ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: August 29, 2012
PROJECT ANALYST: Gloria C. Hale
ASSISTANT CHIEF Martha J. Frisone

PROJECT I.D. NUMBER: F-8827-12/ The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center/ Renovate existing space on the 4th floor for a 16-bed unit with a hematology oncology focus / 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

The Charlotte Mecklenburg Hospital Authority d/b/a Carolinas Medical Center (CMC) proposes to renovate the 4th floor of the main hospital to house a 16-bed adult hematology oncology unit and bring in-house cell processing and apheresis services currently being provided under contract off-site. CMC proposes to renovate 14,500 square feet of existing space, of which 10,500 square feet will house adult hematologic oncology services and 4,000 square feet will house cell processing and apheresis services. The applicant does not propose to develop beds or services or acquire equipment for which there is a need determination in the 2012 State Medical Facilities Plan (SMFP). However, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 40 of the 2012 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."

The applicant states that they will work with their experienced architects and engineers to develop energy efficient systems for the proposed project. Specifically, the applicant states:

"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.*
- *Use Environmental Protection Agency Energy Star for Hospitals rating system to compare performance following 12 months of continuous operation.*
- *Refer to United States Green Building Council (USGBC) LEED guidelines and GGHC to identify opportunities to improve the efficiency and performance.*

CMC utilizes and enforces engineering standards that mandate use of state-of-the-art components and systems. The proposed project will be designed in full compliance with applicable local, state, and federal requirements for energy efficiency and consumption."

The applicant adequately demonstrates the proposal includes 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, The Charlotte Mecklenburg Hospital Authority d/b/a Carolinas Medical Center (CMC), proposes to renovate the 4th floor of CMC to house 16 adult medical/surgical beds with a hematology oncology focus. In addition, cell processing and apheresis services that are currently being contracted for will be brought in-house on the 4th floor. The proposed changes involve the following areas which are described below.

In Section III.1(a), page 19, the applicant states:

- *"Renovation of four existing licensed private rooms, seven former private rooms, five former semi-private rooms, a former newborn nursery, and support space located on Unit 4B of the medical center to house sixteen right-sized private medial/surgical beds;*

- *Renovation of former support, storage, and office space located on the connecting corridor between units 4B and 4T to house support areas for the proposed unit; and*

- *Renovation of space vacated by endoscopy services on Unit 4M in connection with previously approved Project ID #F-8761-11, to house cell processing and apheresis services, currently contracted ancillary services which CMC proposes to bring in-house in conjunction with the proposed project."*

<u>Population to be Served</u>

The following table illustrates projected patient origin for CMC's adult general acute care beds for the first two operating years of the project as provided in Section III.4 (c), page 83.

CMC Adult General Acute Care Beds

County	*Current Year: % of Total Patients*	*Year 1: % of Total Patients*	*Year 2: % of Total Patients*
Mecklenburg	55.6%	56.0%	57.8%
Gaston	4.7%	4.5%	4.7%
York, SC	5.9%	4.7%	1.7%
Cleveland	3.4%	3.7%	3.8%
Union	5.8%	4.3%	4.4%
Lincoln	2.6%	2.8%	2.9%
Cabarrus	2.2%	2.4%	2.5%
Iredell	2.0%	2.2%	2.2%
Lancaster, SC	2.0%	1.8%	1.9%
Other*	15.9%	17.5%	18.1%
Total	100.0%	100.0%	100.0%

*Other includes over 120 cities, counties, and other states

The applicant addresses access to the medically underserved by stating that CMC draws patients from a larger geographic region than other providers in the region, and on page 73, also states that it is *"recognized as the safety net provider for the medically underserved in Mecklenburg County. CMC has historically provided services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay as demonstrated in the medical center's admissions policies…CMC has historically demonstrated a commitment to ensuring equitable access and will continue to provide such services in the service area."* Exhibit 17, page 357, contains a copy of CMC's admission policies.

The applicant adequately identified the population it proposes to serve.

