ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: May 16, 2013

PROJECT ANALYST: Jane Rhoe-Jones
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: P-10082-13 / CarolinaEast Medical Center, Inc. / Acquire fixed cardiac catheterization equipment / Craven 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.

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The 2013 State Medical Facilities Plan (SMFP) identifies a need determination for one additional unit of fixed cardiac catheterization equipment in the Craven/Jones/Pamlico County cardiac catheterization service area. Cardiac catheterization services are provided by the applicant, Carolina East Medical Center which currently operates two fixed cardiac catheterization units. Carolina East Medical Center (CEMC) proposes to add one unit of fixed cardiac catheterization equipment for a total of three fixed units upon project completion. CEMC is a 350-bed regional tertiary care provider located at 2000 Neuse Boulevard, New Bern, in eastern North Carolina.

CEMC proposes to develop no more than one fixed cardiac catheterization unit in the Carteret/Jones/Pamlico Service Area, which is conforming to the applicable need determination in the 2013 SMFP. 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."

In Section III.2, page 69, regarding Policy Gen-3: Basic Principles, the applicant states:

"*Not applicable. The proposed project does not involve a new institutional health service for which there is a need determination in the North Carolina 'SMFP'.*"

However, Policy Gen-3: Basic Principles is applicable as this project was submitted due to a need determination Carteret County in the 2013 SMFP. See the 2013 SMFP, Chapter 9, page 212. The Project Analyst quotes the following from CEMC's application related to quality/safety, access and healthcare value.

Promote Safety and Quality

In Exhibit 9 the applicant provides a copy of the CEMC Performance Improvement Plan and the utilization and risk policies and plans. In Section II.7(a) and (b), pages 24-27, the applicant discusses the quality of services provided at CEMC. The applicant states:

"*CEMC states as the purpose of its Performance Improvement Plan 'to provide a structured, organizational process for measuring the function of important processes and services, and, when indicated, identifying changes that enhance performance in conjunction with CarolinaEast Medical Center's Mission, Vision, and Value statements.' The Performance Improvement Plan also includes an 'integrated patient safety program' which includes a 'structure for measuring and assessing the effectiveness of the performance improvement and safety improvement activities.*'

CEMC defines quality as 'the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.' Dimensions of quality performance include:

- *Patient perspective issues;*
- *Safety of the care environment;*
- *Accessibility;*
- *Appropriateness;*
- *Continuity;*
- *Effectiveness;*
- *Efficacy;*
- *Efficiency; and,*
- *Timeliness of care, treatment and services.*

…

CEMC uses the Fast PDCA (Plan, Do, Check, Act) model and the Lean model, both focusing on continuous quality improvement …

… The quality processes in place impact its risk management outcomes as well in that a high quality program is less likely to incur patient safety events because of the process standards adhered to by the staff and physicians."

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 VI, pages 91-110, CEMC discusses varied aspects of accessibility to services at the medical center, including to the cardiac catheterization services.

In Section VI.2, page 91, the applicant states,

"*CEMC does not discriminate against low-income persons, racial or ethnic minorities, women, handicapped persons, the elderly, or other underserved persons, including the medically indigent. CEMC provides access to care to all patients regardless of age, race, national or ethnic origin, disability, gender, income, or immediate ability to pay. Patients are admitted and services rendered in compliance with:*

1. *Title VI of Civil Rights Act of 1963*
2. *Section 504 of Rehabilitation Act of 1973*
3. *The Age Discrimination Act of 1975*
4. *Americans with Disabilities Act*"

CEMC also discusses the various health fairs, health screenings and community outreach events via partnerships with local community service organizations and businesses. These events are designed for the general public as well as targeted population segments in the service area.

CEMC further discusses the charity policy, transfer policy for patients needing services that the medical center does not provide such as for pediatric cardiac patients. Exhibit 6 contains a sample transfer agreement and a list of existing transfer agreements. CEMC states that the medical center is in compliance with the federal EMTALA law (The Emergency Medical Treatment and Labor Act), thus all patients who present to the medical center are examined and/or treated, based on their medical condition. Further, CEMC states that the medical center provides annual grants to the two free clinics serving the uninsured and underinsured in the CEMC community.

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

Healthcare Value

In SectionV.7, page 88, CEMC discusses cost effectiveness and states,

> "*Because the proposed project will renovate existing space within the medical center rather than construct a new addition, the costs to develop the additional capacity will be much less than they would be with new construction. The third catheterization laboratory will utilize existing support services, the same administrative director and physicians. As part of the medical center, support services such as admissions, medical records and materials management are already in place and will not require additional FTEs to support the additional cardiac catheterization capacity. In light of the high costs associated with cardiac services, these are important cost savings factors*."

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

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

> *"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 Section III.2, page 69, regarding Policy Gen-4, the applicant states:

> "*Because the project does not include the construction of new space, the ability to improve energy efficiencies and conservation of resources rests in the current efficiencies present in the existing facility and the efficiencies present with the new equipment. However, as with all CEMC's services, engineering management constantly seeks ways to improve and conserve energy and more efficiently utilize hospital resources. This project will be no different. …*"

However, CEMC does include an energy efficiency and sustainability statement regarding this project in Exhibit 13.

The applicant adequately describes the project's plan to assure improved energy efficiency and water conservation. Thus, the application is conforming to Policy GEN-4 in the 2013 SMFP.

See Criteria (3) and (13c) for additional discussion. The application is consistent with Policy 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/Jones/Pamlico 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.

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CEMC proposes to add one unit of fixed cardiac catheterization equipment for a total of three fixed units upon projection completion. CEMC began providing cardiac catheterization services in Craven County in 1988. In 1993, the medical center broadened its services to include open heart surgery and interventional procedures. Currently CEMC's cardiac services program includes has two cardiac surgeons, six cardiologists (four interventional and two diagnostic), and two electrophysiologists. CEMC, as the only cardiac catheterization provider in the Craven/Pamlico/Jones service area, states that more than 230 open heart surgery procedures and greater than 2,500 diagnostic-equivalent cardiac catheterizations were performed in 2012.

In Section II, pages 14-20, the applicant states,

> "*Because of the quality of its cardiac services, CEMC's cardiac catheterization volumes have continued to escalate and for the past 24 months have operated at 80 percent of the capacity of the two fixed cardiac catheterization laboratories, which has resulted in a need in Craven, Jones and Pamlico counties for one additional unit of cardiac catheterization equipment as defined in the '2013 State Medical Facilities Plan.' … The additional catheterization unit will result in a total of three cardiac catheterization laboratories in operation at the medical center*."

The project scope as proposed in this application includes the following components:

- Existing and proposed cardiac catheterization services – "*CEMC is a comprehensive cardiac services facility and, as such, provides a full range of cardiac services including open heart surgery, diagnostic and interventional cardiac catheterization and electrophysiology services.*
  …

  No pediatric cardiac catheterization procedures are or will be performed at CEMC." …

- Proposed equipment – "*… this state-of-the-art x-ray system can be customized to support a full range of diagnostic, interventional and cardiovascular procedures.*

  The proposed equipment uses a fully integrated single-host concept comprised of five functional building blocks that will meet a wide range of clinical needs for interventional and diagnostic imaging with exceptional image quality, real time image displays, innovative dose efficiency, and improved image management for excellent clinical versatility without compromising quality."

- Proposed renovation – "*the cardiac catheterization department is located on the first floor of the medical center between the radiology department and the surgery department*.

