

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 28, 2017

Findings Date: February 28, 2017

Project Analyst: Tanya S. Rupp

Assistant Chief: Martha Frisone

Project ID #: P-11276-16

Facility: CarolinaEast Medical Center

FID #: 923126

County: Craven

Applicant: CarolinaEast Medical Center, Inc.

Project: Acquire angiography equipment and install it in an existing operating room which will be developed into a hybrid operating room

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, CarolinaEast Medical Center, Inc. (CEMC) proposes to acquire angiography equipment to be installed in an existing operating room (OR) located in the hospital, which it will develop into a hybrid OR. A hybrid OR is one that combines interventional and imaging services with appropriate operating room features. In Section III.1, page 32, the applicant states it expects to use the hybrid OR primarily for cardiovascular procedures, but will provide other procedures as needed.

#### **Need Determination**

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2016 State Medical

Facilities Plan (2016 SMFP). Therefore, there are no need determinations in the 2016 SMFP that are applicable to this review.

### **Policies**

There is one policy applicable to this review. Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES which states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN 4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy-GEN 4. The plan shall not adversely affect patient or resident health, safety, or infection control.”*

The capital expenditure for this proposed project is greater than \$2.0 million, but less than \$5.0 million. In Section III, pages 40 - 42 and Section XI.7, pages 104 - 106, the applicant describes the proposed project’s plan to assure improved energy efficiency and water conservation. The application is consistent with Policy GEN-4.

### **Conclusion**

In summary, the applicant adequately demonstrates that its proposal is consistent with Policy GEN-4. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic

minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

CEMC proposes to acquire angiography equipment to be installed in an existing operating room (OR) located in the hospital, which it will develop into a hybrid OR. A hybrid OR is one that combines interventional and imaging services with appropriate operating room features, obviating the need to move patients from room to room for imaging and surgical services. The applicant states in Section II.1, page 15, that it received an exemption from certificate of need (CON) law in 2014 to expand and renovate existing space in its women's and children's center on the main hospital campus. As part of that renovation, the applicant was approved to replace two existing ORs to bring them to industry standards. In this application, the applicant proposes to acquire hybrid lab angiography equipment and install it in one of the two renovated ORs, creating one hybrid OR in the hospital.

**Patient Origin**

The 2016 SMFP does not define the service area for angiography equipment. Likewise, the Criteria and Standards for Major Medical Equipment (10A NCAC 14C .3100), which are applicable to this review, do not define a service area. In Section III.5, pages 45 - 47, the applicant defines its service area for the proposed services as Craven, Carteret, Onslow, Jones and Pamlico counties.

In Section III.4, page 45, the applicant provides, by percentage, the current patient origin for the types of services that are typically performed in a hybrid OR, as shown in the table below.

**CEMC  
Current Patient Origin  
by County of Residence**

COUNTY	% OF TOTAL
Craven	44.6%
Carteret	24.1%
Onslow	13.4%
Jones	5.4%
Pamlico	5.4%
Other	7.1%
<b>Total</b>	<b>100.0%</b>

Numbers may not foot due to rounding  
\*On page 45, the applicant states "other" includes Beaufort, Cumberland, Duplin and Hyde counties and other states.

In Section III.5, page 47, the applicant projects patient origin for its angiography services during the first two operating years following completion of the project, as shown in the table below:

**CEMC**  
**Projected Patient Origin by County of Residence**

COUNTY	OY 1 % OF TOTAL	OY 2 % OF TOTAL
Craven	44.6%	44.6%
Carteret	24.1%	24.1%
Onslow	13.4%	13.4%
Jones	5.4%	5.4%
Pamlico	5.4%	5.4%
Other	7.1%	7.1%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Numbers may not foot due to rounding

\*On page 47, the applicant states “other” includes Beaufort, Cumberland, Duplin and Hyde counties and other states.

