ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: September 6, 2013

PROJECT ANALYST: Jane Rhoe-Jones
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: P-10116-13 / Carteret County General Hospital Corporation d/b/a Carteret General Hospital / Acquire one unit of shared fixed cardiac catheterization equipment / Carteret County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

As a result of an adjusted need determination petition, the 2013 State Medical Facilities Plan (SMFP) identifies a need determination for one unit of shared fixed cardiac catheterization equipment in the Carteret County cardiac catheterization service area. Carteret County General Hospital Corporation d/b/a Carteret General Hospital (CGH) proposes to acquire one unit of shared fixed cardiac catheterization equipment. CGH is a 135-bed acute care hospital located at 3500 Arendell Street, Morehead City, in eastern North Carolina.

CGH's proposal to acquire one unit of shared fixed cardiac catheterization equipment to be located in the Carteret County cardiac catheterization service area is conforming to the applicable adjusted need determination in the 2013 SMFP. CGH proposes to renovate and expand its current imaging department for the new equipment which will perform both cardiac catheterization and angiography procedures. Although cardiac catheterization services will be a new institutional health service for CGH, the hospital has been providing angiography services for 24 years (since 1989) and proposes to replace angiography equipment which has been in service for 17 years.

There are two policies in the 2013 SMFP applicable to this proposal – Policy GEN-3 and Policy Gen-4.

Policy GEN-3: Basic Principles, pages 42-43 of the 2013 SMFP 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 100-101, regarding safety and quality, the applicant states:

> "*CGH was recognized for it achievement in implementing the American Heart Association/American Stroke Association's Get with the Guidelines for coronary artery disease and heart failure. CGH earned the GOLD award for heart failure in both 2011 and 2012. It is recognized as a Center of Excellence for Stroke. … In 2012, CGH was named on of the top hospitals in the state in managing transitions in care and reducing readmissions, and in 2013 CGH became a participant in the Lean Collaborative program sponsored by the North Carolina Hospital Association. The latter will help CGH sustain efficiency while meeting evidence-based care guidelines.*
>
> …
>
> *In a planning context, this request meets the standards of safety and quality. It moves Carteret County closer to the American Heart Association (AHA) cardiac care standard of 30 minutes door to treatment for STEMI patients. It would put cardiac catheterization service at a county hospital that exceeds CMS minimum quality standards and has been recognized as a Gold Standard for heart care.*
>
> …
>
> *Invasive cardiologists on the CGH medical staff whose group also services CarolinaEast will assure that physicians can maintain volume required to sustain skill levels. Carteret General has demonstrated willingness to partner with top level tertiary providers to maintain technician competency. …*"

In Section V.7, page 135, the applicant states,

> "… *The project will significantly improve local cardiac care program quality. By enabling more patients to remain in the county for cardiac care, CGH will improve the standard of care available within 30 minutes reach of most Carteret County and many Onslow County residents. Persons who have vascular disease will be more comfortable staying in the community for their total care, thus improving coordination of all of their medical treatments. The project will be part of CGH commitment to high scores in quality benchmarking programs. … Please see Exhibit 16 for CGH scores in its cardiac care core measures. …*"

The applicant adequately demonstrates that the proposed project will promote safety and quality in the delivery of health care services.

Promote Equitable Access

In Section III.2, page 102, regarding access, the applicant states,

> "*CGH uses strategies and activities to assure that physicians and medical staff provide care to all patients including the medically underserved. Financial and charity policies are described in Exhibit 33 and Patients Rights are described in Exhibit 32.*
>
> *A shared fixed cardiac catheterization laboratory in Carteret County would remove a geographic isolation barrier and enable … community access to provide a diagnostic service that has demonstrated demand among residents of the county.*
>
> …
>
> *As noted in Section VI.2. CGH has a policy of accessibility to all persons regardless of race, gender, religion, disability, or source of coverage. CGH proposes a high ration of Medicare and Medicaid beneficiaries among users of the proposed services …*"

See Section VI, pages 139-149 for more in-depth information regarding access to the applicant's services to low income and underserved persons (also via community programs), women, racial and ethnic minorities, handicapped persons, elderly, means of access to services, working and referral agreements with other healthcare providers, existing and proposed payor mix, etc. Also in Section VI, page 138, the applicant states that each category of underserved persons has access to emergency services at CGH under Emergency Medical Treatment and Active Labor Act (EMTALA) regulations.

The applicant adequately demonstrates that the proposal will promote equitable access to services for patients with limited financial resources and availability of capacity to provide these services.

Healthcare Value

In Section III, page 102, the applicant states,

> "*The shared fixed cardiac catheterization/angiography equipment offers economy of scale that offsets smaller volumes of cardiac catheterization procedures with other vascular procedures*."

In SectionV.7, page 134, CGH discusses cost effectiveness and states,

> "*By financing the project with cash and containing capital expenditures within a target budget, CGH will need minimal increases in patient care charges to offset the costs.*"

The applicant further states that economies of scale can be achieved in staffing costs and in the costs of providing the service because the same technical and nursing staff can provide care to both the cardiac and vascular patients. This proposed service will also give patients the option to seek care in their community versus incurring the costs of traveling to academic medical centers.

The applicant adequately demonstrates that the proposed project will promote equitable access and maximize healthcare value for resources expended.

The application is consistent with Policy GEN-3.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, page 44 of the 2013 SMFP states:

> "*Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*
>
> *In approving certificate of need proposing an expenditure greater than $5million 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 exceed energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*
> *Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described*

in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

In Section III.2, page 102, regarding Policy GEN-4, the applicant states:

"*Please see Section XI.7 for the written outline statement describing the project's plan to assure improved energy efficiency and water conservation. The plan does not adversely affect patient or resident health, safety or infection control*. …"

In Section XI.7, pages 187-188, CGH includes a written statement describing the energy efficiency and water conservation components of this project.

The application is conforming to Policy GEN-4.

In summary, the application is consistent with Policies GEN-3 and GEN-4 and is conforming to the adjusted need determination in the 2013 SMFP for one unit of shared fixed cardiac catheterization equipment in the Carteret County cardiac catheterization service area. 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

CGH proposes to acquire one unit of shared fixed cardiac catheterization equipment. CGH will initially provide diagnostic procedures only and will acquire equipment that is capable of both cardiac catheterization and angiography services upon completion of the project. Cardiac catheterization services will be a new service at CGH and in Carteret County. CGH has provided angiography services since 1989. CGH also proposes to replace the existing angiography equipment that CGH has been using for 17 years and add 5,422 square feet to the hospital's existing imaging department, where the new equipment will be housed. Currently, the closest provider of cardiac catheterization services is CarolinaEast Medical Center located in the Craven/Pamlico/Jones service area.

On page 25, the applicant states,

"*the proposed shared fixed cardiac catheterization equipment will allow CGH to offer expanded services for the diagnosis and treatment of vascular disease, including peripheral vascular disease. Peripheral vascular disease shares the same risk factors as coronary artery disease and the diseases often occur together.* …

The laboratory may also be used for pacemaker insertion and repair, procedures that occur only in the operating rooms at CGH at present."

Existing angiography services include:

- Vascular angioplasty, including femoral, iliac, peripheral, extremity, and renal arteries and veins
- Arterial embolization
- Arteriograms – peripheral, extremity, pulmonary, vascular and renal
- Aortagrams
- Biopsy
- Cholangiograms
- Nephrostomy tube placement
- Aortic and celiac arch evaluations
- Splenic, vertebral and subclavian artery evaluation
- Arterial stent placement
- Vertebroplasty
- Porta Cath evaluation

Proposed angiography services include:

- Advanced visualization including peripheral and internal vascular angiography and vascular stenting.

CGH plans to renovate the imaging department and add 5,422 square feet to it. This location is near the emergency department and accessible to the new outpatient registration area. Exhibit 8 includes the proposed floor plans.

Population to be Served

In Section III.5(a), page 108, the applicant states that the current patient origin for angiography services consists of: 97% from Carteret, Craven and Onslow counties, less than 2% from other North Carolina Counties; and less than 2% from out of state.