  …

  CEMC's cardiovascular ICU (CVICU), located between the cardiac catheterization department and the surgery department, is in the process of relocation to the third floor adjacent to the other intensive care units (medical/surgical). The space vacated by the relocation of CVICU (1,888 SF) is sufficient to accommodate the new cath lab … In order to create a more functionally designed unit, CEMC proposes to redesign and renovate the majority of the cardiac catheterization department as noted on the project drawings included in Exhibit 4. The proposed project will not involve either of the two existing cardiac catheterization laboratories or the electrophysiology laboratory but with renovation, CEMC plans to improve the patient and staff flow within the department, to create more storage space, and to improve patient preparation and recovery areas. … "

Population to be Served

In Section III.5(a) and (c), page 72, the applicant states that the proposed service area includes Craven County, Pamlico and Jones counties as the primary service area and Carteret and Onslow counties as the secondary service area. CEMC also states that during FY 2012, over 56 percent of its cardiac catheterization procedures originated from the primary service area. The secondary service area generated almost 39 percent of CEMC's cardiac catheterization procedures.

In Section III.5(d), page 74, CEMC discusses the impact of the proposed cardiac catheterization laboratory at Carteret General Hospital. The applicant states,

> "*… the projected catheterization volume for the project years has been adjusted to account for the expected future development of a shared fixed cardiac cath lab at Carteret General Hospital (CGH). Since CEMC expects Carteret County diagnostic procedures to shift back to CGH when that lab is developed, CEMC adjusted its future patient origin accordingly …*"

In Section III.5(c), page 74, this change is reflected in the table the applicant provides. Tables are set forth below which depict CEMC's current and projected cardiac catheterization patient origin, by percentage and by county of residence.

CEMC Cardiac Catheterization Current Patient Origin FY 10/1/2011 - 09/30/2012		
County	**Number of Patients**	**Patient %**
Craven	841	45.3%
Carteret**	555	29.9%
Onslow	168	9.0%
Pamlico	118	6.4%
Jones	89	4.8%
Other*	86	4.6%
Total	1857	100%

Source: CEMC internal data. *Other: Alamance, Beaufort, Chatham, Currituck, Duplin, Gaston, Guilford, Henderson, Hyde, Lenoir, Mecklenburg, Mitchell, Nash, Orange, Pender, Pitt, Sampson, Wake, Wayne, Wilkes, Wilson, and Yadkin counties.

In the table immediately above, the number of patients per county was submitted by the applicant in clarifying information requested by the Agency.

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CEMC Cardiac Catheterization Projected Patient Origin – Project Years 1 & 2				
County	**Year 1 Projected Lab Procedures**	**Year 1 % Lab Procedures**	**Year 2 Projected Lab Procedures**	**Year 2 % Lab Procedures**
Craven	1,085	55.5%	1,169	55.5%
Carteret*	276	14.1%	297	14.1%
Onslow	217	11.1%	233	11.1%
Pamlico	152	7.8%	164	7.8%
Jones	115	5.9%	124	5.9%
Other**	111	5.7%	120	5.7%
Total	1,956	100.0%	2,107	100.0%

***** *CEMC expects Carteret County diagnostic procedures to shift back to CGH when that laboratory is developed.* ****** See table immediately above.

The applicant adequately identifies the population proposed to be served.

Need for Fixed Cardiac Catheterization Equipment

In Section III, pages 54-66, the applicant discusses the assumptions and methodology used to demonstrate the need for the proposed services. The applicant states the following factors:

1. Need Determination

In Section III, page 54, the applicant states, "*The 2013 SMFP has identified a need for one additional unit of fixed cardiac catheterization equipment for Craven, Jones, and Pamlico counties. As the only cardiac care facility in the service area, the need was created by the highly utilized cardiac catheterization service at CEMC.*"

2. Only Comprehensive Cardiac Care Facility in the Area

In Section III, pages 54-55, the applicant states, "*… the cardiac catheterization department is the only cardiac care facility in the SHCC-designated cardiac catheterization equipment service area of Craven, Jones and Pamlico counties. … CEMC's cardiac services extend to an area greater than these three counties. In fact, CEMC's cardiac catheterization department is actually a regional provider, particularly for interventional catheterizations and open heart procedures. As noted in the patient origin tables included in … III.4.(b), in FY 2012 more than 40 percent of CEMC's catheterization patients came from counties outside of the service area. Furthermore, CEMC is the only non-academic, community medical center in HSA VI, east of I-95 that includes a comprehensive cardiac care service. Data from the Sate Center for Health Statistics indicates that of the top ten counties in North Carolina with the highest age-adjusted mortality rate for heart disease between 2007 and 2011, nearly half of the counties are in HSA VI. Moreover, one of the top ten counties, Jones County, is included in the cardiac catheterization equipment service area with Craven and Pamlico counties, all of which are included in the 2013 SMFP need for the cardiac catheterization equipment proposed in this application.*"

Rank	County	2007-2011 Age-Adjusted Death Rate
1	Washington	341.6
2	Martin	275.4
3	Swain	264.4
4	Tyrrell	261.4
5	Bladen	259.1
6	Richmond	258.9
7	Jones	251.2
8	Columbus	250.2
9	Lincoln	248.3
10	Hoke	246.6

Source: (http://www.schs.state.nc.us/schs/deaths/lcd/2011/heartdisease.html)

3. Community Impact on CEMC Cardiac Catheterization Utilization

In Section III, pages 57-59, the applicant states the following about the growth of CEMC's cardiac catheterization program, "*For example, data provided in the respective SMFPs indicate that from 2010 to 2012, CEMC's cardiac catheterization volumes experienced a compound annual growth rate of over six percent. Currently, the catheterization laboratories at CEMC are operating well past 5:00 PM and as late as 10:00 PM several nights a week to accommodate the need for cardiac catheterization procedures. … As a result, its cardiac catheterization laboratories have continued to operate in excess of 80 percent of capacity over the past two years. With the development of the third room, CEMC*

will be able to meet the need for greater cardiac catheterization capacity which will continue to support its commitments to the community and the patients..."

In summary, CEMC states its need to add another cardiac catheterization unit due to the following:

- SMFP data shows that from 2010-2012, a compound annual growth rate (CAGR) of more than 6%.
- CEMC is the only cardiac care facility in the service area of Craven, Jones and Pamlico counties. CECM is a regional provider for interventional cardiac catheterizations and open heart procedures.
- Greater than 80% utilization for the past two fiscal years – 2011 and 2012.
- The mortality rate for heart disease in the service area. Four of the top ten counties for heart disease mortality are in HSA VI – Washington, Martin, Tyrell and Jones counties.
- Regional area population growth and population aging.

In Section III, pages 60-61, the applicant discusses historical utilization for the most recent three fiscal years, which is shown in the following table.

CEMC Cardiac Catheterization Historical Volume and CAGR						
Year	**Diagnostic Procedures***	**Interventional (Therapeutic) Procedures**	**Total**	**Weighted Diagnostic Procedures**	**Weighted Interventional (Therapeutic) Procedures**	**Total Weighted Diagnostic-Equivalent Procedures**
FY 2010	1,065	638	1,703	1,065	1,117	2,182
FY 2011	1,221	756	1,977	1,221	1,323	2,544
FY 2012	1,125	803	1,928	1,125	1,405	2,530
CAGR 2010-2012	2.8%	12.2%	6.4%	NA	NA	NA

*Diagnostic procedures-not converted to diagnostic-equivalent procedures. NA = not applicable.

