

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 1, 2017

Findings Date: November 1, 2017

Project Analyst: Gregory F. Yakaboski

Team Leader: Lisa Pittman

Project ID #: F-11356-17

Facility: CaroMont Regional Medical Center

FID #: 943184

County: Gaston

Applicant(s): Gaston Memorial Hospital, Inc.

Project: Acquire a Siemens Artis zee biplane system for cardiac thoracic surgery and develop a vascular hybrid operation room

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Gaston Memorial Hospital, Inc. (Gaston Memorial), the applicant, d/b/a as CaroMont Regional Medical Center (CRMC) is an existing acute care hospital located in Gastonia, Gaston County. Gaston Memorial is part of the CaroMont Health System. CRMC is proposing to both acquire major medical equipment, specifically a Siemens Artis zee biplane system for cardiac thoracic surgery (Siemens Artis zee system) and develop a vascular hybrid operating room at CRMC through the renovation and upgrading of an existing general operating room and then installation of the Siemens Artis zee system. The existing general operating room is operating room #6 at CRMC. CRMC currently has a total of 22 operating rooms and, upon project completion, would still have 22 operating rooms.

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 2017 State Medical Facilities Plan (2017 SMFP).

Policies

The following policy is applicable to this review:

- **Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities**

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities

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 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy-GEN 4. The plan shall not adversely affect patient or resident health, safety, or infection control.

In Section III, page 23 and Exhibit B.11, the applicants provide a written statement describing the proposed project's plan to assure improved energy efficiency and water conservation including energy efficient lighting integrated with central controls, plumbing fixtures that comply with maximum consumption limits outlined in the North Carolina Plumbing Code and LED lighting. The application is consistent with Policy GEN-4.

Conclusion

In summary, the applicants demonstrate that the proposal is conforming to all applicable policies in the 2017 SMFP. 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

CRMC is proposing to acquire major medical equipment, specifically a Siemens Artis zee system, and develop a vascular hybrid operating room by renovating an existing general operating room and then installing the Siemens Artis zee system.

Patient Origin

The 2017 SMFP does not define the service area for the proposed project. In Section C, page 41, CRMC defines the service as the three county area consisting of Gaston, Cleveland and Lincoln counties for the proposed medical equipment and vascular hybrid operating room. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 37, the applicant provides a table showing the historical patient origin for the proposed surgical services for the last Full Fiscal Year (FFY) 7/1/15 to 6/30/16, as shown in the table below:

Surgical Service Component: 7/1/15 to 6/30/16

Counties	# of Patients	% of Total
Gaston	280	74.1%
Cleveland	44	11.6%
Lincoln	18	4.8%
Mecklenburg	5	1.3%
Rutherford	4	1.1%
Other NC Counties	5	1.3%
Other SC Counties	22	5.8%
Total	378	100.0%

In Section C.3, page 38, the applicant identifies the number of patients and the patient origin of the patients it proposes to serve during the first three years of operation following project completion, as illustrated in the table below:

Projected Patient Origin for the Vascular Hybrid Operating Room

	OY1 10/1/18-9/30/19		OY2 10/1/19-9/30/20		OY3 10/1/20-9/30/21	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Gaston	360	77.3%	366	77.3%	370	77.3%
Cleveland	38	8.2%	39	8.2%	39	8.2%
Lincoln	20	4.4%	21	4.4%	21	4.4%
Mecklenburg	5	1.0%	5	1.0%	5	1.0%
Rutherford	2	0.5%	2	0.5%	2	0.5%
Other NC Counties	16	3.4%	16	3.4%	16	3.4%
Other SC Counties	25	5.2%	25	5.2%	25	5.2%
Total	466	100.0%	473	100.0%	479	100.0%

The applicant provides the assumptions and methodology for the projections above on page 38. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section C, pages 24-51, Section N, page 99, and supplemental documentation, the applicant describes the need for the Siemens Artis system, and the development of a vascular hybrid operating room by renovating an existing general operating room at CRMC as follows:

- CRMC provides extensive surgical services, is a Level III Trauma Center, has Chest Pain Center Accreditation, and CRMC’s heart program is nationally ranked for top-quality care.
- CRMC proposes performing two categories of procedures in the hybrid vascular operating room: cardiovascular and vascular applications. Cardiac surgery involves an invasive procedure by opening up a patient’s chest to perform the needed surgery. Development of the hybrid vascular operating room will allow the performance of minimally invasive procedures on patients at CRMC which patients would previously have been treated with an invasive procedure. (See Table on page 45 of the application and supplemental information for a detailed list of the procedures planned to be performed in the proposed hybrid vascular operating room.)
- In addition, the Siemens Artis system and hybrid vascular operating room will now permit CRMC surgeons to perform transcatheter aortic valve replacement (TAVR) procedures on certain patients who, in the past, were referred outside of CRMC.
- There are no other Siemens Artis system’s within CRMC’s service area.
- The proposed development of the hybrid vascular operating room with a Siemens Artis system at CRMC will be *“the regions most advanced vascular surgical suite and leverages multi-disciplinary resources to deliver:*
 - Fewer surgeries
 - Safer procedures

- *Shorter hospital stays*
 - *Faster recoveries*
 - *Better outcomes”* (See page 25 of the application.)
- Over the past four years CRCM’s lack of a hybrid vascular operating room with a Siemens Artis system has led CRMC to experience both a decline in expected cardiac procedures at CRMC due to both patients initially seeking care outside of Gaston County and CRMC cardiac surgeons referring cardiac patients to cardiac programs that offered TAVR procedures.

Based on review of the information provided by the applicant in Section C and supplemental information, the applicant adequately demonstrated the need to acquire the Siemens Artis system, and develop a vascular hybrid operating room by renovating an existing general operating room at CRMC as follows:

Projected Utilization

In supplemental information, the applicant provides projected utilization of the proposed hybrid vascular operating room with the Siemens Artis system for the first three FY as illustrated in the table below.

Procedures	OY1 (FFY2019)	OY2 (FFY2020)	OY3 (FFY2021)
Cardiac	200	200	200
Vascular	233	239	244
TAVR	33	34	35
Total Procedures	466	473	479

In supplemental information, the applicant provides the methodology and assumptions underlying the projected utilization as summarized below:

Historic, Interim and Projected Cardiac and Vascular Procedures at CRMC

Procedures	FFY2014	FFY2015	FFY2016	FFY2017*	FFY2018	OY1 (FFY2019)	OY2 (FFY2020)	OY3 (FFY2021)
Cardiac	239	263	208	200	200	200	200	200
Vascular	141	153	170	222	228	233	239	244
TAVR	0	0	0	0	0	33	34	35
Total	380	416	378	422	428	466	473	479
% Increase	na	9.5%	(10.1%)	11.6%	1.4%	8.9%	1.5%	1.3%

*Annualized

Note: Without the TAVR procedures the percent increase from FFY2018 to FFY2019(OY1) is only 1.4% (439/433 = 1.0138 or 1.4% increase)

- The decline in cardiac procedures is not expected to continue, but to plateau based on the development of the proposed project.
- CRMC, to be conservative, projected no growth in cardiac procedures.
- Vascular procedures are projected to grow by 1.5%.

- CRMC would capture TAVR procedures which CRMC’s cardiac surgeons currently are referring to facilities that have the capability to perform TAVR procedures.
- Certain cardiac patients who are residents of CRMC’s 3-county service area who are not initially coming to CRMC but are migrating out of the service area to other facilities because CRMC lacks the ability to perform minimally invasive procedures without the Siemens Artis system would be recaptured by CRMC.

In Section C, page 52, the applicant states that the maximum annual capacity for the Siemens Artis system is 1,872 hours. The applicant has categorized the types of procedures that will be performed in the hybrid vascular operating room with the Siemens Artis system in three categories: cardiac, vascular and TAVR. To calculate projected percentage of capacity for the proposed project that applicant, as shown in the tables below, subdivided the cardiac category into “Open AVR/MVR” and “Cardiac”.

The applicant first allocated the projected procedures by category as shown in the table below.

