

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 25, 2019

Findings Date: July 25, 2019

Project Analyst: Bernetta Thorne-Williams

Assistant Chief: Lisa Pittman

Project ID #: P-11701-19

Facility: CarolinaEast Medical Center

FID #: 923126

County: Craven

Applicant: CarolinaEast Medical Center, Inc.

Project: Acquire a third heart lung bypass machine to be used as backup for emergency coverage only

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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.

NA

CarolinaEast Medical Center, Inc. (CEMC) proposes to acquire a third heart lung bypass machine to be used as backup for emergency coverage only.

Need Determination

The applicant does not propose to increase the number of licensed beds in any category, add any new health services, or acquire equipment for which there is a need determination in the 2019 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2019 SMFP that are applicable to this review.

Policies

There are no policies in the 2019 SMFP which are applicable to this review.

Conclusion

In summary, 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 2019 State SMFP. There are no policies in the 2019 SMFP that are applicable to this review. Therefore, this criterion is not applicable.

- (2) Repealed effective July 1, 1987.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 a third heart lung bypass machine to be used as backup for emergency coverage only.

Patient Origin

On pages 99-102, the 2019 SMFP discusses open heart surgery services in North Carolina. Open heart surgery services, as defined in Gen. Stat. §131E-176(18b) “*means the provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects.*”

Table 7A, page 100 of the 2019 SMFP, indicates there were 22 open-heart surgery programs in North Carolina in 2017, providing a statewide total of 10,005 procedures.

The 2019 SMFP does not discuss a need methodology or provide a definition of “service area” for open heart surgery services. However, Step 1, on page 55 of the 2019 SMFP defines the service area for operating rooms as the planning area in which the operating room is located. “*The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.*” Figure 6.1 on page 60 of the 2019 SMFP shows Craven County as a multicounty operating room service area which includes Jones and Pamlico counties. Thus, the service area for this project consists of Craven, Jones and Pamlico counties. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 35 and C.3, page 36, the applicant provides the historical and the projected patient origin for the first three full fiscal years (Full FY) of the proposed project, by county, as illustrated in the tables below.

CEMC Historical Open Heart Cases Utilization*** FFY18		
County	Heart-Lung Bypass Patients	Percent of Total
Craven	93.0	36.3%
Carteret	78.0	30.5%
Onslow	41.0	16.0%
Pamlico	15.0	5.9%
Jones	10.0	3.9%
Beaufort	5.0	2.0%
Other*	14.0	5.5%
Total**	256.0	100.0

*Includes: Lenoir, Pitt, Duplin, Forsyth, Johnston, Martin, Pender, and Rockingham counties and other states

**Totals may not foot due to rounding

***FFY= Federal Fiscal Year (October 1 – September 30)

CEMC Projected Open Heart Cases Utilization						
County	Full FY1 FFY21		Full FY2 FFY22		Full FY3 FFY23	
	Heart-Lung Bypass Patients	Percent of Total	Heart-Lung Bypass Patients	Percent of Total	Heart-Lung Bypass Patients	Percent of Total
Craven	109.0	36.3%	115.0	36.3%	121.0	36.3%
Carteret	92.0	30.5%	97.0	30.5%	102.0	30.5%
Onslow	48.0	16.0%	51.0	16.0%	54.0	16.0%
Pamlico	18.0	5.9%	19.0	5.9%	20.0	5.9%
Jones	12.0	3.9%	12.0	3.9%	13.0	3.9%
Beaufort	6.0	2.0%	6.0	2.0%	7.0	2.0%
Other*	16.0	5.5%	17.0	5.5%	18.0	5.5%
Total**	300.0	100.0%	317.0	100.0%	334.0	100.0%

*Includes: Lenoir, Pitt, Duplin, Forsyth, Johnston, Martin, Pender, and Rockingham counties and other states

**Totals may not foot due to rounding

On page 35, the applicant states that each procedure represents one patient.

On page 36, the applicant states that projected patient origin is based on historical patient origin.