The applicant states,

"*As shown in the table above, the interventional procedures are growing at a much higher rate of 12.2 percent as compared to the diagnostic procedures. Overall, cardiac catheterization procedures at CEMC have experienced a 6.4 percent CAGR since FY 2010. Although the volume was flat from FY 2011 to FY 2012 due to a decrease in diagnostic procedures, CEMC believes the long term trend will continue to show growth, as the population of the service area both grows and ages.*

The diagnostic and interventional procedures shown in the above table were converted to diagnostic-equivalent procedures using definitions in 10A NCAC 14C .1601(2) where adult diagnostic procedures are weighted by a factor of 1.00 and interventional procedures by a factor of 1.75.

Given that the capacity of a single cardiac catheterization unit is 1,500 diagnostic-equivalent procedures as defined in the 2013 SMFP, the total capacity of the two existing cardiac catheterization units at CEMC is 3,000 diagnostic-equivalent procedures. CEMC therefore

operated at 73 percent capacity in 2010, 85 percent capacity in FY 2011 and 84 percent capacity in FY 2012, thus demonstrating the need for [sic] *additional unit to meet the growing demand*."

CEMC Projected Cardiac Catheterization Utilization

In Section III, pages 61-66, CEMC provides the assumptions and methodology in projecting future cardiac catheterization utilization. The applicant states,

"*… historical utilization of cardiac volume at CEMC has grown at a CAGR of 6.4 percent, based on 2.8 percent growth in diagnostic volume and 12.2 percent grown in interventional volume. To project future utilization, CEMC projected nominal, or baseline growth to continue at those same rates. … First using data from the 2010 through 2013 SMFPs (the last three years available), the CAGR for diagnostic, interventional and total volume is 13 percent, 25 percent, and 16 percent, respectively. … Next, the CAGR accounts for the slowing growth from 2011 to 2012. For example, the one-year growth rate in total volume from 2010 to 2011 is 16.1 percent; using the CAGR for the three year period of 6.4 percent reflects a more conservative trend. In addition the population is projected to continue growing and aging, which will drive long term growth in the service, notwithstanding any one-year anomaly in the utilization. Finally, … CEMC is also adjusting future volume to account for expected market changes; thus, the final projected growth rate is approximately one-half of the historical growth rate, as shown below*."

CEMC Projected Future Utilization			
Year	**Diagnostic Procedures**	**Interventional (Therapeutic) Procedures**	**Total**
FY 2013	1,156	901	2,057
FY 2014	1,188	1,011	2,199
FY 2015	1,221	1,134	2,355
FY 2016	1,255	1,272	2,527
FY 2017	1,290	1,427	2,717

"*Next, CEMC accounted for the expected future development of the shared fixed cardiac cath lab at Carteret General Hospital (CGH). The 2013 SMFP shows the need for a shared fixed lab in Carteret County, and CEMC expects CGH to apply. … As a result, CEMC expects some diagnostic procedures that have historically been performed at CEMC to shift to CGH when that lab is developed. In an attempt to estimate the impact of that shift, CEMC asked its cardiologists (who are part of the same group that practices at CGH) to estimate the percentage of Carteret County patients that would shift to CGH; however, the physicians indicated that while they expect the new shared cath lab at CGH to be well-utilized, they did not anticipate much, if any, negative impact on CEMC. Since the expansion of access through the development of a shared cath lab in Carteret County may lead to an increase in patients having caths, the use rate could also be expected to increase, enabling both facilities to have well-utilized equipment.*

Nonetheless, in order to be conservative in its utilization projections, CEMC projects that 100 percent of the diagnostic procedures from Carteret County that historically been performed at

CEMC will shift to CGH following development of its shared cath lab. The historical procedures performed at CEMC on Carteret County patients are shown in the following table."

Carteret County Cardiac Catheterization Utilization at CEMC			
Year	**Carteret County Diagnostic Procedures**	**Carteret County Interventional (Therapeutic) Procedures**	**Carteret County Total**
FY 2010	307	162	469
FY 2011	334	177	511
FY 2012	341	214	555
CAGR FY 2010-2012	5.4%	14.9%	8.8%

"*As shown, the procedures from Carteret County have grown at a higher rate than the total procedures at CEMC. In an effort to continue to be conservative, CEMC projected the Carteret County procedures to continue to grow at their historical CAGR before subtracting them from the projected utilization at CEMC. Since CGH is not expected to perform interventional procedures, the following table shows the projected Carteret County diagnostic procedures only*."

Projected Carteret General Hospital Adult Cardiac Catheterization Diagnostic Procedures	
Year	**Adult Diagnostic Procedures**
FY 2013	359
FY 2014	379
FY 2015	399
FY 2016	421
FY 2017	443
CAGR	5.4%

"*Since the review for the shared fixed cardiac cath lab in Carteret County will begin only two months after the review of this application, CEMC expects the first three fiscal years of that project to be the same as those for its project: FY 2015 through FY 2017. Thus CEMC expects no shifts to occur until FY 2015. CEMC subtracted the procedures expected to shift to Carteret County starting in FY 2015 to calculate revised total projected procedures, as shown in the following table*."

CEMC Revised Total Cardiac Catheterization Procedures (Excluding Projected Carteret General Hospital Diagnostic Procedures)					
Year	**Adult Diagnostic Procedures**	**Less Shifted CGH Diagnostic Procedures**	**Revised CEMC Total Adult Diagnostic Procedures**	**Interventional (Therapeutic) Procedures**	**Total**
FY 2013	1,156	0	1,156	901	2,057
FY 2014	1,188	0	1,188	1,011	2,199
FY 2015	1,221	(399)	822	1,134	1,956
FY 2016	1,255	(421)	835	1,272	2,107
FY 2017	1,290	(443)	847	1,427	2,274

"*CEMC believes these revised utilization projections result in reasonable and conservative growth projections for the cardiac cath service. Specifically, the CAGR for the revised diagnostic procedures is -7.5 percent, and the total CAGR is only 2.5 percent, less than one-half the historical CAGR for total procedures of 6.4 percent shown above. Given that increased access to diagnostic cath in Carteret County may increase the use rate and result in a greater number of patients being referred to CEMC for interventional cath, the use of the historical CAGR for interventional procedures is also conservative.*

In a final step, the revised diagnostic and interventional procedures shown in the above table were converted to diagnostic-equivalent procedures using the definitions in 10A NCAC 14C .1601(2) where adult diagnostic procedures are weighted by a factor of 1.00 and interventional procedures by a factor of 1.75. The following table summarizes the results of CEMC's methodology:"

CEMC's Revised Projected Therapeutic and Interventional Cardiac Catheterization Procedures			
Year	**Revised Weighted Adult Diagnostic Procedures**	**Weighted Interventional (Therapeutic) Procedures**	**Total**
FY 2013	1,156	1,577	2,733
FY 2014	1,188	1,769	2,957
FY 2015	822	1,984	2,806
FY 2016	835	2,226	3,061
FY 2017	847	2,497	3,344

"*As discussed in the rules, the capacity of a unit of cardiac catheterization equipment is 1500 procedures. Based on the utilization shown above, CEMC projects that the three cardiac catheterization units will be operating at a combined capacity of 74 percent by the third fiscal year following the project completion (1,500 x 3 = 4,500; 3,344 / 4,500 = 74.3%). As defined in 10A NCAC 14C .1603, any machine performing at least 60 percent capacity by the fourth quarter of the third year is considered to meet the performance standard; therefore, CEMC has demonstrated the quantitative need for the proposed cardiac cath unit.*

… CEMC believes is [sic] *has used a conservative approach to estimate the impact of the expected development of a shared fixed cath lab in Carteret County, the medical center is projected to meet the required performance standard for three cath labs by the end of FY 2013. Specifically, 60 percent of the capacity of three cath labs is 2,700 diagnostic-equivalent procedures (4,500 x .6 = 2,600). Thus, with a growth of just 170 diagnostic-equivalent procedures over FY 2012 volume, CEMC meets the performance standard for three cath labs. In fact, CEMC is projected to approach 100 percent of capacity of its two existing labs by the second intervening year, which also exceeds the minimum performance standard for three labs. This utilization can be achieved by maintaining and expanding the extension of operating hours for the cardiac cath services that exists* [sic] *currently; however, that solution is … less than optimal for the long term. CEMC … needs a third cardiac cath lab based on the current and intervening utilization projections, and will continue to need three cardiac cath labs even after considering the potential impact of a new lab in Carteret County*."

