served.

**Analysis of Need**

In Section III.1(a-b), pages 29-45, the applicants describe the factors which they state support the need for the proposed project, including:

- Historical growth of EP procedures completed at NHPMC entails flat volumes from 2006 to 2012, followed by significant increased demand during 2013-2015 as a result of new and innovative treatments for cardiac arrhythmias. The number of procedures increased from 1,919 procedures in the 12 months ending in March 2014 to 2,615 procedures in the 12 months ending in December 2016, a growth rate of 18.1% per year. Utilization of the EP laboratories grew from 89% to 114% in the number of patients during the same time period (pages 29-33 and Exhibit 14, Table 7).
- Changes in physician resources and EP expertise at NHPMC such as cardiac ablation and the resultant increase in the number of EP procedures per patient, which ranges from 2.1 procedures per patient in 2013 to 2.6 procedures per patient in 2016 (pages 33-37).
- Increasing utilization of EP procedures to treat cardiac arrhythmias is rising as the incidence and prevalence of cardiac arrhythmias such as atrial fibrillation (AF) increases. The prediction model used by Colilla and associates projects the incidence of AF to double from 1.2 million patients in 2010 to more than double or 2.6 million in 2030; while the prevalence of AF is predicted to increase from 5.2 million patients to 12.1 million cases during the same time period (pages 32-33). [*Atrial Fibrillation: Addressing Rising Cost with Tools that Work, The Society of Cardiovascular Patient Care White Paper*]
- Population growth in Mecklenburg and surrounding counties with 75% of NHPMC EP patients originating from Mecklenburg, Union and Rowan counties. While NHPMC market share has remained consistent from 2013-2015, there is a shift in patient origin as a larger percentage of patients are originating outside of Mecklenburg County. Mecklenburg County experienced a five year compound annual growth rate (CAGR) for 2011-2016 of 2.32%; while other counties in its market area experienced

growth rates from .07% to 2.10%. During the next five year period 2016-2021, the NC Office of State Budget and Management (NCOSBM) projects that Mecklenburg County will experience a slightly lower CAGR, 2.00% (pages 37-39).

- New EP markets beyond Mecklenburg County are evidenced by the 6.0% decrease in patient origin from Mecklenburg County and increases in patient origin from Union, Rowan and Iredell counties of 3.0%, 2.7% and 0.8%, respectively from 2013-2015 (pages 39-40). The applicants state that these increases are attributable to NHPMC EP consultation offices that have been established in recent years in its market area.

In Section III, page 40, the applicants state,

*“Utilization of the two existing EP laboratories at NHPMC currently exceeds 90% of capacity. As a result, additional operational hours have been added, increasing the time some patients, who must not eat or drink prior to the procedure, must wait to receive treatment. The proposed acquisition of a new Siemens Artis Zee Angiography System for the NHPMC EP Program will result [sic] increased capacity to meet the expanding demand for EP services in Mecklenburg County and surrounding counties.”*

The applicant’s representations regarding the need for a third EP laboratory to serve existing and projected patients are reasonable and adequately supported.

### Projected Utilization

In Section III, pages 40-45, the applicants state their five-step methodology, summarized below, to project utilization of the third EP laboratory at NHPMC. The applicants state,

*“NHPMC projected total future utilization of the proposed third EP laboratory based upon historic EP case volume at NHPMC using a reasonable growth rate.*

...

*The methodology to project the need for a third EP lab at NHPMC is described in detail below, but follows the following basic methodology.*

$$\text{Projected EP Procedures} = \text{Base Year EP Patients} \times \text{Growth Rate} \times \text{EP Procedures per Patient}''$$

### Step 1

Determine Base Year Data for NHPMC EP Patients - The applicants assume the proposed EP laboratory will become operational by July 2017. They annualize volume from June 2015 to March 2016 to estimate base year volume, as shown in the following table that the applicants provided in clarifying information on July 14.

