

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2016

Findings Date: September 27, 2016

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: O-11191-16

Facility: New Hanover Regional Medical Center

FID #: 943372

County: New Hanover

Applicant: New Hanover Regional Medical Center

Project: Acquire a third dedicated cardiac electrophysiology lab

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

New Hanover Regional Medical Center (NHRMC) proposes to acquire equipment for a third dedicated electrophysiology lab located at 2131 S. 17<sup>th</sup> Street in Wilmington, New Hanover County.

#### **Need Determination**

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2016 State Medical Facilities Plan (2016 SMFP). Therefore, there are no need determinations in the 2016 SMFP that are applicable to this review.

## **Policies**

There is one policy applicable to this review. 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, the Certificate of Need Section 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 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 capital expenditure for this proposed project is greater than \$2.0 million but less than \$5.0 million. In Section III, page 59 and Section XI.7, page 121, the applicant provides a written statement describing the proposed project’s plan to assure improved energy efficiency and water conservation. The application is consistent with Policy GEN-4.

## **Conclusion**

In summary, the applicant adequately demonstrates that its proposal 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

NHRMC proposes to acquire equipment for a third dedicated electrophysiology lab at its main campus. The proposed EP lab will occupy 1,125 square feet on the first floor of the hospital across the hall from the existing dedicated EP labs. The new EP lab and EP control room will move into hospital space currently utilized as offices, conference room and stereotactic radiology.

**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 Section III.5, page 63, the applicant identifies the primary service area as New Hanover, Brunswick, Columbus, Onslow and Pender counties with additional in-migration from other counties in both North Carolina and South Carolina.

On page 63, the applicant provides, by percentage, the current patient origin for EP services, based on annualized data for FFY2016, as shown in the table below.

**NHRMC  
Current EP Patient Origin by County of Residence**

<b>County</b>	<b>Percentage</b>
New Hanover	40.6%
Brunswick	24.8%
Pender	10.2%
Columbus	8.5%
Onslow	7.5%
Bladen	2.4%
Duplin	2.2%
Sampson	1.4%
In-Migration	2.4%
<b>TOTAL</b>	<b>100.0%</b>

In Section III.5, page 65, the applicant provides the projected patient origin for EP services during the first two operating years following completion of the project, as shown in the table below.

**NHRMC  
 Projected EP Patient Origin by County of Residence**

County	Percentage	Projected Patients	
		FY 1	FY 2
<b>Primary Service Area</b>			
New Hanover	40.6%	711	747
Brunswick	24.8%	434	456
Pender	10.2%	179	188
Columbus	8.5%	149	156
Onslow	7.5%	131	138
<b>Secondary Service Area</b>			
Bladen	2.4%	42	44
Duplin	2.2%	25	26
Sampson	1.4%	42	44
In-Migration	2.4%	42	44
<b>TOTAL</b>	<b>100.0%</b>	<b>1,752</b>	<b>1,839</b>

The applicant provide the assumptions and methodology used to project patient origin on page 65, stating “*NHRMC expects its patient origin to remain relatively consistent through FY2020.*”

The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section III, pages 50-57, and referenced exhibits, the applicant documents the need for the proposal which are summarized below:

- EP Lab Utilization- EP procedures performed at NHRMC almost doubled between FY2014 and FY2015 (due to the electrophysiologists at Cape Fear Heart Associates changing the manner in which they conducted their clinics and on-call coverage which opened up time for the physicians to focus on performing EP procedures) and NHRMC is projecting a slight increase in FY 2016. (See application page 57)
- NHRMC Physician Group- NHRMC’s physician recruitment and network growth supports the development of an additional EP lab. (See application page 54)
- New NHRMC Services- NHRMC began operating Physician Quality Partners, An Accountable Care Organization, in January 2014 which has led to an increase in market share. (See application pages 55-56)
- Population Growth Trends in both New Hanover County and the Primary Service Area- Projected population growth in both New Hanover County and the primary service area supports the need for an additional EP lab to be developed. (pages 51-53)

Based on review of the information provided by the applicant in Section III, the applicants adequately demonstrates the need to develop a third EP lab at NHRMC’s main campus.

Projected Utilization – Operating Rooms

In Section IV., page 69, the applicant provides historical and projected utilization for the EP labs for the first three Operating Years (OYs) [FFY 2018 – FFY 2020] following project completion as illustrated in the table below:

Category	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020
EP Procedures	791	1,562	1,589	1,668	1,752	1,839	1,931
Annual Changes		97.5%	1.7%	5.0%	5.0%	5.0%	5.0%

On page 69 of the application, NHRMC projected capacity for its dedicated EP labs as follows:

Step 1: the 3 EP labs would each be available for 52.5 hours per week based on scheduled hours of 7:30 am – 6:00 pm for a combined total of 157.5 hours

Step 2: the 3 EP labs would each be available for 50 weeks per year.