	OY1 (FFY2019)	OY2 (FFY2020)	OY3 (FFY2021)
Cardiac			
Open AVR/MVR	50	50	50
Cardiac	150	150	150
Total- Cardiac	200	200	200
Vascular	233	239	244
TAVR	33	34	35
Total Procedures	466	473	479

Next, the applicant projected “hours per procedure”

	Hours per procedure
Cardiac	
Open AVR/MVR	6
Cardiac	3
Vascular	2
TAVR	4

The applicant then calculated the total procedure hours for OY1-OY3 by multiplying the hours per procedure by the number of projected procedures for each category of procedures for each year. The applicant also calculated projected capacity percentage for each of the first three OY’s.

	OY1 (FFY2019)	OY2 (FFY2020)	OY3 (FFY2021)
Cardiac			
Open AVR/MVR	300	300	300
Cardiac	450	450	450
Total- Cardiac	750	750	750
Vascular	466	478	488
TAVR	132	136	140
Total Procedure Hours	1,348	1,364	1,378
Annual Maximum Capacity*	1,872	1,872	1,872
Projected Capacity Percentage**	72.0%	72.9%	73.6%

Source: Supplemental Information

*See Section C.6, page 52 for Annual Maximum Capacity

**Total Procedure Hours/Annual Maximum Capacity

Projected utilization of the Siemens Artis system in the proposed vascular hybrid operating room at CRMC is based on reasonable and adequately supported assumptions.

Access

In Section C, page 55, the applicant states “CRMC is a not-for-profit organization that does not discriminate against any class of patient based on ability to pay, race, ethnicity, sex, handicap, or age.”

In supplemental information the applicant projects that as of OY2 (10/1/19 to 9/30/20) at CRMC 71.2% of the patients projected to utilize the surgical services for the procedures proposed to be performed in the vascular hybrid operating room will have all or part of their services paid for my Medicare and/or Medicaid, as indicated in the table below:

Payor Source	Entire Facility	Surgical Services**
Medicare*	44.3%	66.9%
Medicaid*	16.2%	4.3%
Self-Pay***	7.9%	3.9%
Insurance*	29.4%	23.6%
Other(Specify)	2.2%	1.2%
Total	100.0%	100.0%

*Including any managed care plans.

**Note: Surgical Services only refers to those procedures planned to be performed in the proposed vascular hybrid operating room.

***Charity Care is included in the Self-Pay Category.

On page 94, the applicant states that “CRMC projects to continue providing vascular services to residents of Gaston, Lincoln and Cleveland counties and does not project its Year 2 payor mix to differ from its current payor mix.” On pages 55-56, the applicant provides a list of the private insurance providers with which it has negotiated to increase access to CRMC services.

The applicants adequately demonstrated the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identified the population to be served, demonstrated the need that the population has for the services proposed and the extent to which all residents of the area, including underserved groups, are likely to 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

CRMC is proposing to acquire major medical equipment, specifically a Siemens Artis zee system, and develop a vascular hybrid operating room by renovating an existing general operating room and then installing the Siemens Artis zee system.

In Section E, page 64, the applicant states that there are no alternatives to the proposed project. CRMC states that *“the TAVR procedure is quickly becoming the gold standard method in replacing an aortic valve... State-of-the-art cardiovascular programs must offer the TAVR procedure or risk having other cardiovascular patients seek care at programs that do offer the TAVR procedure...CRMC is the second largest open heart program that does not offer the TAVR procedure. ... CRMC risks losing patients previous serve [sic] in Gaston County to TAVR programs outside of Gaston County without the establishment of a TAVR program.”*

After considering the alternatives to its proposal, the applicants believe the most effective alternative is to acquire a Siemens Artis system and develop a vascular hybrid operating room by renovating an existing operating room at CRMC.

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

In summary, the applicants adequately demonstrate that this proposal is their least costly or most effective alternative to meet the identified need to acquire a Siemens Artis system for vascular hybrid operating room at CRMC in Gaston County. Therefore, the application is conforming to this criterion subject to the following conditions:

- 1. Gaston Memorial Hospital, Inc. shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the**

event that representations conflict, Gaston Memorial Hospital, Inc. shall materially comply with the last made representation.

- 2. Gaston Memorial Hospital, Inc. shall acquire a Siemens Artis system and develop a vascular hybrid operation room.**
 - 3. Upon completion of the project, CaroMont Regional Medical Center shall be licensed for no more than twenty-two ORs.**
 - 4. Gaston Memorial Hospital, Inc. shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 - 5. 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, Gaston Memorial Hospital, 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.**
 - 6. Gaston Memorial Hospital, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency 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

CRMC is proposing to acquire major medical equipment, specifically a Siemens Artis zee system, and develop a vascular hybrid operating room by renovating an existing general operating room and then installing the Siemens Artis zee system.