Need for the Proposed Project

The applicant proposes in Section III.1(a), page 41, to renovate existing space to *"improve the physical environment and consolidate existing adult hematologic oncology services and to accommodate in-house provision of cell processing and apheresis services at CMC, in order to optimize patient care."* Currently, most adult hematology oncology patients are admitted to one of the beds on Unit 4T, however some are admitted to any available medical/surgical bed in the medical center. This is not considered ideal since many of these patients are immumocompromised. The renovation is intended to make improvements to the physical environment that will better control for contaminants and thus, reduce the risk of infection. To achieve this, the applicant proposes to develop sixteen private patient rooms with higher (positive) pressure, high-efficiency air (HEPA) filters, and individual air ducts. The unit will have a double door entryway to help ensure positive pressure and infection control, and 14 of the 16 patient rooms will have ante rooms to maintain negative pressure between each room and the unit corridor. Two patient rooms will be isolation rooms to be used with patients who are immumocompromised and have infections. The unit's air handling system will also be modified to function with 12 exchanges per hour rather than six exchanges per hour as is the standard for general medical/surgical patient rooms. In addition, the unit will have solid, seamless flooring and a hard, non-porous ceiling to further decrease the collection of

contaminants and dust. Moreover, patient rooms will be larger to accommodate a recliner or sleeper for family members and to accommodate the variety of equipment that may be needed by patients during their stays.

The applicant further states on page 52, *"By consolidating these patients in one location, CMC can more effectively create a controlled environment where the likelihood of infection is greatly reduced."*

In addition to these renovations, the applicant proposes to bring in-house the ancillary services of cell processing and apheresis that are currently being provided on contract. By bringing these services in-house on the 4th floor, cell viability will be enhanced by eliminating the need for specimens to be transported by air out of state. Inefficiencies related to transport schedules will also be eliminated and the continuity of care improved.

Lastly, the proposed unit will benefit from the expertise of additional specialists. In Section III.1(a), page 54, the applicant states, *The proposed unit will also benefit from enhanced access to nursing specialization and readily available specialists. …CMC will hire a hematologic oncology nurse manager, and hematologic oncology nurse practitioners to bring nursing specialization to the proposed renovated and consolidated unit."* CMC has also recruited two physicians specializing in hematology-oncology who have clinical interests that will be brought to bear on CMC's continuing research and development in the areas of hematology and oncology.

In summary, the applicant states in Section III.1 (a), page 57, that *"The proposed project, in conjunction with CMC's recent recruitment efforts, will enhance hematologic oncology services-improving quality and safety, care continuity (via cell processing and apheresis services), and increasing patient access to specialists and the most appropriate physical environment."*

In Section III.6, page 68, the applicant provides a table, as depicted below, that projects the adult general acute care bed patient days for the two years prior to project implementation and for the first three project years.

Adult General Acute Care Bed Utilization

Calendar Year	*CMC Adult General Acute Care Patient Days*	*Shift to CMC-Fort Mill*	*Shift to CMC-Pineville*	*Final Projected Adult General Acute Care Patient Days*	*ADC*	*Beds*	*Occupancy*
2012	143,394	-	-	143,394	392.9	405	97.0%
2013	145,712	-	(13,037)	132,676	363.5	418	87.0%
PY1: 2014	148,068	0	(13,379)	134,689	369.0	418	86.9%
PY2: 2015	150,462	(4,116)	(13,732)	132,614	363.3	418	86.9%
PY3: 2016	152,894	(4,235)	(14,094)	134,564	368.7	418	88.2%

In Section III.b, page 61, the applicant provides a summary description of the methodology used to determine projected patient days and admissions for adult general acute care beds as follows:

Step	Description
1	Examine CMC's *Historical Adult General Acute Care Bed Utilization and Projected Population.*
2	Determine the *Projected Adult General Acute Care Bed Patient Days Prior to Shifts* by applying projected growth rates to historical patient days.
3	*Convert Federal Fiscal Year data to Calendar Year data.*
4	Determine the projected *Shift of Patient Days from CMC to CMC-Fort Mill.*
5	Determine the projected *Shift of Patient Days from CMC to CMC-Pineville.*
6	Determine the *Projected Adult General Acute Care Bed Patient Days* by subtracting shifted volume from the projected CMC volume.
7	Determine *Projected Adult General Acute Care Admissions* by dividing projected patient days by the historical average length of stay.

Adult general acute care patient days have grown at a greater rate at CMC than the population of the service area and continued growth in population is expected. CMC chose to use its service area growth rate of 1.62 percent to conservatively project its annual adult general acute care patient days rather than Mecklenburg County's population growth rate of 1.78 percent. CMC believes that with the addition of the recently approved 13 adult medical/surgical beds from Project ID #F-8761-11 that are to be operational by January 1, 2013, its growth rates are sustainable.