<b>NHPMC EP PATIENT VOLUME</b>		
	<b>July 2015-March 2016</b>	<b>July 2015-June 2016</b>
Actual # Patients	786	
Annualized # Patients		1,048

Source: Exhibit 14, Tables 6-7

Step 2

Determine EP Patient Growth Rate – the applicants use historical growth of EP patients at NHPMC (March 2013-June 2016) and a weighted population growth rate in the NHPMC EP market share area.

<b>NHPMC HISTORICAL GROWTH RATE</b>		
<b>Year/Quarter</b>	<b>Patients</b>	<b>Average Annual Growth</b>
Total Q2 2013-Q1 2014	874	
Total Q2 2014-Q1 2015	1,036	
Total Q2 2015-Q1 2016	1,033	
<b>Average Annual Growth Rate April-March</b>		<b>9.10%</b>

Source: Exhibit 14, Table 2

To determine a weighted population growth rate, each county’s population growth rate is multiplied by its patient origin percent. The results are summed and reflect a weighted population growth rate.

The applicants state that although EP patient growth was 9.10% for the April 2013-March 2016 timeframe, they realize that new regional EP cardiology consultations will slow, so they have calculated a weighted EP market area population growth rate.

For each county in the service area, the applicants multiply the projected population growth rate by patient origin percent. The weighted EP market area growth rate is 1.58% for the proposed service area, as shown below. See Section III, page 42.

<b>PROJECTED NHPMC EP COUNTY WEIGHTED POPULATION GROWTH RATES</b>			
<b>Patient Origin</b>	<b>CAGR Population Growth Rate 2016-2020*</b>	<b>Patient Origin %</b>	<b>Weighted EP Population Growth Rate</b>
	A	B	A x B
Mecklenburg	2.00%	52.2%	1.04%
Union	1.97%	13.5%	0.27%
Rowan	0.00%	9.9%	0.00%
Gaston	0.68%	4.2%	0.03%
York, SC	1.76%	3.4%	0.06%
Lincoln	0.74%	2.7%	0.02%
Iredell	1.21%	2.6%	0.03%
Cabarrus	1.94%	2.0%	0.04%
North Carolina	1.01%	9.5%	0.10%
<b>Total</b>			<b>1.58%</b>

\*NCOSBM

The applicants state that they do not believe that the weighted population growth rate of 1.58% is reasonable given the increases in the number of EP patients, the increases in the patients treated with atrial fibrillation, as well as the impact of the growth in the total number of EP procedures. Therefore, the applicants averaged the historical growth rate of 9.10% and the weighted population growth rate of 1.58% to arrive at a growth rate of 5.34% for EP patient volume.

**Step 3**

Calculate Projected NHPMC EP Patients – the applicants project EP patients using the base year patient volume from Step 1 (July 2015-June 2016 = 1,048 patients) and the average growth rate calculated in Step 2, (5.34%) as depicted in the following table.

<b>NHPMC PROJECTED EP PATIENTS</b>						
	<b>Historical Base Year July 2015- June 2016</b>	<b>Growth Rate</b>	<b>Interim Year July 2016- June 2017</b>	<b>PY 1 July 2017- June 2018</b>	<b>PY 2 July 2018- June 2019</b>	<b>PY 2 July 2019- June 2020</b>
EP Patients	1,048	5.34%	1,104	1,163	1,225	1,290

Source: Exhibit 14, Table 1

**Step 4**

Calculate the Number of Projected EP Procedures at NHPMC – the applicants multiply projected patients by procedures per patient to derive their projected EP procedures. The applicants state on page 36 that EP procedures increased from 2.1 procedures per patient in the first quarter of 2013 to 2.6 procedures per patient in the first quarter of 2016. The projected EP procedures are shown in the following table.

<b>NHPMC PROJECTED EP PROCEDURES</b>				
	<b>Interim Year Jul 2016-Jun 2017</b>	<b>PY1 Jul 2017-Jun 2018</b>	<b>PY2 Jul 2018-Jun 2019</b>	<b>PY3 Jul 2019-Jun 2020</b>
Patients	1,104	1,163	1,225	1,290
Procedures per Patient	2.6	2.6	2.6	2.6
Procedures	2,870	3,024	3,185	3,355

Source: Exhibit 14, Table 2, and application, page 44

Utilizing a 5.34% increase in patients per year, and 2.6 procedures per person results in a 5.63% growth rate in EP per year from FY17-FY20. This is less than the 18.1% average annual growth rate experienced at NHPMC during the last three years (Exhibit 14, Table 2).