The applicant provides the assumptions and methodology used to project patient origin on page 47, stating “*The projected patient origin is based on the FY 2016 patient origin for cases CEMC has historically provided that would be performed in the proposed hybrid operating room.*”

The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section III.1, pages 31 – 33, the applicant discusses the need the hospital has for the proposed equipment. Currently, CEMC has a C-arm fluoroscopy unit for its fluoroscopic imaging; however, that equipment is limited in its scope. The applicant states the acquisition of the proposed equipment will help CEMC to more effectively serve its patients and enhance the quality of the services it provides by allowing for the provision of detailed imaging and surgical procedures in one room in the hospital. The proposed equipment is designed for imaging in the operating room setting and provides greater accuracy in image-guided procedures at low radiation doses. Additionally, the ergonomic design of the equipment allows physicians, surgeons and anesthesiologists free access to the patient.

The applicant states on page 32 that it currently performs endovascular AAA procedures (endovascular abdominal aortic aneurysm repair) using its C-arm, but states the imaging capability of the C-arm is limited. Acquiring the proposed angiography equipment will allow for more precise and in-depth imaging for the endovascular AAA procedures. In addition, the proposed equipment will allow CEMC to provide transcatheter aortic valve replacement (TAVR) procedures, which it currently is unable to provide. TAVR is a minimally invasive, image-guided valve replacement procedure. Without the proposed equipment, the applicant states patients would have to undergo open heart surgery for the valve replacement, which carries significantly more risk and expense. The applicant projects it will perform both cardiovascular procedures and other procedures, such as percutaneous nephrolithotomy procedures (PNL), which remove kidney stones.

In Section III.1, page 32, the applicant states:

*“As TAVR procedures are fast becoming the standard of care for valve replacement, many patients currently seek such care at facilities with TAVR capabilities, thus requiring them to travel out of their home county for care. Further, as a tertiary provider and regional referral center, patients often travel to CEMC for care; without the ability to provide TAVR procedures, patients would have to travel even further for care. As a CMS rated Five Star hospital with a Cardiovascular Center of Excellence ..., and as the only acute care hospital in the county, EMC believes it is critical ... that it have the capability of performing cardiovascular procedures that are the standard of care and are of the highest quality.”*

In addition, in Section III.1, page 36, the applicant states it is actively recruiting a cardiothoracic surgeon who specializes in TAVR procedures. The applicant states the new surgeon will begin serving CEMC’s patients in 2018.

Based on a review of the information provided by the applicant in Section III.1, the applicant adequately demonstrates the need for the proposed angiography equipment.

Projected Utilization

In Section III.1, pages 33 - 39, the applicant projects the utilization of the proposed angiography equipment, as summarized below:

- The applicant calculated a 3.8% Compound Annual Growth Rate (CAGR) in the number of cases, for the types of procedures it has historically performed that would normally be performed in a hybrid OR, using its own internal data from FY 2013 to FY 2016. See the following table, which summarizes the applicant’s findings:

	FY 2013	FY 2014	FY 2015	FY 2016	CAGR
Cases typically performed in hybrid OR	100	109	102	112	3.8%

\*Source: application page 34

- The applicant projects that the number of cases performed will grow by 3.8%, commensurate with its historical CAGR, through the third project year, FY 2020. The applicant states the added capability to perform TAVR procedures will also increase utilization, since patients in need of this type of service will now be served at CEMC, rather than traveling out of the county. See the following table, which illustrates projected utilization of the proposed equipment following project completion:

	FY 2017	FY 2018	FY 2019	FY 2020	CAGR
Cases to be performed in hybrid OR	116	121	125	130	3.8%

\*Source: application page 35

- The applicant utilized internal data to determine the percentage mix of outpatient and inpatient cases it has historically performed. The applicant states FY 2016 represents its most recent experience, as illustrated in the following table:

TYPE	FY 2016	% OF TOTAL CASES
IP Cases	95	84.8%
OP Cases	17	15.2%
<b>Total</b>	<b>112</b>	<b>100.0%</b>

\*Source: application page 35

- In Section III.1, page 36, the applicant applies the 3.8% growth percentage to the FY 2016 mix of outpatient and inpatient cases, as illustrated in the following table:

TYPE	FY 2017	FY 2018	FY 2019	FY 2020
Inpatient (85%)	99	102	106	110
Outpatient (15%)	18	18	19	20
Total Cases in hybrid OR	116	121	125	130