The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

CEMC currently operates two heart-lung bypass machines, the proposed third heart-lung bypass machine will be used to provide backup for emergency coverage only. In Section C.4, pages 37-43, the applicant discusses the need for the additional heart-lung bypass machine. On page 37, the applicant states,

“The proposed project involves the acquisition of a third heart-lung bypass machine to assure adequate coverage in the event of an emergency while the two existing machines are in use. The need for the proposed project is based on population growth and aging in CEMC’s service area, the growth in cardiac services at CEMC, and the need for adequate coverage for emergent open heart surgical cases requiring the use of a heart-lung bypass machine.”

Population growth and aging of the population

On page 37, the applicant defines its service area (SA) as consisting of Craven, Carteret, Jones, Onslow and Pamlico counties. The applicant states, as the only open-heart surgery provider in eastern North Carolina north of Wilmington and east of Greenville, that growth within the population is one of the driving forces behind the need for an additional heart-lung bypass machine. The applicant states that the five counties that comprise its service area are projected to have a compound annual growth rate (CAGR) of 0.7 percent from 2019 through 2024. Additionally, the applicant states that in 2019, 15.3 percent of the population in the applicant’s SA were 65 or older. By 2024, the applicant projects that 16.6 percent of the population in the SA will be over the age of 65 which is an increase of 1.3 percent (pages 37-38).

Growth of cardiac services

The applicant states that the need for a third heart-lung bypass machine to be used for backup emergencies is also driven by the recent growth in cardiac services. The applicant states that CEMC experienced a 10.9% CAGR from FFY 2014 through FFY 2018. The applicant further states that it made an error in reporting 244 open heart surgery cases on its 2019 license renewal application (LRA), instead of 256 open heart surgery cases. The applicant states CEMC submitted a correction to the Acute and Home Care Licensure and Certification Section, Division Health Service Regulation (DHSR). The applicant states that in addition to being used for open heart surgical cases, that heart-lung bypass machines are also used for some interventional procedures which includes Transcatheter Aortic Valve Replacement (TAVR), mitral valve cases (which the applicant projects to begin in 2020), and on cases that require Automated Implantable Cardioverter-Defibrillator (AICD) devices or pacemakers. The applicant states CEMC is projecting significant growth in various services that will increase the utilization of its existing heart-lung bypass machines or will require a machine to be on standby. The applicant states that some of the cases will be generated due to the implementation of a new valve clinic (pages 38-40).

Need for emergency backup machine

The applicant states it is a significant risk to have a patient in need of emergency open heart surgery when there is not a heart-lung bypass machine available. The applicant states that

once per week CEMC has experienced an instance when both heart-lung bypass machines were in use. The applicant further states that in January and February (2019), there were 13 instances of both heart-lung bypass machines being utilized at the same time. The applicant states that in the event both machines are unavailable, a patient would either have to be placed on an intraaortic balloon pump (IABP) or transferred to another hospital. The applicant states that both alternatives place the patient at risk for complications or death. The applicant states that ground transport to Vidant Medical Center in Greenville (the closest hospital), takes approximately one hour and air transport takes approximately 30 minutes. Neither of those times include the time that it takes to prep the patient for transportation (pages 40-42).

The information provided by the applicant is reasonable and adequately supported for the following reasons:

- The applicant uses reasonable and credible national data to make assumptions with regard to identifying the population to be served, the projected growth and aging within its identified service area, and the need the identified population has for the proposed services.
- The applicant provides reasonable information to support the need for the addition of a third heart-lung bypass machine to be used as backup for emergency coverage only.

Projected Utilization

The applicant provides its assumptions and methodology for projected utilization in Section Q. The following table provides the historical and projected utilization for the heart-lung bypass machines at CEMC, as shown in the table below:

CEMC Heart-Lung Bypass Machines

	FFY 2016	FFY 2017	FFY 2018	FFY 2019	FFY 2020	FFY 2021 PY1	FFY 2022 PY2	FFY 2023 PY3
Number of Units	2	2	2	2	2	2	2	2
Actual and projected number of cases	221	248	256	270	285	300	317	334

Note: In Section Q, the applicant states that at no time will the proposed third heart-lung bypass machine be used for scheduled procedures.