Step 3: machine down time of one (1) percent.

Step 4: Total available hours combined for the 3 EP labs (157.5 hours x 50 weeks = 7,875 hours) Subtract 78.75hours (1% down time):  $7,875 - 78.75 = 7,796.25$  available hours

Step 5: Total EP Case Capacity for the 3 EP labs: Divide 7,796.25 available hours by the average hours of each EP case (3.5 hours) =  $2,227.5$  ( $7,796.25 / 3.5 = 2,227.5$ )

Step 6: Capacity for an individual EP lab:  $2,227.5$  (capacity for the 3 EP labs) / 3 = 742 cases per EP lab.

Projected utilization by both EP procedures and as a percentage of capacity of the EP labs is illustrated in the table below.

Column	Category	FY2018	FY2019	FY2020
A	EP Procedures	1,752	1,839	1,931
B	EP Labs	3	3	3
C	Capacity per EP Lab	742	742	742
D	Annual Changes	5.0%	5.0%	5.0%
E	% of Capacity [A/ (B x C)]	78.6%	82.5%	86.7%

Source data: Section IV, pages 68-69

In Section IV.1, page 69 and Exhibit 9, the applicant provide the assumptions and methodology used to project EP lab utilization, which are summarized below.

- Historical EP procedures for FFY 2015 and FFY 2016 (annualized for FFY 2016)

- Market research by an independent research growth projecting a 5.0% compound annual growth rate (CAGR) in the electrophysiology market based on population, aging of the population and frequency of cardiac arrhythmias.

Furthermore, based on the historical number of EP procedures from FY2015 and an annualized number of EP procedures for FY2016 the two existing EP labs at NHRMC operated at 105% of capacity for FY2015 and will operate at 107% of capacity for FY2016 as illustrated in the table below.

	Category	FY2015 (actual)	FY2016 (annualized)	FY2017 (interim)	FY2018 (OY1)	FY2019 (OY2)	FY2020 (OY3)
A	EP Procedures	1,562	1,589	1,668	1,752	1,839	1,931
B	EP Labs	2	2	2	3	3	3
C	Capacity per EP Lab	742	742	742	742	742	742
D	EP Labs- Total Capacity (B x C = D)	1,484	1,484	1,484	2,226	2,226	2,226
E	Annual Changes	na	1.7%	5.0%	5.0%	5.0%	5.0%
F	% of Capacity [A / D = F]	105.2%	107.0%	112.4%	78.7%	82.6%	86.7%

Source data: Section IV, pages 68-69

If the proposed third EP lab is approved even with no increase in the number of EP procedures beyond the annualized EP procedures for FY 2016 of 1,589 the three EP labs at NHRMC would be operating at 71.4% of capacity ( $1,589 / 2,226 = 0.7138$  or 71.4%) for each of the operating years.

Projected utilization is based on reasonable and adequately supported assumptions.

### Access

In Section VI.2, pages 87-88, NHRMC describes how low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other underserved persons, including the medically indigent will have, and will continue to have, access to the EP services. Furthermore, on page 87, the applicant states

*“The inpatient service will be available to all persons without regard to income, race, age, color, creed, religion, national origin, disability or level of care required.”*

In Sections VI.112-13, page 94, the applicant provides the payor mix for NHRMC EP Services for the last full fiscal year (FY 2015- 10/1/14 to 9/30/15), as shown in the following table:

<b>NHRMC- EP Services Payor Mix (FY 2015- 10/1/14 to 9/30/15)</b>	
<b>Payor</b>	<b>Cases as % of Total Cases</b>
Self-Pay / Charity	1.1%
Medicare / Medicare Managed Care	73.9%
Medicaid	4.0%
Managed Care/ Commercial	18.6%
Other (Government)	2.0%
Other	0.4%
<b>Total</b>	<b>100.0%</b>

In Section VI.15, page 96, the applicant provides the projected payor mix for NHRMC EP Services during Operating Year Two (FY 2019- 10/1/18 to 9/30/19), as shown in the following table:

<b>NHRMC- EP Services Payor Mix (FY 2019- 10/1/18 to 9/30/19)</b>	
<b>Payor</b>	<b>Cases as % of Total Cases</b>
Self-Pay / Charity	1.1%
Medicare / Medicare Managed Care	73.9%
Medicaid	4.0%
Managed Care/ Commercial	18.6%
Other (Government)	2.0%
Other	0.4%
<b>Total</b>	<b>100.0%</b>

As shown in the table above, the applicant projects that a total of 77.9% of all cases for EP Services will be covered by either Medicare or Medicaid (73.9% Medicare and 4.0% Medicaid). The applicant’s projected payor mix for the proposed third EP Lab is based on the historical payor mix for EP services at NHRMC.

