ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: September 30, 2013
PROJECT ANALYST: Gloria C. Hale
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: F-10158-13/ The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center/ Develop a second hybrid OR by acquiring and installing endovascular imaging equipment in an existing OR/ Mecklenburg County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Carolinas Medical Center (CMC) proposes to acquire one hybrid angiographic endovascular imaging system to create a second hybrid operating room (OR) in one of its existing ORs located on the fifth floor of CMC. The applicant does not propose to increase the number of licensed ORs at CMC, acquire any medical equipment or develop any health service facility beds for which there is a need determination in the 2013 State Medical Facilities Plan (SMFP).

However, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 43 of the 2013 SMFP, is applicable to the review of this proposal. Policy GEN-4 states:

> *"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement*

describing the project's plan to assure improved energy efficiency and water conservation.

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

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

In Section III.2, pages 61-63, the applicant addresses Policy GEN-4 and the hospital's plan for improved energy efficiency and water conservation. The applicant states that it:

"…employs a Facility Management Group with experienced, highly trained and qualified architects, engineers, project managers, tradesmen and technicians, who design, construct, operate and maintain CHS facilities. Medical center equipment is maintained on a computerized preventive maintenance schedule and monitored using integrated building control systems. CHS's multi-disciplinary team participates during planning and design to ensure that new systems and components incorporate demonstrated best practices as well as to recommend new and improved practices."

In addition, the applicant states that in April 2013, CMC was awarded the Practice Greenhealth's Partner for Change Award, for having established and continuously improved upon the facility's environmental programs toward the goal of sustainability. Moreover, the applicant states:

"CMC will work with experienced architects and engineers to develop this proposed project to ensure energy efficient systems are an inherent part of the proposed project to the degree appropriate with the proposed renovations. The design team for the proposed project has Energy Star, Leadership in Energy and Environmental Design (LEED) and Hospitals for a Healthy Environment Green

Guide for HealthCare (GGHC) experience. Together the team seeks to deliver the following:

- *Meet or exceed the requirements of the North Carolina Building Code in effect when construction drawings are submitted for review to the DHSR Construction Section.*
- *Use a Commissioning Agent to verify facility operates as designed.*
- *Refer to United States Green Building Council (USGBC) LEED guidelines and GGHC to identify opportunities to improve the efficiency and performance.*
- *Design for maximum efficiency and life cycle benefits within each mechanical system: heating, cooling, water, sewer, and irrigation.*
- *Provide, as necessary, heat recovery systems to extract heat normally lost in exhaust air and transfer this energy to incoming ventilation air to reduce energy usage."*

The applicant adequately demonstrates the proposal includes a plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4 and 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

The applicant proposes to acquire an angiographic endovascular imaging system to be installed in one of CMC's existing operating rooms on the fifth floor of the hospital, thereby developing a second hybrid OR. OR 19 will be renovated and become part of adjacent OR 20 to accommodate the endovascular imaging system, a control room, a shared clean core space between the two hybrid operating rooms, and storage space. OR 19 is located in operating room suite Core D adjacent to CMC's hybrid OR 18 which houses existing endovascular imaging equipment. OR 20 will be relocated to an existing storage room, *"Storage Room 5012"*, located in operating room suite Core E. The storage room will be renovated and upgraded to an operating room. Existing equipment from OR 20 will be relocated there. The newly relocated OR 20 will be adjacent to OR 31 on the fifth floor.

CMC's current OR inventory is 47 ORs, 32 of which are located in the main surgery department located on the fifth floor of the medical center. A listing of CMC's ORs by type is illustrated as follows:

CMC
2012 Operating Room Inventory*

Type	Number of ORs
Dedicated Open Heart Surgery	5
Dedicated C-Section	4
Other Dedicated Inpatient Surgery	1
Dedicated Ambulatory Surgery	11
Shared - Inpatient/Ambulatory Surgery	26
Total Surgical ORs	**47**

* Source: 2012 CMC's License Renewal Application

In Section II.1(a), page 23, the applicant states that the proposed angiographic endovascular imaging system is designed for imaging in the operating room environment and that it includes the injector, training, integrated vascular access ultrasound, portable ultrasound, surgical suite integration, surgical workplaces, and continuous autotransfusion system. The applicant further states:

> *"The proposed system enables image-guided surgery, one stop pre- and post-operative imaging, endovascular therapy, and provides the anesthesiologist with free access to the patient.*
>
> …
>
> *The intravascular imaging system will be used for the qualitative and quantitative evaluation of vascular morphology in vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structure, thrombus formation, and used in combination with interventional therapies such as balloon angioplasty or atherectomy."*

In addition, the proposed equipment has multiple axes which provide for more flexibility and multiple work positions, thereby allowing for greater comfort and precision for clinicians. Moreover, the proposed equipment enhances image clarity and visualization while also significantly reducing the radiation dose to the patient, staff, and physician. In summary, the applicant states, on page 27, *"The system's advanced imaging capabilities enhance the decision making of clinicians and facilitate faster and more effective procedures."*

<u>Population to be Served</u>

In Section III.4(a) and (b), pages 66-67, the applicant provides the current patient origin by county of residence for the entire facility and for the existing hybrid OR for CY 2012, as shown in the following table:

CMC Acute Care Beds and Hybrid OR Patient Origin
CY 2012

County	**CMC Acute Care Beds Patient Origin**	**CMC Hybrid OR Patient Origin**
Mecklenburg	55.1%	33.7%
York, South Carolina	5.9%	8.3%
Lancaster, South Carolina	2.0%	6.0%
Union	6.1%	6.0%
Cleveland	3.6%	5.5%
Gaston	5.4%	5.5%
Cabarrus	2.4%	4.8%
Iredell	1.7%	4.2%
Lincoln	2.4%	2.5%
Other*	15.4%	23.3%
Total	**100%**	**100%**

*Other includes additional counties in North Carolina and other states as listed in Section III, pages 66-67.