In summary, CEMC has provided historical and projected cardiac catheterization data with respective assumptions and methodology. Although Carteret General Hospital's cardiac catheterization laboratory would impact CEMC's diagnostic utilization, the data shows growth in CEMC's overall cardiac catheterization utilization. One of CEMC's assumptions is that CEMC will perform more interventional cardiac catheterizations due to Carteret General Hospital's cardiac catheterization diagnostic capabilities. CEMC has stated that a conservative approach was used, yet future demand warrants the third cardiac catheterization unit.

As defined in 10A NCAC 14C .1603, any machine performing at least 60 percent capacity by the fourth quarter of the third year is considered to meet the performance standard. CEMC projects that its cardiac catheterization units will be performing at 74.3% capacity by the fourth quarter of the third project year. CEMC has adequately demonstrated the quantitative need for the proposed third cardiac catheterization unit. The applicant adequately demonstrates that its projected utilization is based on reasonable assumptions.

Therefore, CEMC adequately identifies the population to be served and demonstrates the need to acquire the third fixed cardiac catheterization unit. 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.

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In Section III.3, page 69, the applicant discusses the alternatives to the proposed project that were considered prior to submission of this application and the basis for selection of the proposed project.

- The first alternative the applicant considers is maintaining the status quo. However, this alternative is not deemed to be an effective alternative because of the high utilization of the two current cardiac catheterization units. CEMC states that this high volume has led to extending hours of operating until late night. This has caused hardship on patients and staff, and over use of the equipment.

- The second alternative CEMC considered is a mobile cardiac catheterization unit. However, CEMC did not choose this option for several reasons: (1) the existing

catheterization laboratories are operating at greater than 80% volume thus, an additional fixed laboratory versus a mobile laboratory that would provide only intermittent service; (2) the need determination in the 2013 SMFP is for a fixed cardiac catheterization laboratory, not a mobile one; as the need was created by the high volume usage at CEMC. Furthermore, contracting with a mobile vendor would not meet the need in Craven, Jones and Pamlico counties for the identified fixed unit need.

- CEMC chose a third alternative which is to acquire a third cardiac catheterization unit. This alternative was chosen due to the need identified in the 2013 SMFP and the high volume utilization of the two current cardiac catheterization units. Also, to acquire the third cardiac catheterization unit will enhance the capacity in the service area, while being the least costly alternative as space, staff and other overhead expenses will be shared among the three cardiac catheterization units.

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. **CarolinaEast Medical Center shall materially comply with all representations made in its certificate of need application and in any supplemental information requested by the Certificate of Need Section.**

2. **CarolinaEast Medical Center 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. **CarolinaEast Medical Center 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.

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In Section VIII, page 104, the applicant states that the total capital costs of the project is $3,466,021, and will be funded through accumulated reserves. The capital costs include the following:

- $1,621,618 - construction contract
- $1,430,891 - fixed equipment
- $ 207,825 - other equipment, furniture and IT
- $ 150,000 - architect/engineering fees
- $ 55,687 - other including contingency

In Exhibit 3 CEMC provides an equipment quote from the proposed vendor of the cardiac catheterization equipment. In Exhibit 11, the applicant provides a February 15, 2013 letter from the President of CEMC attesting to the proposed cardiac catheterization equipment conformance with guidelines. In Section IX, page 124, the applicant states that this application does not propose a new service, and no start-up expenses are projected. Exhibit 18 contains a February 15, 2013 letter from the Chief Financial Officer documenting the availability of funds for the project and states in part:

> "*CarolinaEast Healthcare System will fund the capital costs of the project, estimated to be $3,466,021 with hospital reserves. As shown on page 11 of the FY 2011 audited financials included with the application, CarolinaEast Healthcare System has sufficient cash and assets limited as to use in reserves required capital costs of the proposed project.*"

Exhibit 19 contains the audited financial statements (which are reported in thousands) for the CarolinaEast Healthcare System. As of September 30, 2012, CarolinaEast Healthcare System reported $376,499,372 in total current assets; including $35,706,638 in cash and cash equivalents. In Section VIII.9(b), the applicant states,

> "*Exhibit 19 includes the two most recent consolidated audited financials for CarolinaEast Healthcare System. On page 11, under 'Current Assets: cash and cash equivalents,' the amount of $12,644,637 and 'Assets Limited as to Use,' the amount of $840,998 are available for the proposed project.*"

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposed project.

The Financials Section (Forms A-E) for CarolinaEast Medical Center is contained in pages 138-145 of the application. The table below summarizes Net Income (total revenue – total expenses) for the entire CarolinaEast Healthcare System and also for the cardiac catheterization service component in the proposed project for the first three full project years (pages 143-145).

CarolinaEast Healthcare System Net Revenue, Expenses and Net Income Summary			
	Project Year 1 10/01/14to 9/30/15	**Project Year 2 10/01/15 to 9/30/16**	**Project Year 3 10/01/16 to 9/30/17**
Revenue	$324,962,901	$337,961,417	$351,479,874
Expenses	$315,267,456	$327,857,417	$340,950,977

Net Income	**$9,695,446**	**$10,104,001**	**$10,528,898**
CarolinaEast Medical Center Cardiac Catheterization Net Revenue, Expenses and Net Income Summary			
Revenue	$20,859,686	$23,055,723	$25,531,873
Expenses	$8,678,107	$9,525,571	$10,479,754
Net Income	**$12,181,580**	**$13,530,153**	**$15,052,119**

In Form B (the projected revenue and expense statement), page 142, the applicant projects that revenues for the entire hospital system will exceed total operating expenses in each of the first three years of the project.

In Form C, page 143 - the projected revenue and expense statement for CEMC Cardiac Catheterization, the applicant projects that revenues will exceed total operating expenses for the service component in each of the first three years of the project. See below table:

CEMC Cardiac Catheterization Revenue and Expenses			
	Year 1	Year 2	Year 3
Total Revenue	20,859,686	23,055,723	25,531,873
Total Expenses	8,768,107	9,525,571	10,479,754
Net Income	**12,181,580**	**13,530,153**	**15,052,119**

In Form D, page 144, the applicant provides projected average charges for the cardiac catheterization service component for the first three project years. See below table:

CEMC Gross Revenue Cardiac Catheterization			
Project Year 1 (10/1/2014 - 9/30/2015)			
	% of Total	**# of Procedures**	**Projected Average Charge**
Self Pay/Other	8.6%	204	24,601
BCBS Commercial	18.1%	427	22,621
Tricare	3.1%	72	24,300
Medicare	64.9%	1,529	22,113
Medicaid	5.3%	124	21,181
Total	100.0%	2,355	22,438
Project Year 2 (10/1/2015 - 9/30/2016)			
	% of Total	**# of Procedures**	**Projected Average Charge**
Self Pay/Other	8.6%	218	25,339

BCBS Commercial	18.1%	459	23,300
Tricare	3.1%	77	25,029
Medicare	64.9%	1,640	22,776
Medicaid	5.3%	133	21,816
Total	100.0%	2,527	23,111
Project Year 3 (10/1/2016 - 9/30/2017)			
	% of Total	**# of Procedures**	**Projected Average Charge**
Self Pay/Other	8.6%	235	26,100
BCBS Commercial	18.1%	493	23,999
Tricare	3.1%	83	25,779
Medicare	64.9%	1,764	23,460
Medicaid	5.3%	143	22,471
Total	100.0%	2,717	23,805

In summary, the CEMC adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. 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

In Section III, pages 71-74, CEMC discusses its primary and secondary service area. CEMC serves as a regional tertiary care provider in eastern North Carolina. CEMC is the only acute care provider in Craven County, the only provider of open heart services, and the only provider of cardiac catheterization services. Furthermore, CEMC is the only hospital in the three county SMFP service area comprised of Craven, Jones and Pamlico counties. CEMC has designated Carteret and Onslow counties as the secondary service area. There is one acute care hospital in Carteret County – Carteret General Hospital and one acute care hospital in Onslow County – Onslow Memorial Hospital (there is a military hospital in Onslow County which is not a part of the SMFP inventory of acute care facilities).