The applicant adequately demonstrates that medically underserved groups would have adequate access to the proposed ambulatory surgical services.

**Conclusion**

In summary, the applicant adequately identifies the population to be served, adequately demonstrate the need that this population has for the proposed 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 60-61, the applicant describes 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. See Criterion (3) for discussion regarding the historical utilization of the two existing EP labs.
- Joint Venture- the applicant states that because of “Stark” regulations, facility needs, costs and the need for surgical backup a joint venture is not a feasible alternative.
- Extend Hours of Operation- Current hours for EP services at NHRMS are 7:30 am to 6:00 pm. The last EP study of the day is scheduled for 3:00 due to the fact that on average a study takes 3.5 hours and can take as long as 4.5 hours which means staff at the facility until at least 7:30 not including recovery for the patient. Extending operations by even a couple of hours could potentially keep staff on site until 11:00 pm with negative impact on costs, staff and equipment. Therefore, NHRMC did not deem this a feasible alternative.
- Perform EP Studies in Cardiac Catheterization Suite- NHRMC will need an additional cardiac catheterization suite within the next two years. Already in FY2015 NHRMC had to use a cardiac catheterization suite for EP studies due to demand, something which it had not had to do since it opened its second dedicated EP lab in 2004. NHRMC determined that this was not an effective alternative.
- Add a Third EP Laboratory at NHRMC – the applicant states 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 applicable statutory and regulatory review criteria, and thus, is approvable. An application that cannot be approved cannot be an effective alternative.



The applicant adequately demonstrate that the proposed alternative is the most effective or least costly alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **New Hanover Regional Medical Center shall materially comply with all representations made in the certificate of need application.**
  2. **New Hanover Regional 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. **New Hanover Regional 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. **New Hanover Regional 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

NHRMC proposes to acquire equipment for a third dedicated electrophysiology lab at its main campus.

**Capital and Working Capital Costs**

In Section VIII.1, page 107, the applicant projects the total capital cost of the project will be \$2,671,315, which includes:

Construction	\$775,000
Fixed Equipment	\$950,000
Movable Equipment	\$736,315
IT Equipment	\$ 25,000
Architect & Engineering	\$ 90,000
Legal Fees/ Market Analysis	\$ 35,000
Other (Contingency)	<u>\$ 60,000</u>
Total:	\$2,671,315

In Section VIII.2, page 106, the applicant includes a list of the proposed medical equipment. In Section IX.1-3, page 112, the applicant states that EP services are currently offered and there is no need for working capital.

**Availability of Funds**

In Section VIII.3, page 109, the applicant states that the capital costs of the proposed project will be paid for by accumulated reserves of NHRMC.

Exhibit 18 contains a letter dated June 1, 2016 from the Chief Financial Officer of NHRMC which states that NHRMC will commit the \$2,671,315 identified as needed in Section VIII of the application for the development of a third electrophysiology lab and that he has the authority to commit these funds on behalf of NHRMC.

Exhibit 19 contains a copy of annual financial report of New Hanover Regional Medical Center for the year ending September 30, 2015 with report Independent Auditor which shows \$126,588,000 in Cash and Cash Equivalent and \$325,620,000 in Noncurrent Cash and Investments designated for capital improvements.

The applicants adequately demonstrate that sufficient funds will be available for the capital needs of the project.

**Financial Feasibility**

In the projected revenue and expense statement (Forms C), the applicant projects revenues for electrophysiology service will exceed operating expenses in each of the first three operating years following completion of the proposed project, as shown in the table below.

	<b>OY 1 (FY 2018)</b>	<b>OY 2 (FY 2019)</b>	<b>OY 3 (FY 2020)</b>
Total Revenues	\$25,076,700	\$26,973,278	\$29,012,175
Total Expenses	\$18,265,009	\$19,639,978	\$21,130,360
Net Income	\$6,811,691	\$7,333,300	\$7,881,815

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

**Conclusion**

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

demonstrates 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

NHRMC proposes to acquire equipment for a third dedicated electrophysiology lab at its main campus. 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. Providers may serve residents of counties not included in their service area.

