

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 23, 2016

Findings Date: November 23, 2016

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: M-11213-16

Facility: Cape Fear Valley Medical Center

FID #: 943057

County: Cumberland

Applicant(s): Cumberland County Hospital System, Inc.

Project: Acquire one additional fixed cardiac catheterization unit for a total of four units

### 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

Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Medical Center (“CFVMC” or “the applicant”) proposes to acquire one additional fixed unit of cardiac catheterization equipment pursuant to the need determination in the 2016 State Medical Facilities Plan (SMFP) for a total of four units upon project completion. The applicant currently has three fixed cardiac catheterization units located on the main hospital campus.

## **Policies**

There are two policies in the 2016 SMFP which are applicable to this review: Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-3: Basic Principles, states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### Promote Safety and Quality

In Section II.7, pages 15 – 17, and Section III.2, page 40, the applicant describes how it believes the proposed project would promote safety and quality. Exhibits 7, 9 and 10 all provide copies of the applicant’s policies with regard to patient safety and quality. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

### Promote Equitable Access

In Section III.2, pages 38 - 39, Section VI, pages 68 - 75, and Exhibit 20, the applicant describes how it believes the project would promote equitable access to cardiac catheterization services in Cumberland County. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote equitable access.

### Maximizing Healthcare Value

In Section III.2, page 38, the applicant describes how it believes the proposed project would maximize healthcare value with regard to cardiac catheterization services in Cumberland County. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the

adjusted need determination identified in the 2016 SMFP. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4 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 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.”*

In Section VIII.2, page 84, the applicant states the proposed capital expenditure is \$3,180,527. In Section III.2, pages 41 - 43, the applicant describes its plan to assure improved energy efficiency and water conservation as part of the project. In Exhibit 4, the applicant provides a letter dated September 1, 2016 from an architect that details the energy efficiency and water conservation plans that are incorporated into the design of the area to be renovated to house the proposed cardiac catheterization equipment. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

### **Conclusion**

In summary, the applicant adequately demonstrates that its proposal is consistent with the need determination in the 2016 SMFP, Policy GEN-3 and 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

Cape Fear Valley Medical Center proposes to acquire one additional unit of fixed cardiac catheterization equipment to be located on the main hospital campus pursuant to the need determination in the 2016 SMFP. The applicant will operate a total of four fixed cardiac catheterization units following completion of this project.

**Patient Origin**

On page 179, the 2016 SMFP defines the service area for cardiac catheterization equipment (fixed or shared) as the cardiac catheterization equipment planning area in which the equipment is located. Thus, the service area for Cape Fear Valley Medical Center is Cumberland County. Providers may serve residents of counties not included in their service area.

In Sections III.1, page 26, the applicant provides the current (FFY 2015) patient origin for the cardiac catheterization services at CFVMC, as summarized in the table below.

**CFVMC Cardiac Catheterization Services  
Patient Origin, FFY 2015**

<b>COUNTY</b>	<b>% Pts.</b>
Cumberland	70.0%
Bladen	4.5%
Harnett	6.2%
Hoke	3.3%
Robeson	6.5%
Sampson	5.3%
Other	4.1%
<b>Total</b>	<b>100.0%</b>

Numbers may not foot due to rounding

In Section III.5, pages 44 and 45, the applicant projects the following patient origin for cardiac catheterization services at CFVMC:

**CFVMC Cardiac Catheterization Services  
Projected Patient Origin**

<b>COUNTY</b>	<b>% PTS.</b>
Cumberland	74.2%
Bladen	4.1%
Harnett	2.3%
Hoke	4.4%
Robeson	6.9%
Sampson	4.8%
Other	3.2%
<b>Total</b>	<b>100.0%</b>

Numbers may not foot due to rounding

In Section III.5, page 46, the applicant states that in October 2014, CFVHS began to manage Harnett Health. At that time, Central Harnett Hospital did not have a fixed cardiac catheterization unit; therefore, cardiac catheterization volume shifted from Central Harnett Hospital to CFVMC. In July 2016, Central Harnett Hospital was approved to acquire one unit of shared fixed cardiac catheterization equipment, which it projects to operate in October 2017. The cardiac catheterization unit proposed in this application is projected to operate in October 2018. Thus, the applicant projects that cardiac catheterization volume will again shift to Central Harnett Hospital from CFVMC. The applicant therefore projects patient origin for cardiac catheterization services following completion of this project to resemble CFVMC patient origin for cardiac catheterization services in FFY 2013, prior to the time CFVMC began to manage Harnett Health.