**Step 5**

Calculate NHPMC EP Laboratory Need – the applicants utilize EP procedures projected in Step 4 and their defined capacity for one EP laboratory at NHPMC, (1,170 EP procedures) to calculate the number of EP laboratories needed to meet projected demand [4.5 EP procedures per day x 260 days per year = 1,170 EP procedures per year]. The applicants state that capacity was determined by a review of historical EP cases over a period of three years (Exhibit 14,

Table 5). NHPMC leadership determined that capacity of the current two EP laboratories, without extended hours was reached in 2014. The applicants state that the following table is based upon projections in Steps 1 through 4 and the capacity for EP laboratories as determined for NHPMC.

<b>NHPMC PROJECTED EP LABORATORIES NEEDED</b>						
	<b>Historical Base Year Jul2015- Jun2016</b>	<b>Projected Growth Rate</b>	<b>Interim Year Jul2016- Jun2017</b>	<b>PY1 Jul2017- Jun2018</b>	<b>PY1 Jul2018- Jun2019</b>	<b>PY1 Jul2019- Jun2020</b>
Patients	1,048	5.34%	1,104	1,163	1,225	1,290
Procedures per patient	2.53		2.6	2.6	2.6	2.6
Procedures	2,615		2,870	3,024	3,185	3,355
Maximum Procedures per Room per Day	4.5		4.5	4.5	4.5	4.5
Capacity per EP Laboratory (procedures per day x 260 days)	1,170	1,170	1,170	1,170	1,170	1,170
EP Laboratories Needed	2.2		2.5	2.6	2.7	2.9

Source: Exhibit 14, Table 1, and application, page 45

The table above illustrates the applicants’ projected need for three EP laboratories at NHPMC. During FY16, the applicants’ EP laboratories were already operating above capacity.

The applicants’ projections are based on historical utilization and are supported by population growth projections in the service area. Exhibit 17 contains letters from physicians and staff expressing support for the project; while Exhibit 26 contains a community support letter. Projected utilization is based on reasonable and adequately supported assumptions. Therefore, the applicants adequately demonstrate the need to acquire one cardiac EP laboratory.

**Access**

In Section VI.2, pages 68-70, the applicants state that NHPMC provides EP services to all patients who need the services regardless of their race, sex, age, religion, creed, disability, national origin or ability to pay. The applicants further state that they do not discriminate against the aforementioned groups or other medically underserved persons, regardless of their ability to pay. In Section VI.15, page 79, the applicants project that 60.91% of patients to be served will be Medicare beneficiaries and 3.30% will be Medicaid recipients. The applicants adequately demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services.



## **Conclusion**

In summary, the applicants adequately identify the population to be served, demonstrate the need the population has for the project and adequately demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

- (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

- (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

In Section III.3, pages 48-49, the applicants discuss the alternatives considered prior to submitting the application, which include:

- Maintain the Status Quo - the applicants state that this is not a viable option because capacity has been exceeded with the existing two EP laboratories.
- Expand Clinical Hours in Two Existing EP Laboratories – the applicants state that this alternative would not be optimal for patient care because as they have stated in Section III of the application, the average number of EP procedures per patient has increased and the time per procedure has also increased, which can cause scheduling difficulties and delays for patients.
- Utilize Existing Cardiac Catheterization Equipment at NHPMC – the applicants state that this is not an optimal alternative because the utilization in the three cardiac catheterization laboratories was greater than 65% in 2015. Furthermore, the cardiac catheterization rooms do not include all the necessary equipment to perform all routine and specialized EP procedures; even though equipment is similar, the requirements for the two types of procedures are not identical.
- Develop Dedicated EP Services at a Different Novant Health Facility in Charlotte – the applicants state that this alternative is not viable because the majority of diagnostic and treatment procedures for arrhythmias are not appropriate for community hospitals due to the risks. Therefore, because NHPMC is a tertiary hospital with an experienced EP team, it is best suited for EP procedures.