The applicant states, in Section III.5(a), pages 67-68:

> "*CMC projects that Mecklenburg County will remain its primary service area and Union, Gaston, Cleveland, Cabarrus, Lincoln and Iredell counties in North Carolina, and York and Lancaster counties in South Carolina, will comprise the secondary service area. Over 33 percent of CMC's hybrid operating room patients originated from Mecklenburg County in 2012. Patients from the eight nearby counties listed above (Union, Gaston, Cleveland, Cabarrus, Lincoln, Iredell, York (SC), and Lancaster (SC) counties) represent approximately 43 percent of the medical center's hybrid operating room patients in 2012. Together, CMC's primary and secondary service areas accounted for more than 76.5 percent of CMC's hybrid operating room patients in CY 2012."*

The applicant provides projected patient origin by county of residence for the proposed hybrid OR for the first two full years of operation following completion of the project in Section III.5(c), page 70, as illustrated below:

County	Projected Hybrid OR Patient Origin (Project Years 1 & 2)
Mecklenburg	33.7%
York, South Carolina	8.3%
Lancaster, South Carolina	6.0%
Union	6.0%
Cleveland	5.5%
Gaston	5.5%
Cabarrus	4.8%
Iredell	4.2%
Lincoln	2.5%
Other*	23.3%
Total	**100%**

*Other includes additional counties in North Carolina and other states as listed in Section III, page 70.

The applicant adequately identified the population it proposes to serve.

Need for the Proposed Project

In Section III.1(a), beginning on page 50, the applicant states that CMC has a need for additional hybrid operating room capacity that will improve access and provide patients with appropriate, state-of-the-art care. The applicant states, on page 51, since current capacity is limited in its existing hybrid operating room, procedures that could otherwise benefit from the use of the hybrid angiographic endovascular imaging system technology are being done in a regular operating room using a mobile C-arm. The applicant states,

> *"According to surgeons practicing at the medical center, there are two main disadvantages associated with utilizing mobile C-arm technology:*
> - *Results in longer case time which increases patient infection risk*
> - *Inferior image quality creates difficulty visualizing guide wires*
>
> . . .
>
> *The image quality on the fixed imaging systems is superior to standard mobile C-arm technology."*

The expanded capacity of the second hybrid operating room will allow for a majority of procedures that would otherwise need to use C-arm technology to be moved to a more optimal environment. In addition, the proposed second hybrid operating room will address growing volume. According to the Advisory Board Company, a global research, consulting, and technology firm, *"procedures that are best performed, and in some cases*

can only be performed in a vascular operating room setting, will experience growth from 2010 through 2015…" This is illustrated in the following table:

Service	Projected Growth 2010-2015
Cardiac Valve Surgery	9%
Percutaneous Valve Surgery	228%
Abdominal Aortic Aneurysm Endografts	153%
Thoracic Aortic Aneurysm Endografts	51%
Carotid Artery Stent Procedures	136%

In addition, the applicant states that it is essential, as a Level 1 trauma center and quaternary facility, to leave some hybrid operating room capacity available for emergent cases. As emergent cases are expected to grow in the coming years, the applicant states, *"In order to continue to adequately meet the growing need in a safe and timely manner, the medical center must expand its hybrid operating room capacity."*

In addition, the proposed project will necessitate the need to renovate existing OR 19 and OR 20 to accommodate the imaging system. The remaining OR square footage will be inadequate for an operating room, below the 600 square feet standard recognized by the American Institute of Architects' Guidelines for Hospital Construction. Therefore, the proposed project will also include relocating existing OR 20 to space currently being used as a storage room, and renovating it for use as OR 20.

In Section II.5, page 32, the applicant summarizes its need for the angiographic endovascular imaging system as follows:

> *"The proposed project represents an innovative technology that provides a higher level of quality care for patients.*
>
> ...
>
> *As an academic medical center, the acquisition of the proposed equipment is essential to the continued mission of CMC's cardiovascular and neurosurgical programs, which strive to provide cutting edge care at all times. Endovascular imaging equipment in the operating room is quickly becoming the standard of care for many vascular procedures. Patients travel to the medical center from all over the state and beyond expecting to receive high-quality, state-of-the-art care. The acquisition of this equipment will provide CMC with the capacity necessary to allow the medical center to continue meeting the needs of its patients and their expectations."*

<u>Projected Utilization</u>

In Section III.1(b), page 55, the applicant provides its historical hybrid OR utilization, as illustrated below:

CMC Historical Hybrid OR Utilization
CY 2010 – CY 2013

	CY 2010*	CY 2011	CY 2012	Q1 2013	CY 2013 annualized
Total Cases	99	376	455	138	552
% Growth		279%	21%		21%

*July 21, 2010 – December 31, 2010

The applicant states, in Section III, page 55, that based on historical experience, CMC's hybrid operating room cases take an average of 3.7 hours each. Given 100% of the annual capacity of an OR of 2,340 hours[1], a quarter of which is equal to 585 hours, the utilization of CMC's hybrid OR for the first quarter of CY 2013 is 87% (138 cases X 3.7 hours per case = 511 hours/585 hours = .87 or 87%). In addition, the applicant states, on pages 55-56, *"Due to the long case times of hybrid operating room procedures it is difficult to schedule multiple procedures back-to-back, thus greater utilization of the room is not reasonable as many procedures would need to be scheduled beginning late in the day which is not convenient for patients and physicians."* Moreover, CMC surgeons have identified patients who are currently being treated via a mobile C-arm as being appropriate for the hybrid OR's services. The applicant illustrates the growth in patients treated via mobile C-arm in the following table:

	CY 2010	CY 2011	CY 2012	YTD 2013*	CY 2013 annualized
Mobile C-Arm Cases	204	226	304	114	342
% Growth		11%	35%		12.5%

*YTD 2013 data is from January 1, 2013 through April 30, 2013.