There is currently no cardiac catheterization capability in Carteret County; although Carteret General Hospital will be applying for a certificate of need per an adjusted need determination in the SMFP. CEMC has included the potential impact of a diagnostic cardiac catheterization unit at Carteret General Hospital. See Criterion (3) for discussion regarding projected utilization and impact on CEMC's cardiac catheterization volume which is incorporated hereby as if set forth fully herein.

Onslow Memorial Hospital has one fixed cardiac catheterization unit. According to the 2013 SMFP, page 208, *Table 9W: Fixed Cardiac Catheterization Equipment, Capacity and Volume,* the number of reported procedures is shown below in the chart.

CEMC

Primary and Secondary Service Area Service Area Diagnostic Cardiac Catheterization Procedures 2009 - 2011			
Hospital/County	**2009**	**2010**	**2011**
CEMC/Craven	1,429	1,570	1,828
NA/Jones	0	0	0
NA/Pamlico	0	0	0
Carteret General Hospital/ Carteret	0	0	0
Onslow Memorial/Onslow	45	16	17

Source: 2013 State Medical Facilities Plan.

These hospitals are not comparable to CEMC in the volume of cardiac catheterization services. From the 2013 SMFP, *Table 9S: Adult Diagnostic Fixed Cardiac Catheterization Procedures* by Facility and Aggregate Cardiac Catheterization Totals*, the above table shows the average number of cardiac catheterization procedures by facility for each hospital over the most recent three years. CEMC also performs therapeutic cardiac catheterizations and Onslow Memorial Hospital is a referral source for therapeutic cardiac catheterizations and open heart patients.

The 2013 SMFP shows a need determination for one cardiac catheterization unit in the Craven/Jones/Pamlico Cardiac Service Area. CEMC states that this need was identified due to the volume of cardiac catheterization procedures at CEMC. CEMC states that two additional factors are driving the medical center's quest for a third cardiac catheterization unit.

In Section III, page 59, CEMC states,

> "*… As the primary interventional catheterization service for the area, CEMC is committed to accept and to provide cardiac care for patients as needed. CEMC's commitment requires additional capacity in the cardiac catheterization laboratories. Finally, as a … comprehensive cardiac facility, residents and physicians of the greater Craven County community prefer the … cardiac services provided by CEMC. As a result, its cardiac catheterization laboratories have continued to operate in excess of 80 percent of capacity during the past two years. …*"

In Section IV, page 78, the applicant provides historical utilization. The table below shows CEMC's cardiac catheterization utilization for the full two years prior to the submission of the application.

CEMC Cardiac Catheterization Historical Utilization 2012 - 2012		
Cardiac Catheterization	**Prior Full FY 10/1/10 – 9/30/11**	**Last Full FY 10/1/11 – 9/30/12**
#Units	2	2
#Diagnostic Procedures	1,221	1,125
#Therapeutic Procedures	756	803

#Diagnostic Equivalent Procedures	2,544	2,350

The applicant adequately demonstrates the need to acquire a third cardiac catheterization unit. Projected utilization is based on reasonable, credible, and supported assumptions. A description of the methodology and assumptions that CEMC uses to project utilization is provided in Section III.b, pages 59-66. A summary can be found in response to Criterion (3) of the findings regarding projected utilization and is incorporated as if fully set forth herein. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities, and therefore the application is conforming to this criterion.

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

C

In Section VII.3(a), page 113, the applicant states the following in regard to staffing requirements of the proposed project:

> "*No new positions will be established as a result of the proposed project. All positions identified in Table VII.1 already exist at CEMC. Incremental FTEs to be added in existing positions by the second full fiscal year of the project are identified in Table VII.1.(b).*"

In Section VII.1(a) and (b), pages 111-112, the applicant provides current and proposed staffing as shown in the following table.

CEMC Current and Proposed Cardiac Catheterization Staffing		
Positions	**Current (FY 2012)**	**Proposed (FY 2016)**
RN	7	9
Technicians	6	9
Lab Support Technicians (PCT)	2	3
Total	15	21

In Section VII.8, page 115, CEMC states that Dr. T. Reed Underhill is chief of staff. In Section II.8, page 50, CEMC states that Dr. Alex Kirby is medical director of the cardiac catheterization department and that Dr. Kirby is board certified in internal medicine. CEMC states that he will continue to serve as medical director after project completion. In Exhibit 12, Dr. Kirby's curriculum vitae states that he is also board certified in interventional cardiology, general cardiology and nuclear cardiology. Exhibit 23 (pages 491 and 497) contains letters of support from Dr. Underhill and Dr. Kirby, respectively.

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, page 22, the applicant states that the ancillary and support services required for the proposed project are already available. In Exhibit 5, page 260, is a February 15, 2013 letter from the President and Chief Executive Officer stating such and that the necessary ancillary and support services will continue to support CEMC cardiac catheterization services. Those ancillary and support services include: laboratory, radiology, pharmacy, dietary, housekeeping, maintenance and administration. In Exhibit 6, pages 261-273, CEMC provides its transfer agreement list and a sample transfer agreement. In Exhibit 7, pages 274-280, the applicant provides a sample of the CEMC transfer agreement policy. Exhibit 23, pages 490-565, contains physician letters of support for the proposed project; including letters from referring physicians for the cardiac catheterization services. 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.

NA

(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 107, the applicant provides the payor mix for Fiscal Year 2012 for the entire medical center and the cardiac catheterization laboratory, as illustrated in the below table:

CEMC FY 2012 Payor Mix % of Current Patient Days/Procedures As Percent of Total Utilization		
	CEMC Entire Facility	**Cardiac Catheterization Service**
Self Pay / Indigent/Charity/ Other*	9.3%	8.6%
Medicare/Medicare Managed Care	59.5%	64.9%
Medicaid	13.1%	5.3%
TriCare	6.2%	3.1%
Commercial/Managed Care	11.92%	18.1%
TOTAL	100.0%	100.0%

*Other includes workers compensation and other government payors.

In Section VI.6, page 102, the applicant states in part:

"*CEMC's services are and will remain accessible to Medicare and Medicaid recipients, the uninsured, and the underinsured. Patient Financial Services Counselors assist patients and families in understanding their eligibility for financial support.*"

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. The data in the table was obtained on March 14, 2013. More current data, particularly with regard to the estimated percentages of the uninsured, was not available.

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 offered by CarolinaEast Medical Center.