\*Source: application page 36

- On pages 36 – 37, the applicant describes its plans for recruiting a cardiothoracic surgeon in FY 2018 who is “*fellowship trained specifically in the use of the hybrid operating room for TAVR procedures....*” The applicant projects that the hybrid OR with the proposed angiography equipment, combined with the new surgeon specializing in TAVR procedures will increase the volume of procedures annually at CEMC, as illustrated in the following table:

Incremental Impact of New Surgeon FY 2018 – FY 2020			
	FY 2018	FY 2019	FY 2020
Inpatient Cases (85%)	271	339	352
Outpatient Cases (15%)	49	61	63
<b>Total Cases</b>	<b>320</b>	<b>400</b>	<b>415</b>

\*Source: application page 37

- On page 36, the applicant explains that it bases the projected incremental impact of the new physician on the experience of other NC hospitals that developed hybrid ORs.
- The applicant initially projects an 80% ramp up and then growth in utilization consistent with the historical CAGR at CEMC. The applicant states the hybrid OR will not be used exclusively for cardiothoracic procedures; thus, total utilization in the hybrid OR will increase as well, as shown in the following table:

**Total Hybrid OR Utilization, FY 2018 – FY 2020**

	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>
Historical Inpatient	102	106	110
Historical Outpatient	18	19	20
New Surgeon Inpatient	271	339	352
New Surgeon Outpatient	49	61	63
<b>Total</b>	<b>441</b>	<b>525</b>	<b>546</b>

\*Source: application page 37

- On page 38, the applicant provides a table to illustrate projected surgical hours through the first three project years, as shown below:

	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>
Total Cases	441	525	546
Total Inpatient	374	446	463
Total Outpatient	67	80	83
Total Hours	1,222	1,457	1,513
Total ORs Needed	0.65	0.78	0.81

\*Source: application page 37

Applicant states total hours are calculated pursuant to the 2016 SMFP: 3 hours times IP volume plus 1.5 hours times OP volume; total ORs needed calculated as total hours / 1,872

CEMC is the only hospital in Craven County, and currently has no hybrid OR. There are no hospitals in Jones or Pamlico counties. The hospital in Onslow County does not report having a hybrid OR on its 2017 Hospital License Renewal Application (LRA). The 2017 LRA was not yet available for the hospital in Carteret County. In addition, there are no ambulatory surgical facilities with ORs in Pamlico or Jones counties. CEMC is actively recruiting a cardiothoracic surgeon who specializes in the types of procedures normally performed in a hybrid OR, and anticipates this surgeon to be on staff by FY 2018. Given that the historical utilization of its existing ORs for the types of procedures normally performed in a hybrid OR has grown by a CAGR of 3.8% over the last three fiscal years without a hybrid OR and without a cardiothoracic surgeon trained in TAVR procedures, its utilization projections are supported and reasonable.

Projected utilization is based on reasonable and adequately supported assumptions.

**Access**

In Section VI.2, pages 62 - 70, CEMC describes how low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved persons, including the medically indigent, currently have and will continue to have access to the services proposed for the hybrid OR.

In Sections VI.12-13, pages 76 - 77, the applicant provides CEMC’s payor mix for the entire facility and for the type of cases that will be performed in the hybrid OR on the proposed equipment for the last full fiscal year (FY 2016), as shown in the following table:

**CEMC Entire Facility FFY 2015**

PAYOR CATEGORY	% OF TOTAL
Self Pay/Indigent/Charity	4.6%
Medicare/Medicare Managed Care	62.1%
Medicaid	12.6%
Managed Care/Commercial	13.0%
Other (Tricare, Worker's Comp, Other Govt)	7.7%
<b>Total</b>	<b>100.0%</b>

Totals may not foot due to rounding

**CEMC Case Types Performed in Hybrid OR FFY 2015**

PAYOR CATEGORY	% OF TOTAL
Self Pay/Indigent/Charity	1.8%
Medicare/Medicare Managed Care	75.0%
Medicaid	1.8%
Managed Care/Commercial	20.5%
Other (Tricare, Worker's Comp, Other Govt)	0.9%
<b>Total</b>	<b>100.0%</b>