In Section III, pages 65-66, the applicant describes its service area for EP Services and states,

*“There are no hospitals within the service area that provide EP services. In fact the closest providers of EP services are in Fayetteville and New Bern, which are 92 miles and 93 miles away, respectively.”*

The discussion regarding analysis of need found in Criteria (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposed project would not result in the unnecessary duplication of existing electrophysiology labs in New Hanover County. Consequently, 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, page 99, the applicant projects staffing for EP services in the second operating year, as illustrated in the following table:

<b>NHRMC- EP Services Proposed Staffing OY 2 (FY 2019)</b>	
<b>Position</b>	<b># of Full Time Equivalent (FTE) Positions</b>
Staff RN	5.0
Technician	7.0
Manager	0.25
<b>TOTAL</b>	<b>12.25</b>

As shown in the table above, the applicant projects to employ 12.25 FTEs in the second operating year. In Section VII.1, page 98, the applicant states that for FY2016 EP services had 9.25 FTEs. In Section VII.3, page 100, the applicant states that “*it has not had any trouble recruiting staff in the past*” due to its agreements with area community colleges, universities and clinical training programs, competitive pay and benefits and activity in the community at large which permits NHRMC to have interactions with potential new hires. Exhibit 12 contains a letter signed by Michael Yarnoz, M.D., which expresses his commitment to continue to serve as Medical Director of EP services at NHRMC.

Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in the pro forma financial statements.

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

In Section II.2, page 33, the applicant identifies the ancillary services that will be provided. EP services are currently offered at NHRMC and the ancillary services identified will be provided by hospital staff. Exhibit 6 contains a letter dated June 1, 2016 for the President and CEO of NHRMC which indicates the ancillary and support services available at NHRMC.

In Section V.4, page 73, the application states that “*NHRMC has long-standing, established relationships with local healthcare providers such as home health agencies, skilled nursing and assisted living facilities, and emergency services....All major healthcare providers relevant to the EP lab, including referring physicians, hospitals and healthcare agencies, are aware of and support this project*”. Exhibit 23 contains letters of support.

The applicant adequately demonstrates that all necessary ancillary and support services will be available and that the proposed services will 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

NHRMC proposes to acquire equipment for a third dedicated electrophysiology lab in 1,125 square feet of renovated space on the first floor of the hospital across the hall from the existing dedicated EP labs. The new EP lab and EP control room will move into hospital space currently utilized as offices, conference room and stereotactic radiology. In Section XI.7, the applicant discusses the features and methods that will be used to maintain energy efficient operations and sustainability and contain costs of utilities. Exhibit 22 contains a letter from ECA Architecture, PC which provides cost estimates relating to relocation and renovation costs for the proposed third dedicated EP lab which are consistent with the costs estimates found in Section VII, Line 11, page 72 of the application. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative for the proposed construction project. Furthermore, the applicant adequately demonstrates that the proposed construction project would not unduly increase the costs and charges of providing EP lab services. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that applicable energy saving features have been incorporated into the construction plans. 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 Sections VI.112-13, page 94, the applicant provides the payor mix for both the entire NHRMC facility and for NHRMC EP Services for the last full fiscal year (FY 2015- 10/1/14 to 9/30/15), as shown in the following table:

<b>NHRMC- Entire Facility Payor Mix (FY 2015- 10/1/14 to 9/30/15)</b>	
<b>Payor</b>	<b>Cases as % of Total Cases</b>
Self-Pay / Charity/ Other	10.7%
Medicare / Medicare Managed Care	51.5%
Medicaid	19.6%
Managed Care/ Commercial Insurance	18.2%
Total	100.0%

<b>NHRMC- EP Services Payor Mix (FY 2015- 10/1/14 to 9/30/15)</b>	
<b>Payor</b>	<b>Cases as % of Total Cases</b>
Self-Pay / Charity	1.1%
Medicare / Medicare Managed Care	73.9%
Medicaid	4.0%
Managed Care/ Commercial	18.6%
Other (Government)	2.0%
Other	0.4%
Total	100.0%