Exhibit 15 includes the methodology used to determine the number of acute care discharges that will shift from CMC to CMC-Fort Mill. Likewise, Exhibit 16 includes the methodology used to determine the number of combined adult ICU and adult acute care discharges to shift from CMC to CMC-Pineville. CMC-Pineville was approved for a major expansion project in 2008 (Project ID# F-7979-07) that will result in shifting patients from both CMC and CMC-

Mercy to CMC-Pineville. Both patient shifts were subtracted from CMC projected patient days. The applicant further notes in Section III.6, page 68, that:

> *"…the volume declines through the project years are directly attributable to the completion of the CMC-Pineville expansion and renovation project and the opening of the CMC-Fort Mill. These shifts in volume represent a one-time shift in volume which will allow CMC to continue growing its patient volume, as shown by the increase demonstrated from 2015 to 2016. "*

In order to calculate projected admissions, CMC utilized the same average length of stay that it used in calendar years 2009 to 2011 for adult general acute care beds, even though *"the shift of patients to CMC-Fort Mill is likely to involve cases with shorter lengths of stay with the result that the remaining patients will have longer lengths of stay."* CMC's projections will result in 88.2 percent occupancy of adult general acute care beds in project year three which is above the target occupancy rate of 75.2 percent for these beds. Note: this project does not result in the increase in the number of acute care beds. The scope of the project is limited to renovation of existing acute care beds.

In summary, the applicant adequately identified the population to be served and identified the need the population has for the proposed renovations. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section III.3, pages 76-78, the applicant describes the alternatives considered, including maintaining the status quo and renovating and enhancing adult hematolgic oncology services as proposed, but developing cell processing and apheresis services off-site. The applicant states the alternative of maintaining the status quo is non-optimal and inconsistent with recent efforts to enhance hematologic oncology services through the addition of two hematologic oncology specialists which will enable the facility to provide patients with increased access to a broad range of specialized hematologic oncology services. In addition, the status quo would not provide for the unique changes to the physical environment designed to improve quality of care to these immunocompromised patients.

The other alternative described, renovating and enhancing adult hematologic oncology services as proposed, but continuing the cell processing and apheresis services off-site, is not considered to be ideal due to the *"delicate nature of what is being transported."* With the cell processing and apheresis services on site and the addition of two hematologic oncology specialists, CMC proposes direct and timely access to the cells needed for anticipated increases in clinical research activities. The applicant states that accommodating cell processing and apheresis on site in close proximity to the proposed unit and the hospital's blood bank is the most effective alternative. The applicant adequately demonstrates that none of the alternatives is as effective as the proposed alternative for meeting the need.

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

The applicant adequately demonstrates that its proposal is the least costly or most effective alternative. 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 not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and which would otherwise require a certificate of need.**

3. **The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall 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 representations in the written statement as described in paragraph one of Policy GEN-4.**

4. **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.2, pages 120-121, the applicant states that the total capital cost of the project will be $10,445,000, including $5,901,500 for the construction contract, and $4,543,500 for miscellaneous project costs. In Section IX, page 125, the applicant states there will be no start-up or initial operating expenses associated with this project. In Section VIII.2, page 121, the applicant states that the capital cost of the project will be funded by bond issue.

The availability of the bond financing is documented in Exhibit 25 in a letter signed by the Chief Financial Officer of Carolinas Healthcare System (CHS), which states:

> *"Carolinas Healthcare System will fund the capital cost from a recent bond issue. This expenditure will not impact any other capital projects currently underway or planned for at this time. For verification of the availability of these funds and our ability to finance these projects internally, please refer to the cover page from the official statements from bond issue, which as been included with this letter."*

Exhibit 26, page 428, of the application contains the two most recent audited financial statements for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System. As of December 31, 2011, the applicant had $5,595,420 in total assets and deferred outflows, and $2,911,029 in net assets (total assets and deferred outflows less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the project.

The applicant provided pro forma financial statements for the first three years of the project, for the entire hospital and for the pertinent component of the proposed project. The applicant projects that operating expenses will exceed revenues in each of the first three operating years for adult general acute care beds. However, the applicant projects a positive net income for the entire hospital 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. See the Financials section of the application following Section 12 for the assumptions and pro formas. See Criterion (3) for discussion of utilization projections which is hereby incorporated as if set forth fully herein. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Therefore, the application is conforming to this criterion.