In Section III.5(a), page 108, regarding the new cardiac catheterization service, the applicant states,

"*The proposed service area for a shared fixed cardiac catheterization laboratory, as defined by the 2013 State Medical Facilities Plan is Carteret County.*

The primary service area is within 23 miles of Carteret County. CGH has conservatively excluded parts of Craven County that are inside this boundary because of the active cardiac care program at CarolinaEast Medical Center in New Bern.

For angiography services, CGH has included the traditional CGH service area which does include parts of Craven County including Newport and Havelock."

In Section III.5(c), pages 109-110, the applicant provides the projected patient origin for the new cardiac catheterization service and for the existing angiography service. In Section III.5(d), pages 110-112, the applicant provides the assumptions and methodology used to project patient origin. The projections are shown below in the following two tables.

CGH Cardiac Catheterization
Projected Patient Origin
Project Year 1 (2015) & Year 2 (2016)

County	Year 1 Projected Lab Procedures	Year 1 % Lab Procedures	Year 2 Projected Lab Procedures	Year 2 % Lab Procedures
Carteret	123	71.1%	187	78.6%
Craven	0	0.0%	0	0.0%
Onslow	47	26.9%	46	19.4%
Other*	3	2.0%	5	2.0%
Total	173	100.0%	238	100.0%

*****Other includes NC counties: Duplin, Guilford, Jones, Macon, Nash, Orange, Pamlico, Pender, Pitt, Surry, Transylvania, Wake, Wayne, and out of state. The applicant states that patient origin depicted in *Other* will vary from year to year.

CGH Angiography
Projected Patient Origin
Project Year 1 (2015) & Year 2 (2016)

County	Year 1 Projected Lab Procedures	Year 1 % Lab Procedures	Year 2 Projected Lab Procedures	Year 2 % Lab Procedures
Carteret	296	76.5%	446	76.4%
Craven	27	7.0%	41	7.0%
Onslow	43	13.3%	65	13.3%
Other*	13	3.3%	19	3.3%
Total	387	100.0%	583	100.0%

*****Other includes NC counties: Duplin, Guilford, Jones, Macon, Nash, Orange, Pamlico, Pender, Pitt, Surry, Transylvania, Wake, Wayne, and out of state. The applicant states that patient origin depicted in *Other* will vary from year to year.

The applicant adequately identifies the population proposed to be served.

Need for Shared Fixed Cardiac Catheterization Equipment

In Section III.1, pages 66-99, the applicant discusses the need/demand for cardiac catheterization services in Carteret County, the need/demand for angiography services; and the need to locate the cardiac catheterization services at CGH versus elsewhere in the service area. The following is a brief summary of that discussion.

On page 66, the applicant states, "*The 2013 SMFP identifies an adjusted need determination for one unit of shared fixed cardiac catheterization equipment in Carteret County (Table 9Z). This adjusted need was included in response to a Petition filed by Carteret General Hospital in 2012*."

Also on page 66, the applicant lists several factors to justify need for the shared fixed cardiac catheterization equipment at CGH, including:

1. Cardiac catheterization services are not available in Carteret County
2. Age and health status of the Carteret County population
3. Demographics and geography of Carteret County
4. History of out of area referrals to CarolinaEast Medical Center

See pages 69-77, for the applicant's discussion of each of these factors The following are highlights of the information and data presented:

- According to the NC Center for Health Statistics, the heart disease death rate for Carteret County was 49% higher than the state for the years 2007-2011 – Carteret County had 272.2 deaths per 100,000 compared to 183.6 for the state.
- According to *2012 State of the County Health Report, Carteret County*, between 2006 and 2010, heart disease (32%) and vascular disease (8%) combined caused more deaths than cancer (35%).
- Carteret General Hospital is the only acute care hospital in Carteret County and the closest hospital to Morehead City. CGH is also the closest to Havelock and Newport in Craven County; and within 23 miles of Swansboro in Onslow County.
- The North Carolina Office of Budget and Management (NCOSBM) forecasts population growth and aging in Carteret County. Carteret County population is older and growing faster than the state average (OSBM January 2013).

On page 78, the applicant states that CGH already has several elements of a strong cardiac care program which include:

- Mobile emergency care staffed with advanced life support (ALS) trained paramedics
- Critical Care Unit (CCU)
- Board certified cardiologists trained in diagnostic cardiac catheterization
- Cardiac rehabilitation
- Thrombolytic therapy
- Pacemaker implantation
- Angiography

On pages 87-98, the applicant provides statistical data which shows an unmet need for cardiac catheterization and angiography services at CGH. On page 87, the applicant states that the population of the primary service area will need 644 cardiac catheterizations in 2017. The applicant used the data in Table 9S in the 2013 SMFP to calculate a statewide cardiac catheterization use rate which was held constant and applied to the projected population of the primary service area.

In Section III, pages 88-89, the applicant discusses the number of cardiac catheterization procedures performed on residents of Carteret County at CarolinaEast Medical Center (CEMC). Specifically, CGH states that in Project ID# P-10082-13, CEMC states 341 diagnostic cardiac catheterizations were performed at CEMC on Carteret County residents in 2012. Moreover, the applicant states that according to data obtained from Truven, 769 Carteret County residents had a cardiac catheterization procedure in 2011. All of these Carteret County residents had to leave the county for their cardiac catheterization procedure.

On page 83, the applicant states,

> "*Carteret General has had an angiography laboratory since 1989. It was last replaced in 1996, … The equipment's age equates to more that 50% downtime, maintenance costs have spiraled, and replacement parts are no longer available. The community would benefit from an investment that serves both cardiac and vascular patients, many of whom have the same chronic disease.*
>
> *With improved capabilities, a CGH shared fixed cardiac catheterization laboratory would have capability for procedures like vascular repair, pacemaker insertions, and vascular access stents, which can only be done in the operating room today. It could also offer varicocele repairs, treatment of uterine fibroids, AV shunts for patients on chronic end stage renal dialysis, and intra-arterial tPA therapy*. …"

On page 93, the applicant states,

> "*Need for angiography procedures is more difficult to estimate, because the North Carolina Licensure Renewal applications do not consistently collect this information. CGH has estimated this need from use rates for vascular disease and pacemakers that were reported by several different sources*.
>
> *Uterine Fibroids*
> *Uterine Fibroids are the most common neoplasm in females, and may affect about 25 percent of white women and 50 percent of African American women during their reproductive years (Wallach EE, Vlahos NF [August 2004]. 'Uterine myomas: an overview of development, clinical features, and management.' Obstet Gynecl 104 [2]): 393-406…). Removal of the fibroid by uterine artery embolization is a more favorable treatment than hysterectomy, because it leaves the uterus intact. At these prevalent rates, CGH calculated persons in need in Craven, Onslow and Carteret Counties.*
>
> *According to data from NCOSMB, the three primary counties served by CGH have approximately 20,000 females of childbearing age … At reported fibroid rates, 28 percent (0.5 x 10% + 0.25 * 90%) will have uterine fibroids. If only 2 percent require treatment, the need would be 115 cases from the FY 2017 market share of the population served by CGH. Please see Exhibit 24 for detailed calculations.*

…

Vascular Disease
Atherosclerosis is a disease of the vascular system that results in reduced blood floow [sic] *and ultimately tissue disease and destruction. The main risk factors are cigarette smoking, diabetes mellitus, hypertension and hyperlipidemia. …*

As noted in Exhibit 28, Carteret and Onslow County death rates from cardiovascular disease exceeded the North Carolina 2010 average of 300 and the US Average of 291.1 per 100,000. Rates in Craven County approximate the state average. Results of the disease include stroke, congestive heart failure and death. …

…

Treatment for vascular disease involves revascularization, thrombolytic agents like tissue-plasminogen delivery to break up clots, and vascular angioplasty. Repairs can occur in vital organs, limbs, extremities and in the cerebrovascular system."

In Section III, pages 95-98, the applicant provides the assumptions and methodology used to determine the use rate for vascular angiography services in Carteret County.

