ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional

NC = Nonconforming NA = Not Applicable

DECISION DATE: April 12, 2013

PROJECT ANALYST: Julie Halatek
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: F-10075-13 / The Charlotte-Mecklenburg Hospital Authority

d/b/a Carolinas Medical Center / Renovate and consolidate acute care laboratory operations in existing space on the fourth floor of

Carolinas Medical Center / 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.

 \mathbf{C}

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center (CMC) proposes to renovate and consolidate acute care laboratory (lab) operations in existing space located on the fourth floor of the main campus of CMC. The acute care lab operations are currently fragmented across two separate facilities—CMC and CMC-Mercy. The applicant does not propose to develop beds or services or acquire equipment 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 47-49, the applicant states:

"CHS [Carolinas HealthCare System] is committed to energy efficiency and sustainability that balances the need for healthcare services and environmental sustainability in the communities it serves. The project's plan to assure improved energy and water conservation in accordance with Policy Gen-4 requirements is discussed below.

...

"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 (GGHG) 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-ofthe-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 included a written statement describing the project's plan to assure improved energy efficiency sustainability 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.

 \mathbf{C}

CMC proposes to renovate and consolidate acute care lab operations in existing space located on the fourth floor of the CMC campus. The acute care lab operations are currently fragmented across two separate facilities—CMC and CMC-Mercy. In Section II.1, page 19, the applicant states that its current lab serves as an acute care lab and a core reference lab for the Carolinas Laboratory Network (CLN) Charlotte-area hospitals. According to the applicant, both the core reference lab and the acute care lab have experienced growth and have outgrown their current utilized space. The applicant states that in particular, the labs are fragmented across several facilities, which makes them less efficient than if the labs were consolidated in one location. The project has two phases—the core reference lab will be relocated first and then the acute care lab will be consolidated. The applicant submitted two separate applications—one for the core reference lab (see project ID #F-10076-13) and this one for the acute care lab.

Population to be Served

In Section III.5(a), page 54, the applicant states that Mecklenburg County is the primary service area and the secondary service area includes Union, Gaston, Cabarrus, Cleveland, Lincoln, Burke and Iredell counties in North Carolina and York and Lancaster counties in South Carolina.

The following table illustrates historical and projected patient origin for acute care lab services for the first two operating years of the project as reported by the applicant in Section III.4(b), page 53, and Section III.5(c), page 56. Note: for a complete list of the 88

counties comprising the "Other" category, please see application pages 52 and 56. "Other" also includes other states.

CMC Lab Patient Origin					
	Current FY 2011	Projected FFY 2016 and 2017			
County	% of Total	# of Procedures Year 1	% of Total	# of Procedures Year 2	% of Total
Mecklenburg	47.4%	3,663,787	47.7%	3,934,053	47.7%
Union	6.6%	429,589	5.6%	457,634	5.5%
York, SC	6.2%	422,926	5.5%	452,379	5.5%
Gaston	4.8%	364,955	4.7%	392,044	4.8%
Cabarrus	3.5%	285,344	3.7%	306,798	3.7%
Cleveland	2.8%	228,275	3.0%	245,438	3.0%
Lincoln	2.3%	187,512	2.4%	201,610	2.4%
Lancaster, SC	2.2%	158,448	2.1%	169,947	2.1%
Burke	1.9%	154,901	2.0%	166,547	2.0%
Iredell	1.8%	146,748	1.9%	157,782	1.9%
Other	20.5%	1,671,301	21.7%	1,796,958	21.8%
Total	100.0%	7,684,467	100.0%	8,249,003	100.0%

The totals displayed in the table may not compute to exactly 100% due to rounding. Additionally, the total number of procedures each year does not add up to what the applicant says it does. For example, the total for the column headed "# of Procedures Year 1" is 7,684,467 per the applicant; however, when the analyst adds the numbers listed the total is 7,713,786, a difference of only 29,319 procedures, or less than 0.4% of the total number of procedures [7,713,786-7,684,467=29,319; 29,319/7,713,467=0.0038].

The applicant adequately identified the population it proposes to serve.

