ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: July 29, 2016
Findings Date: July 29, 2016

Project Analyst: Tanya S. Rupp
Team Leader: Fatimah Wilson

Project ID #: M-11160-16
Facility: Central Harnett Hospital
FID #: 050926
County: Harnett
Applicant(s): Harnett Health System, Inc.
Project: Acquire one shared fixed cardiac catheterization unit pursuant to the adjusted need determination in the 2016 SMFP

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

Central Harnett Hospital (CHH) and Betsy Johnson Hospital (BJH), both located in Harnett County, make up the Harnett Health System (HHS). The applicant, HHS proposes to acquire one unit of shared fixed cardiac catheterization equipment to be located on the CHH campus pursuant to the adjusted need determination in the 2016 State Medical Facilities Plan (SMFP). Both CHH and BJH are on the same hospital license.

In 2014, Cape Fear Valley Health System (CFVHS) assumed management of CHH. CFVHS provides extensive cardiac services, including diagnostic, surgical and rehabilitation, and is combining that expertise with the cardiac services already being offered at CHH. Currently, there is no fixed or mobile cardiac catheterization equipment located in Harnett County;

therefore, CHH must transfer all of its patients, including emergency patients who are in need of cardiac services, outside the county.

In 2015, the applicant submitted a petition to the State Health Coordinating Council (SHCC) requesting an adjusted need determination for shared fixed cardiac catheterization equipment in Harnett County. The applicant's petition was subsequently approved and the adjusted need determination was included in the 2016 SMFP.

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 III.2, pages 68 - 70, the applicant describes how it believes the proposed project would promote safety and quality. Exhibit 9 contains a copy of the applicant's policies with regard to patient safety and quality and Exhibit 11 provides a copy of the applicant's *"Performance Improvement Plan"*. 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 67 - 68, Section VI, pages 84 - 93, and Exhibit 14, the applicant describes how it believes the project would promote equitable access to cardiac catheterization services in Harnett 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, pages 66 - 67, the applicant describes how it believes the proposed project would maximize healthcare value. In Exhibit 14, in its petition for an adjusted need determination, the applicant also indicates how it believes the project would maximize healthcare value for cardiac

catheterization services. 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 102, the applicant states the proposed capital expenditure is $3,280,726. In Section III.2, pages 70 – 72, the applicant describes its plan to assure improved energy efficiency and water conservation as part of the project. In Exhibit 5, the applicant provides a letter dated April 15, 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

The applicant proposes to acquire one unit of shared fixed cardiac catheterization equipment to be located on the CHH campus pursuant to the adjusted need determination in the 2016 SMFP.

Population to be Served

On page 179, the 2016 SMFP defines the service area for cardiac catheterization equipment (fixed or shared) as *"a single county, except where there is no licensed acute care hospital located within the county."* Thus, the service area for CHH is Harnett County. Providers may serve residents of counties not included in their service area.

In Sections III., page 73, the applicant provides the current (FFY 2015) patient origin for the entire hospital (currently no cardiac catheterization services are available at CHH), as summarized in the table below.

Central Harnett Hospital Current Patient Origin

COUNTY	IN PATIENT ADMISSIONS	IN PATIENT SURGERY	OUTPATIENT SURGERY	OUTPATIENT MRI	EMERGENCY DEPARTMENT
Harnett	58.65%	71.22%	62.76%	62.27%	66.37%
Johnston	8.73%	9.73%	11.65%	10.74%	6.47%
Cumberland	12.70%	5.41%	7.21%	9.50%	10.36%
Sampson	8.43%	9.59%	12.47%	9.70%	5.63%
Wake	6.28%	2.43%	1.87%	3.68%	5.54%
Lee	2.74%	0.14%	0.17%	2.13%	3.28%
All Other	2.47%	1.49%	3.87%	1.97%	2.35%
Total	100.0%	100.0%	100.0%	100.0%	100.0%

Source: table page 73. Numbers may not foot due to rounding

In Section III.5, page 75, the applicant projects the following patient origin for cardiac catheterization services at CHH:

Projected Patient Origin for Cardiac Catheterization Services FFY 2018 – 2020

COUNTY	% PATIENTS
Harnett	90.0%
Other Counties	10.0%
Total	100.0%

Source: table page 75

In Section III.5, page 75, the applicant states:

> *"To estimate patient origin for the proposed cardiac catheterization services at Central Harnett, Harnett Health reviewed patient origin for emergency services, MRI and inpatient admissions and in-migration for 11 cardiac centers in counties with only one provider of cardiac catheterization. … Average in-migration, eliminating the two highest and lowest outliers to avoid skewing the data … is greater than 30% with a range of 15.8% to 49.6%.*
>
> *Harnett Health assumes that 10% of total cardiac catheterization patients will be from outside Harnett County …."*

The applicant assumes 90% of its cardiac catheterization patients will be from Harnett County. The applicant adequately identifies the population to be served.

Analysis of Need

In Section III.1, pages 38 – 54, the applicant describes the factors which it states support the need for the proposed project, including:

- Lack of access to cardiac catheterization services in Harnett County, and the fact that patients in need of these services must travel between 34 to 72 minutes outside the county to receive these services (pages 38 – 39).

- Heart disease statistics describing the increased possibility of death when there is increased time between the onset of a cardiac incident and treatment (pages 40 -42).

- Harnett County health status and heart disease death statistics as compared to North Carolina as a whole. The applicant found that heart disease is the leading cause of death in Harnett County, while it is the number two cause of death in the state as a whole. The applicant states that these statistics and the fact that Harnett County currently has no cardiac catheterization equipment are critical to addressing the health needs of Harnett County residents. In addition, the applicant states cardiac catheterization volume for Harnett County residents in FFY 2013 to FFY 2015 ranged from 1,786 to 2,035 procedures, which included both diagnostic and interventional. The applicant states all of those patients had to be referred out of county for treatment, which increases the likelihood of death because of the lengthy travel times (pages 42 – 45).

- The population composition of Harnett County and the historical market share of cardiac catheterization services provided to residents of Harnett County at other locations. The applicant compared nine other counties in North Carolina that are similar in population numbers to Harnett County. Of those counties, there is only one that has higher cardiac mortality rates, and Harnett County is the only county with no cardiac catheterization services (pages 46 – 49).

- Among all the North Carolina Counties with populations in excess of 120,000, Harnett County is one of three without cardiac catheterization equipment. The applicant states the population growth in Harnett County necessitates cardiac catheterization equipment inside the county. In addition, the growth of the surrounding counties to which Harnett County residents travel for cardiac catheterization services (like Wake, Johnston, and Cumberland) has made travel times increasingly time-consuming and stressful for patients (pages 47 – 49).

- The population of Harnett County is increasing; the applicant states it is the fourth fastest growing county in the state. Despite this, 100% of its residents in need of cardiac catheterization services must leave the county for those services. Citing information from the North Carolina Office of State Budget and Management (OSBM), the applicant states the compound annual growth rate (CAGR) for Harnett County from 2010 to 2016 was 2.0%, which is comparable to large metropolitan counties such as Wake and Mecklenburg (pages 51 – 52).

- Harnett Health is the licensee and operator for both CHH and BJH in Harnett County. Emergency volumes at CHH have increased nearly 45% from its opening in January 2013 to 2015. The applicant states that in FFY 2015, there were nearly 65,000 emergency visits at Harnett Health hospitals (both CHH and BJH). The applicant states that of those emergency visits, cardiac patients represent the largest volume that must be transported to other locations, because Harnett County does not have cardiac catheterization services (pages 52 – 53).

Projected Utilization

In Section III.1, pages 55 - 65, the applicant projects utilization for the cardiac catheterization equipment using an eight-step methodology, summarized below.