Capital and Working Capital Costs

In Section F, page 65 and Form F.1a in Section Q, the applicant projects the capital cost for the proposed project, as summarized in the table below:

Projected Capital Costs

Construction/Renovation Contracts	\$616,005
Construction Contingency	\$61,601
Architect/Engineering Fees/Reimbursable	\$123,991
Fixed Medical Equipment	\$2,043,689
Furniture, Fixtures, and Non-Medical Equipment	\$1,904,000
Consultant Fees (CON Prep and CON Fee)	\$41,900
Other-Contingency	\$206,989
Total	\$4,998,175

In Section F, page 67, the applicant states that the working capital needs for the proposed project will be \$135,973 (Start-up expenses). As CRMC has an operational surgical department there are no projected initial operating expenses for the proposed project.

Availability of Funds

In Section F, page 65, the applicant states that the proposed project will be financed through the accumulated reserves of Gaston Memorial Hospital.

In Exhibit F.2, the applicant provides a letter from Chris Peek, President and CEO of Gaston Memorial Hospital, Inc., which states that that \$4,998,175 is available for the proposed project from the accumulated reserves of Gaston Memorial Hospital, Inc. and that Gaston Memorial Hospital, Inc. will also obligate and commit \$135,973 for the sole purpose of funding the working capital required to make the vascular hybrid operating room operational. The letter refers to the audited consolidated balance sheets of Gaston Memorial Hospital, Inc. in Exhibit F.2 and specifically the line “*Assets limited as to use: Internally Designated*” on page 11 in the amount of \$530 million. Mr. Peek states that he has “*the authority to commit these funds on behalf of Gaston Memorial Hospital, Inc.*” The audited combined financial statements of CaroMont Health, Inc. (Gaston Memorial Hospital, Inc.) and Affiliates contained in Exhibit F.2, page 11, document \$530,774,753 as of June 30, 2016 in the line “*Assets limited as to use: Internally Designated*.”

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

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In the pro forma financial statement Form F.4, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1st Full Fiscal Year 7/1/18-6/30/19	2nd Full Fiscal Year 7/1/19-6/30/20	3rd Full Fiscal Year 7/1/20-6/30/21
Total Procedures	466	473	479
Total Gross Revenues (Charges)	\$52,467,886	54,887,339	\$57,404,738
Total Net Revenue	\$17,195,703	\$17,971,145	\$18,777,638
Average Net Revenue per procedure	\$36,900	\$37,993	\$39,201
Total Operating Expenses (Costs)	\$14,848,993	\$15,624,529	\$16,301,783
Average Operating Expense per procedure	\$31,864	\$33,032	\$34,032
Net Income	\$2,346,709	\$2,346,616	\$2,475,855

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. The applicant adequately demonstrates 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 financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. 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

CRMC is proposing to acquire major medical equipment, specifically a Siemens Artis zee system, and develop a vascular hybrid operating room by renovating an existing general operating room and then installing the Siemens Artis zee system.

The 2017 SMFP does not define the service area for the proposed project. In Section C, page 41, CRMC defines the service as the three county area consisting of Gaston, Cleveland and Lincoln counties for the proposed medical equipment and vascular hybrid operating room. Facilities may also serve residents of counties not included in their service area.

Currently, there are no other Siemens Artis Systems in the proposed service area. Further, CRMC currently has 22 total operating rooms, and upon project completion, would have 22 total operating rooms.

The applicants adequately demonstrate that the proposed project would not result in the unnecessary duplication of a Siemens Artis system in the proposed service area. Consequently, the application is conforming to this criterion.

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

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In Section H and Form H in Section Q, page 125, the applicant provides a table documenting five full time equivalents (FTEs) for the proposed vascular hybrid operating room for the first three OYs which, as shown in Form H, is an increase of three FTEs from the general operating room. See the table below.