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

C

The applicant, Carolinas Medical Center, proposes to renovate existing space on the fourth floor of the hospital to consolidate existing adult hematologic oncology services and to accommodate the in-house provision of cell processing and apheresis services. The applicant does not propose any new services or additional beds or equipment. Rather, existing services will be consolidated in renovated space. The applicant adequately demonstrated that the proposal would not result in an unnecessary duplication of existing and approved services. Therefore, the application is conforming to this criterion.

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

C

In Section VII.1(a), pages 110-113, the applicant provides both the current and proposed staffing for CMC's adult general acute care beds, and the proposed staffing for CMC's renovated adult hematologic oncology unit. The proposed staffing for the renovated adult hematologic oncology unit will utilize 16.00 FTEs, 11.50 FTEs of which will be existing adult general acute care staff. The remaining 4.50 FTEs will be hired upon completion of the project. The staffing for CMC's current and proposed adult general acute care beds is displayed in tables in Sections VII.1(a) and VII.1(b), pages 110-111, respectively, and is compiled in the following table:

Current Staffing CY 2012			**Proposed Staffing CY 2015**	
POSITION	*TOTAL # OF FTE POSITIONS EMPLOYED*	*AVERAGE ANNUAL SALARY PER FTE POSITION*	*TOTAL # OF FTE POSITIONS EMPLOYED*	*AVERAGE ANNUAL SALARY PER FTE POSITION*
Physicians	N/A	N/A	N/A	N/A
Physicians Assistants	N/A	N/A	N/A	N/A
Total Adult General Acute Care Beds				
Registered Nurse	611.51	$68,682	611.51	$77,257
Clinical Nurse Specialist	0	$0	1.00	$81,120
Nurse Practitioner	0	$0	2.50	$162,240
Technician/ Nurse Assistant	218.98	$30,566	218.98	$34,382
Unit Secretary	68.22	$34,914	68.22	$39,273
Supervisor	17.00	$95,223	17.00	$107,113
Nurse Manager	0	$0	1.00	$108,160
Total	915.71		920.21	

The proposed staffing for CMC's renovated hematologic oncology unit is provided in Section VII.1(b), page 112, as follows:

Proposed Staffing CY 2015

POSITION	*TOTAL # OF FTE POSITIONS EMPLOYED*	*AVERAGE ANNUAL SALARY PER FTE POSITION*
Physicians	N/A	N/A
Physician Assistants	N/A	N/A
Hematologic Oncology Unit		
Registered Nurse	7.00	$77,257
Clinical Nurse Specialist	1.00	$81,120
Nurse Practitioner	2.50	$162,240
Inpatient Nursing Assistant/Clerical	4.5	$34,382
Nurse Manager	1.00	$108,160
Total	16.00	

"Note: Registered Nurse and Inpatient Nursing Assistant/ Clerical staffing in the Hematologic Oncology Unit is not incremental to the staffing for total adult general acute care beds. As such, staffing for the Registered Nurse and Technician/ Nurse Assistant categories in the proposed staffing for total adult general acute care beds in the previous table remains the same as current staffing…"

In addition, in Section VII.1(b), page 113, the applicant provides the proposed staffing for CMC's cell processing and apheresis services that are currently outsourced but will be moved in-house. Five FTEs will be hired for the cell processing and apheresis services component of the project as illustrated below:

Proposed Staffing CY 2015

POSITION	*TOTAL # OF FTE POSITIONS EMPLOYED*	*AVERAGE ANNUAL SALARY PER FTE POSITION*
Cell Processing Lab		
PhD/Scientist	1.00	$189,280
Lab Technician	2.00	$64,896
Manager	1.00	$81,120
Apheresis Services		
Registered Nurse	1.00	$64,896
Total	5.00	

In addition, in Section VII.8(a), page 117, the applicant identifies the President of the Medical Staff at CMC and two physicians who will begin working as Chair and Vice Chair of the Department of Hematologic Oncology and Blood Disorders in September 2012.