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 the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
New Hanover	16%	52%	23%	18%	9%	19%
Brunswick	27%	51%	19%	16%	12%	19%
Pender	17%	50%	26%	15%	13%	20%
Columbus	18%	51%	40%	24%	15%	21%
Onslow	8.0%	45%	33%	14%	11%	16%
Bladen	19%	52%	45%	26%	16%	20%
Duplin	16%	51%	48%	28%	11%	26%
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 applicant'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 applicant demonstrates that it 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.11, page 93, the applicant states that NHRMC "fulfilled its Hill-Burton obligation and does not have any related obligation under any applicable federal regulations to provide uncompensated care, community service or access by minorities and the handicapped." In Section VI.10, page 93, the applicant states that there have been no civil rights equal access complaints filed against NHRMC in the last 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 Sections VI.14-15, pages 95-96, the applicants provide the projected payor mix for both the entire NHRMC facility and for NHRMC EP Services during Operating Year Two (FY 2019- 10/1/18 to 9/30/19), as shown in the following table:

<b>NHRMC- Entire Facility Payor Mix (FY 2019- 10/1/18 to 9/30/19),</b>	
<b>Payor</b>	<b>Cases as % of Total Cases</b>
Self-Pay / Charity/ Other	10.7%
Medicare / Medicare Managed Care	51.5%
Medicaid	19.6%
Commercial Insurance	18.2%
Total	100.0%

<b>NHRMC- EP Services Payor Mix (FFY 2019- 10/1/18 to 9/30/19),</b>	
<b>Payor</b>	<b>Cases as % of Total Cases</b>
Self-Pay / Charity	1.1%
Medicare / Medicare Managed Care	73.9%
Medicaid	4.0%
Managed Care/ Commercial	18.6%
Other (Government)	2.0%
Other	0.4%
Total	100.0%

As shown in the table above, the applicant projects that 73.9% of all cases for EP Services will be covered by Medicare and 4.0% of all the cases for EP Services will be covered by Medicaid.

The applicant adequately demonstrates that medically underserved groups would have adequate access to the proposed ambulatory surgical services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.9, page 92, the applicant describes the range of means by which a person will have access to the proposed electrophysiology lab. The applicant adequately demonstrates that it will offer a range of means by which a person will have access to the proposed 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, page 70, the applicant describes how the proposed project will accommodate the clinical needs of area health professional training programs. The applicant states:

*“NHRMC is committed to collaborative relationships with local and regional health professional training programs. NHRMC currently has agreements with over 110 health professional training programs.”*

Exhibit 10 contains both a list of the training programs that NHRMC has existing agreements with and an example of a training program affiliation agreement. On page 70 the applicant states that students in these training programs will continue to have access, as needed, to EP services.

The information provided is reasonable and adequately supports a determination that 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

NHRMC proposes to acquire equipment for a third dedicated electrophysiology lab at its main campus. 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.

In Section III, pages 65-66, the applicant describes its service area for EP Services and states,

*“There are no hospitals within the service area that provide EP services. In fact the closest providers of EP services are in Fayetteville and New Bern, which are 92 miles and 93 miles away, respectively.”*

In Section V.7, pages 75-85, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services.

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access to the proposed services.

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

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant adequately demonstrates that they will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are 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, page 12, New Hanover Regional Medical Center identifies the 16 health care facilities it owns 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 NHRMC was not found to be out of compliance with one or more Medicare conditions of participation. At this time, New Hanover Regional Medical Center 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 NHRMC, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

NHRMC 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 45, the applicant provides 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 45, the applicant provides the following table showing the number of patients who will use the service by county of residence:

**NHRMC  
 Projected EP Patients by County of Residence**

County	Percentage	Projected Patients		
		OY 1 FY2018	OY 2 FY2019	OY 3 FY2020
New Hanover	40.6%	711	747	784
Brunswick	24.8%	434	456	479
Pender	10.2%	179	188	197
Columbus	8.5%	149	156	164
Onslow	7.5%	131	138	145
Bladen	2.4%	42	44	46
Duplin	2.2%	25	26	27
Sampson	1.4%	42	44	46
In-Migration	2.4%	42	44	46
<b>TOTAL</b>	<b>100.0%</b>	<b>1,752</b>	<b>1,839</b>	<b>1,931</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 46, the applicant documents the maximum number of procedures that existing equipment that is used for similar procedures in the facility if capable of performing.
  
- (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, pages 46-47, the applicant provides tables showing the quarterly projected utilization of NHRMC's EP laboratories for the first three years following completion of the project to add a third dedicated EP laboratory.
  
- (5) *all the assumptions and data supporting the methodology used for the projections in this Rule.*
  - C- The applicant provides the assumptions and data supporting the methodology used for the projections in Section IV, pages 68-69, and in Exhibit 9.
  
- (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 applicant is not proposing to acquire new major medical technology.