Projected Utilization

In Section IV.1, pages 115-124, the applicant provides projected utilization and the assumptions and methodology used to project utilization for the proposed shared fixed cardiac catheterization equipment. Each methodology is described below:

Cardiac Catheterization – Methodology and Assumptions

- Step 1. Obtain Carteret and Onslow county population data from the North Carolina Office of State Budget and Management (NCOSBM). CGH assumes no procedures from Craven County because of CarolinaEast Medical Center's cardiac care program.
- Step 2. Estimate Carteret and Onslow county diagnostic cardiac catheterization use rates for fiscal years 2015-2017.
- Step 2a. Calculate the state use rate and rate of annual percent change for diagnostic cardiac catheterizations using data in Table 9S of the SMFP and the NCSOBM population data.
- Step 2b. Calculate a statewide trend rate for diagnostic cardiac catheterizations. The applicant states that the trend of a decrease in the use rate is slowing down.
- Step 2c. For Carteret County, CGH used the statewide forecasted use rate for FY 2015 (5.74 per 1,000 population). For Onslow County, CGH used the statewide forecasted use rates for FY 2015-2017, which decline slightly each year. The applicant holds the use rate constant for Carteret County due to a higher median age of the population and a higher county use rate.
- Step 3. Estimate adult diagnostic cardiac catheterization volumes in Carteret and Onslow counties. Multiply the populations in Step 1 by the use rates in Step 2. See the table below from page 119. Note: CarolinaEast Medical Center stated in its certificate of need application for cardiac catheterization equipment (P-10082-13), that diagnostic procedures

currently performed there would go to CGH when the CGH cardiac catheterization program begins.

Estimated Adult Diagnostic Cardiac Catheterization Procedures (all facilities) FY 2015 - FY2017			
County	**2015**	**2016**	**2017**
Carteret	411	416	422
Onslow	1,145	1,137	1,132
Total	1,556	1,553	1,554

- Step 4. Estimate the CGH market share for Carteret and Onslow counties. See the table below from page 119 of the application. Assumption: Carteret County market share will grow by 15% in the first project year and 7% in the subsequent two project years. Onslow County market share will remain constant although Onslow County has very little activity in the cardiac catheterization program in the county. Furthermore, the applicant states only part of Onslow County is in CGH's 23 mile radius primary service area. The applicant stated that assumptions were based on the acute care patient origin reported on the license renewal applications for Carteret General Hospital and Onslow Memorial Hospital.

Carteret General Hospital Estimated Market Share: Adult Diagnostic Cardiac Catheterization Procedures FY 2015 - FY2017			
County	**2015**	**2016**	**2017**
Carteret	30.0%	45.0%	52.0%
Onslow	4.1%	4.1%	4.1%
Total	34.1%	49.1%	56.1%

- Step 5. Calculate the number of cardiac catheterization procedures to be performed at CGH. Multiply the results of Step 3 by the results of Step 4.
- Step 6. Calculate the number of out of area cardiac catheterization procedures. CGH assumes out of area will equal 2% of the total.

Carteret General Hospital Adult Diagnostic Cardiac Catheterization Procedures FY 2015 - FY2017			
County	**2015**	**2016**	**2017**
Carteret	123	187	219
Onslow	47	46	46
Out of Area	3	5	5
Total	173	238	271

Angiography – Methodology and Assumptions

- Step 1. Estimate Carteret County angiography use rates per 1,000 population for 2015-2017. The tables below are from pages 121-122 of the application.

Carteret County Estimated Angiography Use Rates per 1,000 Population 2015-2017							
Year	**2004 Peripheral Vascular**	**Uterine Fibroid Repair**	**Pacemaker**	**Varicocele Repair**	**Total**	**Annual Rate Reduction**	**Adjusted Angiography Procedures/1000**
2015	10.90	1.86	1.36	.408	14.5	1.0%	13.81
2016	10.90	1.86	1.36	.408	14.5	1.0%	13.67
2017	10.90	1.86	1.36	.408	14.5	1.0%	13.53

Carteret County Pacemaker Rate		
	FY 2010	**FY 2011**
Procedures	105	92
Procedures/1000	1.57	1.36

- Step 2. Estimate Angiography Procedures in Carteret County. The table below is from page 122 of the application.

Estimated Carteret County Angiography Procedures Project Years 2015-2017			
Year	**Estimated Angiography Procedures per 1,000 Population**	**Carteret County Population**	**Estimated Carteret Angiography & Pacemaker Procedures**
2015	13.8	71,522	988
2016	13.7	72,482	991
2017	13.5	73,439	994

- Step 3. Estimate CGH's market share for Carteret County angiography procedures. Assumption: both angiography and cardiac catheterization services will grow at the same rate and market share. The angiography program is treated as a new program because of significant improvement in capability of the equipment.
- Step 4. Estimate the percentage of forecasted CGH procedures that are from Carteret County. Assumption: 2012 percentage of Carteret County inpatient days at CGH (76.3%).
- Step 5. Calculate the number of angiography procedures to be performed at CGH. The table below is from page 123 of the application.

Estimated Carteret General Hospital Angiography Procedures Project Years 2015-2017			
Year	**Estimated Angiography Procedures per 1,000 Population**	**Carteret County Population**	**Estimated Carteret Angiography & Pacemaker Procedures**
2015	296	76.3%	388

2016	446	76.3%	584
2017	13.5	76.3%	677

- Step 6. Estimate the number of pacemaker insertions/implants by multiplying angiography procedures by estimated percentage of pacemakers. Assumption: pacemaker insertions/implants represent a small percentage of total angiography procedures. Assumption: because this service has traditionally been performed by general surgeons, some referring physicians may prefer to continue in that manner. Thus, the number of pacemaker insertions/implants to be performed in the proposed shared fixed cardiac catheterization laboratory will increase more slowly than other angiography procedures. The table below is from page 124 of the application.

Carteret General Hospital Estimated Angiography Procedures & Percentages Project Years 2015-2017			
	2015	**2016**	**2017**
Procedures	18	22	23
Percentage	5.0%	4.0%	3.5%

- Step 7. Subtract the number of pacemaker inserts/implants from total angiography procedures. The table below is from page 124 of the application.

Carteret General Hospital Angiography & Pacemaker Procedures Project Years 2015-2017			
	2015	**2016**	**2017**
Other Angiography	369	562	654
Pacemakers	18	22	23
Total	387	584	677

- Step 8. Assumption: some procedures performed with current angiography equipment may be done more cost effectively with other existing hospital equipment at CGH. This explains the drop in interim year procedures depicted in the table on page 126 (Fiscal Year 2012 – 596 angiography procedures; Interim Fiscal Years 2013 and 2014 – 258 angiography procedures).

The following table illustrates historical and projected utilization as reported on page 126 of the application.

Carteret General Hospital Cardiac Catheterization and Angiography Utilization Current & Projected						
Cardiac Catheterization	**FY 2011**	**FY 2012**	**Interim 2013 & 2014**	**Project Year 2015**	**Project Year 2016**	**Project Year 2017**
# Units	0	0	0	1	1	1
# Diagnostic Procedures	0	0	0	173	238	271
# Therapeutic Procedures	0	0	0	0	0	0

# Diagnostic Equivalent Procedures	0	0	0	173	238	271
Angiography						
# Units	1	1	1	See above	See above	See above
# Angiography Procedures	354	596	258	369	561	654
# Pacemakers	0	0	0	18	22	23
Total	354	596	258	387	583	677
All Procedures						
# Units	1	1	1	1	1	1
# Procedures	354	596	258	560	821	948
Compound annual growth rate FY 2012 – FY 2017						9.7%

In Section II, page 60, CGH projects that the proposed shared fixed cardiac catheterization equipment will perform 246 cardiac catheterization and angiography procedures during the fourth quarter of the third project year which exceeds the 225 required by 10A NCAC 14C .1603(d)(1). CGH adequately demonstrates that the projected utilization is based on reasonable, credible and supported assumptions.

In summary, CGH adequately identifies the population to be served and adequately demonstrates the need that population has for the proposed shared fixed cardiac catheterization equipment. 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.