Step 1

Using Truven inpatient and outpatient data, combined with population data from the North Carolina OSBM, the applicant calculated an historical use rate for cardiac catheterization procedures in Harnett County from FFY 2013 – 2015. Below is a table from page 56 that shows the number of cardiac catheterization procedures performed on Harnett County residents form FFY 2013 through the first nine months of FFY 2015:

Harnett County Cardiac Catheterization Use Rates (FFY 2013 – FFY 2015)

VISIT TYPE	FFY 2013	FFY 2014	FFY 2015 (9 MONTHS)
Inpatient	1,084	1,247	851
Outpatient	702	867	675
Total	**1,786**	**2,114**	**1,526**

Source: page 56

Below is a table that shows the Harnett County cardiac catheterization use rate from FFY 2013 – 2015 (annualized):

Harnett County Cardiac Catheterization Use Rate FFY 2013 – 2015 (annualized)

HARNETT COUNTY	FFY 2013	FFY 2014	FFY 2015 (ESTIMATED)
Total Harnett County cardiac catheterization procedures performed in North Carolina	1,786	2,114	2,035
Harnett County population	123,432	125,730	127,986
Cardiac catheterization use rate per 1,000 population	**14.47**	**16.81**	**15.90**

Source: page 56

Step 2

Using the use rate calculated in Step 1, the applicant calculated the three year average use rate of 15.73 [(14.47 + 16.81 + 15.90) / 3 = 15.73] from FFY 2013 – 2015. The applicant used the average to project future cardiac catheterization volume in Harnett County, as shown in the table below:

Projected Harnett County Cardiac Catheterization Utilization, FFY 2016 - 2020

HARNETT COUNTY	2016	2017	2018	2019	2020
Population	130,243	132,497	134,751	137,005	139,259
Average use rate	15.73	15.73	15.73	15.73	15.73
Projected cardiac catheterization procedures	2,048	2,084	2,119	2,155	2,190

Source: page 57

Step 3

On pages 58 – 59, the applicant states that currently 100% of Harnett County residents must travel outside of Harnett County for cardiac catheterization services. Using Truven data, the applicant determined that CFVMC's market share of those Harnett County residents receiving cardiac catheterization services has increased from 16.4% in FFY 2013 to 24.2% in the first nine months of FFY 2015. Similarly, the applicant states the market share of Harnett County residents needing cardiac catheterization services receiving treatment at WakeMed, Rex, and UNC Health Systems has decreased over the same time period (FFY 2013 – 2015). The applicant attributes the decrease in market share and the increase in market share at CFVHS to the impact of the partnership between CFVHS and CHH; particularly with regard to cardiology services. The applicant states it assumes a 40% market share of all Harnett County residents needing cardiac catheterization services by the fourth quarter of the third year of operation (FFY 2020), based on the fact that placing cardiac catheterization equipment in the county would mean that it would be closer than existing out-of-county providers for more than 90% of Harnett County residents.

In addition, the applicant examined historical market share of emergency services in Harnett County, and determined that Harnett Health (both CHH and BJH) provided emergency services to 65% - 70% of all Harnett County residents seeking emergency care in FFY 2013 – 2015. The applicant states Harnett Health also has over 9% of the emergency market share of Sampson County patients, 5% of the Johnston County and Cumberland County emergency market share, and 1.2% of the Wake County emergency market share (see page 59). The applicant also states that 240 Harnett County patients are transported annually to other counties for cardiac

catheterization procedures. Having cardiac catheterization equipment in Harnett County would retain many of those emergency patients who currently leave the county.

Step 4

The applicant takes into account the in-migration of patients from other counties who would potentially travel to Harnett County for cardiac catheterization services. The applicant states on page 60 that the locations of BJH in the eastern part of the county and CHH in the central part of the county resulted in an in-migration of 15.8% to 49.6% from other counties for most services provided at HHS facilities (particularly emergency and MRI services). In addition, the applicant states a 15 mile radius drawn from Lillington, which is nearly the center of the county, encroaches into Wake, Sampson, Cumberland and Johnston counties. The applicant thus projects that 10% of the total cardiac catheterization patients will travel to CHH from surrounding counties for cardiac catheterization services, particularly for those patients residing closer to CHH than to one of the major hospitals in a neighboring county.