- The applicant’s fiscal year (FY) corresponds with the federal fiscal year (FFY) which follows an October 1 through September 31 timeframe.
- The applicant projects the proposed project will be operational at the beginning of the second quarter of FFY2020, therefore the first three full fiscal years are FFY2021, FFY2022 and FFY 2023.
- CEMC is applying for its third heart-lung bypass machine pursuant to 10A NCAC 14C .1703(b)(3). This rule does not require the applicant to meet a performance standard as the proposed third heart-lung bypass machine will only be used to provide backup coverage in the event of an emergency.
- The applicant projects the future utilization of its two existing heart-lung bypass machines on its historical utilization which experienced a 10.9 percent CAGR from

FFY 2014 through FFY2018. The applicant then compares its CAGR to those of North Carolina, as a whole, for procedures utilizing a heart-lung bypass machine. However, the number of procedures for FFY18 were not available at the time the application was submitted. The Project Analyst included the FFY18 data, as shown in the table below.

**CarolinaEast Medical Center and North Carolina Open Heart Procedures
 Utilizing a Heart-Lung Bypass Machine**

	FFY 2014	FFY 2015	FFY 2016	FFY 2017	FFY 2018	CAGR 2014- 2018
CEMC - Procedures utilizing the heart-lung bypass machine	169	208	221	248	256	10.9%
Percent Growth per year		23.1%	6.3%	12.2%	3.2%	
North Carolina – Procedures utilizing the heart-lung bypass machine	9,627	9,567	9,814	10,005	9,960*	0.9%
Percent Growth		-0.6%	2.6%	1.9%	-0.4%	

Source: 2016-2019 SMFP, CEMC 2019 LRA

*Source: Proposed 2020 SMFP, Table 7B

- As shown in the table above, CEMC experienced positive percent growth on its two heart-lung bypass machines from FFY2014-FFY2018, whereas all the heart-lung bypass machines in North Carolina experienced a much lower rate of growth during that same time period.
- The applicant projects utilization forward for its heart-lung bypass machine using one half of its four-year CAGR (5.5 percent), as shown in the table below.

**CarolinaEast Medical Center Projected Procedures
 Utilizing a Heart-Lung Bypass Machine**

	FFY 2019	FFY 2020	FFY 2021	FFY 2022	FFY 2023	CAGR
CEMC - Procedures utilizing the heart-lung bypass machine	270	285	300	317	334	6.9%
Percent Growth		5.5%	5.3%	5.6%	5.4%	

- The applicant projects an annual growth of 5.5 percent each year of the proposed project, which is a CAGR of 6.9 percent.
- The applicant does not propose to schedule any procedures on the proposed third heart-lung bypass machine, but rather will use the machine for emergency backup. The applicant projects, based on its historical utilization, that 52 unscheduled procedures per year or one unscheduled procedure per week will be performed on the proposed backup heart-lung bypass machine.

Projected utilization is reasonable and adequately supported for the following reasons:

- the applicant had a 10.9 percent CAGR for procedures performed on its two existing heart-lung bypass machines FFY2014-FFY2018.

- the applicant projects the number of procedures to be performed from FFY2019 to FFY2023 using one half of its four-year CAGR (5.5%).
- the applicant projects to use the backup heart-lung bypass machine approximately 52 times during the year, or one time per week for emergency procedures only.

Access

In Section C.11, pages 47-48, the applicant states that, CEMC does not discriminate regardless of age, race, national or ethnic origin, disability, gender, income, or ability to pay. In Section L.3, page 88, the applicant provides the projected payor mix during OY2, for the entire hospital and the proposed service component, as illustrated below.

CEMC Projected Payor Mix OY2		
Payment Category	Entire Facility	Open Heart Surgery Services
Self Pay	5.8%	7.0%
Medicare*	61.7%	67.6%
Medicaid*	12.9%	4.8%
Insurance**	19.6%	20.6%
Total*	100.0%	100.0%

*Includes managed care plans

**Workers compensation and Tricare are included in the insurance payor category

The applicant states on page 88, that CEMC does not keep internal records on charity care because any category can receive charity care.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.

- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

(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

The applicant does not propose to reduce, eliminate or relocate a facility or a service. The applicant proposes to add a third heart-lung bypass machine to be used as backup for emergency coverage only. Therefore, Criterion (3a) is not applicable to this review.