- Add a Third EP Laboratory at NHPMC – the applicants state that this is the only viable alternative to meet the increased EP volume, the resulting need and to optimize existing efficiencies.

Furthermore, the application is conforming to all other statutory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicants adequately demonstrate that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Novant Health, Inc. and The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center shall materially comply with all representations made in the certificate of need application and clarifying information. In those instances where representations conflict, Novant Health, Inc. and The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center shall comply with the last made representation.**
  - 2. Novant Health, Inc. and The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center shall acquire equipment for no more than one cardiac electrophysiology laboratory as part of this project for a total of three cardiac electrophysiology laboratories following completion of the project.**
  - 3. Novant Health, Inc. and The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VIII of the application or that would otherwise require a certificate of need.**
  - 4. Novant Health, Inc. and The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section 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

In Section VIII.2, pages 92-93, the applicants state the total capital cost is projected to be as follows:

<b>NHPMC EP LABORATORY PROJECTED CAPITAL COST</b>	
<b>ITEM</b>	<b>COST</b>
EP Equipment	\$1,621,048
Construction	\$ 628,692
Miscellaneous (IT, furniture, consultant & regulatory fees, A&E fees, nurse call system, etc.)	\$ 155,760
<b>Total Capital Cost</b>	<b>\$2,405,500</b>

In Section IX.1, page 99, the applicants state there will be no start-up expenses and no initial operating expenses associated with the project.

**Availability of Funds**

In Section VIII.6, page 93, the applicants state that the entire capital cost of the project will be funded with accumulated reserves. In Exhibit 29, the applicants provide a May 9, 2016 letter from the Senior Vice President of Finance of Novant Health (the parent company of NHPMC), documenting the availability of sufficient funds for the capital costs of the proposed project. Exhibit 25 contains the Novant Health consolidated balance sheets which indicate that as of December 31, 2015, Novant Health had \$354,403,000 in cash and cash equivalents and total net assets of \$2,888,769,000. The applicants adequately demonstrate that sufficient funds will be available for the capital and working capital needs of the project.

**Financial Feasibility**

In the pro forma financial statements for NHPMC’s EP laboratory services (Form C), the applicants project that revenues will exceed operating expenses in each of the first three operating years of the project, as shown below in the table.

<b>NHPMC EP Laboratory Services</b>			
	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>
Total Net Revenues	\$21,989,312	\$24,088,034	\$26,380,821
Total Expenses	\$13,498,801	\$15,061,707	\$16,816,674
<b>Net Income (Loss)</b>	<b>\$8,490,510</b>	<b>\$9,026,327</b>	<b>\$9,564,147</b>

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) are incorporated herein by reference. The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**Conclusion**

In summary, the applicants adequately demonstrate that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicants adequately

demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (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 applicants propose to acquire equipment for a third cardiac electrophysiology (EP) laboratory to be located at NHPMC.

The 2016 SMFP does not define the service area for EP laboratories. The Criteria and Standards for Major Medical Equipment do not define the service area. Providers may serve residents of counties not included in their service area.

In Section III.5 page 50, the applicants define their primary market area as Mecklenburg, Union, Rowan, Gaston, Lincoln, Iredell and Cabarrus counties and York SC. There are three other existing providers of EP laboratory services in Mecklenburg County, and a total of 10 existing providers in the nine counties in NHPMC's market area.

The following table identifies the providers by county, number of EP units and the number of EP procedures during FY 2015, summarized from the 2016 LRA Registration and Inventory of Medical Equipment.