Totals may not foot due to rounding

In Section VI.15, page 78, the applicant provides the projected payor mix for CEMC for the proposed equipment during Operating Year Two (FY 2019), as shown in the following table:

**CEMC Hybrid OR OY 2**

PAYOR CATEGORY	% OF TOTAL
Self Pay/Indigent/Charity	1.8%
Medicare/Medicare Managed Care	75.0%
Medicaid	1.8%
Managed Care/Commercial	20.5%
Other (Tricare, Worker's Comp, Other Govt)	0.9%
<b>Total</b>	<b>100.0%</b>

Totals may not foot due to rounding

As shown in the table above, the applicant projects that a total of 76.8% of all cases for angiography services in the hybrid OR will be covered by either Medicare or Medicaid (75.0% Medicare and 1.8% Medicaid). The applicant's projected payor mix for the proposal is based on the historical payor mix for similar services at CEMC.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed ambulatory surgical services.

**Conclusion**

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that this population has for the proposed project and adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.



- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section III.3, pages 42 - 43, the applicant describes the one alternative it considered prior to submitting the application, as summarized below:

- Maintain the Status Quo- the applicant states this is not an effective alternative because it would not be in the best interest of CEMC's patients and would not achieve CEMC's goal of providing state-of-the-art minimally invasive vascular replacement surgeries and other needed procedures. The applicant also states maintaining the status quo would not be consistent with CEMC's mission to provide the highest possible quality care to its patients.

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

- 1. CarolinaEast Medical Center shall materially comply with all representations made in the certificate of need application.**
- 2. CarolinaEast Medical Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VIII of the application and that would otherwise require a certificate of need.**
- 3. CarolinaEast Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

CEMC proposes to acquire angiography equipment to be installed in an existing operating room (OR) located in the hospital, which it will develop into a hybrid OR.

**Capital and Working Capital Costs**

In Section VIII.2, pages 91 - 92, the applicant projects the total capital cost of the project will be \$2,520,286, which includes:

Fixed Equipment	\$2,269,669
Architect & Engineering fees	\$ 21,500
Other (Contingency)	<u>\$ 229,117</u>
Total:	\$2,520,286

In Section IX.1-3, page 96, the applicant states that the proposed project involves existing services; therefore, there is no need for working capital associated with the project.

**Availability of Funds**

In Section VIII.3, page 92, the applicant states that the capital costs of the proposed project will be paid for with the accumulated reserves of CEMC.

Exhibit 15 contains a letter dated November 15, 2016 from the Vice President of Finance and Chief Financial Officer of CEMC which states that she has the authority to commit these funds on behalf of CEMC, and that CEMC will commit the \$2,520,286 identified as needed in Section VIII of the application for the development of the project as proposed.

Exhibit 16 contains a copy of the audited financial report for CEMC for the year ending September 30, 2015, which shows \$30,331,645 in cash and cash equivalents, \$495,399,087 in total assets and \$432,687,758 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

**Financial Feasibility**

In Section XIII, the applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

**CEMC Revenues and Expenses for Angiography Services**

	<b>PROJECT YEAR 1 (FY 2018)</b>	<b>PROJECT YEAR 2 (FY 2019)</b>	<b>PROJECT YEAR 3 (FY 2020)</b>
Number of Cases	441	525	546
Total Gross Revenue (Charges)	\$55,273,648	\$67,865,181	\$72,592,248
Total Net Revenue	\$17,416,928	\$21,384,566	\$22,874,082
Total Operating Expenses (Costs)	\$12,674,010	\$15,264,373	\$16,258,973
<b>Net Profit</b>	<b>\$4,742,918</b>	<b>\$6,120,193</b>	<b>\$6,615,110</b>

Source: application page 112

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section XIII or the Pro Forma tab of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates the availability of sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**Conclusion**

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and operating needs of the project and that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding costs and charges. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

**C**

CEMC proposes to acquire angiography equipment to be installed in an existing operating room (OR) located in the hospital, which it will develop into a hybrid OR. The applicant received an exemption in 2014 to expand and renovate existing space in its women's and children's center on the main hospital campus. As part of that renovation, the applicant was approved to replace two existing ORs to bring them to industry standards. In this application, the applicant proposes to acquire hybrid lab angiography equipment and install it in one of the two renovated ORs, creating one hybrid OR in the hospital.