(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

The applicant proposes to add a third heart-lung bypass machine to be used as backup for emergency coverage only.

In Section E.1, page 62, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo - The applicant states this option was rejected immediately because it was not in the best interest of CEMC's patients and did not ensure adequate heart-lung bypass capacity in the event of an emergency.
- Acquire a third heart-lung bypass machine to be used for scheduled cases - Despite constant growth of its cardiology program, the applicant did not believe its current utilization warranted the addition of an additional machine to be used for scheduled procedures. Therefore, this alternative was rejected.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- as the only provider of open heart surgery services in eastern North Carolina north of Wilmington and east of Greenville, CEMC has experienced constant growth in its cardiology services,
- the proposed heart-lung bypass machine would only be used for emergency procedures, and

- maintaining the status quo does not address the potential need for additional capacity in the event of an emergency.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. CarolinaEast Medical Center, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to 10A NCAC 14C .1703(b)(3), CarolinaEast Medical Center, Inc. shall acquire one additional heart-lung bypass machine to be used to provide backup coverage in the event of an emergency only, for a total of no more than three heart-lung bypass machines at CarolinaEast Medical Center.**
- 3. CarolinaEast Medical Center, Inc. shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.**
- 4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, CarolinaEast Medical Center, Inc. shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service**
- 5. CarolinaEast Medical Center, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to the issuance of the certificate of need.**

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

C

The applicant proposes to add a third heart-lung bypass machine to be used as backup for emergency coverage only.

Capital and Working Capital Costs

In Section Q, the applicant projects the total capital cost of the project as shown in the table below.

Medical Equipment Cost	\$247,597
Contingency Costs	\$43,610
Total*	\$291,206

*Totals may not foot due to rounding

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 66-67, the applicant projects that no start-up or initial operating expenses will be associated with the proposed project because the proposed project does not involve a new service. On page 67, the applicant provides the assumptions and methodology used to project the working capital.

Availability of Funds

In Section F, page 65, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	CarolinaEast Health System, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$291,206	\$ 291,206
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$291,206	\$291,206

* OE = Owner's Equity

Financial Feasibility

In Section Q, the applicant provided pro forma financial statements for open heart surgery procedures which require the use of the heart-lung bypass machine for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicant

projects that revenues will exceed operating expenses in the first operating year and that operating expenses will exceed revenues in the second and third operating years of the project, as shown in the table below.

	1st Full Fiscal Year FFY2021	2nd Full Fiscal Year FFY2022	3rd Full Fiscal Year FFY2023
Total Procedures	300	317	354
Total Gross Revenues (Charges)	\$45,261,364	\$49,169,285	\$53,414,620
Total Net Revenue	\$14,571,864	\$15,666,398	\$16,844,436
Average Net Revenue per procedure	\$48,573	\$49,421	\$47,583
Total Operating Expenses (Costs)	\$14,506,800	\$15,816,602	\$16,885,236
Average Operating Expense per procedure	\$48,356	\$49,895	\$47,698
Net Income	\$65,064	(\$150,204)	(\$40,800)

However, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project for the entire hospital.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (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 a third heart lung bypass machine to be used as backup for emergency coverage only.

On pages 99-102, the 2019 SMFP discusses open heart surgery services in North Carolina. Open heart surgery services, as defined in Gen. Stat. §131E-176(18b) “*means the provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects.*”

The 2019 SMFP does not discuss a need methodology or provide a definition of “service area” for open heart surgery services. However, Step 1, on page 55 of the 2019 SMFP defines the service area for operating rooms as the planning area in which the operating room is located. *“The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.”* Figure 6.1 on page 60 of the 2019 SMFP shows Craven County as a multicounty operating room service area which includes Jones and Pamlico counties. Thus, the service area for this project consists of Craven, Jones and Pamlico counties. Facilities may also serve residents of counties not included in their service area.

According to the 2019 SMFP, Table 7A, there were 22 facilities in North Carolina that provided 10,005 open-heart surgery procedures in 2017, as shown in the table below.