	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)**
Craven County	15.0%	6.5%	19.6%
Jones County	20.0%	9.8%	20.9%
Pamlico County	18.0%	8.1%	20.3%
Statewide	17.0%	6.7%	19.7%

The DMA website also contains the *Medicaid Annual Report, for State Fiscal Year (SFY) 2008*, the most recent fiscal year for which this data are available. According to this report, the elderly and disabled Medicaid recipients in North Carolina comprised 29% of total Medicaid recipients. Additionally, there were 145,898 aged (age 65+) Medicaid recipients in SFY 2008, which comprised 8.5% of the total Medicaid eligibles in North Carolina [145,898 / 1,726,412 total eligibles = 0.0845]. The July 2011 county population data showed that the aged (persons aged 65 and above) comprised 16% of the Craven County population (OSBM Demographic County Totals). In Craven County, Medicaid data is available for the first three months of CY 2013. The data shows that, for the first three months of 2013, the aged comprised 7.7% of the total Medicaid eligibles in Craven County [1,152 aged / 14,928 total eligibles = 0.0772].

Medicaid Recipients by Eligibility category data compare North Carolina Medicaid recipients grouped by age for SFY 2008 with the general population of the entire state, as shown in the table below:

MEDICAID RECIPIENTS BY ELIGIBILITY CATEGORIES VS. GENERAL POPULATION SFY 2008		
ELIGIBILITY CATEGORY	**MEDICAID**	**GENERAL**

	RECIPIENTS	POPULATION
Children (aged 5 – 20 years)	38%	24%
Adults (aged 21-64 years)	31%	57%
Children (aged birth-4 years)	21%	7%
Elderly (aged 65 and older)	10%	12%

As shown in the table below, of Medicaid recipients grouped by age, children ages five to 20 constitute the largest group (38% versus 24% in the general population); while adults aged 21 to 64 are the second largest group (31% versus 57%); followed by young children from birth to age four (21% versus 7%), and the elderly ages 65 and older (10% versus 12%).

Medicaid Recipients by Eligibility Categories vs. General Population SFY 2008

Eligibility Category	Medicaid Recipient %	General Population %
Children (aged 5-20 years)	38%	24%
Adults (aged 21-64 years)	31%	57%
Children (aged birth-4 years)	21%	7%
Elderly (aged 65 and older)	10%	12%

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. The statewide percentage of Medicaid recipients receiving dental services was 48.6% for those aged 20 and younger in SFY 2010 (Craven County's percentage was 51.9% for those age 20 and younger) and it was 31.6% for those age 21 and older (Craven County's percentage was 32.8% 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. Provisional county level data on this website shows that Craven County had a certified projected total population of 104,965 as of July 1, 2011. Fifty-one percent [53,776] of the county's total population was age 45 and older. 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 CarolinaEast Medical Center. 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 106, the applicant states there have been no civil rights complaints filed against CEHS in the past five years.

In Section VI.11, page 106, 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, pages 108-109, the applicant provides the projected payor mix (expected to be consistent with historical payor mix) for the entire facility and each service component in the second operating year (FY2016), following project completion, as shown in the following table:

CEMC 2nd Full FY(10/1/2015 - 9/30/2016) Payor Mix As Percent of Total Utilization		
	Entire Facility	**Cardiac Catheterization Laboratory**
Self Pay / Indigent/Charity/ Other*	9.3%	8.6%
Medicare/Medicare Managed Care	59.5%	64.9%
Medicaid	13.1%	5.3%
TriCare	6.2%	3.1%
Commercial/Managed Care	11.9%	18.1%
TOTAL	100.0%	100.0%

*Other includes worker's compensation and other government payors.

In Section VI.2, page 91, the applicant states in part,

"*CEMC does not discriminate against low-income persons, racial or ethnic minorities, women, handicapped persons, the elderly, or other underserved persons, including the medically indigent. CEMC provides access to care to all patients regardless of age, race, national or ethnic origin, disability, gender, income, or immediate ability to pay. Patients are admitted and services are rendered in compliance with: Title VI of the Civil Rights Act of 1963, Section 504 of Rehabilitation Act of 1973, The Age Discrimination Act of 1975 and Americans with Disabilities Act.*"

Exhibit 15 contains CEMC's Charity Care Policy and Exhibit 16 contains the Credit and Collection Policy. The applicant demonstrates that medically underserved populations will have adequate access to the cardiac catheterization services provided at CEMC. 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 105, the applicant states that patients have access to CEMC services through physician referrals and the emergency department. 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 80-2, the applicant provides existing student clinical training affiliations and lists the training programs with which agreements are in place. The following table shows some of these affiliations; while Exhibit 14, pages 361-374 contains a complete list of affiliations. Exhibit 14 also contains a sample training affiliation agreement for health professions.

CEMC Health Professions Training Relationships	
School	**Clinical Program**
Beaufort College	Medical Laboratory Science & Nursing
Brunswick Community College	Health Information Technology
Campbell University	Pharmacy
Carteret Community College	Nursing, Nursing Assistant & Radiology
Duke Medical Center	Certified Registered Nurse Anesthetist, Nursing, Physical & Occupational Therapy
East Carolina University	Cardiac Rehabilitation, Health Fitness, Physician Assistant, Social Work & Nutrition/Dietetics
Eastern Virginia Medical School	Physician Assistant

Pitt Community College	Cardiovascular Interventional Technology, Medical Cardiovascular Sonography, Nuclear Medicine, Computed Tomography, MRI, & Radiation Oncology

The applicant states that as the only acute care provider in Craven County, CEMC's health professions training relationships are long-standing. In addition to institutions of higher education, CEMC also provides hands on experience for four area high schools as part of their health occupations curricula. The applicant adequately demonstrates that the proposed services accommodate the clinical needs of health professional training programs in the area. 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

See Section V.7, pages 88-89, in which CEMC discusses how the proposed project will foster competition by promoting cost-effectiveness, quality and access to outpatient services. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to acute care services in Craven County and surrounding counties (Jones, Pamlico, Carteret and Onslow). The following conclusions are based on a review of the information in Sections II, III, V, VI and VII and the ProFormas:

- The applicant adequately demonstrates the need to acquire a third fixed cardiac catheterization and that it is a cost-effective alternative. In Section V.7, page 88, the applicant discusses the cost effectiveness of renovating space rather constructing new space, thus the cost will be much less. Furthermore, existing support services and staff will also be used for the third cardiac catheterization laboratory at a cost savings to CEMC and the greater service area.

- The applicant proposes to provide quality services; and states in Section II, pages 24-26,

  "*The goals and priorities of CEMC's performance improvement process include promoting patienet* [sic] *safety and continuous improvement of care as measured by clinical outcomes, quality dimensions and customer*

satisfaction. Priorities are idenfified [sic] *by CEMC's governing board and are reevaluated and determined on an annual basis*."

In Section V.7, page 88, the applicant states,

"*CEMC believes the high quality of and added capacity to its existing cardiac catheterization program will allow residents of the greater Craven County areas to be cared for in a nearby facility when they might otherwise have had to be transported to Vidant Medical Center in Greenville or to one of several hospitals in the Triangle area. Additional capacity at CEMC not only improves access to heart services locally but also provides competition to the heart services programs in Greenville and the Triangle*."

- The applicant proposes to provide adequate access to medically underserved populations. In Section VI, pages 91-92, the applicant states:

"CEMC does not discriminate against low-income persons, racial or ethnic minorities, women, handicapped persons, the elderly, or other underserved persons, including the medically indigent. CEMC provides access to care to all patients regardless of age, race, national or ethnic origin, disability, gender, income, or immediate ability to pay. …

As the sole acute healthcare provider for a three-county area in rural coastal North Carolina and as the tertiary provider for a broader region, CEMC recognizes its role within the greater community to make high quality healthcare more accessible and affordable for all."