Step 5

On pages 60 – 61, the applicant projects the number of patients projected to receive cardiac catheterization services at CHH in FFY 2018 – 2020, using the average market share calculated in Step 2 and population growth statistics from the North Carolina OSBM. The applicant gradually ramped up CHH's quarterly market share of Harnett County cardiac catheterization residents, beginning with 15% in the first quarter of FFY 2018, and ending with the projected 40% market share in the last quarter of FFY 2020, the third year of operation following the addition of the cardiac catheterization equipment at CHH. Similarly, the applicant applied the 10% projected in-migration from other counties from *Step 4*. See the following table from page 61:

Projected Cardiac Catheterization Volume at CHH FFY 2018 - 2020

	PY 1 – FFY 2018				PY 2 – FFY 2019				PY 3 – FFY 2020			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Quarterly volume	521	530	530	530	530	539	539	539	539	548	548	548
Market share	10%	15%	20%	25%	27%	29%	31%	33%	35%	37%	39%	40%
# Procedures Harnett County residents	52	79	106	132	143	156	167	178	189	203	214	219
In-Migration	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
Total cardiac catheterization volume	58	88	118	147	159	174	186	198	209	225	237	243

Source: page 61

Thus, the applicant projects a quarterly ramp-up in the number of cardiac catheterization procedures to be performed at CHH in the first three project years.

Step 6

With regard to peripheral angiography procedures, the applicant calculated an average use rate of 2.1 per 1,000 population. The applicant assumes the same 10% out-of-county in-migration factor for angiography procedures as it does for cardiac catheterization procedures. Thus, the

applicant projects the following number of angiography procedures in the first three calendar years of the project:

Projected Peripheral Angiography Procedures CY 2017 - 2020

	CY 2017	CY 2018	CY 2019	CY 2020
Harnett county population	132,497	134,751	137,005	139,259
Use Rate (10% of capacity)	2.1	2.1	2.1	2.1
# Procedures	278	283	288	293

Source: page 62

The applicant also provides projected utilization for the first three project years, which are FFY 2018 – 2020, as shown in the following table from page 62:

CHH Projected Peripheral Angiography Procedures, FFY 2018 - 2020

	PY 1 – FFY 2018				PY 2 – FFY 2019				PY 3 – FFY 2020			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Quarterly volume	70	71	71	71	71	72	72	72	72	73	73	73
Market share	5%	6%	7%	8%	10%	11%	12%	13%	15%	16%	17%	18%
# Procedures Harnett County residents	3	4	5	6	7	8	9	9	11	12	12	13
In-Migration	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
Total peripheral angiography volume	4	5	6	6	8	9	10	10	12	13	14	15

Source: page 62

The applicant states on page 63 that the projected market share for peripheral angiography procedures is less than the projected marked share for cardiac catheterization procedures because of the non-emergent aspect of the angiography procedures. The applicant states it used a *"conservative"* market share based on all of its inpatient and outpatient services. The data shows it ramped up in the same manner it did for cardiac catheterization services, arriving at an 18% market share of all peripheral angiography procedures performed on Harnett County residents in the last quarter of the third project year (FFY 2020).

Step 7

With regard to electrophysiology services performed on the cardiac catheterization equipment, the applicant estimates Harnett County use rate will be 3.9. The applicant assumes the same 10% out-of-county in-migration factor for electrophysiology services as it does for cardiac catheterization and peripheral angiography procedures. Thus, the applicant projects the following number of electrophysiology procedures in the first three calendar years of the project:

Projected Electrophysiology Procedures CY 2017 - 2020

	2017	2018	2019	2020
Harnett county population	132,497	134,751	137,005	139,259
Use Rate	3.9	3.9	3.9	3.9
# Procedures	516	525	534	542

Source: page 64

The applicant also provides projected utilization for the first three project years, which are FFY 2018 – 2020, as shown in the following table from page 64:

CHH Projected Electrophysiology Procedures, FFY 2018 - 2020

	PY 1 – FFY 2018				PY 2 – FFY 2019				PY 3 – FFY 2020			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Quarterly volume	129	131	131	131	131	133	133	133	133	136	136	136
Market share	5%	6%	7%	8%	10%	11%	12%	13%	15%	16%	17%	18%
# Procedures Harnett County residents	6	8	9	10	13	15	16	17	20	22	23	24
In-Migration	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
Total electrophysiology volume	7	9	10	12	15	16	18	19	22	24	26	27

Source: page 64

The applicant states it used a *"conservative"* market share based on all of its inpatient and outpatient services. The data shows it ramped up in the same manner it did for cardiac catheterization and used the same market share as it did for peripheral angiography services, which is an 18% market share of all electrophysiology procedures performed on Harnett County residents in the last quarter of the third project year (FFY 2020).