CMC experienced a 35% growth in C-arm cases from CY 2011 and CY 2012 and a 12.5% growth from CY 2012 to CY 2013 with YTD 2013 data annualized.

Since the C-arm cases have been identified as being appropriate for the hybrid OR's services, the applicant combines the historical hybrid OR cases with the C-arm cases for CY 2012, calculates total hours per case, and demonstrates the need for the proposed hybrid OR as illustrated in the following table:

[1] *2013 State Medical Facilities Plan*, page 68.

2012 Cases Appropriate for Hybrid OR

	CY 2012
Hybrid OR Cases	455
Mobile C-Arm Cases	304
Total Hybrid and Mobile C-Arm Cases	759
Hours per Case	3.7
Total Case Hours	2,801
Hybrid OR Need*	**1.5**

*Hybrid OR need defined as 1,872 hours per OR, the 2013 SMFP standard for calculating OR need. Therefore, 2,801 hours /1,872 hours equals 1.5.

Although CMC's historical hybrid OR growth rate was 21% from CY 2011 to CY 2012 and is projected to be 21% from CY 2012 to CY 2013 annualized, the applicant chose to use a conservative growth rate of 5% in projecting its utilization of the proposed hybrid OR for the first three full operating years, CY 2015 – CY 2018. CMC's projected utilization from CY 2012 through CY 2017, is depicted in the following table:

CMC
Projected Utilization of Hybrid ORs

	CY 2012	CY 2013	CY 2014	First Full CY 2015	Second Full CY 2016	Third Full CY 2017	CAGR
Hybrid OR Cases	455	478	502	527	553	581	5%
Mobile C-Arm Cases Not Performed in Hybrid OR	304	319	335	352	370	388	5%
Total Cases Performed in Hybrid OR	455	478	502	879	923	969	5%
Hours per Case	3.7	3.7	3.7	3.7	3.7	3.7	
Total Hybrid OR Case Hours	1,684	1,769	1,857	3,251	3,414	3,584	
Hybrid OR Need*	**0.9**	**0.9**	**1.0**	**1.7**	**1.8**	**1.9**	

*Hybrid OR need defined as 1,872 hours per OR, the 2013 SMFP standard for calculating OR need.

As stated in Section III.1(a), page 50, the applicant adequately demonstrated the need to develop a second hybrid OR that will *"address CMC's need for additional hybrid operating room capacity as well as enable the medical center to improve access and accommodate all of its patients with the most appropriate, state-of-the-art care."*

In summary, the applicant adequately demonstrated the need the population projected to be served has for the proposed project and the projected utilization is based on reasonable and supported assumptions. Therefore, CMC adequately demonstrated the need to

develop the proposed second hybrid OR and the application is conforming to this criterion.

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

NA

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

CA

In Section III.3, pages 63 - 65, the applicant discusses the alternatives considered prior to the submission of this application, which include:

1. Maintain the Status Quo
2. Expand the Hours of the Existing Hybrid Operating Room
3. Acquire Endovascular Imaging Equipment to be Located in an Angiography Suite
4. Develop the Second Hybrid OR without Replacing OR 20
5. Develop the Project as Proposed

1. Maintain the Status Quo - The applicant rejected maintaining the status quo since it would not be in the best interest of its patients. It states that as an academic medical center, it serves as a regional referral center for high acuity, specialty services and is a safety-net provider with an obligation to its patients. Furthermore, the applicant states, on page 63, "*The proposed equipment is essential for modern endovascular procedures to avoid image related complications.*" Without this equipment, CMC would not be able to improve access to operating room-based endovascular procedures.

2. Expand the Hours of the Existing Hybrid Operating Room – The applicant considered this option in order to accommodate growing demands for the services of the hybrid operating room. However, additional staffing would be required and would put an added burden on surgeons already working long hours, potentially jeopardizing high-quality outcomes. Therefore, this alternative was rejected due to financial and patient safety reasons.

3. Acquire Endovascular Imaging Equipment to be Located in an Angiography Suite – This alternative would involve new construction in an angiography suite and would not be possible since angiography suites are not licensed operating rooms. The procedures that would need to be performed with the endovascular imaging equipment would need to be performed in a licensed operating room, therefore, this alternative was rejected.

4. Develop the Second Hybrid OR without Replacing OR 20 – The applicant determined that in order to have enough space for the second hybrid OR, it would need to utilize OR 20 space to expand OR 19. Remaining square footage would be inadequate for an OR. Not relocating OR 20 would not be in the best interest of its patients.

5. Develop the Project as Proposed – the applicant's proposed project is the best alternative for a number of reasons, including its location adjacent to its existing hybrid OR. The location of the room will *"help maximize physician workflow and productivity, while decreasing turnover time."* In addition, increasing the size of OR 19 to accommodate the endovascular imaging system will enable CMC to better utilize existing space by *"creating shared clean core space between the hybrid operating rooms."* Moreover, the applicant states that the proposed project will enhance CMC's ability to provide the best level of care possible.