Need for the Proposed Project

The applicant states the project is needed for two reasons: 1) the need to continue providing both core reference lab services and acute care lab services; and 2) trends in laboratory operations.

Continue to provide both core reference lab services and acute care lab services

In Section III.1(a), page 40, the applicant states that it could potentially outsource core reference lab operations (defined as outreach/routine physician reference testing and specialized testing). However, the applicant states that specialized testing is a key aspect of several of CHS's clinical programs. Additionally, some of the specialized clinical programs that CHS offers, such as transplant services and oncology services, require hospital-based testing, and standards demand same-day results.

The acute care lab, according to the applicant, serves as a rapid response lab focused on speed and consistency. At this time, according to the applicant on page 39, the services at the acute care lab are fragmented between two facilities and need to be renovated and consolidated in order to eliminate unnecessary waste and decrease the likelihood of error.

Trends in laboratory operations

In Section III.1, page 38, the applicant states, "Historically, lab operations have been well-utilized and have experienced considerable growth in recent years. As documented...CMC's billable laboratory procedures have experienced a compound annual growth rate (CAGR) of 7.35 percent since 2009." The applicant states it projects continued laboratory volume increases based on inpatient and outpatient growth rates, increases in the number of Carolinas HealthCare System (CHS) and independent physician practices, and the population growth rate.

Additionally, on page 38, the applicant states:

"National trends also indicate continued growth in lab services. According to Laboratory Economics, a trade industry newsletter, Medicare Part B spending on lab services grew at a 4.3 percent CAGR from 2006 to 2011. At the same time, the reference lab testing market is growing at eight percent per year according to an analysis of reference lab testing in the United States conducted in 2010 by G2 Intelligence, a leading provider of professional markets analysis. Yet another analysis from G2 Intelligence estimates that the lab market in the United States will grow nearly \$50 billion (8.4 percent CAGR) between 2010 and 2018."

Projected Utilization

In Section IV.1, pages 62-63, the applicant provides the historical and projected utilization for CMC's lab services, as shown in the table below.

Lab Procedures		
FFY 2010	5,227,721	
FFY 2011	5,662,307	
FFY 2012 (annualized)	5,887,864	
FFY 2013 (projected)	6,320,413	
FFY 2014 (projected)	6,784,739	
FFY 2015 (projected)	7,283,176	
FFY 2016 (Year 1)	7,818,231	
FFY 2017 (Year 2)	8,392,593	
FFY 2018 (Year 3)	9,009,151	

In Section III.1, pages 41-45, the applicant describes the assumptions and methodology used to project laboratory utilization at CMC. On page 41, the applicant states, "...CMC's primary method of reporting lab volume, revenue, and costs is based on

CPT-coded procedures." The applicant states it assessed the historical growth rate of CPT-based billable laboratory procedures to project laboratory volumes. Additionally, the applicant states CMC is responsible for billing for all laboratory services, regardless of the physical location of the service. The applicant reports the number of laboratory procedures from fiscal year 2009 through 2012 (annualized), as illustrated below.

	FFY 2009	FFY 2010	FFY 2011	FFY 2012 (annualized)	2009-2012 CAGR
Laboratory Procedures*	4,759,866	5,227,721	5,662,307	5,887,864	7.35%

^{*} Includes both acute care and core reference laboratory operations.

As shown in the table above, between FFY 2009 and FFY 2012 (annualized), the compound annual growth rate (CAGR) was 7.35%.

On page 42, the applicant states

"...From 2009 through 2011, CMC's lab added coverage to Cabarrus Family Medicine (multiple offices), offices from the NorthEast Physician Network, Metrolina Nephrology, urgent care centers, freestanding emergency departments, and two patient service centers (blood draw stations) in Gastonia and Rock Hill. Following the addition of these large entities in 2009 and 2011, the growth rate from 2011 through 2012 (annualized) subsequently slowed because the lab has reached capacity."

To project future laboratory utilization, including volume, revenue, and cost of laboratory operations, the applicant states it applied the historical 7.35 percent compound annual growth rate to the FFY 2012 (annualized) laboratory procedures shown above. The applicant states applying the 7.35 percentage is reasonable because its laboratory has historically been well-utilized and the laboratory will no longer be hindered by capacity constraints. The applicant also states it expects the laboratory volumes to increase as a result of CMC's inpatient and outpatient growth rates, increases in physician practices, and the population growth rate in Mecklenburg County.