Step 8

In the last step of its methodology, the applicant added the projected number of cardiac catheterization procedures, peripheral angiography procedures, and electrophysiology procedures together for a total projected number of procedures to be performed on the proposed cardiac catheterization unit at CHH. See the following table, from page 65:

Projected Utilization – Shared Fixed Cardiac Catheterization Equipment, FFY 2018 - 2020

	PY 1 – FFY 2018				PY 2 – FFY 2019				PY 3 – FFY 2020			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Cardiac Catheterization	58	88	118	147	159	174	186	198	209	225	237	243
Peripheral Angiography	4	5	6	6	8	9	10	10	12	13	14	15
Electrophysiology	7	9	10	12	15	16	18	19	22	24	26	27
Combined quarterly total	69	102	133	165	181	199	213	227	244	262	277	285
Total projected volume				**469**				**820**				**1,068**

Source: page 65

Currently, there is no shared fixed cardiac catheterization equipment in Harnett County. In Section III.1, page 41 that there is a direct correlation between the increased time it takes to treat a person who is suffering from an ST elevated myocardial infarction (a type of heart attack) and the mortality rate from such an attack. The applicant shows that 100% of Harnett County residents currently travel out of county for cardiac catheterization procedures. Harnett County is one of the fastest growing counties in North Carolina, and the primary cause of death is Harnett County is cardiac related. Based on those statistics, as well as the market share calculated by the applicant of Harnett County residents who receive cardiac catheterization services in surrounding counties, the applicant projects it will perform 1,068 cardiac catheterization procedures by the end of the third year of operation, FFY 2020. The applicant's projections are based on historical utilization and are supported by population growth projections in the service area. Exhibit 17 contains 25 letters from local physicians in the proposed service area expressing support for the project, and

an intent to refer patients for cardiac catheterization services to CHH. Projected utilization is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to acquire one unit of fixed shared cardiac catheterization equipment.

Access

In Section VI.2, pages 84 - 85, 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 19 the applicant provides a copy of its financial policies that describe admissions criteria with regard to ability to pay. In Section VI.12, page 92, the applicant states that in FFY 2015, 53.5% of the patients who were served at HHS were Medicare beneficiaries and 21.2% were Medicaid beneficiaries. In Section VI.14, page 92, the applicant projects the same payor mix for the hospital in the second project year, based on its historical experience. In Section VI.15, page 93, the applicant projects that 48.6% of the cardiac catheterization patients to be served will be Medicare beneficiaries and 12.3% will be Medicaid recipients. The applicant states on page 93 that the projections are based on the historical experience of CFVMC Heart & Vascular Center patients from Harnett County. 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, pages 72 - 73, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Locate the Proposed Cardiac Catheterization Equipment at Betsy Johnson Memorial Hospital - the applicant states that this option is not the best to address patient needs in the county. CHH is more centrally located than BJH and thus more readily

accessible for a greater percentage of residents. In addition, CHH has existing space available that could be renovated without displacing other patients or services.

- Convert a Larger Operating Room at CHH to the Proposed Cardiac Catheterization Suite – the applicant states this is not a viable option because it would cost more than the proposed project and would not provide the best alternative for patient convenience, flow and privacy.

- Lease a Mobile Cardiac Catheterization Unit – CHH considered leasing a mobile cardiac catheterization unit and wait until volume reaches 240 procedures (the threshold number for a need determination), and then apply for a fixed shared cardiac catheterization unit. However, this was determined to be an expensive option that would not be best suited to serve Harnett County residents who need cardiac catheterization services.

After considering the alternatives, the applicant states the proposed alternative is the most effective alternative to meet the identified need.