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

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

1. **The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall materially comply with all representations made in its certificate of need application.**

2. **The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall acquire no more than one angiographic endovascular imaging system to be installed in an existing operating room.**

3. **The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall not perform cardiac catheterization procedures that are routinely performed in a cardiac catheterization room on the angiography equipment in the hybrid operating room.**

4. **Upon completion of this project, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall be licensed for no more than 47**

operating rooms, including 5 open heart surgery, 4 dedicated C-Section, 1 other dedicated inpatient surgery, 11 dedicated ambulatory surgery operating rooms, and 26 shared operating rooms.

5. **The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and which would otherwise require a certificate of need.**

6. **Prior to issuance of the certificate of need, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing to the Certificate of Need Section.**

(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

In Section VIII, page 106, the applicant states the total capital cost of the project will be $4,999,133. This includes $2,558,169 for a hybrid angiographic endovascular imaging system and $1,400,000 in construction costs to renovate two existing ORs to house the imaging system, control room, clean core, and storage space, and to relocate one of these existing ORs to renovated space currently being used as a storage room. In Section IX, page 111, the applicant states that there are no start-up expenses for the proposed project since it is an existing service.

In Section VIII.3, page 106, the applicant indicates that the project will be funded with the accumulated reserves of its parent, Carolinas HealthCare System (CHS) in the amount of $4,999,133, the total cost of the project. Exhibit 27 contains a signed letter from the Executive Vice-President and Chief Financial Officer of CHS dated July 15, 2013, which states:

> *"As the Chief Financial Officer for Carolinas HealthCare System,…I am very familiar with the organization's financial position. The total capital expenditure amount for this project is estimated to be $4,999,133.*
> …
> *Carolinas HealthCare System will fund the capital cost from existing accumulated cash reserves."*

Exhibit 28 of the application contains the recent audited financial statements for The Charlotte-Mecklenburg Hospital Authority d/b/a CHS for the years ending December 31, 2012 and December 31, 2011. As of December 31, 2012, CHS had $85,603,000 in cash

and cash equivalents, $6,027,401,000 in total assets and $3,313,001,000 in total net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

The applicant provided pro forma financial statements for the first three years of the project. The applicant projects revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below,

CMC
Hybrid OR Services

	Project Year 1 CY 2015	**Project Year 2 CY 2016**	**Project Year 3 CY 2017**
Projected Number of hybrid surgical cases	879	923	969
Projected Average Charge (Gross Patient Revenue / Projected # of cases)	$149,974	$154,464	$159,123
Gross Patient Revenue	$131,826,799	$142,570,683	$154,190,194
Deductions from Gross Patient Revenue	$94,136,677	$102,470,050	$111,525,584
Net Patient Revenue	$37,690,122	$40,100,633	$42,664,609
Total Expenses	$32,493,889	$34,769,432	$37,220,520
Net Income	$5,196,233	$5,331,201	$5,444,089

The applicant also projects a positive net income for the entire facility in each of the first three operating years of the project. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See pages 131-133 of the application following the pro forma financial statements for the assumptions regarding costs and charges. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges, and therefore, the application is conforming to this criterion.

The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues, and 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

The applicant proposes to acquire an angiographic endovascular imaging system to create a second hybrid OR in an existing OR. The proposal will not result in the development of an additional OR. Instead, an existing OR, adjacent to the existing hybrid OR, will be renovated for the hybrid OR. Since additional space will be needed to house the

angiographic endovascular imaging system and create clean core space between the two hybrid ORs, an additional adjacent OR will be renovated. Remaining square footage will be inadequate for an OR, therefore it will be relocated to a renovated storage room on the same floor.

The proposed angiographic endovascular imaging equipment allows clinicians to provide many different procedures such as open surgical cases and catheter-based procedures within a single operating room rather than having to relocate the patient. It is designed to enhance clinicians' decision making and facilitate faster and more effective procedures.

The applicant adequately demonstrates the need to acquire the proposed specialized angiographic endovascular system to create a hybrid OR in an existing OR. See the discussion in Criterion (3) which is incorporated hereby as if fully set forth herein. Therefore, the applicant adequately demonstrated that the proposal would not result in an unnecessary duplication of existing and approved services. Consequently, the application is conforming to this criterion.

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

C

In Sections VII.1(a) and VII.1(b), pages 96-97, the applicant provides the current and proposed staffing for CMC's hybrid OR and states that its physicians, including surgeons, are employed under a separate entity, Carolinas Physician Network. Therefore, they are not included in current or proposed staffing for the hybrid OR. Current and proposed staffing for the second full fiscal year following completion of the project are illustrated below:

CMC Hybrid ORs
Current and Proposed Staffing

Position	Current Full Time Equivalent (FTE) Positions	Second Full Fiscal Year FTE Positions
Hybrid OR		
Cardiovascular Interventional Specialist	3.0	6.0
Clinical Nurse I/II/III	1.0	2.0
Surgical Technologist I/II	1.0	2.0
Certified Registered Nurse Anesthetist (CRNA)	1.0	2.0
Impacted Ancillary and Support Departments		
Housekeeping	1.0	1.0
Total FTEs	**7.0**	**13.0**

As shown in the table above, the applicant anticipates it will need three additional Cardiovascular Interventional Specialist positions, one additional Clinical Nurse I/II/III position, one additional Surgical Technologist I/II position, and one additional CRNA position. No new positions will result from the proposed project as CMC already employs staff in each of the above positions. In addition, the applicant states that it has all of the physicians that are needed for the proposed project. In Section V.3(c), page 79, the applicant states that the services of the hybrid OR will be overseen by Dr. Frank Arko, III, a vascular surgeon. Dr. Arko's curriculum vitae is provided in Exhibit 17. The Chief of the Medical Staff at CMC will continue to be Dr. Jack Lucas.