The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section III.1, pages 26 - 36, the applicant provides the methodology and assumptions used to describe the factors which it states support the need for the proposed project, including:

- The need determination in the 2016 SMFP (pages 26 and 27).
- The historical utilization of cardiac catheterization services at CFVMC since the hospital began offering those services in 1988 shows that demand has increased and is still increasing. The applicant states that in the last five years alone, utilization has increased by a Compound Annual Growth Rate (CAGR) of 8.3% (pages 27 – 28).
- The existing three cardiac catheterization units at CFVMC operate 12 hours per day for five days per week, as well as Saturday hours. There are still patients who end up on a lengthy waiting list or are turned away. The fourth unit will help to alleviate these issues and increase patient access to needed cardiac catheterization services (page 28).
- Cape Fear Valley Medical Center produced a Community Needs Assessment, using statistics from the North Carolina Center for Health Statistics. According to that study, heart disease is the primary cause of death in Cumberland County, with age adjusted mortality rates that are 17% greater than in the state as a whole. The addition of a fourth cardiac catheterization unit at the hospital, particularly in light of the

current utilization, will help to address the cardiac patients’ needs in Cumberland County (pages 28 – 30).

- In addition to regular patient demand for cardiac catheterization services in Cumberland County, CFVMC’s emergency department continues to increase, despite the opening of the FirstHealth Hoke Hospital in contiguous Hoke County. According to the applicant, over 50% of the emergency visits to CFVMC’s emergency department have historically been patients with cardiac issues. The applicant states that analysis of recent historical utilization of emergency and cardiac catheterization services indicate that utilization will increase by more than 20% in a one-year period. The addition of a fourth cardiac catheterization unit will help to meet the increasing demand for those services (page 30).
- The applicant states the population growth in Cumberland County and the five surrounding counties shown above is projected to increase by an average of 0.7% CAGR from 2016 – 2021, according to the North Carolina Office of State Budget and Management (NC OSBM). According to the applicant, the age group most likely to suffer cardiac issues is the 55 and over group. The applicant states the median age of patients who presented to the hospital with cardiac issues was 64.4 years of age. According to the NC OSBM, the 55 and over population group in Cumberland County and the five surrounding counties is projected to increase at a CAGR of 2.0% for the same time period (2016 – 2021) (pages 30 – 32).

Projected Utilization

In Section III.1, pages 33 - 36, the applicant projects utilization for the cardiac catheterization equipment using a four-step methodology, summarized below.

Step 1: Determine FFY 2016 Base Cardiac Catheterization Procedure Volume at CFVMC

In Section III, page 33, and in Exhibit 11, Table 2, the applicant states it compared CFVHS internal cardiac catheterization data with historical data from the hospital’s License Renewal Applications (LRAs) to project future volume and determined that historical utilization at CFVMC is a good indicator of future growth of cardiac catheterization service. The applicant states the growth from FFY 2015 to FFY 2016 (annualized) was 6.9%, and estimated that FFY 2016 volume would be 4,430 cardiac catheterization procedures. See the following table, from page 34 and Exhibit 11, table 2:

**Historical Growth Cardiac Catheterization Procedures  
 CFVMC, FFY 2013 – FFY 2016  
 Non-Weighted Procedures**

	FFY 2013	FFY 2014	FFY 2015	FFY 2016 – OCTOBER – MAY ANNUALIZED	CAGR FFY 2013 - 2016
Total Procedures	2,993	3,768	4,144	4,430	
Annual Growth		25.9%	10.0%	6.9%	14.0%

Source: application page 34

On page 34, the applicant states the overall CAGR is high (14%), despite a decrease in utilization from FFY 2014 to FFY 2016. The applicant attributes the temporary decrease in utilization to the offering of cardiac catheterization services at FirstHealth Moore Regional Hospital-Hoke in 2014. The applicant states historical utilization, population growth projections, and the increasing incidence of cardiac disease in the service area combine to demonstrate that demand for cardiac catheterization services at CFVMC will continue to increase.