In Sections VII.3(b) and VII.6(a)(b), pages 114 - 116, the applicant provides its recruitment and staff retention plan. The applicant states that it has numerous resources from which to obtain staff, including Carolinas College of Health Sciences, Cabarrus College of Health Sciences, and Mercy School of Nursing. A listing of procedures for recruiting nursing and non-nursing staff is also provided which includes: 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. In addition, a number of incentives are provided for recruitment purposes, as are a number of programs for staff retention.

The applicant demonstrated the availability of adequate of health manpower and management personnel to provide the proposed services for a 16-bed adult hematologic oncology unit and an in-house cell processing lab and apheresis services. Therefore, the application is conforming to this criterion.

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

C

The applicant states in Section II.2(b), page 32, that existing ancillary and support services will be provided. In addition, Exhibit 4 contains a letter from the Acting President of CMC documenting the availability of these services which states:

> *"…CMC…currently has all ancillary and support services in place necessary to support hospital operations. These existing ancillary and support services will also support the medical center's proposed renovation and consolidation of adult hematologic oncology services.*
>
> *In addition, existing ancillary and support services will also support cell processing and apheresis. In particular, cell processing and apheresis may require the use of any of CMC's existing ancillary and support services including housekeeping, couriers, maintenance, and administration among others."*

CMC has established relationships with area healthcare facilities as evidenced by formal transfer agreements it has with them. Exhibit 20 contains a list of these facilities. CMC also states it has *"strong and established relationships with area providers"* and includes letters of support from area physicians in Exhibit 30.

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 107-108, the applicant provides the payor mix for Calendar Year 2011 for both the entire hospital and for adult general acute care beds, as illustrated in the table below:

Carolinas Medical Center CY 2011 Payor Mix % of Current Patient Days/Procedures As Percent of Total Utilization		
	CMC Entire Facility	Adult General Acute Care Beds
Self Pay / Indigent/Charity	7.8%	11.6%
Medicare/Medicare Managed Care	32.0%	48.4%
Medicaid	30.5%	15.5%
Commercial Insurance	1.7%	1.4%
Managed Care	28.3%	23.1%
Other	N/A	N/A
Total	100.0%	100.0%

In Section VI.5, page 103, the applicant states:

> *"No patient will be denied treatment at CMC. CMC's services are and will remain accessible to Medicare and Medicaid recipients, the uninsured, and the underinsured. CMC Financial Counselors assist patients and families in understanding their eligibility for financial support*."

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for the years indicated. The data in the table was obtained on July 23, 2012. More current data, particularly with regard to the estimated percentages of the uninsured, was not available.

	Total # of Medicaid Eligibles as % of Total Population, June 2010	**Total # of Medicaid Eligibles Age 21 and older as % of Total Population, June 2010**	**% Uninsured CY 2008-CY2009 (Estimate by Cecil G. Sheps Center)**
Mecklenburg County	15.0%	2.0%	15.9%
Statewide	17.0%	4.0%	17.2%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA

website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of Medicaid recipients receiving dental services was 48.6% for those aged 20 and younger in SFY 2010 (Mecklenburg County's percentage was 44.1% for those age 20 and younger) and it was 31.6% for those age 21 and older (Mecklenburg County's percentage was 30.7% for those age 21 and older). Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. Provisional county level data on this website shows that Mecklenburg County had a total population of 957,938 as of July 1, 2011. Seventy-three percent of the county's total population was age 20 and older. Population estimates were available by age, race and gender by county, however a direct comparison to the applicants' 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 demonstrated that medically underserved populations currently have adequate access to Carolinas Medical Center. Therefore, the application is conforming to this criterion.

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

C

The applicant states that it has had no obligations to provide uncompensated care, however it does provide charity care. In Section X.8(c)(d), pages 104-105, estimates are provided of the amount of charity care that will be provided in the first two years of the project. Over $12 million in charity care is expected to be provided in both years one and two, which is 16.3% of net revenue in both years.

In addition, the applicant states that there have been no civil rights equal access complaints filed against them or any affiliated entity of Carolinas HealthCare System (CHS) in the last five years.

In addressing equal access, the applicant states in Section VI.4(a), page 101, as noted in CHS's Non-Discrimination Policy, *"[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."*** [Emphasis in original.] See Exhibit 17 for CMC's Hospital Admission, Credit, and Collection Policy.