For recruitment of needed nursing staff, the applicant states, in Section VII.6(a), pages 100-101, that it has three schools of nursing from which it can recruit: Cabarrus College of Health Sciences, Mercy School of Nursing, and Carolinas College of Health Sciences at CMC. In addition, it often utilizes the following procedures to recruit nursing and non-nursing staff:

- *"Employee referral bonuses;*
- *Hospital website job postings;*
- *Career fairs;*
- *Providing facilities as host sites for professional clinical training programs; and,*
- *Advertising in professional journals and job posting websites."*

Furthermore, the applicant states, on page 99, that is has numerous resources from which to obtain staff, including health professionals who use CMC and Carolinas College of Health Sciences for educational purposes who may join CMC staff once their training is complete. Since CMC is *"the flagship hospital"* of the Carolina HealthCare System and

the fourth largest employer in the state, it does not anticipate any difficulty in recruiting the additional FTEs needed for the proposed project.

The applicant demonstrated the availability of adequate health manpower and management personnel to provide the proposed service, and therefore, the application is conforming to this criterion.

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

C

The applicant is a full-service acute care hospital, therefore it has all ancillary and support services in place as part of its day to day operations. In Section II.2(a), page 30, the applicant states that these services will also support the proposed project. Support needed for patients treated in the operating room may include existing ancillary and support services such as laboratory, radiology, pharmacy, dietary, housekeeping, maintenance, and administration, in addition to others. The applicant provides a letter in Exhibit 6 dated July 15, 2013 and signed by CMC's President, that attests to the availability of necessary ancillary and support services and associated staffing for the proposed endovascular operating equipment and hybrid OR.

The applicant discusses how its proposed project will be coordinated with the healthcare system in Section V, pages 78-81. As an existing healthcare facility, CMC has relationships with area healthcare providers and also coordinates a continuum of health services with area hospitals and other healthcare providers such as CMC-Randolph, CMC-Mercy, Carolinas Rehabilitation, and Huntersville Oaks nursing home within Mecklenburg County. CHS, of which CMC is the flagship hospital, provides a broad range of healthcare and human services that represent a continuum of care. Therefore, its relationships with area providers, including area physicians, are well established. Exhibit 32 contains numerous letters of support from area physicians for the proposed project. The applicant adequately demonstrated the availability of the necessary ancillary and support services and that the proposed services would be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

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

NA

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

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

C

In Sections VI.12 and VI.13, pages 92 - 93, the applicant provides its historical payer mix for the entire hospital and for its hybrid OR for CY 2012, its last full fiscal year, as illustrated in the table below:

CMC Payer Mix
Percent of Total Utilization CY 2012

	Entire Facility Patients	Hybrid OR Cases
Self Pay/ Indigent/ Charity/ Other*	7.2 %	4.4%
Medicare/ Medicare Managed Care	31.3%	61.4%
Medicaid	31.3%	8.8%
Managed Care/ Commercial Insurance	30.2%	25.4%
Total	**100.0%**	**100.0%**

*Other includes workers compensation and other governmental payers.

In Section VI.2, page 85, the applicant states:

> *'[n]o individual shall be subject to discrimination or denied the benefits of the services, programs, or activities of the Carolinas HealthCare System on the basis of race, color, religion, national origin, sex, age, disability or source of payment.'*

Exhibit 24 contains CHS' Charity Care Policy which applies to CMC. The applicant states, in Section VI.4(b), page 87,

> *"CHS offers financial assistance to medically indigent patients who are uninsured or who are underinsured due to a health insurance policy that pays a minimal benefit. Medical indigence is determined using the most current Federal Poverty Guidelines as the basis, including patient income and asset information to support the decision. Patients who are not eligible for any third party coverage or CHS financial assistance and who are unwilling or unable to pay, may become eligible for CHS's extended payment arrangements."*

In addition, CMC complies with the standards and provisions of the North Carolina State Building Code Volume 1-C Accessibility Code as well as the Americans with Disabilities Act. CHS' Hospital Admission, Credit and Collection Policy, which also includes its Non-Discrimination Policy, is provided in Exhibit 23.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. Mecklenburg County comprises 33.7 percent of the projected patient origin for the proposed service, while Union County comprises 6.0% and Gaston comprises 5.5%

	Total # of Medicaid Eligibles as % of Total Population June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Mecklenburg County	15.0%	5.1%	20.1%
Union County	11.0%	3.4%	18.0%
Gaston County	20.0%	8.6%	19.0%
Statewide	**17.0%**	**6.7%**	**19.7%**

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group would not typically utilize the services proposed for the hybrid OR.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger (Mecklenburg County percentage was 44.1%) and 31.6% for those age 21 and older (Mecklenburg County percentage was 30.7%). Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The NCOSBM website provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race and gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant adequately demonstrated that medically underserved populations currently have adequate access to the services offered at CMC. 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

The applicant states, in Section VI.11, page 92, that it has had no obligation to provide uncompensated care during the last three years and that it provides a considerable amount of charity care and bad debt. The applicant states, in Section VI.8(a) and (b), page 89, that it provided 17.8% and 7.8% of its net revenue in charity care and bad debt, respectively, in CY 2012, its last full fiscal year.

In Section VI.10(a), page 91, the applicant states that no civil rights equal access complaints have been filed against any affiliated CHS entity in the last five years. Therefore, the application is conforming to this criterion.