The applicant supplies supporting documentation in Exhibits 17-18. Projected utilization is based on reasonable, credible, and supported assumptions.

The applicant adequately demonstrated the need to renovate and consolidate its existing acute care lab to handle expected growth in procedures performed.

In Section VI.2, page 73, the applicant states how the residents of the service area will have access to the proposed services, including those residents that are low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups. The applicant states:

"CMC provides services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay."

The applicant states that in the most recent full year of data available (FY 2011), CMC provided more than \$268 million (8.1% of gross revenue) in charity care or bad debt. See Exhibit 16 for a copy of CHS's System-Wide Hospital Admission, Credit and Collection Policy, which includes the Non-Discrimination Policy.

In summary, the applicant adequately identified the population to be served and demonstrated the need the population has for the project. 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 49-51, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) <u>Maintain the Status Quo</u> the applicant decided doing nothing would not improve acute care lab services and would result in continued fragmentation of services. The applicant states that the status quo results in unnecessary waste in operations by requiring duplicative resources in multiple places at the same time.
- 2) Consolidate Both Acute Care and Core Reference Lab Operations at CMC the applicant concluded that this option would result in lab operations exceeding testing capacity quickly, which would then necessitate further expansion or relocation. The applicant states that while it is a feasible option in the short-term, this alternative is not cost-effective in the long term.
- 3) Consolidate Acute Care Lab Operations at CMC; Develop an Off-site Lab for Specialty Testing and Outsource Physician Outreach Testing The applicant states that this option would have only a moderate impact on space requirements, as specialized areas of testing would still require the same equipment and space even without the outreach testing. The applicant states that a new off-site lab would be

needed in this situation regardless and therefore it is not the most effective alternative.

The applicant concluded that developing the project as proposed was its most effective and least costly alternative because developing a core reference lab away from the acute care lab will free up space to renovate and consolidate the acute care lab, thereby eliminating unnecessary waste and providing the most efficient services for its customers (patients, physicians, and other staff).

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and thus, is approvable. A project 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 the 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. 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.

 \mathbf{C}

In Section VIII.2, pages 93-94, the applicant states that the total capital cost of the project will be \$3,754,728, including \$2,615,228 for construction; \$258,750 for moveable equipment; \$323,250 for interiors; \$494,200 for consultant fees; and \$63,300 for contingency costs. In Section IX, page 99, the applicant projects there will be no start-up expenses or initial operating expenses associated with the proposed project. In Section VIII.3, page 95, the applicant states that the project will be funded by means of CHS's accumulated reserves. Exhibit 20 contains a January 15, 2013 letter signed by the Chief Financial Officer for CHS, which states:

"As the Chief Financial Officer for Carolinas HealthCare System, I am responsible for the financial operations of Carolinas Medical Center. As such, I am very familiar with the organization's financial position.

...

"Carolinas HealthCare System will fund the capital cost from existing accumulated cash reserves. This expenditure will not impact any other capital projects currently underway or planned for at this time."

Exhibit 21 of the application contains the audited financial statements for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center for the years ending December 31, 2011 and December 31, 2010. As of December 31, 2011, CMC had \$53,073,000 in cash and cash equivalents, \$2,201,745,000 in unrestricted net assets and \$2,911,029,000 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, for the entire hospital and the proposed core reference lab and acute care lab. The applicant projects that CMC lab revenues will exceed operating expenses in each of the first three full fiscal years, as illustrated in the table below. Note: the applicant does not distinguish between the Core Reference Lab and the Acute Care Lab in the following table.