<b>NHPMC MARKET AREA                  EP LABORATORIES AND NUMBER OF PROCEDURES                  BY FACILITY &amp; COUNTY                  FY 2015</b>		
	<b>EP LABS</b>	<b>TOTAL EP PROCEDURES</b>
<b>Mecklenburg County</b>		
Novant Health Presbyterian Medical Center	2	1017
Carolinas Medical Center	2	1832
Carolinas Healthcare System - Pineville	1	591
Novant Health Matthews Medical Center	0	90
<b>Cabarrus County</b>		
Carolinas Healthcare System - NorthEast	1	494
<b>Catawba County</b>		
Frye Regional Medical Center	1	854
Catawba Valley Medical Center	1	236
<b>Cleveland County</b>		
Carolinas Healthcare System - Cleveland	0	65
<b>Gaston County</b>		
CaroMont Regional Medical Center	1	789
<b>Iredell County</b>		
Davis Regional Medical Center	1	0
<b>Rowan County</b>		
Novant Health Rowan Medical Center	1	61
<b>Stanley County</b>		
Carolinas Healthcare System - Stanley	1	0
<b>Union County</b>		
Carolinas Healthcare System - Union	0	27
<b>Total</b>	<b>12</b>	<b>6,056</b>

Source: 2016 LRA Registration and Inventory of Medical Equipment

As shown in the above table, in NHPMC’s market area, there are 12 EP laboratories, with the number of procedures ranging from 1,832 to 0. Two facilities, including NHPMC have two EP laboratories. NHPMC has the second highest number of EP procedures with 1,017; while two facilities reported performing no procedures.

In Section II, page 17, the applicants state that the EP laboratories operate from Monday-Friday, 7:00 a.m. to 3:30 p.m., and that the schedule will not change with the addition of the third laboratory. In Section II, page 32 and Exhibit 14, Table 1, the applicants state that current utilization is 110% and due to this utilization rate, for two years NHPMC has had to expand hours a couple of days each week. In Exhibit 14, Table 5, the applicants provide a table which shows historical growth of its EP services. The table shows that from January 2013 to March 2016, average procedures per day per EP laboratory increased from 3.7 per day to 5.2 per day in the first quarter of 2016. In Section III, page 44, the applicants state that staff began working extended hours several days per week in 2015; indicating that capacity of the existing equipment was met in 2014.

The applicants propose to acquire equipment for a third EP laboratory for a total of three EP laboratories at NHPMC upon project completion. The applicants adequately demonstrate in the application that the third EP laboratory is needed at NHPMC. The applicants adequately

demonstrate that their projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In Section III, pages 43-45, the applicants project the growth in EP patients and EP procedures resulting in the need for a third EP laboratory as shown below in the table.

<b>NHPMC PROJECTED EP LABORATORIES NEEDED</b>						
	<b>Historical Base Year Jul2015- Jun2016</b>	<b>Projected Growth Rate</b>	<b>Interim Year Jul2016- Jun2017</b>	<b>PY1 Jul2017- Jun2018</b>	<b>PY2 Jul2018- Jun2019</b>	<b>PY3 Jul2019- Jun2020</b>
Patients	1,048	5.34%	1,104	1,163	1,225	1,290
Procedures per patient	2.53		2.6	2.6	2.6	2.6
Procedures	2,615		2,870	3,024	3,185	3,355
Maximum Procedures per Room per Day	4.5		4.5	4.5	4.5	4.5
Capacity per EP Laboratory (procedures per day x 260 days)	1,170	1,170	1,170	1,170	1,170	1,170
EP Laboratories Needed	2.2		2.5	2.6	2.7	2.9

Source: Exhibit 14, Table 1

NHPMC is projected to reach capacity for a third EP laboratory during the third year of operation (FY2020). The applicants adequately demonstrate the need to acquire the proposed EP equipment for greater efficiency and improved patient access to the proposed services. Consequently, the applicants adequately demonstrate the proposed project would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the applicant's service area. Therefore, the application is conforming to this criterion.

- (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 VII.1(a-b), pages 80-81, the applicants provide current and projected staff for the EP laboratories as shown in the following table.