Step 2: Determine Growth Rate for Cardiac Catheterization Procedures at CFVMC

In Section III.1, pages 33 – 35, the applicant states a variety of factors will impact the growth in cardiac catheterization volume at CFVMC. The hospital is increasing its cardiac services medical staff, has entered into a management agreement with Harnett Health, and has opened Cape Fear Valley Hoke Hospital. Furthermore, the applicant determined that patients who are most at risk for cardiac disease are between the ages of 40 – 79. The applicant determined that the age group 55 and older represents the most reasonable growth rate for projecting future cardiac catheterization utilization at the hospital. The applicant calculated a “*weighted population growth rate*” for the age group 55 and older in its defined service area. This rate takes into consideration both patient origin for cardiac catheterization services at the hospital and projected population growth for the area. See the following table, from page 34 that illustrates this projected growth:

**CFVMC Service Area 55+ Weighted Population Growth Rate**

COUNTY	2016	2017	CAGR 2016 – 2017	PATIENT ORIGIN 2013	WEIGHTED POPULATION GROWTH
Bladen	11,928	12,520	1.0%	4.1%	0.04%
Cumberland	75,780	83,916	2.1%	74.2%	1.53%
Harnett	29,773	34,592	3.0	2.3%	0.07%
Hoke	10,002	12,309	4.2	4.4%	0.19%
Robeson	34,897	36,812	1.1	6.9%	0.07%
Sampson	19,177	20,497	1.3	4.8%	0.06%
All Other (NC State Rate)	2,841,343	3,192,612	2.4	3.2%	0.08%
<b>Weighted Population Growth Rate</b>					<b>2.04%</b>

Source: Application page 34 and Exhibit 11, Table 5

The applicant states on pages 34 – 35 that the projected increase in cardiac catheterization procedures at CFVMC is based on the “*weighted population growth in the six county service area.*”

Step 3: Calculate CFVMC Future Cardiac Catheterization Volume

In Section III, page 35, the applicant states it used the base year data from *Step 1* and the population growth rate from *Step 2* to project future cardiac catheterization volume at

CFVMC. The applicant also assumed that 90% of the cardiac catheterization volume to be performed at Central Harnett Hospital will result from a shift of patients from CFVMC. That is not to say that the applicant projects that 90% of the projected volume of CFVMC will shift to Central Harnett Hospital; rather, 90% of Central Harnett Hospital’s projected volume will come from CFVMC. Additionally, the shift in volume to Central Harnett Hospital and decrease in volume at CFVMC is projected to be temporary. Furthermore, since utilization at CFVMC was in excess of 100% for the last several years, and since the incidence of cardiac issues in the service area is likely to increase in the service area, the applicant projects the utilization of cardiac catheterization services at CFVMC will continue to increase.

When combined with the growth projected for Central Harnett Hospital’s cardiac catheterization services, the applicant projects the following utilization for CFVMC’s four cardiac catheterization units:

**Combined Utilization CFVMC and HHS Cardiac Catheterization Services**

	2016	2017	2018	2019	2020	2021
CFVHS Cath Volume	4,430	4,520	4,243	4,062	3,979	4,061
Annual Growth	7%	2%	-6%	-4%	-2%	2%
Harnett Health			411	716	915	933
Combined Total	4,430	4,520	4,654	4,778	4,894	4,994
<b>Annual Growth</b>		<b>2%</b>	<b>3%</b>	<b>3%</b>	<b>2%</b>	<b>2%</b>

Source: Application page 35.