C

In Section III.3, pages 103-106, the applicant discusses the alternatives to the proposed project that were considered prior to submission of this application and the basis for selecting to proceed with the proposed project.

- The first alternative that CGH considered is maintaining the status quo. However, CGH states,

> "*CGH considered and rejected the status quo. It represents an inconvenience and access barrier for patients, and does not meet the North Carolina standard of cardiac care for comparable sized communities. As a result, cardiac care is the number one cause of hospital outmigration for Carteret County residents. As demonstrated in Section III.1, Carteret County alone has a significant number of patients who seek cardiac catheterization services.*
>
> *CGH currently provides many of the alternatives to cardiac catheterization such as transesophageal echocardiogram (ECG), CT scan or MRI, Nuclear scan stress test, stress thallium and spiral CT (computed tomography) scanning.*
>
> *At this time, cardiac catheterization is the most accurate test for looking at coronary arteries and identifying the location, number, and severity of blockages that are affecting heart muscle. …*
>
> *Data from CarolinaEast and Truven indicate significant numbers of patients are leaving Carteret County each year to get diagnostic catheterization. CGH determined that cardiac catheterization is essential for the hospital.*

- The second alternative that CGH considered is stand-alone cardiac catheterization equipment for a dedicated cardiac catheterization laboratory, but concluded that single use equipment would not adequately serve their patient population.

- The third alternative that CGH considered is angiography hemodynamic monitoring. However, the hospital concluded that procedures performed in this way take longer, involve additional risk for the patient and are more expensive.

- The fourth alternative that CGH considered is performing therapeutic cardiac catheterizations, but at the time the application was submitted, such a proposal could not be approved.
- The fifth alternative that CGH considered is a joint venture with an existing owner of mobile cardiac catheterization equipment. The applicant chose not to pursue this alternative and states,

> "*Cardiac events do not schedule themselves to fit mobile unit schedules. Continuous quality assurance and quality improvement is difficult to maintain and enforce; and there is significant demand in a growing and aging community. CGH believes it can operate more efficiently and provide better quality with its own resources.*"

- The sixth alternative that CGH considered is vendor financing, but deems it more cost effective to use the hospital reserves to finance the project.
- The seventh alternative that CGH considered is to work with others in development of the program. The hospital will work with its physicians and comprehensive cardiac

care hospitals to ensure that CGH's patients will have the best possible care at CGH or be transferred elsewhere if necessary.

CGH states the most cost effective alternative is to develop a shared fixed cardiac catheterization program. The applicant states,

> "*… acquisition of fixed equipment that can be used for both cardiac catheterization and non-cardiac angiography … is the most cost effective solution. This will permit CGH to serve people with vascular disease, to have a single technical staff trained for both cardiac and vascular programs …*
>
> *Construction of a new addition proved the most effective of the construction alternatives considered. The chosen Option D, avoided relocation costs of other departments … and disruptive internal renovation.*"

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

The applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Carteret County General Hospital Corporation d/b/a Carteret General Hospital shall materially comply with all representations made in the certificate of need application.**

2. **Carteret County General Hospital Corporation d/b/a Carteret General Hospital shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and which would otherwise require a certificate of need.**

3. **Carteret County General Hospital Corporation d/b/a Carteret General Hospital shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing to the Certificate of Need Section 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.

In Section VIII.2.C, pages 169-170, the applicant states that the total capital cost of the project is $4,925,862, and will be funded through accumulated reserves. The capital costs include the following:

Carteret General Hospital Cardiac Catheterization and Angiography Capital Costs	
Construction contract	$1,907,571
Fixed equipment	$1,863,791
Consulting fees (architectural/engineering, CON preparation)	$ 739,500
Contingency	$ 400,000
Landscaping	$ 15,000
Total Capital Cost	$4,925,862

In Exhibit 7, CGH provides an equipment cost worksheet for the proposed cardiac catheterization equipment. In Section IX, page 175, the applicant states that the start-up expenses associated with this project are $216,829. Exhibit 39 contains an April 1, 2013 letter from the CGH Chief Financial Officer, which states in part:

> "*… The project will be financed with Carteret County General Hospital Incorporated accumulated reserves. … Please see the line item 'Cash and Cash Equivalents' on the Fiscal Year 2012 audited Balance Sheet … The amount of $79,654,196 is more than sufficient to cover the capital costs and working capital requirements oft the project ...*"

Exhibit 40 contains the most recent audited financial statements (which are reported in thousands) for Carteret County General Hospital, Inc. Exhibit 40, page 905, indicates that, as of September 30, 2012, Carteret County General Hospital, Inc. had $106,631,804 in total current assets; including $79,654,196 in cash and cash equivalents.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the proposed project.
In Form D, pages 202-207, the applicant provides the projected average charge as shown in the following tables:

Carteret General Hospital Cardiac Catheterization Projected Average Charge by Payor			
Project Year 1 (10/1/2014 - 9/30/2015)			
	% of Total	**# of Cases**	**Projected Average Charge**
Medicare	61.1%	106	$10,039
Commercial	21.1%	37	$10,039
Self Pay	8.2%	14	$10,039
Medicaid	5.3%	9	$10,039
Tricare	4.3%	7	$10,039
Total	100.0%	173	
Project Year 2 (10/1/2015 - 9/30/2016)			
	% of Total	**# of Cases**	**Projected**

			Average Charge
Medicare	61.1%	146	$10,441
Commercial	21.1%	50	$10,441
Self Pay	8.2%	20	$10,441
Medicaid	5.3%	13	$10,441
Tricare	4.3%	10	$10,441
Total	100.0%	238	
Project Year 3 (10/1/2016 - 9/30/2017)			
	% of Total	**# of Cases**	**Projected Average Charge**
Medicare	61.1%	165	$10,859
Commercial	21.1%	57	$10,859
Self Pay	8.2%	22	$10,859
Medicaid	5.3%	14	$10,859
Tricare	4.3%	12	$10,859
Total	100.0%	271	

Carteret General Hospital Angiography Projected Average Charge by Payor			
Project Year 1 (10/1/2014 - 9/30/2015)			
	% of Total	**# of Cases**	**Projected Average Charge**
Medicare	61.1%	225	$9,807
Commercial	21.1%	78	$9,807
Self Pay	8.2%	30	$9,807
Medicaid	5.3%	20	$9,807
Tricare	4.3%	16	$9,807
Total	100.0%	369	
Project Year 2 (10/1/2015 - 9/30/2016)			
	% of Total	**# of Cases**	**Projected Average**

			Charge
Medicare	61.1%	343	$10,199
Commercial	21.1%	118	$10,199
Self Pay	8.2%	46	$10,199
Medicaid	5.3%	30	$10,199
Tricare	4.3%	24	$10,199
Total	100.0%	561	
Project Year 3 (10/1/2016 - 9/30/2017)			
	% of Total	**# of Cases**	**Projected Average Charge**
Medicare	61.1%	399	$10,607
Commercial	21.1%	138	$10,607
Self Pay	8.2%	54	$10,607
Medicaid	5.3%	35	$10,607
Tricare	4.3%	28	$10,607
Total	100.0%	654	

Carteret General Hospital Pacemaker Projected Average Charge by Payor			
Project Year 1 (10/1/2014 - 9/30/2015)			
	% of Total	**# of Cases**	**Projected Average Charge**
Medicare	61.1%	11	$25,958
Commercial	21.1%	4	$25,958
Self Pay	8.2%	2	$25,958
Medicaid	5.3%	1	$25,958
Tricare	4.3%	1	$25,958
Total	100.0%	18	
Project Year 2 (10/1/2015 - 9/30/2016)			

	% of Total	# of Cases	Projected Average Charge
Medicare	61.1%	14	$26,997
Commercial	21.1%	5	$26,997
Self Pay	8.2%	2	$26,997
Medicaid	5.3%	1	$26,997
Tricare	4.3%	1	$26,997
Total	100.0%	22	
Project Year 3 (10/1/2016 - 9/30/2017)			
	% of Total	**# of Cases**	**Projected Average Charge**
Medicare	61.1%	14	$28,077
Commercial	21.1%	5	$28,077
Self Pay	8.2%	2	$28,077
Medicaid	5.3%	1	$28,077
Tricare	4.3%	1	$28,077
Total	100.0%	23	

The financial pro formas (Forms A-E) are found on pages 193-212 of the application. The table below illustrates revenues and expenses for the entire hospital and for the cardiac catheterization and angiography service component for each of the first three project years.

