

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: April 11, 2013

PROJECT ANALYST: Kimberly Randolph

ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: F-10076-13/ The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center/ Consolidate core reference laboratory operations at a new location in Mecklenburg County which will be licensed as part of Carolinas Medical Center (Phase I)/ 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 lease 28,400 square feet in Mecklenburg County to consolidate and relocate its core reference laboratory operations, which currently have clinical service components located in three facilities: CMC; CMC-Mercy; and Carolinas Rehabilitation. In Section I, pages 7-8, the applicant states the proposed consolidation and relocation of the core reference laboratory is Phase I, (the subject of this application) of a larger two phase project designed to consolidate CMC's entire laboratory operation at two separate sites. Phase II, Project I.D. #F-10075-13, is the applicant's proposal to consolidate, relocate, and renovate its acute care laboratory operations, which will not be discussed in these findings, since the applicant submitted a separate and concurrent application for each phase.

On page 21, the applicant states it proposes to relocate its core reference laboratory operations because

*“...these operations have since outgrown CMC’s facility and have begun to hamper efficiencies relative to CMC’s acute care lab operations. In particular, CMC’s lab has experienced growth that exceeds the capacity of the medical center’s lab department.”*

On pages 21-28, the applicant states it proposes to:

- Consolidate and relocate current clinical core reference laboratory operations; and
- Consolidate and relocate non-clinical core reference laboratory functions.

The applicant does not propose to develop beds, add new health services, or acquire equipment for which there is a need determination in the 2012 State Medical Facilities Plan (2012 SMFP). Therefore, there are no need determinations in the 2012 SMFP that are applicable to this review.

However, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 40 of the 2012 SMFP, is applicable to this review. This policy 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 provides its written statement in Section III.2, pages 48-50, which 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 (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 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.

C

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center proposes to lease 28,400 square feet of existing space in Mecklenburg County at 5040 Airport Center Parkway, Building H, Charlotte, to consolidate and relocate its current core reference laboratory operations. The core reference laboratory currently has service components located in three facilities: CMC; CMC-Mercy; and Carolinas Rehabilitation. In Section II.1, page 24, the applicant states the equipment associated with the core reference laboratory operation will be relocated to the leased space to create a comprehensive core reference laboratory.

In Section II.1, pages 20-21, the applicant states “*core reference lab operations include chemistry (basic/routine as well as special), hematology (basic/routine as well as special), microbiology (including mycology), molecular testing, immunology, cytogenetics (including a cytogenetic technique called FISH (Fluorescent in Situ Hybridization)), blood bank, central processing, and reference processing.*”

On page 20, the applicant also states “*CMC’s lab currently serves as an acute care lab and as the core reference lab for the Carolinas Laboratory Network (CLN) Charlotte-area hospitals. The lab department has experienced substantial growth and the services have outgrown CMC’s facility.*” On page 20, the applicant also states “*...CLN encompasses the lab services of eight Charlotte-area hospitals: CMC, CMC-Mercy, CMC-Pineville, CMC-University, CMC-Union, CMC-Lincoln, Anson Community Hospital, and CMC-NorthEast.*”

In Section II.1, pages 20-28, the applicant states the proposed relocation of the core reference laboratory includes the components discussed below.

- Consolidate and relocate current clinical core reference laboratory operations – the applicant proposes to consolidate and relocate the following current clinical core reference laboratory operations into one comprehensive core reference laboratory.

<b>Facility</b>	<b>Current Core Reference Laboratory Square Feet</b>	<b>Current Location*</b>
CMC	18,665**	4 <sup>th</sup> Floor
CMC-Mercy	2,781	3 <sup>rd</sup> Floor
Carolinas Rehabilitation	2,180	1 <sup>st</sup> Floor
<b>Total</b>	<b>23,626</b>	

\* Illustrated in Exhibit 5, pages 166-168.

\*\* Includes the clinical core reference laboratory and the acute care laboratory operations.

The applicant states the consolidation and relocation will result in vacant space at all three of the facilities listed above. The vacant space will be renovated as part of Phase I to make it safe for future use. On page 21, the applicant proposes to

continue to support all eight CLN Charlotte-area hospitals and to focus on specialized and routine testing for physician offices in the core reference laboratory operation. The applicant states the current core reference laboratory operation located at CMC has “...*begun to hamper efficiencies relative to CMC’s acute care lab operations.*” On pages 21-22, the applicant states that consolidating the core reference laboratory operations in one facility will relieve current capacity constraints at CMC and eliminate inefficiencies and logistical challenges related to specimen transport and resource utilization.

On page 25, and Exhibit 5, page 181, the applicant illustrates the proposed core reference laboratory operations to be relocated as shown below.

Facility	Current Core Reference Laboratory Operations to be Relocated
CMC	Basic/Routine Chemistry* Special Chemistry Basic/Routine Hematology* Special Hematology Central Processing* Microbiology* Reference Processing
CMC-Mercy	Immunology Molecular Testing
Carolinas Rehabilitation	Cytogenetics, Including FISH

\* CMC will maintain a portion of these services at the main hospital facility as part of the acute care laboratory operation.

- Consolidate and relocate non-clinical core reference laboratory functions – on page 26, and Exhibit 5, pages 169-170, the applicant proposes to consolidate and relocate the following non-clinical core reference laboratory functions.