STATEWIDE OPEN-HEART SURGERY PROCEDURES				
FACILITY	CITY	COUNTY	# OF PROCURES PERFORMED IN FY2017*	# OF PROCURES PERFORMED IN FY2018**
Cape Fear Valley Medical Center	Fayetteville	Cumberland	292	238
CarolinaEast Medical Center	New Bern	Craven	248	256
Carolinas HealthCare System - NorthEast	Concord	Cabarrus	235	273
Carolina HealthCare System - Pineville	Charlotte	Mecklenburg	252	225
Carolinas Medical Center	Charlotte	Mecklenburg	869	682
CaroMont Regional Medical Center	Gastonia	Gaston	230	278
Cone Health	Greensboro	Guilford	547	627
Duke Regional Hospital	Durham	Durham	98	148
Duke University Hospital	Durham	Durham	1,095	1,130
FirstHealth Moore Regional Hospital	Pinehurst	Moore	351	288
Frye Regional Hospital	Hickory	Catawba	232	222
High Point Regional Health System	High Point	Guilford	129	112
Mission Hospital	Asheville	Buncombe	962	939
New Hanover Regional Medical Center	Wilmington	New Hanover	482	480
North Carolina Baptist Hospital	Winston-Salem	Forsyth	689	758
Novant Health Forsyth Medical Center	Winston-Salem	Forsyth	580	635
Novant Health Presbyterian Medical Center	Charlotte	Mecklenburg	397	406
Rex Hospital	Raleigh	Wake	612	602
Southeastern Regional Medical Center	Lumberton	Robeson	39	44
University of North Carolina Hospitals	Chapel Hill	Orange	445	430
Vidant Medical Center	Greenville	Pitt	654	675
WakeMed	Raleigh	Wake	567	512
Total Procedures			10,005	9,960

Source: *Table 7A, 2019 SMFP

**Table 7B, Proposed 2020 SMFP

CEMC proposes to acquire a third heart-lung bypass machine to be used as backup for emergency coverage only. The applicant does not propose any new or expanded services. CEMC’s open-heart surgery procedures performed with the use of a heart-lung bypass machine, increased 3.2 percent from FFY17 to FFY18.

In Section G, page 72, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved open heart services with a heart-lung bypass machine in Craven County. The applicant states:

“CEMC is the only facility in the proposed service area that offers open heart surgery with a heart-lung bypass machine ... The third heart-lung bypass machine will be used solely to assure appropriate coverage for emergencies and in no instance will it be scheduled for use at the same time as CEMC’s two existing heart-lung bypass machines.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant adequately demonstrates the need for a third heart-lung bypass machine to be used for emergency coverage.
- The applicant demonstrates that CEMC is the only provider of open-heart services in Craven County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 Q, Form H, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

POSITION	CURRENT FTE STAFF	PROJECTED FTE STAFF YEAR 2
Perfusionist	2.00	3.00
Certified Registered Nurse Anesthetists	6.00	6.00
Registered Nurse	4.90	5.90
Surgical Technician	3.00	4.00
Nurse Assistant II	0.50	0.50
Scheduler	0.20	0.20
Registered Nurse first Assistant	1.00	2.00
Total	17.60	21.60

The assumptions and methodology used to project staffing are provided in Section Q, Form H. Adequate costs for health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 74-75, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H.4, page 76, the applicant names Dr. Ryan Holland, as the Chairman of Clinical Service of Surgery. In Exhibit H.4, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 I.1, page 77, the applicant identifies the necessary ancillary and support services that are required for the proposed project including, laboratory, radiology, pharmacy, dietary, housekeeping, maintenance, and administration services, among others. Exhibit I.1 contains a letter dated April 15, 2019 from the President and CEO of CarolinaEast Medical Center documenting the availability of the necessary ancillary and support services. In Section I.2, pages 77-78, the applicant describes its existing and proposed relationships with other local health care and social services providers. The applicant provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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

The applicant does not propose any new construction or renovation of existing space as part of this project. Therefore, Criterion (12) is not applicable to this review.

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

C

In Section L.1(b), page 87, the applicant provides the historical payor mix during FY2018 for the entire hospital and the proposed service component, as shown below.