The 2016 SMFP does not define the service area for angiography equipment. Likewise, the Criteria and Standards for Major Medical Equipment (10A NCAC 14C .3100), which are applicable to this review, do not define a service area.

In Section III.5, pages 45 - 47, the applicant defines its service area for the proposed services as Craven, Carteret, Onslow, Jones and Pamlico counties.

On page 47, the applicant states,

*“CEMC is not aware of any other providers in the service area that provide hybrid operating room services. Nonetheless, the utilization of this service is not publicly reported and, therefore, CEMC does not have access to utilization over the last full fiscal year.”*

CEMC is the only hospital in Craven County and currently has no hybrid OR. There are no hospitals in Jones or Pamlico counties. The hospital in Onslow County does not report having a hybrid OR on its 2017 LRA. The 2017 LRA was not yet available for the hospital in Carteret County. In addition, there are no ambulatory surgical facilities with ORs in Pamlico or Jones counties.

The applicant adequately demonstrates the need to acquire the proposed angiography equipment and adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved hybrid OR services in the proposed service area. Therefore, the application is conforming to this criterion.

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

C

In Section VII.1 and VII.2, pages 80 - 81, the applicant provides the current staffing (FY 2016) and the proposed staffing for the service in Operating Year 2 (FY 2019), as shown in the table below.

**CEMS Current and Proposed Staffing**

POSITION	NUMBER OF FTE POSITIONS	
	CURRENT (FY 2016)	PROPOSED (FY 2019)
RN	2.6	2.6
Surgical Technician	1.1	1.1
Specials Technician	0.0	1.1
Scheduler	0.2	0.2
CSS Technician	0.2	0.2
EVS	0.2	0.2
NA II	0.2	0.2
CRNA	1.1	1.1
<b>Total</b>	<b>5.6</b>	<b>6.7</b>

In Section VII.3, page 84, and Section VII.6, pages 85 - 86, the applicant describes its experience and process for recruiting and retaining staff. In Exhibit 5, the applicant provides a copy of a November 15, 2016 letter from Piotr Dumicz, M.D., expressing his commitment to serve as the Medical Director for the facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section II.2, page 19, the applicant identifies the ancillary and support services that will be provided by hospital staff. Exhibit 3 contains a letter dated November 15, 2016 from the President and CEO of CEMC which confirms the ancillary and support services are available at CEMC.

In Section V.4, page 58, the applicant states: "*As the only hospital in the county, CEMC has established relationships with area healthcare providers.*" In Exhibit 4, the applicant provides copies of existing transfer agreements between CEMC and other area healthcare providers. In addition, in Exhibit 18, the applicant provides letters of support for the proposal from area physicians.

The applicant adequately demonstrates that all necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
  - (i) would be available under a contract of at least 5 years duration;

- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

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 – VI.13, pages 76 - 77, the applicant provides CEMC's payor mix for the entire facility for the type of cases to be performed in the hybrid OR.

**CEMC ENTIRE FACILITY  
LAST FY (FY 2016)**

<b>PAYOR TYPE</b>	<b>% OF TOTAL</b>
Self-Pay/Indigent/Charity	4.6%
Medicare/Medicare Managed Care	62.1%
Medicaid	12.6%
Managed Care/Commercial	13.0%
Other*	7.7%
<b>Total</b>	<b>100.0%</b>

Totals may not foot due to rounding

\*On page 77 the applicant states "other" includes Tricare, Worker's Comp, and 'other Government'

**CEMC CASE TYPES PERFORMED IN HYBRID OR  
 LAST FY (FY 2016)**

PAYOR TYPE	% OF TOTAL
Self-Pay/Indigent/Charity	1.8%
Medicare/Medicare Managed Care	75.0%
Medicaid	1.8%
Managed Care/Commercial	20.5%
Other*	0.9%
<b>Total</b>	<b>100.0%</b>