*Step 4: Determine the Number of Cardiac Catheterization Units Needed at CFVMC*

In Section III, pages 36 – 37, the applicant determines that, as a result of the projected volume of cardiac catheterization procedures to be performed at CFVMC even after the shift of patients to Central Harnett Hospital, a fourth cardiac catheterization unit is needed at the hospital to meet the increasing demand for cardiac catheterization services. See the following table, from page 36:

	PY1 FFY 2010	PY 2 FFY 2020	PY 3 FFY 2021
Projected CFVMC Cardiac Catheterization Adjusted Volume	4,062	3,979	4,061
Percent Therapeutic	43.4%	43.4%	43.4%
Number Therapeutic	1,764	1,728	1,764
Percent Diagnostic	56.6%	56.6%	56.6%
Number Diagnostic	2,298	2,251	2,297
Weighted CC Cases (Therapeutic = 1.75 diagnostic cath)	5,386	5,276	5,384
Cardiac Catheterization Rooms Needed @ 1,200 Cases per Room	4.5	4.4	4.49
Current CFVMC Room Inventory	3.0	3.0	3.0
Additional Need Rounded to SMFP Standard	1	1	1

Source: application page 36

Currently, CFVMC is the only provider of cardiac catheterization services in Cumberland County. In Project ID #M-11160-16, Central Harnett Hospital was approved to develop cardiac catheterization services and acquire one unit of shared fixed cardiac catheterization

unit, which will relieve some of the high utilization and demand at CFVMC. In Section III.1, the applicant shows that the primary cause of death in Cumberland County is cardiac related, and that 50% of the emergency admissions to the hospital are the result of acute myocardial infarction. Based on historical utilization of existing cardiac catheterization services at the hospital and projected population growth in the service area, the applicant projects it will perform 4,061 cardiac catheterization procedures by the end of the third year of operation, FFY 2021. Exhibit 15 contains 51 letters from local physicians in the proposed service area expressing support for the project for additional cardiac catheterization services at CFVMC. Exhibit 17 contains letters of support from the community, including emergency services, expressing support for the additional cardiac catheterization unit at CFVMC. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. Therefore, the applicant adequately demonstrates the need to acquire one unit of fixed shared cardiac catheterization equipment.

### **Access**

In Section VI.2, pages 67 - 69, the applicant states it is committed to providing cardiac catheterization services to all patients who need the services regardless of race, creed, religion, handicap, economic status, social status, or ability to pay. In Exhibit 20 the applicant provides a copy of its financial policies that describe admissions criteria with regard to ability to pay. In Section VI.12, page 74, the applicant states that in FFY 2015, 51.0% of the patients who were served at CFVMC were Medicare beneficiaries and 24.6% were Medicaid beneficiaries. In Section VI.14, page 75, the applicant states the projected payor mix for cardiac catheterization services at CFVMC in the second project year is based on its historical experience. In Section VI.15, page 75, the applicant projects that 54.2% of the cardiac catheterization patients to be served will be Medicare beneficiaries and 10.3% will be Medicaid recipients. The applicant states on page 75 that the projections are based on the current payor mix at CFVMC. Payor mix is also based on the anticipated shift in cardiac catheterization patients from CFVMC back to Central Harnett Hospital as stated in Section III, page 46. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

### **Conclusion**

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the project and adequately demonstrates 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, page 43, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Not File a CON Application – the applicant states this is not an effective alternative because utilization of the current cardiac catheterization equipment at CFVMC is over 100%, operating five days per week for 12 hours each day, and three hours on Saturday.
- Locate the Proposed Fourth Cardiac Catheterization unit at HighSmith Rainey Specialty Hospital – the applicant states this is not an effective alternative; while HighSmith Rainey Specialty Hospital is the only other acute care hospital in Cumberland County, it is a long-term acute care hospital and does not provide tertiary care services. Therefore, the cardiac catheterization unit would not be utilized at that facility.

After considering the alternatives, the applicant states the proposed alternative is the most effective alternative to meet the identified need and to alleviate high utilization at CFVMC.