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

C

In Sections VI.14(a) and VI.15(a), pages 93 - 94, the applicant provides the projected payer mix for the second full fiscal year of operation for the entire facility and for the hybrid OR, as illustrated in the table below:

CMC Projected Payer Mix
Percent of Total Utilization CY 2016

	Entire Facility Patients	**Proposed Hybrid OR Cases**
Self Pay/ Other*	7.2 %	4.4%
Medicare/ Medicare Managed Care	31.3%	61.4%
Medicaid	31.3%	8.8.%
Managed Care/ Commercial Insurance	30.2%	25.4.%
Total	**100.0%**	**100.0%**

*Other includes workers compensation and other governmental payers.

The applicant adequately demonstrated that medically underserved populations will have adequate 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.

C

In Section VI.9(a), pages 90-91, the applicant states that patients have access to the proposed services through referrals by physicians with admitting privileges at CMC and by being admitted through CMC's emergency department. Furthermore, as stated on page 91, as an established provider, CMC *"has informal agreements with local and regional health care agencies that refer patients, through a physician, to the medical center's services."*

The applicant adequately demonstrated it offers a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section V.1(a), page 76, the applicant states that CMC provides opportunities for clinical education in its facilities to numerous medical and allied health professions students annually. Health professions programs include nursing and radiologic technology, surgical technology, medical technology, pastoral education and others offered through Carolinas College of Health Sciences. Facilities are also used for an affiliated EMT-Paramedic program offered through Central Piedmont Community College and the Mecklenburg Emergency Medical Services Agency, and a Master's degree program in nursing to obtain professional nurse anesthetist training through CMC and the University of North Carolina (UNC) at Charlotte. CMC has established relationships with other educational institutions as well, including Queens University of Charlotte, Gardner-Webb University, Presbyterian School of Nursing and Mercy School of Nursing. CMC also manages the Charlotte Area Health Education Center through a contract with UNC at Chapel Hill to coordinate various education programs and provide continuing medical education for CHS employees and others in an eight county region. The applicant states, on page 77, that its established relationships with area clinical education programs will continue with the completion of the proposed project. Exhibit 21 provides a listing of CMC's current educational affiliations.

The applicant adequately demonstrates that CMC will continue to accommodate the clinical needs of health professional training programs in the area, therefore, the application is conforming to this criterion.

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

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

C

The applicant proposes to acquire an angiographic endovascular imaging system to develop a second hybrid OR in an existing OR. Renovations will be made to two existing ORs to accommodate the angiographic endovascular imaging system, resulting in one of the existing ORs being relocated to existing space.

Mecklenburg County is the service area for the Operating Room Need methodology as defined in the 2013 SMFP. There are 13 healthcare facilities with licensed operating rooms in Mecklenburg County. Operating room inventory, as reported on hospital license renewal applications (LRAs), includes inpatient, ambulatory, shared, C-Section, and Trauma/Burn ORs. CMC has 47 ORs, excluding four C-Section ORs and one Trauma/Burn OR. Hybrid ORs are not reported on LRAs, rather they are reported as shared or inpatient ORs. The only other known facility in Mecklenburg County with at least one hybrid OR is Presbyterian Hospital (Project I.D. #F-10009-12).

In Section V.7, pages 81 – 84, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The proposed project will utilize existing space, provide state-of-the-art surgical services, and improve access to high quality surgical services. See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to acquire an angiographic endovascular imaging system to develop a second hybrid OR in an existing OR and that it is a cost-effective alternative;
- The applicant has and will continue to provide quality services; and
- The applicant has and will continue to provide adequate access to medically underserved populations.

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

CMC is accredited by The Joint Commission, certified for Medicare and Medicaid participation and is licensed by the NC Department of Health and Human Services. It has also received advanced certification for its primary stroke center and certification for its end stage renal disease program and its heart failure program. Exhibit 9 includes a letter from the President of CMC, dated July 15, 2013, which states:

> *"The proposed services will be provided in conformance with all applicable facility, programmatic, and service specific licensure, certification, and The Joint Commission accreditation standards."*

In Section II.7(a) and (b), pages 33-36, the applicant describes its methods for insuring and maintaining quality care. CMC has a Quality Assessment and Performance Improvement Plan in place, *"to systematically monitor and evaluate patient care and clinical performance."* A copy of the plan is provided in Exhibit 10. This ongoing program involves medical and administrative staff in addition to board members. The goals for the plan, and therefore for maintaining quality, include:

- *"Aligning with System goals and initiatives;*
- *Measuring and improving the satisfaction and quality of services provided;*
- *Identifying and improving systems and processes related to patient care, safety, and clinical processes;*
- *Creating effective systems to measure, assess and improve the processes and outcomes associated with patient care; and*
- *Improving the overall understanding of continuous quality improvement tools and techniques within the organization."*

In addition, CMC monitors care through its Utilization Management Plan, provided in Exhibit 11, which addresses "*the operational procedures that will be followed with respect to the review of all patients."* Lastly, the facility operates under CHS' Risk Management Plan which is designed to "*prevent and reduce the risk of injury to patients, visitors, employees and medical staff members and to protect the organization's financial resources."* A few of the objectives of this plan include:

- Providing a safe environment for patients;
- Minimizing the frequency and severity of incidents and responding to them with a plan of corrective action;

- Providing safety training to personnel;
- Assisting with coordinating activities on compliance with all applicable regulations; and,
- Ensuring that risk management activities are integrated with performance improvement activities.

Moreover, the applicant states that the plans described above will *"continue to guide the services provided by the medical center, including endovascular services, as proposed in this project."*

According to the files in the Acute and Home Care Licensure and Certification Section in the Division of Health Service Regulation, no incidents have occurred at CMC within the eighteen months immediately preceding the date of the decision for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

The application is conforming with all applicable Criteria and Standards for Major Medical Equipment, promulgated in 10A NCAC 14C .3100. The specific criteria are discussed below.