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. **Harnett Health System, Inc. shall materially comply with all representations made in the certificate of need application.**

2. **Harnett Health System, Inc. shall acquire no more than one shared fixed cardiac catheterization unit as part of this project.**

3. **Harnett Health System, Inc. 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. **Harnett Health System, Inc. 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

In Section VIII.2, page 102, the applicant states the total capital cost is projected to be as follows:

ITEM	COST
Construction (renovation of existing space)	$ 499,207
Equipment (fixed, movable, and furniture)	$2,611,540
Miscellaneous (financing/Consultant Fees)	$ 169,979
Total Capital Costs	**$3,280,726**

In Section IX.1, page 108, the applicant projects initial operating expenses in the amount of $60,000 and start-up costs in the amount of $150,000, for a total working capital of $210,000.

Availability of Funds

In Section VIII.3, page 103, the applicant states the entire capital cost of the project will be funded with a loan from Cape Fear Valley Health System. In Exhibit 29, the applicant provides an April 15, 2016 letter from the Chief Financial Officer of Cape Fear Valley Medical Center, confirming the loan to CHH for the capital costs of the proposed project. Exhibit 29 also contains an April 15, 2016 letter signed by the interim president of Harnett Health System that commits to repay the loan to CFVHS pursuant to an interest-free loan agreement between the two facilities. Exhibit 30 contains Cape Fear Valley Medical Center's consolidated balance sheets which indicate that as of September 30, 2015, CFVMC 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 that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

In the pro forma financial statements for CHH'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.

CHH Cardiac Catheterization Services

	FFY 2018	FFY 2019	FFY 2020
Total Net Revenues	$2,910,971	$5,140,440	$6,762,061
Total Operating Expenses	$2,062,459	$2,726,984	$3,164,130
Net Income (Loss)	**$ 848,512**	**$2,413,456**	**$3,597,931**

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 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

The applicant proposes to acquire one unit of shared fixed cardiac catheterization equipment to be located on the CHH campus pursuant to the adjusted need determination in the 2016 SMFP.

On page 179, the 2016 SMFP defines the service area for cardiac catheterization equipment (fixed or shared) as *"a single county, except where there is no licensed acute care hospital located within the county."* Thus, the service area for CHH is Harnett County. Providers may serve residents of counties not included in their service area.

There are no fixed or mobile cardiac catheterization units operating in Harnett County. The applicant proposes to acquire one shared fixed cardiac catheterization unit for use at CHH. The applicant adequately demonstrates in its application that the proposed cardiac catheterization unit is needed in Harnett County, based on reasonable and adequately supported assumptions. 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 Harnett 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 94, the applicant states that it proposes 9.3 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.3, page 95, the applicant describes its experience with and process for recruiting and retaining staff. In Exhibit 26, the applicant provides a copy of the job descriptions and copies of employee orientation policies. In Section VII.8, page 99, the applicant identifies Dr. Olaleakn Folarin as Medical Director for CHH. Exhibit 17 of the application contains copies of letters from area physicians expressing support for the proposed project. Exhibit 16 contains copies of letters from other 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 27 - 28, the applicant describes the manner by which it will provide the necessary ancillary and support services. Exhibit 6 includes an April 15, 2016 letter from the CHH Administrator which describes the ancillary and support services currently available will continue to be available following the addition of the proposed shared fixed cardiac catheterization equipment. Exhibits 16 and 17 contains letters of support and referral intentions from area physicians and other local health care providers. 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 1,285 square feet of existing space to develop a cardiac catheterization suite at CHH. Exhibit 5 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 102 of the application. In Exhibit 5, the architect also describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. 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 92, the applicant reports the following payor mix for the entire hospital (currently no cardiac catheterization services are available at CHH) for FFY 2015:

PAYOR CATEGORY	% TOTAL UTILIZATION
Self-Pay/Indigent/Charity	7.5%
Medicare/Medicare Managed Care	53.5%
Medicaid	21.2%
Commercial Insurance	7.9%
Managed Care	3.2%
Other	6.7%
Total	**100.0%**

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****
Harnett	11%	51%	37%	21%	10%	19%
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 91, the applicant states:

> *"Harnett Health has no obligation under any applicable Federal regulation to provide uncompensated care. However, Harnett Health provided $60,089,614 in charity care and bad debt during FY 2015. As a responsible member of the community, Harnett Health 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 91, the applicant states that no civil rights complaints were filed against Harnett Health 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, pages 92 - 93, the applicant projects payor mix during the second year of operation following project completion for the entire hospital and for cardiac catheterization services, which are shown in the following tables.