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 applicant adequately demonstrates 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. Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Medical Center shall materially comply with all representations made in the certificate of need application.**
- 2. Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Medical Center shall acquire no more than one fixed cardiac catheterization unit as part of this project, for a total of four fixed cardiac catheterization units.**

3. **Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley 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 VII of the application and that would otherwise require a certificate of need.**
  4. **Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and 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

The applicant proposes to acquire one additional unit of cardiac catheterization equipment for a total of four cardiac catheterization units on the main hospital campus. In Section VIII.2, page 84, the applicant states the total capital cost is projected to be as follows:

ITEM	COST
Construction (renovation of existing space)	\$1,275,000
Equipment (fixed, movable, and furniture)	\$1,685,527
Miscellaneous (financing/Consultant Fees)	\$ 220,000
<b>Total Capital Costs</b>	<b>\$3,180,527</b>

In Section IX.1, page 89, the applicant projects there will be no initial operating expenses or start-up costs associated with this project.

**Availability of Funds**

In Section VIII.3, page 85, the applicant states the entire capital cost of the project will be funded with the accumulated reserves of Cape Fear Valley Health System (CFVHS). In Exhibit 25, the applicant provides an August 15, 2016 letter from the Chief Financial Officer of Cape Fear Valley Medical Center, confirming the availability of sufficient funds for the capital costs of the proposed project. Exhibit 25 also contains CFVHS's consolidated balance sheets which indicate that as of September 30, 2015, CFVHS had \$39,199,000 in cash and cash equivalents. In addition, the applicant had net assets of \$336,653,000 (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

### **Financial Feasibility**

In the pro forma financial statements for the applicant's cardiac catheterization services (Form C), the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as shown in the table below.

	<b>FFY 2018</b>	<b>FFY 2019</b>	<b>FFY 2020</b>
Total Net Revenues	\$35,374,956	\$35,171,912	\$36,435,192
Total Operating Expenses	\$ 9,387,052	\$ 9,506,980	\$ 9,909,355
<b>Net Income (Loss)</b>	<b>\$25,996,905</b>	<b>\$25,664,931</b>	<b>\$26,525,837</b>

Totals may not foot due to rounding

The assumptions used by the applicant 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 applicant adequately demonstrates the availability of sufficient funds for the operating needs of the project and that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs.

### **Conclusion**

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital operating 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**

Cape Fear Valley Medical Center proposes to acquire one additional unit of fixed cardiac catheterization equipment to be located on the hospital campus pursuant to the need determination in the 2016 SMFP. The applicant will operate a total of four fixed cardiac catheterization units following completion of this project.

On page 179, the 2016 SMFP defines the service area for cardiac catheterization equipment (fixed or shared) as the cardiac catheterization equipment planning area in which the equipment is located. Thus, the service area for Cape Fear Valley Medical Center is Cumberland County. Providers may serve residents of counties not included in their service area.

Cape Fear Valley Medical Center is currently the only provider of cardiac catheterization services in Cumberland County. The applicant adequately demonstrates in its application that the proposed additional cardiac catheterization unit is needed in Cumberland County, based on reasonable and adequately supported assumptions, including existing utilization in excess of 100%. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved cardiac catheterization services in Cumberland County. 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, page 76, the applicant states that it proposes 4.0 additional full-time equivalent (FTE) positions to staff the cardiac catheterization unit. The applicant further states it bases its projections on the experience of CFVMC. In Section VII.6, page 79, the applicant describes its experience with and process for recruiting and retaining staff. In Exhibit 21, the applicant provides a copy of the job descriptions and copies of employee orientation policies. In Section VII.8, page 81, the applicant identifies Bradley Broussard, M.D. as the Chief of Staff/Medical Director. In Exhibit 16, the applicant provides an August 15, 2016 letter from Fr. Thor E. Klang, currently the Medical Director of Invasive Cardiology at CFVMC, in which Dr. Klang commits to serve as Medical Director for cardiac catheterization services at CFVMC. Exhibits 17 and 18 contain copies of support letters from other physicians and area health providers expressing support for the project. The applicant adequately demonstrates 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

In Section II.2, pages 13 - 14, the applicant describes the manner by which it will provide the necessary ancillary and support services for the proposed project. Exhibit 5 includes an August 15, 2016 letter from the COO and Vice President for Ambulatory Services at CFVMC which lists the ancillary and support services that are currently available and will continue to be available following the addition of the proposed fixed cardiac catheterization equipment. Exhibits 15 and 17 contain letters of support and referral intentions from area physicians and

other local health care providers, and Exhibit 18 contains letters of support from members of the community. The applicant adequately demonstrates that necessary ancillary and support services are 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