Totals may not foot due to rounding

\*On page 77 the applicant states "other" includes Tricare, Worker's Comp, and 'other Government'

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Craven	17%	49%	34%	16%	13%	17%
Carteret	22%	51%	14%	15%	13%	19%
Onslow	8%	45%	33%	14%	11%	16%
Jones	22%	51%	38%	22%	17%	22%
Pamlico	26%	49%	26%	18%	11%	20%
Beaufort	22%	52%	34%	19%	14%	20%
Cumberland	11%	51%	55%	18%	11%	16%
Duplin	16%	51%	48%	28%	11%	26%
Hyde	18%	45%	29%	22%	10%	23%
Statewide	15%	51%	36%	17%	10%	15%

Source: [http://www.census.gov/quickfacts/table\\_2014EstimateasofDecember22\\_2015](http://www.census.gov/quickfacts/table_2014EstimateasofDecember22_2015).

\*Excludes "White alone" who are "not Hispanic or Latino"

\*\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicant adequately demonstrates that it currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section VI.11, page 76, the applicant states that CEMC *“has had no obligations to provide uncompensated care during the last three years. ... CEMC regularly partners with local community service organizations and business to facilitate health fairs and screenings for the public at large as well as targeted segments of the population ... in addition to charity care CEHS provides....”* In Section VI.10, page 76, the applicant states that there have been no civil rights equal access complaints filed against CEMC in the last five years. The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Sections VI.14 – VI.15, pages 77 - 78, the applicant projects the payor mix for both the entire facility and for the type of cases projected to be performed in the hybrid OR in the second Operating Year (FY 2019), as shown in the following tables:

**ENTIRE FACILITY SECOND OPERATING YEAR (FY 2019)**

<b>PAYOR TYPE</b>	<b>% OF TOTAL UTILIZATION</b>
Self-Pay/Indigent/Charity	4.6%
Medicare/Medicare Managed Care	62.1%
Medicaid	12.6%
Managed Care/Commercial	13.0%
Other*	7.7%
<b>Total</b>	<b>100.0%</b>

Totals may not foot due to rounding

\*On page 77 the applicant states “other” includes Tricare, Worker’s Comp, and ‘other Government’



**CASES TO BE PERFORMED IN HYBRID OR  
SECOND OPERATING YEAR (FY 2019)**

<b>PAYOR TYPE</b>	<b>% OF TOTAL UTILIZATION</b>
Self-Pay/Indigent/Charity	1.8%
Medicare/Medicare Managed Care	75.0%
Medicaid	1.8%
Managed Care/Commercial	20.5%
Other*	0.9%
<b>Total</b>	<b>100.0%</b>

Totals may not foot due to rounding

\*On page 77 the applicant states "other" includes Tricare, Worker's Comp, and 'other Government'

As shown in the table above, the applicant projects that 75.0% of all cases to be performed on the proposed equipment in the hybrid OR will be covered by Medicare and 1.8% will be covered by Medicaid.

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

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

C

In Section VI.9, pages 74 - 75, the applicant describes the range of means by which a person will have access to the proposed angiography equipment and hybrid OR services. The applicant adequately demonstrates that it will offer a range of means by which a person will have access to the proposed services. Therefore, the application is conforming to this criterion

- 14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1, pages 53 - 55, the applicant describes how the proposed project will accommodate the clinical needs of area health professional training programs. The applicant states:

*"CEMC has established collaborative relationships with a large number of health professional training programs in the area. As the only acute care facility in Craven County, CEMC has long been a supporter of education and is particularly supportive of clinical training for area students."*

The applicant provides a table on pages 53 – 54 that shows the colleges with which CEMC currently has clinical training agreements. In Exhibit 8, the applicant provides an example of a training program affiliation agreement.

The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
  - (16) Repealed effective July 1, 1987.
  - (17) Repealed effective July 1, 1987.
  - (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

## C

CEMC proposes to acquire angiography equipment to be installed in an existing operating room (OR) located in the hospital, which it will develop into a hybrid OR. The applicant received an exemption in 2014 to expand and renovate existing space in its women's and children's center on the main hospital campus. As part of that renovation, the applicant was approved to replace two existing ORs to bring them to industry standards. In this application, the applicant proposes to acquire hybrid lab angiography equipment and install it in one of the two renovated ORs, creating one hybrid OR in the hospital.