Carteret General Hospital Entire Hospital			
	Project Year 1 10/01/14 to 9/30/15	**Project Year 2 10/01/15 to 9/30/16**	**Project Year 3 10/01/16 to 9/30/17**
Net Revenue	$151,977,201	$162,310,398	$172,656,710
Total Expenses	$136,048,741	$143,243,873	$148,734,324
Net Income	**$15, 928,460**	**$19,066,525**	**$23,922,385**
Cardiac Catheterization/Angiography Services			
Net Revenue	$2,115,921	$3,088,613	$3,555,765
Total Expenses	$2,144,974	$2,656,881	$2,900,396
Net Income	**($29,053)**	**$431,732**	**$655,369**

As shown in the table above, the applicant projects that net revenue for the entire hospital will exceed total operating expenses in each of the first three years of the project. Also as shown in the above table, the applicant projects that net revenue for the cardiac catheterization/angiography service will exceed total operating expenses beginning in the second year of the project. Projected net revenues and expenses are based on reasonable, credible and supported assumptions, including projected utilization. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.

In summary, CGH adequately demonstrates the availability of sufficient funds 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

As a result of an adjusted need determination petition, the 2013 SMFP identifies a need determination for one unit of shared fixed cardiac catheterization equipment in the Carteret County cardiac catheterization service area. CGH is the only hospital in Carteret County. There is no existing fixed or mobile cardiac catheterization equipment operating in Carteret County. On page 68, the applicant states,

> "*Carteret County geography consists of two peninsulas, a total of 100 miles long. Residents of some communities in the Down East peninsula are an hour from Carteret General (Cedar Island), and 1.5 hours from the nearest cardiac catheterization laboratory at CarolinaEast Medical Center in New Bern. In good traffic, the nearest cardiac catheterization laboratory (CarolinaEast) is at least 45 minutes from Carteret General. Heavy military traffic associated with Cherry Point Marine Air Station often limits travel speed between CGH and CarolinaEast, especially at twice daily shift changes. …*
>
> *In the western part of the county, Croatan National Forest segregates Carteret from New Bern. CarolinaEast Medical Center is 35 minutes from the closest Carteret County community, Newport. However, Newport is only 16 minutes from Carteret General. The American Heart Association (AHA) cardiac care standard is 30 minutes*
> *from door to treatment.* Most residents of Carteret County are more than 45 minutes from the cardiac catheterization door today*.
> *(American Heart Association. *http://circ.ahajournals.org/content/110/5/588/F1.expansion.html*)
>
> *Morehead City, where CGH is located is in the center of the county …*
>
> *Swansboro in Onslow County is within 22 miles and 30 minutes of Morehead City. It is 55 minutes from CarolinaEast. Onslow Memorial does not have an active cardiac catheterization program according to it 2013 License Renewal Application. Moreover, to reach Onslow Memorial, residents of Swansboro must travel Highway 24 through Camp Lejeune Marine Corps Base. This is also a tourist route that slows in peak season.*"

On page 69, the applicant states,

> "*The proposed project would bring cardiac catheterization closer to a large and growing population of persons in need of cardiac diagnostic services. It would permit*

Carteret County to build reasonable capacity in a hospital program that is already committed to and involved in regional cardiac care network.

According to the 2012 State of the County Health Report Carteret County has a year round population of approximately 68,000 that seasonally increases to approximately 150,000 (Exhibit 45). Carteret General, located in Morehead City, is the sole community hospital in Carteret County. Although heart disease is tied with cancer as its leading cause of death, the county has no cardiac catheterization equipment."

On pages 98-99, the applicant further states,

"*According* [sic] *the 2013 State Medical Facilities Plan, page 213, Carteret County is the Service Area*.

As demonstrated in the Map on page 77, CGH, in Morehead City, is central to the county population. According to data from Claritas in Exhibit 23, it is within 23 miles of 93,000 people. CGH is the only hospital in the county and the only applicant that meets the criteria for the shared fixed cardiac catheterization laboratory identified as needed in the 2013 State Medical Facilities Plan. …"

The applicant adequately demonstrates the need to offer cardiac catheterization services, which are not currently available in Carteret County. Angiography services are already available in Carteret County at CGH. Therefore, the applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

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

C

CGH currently provides angiography services only and is staffed for that service. However, cardiac catheterization will be a new service, thus requiring additional staff. In Section VII.3(a), page 161, the applicant states the following in regard to staffing requirements of the proposed project:

"*Because the shared fixed cardiac catheterization laboratory will be a new service, all nursing and tech staff will be new positions for CGH. Some of the positions may be recruited from within CGH. Part time positions may be shared with other departments.*"

In Section VII.1(a), pages 151-154, the applicant provides the current staffing for the angiography service. In Section VII.1(b), pages 155-157, the applicant provides proposed staffing for the cardiac catheterization/angiography service in Project Year 2. The following table illustrates the number of full-time equivalent (FTE) positions.

CGH Current Angiography and Proposed Cardiac

Catheterization/Angiography Staffing		
Positions	**Current FTEs (FY 2012)**	**Proposed FTEs (FY 2016)**
RN	0.5	2.0
Laboratory Technician	0.5	---
Radiology Technologist	---	1.1
Radiology Technician	---	1.1
Administrator (Manager)	0.1	0.2
Clerical	---	0.4
Total	1.1	4.8

In Section VII.8, page 165, CGH states that Dr. Richard Rosania is chief of staff. In Section II.8, page 62, CGH states that Dr. Scott Ard has indicated his willingness to serve as medical director of the cardiac catheterization service and that Dr. Ard is board certified in internal medicine. Exhibit 20 includes a letter from Dr. Ard indicating that he supports the proposal and is willing to serve as medical director. He also states that he has specialized training in invasive non-interventional cardiology. Exhibit 6 contains a copy of Dr. Ard's curriculum vitae.

The applicant demonstrates the availability of adequate health manpower and management personnel for the provision of 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 29-31, the applicant documents the availability of ancillary and support services required for the provision of cardiac catheterization/angiography services. Exhibit 9, pages 517-519, consists of a March 2013 letter from the Vice President of Operations stating that the necessary ancillary and support services will be available. Those ancillary and support services include, but are not limited to: laboratory, radiology, pharmacy, anesthesia, electrocardiography, echocardiography, blood bank, nuclear medicine and immediate endocardiac catheter pacemaking. In Exhibit 10, the applicant provides copies of CGH's patient referral and transfer agreement policies. In Exhibit 11, CGH provides copies of the cardiac care transfer agreements. Exhibit 41 contains letters of support from CGH cardiologists and radiologists for the proposed project. Exhibit 42 contains letters of support from other physicians and healthcare providers. During the public comment period, additional letters of support were received from physicians, an elected official, a Morehead City business and the community-at-large.

The applicant adequately demonstrates that the proposed project will be coordinated with the existing health care system and that the necessary ancillary and support services will be available. 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

In Section XI.4, pages 183-184, the applicant describes the plan to construct 4,960 square feet of new space and renovate 462 square feet of existing space for a total of 5,422 square feet in the shared fixed cardiac catheterization laboratory upon project completion. Exhibit 34 contains a certified cost estimate from an architectural firm which projects that the construction cost and associated costs will be $2,863,071. However, in clarifying information requested from the Agency, the applicant lists fees in the amount of $659,500 related to architectural and engineering fees which are consistent with the projected costs stated in Section VIII. In the clarifying information, the applicant states, "*The amount on the line for Architect and Engineering fees includes $343,000 for Architect and Engineering Fees and 316,500 for Other Signage and Testing, Insurance, Surveys Commissioning and moving. The architect fee in the Letter from the architect covers only the architect's fees; the $343,000*

also includes Other Inspections and Engineering fees in the amount of $191,500. That latter figure was provided by our independent Project Manager, … Other amounts in the line item for Architect and Engineering Fees on page 170 are: Miscellaneous costs from the Architect's letter, along with Moving, Commissioning and signage cost from our Project Manager. The $150,000 for Furnishings is included with equipment in the line item 'Fixed Equipment.' That line item in the application should have been separately displayed as it was on our worksheets."