The applicant proposes to renovate 835 square feet of existing space in the hospital to house a fourth cardiac catheterization unit. Exhibit 4 contains a letter and supporting documentation from an architect that estimates construction costs that are consistent with the project capital cost projections provided by the applicant in Section VIII.2, page 84 of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design

and means of 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 74, the applicant reports the following payor mix for cardiac catheterization services at CFVMC for FFY 2016:

PAYOR CATEGORY	% TOTAL UTILIZATION
Self-Pay/Indigent/Charity	5.8%
Medicare/Medicare Managed Care	54.2%
Medicaid	10.3%
Managed Care	23.9%
Other	5.8%
<b>Total</b>	<b>100.0%</b>

Numbers may not foot due to rounding

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 and statewide.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Cumberland	11%	55%	55%	18%	11%	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 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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 74, the applicant states:

*“CFVMC has no obligation under any applicable Federal regulation to provide uncompensated care. However, CFVMC provided \$64,561,884 in charity care and \$118,644,648 in bad debt during FFY 2015. As a responsible member of the community, CFVMC will continue to provide uncompensated care.”*

The applicant states it will continue to provide care to all persons, including low income, racial and ethnic minorities, women, handicapped persons, elderly and other underserved populations. In Section VI.10, page 73, the applicant states that no civil rights complaints were filed against CFVMC in the last five years. Therefore, 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.14, page 75, the applicant projects payor mix for the entire hospital and for cardiac catheterization services during the second year of operation following project completion, as shown in the following tables.

**CFVMC Entire Facility Payor Mix FFY 2020**

PAYOR CATEGORY	% TOTAL UTILIZATION
Self-Pay/Indigent/Charity	4.6%
Medicare/Medicare Managed Care	51.0%
Medicaid	24.6%
Commercial Insurance	3.7%
Managed Care	11.5%
Other	4.5%
<b>Total</b>	<b>100.0%</b>

Totals may not foot due to rounding

**CFVMC Cardiac Catheterization Services  
 Payor Mix FFY 2020**

PAYOR CATEGORY	% TOTAL UTILIZATION
Self-Pay/Indigent/Charity	5.8%
Medicare/Medicare Managed Care	54.2%
Medicaid	10.3%
Managed Care / Commercial	23.9%
Other	5.8%
<b>Total</b>	<b>100.0%</b>

Totals may not foot due to rounding

As shown above, the applicant projects that 64.5% of all cardiac catheterization procedures to be provided will be provided to recipients of Medicare/Medicaid. In Section VI.15, page 75, the applicant states projected payor mix for cardiac catheterization services at CFVMC is based on the current payor mix at CFVMC.

The applicant demonstrates that medically underserved populations will have adequate access to the cardiac catheterization services to be offered at CFVMC. 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 73, the applicant describes the range of means by which a person will have access to CFVMC's cardiac catheterization services, including referral by cardiologists or via emergency transport. The applicant adequately demonstrates that the facility will offer a range of means by which patients 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 50, the applicant states that it already has established relationships with residency programs at Campbell University and with the Cumberland County School System, and will continue those relationships following completion of the project. Exhibit 13 contains copies of correspondence from Campbell University, UNC Pembroke and Cape Fear Valley Health System that confirm existing and continued utilization of CFVMC as a clinical training site for cardiac catheterization clinical rotation. The information provided is reasonable and credible and supports a finding of conformity 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

Cape Fear Valley Medical Center proposes to acquire one additional unit of fixed cardiac catheterization equipment to be located on the hospital campus pursuant to the need determination in the 2016 SMFP. The applicant will operate a total of four fixed cardiac catheterization units following completion of this project.

On page 179, the 2016 SMFP defines the service area for cardiac catheterization equipment (fixed or shared) as the cardiac catheterization equipment planning area in which the equipment is located. Thus, the service area for Cape Fear Valley Medical Center is Cumberland County. Providers may serve residents of counties not included in their service area.