CEMC		
Percent of Total Revenue		
Current Payor FY2018		
Payment Category	Entire Hospital	Open Heart Surgery
Self-Pay	5.8%	7.0%
Medicare*	61.7%	67.6%
Medicaid*	12.9%	4.8%
Insurance*	19.6%	20.6%
Total*	100.0%	100.0%

*Includes all managed care plans

Note: Workers compensation and Tricare plans are included in the insurance payor category. Other is included in the self-pay category.

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 and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Craven	19%	49%	34%	15%	13%	12%
Carteret	24%	51%	14%	12%	15%	12%
Onslow	9%	45%	34%	14%	13%	10%
Pamlico	29%	49%	26%	19%	13%	13%
Jones	22%	51%	38%	22%	18%	14%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. 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., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. 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 L.2(a), page 87, the applicant states CEMC is under no obligation to provide uncompensated care, community service or access by minorities and persons with disabilities. In Section L.2(c), page 88, the applicant states, "No complaints have been filed against any affiliated entity of CEMC regarding civil rights equal access in the last five years."

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 L.3, page 88 the applicant provides the projected payor mix during the second full fiscal year for the entire hospital and the proposed service component, as illustrated below.

CEMC Percent of Total Revenue Second Full Fiscal Year (FFY2022)		
Payment Category	Entire Hospital	Open Heart Surgery Services
Self-Pay	5.8%	7.0%
Medicare*	61.7%	67.6%
Medicaid*	12.9%	4.8%
Insurance*	19.6%	20.6%
Total*	100.0%	100.0%

*Includes all managed care plans

Note: Workers compensation and Tricare plans are included in the insurance payor category. Other is included in the self-pay category.

As shown in the table above, in the second full fiscal year, the applicant projects 67.6% of its total open- heart surgery services will be provided to Medicare patients and 4.8% to Medicaid patients. On page 89, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year. The applicant states CEMC projects no change in its projected payor mix which is identical to its current payor mix. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization of open-heart surgery procedures at CEMC.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 L.5, page 90, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 M.1, pages 91-92, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and 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

CEMC proposes to acquire a third heart lung bypass machine to be used as backup for emergency coverage only. The applicant does not propose any new or expanded services.

On pages 99-102, the 2019 SMFP discusses open heart surgery services in North Carolina. Open heart surgery services, as defined in Gen. Stat. §131E-176(18b) “*means the provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects.*”

The 2019 SMFP does not discuss a need methodology or provide a definition of “service area” for open heart surgery services. However, Step 1, on page 55 of the 2019 SMFP defines the service area for operating rooms as the planning area in which the operating room is located. “*The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.*” Figure 6.1 on page 60 of the 2019 SMFP shows Craven County as a multicounty operating room service area which includes Jones and Pamlico counties. Thus, the service area for this project consists of Craven, Jones and Pamlico counties. Facilities may also serve residents of counties not included in their service area.

According to the 2019 SMFP, Table 7A, there were 22 facilities in North Carolina that provided 10,005 open-heart surgery procedures in 2017, as shown in the table below.

STATEWIDE OPEN-HEART SURGERY PROCEDURES				
FACILITY	CITY	COUNTY	# OF PROCURES PERFORMED IN FY2017*	# OF PROCURES PERFORMED IN FY2018**
Cape Fear Valley Medical Center	Fayetteville	Cumberland	292	238
CarolinaEast Medical Center	New Bern	Craven	248	256
Carolinas HealthCare System - NorthEast	Concord	Cabarrus	235	273
Carolina HealthCare System - Pineville	Charlotte	Mecklenburg	252	225
Carolinas Medical Center	Charlotte	Mecklenburg	869	682
CaroMont Regional Medical Center	Gastonia	Gaston	230	278
Cone Health	Greensboro	Guilford	547	627
Duke Regional Hospital	Durham	Durham	98	148
Duke University Hospital	Durham	Durham	1,095	1,130
FirstHealth Moore Regional Hospital	Pinehurst	Moore	351	288
Frye Regional Hospital	Hickory	Catawba	232	222
High Point Regional Health System	High Point	Guilford	129	112
Mission Hospital	Asheville	Buncombe	962	939
New Hanover Regional Medical Center	Wilmington	New Hanover	482	480
North Carolina Baptist Hospital	Winston-Salem	Forsyth	689	758
Novant Health Forsyth Medical Center	Winston-Salem	Forsyth	580	635
Novant Health Presbyterian Medical Center	Charlotte	Mecklenburg	397	406
Rex Hospital	Raleigh	Wake	612	602
Southeastern Regional Medical Center	Lumberton	Robeson	39	44
University of North Carolina Hospitals	Chapel Hill	Orange	445	430
Vidant Medical Center	Greenville	Pitt	654	675
WakeMed	Raleigh	Wake	567	512
Total Procedures			10,005	9,960