Various line drawings of the proposed project are contained in Exhibit 8. In Section III.2, page 103 and Section XI.7, pages 187-188, the applicant describes the energy-saving features to be incorporated into the project.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative for the project it proposes, and that the construction cost will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges which is incorporated hereby as if set forth fully herein. The application is conforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Sections VI.12 and VI.13, page 147, the applicant provides the current payor mix for Fiscal Year 2012 (the most recent), for the entire hospital and the angiography laboratory, as CGH does not currently provide cardiac catheterization services. The payor mixes are illustrated below in the table.

Carteret General Hospital FY 2012 Payor Mix % of Current Patient Days/Procedures As Percent of Total Utilization		
	CGH Entire Facility	**Angiography Service**
Medicare/Medicare Managed Care	42.7%	45.4%
Commercial	24.3%	27.6%
Medicaid	12.2%	8.8%

Self Pay / Indigent/Charity/	12.2%	8.0%
Other - TriCare	8.6%	10.3%
TOTAL	100.0%	100.0%

In Section VI.6, page 143, the applicant states:

> "*CGH's financial policies insure that all eligible individuals, including indigent and other medically underserved persons, receive medically necessary care, regardless of their ability to pay. These policies will extend to the proposed project. Please see CGH's Financial Policy in Exhibit 33 and Financial Assistance Policy in Exhibit 33.*"

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for the years indicated. More current data, particularly with regard to the estimated percentages of the uninsured, was not available.

	Total # of Medicaid Eligibles as % of Total Population, June 2010	**Total # of Medicaid Eligibles Age 21 and older as % of Total Population, June 2010**	**% Uninsured CY 2008-CY2009 (Estimate by Cecil G. Sheps Center)**
Carteret County	14.0%	6.6%	19.5%
Craven County	15.0%	6.5%	19.6%
Onslow County	11.0%	4.2%	23.4%
Statewide	17.0%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the cardiac catheterization services to be offered by Carteret General Hospital.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. In SFY 2010, the statewide percentage of Medicaid recipients receiving dental services was 48.6% for those aged 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina.

Population estimates are available by age, race and gender by county; 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 or women who utilize health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to services provided at CGH. Therefore, the application is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.10, page 146, the applicant states there have been no civil rights complaints filed against CGH in the past five years. In Section VI.11, page 146, the applicant states that during the last three years CEMC has had no obligations to provide uncompensated care. 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 and VI.15, pages 148-149, the applicant provides the projected payor mix for the entire facility and cardiac catheterization/angiography services in Project Year 2 (FY2016) as shown in the following table:

Carteret General Hospital Payor Mix - As Percent of Total Utilization 2nd Full FY(10/1/2015 - 9/30/2016)		
	Entire Facility	**Cardiac Catheterization /Angiography Laboratory**
Medicare/Medicare Managed Care	42.7%	61.1%
Managed Care Commercial	---	21.1%
Commercial	24.3%	---
Medicaid	12.2%	5.3%
Self Pay/Indigent/Charity/	12.2%	8.2%
Other – Government & TriCare	8.6%	---
TriCare	---	4.3%
TOTAL	100.0%	100.0%

*Data based on procedures.

In Section VI.2, pages 138-140, the applicant states,

> "… *Each of the* [medically underserved groups] … *will continue to have access to services at CGH. CGH does not deny needed medical care to any person based on age, race, ethnicity, creed, religion, culture, language, handicap, economic status, social status, or ability to pay. Please see the Financial Adjustments policy in CGH's Financial Policies in Exhibit 33 and Patient Rights in Exhibit 32.*
>
> *As a Medicare and Medicaid-certified provider, CGH does currently, and will continue to serve significant numbers of aged, disabled, and medically indigent patients.*
>
> *Under EMTALA regulations, each of the groups in (a) through (f) above have access to CGH emergency services. CGH has a history of providing interventional radiology to emergency patients. … "*

The applicant demonstrates that medically underserved populations will have adequate access to the cardiac catheterization services to be provided at CGH. 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 145, the applicant states that patients have access to CGH services through physician and physician extender referrals, via the emergency department, other hospitals, and other healthcare providers (e.g. health departments, nursing facilities, home health agencies and rehabilitation centers). The information provided in Section VI.9 is reasonable and credible. 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, pages 127-128, the applicant lists existing student clinical training affiliations. Exhibit 30 contains examples of training affiliation agreements. The following are some of these affiliations: (1) Universities - DeVry, Duke, East Carolina, Frontier Nursing, Hampton, Indiana State, North Carolina Central and the University of North Carolina-Charlotte; and (2) Colleges - Barton, Carteret Community, Coastal Carolina Community, Craven Community, Lenoir Community, Martin Community and Pitt Community. In addition to institutions of higher education, CGH is also a worksite for

Carteret County Schools' Youth Program. The applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs. Therefore, the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

Carteret General Hospital proposes to acquire one unit of shared fixed cardiac catheterization equipment. CGH is the only hospital in Carteret County. There is no existing fixed or mobile cardiac catheterization equipment operating in Carteret County; although CGH has provided angiography services since 1989. This project will introduce cardiac catheterization services and improve existing angiography services in the county.

In Section V.7, pages 132-135, CGH discusses how the proposed project will enhance competition by promoting cost-effectiveness, quality and access to cardiac catheterization services in the service area. See also Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates how any enhanced competition will have a positive impact upon the cost-effectiveness, quality and access to the proposed cardiac catheterization and angiography services in Carteret County. The following conclusions are based on a review of the information in those sections:

- The applicant adequately demonstrates GCH will continue to provide adequate access to medically underserved populations.
- The applicant adequately demonstrates the need to acquire the proposed shared fixed cardiac catheterization equipment and that it is a cost-effective alternative.
- The applicant adequately demonstrates that CGH will continue to provide quality services.

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

CGH is accredited by the Joint Commission on Accreditation of Healthcare Organizations. CGH is also certified for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within eighteen months immediately preceding the data of this decision, for which any sanctions or penalties related to quality of care were imposed by the state on the hospital. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

The application is conforming to all applicable Criteria and Standards for Cardiac Catheterization Equipment, promulgated in 10A NCAC 14C .1600, as discussed below.

.1602 INFORMATION REQUIRED OF APPLICANT

(a) *An applicant that proposes to acquire cardiac catheterization or cardiac Angioplasty equipment shall use the acute care facility/medical equipment application form.*

-C- The applicant used the acute care facility/medical equipment application form.

(b) *The applicant shall provide the following additional information based on the population residing within the applicant's proposed cardiac catheterization service area:*

(1) *the projected annual number of cardiac catheterization procedures, by CPT or ICD-9-CM codes, classified by adult diagnostic, adult therapeutic and pediatric cardiac catheterization procedure, to be*

performed in the facility during each of the first three years following completion of the proposed project, including the methodology and assumptions used for these projections:

-C- In Section II.8, page 44, the applicant provides the projected number of adult diagnostic cardiac catheterization procedures to be performed by ICD-9-CM code for each of the first three years following completion of the project, as shown below in the table. In Section III.1(b), pages 66-98, and Section III.5(d), pages 108-113, the applicant provides the assumptions and methodology used for these projections. In Section II.3, page 47, the applicant states that the proposed cardiac catheterization equipment will be used to perform only adult diagnostic procedures.

Carteret General Hospital
Projected Adult Diagnostic
Cardiac Catheterizations
by ICD-9 Codes

ICD-9 Code	PY 1 FY 2015	PY 2 FY 2016	PY 3 FY 2017
3731	1	1	1
3722	139	191	218
3723	26	36	41
3725	7	10	11
Total	173	238	271

(2) *documentation of the applicant's experience in treating cardiovascular patients at the facility during the past 12 months, including:*

(A) The number of patients receiving stress tests:

-C- In Section II.8, page 46, the applicant states that 1,350 patients received stress tests at CGH from March 2012 through February 2013.