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

CEMC is accredited by the Joint Commission on Accreditation of Healthcare Organizations; including the cardiac catheterization laboratory. CEMC 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 32 and III.1(b), page 64, the applicant provides the projected number of adult diagnostic and therapeutic cardiac catheterization procedures to be performed in CEMC's cardiac catheterization lab for each of the first three years following completion of the project. In Section III.1(b), pages 54-59, 59-66 and Section III.5(d), page 74, the applicant provides the table below in addition to the assumptions and methodology used for these projections. In Section II.8, page 16, the applicant states that the proposed cardiac catheterization equipment will be used to perform diagnostic and therapeutic cardiac catheterization procedures on adults. CEMC does not perform pediatric cardiac catheterization procedures.

CEMC Cardiac Catheterization Projected Patient Origin – Project Years 1 & 2				
County	**Year 1 Projected Lab Procedures**	**Year 1 % Lab Procedures**	**Year 2 Projected Lab Procedures**	**Year 2 % Lab Procedures**
Craven	1,085	55.5%	1,169	55.5%
Carteret*	276	14.1%	297	14.1%
Onslow	217	11.1%	233	11.1%
Pamlico	152	7.8%	164	7.8%
Jones	115	5.9%	124	5.9%
Other**	111	5.7%	120	5.7%
Total	1,956	100.0%	2,107	100.0%

***** *CEMC expects Carteret County diagnostic procedures to shift back to CGH when that laboratory is developed.*
**Other includes Alamance, Beaufort, Chatham, Currituck, Duplin, Gaston, Guilford, Henderson, Hyde, Lenoir, Mecklenburg, Mitchell, Nash, Orange, Pender, Pitt, Sampson, Wake, Wayne, Wilkes, Wilson and Yadkin counties.

(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 33, the applicant states that CEMC performed 1,253 stress tests during FY 2012.

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

-C- In Section II.8, page 33, the applicant states that two patients received intravenous thrombolytic therapies at CEMC during FY 2012.

(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 34, the applicant states that in FY 2012, of 1,857 cardiac catheterization patients, CEMC had 703 patients that presented to the Emergency Room.

(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 34, the applicant states that CEMC, having a comprehensive heart surgery program, did not refer or transfer any cardiac catheterization procedures or open heart surgery procedures during FY 2012.

(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."

-C- In Section II.8, pages 34-35, the applicant states that CEMC performed 1,092 diagnostic cardiac catheterization procedures and 826 therapeutic cardiac catheterization procedures during FFY 2012. The applicant also explained on pages 34-35, the difference in the number of procedures used in this application versus the number of procedures reported in the most recent licensure form (LRA) on file with the Division of Health Service Regulation. The LRA requires patient to be counted as having one procedure per visit to the catheterization lab, regardless of how many diagnostic, interventional or EP procedures that are actually performed.

(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 36-37, the applicant provides the number of adult cardiac catheterization patients from the proposed cardiac catheterization service area that the applicant projects to serve by county of residence. In Section III.1(b), pages 59-66 and Section III.5(d), page 74, CEMC provides the assumptions and methodology used in the projections. CEMC does not provide pediatric cardiac catheterization services.

CEMC Patient Origin Project Year 1 - FY 2015			
County	**Diagnostic**	**Therapeutic**	**Total**
Craven	528	511	1,049
Carteret	0	327	327
Onslow	104	107	211
Pamlico	77	69	146
Jones	56	55	111
Total	776	1,070	1,845

CEMC Patient Origin Project Year 2 - FY 2016			
County	**Diagnostic**	**Therapeutic**	**Total**
Craven	546	573	1,119
Carteret	0	367	367
Onslow	106	120	226
Pamlico	79	77	156
Jones	57	62	119
Total	787	1,200	1,987

CEMC Patient Origin

Project Year 3 - FY 2017			
County	**Diagnostic**	**Therapeutic**	**Total**
Craven	554	643	1,197
Carteret	0	412	412
Onslow	107	135	242
Pamlico	80	87	166
Jones	58	69	127
Total	799	1,346	2,145

(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 37, the applicant states, "*As the leader in cardiac services in Craven County, CEMC receives referrals from most of the physicians on staff at the medical center. Please see Exhibit 23 for letters of support from physicians indicating their intent to admit patients to CEMC for cardiac catheterization services as well as letters of support from the cardiologists who will perform the procedures*." In addition to the letters of support from cardiologists, CEMC includes 50 letters of support from referring physicians.

(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 37, CEMC states that over 72,730 people were cared for in the emergency department and that the medical center maintains radio communication with EMS vehicles.

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

-C- In clarifying information requested by the Agency, the applicant states that CEMC has three cardiac catheterization teams available. In Section II.8, page 38, the applicant discusses the composition of the cardiac catheterization teams and the projected staffing after completion of the project. CEMC states, "*Each of CEMC's cardiac catheterization teams consists of at least one registered nurse (RN), two cardiac technologists (techs), and a physician (cardiologist). These staffing patterns are not expected to change with the proposed project*." In Section VII, pages 111-12, the applicant provides current and projected staffing for the proposed cardiac catheterization equipment and will continue to operate 24 hours, seven days per week.

CEMC Current and Proposed Cardiac Catheterization Staffing

Positions	Current (FY 2012)	Proposed (FY 2016)
RN	7	9
Technicians	6	9
Lab Support Technicians (PCT)	2	3
Total	15	21

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

-C- CEMC provides Exhibit 10 as documentation of staff orientation, performance evaluation and continuing education policy, orientation competency assessment and competency checklist for the department of imaging which includes the cardiac catheterization laboratory.

(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:*

-NA- In Section II.8, page 39, the applicant states, "*CEMC is a comprehensive cardiac services program, including community outreach, emergency treatment of cardiovascular illnesses, non-invasive diagnostic imaging modalities, diagnostic and therapeutic catheterization procedures, open heart surgery and cardiac rehabilitation services. As such, a written agreement with another comprehensive cardiac service program is not necessary*."

The applicant further states that for very complex procedures that CEMC does not perform (such as pediatric cardiology and heart transplantation), patients are transferred to Vidant Medical Center-Greenville, UNC Hospitals or Duke University Hospital.

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

-C- In Section II.8, page 40, CEMC states that the medical center follows the patient selection criteria as set forth in the American College of Cardiology and the Society for Cardiac Angiography and Interventions. CEMC states that both are endorsed by the American Heart Association (AHA) and the Diagnostic and Interventional Catheterization Committee of the Council on Clinical Cardiology of the AHA. CEMC's referral process for patients with more complex needs is stated immediately above in 10A NCAC 14C .1602 (8).

(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- In Exhibit 3 is documentation of the contractual arrangements for the acquisition of the proposed cardiac catheterization equipment and Section VIII.2, page 119, includes itemization of the cost of the equipment.

(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 40-41, CEMC states that the cardiac catheterization equipment was chosen based on the specifications required in the CEMC catheterization laboratory and the guidelines of appropriate accrediting agencies. Exhibit 11 contains a letter from the CEMC president attesting that the CEMC catheterization laboratory and the proposed equipment will follow those guidelines.

.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.*

-C- In Section II, page 41, CEMC projects utilization for three cardiac catheterization units during the fourth quarter of the third year following project completion. The standard is 60% of capacity for each item of cardiac catheterization equipment. According to 10A NCAC 14C **.**1601, one therapeutic procedure is valued at 1.75 diagnostic equivalent procedure; while capacity of one unit of catheterization equipment is 1,500 diagnostic-equivalent procedures per year. Three units of cardiac catheterization equipment as CEMC proposes equates to 4,500 total diagnostic-equivalent procedures per year. Therefore, 60% of 4500 diagnostic-equivalent procedures is

2700 diagnostic-equivalent procedures. CEMC projections meet that standard as shown in the following four tables.