Source: *Table 7A, 2019 SMFP

**Table 7B, Proposed 2020 SMFP

In Section N.1, pages 93-94, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. As the only provider of open heart bypass surgery in the service area, the applicant states the following on pages 93-94,

“The flexibility and cost savings associated with the ability to move the proposed heart-lung bypass machine into any of CEMC’s five heart capable operating rooms, rather than developing an additional dedicated open heart operating room for emergencies, is an effective use of physician and financial resources. ... With additional capacity, CEMC will be able to ensure that capacity is available for patients who need open heart surgery urgently or emergently, even when the two existing heart-lung bypass machines are in use at the same time.”

In Section G, page 72, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved open heart services with a heart-lung bypass machine in Craven County. The applicant states:

“CEMC is the only facility in the proposed service area that offers open heart surgery with a heart-lung bypass machine ... The third heart-lung bypass machine will be used solely to assure appropriate coverage for emergencies and in no instance will it be scheduled for use at the same time as CEMC’s two existing heart-lung bypass machines.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 A.1, page 10, the applicant states CarolinaEast Health System (CEHS) is the parent company of CarolinaEast Medical Center, Inc. In Section O.3, page 97, the applicant states that CEHS does not own, operate or manage any other licensed acute care facility in North Carolina.

Further, the applicant states that during the 18 months immediately preceding the submittal of the application, the applicant was not determined by the Acute and Home Licensure and Certification Section, DHR or the Centers for Medicare and Medicaid Services to have operated out of compliance with any Medicare Conditions of Participation. After reviewing and considering information provided by the applicant and the Acute and Home 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

The Criteria and Standards for Open-Heart Surgery Services and Heart-Lung ByPass Machines as promulgated in 10A NCAC 14C .1700 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

SECTION .1700 – CRITERIA AND STANDARDS FOR OPEN-HEART SURGERY SERVICES AND HEART-LUNG BYPASS MACHINES

10A NCAC 14C .1703 PERFORMANCE STANDARDS

- (a) An applicant that proposes to develop open-heart surgery services shall:
- (1) demonstrate that the projected utilization and proposed staffing patterns are such that each open heart surgical team shall perform at least 150 open heart surgical procedures in the third year following completion of the project; and
 - (2) document the assumptions and provide data supporting the methodology used to make these projections.
- NA- The applicant does not propose to develop open-heart surgery services.
- (b) An applicant that proposes to acquire a heart-lung bypass machine shall demonstrate either:
- (1) that the applicant's projected annual utilization of its existing, approved, and proposed heart-lung bypass machines (other than a machine acquired pursuant to 10A NCAC 14C .1703(b)(3)) will be at least 200 open heart surgical procedures per machine during the third year following completion of the project;
 - (2) that the projected annual utilization of its existing, approved, and proposed heart-lung bypass machines (other than a machine acquired pursuant to 10A NCAC 14C .1703(b)(3)), will be at least 900 hours per year during the third year following completion of the project, as measured in minutes used or staffed on standby for all procedures; or
 - (3) that the proposed machine is needed to provide coverage for open-heart surgery emergencies and will not be scheduled for use at the same time as the applicant's equipment used to support scheduled open heart surgical procedures.

- C- In Section C.4, pages 37-43, the applicant demonstrates that the proposed third heart-lung bypass machine is needed to ensure emergency backup coverage. The proposed heart-lung bypass machine will not be used for scheduled procedures. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.