(B) The number of patients receiving intravenous thrombolytic therapies:

-C- In Section II.8, page 46, the applicant states that 29 patients received intravenous thrombolytic therapies (for sinus tachycardia segment elevation myocardial infarction [STEMI]) at CGH between March 1, 2012 and February 28, 2013. Stroke and other non-STEMI patients are excluded.

(C) *The number of patients presenting in the Emergency Room or admitted to the hospital with suspected or diagnosed acute myocardial infarction:*

-C- In Section II.8, page 46, the applicant states that 1,073 patients presented to the emergency room or were admitted with suspected myocardial infarction.

(D) *The number of patients referred to other facilities for cardiac catheterization procedures or open heart surgery procedures, by type of procedure:*

-C- In Section II.8, page 46, the applicant states, "*According to CGH EMTALA logs, between February 2012 and February 2013 CGH had 32 STEMI trips from the hospital for patients with a myocardial infarction. CGH has records of two patients with STEMI sent to other facilities for evaluation for interventional cardiology. CGH cannot determine final dispositions for patients referred to other facilities or know if they received cardiac catheterization or open heart surgery procedures. CGH does not presently have the equipment with which to make a definitive diagnosis for these conditions prior to transfer. CGH did review available data for Carteret County residents transported to hospitals for 'Chest Pain.' According to the North Carolina DHSR/EMS database, in 2012, 519 of the 679 Carteret County patients transported to hospitals by ambulance for 'Chest Pain' were taken to CGH. Another 160 Carteret County residents were taken to other hospitals…*"

(E) *The number of diagnostic and therapeutic cardiac catheterization procedures performed during the twelve-month period reflected in the most recent licensure form on file with the Division of Health Service Regulation.*

-NA- CGH does not currently offer cardiac catheterization services.

(3) *the number of cardiac catheterization patients, classified by adult diagnostic, adult therapeutic and pediatric, from the proposed cardiac catheterization service area that the applicant proposes to serve by patient's county of residence in each of the first three years of operation, including the methodology and assumptions used for these projections:*

-C- In Section II.8, pages 48, the applicant provides the number of adult cardiac catheterization patients from the proposed cardiac catheterization service area that CGH projects to serve by county of residence as shown below in the table. In Section III.1(b), pages 66-98, and Section III.5(d), pages 108-113, the applicant provides the assumptions and methodology used for projecting cardiac catheterization utilization. CGH will not provide therapeutic cardiac catheterization or pediatric cardiac catheterization services.

Projected Annual Cardiac Catheterizations by Service Area and Procedure Code				
County & ICD-9 Code	**Description**	**Fiscal Year**		
		2015	**2016**	**2017**
Carteret				
3721	Right Heart	0	1	1
3722	Left Heart	99	150	176
3723	Right&Left Heart	19	28	33
3725	Heart Biopsy	5	8	9
Total		**123**	**187**	**219**
Onslow				
3721	Right Heart	0	0	0
3722	Left Heart	37	37	37
3723	Right&Left Heart	7	7	7
3725	Heart Biopsy	2	2	2
Total		**47**	**46**	**46**
Other*				
3721	Right Heart	0	0	0
3722	Left Heart	3	4	4
3723	Right&Left Heart	1	1	1
3725	Heart Biopsy	4	5	5
Total Procedures		**173**	**238**	**271**

(4) *documentation of the applicant's projected sources of patient referrals that are located in the proposed cardiac catheterization service area, including letters from the referral sources that demonstrate their intent to refer patients to the applicant for cardiac catheterization procedures:*

-C- In Section II.8, page 49, the applicant refers to Exhibits 41 and 42 which contain 25 letters of support from area physicians who state that they support the project and/or will refer patients to CGH for diagnostic cardiac catheterization/angiography services. The specialties include: cardiology, radiology, internal medicine, endocrinology, gastroenterology and anesthesiology.

(5) *evidence of the applicant's capability to communicate with emergency transportation agencies and with an established comprehensive cardiac services program*:

-C- In Section II.8, page 49, the applicant states that there is CGH-based central communication and medical control for all emergency medical system calls. CGH has paramedics based at the hospital emergency department, who staff the communication center and are present on all emergency transports.

(6) *the number and composition of cardiac catheterization teams available to the applicant:*

-C- In Section II.8, page 50, CGH proposes one full time cardiac catheterization team. The team will be comprised of one cardiologist, two nurses and two technicians. In Section VII, pages 151-157, the applicant provides current angiography service staffing and projected staffing for the proposed cardiac catheterization/angiography laboratory. In Section II, page 25, CGH states that the cardiac catheterization/angiography laboratory will initially operate during the hours of 7:30 AM to 4:00 PM, Monday through Friday.

CGH Current Angiography and Proposed Cardiac Catheterization/Angiography Staffing		
Positions	**Current FTEs (FY 2012)**	**Proposed FTEs (FY 2016)**
RN	0.5	2.0
Laboratory Technician	0.5	---
Radiology Technologist	---	1.1
Radiology Technician	---	1.1
Administrator (Manager)	0.1	0.2
Clerical	---	0.4
Total	1.1	4.8

(7) *documentation of the applicant's in-service training or continuing education programs for cardiac catheterization team members:*

-C- In Section II.8, page 50, the applicant states, "… *CGH annually reviews the training needs in every department and uses the results to update its in-service training programs. The evaluation is integrated with annual competency requirements for staff in accordance with its JC accreditation requirements. … Once approved, CGH will develop an in-service and continuing education for cardiac catheterization and advanced angiography procedures that meet appropriate certification and AHA Consensus document standards. All members of the team will be required to maintain ACLS certification … CGH has also developed Standard of Care and Scope of Care documents that will act as the foundation for in-service education and continuing education*…" See Exhibit 10 for the Standard of Care document and Exhibit 54 for the Scope of Care document.

(8) *written agreement with a comprehensive cardiac services program that specifies the arrangements for referral and transfer of patients seen by the applicant and that includes a process to alleviate the need for duplication in cardiac catheterization procedures:*

-C- In Section II.8, page 51, the applicant discusses existing transfer agreements with comprehensive cardiac programs such as Vidant Medical Center-Greenville, CarolinaEast Medical Center-New Bern, Duke University Medical Center and the University of North Carolina

Medical Center. Vidant Medical Center and CarolinaEast Medical Center are located closest to CGH and receive the most transfers from CGH. See Exhibit 11 for copies of the Vidant Medical Center and CarolinaEast Medical Center transfer agreements.

(9) *a written description of patient selection criteria, including referral arrangements for high risk patients:*

-C- In Section II.8, page 52, CGH states that the hospital will follow the standards of the Accreditation for Cardiovascular Excellence (ACE), an accreditation program for cardiac catheterization laboratories. ACE establishes guidelines for identification and referral of high risk patients in facilities that do not have open heart surgery. CGH provides a copy of the standards in Exhibit 19. CGH documents in Exhibit 11 that it already has referral and transfer agreements with several tertiary care medical centers.

(10) *a copy of the contractual arrangements for the acquisition of the proposed cardiac catheterization equipment including itemization of the cost of the equipment:*

-C- Exhibit 7 includes a copy of a proposed contract, which includes itemized costs for the cardiac catheterization equipment. See also Section VIII.2, page 168.

(11) *documentation that the cardiac catheterization equipment and the procedures for operation of the equipment are designed and developed based on the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards (June 2001) report.*

-C- In Section II.b(11), pages 52-53, CGH states that hospital will maintain its program and cardiac catheterization/angiography equipment with the most current Consensus Standards of the American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions ACCF/SCAI.

.1603 REQUIRED PERFORMANCE STANDARDS

.1603(a)(1) *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.

-NA- CGH proposes shared fixed cardiac catheterization equipment.

.1603(a)(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;*

-NA- CGH proposes shared fixed cardiac catheterization equipment for diagnostic procedures only.