<b>CURRENT &amp; PROPOSED STAFFING NHPMC EP LABORATORIES</b>		
<b>Position</b>	<b>FY 2016 FTEs</b>	<b>PY2 FTEs 2018-2019</b>
Nurse Manager	.25	.25
Cardiovascular Invasive Specialist	5.00	8.00
Registered Nurse	1.00	1.00
<b>Total</b>	<b>6.25</b>	<b>9.25</b>

In Section VII.1(a-b), pages 80-81, the applicants state that projected staffing is based on current staffing. Three additional cardiovascular invasive specialists will be hired with the addition of the proposed EP laboratory. In Section VII.3, page 83, the applicants describe NHPMC’s experience with and process for recruiting and retaining staff. In Section VII.8, page 87, the applicants identify Ricky Thompson, MD as Medical Director for the hospital. Exhibit 18 contains a support letter from Kevin Hsu, MD, the Medical Director of the EP Program. Exhibit 17 contains copies of letters from physicians and staff expressing support for the proposed project. Exhibit 19 contains copies of letters of support from Novant Health Board of Directors and leadership. The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (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

NHPMC is an existing tertiary acute care hospital and provides all necessary ancillary and support services for its patients. In Section II.2(a-c) pages 14-15, the applicants state that existing ancillary and support services will continue to be provided. Exhibits 5 and 6 contain additional documentation regarding NHPMC’s ancillary and support services. In Section V, pages 56-61, and Exhibits 5, 7, 16, 17 and 18, the applicants adequately document that EP services are coordinated with the existing health care system.

The applicants adequately demonstrate the availability of the necessary ancillary and support services and that the proposed services would continue to be coordinated with the existing health care system. Therefore, 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

- (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

- (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 applicants propose to renovate 863 square feet of space to develop the proposed third EP laboratory adjacent to the current EP laboratories. Exhibit 4 contains a letter from an architect that estimates construction costs that are consistent with the project capital cost projections provided by the applicant in Section VIII.2, pages 92-93 of the application. Exhibit 4 also contains the line drawings. In Section XI.7, page 106 and Exhibit 15, the applicants describe the methods currently used by the facility and that will be used to maintain efficient energy and water conservation. The applicants adequately demonstrate that the cost, design and means of renovation construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, 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 VI.13, page 78, the applicants provide the payor mix for NHPMC's EP program FY2015, as illustrated in the following table:

<b>NHPMC EP PROGRAM PAYOR MIX FY 2015</b>	
<b>Payor Category</b>	<b>% of Patient Days</b>
Self-Pay/ Indigent/ Charity	1.75%
Medicare/ Medicare Managed Care	60.91%
Medicaid	3.30%
Commercial	.48%
Managed Care & HMO/PPO	32.88%
Other	.68%
<b>Total</b>	<b>100.00%</b>

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for NHPMC's market area.

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial &amp; Ethnic Minority*</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
Mecklenburg	10%	52%	52%	15%	6%	19%
Union	11%	51%	27%	11%	6%	16%
Rowan	16%	51%	27%	18%	12%	19%
Gaston	15%	52%	25%	17%	13%	18%
Lincoln	16%	50%	15%	16%	11%	19%
Iredell	15%	51%	23%	13%	9%	18%
Cabarrus	13%	51%	31%	12%	7%	16%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

\*Excludes "White alone" who are "not Hispanic or Latino"

\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the NHPMC's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicants demonstrate NHPMC currently provides adequate access to medically underserved populations. 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

In Section VI, page 76, the applicants state that they fulfilled their Hill-Burton obligations long ago and that Novant Health's acute care hospitals have continued their commitment to provide care to all persons, regardless of their ability to pay.

In Section VI.10, page 76, the applicants state that no civil rights access complaints have been filed against the parent company, Novant Health any of its affiliated hospitals and surgery centers in the past five years.

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 VI.2, page 68, the applicants state,

*“Novant Health facilities and programs do not discriminate against the above-listed persons, or other medically underserved persons, regardless of their ability to pay.”*

The applicants provide Novant Health's charity and related policies in Exhibits 20-22.

In Section VI.15, page 79, the applicants provide the projected payor mix for NHPMC's EP program during FY2019, the second full fiscal year of operation following completion of the proposed project, as illustrated below in the table.