SECTION .3100 - CRITERIA AND STANDARDS FOR MAJOR MEDICAL EQUIPMENT

10A NCAC 14C .3103 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire new major medical technology or major medical equipment shall use the Acute Care Facility/Medical Equipment application form.

-C- CMC used the Acute Care Facility/Medical Equipment application form.

(b) An applicant shall define a proposed service area for the major medical equipment or new major medical technology which shall be similar to the applicant's existing service area for other health services, unless the applicant documents that other providers outside of the applicant's existing service area are expected to refer patients to the applicant.

-C- In Section II, page 39, the applicant defined the service area for the proposed hybrid OR based on historical patient origin for CMC's first hybrid OR. The applicant states that Mecklenburg County will remain its primary service area, and that Union, Gaston, Cleveland, Cabarrus, Lincoln and Iredell Counties in North Carolina, and York and Lancaster Counties in South Carolina, will comprise its secondary service area. In Section III.5(a), page 68, the applicant states that it expects Mecklenburg County to account for nearly 34% of its hybrid OR patients and its secondary service area counties to account for approximately 43% of these patients. Taken together, these will account for more than 76% of the proposed hybrid OR patients. Moreover, the applicant states, in Section II, page 39, that *"These counties are also consistent with CMC's service area for other higher level, academic services."*

(c) An applicant shall document its current experience in providing care to the patients to be served by the proposed major medical equipment or new major medical technology.

-C- In Section I.12(e), pages 12-21, the applicant describes its experience in providing care to the patients to be served by the proposed project. The applicant states, on page 16, *"Endovascular/hybrid operating room services at CMC are provided through a collaborative effort among the specialized fields of vascular surgery, neurosurgery, interventional radiology, and cardiology. These services are provided through the Sanger Heart & Vascular Institute and CMC Neuroscience and Spine Institute…"* The applicant further states that CMC has provided cardiac care for more than half a century, including interventional cardiology and cardiac surgery. In addition, in 2002, CMC established the Heineman Vascular Center at the Sanger Heart & Vascular Institute as a collaborative effort to provide a single site for treatment and prevention of peripheral arterial and venous problems, focusing on all vessels outside the heart and brain. Moreover, CMC operates the Neuroscience and Spine Institute to provide advanced surgical and nonsurgical treatment for brain, spine and peripheral nerve disorders. Carolinas NeuroSurgery & Spine Associates, a physician practice working at the CMC Neuroscience and Spine Institute, specialize in a wide range of surgeries and procedures and are one of the oldest and largest neurosurgical practices in the country. In addition to all of this experience, CMC began operating its first hybrid OR on July 21, 2010, and therefore has experience in providing the proposed services.

(d) An applicant shall document that the proposed new major medical technology or major medical equipment, its supplies, and its pharmaceuticals have been approved by the U.S. Food and Drug Administration for the clinical uses stated in the application, or that the equipment shall be operated under protocols of an institutional review board whose membership is consistent with the U. S. Department of Health and Human Services' regulations.

-C- See Exhibit 13 for documentation that the proposed equipment is approved for use by the U.S. Food and Drug Administration.

(e) An applicant proposing to acquire new major medical equipment or new major medical technology shall provide a floor plan of the facility in which the equipment will be operated that identifies the following areas:

(1) receiving/registering area;
(2) waiting area;
(3) pre-procedure area;
(4) procedure area or rooms;
(5) post-procedure areas, including observation areas; and
(6) administrative and support areas.

-C- Exhibit 4 contains line drawings for all areas listed above. In Section II, page 40, the applicant states that observation and recovery areas, the operating room for the proposed equipment, and support areas consisting of clean core space will be located on the fifth floor of CMC. Administrative offices, physician lockers and lounges are located on the sixth floor.

(f) An applicant proposing to acquire major medical equipment or new major medical technology shall document that the facility shall meet or exceed the appropriate building codes and federal, state, and local manufacturer's standards for the type of major medical equipment to be installed.

-C- The applicant provides a letter in Exhibit 14 signed by the President of CMC, dated July 15, 2013, stating that the proposed project will be developed in accordance with federal, state and local building codes and standards.

10A NCAC 14C .3104 NEED FOR SERVICES

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

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

-C- In Section II, pages 42-43, the applicant provides a table depicting the historical distribution, by ICD-9 Diagnosis Codes, of hybrid OR patients and patients treated by mobile C-arm technology that would have been appropriate for treatment in a hybrid operating room setting if adequate capacity had been available. Patient projections for the top ten diagnoses for these combined services for project years one through three are provided below:

CMC – Hybrid Operating Room Patients by Diagnosis

ICD-9 Diagnosis	Description	Historical Distribution	CY 2015	CY 2016	CY 2017

Code					
441.4	Abdom Aortic Aneurysm	21.9%	193	202	213
437.3	Nonrupt Cerebral Aneurysm	8.3%	73	77	81
424.1	Aortic Valve Disorder	4.6%	41	43	45
441.3	Rupt Abd Aortic Aneurysm	4.6%	41	43	45
441.01	Dsct of Thoracic Aorta	3.9%	34	36	38
996.74	Comp-Oth Vasc Dev/Graft	3.7%	32	34	36
996.1	Malfunc Vasc Device/Graf	3.0%	26	28	29
433.1	Ocl Crtd Art Wo Infrct	2.5%	22	23	25
440.21	Ath Ext Ntv At W Claudct	2.3%	20	21	22
442.2	Iliac Artery Aneurysm	2.3%	20	21	22

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

-C- In Section II, page 43, the applicant states that it *"relied on the historical distribution of patients by county when projecting patient origin."* Projected numbers of hybrid OR patients by county of origin for the first three full years of operation are provided by the applicant in Section II, page 44, illustrated as follows:

CMC - Projected Patient Origin by County for Hybrid OR

County	Historical Distribution	Projected Patients		
		CY 2015	CY 2016	CY 2017
Mecklenburg	33.7%	296	311	327
York, SC	8.3%	73	77	81
Lancaster, SC	6.0%	53	55	58
Union	6.0%	53	55	58
Cleveland	5.5%	49	51	54
Gaston	5.5%	49	51	54
Cabarrus	4.8%	43	45	47
Iredell	4.2%	37	38	40
Lincoln	2.5%	22	23	25
Other*	23.3%	205	215	226
Total	**100.0%**	**879**	**923**	**969**

*Other includes 38 other counties in North Carolina and other states. See page 44 for complete listing.