.1603(a)(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- In Section IV, Table IV.18, page 126, CGH provides the following chart which shows that the hospital projects to perform 271 diagnostic procedures per one catheterization team by Year 3, which exceeds the minimum standard of 200 procedures.

Carteret General Hospital
Cardiac Catheterization and Angiography Utilization
Current & Projected

Cardiac Catheterization	**FY 2011**	**FY 2012**	**Interim 2013 & 2014**	**Project Year 2015**	**Project Year 2016**	**Project Year 2017**
# Units	0	0	0	1	1	1
# Diagnostic Procedures	0	0	0	173	238	**271**
# Therapeutic Procedures	0	0	0	0	0	0
# Diagnostic Equivalent Procedures	0	0	0	173	238	**271**
Angiography						
# Units	1	1	1	See above	See above	See above
# Angiography Procedures	354	596	258	369	561	654
# Pacemakers	0	0	0	18	22	23

Total	354	596	258	387	583	677
All Procedures						
# Units	1	1	1	1	1	1
# Procedures	354	596	258	560	821	948

.1603(a)(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 II.8, pages 55-57, CGH provides projected patient origin for the primary cardiac catheterization service area, as shown below in the table.

Carteret General Hospital Projected Cardiac Catheterization Procedures Primary Cardiac Catheterization Service Area			
Fiscal Year	**Project Year 1 2015**	**Project Year 2 2016**	**Project Year 3 2016**
Carteret	120	183	214
Onslow	17	16	16
Subtotal Primary Service Area	**137**	**199**	**231**
Total	173	238	271

As shown in the table above, at least 79% of the CGH cardiac catheterization patients are projected to be residents of the primary cardiac catheterization service area [137/173 = 79%; 199/238 = 84%; 231/217 = 85%].

.1603(b) *An applicant proposing to acquire mobile cardiac catheterization 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 Facility Services;*

(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- CGH proposes shared fixed cardiac catheterization equipment.

.1603(c) *An applicant proposing to acquire cardiac catheterization equipment excluding shared fixed and mobile cardiac catheterization equipment shall*:

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

(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- CGH proposes shared fixed cardiac catheterization equipment.

.1603(d) *An applicant proposing to acquire shared fixed cardiac catheterization 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;*

-C- See Section II, Table II.14, page 60. CGH proposes to perform at least 225 cardiac catheterization and angiography procedures by the fourth quarter of the third project year, as shown below in the table.

Carteret General Hospital **Cardiac Catheterization/Angiography Procedures**

By Quarter - Project Years 1-3					
Fiscal Year	QTR 1	QTR 2	QTR 3	QTR 4	Total
2015	56	84	196	224	560
2016	164	205	205	247	821
2017	227	237	237	246	947

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

-C- See Section II, pages 59-60, Section III, pages 66-97, and Section IV, pages 115-126, for documentation of all assumptions and data used for the projections required by this Rule.

.1603(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*;

(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- See Section II.8, page 60. CGH does not propose to perform cardiac catheterization procedures on patients age 14 and under.

.1604 REQUIRED SUPPORT SERVICES

.1604(a) *If the applicant proposes to perform therapeutic cardiac catheterization procedures, the applicant shall demonstrate that open heart surgery services are provided within the same facility*.

-NA- In Section II.8, page 61, CGH states that this proposal is to develop a diagnostic cardiac catheterization program only.

.1604(b) *If the applicant proposes to perform diagnostic cardiac catheterization procedures, the applicant shall document that its patients will have access to a facility which provides open heart surgery services, and that the patients can be transported to that facility within 30 minutes and with no greater risk than if the procedure had been performed in a hospital which provides open heart surgery services; with the exception that the 30 minute transport requirement shall be waived for equipment that was identified as needed in the State Medical Facilities Plan based on an adjusted need determination or the determination of a need for shared-fixed cardiac catheterization equipment.*

-NA- The proposed project was submitted as a result of an adjusted need determination in the 2013 SMFP and is for shared-fixed cardiac catheterization equipment.

.1604(c) *The applicant shall provide documentation to demonstrate that the following services shall be available in the facility:*

(1) electrocardiography laboratory and testing services including stress testing and continuous cardiogram monitoring;
(2) echocardiography service;
(3) blood gas laboratory;
(4) pulmonary function unit;
(5) staffed blood bank;
(6) hematology laboratory/coagulation laboratory;
(7) microbiology laboratory;
(8) clinical pathology laboratory with facilities for blood chemistry;
(9) immediate endocardiac catheter pacemaking in case of cardiac arrest; and
(10) nuclear medicine services including nuclear cardiology.

-C- In Exhibit 9 is a letter from the Vice-President of Operations, stating the availability of the above listed services.

.1605 REQUIRED STAFFING AND STAFF TRAINING

.1605(a) *An applicant proposing to acquire cardiac catheterization equipment shall provide documentation to demonstrate that the following staffing requirements shall be met:*

(1) one physician licensed to practice medicine in North Carolina who has been designated to serve as director of the cardiac catheterization service and who has all of the following credentials:
(A) board-certified in internal medicine by American Board of Internal Medicine, pediatrics by American Board of Pediatrics, or radiology by American Board of Radiologists;
(B) subspecialty training in cardiology, pediatric cardiology, or cardiovascular radiology; and
(C) clinical experience in performing physiologic procedures, angiographic procedures, or both;

-C- In Section VII.8, page 165, CGH states that Dr. Richard Rosania is chief of staff. In Section II.8, page 62, CGH states that Dr. Scott Ard indicates his willingness to serve as medical director of the cardiac

catheterization service and that Dr. Ard is board certified in internal medicine. See Exhibit 20 for Dr. Ard's letter of support and statement of willingness to serve as medical director. Dr. Ard also states that he has specialized training in invasive non-interventional cardiology. Exhibit 6 contains Dr. Ard's curriculum vitae.

.1605(a)(2) *at least one team to perform cardiac catheterizations, composed of at least the following professional and technical personnel:*

(A) one physician licensed to practice medicine in North Carolina with evidence of training and experience specifically in cardiovascular disease and radiation sciences;
(B) one nurse with training and experience specifically in critical care of cardiac patients, cardiovascular medication, and catheterization equipment; and
(C) at least two technicians with training specifically in cardiac care who are capable of performing the duties of a radiologic technologist, cardiopulmonary technician, monitoring and recording technician, and darkroom technician.

-C- CGH proposes to have at least one cardiac catheterization team in the above required configuration. See Section II, pages 63-64 and Section VII, pages 155 and 157, for configuration of the proposed team. A table which shows the composition of the teams is found above in *1602(b)(6) Information Required of Applicant* in these Rules. In Section II, page 64, CGH states that digital recordings have replaced darkrooms in cardiac catheterization laboratories.

.1605(b) *An applicant proposing to acquire cardiac catheterization equipment shall provide documentation to demonstrate that the following staff training shall be provided for members of cardiac catheterization teams:*

(1) American Red Cross or American Heart Association certification in cardiopulmonary resuscitation and advanced cardiac life support; and

-C- In Section II.8, page 65, CGH states that the medical director and all of the other cardiac catheterization staff shall be ACLS certified. Such training is part of the hospital's in-service program.

(2) an organized program of staff education and training which is integral to the cardiac services program and ensures improvements in technique and the proper training of new personnel.

-C- In Section II(b)(2), page 65, CGH references Exhibit 7 which includes a copy of the staff training on the cardiac catheterization equipment

and Exhibit 15 which contains the CGH continuing education policy. CGH states that the hospital will develop a program to ensure continuous improvement in cardiac catheterization technique. Exhibit 21 contains a March 2013 letter of commitment to continuing education and the appropriate training from Dr. Scott Ard. Dr. Ard states his responsibilities as "… *the Medical Director of CCU/PCU for Carteret General Hospital (CGH). In that capacity, I am responsible for oversight of clinical services, to include certain aspects of the proposed shared fixed cardiac catheterization lab*." Further, Dr. Ard has indicated his willingness to serve as medical director of the cardiac catheterization service.