CEMC Project Year 3 Cardiac Catheterization Utilization (Procedures)					
	Quarter 1	**Quarter 2**	**Quarter 3**	**Quarter 4**	**Total**
Diagnostic	212	212	212	212	847
Therapeutic	357	357	357	357	1,427
Total	568	568	568	568	2,274

Note: Numbers do not foot due to computer rounding.

CEMC Project Year 3 Cardiac Catheterization Utilization (Diagnostic-Equivalent Procedures)					
	Quarter 1	**Quarter 2**	**Quarter 3**	**Quarter 4**	**Total**
Diagnostic	212	212	212	212	847
Therapeutic	624	624	624	624	2,497
Total	836	836	836	836	3,344

CEMC Project Year 3 Cardiac Catheterization Capacity (Diagnostic-Equivalent Procedures)					
	Quarter 1	**Quarter 2**	**Quarter 3**	**Quarter 4**	**Total**
Total Procedures	1,125	1,125	1,125	1,125	4,500

CEMC Project Year 3 Cardiac Catheterization Utilization (Percent of Capacity)					
	Quarter 1	**Quarter 2**	**Quarter 3**	**Quarter 4**	**Total**
Total Procedures	74.3%	74.3%	74.3%	74.3%	74.3%

.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;*

-C- In Section II.8, page 43, CEMC provides the following chart which shows that CEMC projects to perform 476 therapeutic procedures per catheterization team by Year 3, which exceeds the minimum standard.

CEMC Annual Therapeutic Cardiac Catheterization Procedures			
	Project Year 1	**Project Year 2**	**Project Year 3**
Therapeutic Procedures	1,134	1,272	1,427
# Catheterization Teams	3	3	3
Procedures per Team	378	424	476

.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 II.8, pages 43-44, CEMC provides the following chart which shows that CEMC projects to perform 847 therapeutic procedures per catheterization team by Year 3, which exceeds the minimum standard. The applicant states, "*Please note that this calculation is based on diagnostic procedures only; however, the cardiac cath teams will perform both diagnostic and therapeutic procedures, the latter of which are shown in response to the previous rule*."

CEMC Annual Diagnostic-Equivalent Cardiac Catheterization Procedures			
	Project Year 1	**Project Year 2**	**Project Year 3**
Diagnostic Procedures	822	835	847
# Catheterization Teams	3	3	3
Diagnostic-Equivalent Procedures per Team	274	278	282

.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 III.5(c), page 74, CEMC identifies Craven County as its primary cardiac catheterization service area with approximately 56% of cardiac catheterization procedures originating from there. CEMC states its secondary cardiac catheterization service area as Carteret, Onslow, Pamlico and Jones counties. Other North Carolina counties and other states complete CEMC patient origin. **Note:** CEMC expects patients from Carteret County to utilize the proposed cardiac catheterization laboratory for which Carteret General Hospital is expected to file a certificate of need application.

CEMC Projected Patient Origin – Cardiac Catheterization Procedures				
County	**Year 1 Projected Lab Procedures**	**Year 1 % of Total Lab Procedures**	**Year 2 Projected Lab Procedures**	**Year 2 % of Total Lab Procedures**
Craven	1,085	55.5%	1,169	55.5%
Carteret^	276	14.1%	297	14.1%
Onslow	217	11.1%	233	11.1%
Pamlico	152	7.8%	164	7.8%
Jones	115	5.9%	124	5.9%
Other*	111	5.7%	120	5.7%
Total	1,956	100.0%	2,107	100.0%

^See above note. *****Other includes: Alamance, Beaufort, Chatham, Currituck, Duplin, Gaston, Guilford, Henderson, Hyde, Lenoir, Mecklenburg, Mitchell, Nash, Orange, Pender, Pitt, Sampson, Wake, Wayne, Wilkes, Wilson and Yadkin counties.

.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- CEMC is not proposing to acquire mobile 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*;

-C- In Section II.8, page 46, CEMC states that 1,092 diagnostic and 826 therapeutic cardiac catheterization procedures were performed at the medical center in federal fiscal year 2012 (FFY). Further, the applicant states that each therapeutic procedure was multiplied by 1.75, and each diagnostic procedure was multiplied by 1.00, and that CEMC's

utilization (as shown in the chart below) is 84.6% which exceeds the 80% threshold as required by 10A NCAC 14C .1601.

CEMC Cardiac Catheterization Utilization FFY 2012	
Diagnostic Procedures	1,092
Therapeutic Procedures	826
Total Procedures	1,918
Therapeutic Adjustment	1.75
Diagnostic Equivalent Procedures	2,537
Capacity per Unit	1,500
Number of Units	2
Total Capacity at CEMC	3,000
Utilization as a % of Capacity	84.6%

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

-C- See 10A NCAC 14C .1603(a)(1) above as CEMC projects to have an average annual rate of 74.3%, which will exceed the average annual rate of 60% of capacity during the fourth quarter of the third project year.

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

-C- In Section III(1)(b), pages 59-66, CEMC provides the assumptions and methodology used in development of the projections for the 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;*

-NA- CEMC is not proposing to acquire shared fixed cardiac catheterization equipment.

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

-NA- CEMC is not proposing to acquire shared fixed cardiac catheterization equipment.

.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- In Section II.8, page 48, CEMC 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*.

-C- In Section II.8, page 48, CEMC states that open heart surgery has been performed at the medical center since 1998 and is performed within the same facility as the proposed cardiac catheterization laboratory, as documented in the 2013 SMFP.

.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.*

-C- In Section II.8, pages 48-49, CEMC states that open heart surgery is performed within the same facility as the cardiac catheterization laboratory, and that the proposed third cardiac catheterization laboratory will not change access to open heart surgery.

.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 Section II.8, pages 49-50, CEMC states that the medical center provides all of the above listed services. Exhibit 5 contains a letter from Raymond Leggett, President of CEMC which verifies that the medical center provides all the services listed immediately above as (1)-(10).

.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 115, CEMC states that Dr. T. Reed Underhill is chief of staff. In Section II.8, page 50, the CEMC states that Dr. Alex Kirby is medical director of the cardiac catheterization department and

that Dr. Kirby is board certified in internal medicine. CEMC states that he will continue to serve as medical director after project completion. In Exhibit 12, Dr. Kirby's curriculum vitae states that he is also board certified in interventional cardiology, general cardiology and nuclear cardiology. Letters of support from Dr. Underhill and Dr. Kirby, are provided in Exhibit 23, pages 491 and 497, respectively.

.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- CEMC provides the three proposed cardiac catheterization teams in Section II, page 43 and provides current and proposed teams in Section VII, pages 111 and 112. A table which shows the composition of the teams is found above in 1602 B (6) Information Required of Applicant in these Rules. Each team is comprised of one registered nurse, two cardiac technicians and a cardiologist.

.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 52, CEMC states, "*All staff must be BCLS and ACLS certified and main current licensing and continuing education requirements of their respective discipline. As each cardiac team consists of one RN and two cardiac techs, the appropriate certifications required for each team are already in place*."

(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 52, CEMC references Exhibit 10, which includes a copy of the staff training, orientation and continuing education program for the department of imaging. CEMC states, "*Exhibit 10 also contains a copy of the medical center's Competency Assessment Policy, which provides a consistent and comprehensive approach to assess, maintain, demonstrate, and improve continually the competence of CEHS personnel who provide care, treatment and services*."