CMC Lab

	Project Yr 1	Project Yr 2	Project Yr 3
	1/1/16-12/31/16	1/1/17-12/31/17	1/1/18-12/31/18
Gross Patient Revenue	\$672,386,347	\$743,436,351	\$821,994,096
Deductions from Gross Patient Revenue	\$442,036,673	\$487,865,318	\$538,443,544
Net Patient Revenue	\$230,349,674	\$255,571,033	\$283,550,552
Total Expenses	\$137,104,755.08	\$150,892,522.68	\$166,102,530.89
Net Income	\$108,455,711	\$121,496,602	\$136,043,254

The applicant also projects a positive net income for the entire hospital in each of the first three full fiscal 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 the financial section of the application for the assumptions regarding cost and charges. See Criterion (3) for discussion of utilization projections which is incorporated hereby 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 charges, 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.

 \mathbf{C}

In this application, the applicant proposes to consolidate its acute care lab services into existing space on the CMC campus. CMC is currently providing the acute care lab services in two facilities—CMC and CMC-Mercy. In Section III.6, page 57, the applicant states "CMC is aware that other providers in the service area offer lab services; however, utilization statistics for these services are not publicly reported." The applicant adequately demonstrates the need for its proposal. See Criterion (3) for discussion regarding the need to consolidate acute care lab services which is incorporated hereby as if set forth fully herein.

The applicant adequately demonstrates that consolidation of existing acute care lab services currently provided by CMC will not result in the unnecessary duplication of existing or approved acute care lab services in Mecklenburg County. 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.

 \mathbf{C}

In Section VII.1, pages 84-85, the applicant provides the current and proposed staffing for its lab operations (both core reference and acute care, but excluding histology operations) for the second full fiscal year, as illustrated in the table below.

Department	Existing FTE	Proposed
	Positions	FTE Positions
PRN (as needed)	0.9	N/A
Aides and Attendants	73.1	106.0
Admin/Management	5.6	13.0
Supervisory	36.4	35.0
Professional	2.0	2.0
Registered Technician	105.1	168.1
Technician	80.3	60.0

Specialist	5.3	6.8
Clerical	18.0	11.0
Temporary Help	0.0*	N/A
Total	326.8	401.9

^{*}The applicant reports a total of 12,428.5 contract hours for temporary help.

As illustrated in the table above, the applicant proposes to increase the number of FTE positions from 326.8 to 401.9. The applicant also proposes to eliminate the use of temporary help and PRN positions. In Section VII.3(a), page 86, the applicant states:

"No new positions will be established as a result of the proposed project. All positions identified in Table VII.1 already exist at CMC."

In Section VII.8(a), page 90, the applicant states that Dr. Jack Lucas, MD, will continue to serve as the Chief of Staff/Medical Director for CMC. See Exhibit 15 for the curriculum vitae of Dr. Edward H. Lipford III, MD, who presently serves as the Medical Director of Laboratories at CMC and has done so since 1989.

The applicant adequately demonstrated the availability of adequate health manpower and management personnel for the provision of the proposed services. Therefore, the application is conforming to this criterion.

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

 \mathbf{C}

CMC is an existing tertiary acute care hospital and already provides acute care lab services. The applicant states the necessary ancillary and support services are currently available. See Section II.2, pages 28-29. See also Exhibit 5 for a letter dated January 15, 2013 from the President of CMC stating that CMC currently has all necessary ancillary and support services required for the operation of the lab services proposed in this application.

Exhibit 6 contains CHS policies and procedures for patient transfer and discharge. Exhibit 7 contains CHS policies regarding blood product administration, transfusions, and reactions. As a Level I trauma center, CMC does not usually transfer patients to another acute care hospitals; rather, patients are transferred to CMC. Exhibit 25 contains physician letters of support.

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;

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The following table illustrates the current payor mix for the entire facility and for laboratory operations during fiscal year 2011 (FY 2011) as reported by the applicant in Sections VI.12 - VI.13, page 81.

Entire Hospital and Acute Care Lab Services				
Payor Mix CY 2011 As a % of Total Utilization				
Entire Hospital Acute Care Lab				
Self Pay/Indigent/Charity/Other*	7.8%	31.9%		
Medicare/Medicare Managed Care	32.0%	26.7%		
Medicaid	30.5%	16.5%		
Managed Care/Commercial 30.0% 25				
Total** 100.0% 100.0%				

^{*}Other includes workers comp and other government payors.

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 Mecklenburg County and statewide.

	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)
Mecklenburg	15%	5.1%	20.1%
Statewide	17%	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.