FTE staffing

	Historical (FFY2016)	OY1 (FFY2019)	OY2 (FFY2020)	OY3 (FFY2021)
Operating Room				
Registered Nurse	1	0	0	0
Scrub Nurse	2	0	0	0
Vascular Hybrid Operating Room				
OR Circulating RN	0	1	1	1
Cath Lab RN	0	1	1	1
Cath Lab Technician	0	1	1	1
Surgical Technician	0	1	1	1
Radiology Technician	0	1	1	1
Total	3	5	5	5

Source: Form H in Section Q, page 125.

Exhibit H.4 contains a letter dated June 10, 2017 from Dr. James Greelish, stating that he is “interested and willing to continue serving in the capacity of Medical Director of the CaroMont Regional Medical Center Cardiovascular Service.” In Section H, pages 75-76 and 78, the applicant describes the methods used to recruit and fill vacant or new positions.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed vascular hybrid operating room. 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.

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In Section I, page 80, the applicant identifies the necessary ancillary and support services and indicates how they are or will be made available. Exhibit I.1 contains a letter from the President and Chief Executive Officer of CaroMont Health stating that either the hospital staff or CaroMont Health corporate staff will provide the necessary ancillary and support services for the proposed vascular hybrid operating room. On page 80 the applicant states that CRMC has existing transfer arrangements, which they expect to continue, with Carolinas Medical Center, Cleveland Regional Medical Center and Carolinas Medical Center-Lincoln. CRMC also has The CaroMont Care Advocates Council, a community based patient advisory council, consisting of “a diverse group of patients, family and community members who meet regularly

to advise CRMC on how to provide better patient-centered care.” The applicant discusses coordination with the existing health care system on pages 80-81 of the application. The applicant adequately demonstrates that the 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.

C

In Section K, pages 84-88, and Exhibits K.2 through K.5, the applicant states that CRMC is an existing hospital, properly zoned, located at 2525 Court Drive, Gastonia with Gaston County holding the fee simple title to the site. CRMC receives water, sewer and power from the City of Gastonia. The proposed project does not include any new construction but does involve the renovation of an existing operating room as identified in the line drawings contained in Exhibit K.2. On page 31 of the application CRMC states “*CRMC proposes to renovate and upgrade an 879 SF operating room in the existing CRMC facility on the main campus at a cost of \$677,000 including contingency. The renovation upgrades will include OR#6 and the adjacent corridors.*” The renovation of the existing operating room includes: structural steel mounts to accommodate the imaging equipment; dimmable lighting and controls; lead line shielding in the walls and doors and an engineering HVAC/lighting ceiling system that will accommodate all ceiling booms and utility penetrations. (See page 24 of the application.) Form F.1a Capital Cost in Section Q, page 111 of the application, categorizes the projected capital costs of the proposed project including \$616,005 in projected construction/renovation costs. In Section B, page 23, Section M, page 86, and Exhibit B.11 the applicant describes its plans for energy-efficiency and water conservation. Exhibit B.11 contains a letter dated February 10, 2017 from Jason L. Moody PE of RNM Engineers which states “*I certify that all new portions of this project within the existing facility will be designed to comply with all applicable energy efficiency and water consumption requirements of the 2012 North Carolina State Building Codes.*” Costs and charges are described by the applicant in the financials section of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative for the proposed renovation and that energy saving features have been incorporated into the construction plans, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

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

C

In Section L, page 92, the applicant provides the payor mix for both the entire facility and the surgical services proposed to be performed in the vascular hybrid operating room for the last Full Fiscal Year (FFY) 10/1/2015 to 9/30/16, as shown in the following table:

Payor Source	Entire Facility	Surgical Services**
Medicare*	44.3%	66.4%
Medicaid*	16.2%	4.5%
Self-Pay***	7.9%	4.2%
Insurance*	29.4%	23.5%
Other(Specify)	2.2%	1.3%
Total	100.0%	100.0%

*Including any managed care plans.

**Note: Surgical Services only refers to those procedures planned to be performed in the proposed vascular hybrid operating room.