<b>NHPMC EP PROGRAM PROJECTED PAYOR MIX PATIENT DAYS AS PERCENT OF TOTAL PATIENT DAYS FY 2019</b>	
<b>Payor Category</b>	<b>% of Patient Days</b>
Self-Pay/ Indigent/ Charity	1.75%
Medicare/ Medicare Managed Care	60.91%
Medicaid	3.30%
Commercial	.48%
Managed Care & HMO/PPO	32.88%
Other	.68%
<b>Total</b>	<b>100.00%</b>

The projected payor mix for EP laboratory services is projected to be the same as the current payor mix. The applicants demonstrate that medically underserved populations would have adequate access to the proposed EP laboratory services.

- (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 VI.9, page 75, the applicants state,

*“Typically, patients will have access to the services at Novant Health Presbyterian Medical Center’s Cardiac EP Program by physician referral to an EP Cardiologist with medical staff privileges at NHPMC. NHPMC Outpatient Cardiac EP services will be available to any person upon referral and a written order from a licensed physician.”*

The applicants adequately demonstrate that NHPMC will offer a range of means by which patients will have access to the facility’s EP services. Therefore, 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 V.1(a), page 56, the applicants state:

*“NHPMC has many established clinical education agreements with area health education programs in the service area and these agreements will encompass the new*

*EP Laboratory once it is operational. Included in Exhibit 16 is a list of Novant Health's clinical education agreements and a sample clinical education agreement."*

In Section V.1(b), page 56, the applicants state:

*"... All educational programs currently rotating through NHPMC will be accorded the opportunity to expand their programs to include the new EP Laboratory once the program is complete. Novant Health and NHPMC are continually open to evaluating new clinical education training programs and institutions as clinically appropriate."*

The information provided is reasonable and credible. 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 applicants propose to acquire equipment for a third cardiac electrophysiology laboratory at NHPMC. The 2016 SMFP does not define a service area for EP equipment. The Criteria and Standards for Major Medical Equipment (10A NCAC 14C .3100) do not define a service area.

There are three other existing providers of EP laboratory services in Mecklenburg County, and a total of 10 existing providers in NHPMC's market area. The following table identifies the providers by county, number of EP units and the number of EP procedures during FY 2015, summarized from the 2016 LRA Registration and Inventory of Medical Equipment.

<b>NHPMC MARKET AREA            EP LABORATORIES AND NUMBER OF PROCEDURES            BY FACILITY &amp; COUNTY            FY 2015</b>		
	<b>EP LABS</b>	<b>TOTAL EP PROCEDURES</b>
<b>Mecklenburg County</b>		
Novant Health Presbyterian Medical Center	2	1017
Carolinas Medical Center	2	1832
Carolinas Healthcare System - Pineville	1	591
Novant Health Matthews Medical Center	0	90
<b>Cabarrus County</b>		
Carolinas Healthcare System - NorthEast	1	494
<b>Catawba County</b>		
Frye Regional Medical Center	1	854
Catawba Valley Medical Center	1	236
<b>Cleveland County</b>		
Carolinas Healthcare System - Cleveland	0	65
<b>Gaston County</b>		
CaroMont Regional Medical Center	1	789
<b>Iredell County</b>		
Davis Regional Medical Center	1	0
<b>Rowan County</b>		
Novant Health Rowan Medical Center	1	61
<b>Stanley County</b>		
Carolinas Healthcare System - Stanley	1	0
<b>Union County</b>		
Carolinas Healthcare System - Union	0	27
<b>Total</b>	<b>12</b>	<b>6,056</b>

Source: 2016 LRA Registration and Inventory of Medical Equipment

As shown in the above table, in NHPMC’s market area, there are 12 EP laboratories, with the number of procedures ranging from 1,832 to 0. Two facilities, including NHPMC have two EP laboratories. NHPMC has the second highest number of EP procedures with 1,017; while two facilities reported performing no procedures.