Valley Medical Center is currently the only provider of cardiac catheterization services in Cumberland County. The applicant proposes to acquire one additional fixed cardiac catheterization unit for use at the hospital, where current utilization of the three existing units remains high. In Section V.7, pages 64 – 65, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed cardiac catheterization services.

See also Sections II, III, V, VI, VII and Exhibit 12 in which the applicant discusses 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 applicant adequately demonstrates 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 applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1), (3) 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 II.7, pages 15 - 17, and Section III.2, page 40, the applicant describes the methods used by CFVMC to ensure and maintain quality care. See also Exhibits 2, 7 and 9. In Section I.12(b), page 6, the applicant lists the other health care facilities in the state that are owned or operated by Cape Fear Valley Health System. In Section II.7(c), page 17, the applicant states none of the facilities associated with Cape Fear Valley Health System has never had a license revoked or had Medicare or Medicaid provider agreements revoked. The information provided by the applicant is reasonable and supports the determination that 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

The application is conforming to all applicable Criteria and Standards for cardiac catheterization equipment and cardiac angioplasty equipment. The specific criteria are discussed below.

**10A NCAC 14C .1603 PERFORMANCE STANDARDS**

(a) *An applicant proposing to acquire cardiac catheterization equipment shall demonstrate that the project is capable of meeting the following standards:*

(1) *each proposed item of cardiac catheterization equipment, including mobile equipment but excluding shared fixed cardiac catheterization equipment, shall be utilized at an annual rate of at least 60 percent of capacity excluding procedures not defined as cardiac catheterization procedures in 10A NCAC 14C .1601(5), measured during the fourth quarter of the third year following completion of the project;*

-C- The applicant demonstrates that the four cardiac catheterization units at CFVMC will perform in excess of 60% utilization during the fourth quarter of the third year of operation following project completion, as shown in the following table:

	PY 1 (FFY 2019)				PY 2 (FFY 2020)				PY 3 (FFY 2021)			
	QTR. 1	QTR. 2	QTR. 3	QTR. 4	QTR. 1	QTR. 2	QTR. 3	QTR. 4	QTR. 1	QTR. 2	QTR. 3	QTR. 4
Volume	1,015	1,015	1,015	1,016	994	994	995	995	1,015	1,015	1,015	1,015
# Therapeutic	441	441	441	441	432	432	432	432	441	441	441	441
# Diagnostic	574	574	574	575	562	562	563	563	574	574	574	574
# Wtd Procedures	1,346	1,346	1,346	1,347	1,319	1,319	1,319	1,319	1,346	1,346	1,346	1,346
Capacity	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500
% Utilization	89.7%	89.7%	89.7%	89.8%	87.9%	87.9%	87.9%	87.9%	89.7%	89.7%	89.7%	89.7%

Table prepared by project analyst using information on page 20 and in Exhibit 11 of the application. Numbers may not foot due to rounding.

(2) *if the applicant proposes to perform therapeutic cardiac catheterization procedures, each of the applicant's therapeutic cardiac catheterization teams shall be performing at an annual rate of at least 100 therapeutic cardiac catheterization procedures, during the third year of operation following completion of the project;*

-C- The applicant demonstrates that the cardiac catheterization teams at CFVMC will perform in excess of 100 therapeutic cardiac catheterization procedures during the third year of operation following project completion, as shown in the table above.

(3) *if the applicant proposes to perform diagnostic cardiac catheterization procedures, each diagnostic cardiac catheterization team shall be performing*

*at an annual rate of at least 200 diagnostic-equivalent cardiac catheterization procedures by the end of the third year following completion of the project;*

- C- The applicant demonstrates that the cardiac catheterization teams at CFVMC will perform in excess of 200 diagnostic cardiac catheterization procedures during the third year of operation following project completion, as shown in the table above.
  - (4) *at least 50 percent of the projected cardiac catheterization procedures shall be performed on patients residing within the primary cardiac catheterization service area;*
  