The 2016 SMFP does not define the service area for angiography equipment. Likewise, the Criteria and Standards for Major Medical Equipment (10A NCAC 14C .3100), which are applicable to this review, do not define a service area. In Section III.5, pages 45 - 47, the applicant defines its service area for the proposed services as Craven, Carteret, Onslow, Jones and Pamlico counties.

CEMC is the only hospital in Craven County and currently has no hybrid OR. There are no hospitals in Jones or Pamlico counties. The hospital in Onslow County does not report having a hybrid OR on its 2017 LRA. The 2017 LRA was not yet available for the hospital in Carteret County. In addition, there are no ambulatory surgical facilities with ORs in Pamlico or Jones counties.

In Section V.7, pages 59 - 60, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the

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

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

- ◆ The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- ◆ The applicant adequately demonstrates that it will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- ◆ The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

The application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

### C

In Section I, page 12, CEMC describes the hospital and outpatient facilities that are included within the CarolinaEast Health System. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of the application through the date of the decision, CEMC was not found to be out of compliance with one or more Medicare conditions of participation. At this time, CarolinaEast Medical Center is in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at CEMC, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of

health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

CEMC is conforming to all applicable Criteria and Standards for Major Medical Equipment as required by 10A NCAC 14C .3100. See discussion below.

**SECTION .3100 - CRITERIA AND STANDARDS FOR MAJOR MEDICAL EQUIPMENT**

**10A NCAC 14C .3104 NEED FOR SERVICES**

(a) *An applicant proposing to acquire major medical equipment shall provide the following information:*

(1) *the number of patients who will use the service, classified by diagnosis;*

-C- In Exhibit 7, the applicant provides a table to illustrate the projected number of patients who will use the angiography equipment for the first three years following completion of the proposed project, classified by diagnosis.

(2) *the number of patients who will use the service, classified by county of residence;*

-C- In Section II.8, page 28, the applicant provides the following table showing the number of patients who will use the service by county of residence:

COUNTY	% OF TOTAL	PY 1 (FY 2018)	PY 2 (FY 2019)	PY 3 (FY 2020)
Craven	44.6%	197	235	244
Carteret	24.1%	106	127	132
Onslow	13.4%	59	70	73
Jones	5.4%	24	28	29
Pamlico	5.4%	24	28	29
Other*	7.1%	31	38	39
<b>Total</b>	<b>100.0%</b>	<b>441</b>	<b>525</b>	<b>546</b>

\*The applicant states 'Other' includes Beaufort, Cumberland, Duplin and Hyde counties and other states.

(3) *documentation of the maximum number of procedures that existing equipment that is used for similar procedures in the facility is capable of performing;*

- C- In Section II.8, page 28, the applicant documents the maximum number of procedures that existing equipment that is used for similar procedures in the facility is capable of performing.
- (4) *quarterly projected utilization of the applicant's existing and proposed equipment three years after the completion of the project; and*
- C- In Section II.8, page 29, the applicant provides a table showing the quarterly projected utilization of its proposed angiography equipment for the first three years following completion of the project.
- (5) *all the assumptions and data supporting the methodology used for the projections in this Rule.*
- C- The applicant provides the assumptions and data supporting the methodology used for the projections in Section III.1(b), pages 33 - 38.
- (b) *An applicant proposing to acquire new major medical technology shall provide the following information:*
  - (1) *the number of patients who will use the service, classified by diagnosis;*
  - (2) *the number of patients who will use the service, classified by county of residence*
  - (3) *quarterly projected utilization of the applicant's proposed new major medical technology three years after the completion of the project;*
  - (4) *documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies;*
  - (5) *documentation of the effect the new major medical technology may have on existing major medical technology and procedures offered at its facility and other facilities in the proposed service area; and*
  - (6) *all the assumptions and data supporting the methodology used for the projections in this Rule.*
- NA- The applicant is not proposing to acquire new major medical technology.