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 45.9% for those age 20 and younger and

^{**}Totals may not add to 100% due to rounding.

30.6% 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. In addition, data is available by age, race or 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 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;

 \mathbf{C}

In Section VI.11, page 80, the applicant states:

"CMC has had no obligations to provide uncompensated care during the last three years. As stated earlier, the medical center provides, without obligation, a considerable amount of bad debt and charity care and in CY 2011 provided approximately \$268 million in bad debt and charity care."

In Section VI.10(a), page 80, the applicant states:

"No complaints have been filed against any affiliated entity of CHS regarding civil rights equal access in the last five years."

The application is conforming to this criterion.

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

 \mathbf{C}

In Section VI.14(a) and Section VI.15(a), pages 82-83, the applicant provides the projected payor mix for the second full fiscal year (2017) of operations for the proposal, as illustrated in the table below.

Entire Hospital and Acute Care Lab Services				
Payor Mix CY 2017 As a % of Total Utilization				
Entire Hospital Acute Care Lab				
Self Pay/Indigent/Charity/Other*	7.8%	31.9%		
Medicare/Medicare Managed Care	32.0%	26.7%		
Medicaid	30.5%	16.5%		
Managed Care/Commercial 30.0% 25.0				
Total** 100.0% 100.0%				

^{*}Other includes workers comp and other government payors.

In Section VI.15(b), page 83, the applicant states:

"CMC based its projected payor mix on the FY 2011 payor mix by volume for the lab. Given the proximity to full implementation of the Affordable Care Act (ACA), CMC expects payor mix shifts in the coming years; however there remains considerable uncertainty.... Therefore, until there is greater clarity to guide reasonable assumptions, CMC has assumed for purposes of these application projects that the payor mix will be consistent with the historical payor mix."

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.

 \mathbf{C}

In Section VI.9(a), page 79, the applicant states that patients will have access to CMC via referrals from physicians with admitting privileges at the medical center, as well as through admissions from the emergency department. 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.

^{**}Totals may not add to 100% due to rounding.

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

 \mathbf{C}

In Section V.1(a), pages 64-65, the applicant provides documentation that CMC will continue to accommodate the clinical needs of area health professional training programs. See Exhibit 13 for a copy of CMC's training agreement as well as a two page listing of all health professional training programs that utilize CMC. 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.

 \mathbf{C}

CMC proposes to renovate and consolidate acute care lab operations in existing space located on the fourth floor of the CMC campus. The acute care lab operations are currently fragmented across two separate facilities—CMC and CMC-Mercy. In Section II.1, page 19, the applicant states that its current lab serves as an acute care lab and a core reference lab for the Carolinas Laboratory Network (CLN) Charlotte-area hospitals. According to the applicant, both the core reference lab and the acute care lab have experienced growth and have outgrown their current utilized space. The applicant states that in particular, the labs are fragmented across several facilities, which makes them less efficient than if the labs were consolidated in one location. The project has two phases—the core reference lab will be relocated first and then the acute care lab will be consolidated. CMC is currently providing acute care lab services. In Section III.6, page 57, the applicant states "CMC is aware that other providers in the service area offer lab services; however, utilization statistics for these services are not publicly reported."

In Section V.7, pages 69-72, 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.

In Section V.7, page 70, the applicant states:

"By consolidating lab operations CMC will improve efficiencies and reduce costs."

...

"Through the proposed project, CMC will raise the bar for quality of care in the service area and drive other providers to deliver the highest quality of care in order to compete."

In Section V.7, page 72, the applicant states:

"By enhancing access to lab services, the proposed project will naturally enhance competition in Mecklenburg County and surrounding areas."

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 consolidate the operations of the acute care lab and that it is a cost-effective alternative;
- The applicant will continue to provide quality services; and
- The applicant 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.

 \mathbf{C}

CMC 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, during a March 4, 2011 survey, a physical environment condition was cited related to life safety concerns during a survey. This physical environment condition remains out of compliance pending an approved waiver by CMS. As of February 25, 2013, the facility is in compliance with all other Conditions of Participation

based on surveys completed October 3, 2011 and June 28, 2012. 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.