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

-C- The applicant states in Section II, page 44, that each of its hybrid OR cases takes, on average, 3.7 hours. The 2013 SMFP states that an average operating room is staffed 2,340 hours per year. Therefore, the maximum number of cases CMC can perform in its hybrid OR is 632 (2,340 total operating hours/3.7 hours each case = 632 cases).

(4) quarterly projected utilization of the applicant's existing and proposed equipment three years after the completion of the project; and

-C- In Section II, page 45, the applicant provides the following projected quarterly utilization for the proposed hybrid OR during the first three project years:

CMC
Hybrid OR Projected Quarterly Utilization

Quarter	Historical Distribution	CY 2015	CY 2016	CY 2017
First	24%	210	221	232
Second	23%	201	211	221
Third	26%	230	241	253
Fourth	27%	238	249	262
Total Patients		**879**	**923**	**969**

(5) all the assumptions and data supporting the methodology used for the projections in this Rule.

-C- The applicant provides the assumptions and methodology used to project utilization of the proposed hybrid OR in Section III.1(b), pages 54-59.

(b) An applicant proposing to acquire new major medical technology shall provide the following information:

(1) the number of patients who will use the service, classified by diagnosis;
(2) the number of patients who will use the service, classified by county of residence;
(3) quarterly projected utilization of the applicant's proposed new major medical technology three years after the completion of the project;
(4) documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies;
(5) documentation of the effect the new major medical technology may have on existing major medical technology and procedures offered at its facility and other facilities in the proposed service area; and
(6) all the assumptions and data supporting the methodology used for the projections in this Rule.

-NA- In Section II, page 46, the applicant states, *"CMC is not proposing to acquire new major medical technology as defined by 10A NCAC 14C .3102(4)."*

10A NCAC 14C .3105 SUPPORT SERVICES

An applicant proposing to acquire major medical equipment or new major medical technology shall identify all ancillary and support services that are required to support the major medical equipment or new major medical technology and shall document that all of these services shall be available prior to the operation of the equipment.

-C- In Section II, page 46, the applicant states that since it is an existing acute care hospital, it already has all necessary ancillary and support services in place. It further states, *"This infrastructure, as well as existing ancillary and support staff, will be sufficient to support the endovascular imaging equipment proposed in this application."* The applicant provides a letter from the President of CMC in Exhibit 6 that documents the availability of ancillary and support services for the proposed project.

10A NCAC 14C .3106 STAFFING AND STAFF TRAINING

(a) An applicant proposing to acquire major medical equipment or new major medical technology shall document that:
(1) trained and qualified clinical staff shall be employed, and
(2) trained technical staff and support personnel to work in conjunction with the operators of the equipment shall be employed.

-C- The applicant discusses its staffing for the proposed project in Section VII.1(b), provides relevant job descriptions in Exhibit 15, and provides a letter from the President of CMC in Exhibit 16 which states that the medical center is committed to employing trained and qualified staff and that this will not change following completion of the proposed project. In addition, the equipment quote from the vendor, provided in Exhibit 5, includes 64 hours of on-site training.

(b) An applicant proposing to acquire major medical equipment or new major medical technology shall provide documentation that physicians who will use the equipment have had relevant residency training, formal continuing medical education courses, and prior on-the-job experience with this or similar medical equipment.

-C- In Section II, page 47, the applicant refers to Exhibit 16, which contains a letter from the President of CMC that indicates the facility will employ appropriately trained and qualified staff for the proposed project, and states, *"…in conformance with 10A NCAC 14C .3106(b) and as documented in its certificate of need application, physicians who will use the proposed equipment have had relevant residency training, formal continuing medical education courses, and prior on-the-job experience with the same or similar medical equipment."* In addition, the applicant includes the physicians' curricula vitae in Exhibit 17.

(c) An applicant shall demonstrate that the following staff training will be provided to the staff that operates the major medical equipment or new major medical technology:
(1) certification in cardiopulmonary resuscitation and basic cardiac life support; and
(2) an organized program of staff education and training which is integral to the operation of the major medical equipment and ensures improvements in technique and the proper training of new personnel.

-C- In Section II, pages 47-48, the applicant discusses the training policy in place at CHS hospitals, referring to its policy in Exhibit 18, which states, *'RNs, LPNs, NAs and other designated nursing staff who perform direct patient care shall have current Basic Life Support for Healthcare Provider (BLS HCP) status according to American Heart Association (AHA) criteria.'* Newly hired nursing staff receive this training within 90 days. In regard to having an organized program of staff education and training integral to the operation of the major medical equipment, the applicant states, on pages 47- 48, that the equipment vendor provides both initial and follow up training for operating room nursing staff, technicians and physicians who will be operating the equipment. Moreover, the applicant states, on page 48, *"The physicians who will utilize the proposed equipment are already trained and proficient in minimally invasive endovascular procedures as documented by the curricula vitae included in Exhibit 17."*