The applicants propose to acquire equipment for a third EP laboratory at NHPMC. In Section V.7, pages 61-67, the applicants discuss how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicants discuss the following:

- Encouraging Cost Effectiveness
- Promoting Quality and Safety
- Providing Access to Services for Patients with Limited Financial Resources
- Making Services Accessible including Proactive Preventative Care and Financial Accessibility to Care, Novant Health Presbyterian Medical Center Honored as ‘Leader in LBG T Equality’ and Creating a New Type of Access: The Electronic Health Record in Novant Health’s Physician Offices, Ambulatory Settings & Acute Care Hospitals

See also Sections II, III, V, VI and VII where the applicants discuss the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicants adequately demonstrate the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicants adequately demonstrate they will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicants demonstrate that they will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (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 I, pages 4-7, the applicants state that their parent company Novant Health, Inc. currently owns, leases, or manages 11 hospitals and eight other types of healthcare facilities in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of the application through the date of the decision Novant Health was not found to be out of compliance with one or more Medicare conditions of participation. At this time, Novant Health, Inc. is 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 Novant Health, the applicants provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

NHPMC is conforming to all applicable Criteria and Standards for Major Medical Equipment as required by 10A NCAC 14C .3100. See discussion below.

**SECTION .3100 - CRITERIA AND STANDARDS FOR MAJOR MEDICAL EQUIPMENT**

**10A NCAC 14C .3104 NEED FOR SERVICES**

(a) *An applicant proposing to acquire major medical equipment shall provide the following information:*

(1) *the number of patients who will use the service, classified by diagnosis;*

-C- In Section II.8, page 25, the applicants provide the projected number of patients that will use the cardiac electrophysiology equipment for the first three years following completion of the proposed project, classified by diagnosis.

(2) *the number of patients who will use the service, classified by county of residence;*

-C- In Section II.8, page 26, the applicants provide the following table showing the number of patients who will use the service by county of residence:

<b>NHPMC PROJECTED EP PATIENTS by COUNTY of RESIDENCE</b>				
<b>County</b>	<b>% of 2015</b>	<b>Projected Patients</b>		
		<b>PY 1</b>	<b>PY 2</b>	<b>PY 3</b>
Mecklenburg	52.2%	607	639	673
Union	13.5%	157	165	174
Rowan	9.9%	115	121	128
Gaston	4.2%	49	51	54
York (SC)	3.4%	39	42	44
Lincoln	2.7%	32	33	35
Iredell	2.6%	30	32	34
Cabarrus	2.0%	24	25	26
Other	9.5%	111	116	123
<b>TOTAL</b>	<b>100.0%</b>	<b>1,163</b>	<b>1,225</b>	<b>1,290</b>

(3) *documentation of the maximum number of procedures that existing equipment that is used for similar procedures in the facility is capable of performing;*

-C- In Section II.8, page 26, the applicants state,

*“Capacity for EP equipment at NHPMC is considered to be 4.5 EP procedures per day 260 days per year or 1,170 EP procedures per year. Capacity was determined by reviewing historical cases per day for three years as reflected in Exhibit 14, Table 5 and discussion with EP leadership at NHPMC. As reflected in Exhibit 14, Table 5, procedures per day averaged 4.5 procedures in 2014. Staff began working extended hours, several days per week in 2015 to meet demand and is working even longer hours to date in 2016, indicating that capacity of the existing equipment, without extended hours was reached in 2014.”*

(4) *quarterly projected utilization of the applicant's existing and proposed equipment three years after the completion of the project; and*

-C- In Section II.8, page 27, the applicants provide a table showing the quarterly projected utilization of NHPMC’s EP laboratories for the first three years following completion of the project to add a third laboratory.

(5) *all the assumptions and data supporting the methodology used for the projections in this Rule.*

-C- The applicants provide the assumptions and data supporting the methodology used for the projections in Section III.1(b), pages 40-45, and in Exhibit 14, Tables 1-6.

(b) *An applicant proposing to acquire new major medical technology shall provide the following information:*

(1) *the number of patients who will use the service, classified by diagnosis;*

(2) *the number of patients who will use the service, classified by county of residence;*

(3) *quarterly projected utilization of the applicant's proposed new major medical technology three years after the completion of the project;*

(4) *documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies;*

(5) *documentation of the effect the new major medical technology may have on existing major medical technology and procedures offered at its facility and other facilities in the proposed service area; and*

(6) *all the assumptions and data supporting the methodology used for the projections in this Rule.*

-NA- The applicants are not proposing to acquire new major medical technology.