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

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In Section VI.6, page 103, the applicant describes the strategies and policies CMC has in place to ensure access to services by the indigent and other medically underserved persons. The applicant states:

> *"CMC's services are and will remain accessible to Medicare and Medicaid recipients, the uninsured, and the underinsured. CMC Financial Counselors assist patients and families in understanding their eligibility for financial support. Further, in compliance with the federal EMTALA law, emergency services and care are provided to all patients who present to the hospital who request examination or treatment of a medical condition to determine if an emergency condition exists."*

In Sections VI.14 and VI.15, pages 108-109, the applicant provides the projected payor mix during the second full fiscal year of operation following completion of the proposed project. The following table shows the projected payor mix for Calendar Year 2015 for both the entire hospital and for adult general acute care beds.

Carolinas Medical Center CY 2015 Payor Mix % of Current Patient Days/Procedures As Percent of Total Utilization		
	CMC Entire Facility	Adult General Acute Care Beds
Self Pay / Indigent/Charity	7.8%	11.6%
Medicare/Medicare Managed Care	32.0%	48.4%
Medicaid	30.5%	15.5%
Commercial Insurance	1.7%	1.4%
Managed Care	28.3%	23.1%
Other	N/A	N/A
Total	100.0%	100.0%

The applicant states in Section VI.14(b), page 109, that *"CMC does not expect any change to its payor mix as a result of the proposed project."*

The applicant 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.

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In Section VI.9(a)(b)(c), pages 105-106, the applicant states that persons will have access to services at CMC through physician referrals from those physicians who have admitting privileges at the medical center and through the emergency department. The applicant further states that *"…as an existing hospital provider in Mecklenburg County, CMC has informal agreements with local and regional healthcare agencies that refer patients, through a physician, to the medical center's services."*

The applicant adequately identified the 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.

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CMC has relationships with numerous programs at area universities and colleges, including, but not limited to, Cabarrus College of Health Sciences and Carolinas College of Health Sciences, and provides educational environments and clinical rotations for residents, medical, physician extender, nursing, radiology, and other allied health professional students annually. CMC also manages the Charlotte Area Health Education Center (AHEC) under a contractual agreement with the University of North Carolina at Chapel Hill. The AHEC coordinates various educational programs for both employees of CMC and throughout an eight-county region. In addition, in Section V.1(a), pages 90-91, the applicant provides documentation that CMC will continue to accommodate the clinical needs of area health professional training programs, including, but not limited to, the Center for Pre-Hospital Medicine, CMC's collaborative program with the University of North Carolina at Charlotte, and Mercy School of Nursing. The applicant states, in Section VI.1(b), page 91, that *"Each of the programs listed above will continue to have access to clinical training opportunities at CMC following the proposed project, as appropriate."* The information provided is reasonable and credible and supports a finding of conformity with 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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In Section V.7, pages 96-97, and Exhibits 9, 10, and 11, CMC discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. In particular, in Section V.7, pages 98-99, the applicant states how the proposed project will enhance competition in the proposed service area:

> *"By improving the facility and enhancing access to a full range of comprehensive hematologic oncology services, typically found only in the state's five academic medical centers, the proposed project will naturally enhance competition in the state. As the region's academic medical center, it is critical for CMC to provide access to the best of these services. The proposed project will have a positive impact on access and quality in the region as it will create a more appropriate physical environment and enhance access to services for these immunocompromised patients. By improving*

and enhancing access to these services in the region, CMC will enhance the level of competition across the state."

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the proposal on cost effectiveness, quality and access to the proposed services. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to adult hematologic oncology services in Mecklenburg County. This determination is based on the information in the application, and the following:

- The applicant adequately demonstrates the need to renovate existing space to consolidate adult hematologic oncology services and to accommodate in-house provision of cell processing and apheresis services at CMC 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.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

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

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Carolinas Medical Center is accredited by the Joint Commission and certified for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, on February 2, 2011 CMC-Main was surveyed as a result of a complaint. That survey resulted in an Immediate Jeopardy (IJ) and condition-level deficiencies. Based on a full survey on March 4, 2011 and a follow-up survey on May 5, 2011, the IJ had been abated and the quality of care deficiencies had been corrected. However, a physical environment condition was cited related to life safety concerns during the March 4, 2011 survey. This condition is still uncorrected due to the facility being granted waivers by CMS. As of July 23, 2012, the facility is in compliance with all other Conditions of Participation. 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