CHH Entire Facility Payor Mix FFY 2019

PAYOR CATEGORY	% TOTAL UTILIZATION
Self-Pay/Indigent/Charity	7.5%
Medicare/Medicare Managed Care	53.5%
Medicaid	21.2%
Commercial Insurance	7.9%
Managed Care	3.2%
Other	6.7%
Total	**100.0%**

CHH Cardiac Catheterization Services
Payor Mix FFY 2019

PAYOR CATEGORY	% TOTAL UTILIZATION
Self-Pay/Indigent/Charity	5.9%
Medicare/Medicare Managed Care	48.6%
Medicaid	12.3%
Commercial Insurance	25.9%
Managed Care	0.0%
Other	7.3%
Total	**100.0%**

As shown above, the applicant projects that 60.9% of all cardiac catheterization procedures to be provided will be provided to recipients of Medicare/Medicaid.

The applicant demonstrates that medically underserved populations will have adequate access to the cardiac catheterization services to be offered at CHH. 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, pages 90 - 91, the applicant describes the range of means by which a person will have access to CHH's cardiac catheterization services. 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 78, the applicant states that it already has established relationships with Campbell University and Central Carolina Community College, and will continue those relationships following completion of the project. Exhibit 20 contains copies of correspondence from Campbell University and Cape Fear Valley Medical Center, confirming that they will utilize CHH as a clinical training site for cardiac catheterization nursing 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

Central Harnett Hospital (CHH) and Betsy Johnson Hospital (BJH), both located in Harnett County, make up the Harnett Health System (HHS). The applicant, HHS proposes to acquire one unit of shared fixed cardiac catheterization equipment to be located on the CHH campus pursuant to the adjusted need determination in the 2016 State Medical Facilities Plan (SMFP). Both CHH and BJH are on the same hospital license.

On page 179, the 2016 SMFP defines the service area for cardiac catheterization equipment (fixed or shared) as *"a single county, except where there is no licensed acute care hospital located within the county."* Thus, the service area for CHH is Harnett County. Providers may serve residents of counties not included in their service area.

There are no fixed or mobile cardiac catheterization units in Harnett County. The applicant proposes to acquire one shared fixed cardiac catheterization unit for use at CHH. In Section V.7, pages 81 - 82, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

"Currently, residents of Harnett County must leave the county and travel for cardiac catheterization, often in urgent or emergency situations. The proposed cardiac

catheterization equipment will be the only cath lab in the service area. However, patients will continue to have a choice and can elect to go out of the service area if they choose. Harnett Health and its partner CFVHS have carefully designed the project [to provide] *high quality care at a competitive price in a more geographically* [accessible] *location."*

See also Sections II, III, V, VI and VII where 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 29 - 30, and Section III, pages 68 - 69 the applicant describes the methods used by CHH to insure and maintain quality care. See also Exhibits 8, 9, and 10. In Section I.6, page 29, the applicant states Harnett Health does not own any other licensed health service facility in North Carolina or in any other state, other than CHH and BJH. In Section II.7(c), page 31, the applicant states none of the facilities associated with Harnett Health 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;

(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;

(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;

(4) at least 50 percent of the projected cardiac catheterization procedures shall be performed on patients residing within the primary cardiac catheterization service area;

-NA- The applicant proposes to acquire shared fixed cardiac catheterization equipment.

(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 shared fixed 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;

(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

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

-NA- The applicant proposes to acquire shared fixed cardiac catheterization equipment.

(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

-C- In Section II, page 36, the applicant projects that the proposed shared fixed cardiac catheterization equipment shall perform a combined total of 285 cardiac catheterization and angiography procedures during the fourth quarter of the third year following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section II, page 36, and in Section III.1, pages 38 - 65, the applicant provides all of its assumptions and data it used in the development of the projections used in this rule. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(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.