***Charity Care 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 & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Gaston	15%	52%	25%	17%	13%	18%
Cleveland	18%	52%	27%	20%	12%	13%
Lincoln	17%	50%	15%	13%	12%	14%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

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

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

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

The applicant 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 L, page 93, the applicant states both that "CRMC is not obligated under any federal regulations to provide uncompensated care, community service, or access by

minorities or handicapped persons” and “CRMC has not had a patient civil rights equal access complaint filed against them 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 supplemental information the applicant provides that as of OY2 (10/1/19 to 9/30/20) 60.5% of the patients at CRMC will have all or part of their services paid for my Medicare and/or Medicaid and that 71.2% of the patients projected to utilize the surgical services for the procedures proposed to be performed in the vascular hybrid operating room will have all or part of their services paid for my Medicare and/or Medicaid, as indicated in the table below:

Payor Source	Entire Facility	Surgical Services**
Medicare*	44.3%	66.9%
Medicaid*	16.2%	4.3%
Self-Pay***	7.9%	3.9%
Insurance*	29.4%	23.6%
Other(Specify)	2.2%	1.2%
Total	100.0%	100.0%

*Including any managed care plans.

**Note: Surgical Services only refers to those procedures planned to be performed in the proposed vascular hybrid operating room.

***Charity Care is included in the Self-Pay Category.

On page 94, the applicant states that *“CRMC projects to continue providing vascular services to residents of Gaston, Lincoln and Cleveland counties and does not project its Year 2 payor mix to differ from its current payor mix.”*

The applicant adequately demonstrates the extent to which each group will have access to the proposed 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.

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In Section L, page 95, the applicant states *“Access to the Siemens Artis system and the vascular hybrid operating room service...is by physician referral.”* The applicant adequately demonstrates the range of means by which residents will have access to the facility. 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 M, page 97, the applicant details a list of seven specific health training programs with which it has existing and on-going relationships. CRMC states that *“These training programs already exist and are considered perpetual, automatic annual renewal, or automatic annual renewal with letter of intent.”* (See page 97.) The seven specific health training programs listed are: Catawba Valley Community College- Certified Surgical Technologists; Central Piedmont Community College-Cardiovascular Technologists; Cleveland Community College-Radiology Technologists and Certified Surgical Technologists; Gardner-Webb College- Registered Nurses; Gaston College-Registered Nurses; UNC Charlotte-Registered Nurses; Wingate University-Registered Nurses. The information provided in Section M is reasonable and credible and supports a finding of conformity to this criterion.

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

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CRMC is proposing to acquire major medical equipment, specifically a Siemens Artis zee system, and develop a vascular hybrid operating room by renovating an existing general operating room and then installing the Siemens Artis zee system.

The 2017 SMFP does not define the service area for the proposed project. In Section C, page 41, CRMC defines the service as the three county area consisting of Gaston, Cleveland and Lincoln counties for the proposed medical equipment and vascular hybrid operating room. Facilities may also serve residents of counties not included in their service area.

Currently, there are no other Siemens Artis Systems in the proposed service area. Further, CRMC currently has 22 total operating rooms, and upon project completion, would have 22 total operating rooms.

In Section N, pages 99-101, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. *“CRMC is the second largest open heart program that does not offer the TAVR procedure and through the acquisition of the Siemens Artis system and the establishment of a TAVR program CRMC will have the ability to directly compete for the CRMC 3-county service area aortic valve patients who are currently referred to TAVR programs located outside of Gaston County and the CRMC 3-county service area. ... This allows patients to ‘price shop’ due to increased out of pocket expenses related to many health insurance plan’s deductibles and copayments.”*

See also Sections B, C, D, E, F, G, I, K, L, N and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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, supplemental information, 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 Criteria (1) and (20) is incorporated herein by reference.
- ◆ The applicant demonstrates that it will continue to provide access to medically underserved populations. The discussion regarding access found in Criteria (1) and (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 A, page 4, Section O, page 105, and Exhibit O.3, the applicant states that Gaston Memorial Hospital, Inc. facilities include CaroMont Regional Medical Center and CaroMont Regional Medical Center-Mt. Holly (CRMC-Mt. Holly) and that CRMC and CRMC-Mt. Holly are the only hospitals owned, operated, or managed by Gaston Memorial Hospital, Inc. in North Carolina. According to the files in the Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of the application through the date of the decision no facilities were found to be out of compliance with one or more Medicare conditions of participation. At this time, both facilities are in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicant and by the Licensure and Certification Section and considering the quality of care

provided at both facilities, 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.

NA