- C- In Section III, page 26, and Section II, page 21, the applicant demonstrates that at least 50% of the projected cardiac catheterization procedures to be performed at CFVMC will be performed on patients residing within the primary cardiac catheterization service area, which is Cumberland County.
  - (b) *An applicant proposing to acquire mobile cardiac catheterization equipment shall:*
    - (1) *demonstrate that each existing item of cardiac catheterization equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization service area of each host facility shall have been operated at a level of at least 80 percent of capacity during the 12 month period reflected in the most recent licensure form on file with the Division of Health Service Regulation;*
    - (2) *demonstrate that the utilization of each existing or approved item of cardiac catheterization equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization service area of each host facility shall not be expected to fall below 60 percent of capacity due to the acquisition of the proposed mobile cardiac catheterization equipment;*
    - (3) *demonstrate that each item of existing mobile equipment operating in the proposed primary cardiac catheterization service area of each host facility shall have been performing at least an average of four diagnostic-equivalent cardiac catheterization procedures per day per site in the proposed cardiac catheterization service area in the 12 month period preceding the submittal of the application;*
    - (4) *demonstrate that each item of existing or approved mobile equipment to be operating in the proposed primary cardiac catheterization service area of each host facility shall be performing at least an average of four diagnostic-equivalent cardiac catheterization procedures per day per site in the proposed cardiac catheterization service area in the applicant's third year of operation; and*
    - (5) *provide documentation of all assumptions and data used in the development of the projections required in this Rule.*

-NA- The applicant proposes to acquire fixed cardiac catheterization equipment, not mobile cardiac catheterization equipment.

*(c) An applicant proposing to acquire cardiac catheterization equipment excluding shared fixed and mobile cardiac catheterization shall:*

*(1) demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, located in the proposed cardiac catheterization service area operated at an average of at least 80 percent of capacity during the twelve month period reflected in the most recent licensure renewal application form on file with the Division of Health Service Regulation;*

-C- CFVMC is the only provider of cardiac catheterization services in the service area. In Section II, page 23, the applicant provides a table to illustrate that each existing item of cardiac catheterization equipment that is located in the proposed service area performed in excess of 100% of utilization in FFY 2015.

*(2) demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, shall be utilized at an average annual rate of at least 60 percent of capacity, measured during the fourth quarter of the third year following completion of the project; and*

-C- In Section II, pages 20 and 23 - 24, the applicant demonstrates that its existing cardiac catheterization units will be utilized at an average annual rate of over 80% of capacity in each quarter of each project year, including the third project year. Therefore, the applicant documents that the existing cardiac catheterization units at CFVMC will perform at an average annual rate of at least 60% of capacity during the fourth quarter of the third year following completion of the project.

*(3) provide documentation of all assumptions and data used in the development of the projections required in this Rule.*

-C- The applicant provides documentation of all assumptions and data used in the development of the projections in this Rule in Section III.1, pages 26 - 37.

*(d) An applicant proposing to acquire shared fixed cardiac catheterization equipment as defined in the applicable State Medical Facilities Plan shall:*

*(1) demonstrate that each proposed item of shared fixed cardiac catheterization equipment shall perform a combined total of at least 225 cardiac catheterization and angiography procedures during the fourth quarter of the third year following completion of the project; and*

-NA- The applicant proposes to acquire one additional unit of fixed cardiac catheterization equipment, not fixed shared cardiac catheterization equipment.

(2) *provide documentation of all assumptions and data used in the development of the projections required in this Rule.*

-NA- The applicant proposes to acquire one additional unit of fixed cardiac catheterization equipment, not fixed shared cardiac catheterization equipment.

*(e) If the applicant proposes to perform cardiac catheterization procedures on patients age 14 and under, the applicant shall demonstrate that it meets the following additional criteria:*

(1) *the facility has the capability to perform diagnostic and therapeutic cardiac catheterization procedures and open heart surgery services on patients age 14 and under; and*

(2) *the proposed project shall be performing at an annual rate of at least 100 cardiac catheterization procedures on patients age 14 or under during the fourth quarter of the third year following initiation of the proposed cardiac catheterization procedures for patients age 14 and under.*

-NA- The applicant does not propose to perform cardiac catheterization services on patients age 14 and under.