Facility	Current Non-Clinical Core Reference Laboratory Functions to be Relocated	Current Location
CMC Annex	Point of Care	2 <sup>nd</sup> Floor
Center Park	Client Services	1 <sup>st</sup> Floor

The relocation will result in vacant space at both CMC Annex and Center Park, which will not be renovated as part of Phase I. In Exhibit 5, page 181, the applicant illustrates the proposed location of the non-clinical core reference laboratory functions in the area labeled Administration.

**Population to be Served**

In Sections III.4, page 54, and III.5, page 57, the applicant provides the historical and projected patient origin data for CMC’s laboratory procedures for the first two operating years of the project, as illustrated below.

County Service Areas	FFY 2011 01/01/11 - 12/31/11		Project Year 1 10/01/15 - 09/30/16		Project Year 2 10/01/16 - 09/30/17	
	# of Lab Procedures	% of Total Lab Procedures	# of Lab Procedures	% of Total Lab Procedures	# of Lab Procedures	% of Total Lab Procedures
Mecklenburg	2,683,933	47.4%	3,663,787	47.7%	3,934,053	47.7%
Union	373,712	6.6%	429,589	5.6%	457,634	5.5%
York, SC	351,063	6.2%	422,926	5.5%	452,379	5.5%
Gaston	271,791	4.8%	364,955	4.7%	392,044	4.8%
Cabarrus	198,181	3.5%	285,344	3.7%	306,798	3.7%
Cleveland	158,544	2.8%	228,275	3.0%	245,438	3.0%
Lincoln	130,233	2.3%	187,512	2.4%	201,610	2.4%
Lancaster, SC	124,571	2.2%	158,448	2.1%	169,947	2.1%
Burke	107,584	1.9%	154,901	2.0%	166,547	2.0%
Iredell	101,922	1.8%	146,748	1.9%	157,782	1.9%
Other*	1,160,773	20.5%	1,671,301	21.7%	1,796,958	21.8%
<b>Total</b>	<b>5,662,307</b>	<b>100.0%</b>	<b>7,684,467</b>	<b>100.0%</b>	<b>8,249,003</b>	<b>100.0%</b>

\* Includes the other North Carolina counties and other states listed on page 54.

In Section III.1, page 44, the applicant states *“Mecklenburg County, the primary service area, is one of the fastest growing counties in the state of North Carolina.”*

On page 58, the applicant states

*“CMC has projected its patient origin to change due to the shift of patients to CMC-Fort Mill and CMC-Pineville during the project years. Please note that the relocation of the core reference lab operations to an off-site facility is not expected to impact patient origin as the proposed site is within 6.2 miles of CMC’s main campus. CMC projected patient origin for lab services based on its existing patient origin, modified to account for the projected shifts to CMC-Fort Mill and CMC Pineville.”*

The applicant adequately identifies the population to be served by the proposed project.

**Demonstration of Need**

In Section III.1, pages 38-42, the applicant discusses the need to consolidate its clinical core reference laboratory operations. On page 39, the applicant states laboratories must continually improve performance and efficiency since patients and physicians rely on laboratory tests to identify risks or symptoms for disease and evaluate treatment options

or results. On page 40, the applicant states that CMC is committed to providing quality and efficient healthcare services and the proposed consolidation, relocation, and expansion of laboratory operations will allow CMC to “...*improve workflow, reduce costs, eliminate bottlenecks, reduce travel time, and provide better productivity.*”

On page 38, the applicant states the unmet need for the proposed project results from the following factors:

- Trends in laboratory operations; and
- Need to consolidate and expand laboratory operations.

#### Trends in laboratory operations

In Section III.1, pages 39-40, the applicant states “*Historically, lab operations have been well-utilized and have experienced considerable growth in recent years. 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 39, 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.”*

#### Need to consolidate and expand laboratory operations

In Section III.1, page 40, the applicant states the need for the proposed project is also a result of the need to consolidate and expand laboratory operations. The applicant states the current space at CMC limits its ability to consolidate, expand, and provide a sustainable solution to address CMC’s current capacity constraints. The core reference laboratory occupies approximately 5,761 square feet of office space in two separate facilities and shares approximately 18,665 square feet of space with the acute care laboratory on the fourth floor of CMC.

On page 41, the applicant states CMC considered outsourcing the core reference laboratory operation to free up space at CMC. However, the applicant identified a continuing need for

specialized testing, which is a key component of CHS' clinical programs and integral to service standards, patient care, research, and education. The applicant states the proposed consolidated core reference laboratory operation will improve quality of care, better utilize resources, and lower costs through improved efficiencies.

The applicant adequately demonstrates the need to consolidate core reference laboratory operations at an off-site facility.

Projected Utilization

In Section IV.1, page 63, the applicant provides the historical and projected utilization for CMC's laboratory services through project completion, as illustrated in the table below.

	<b>FFY 2010</b> 01/01/10 - 12/31/10	<b>FFY 2011</b> 01/01/11 - 12/31/11	<b>FFY 2012</b> 01/01/12 - 12/31/12	<b>FFY 2013</b> 01/01/13 - 12/31/13	<b>FFY 2014</b> 01/01/14 - 12/31/14	<b>FFY 2015</b> 01/01/15 - 12/31/15
Laboratory Procedures*	5,227,721	5,662,307	5,887,864	6,320,413	6,784,739	7,283,176

\* Includes both acute care and core reference laboratory procedures.

In Section III.1, page 45, the applicant provides the projected utilization for CMC's laboratory services through the third fiscal year after project completion, based on an October 1, 2015 project completion date, as illustrated in the table below.

	<b>**FFY 2016</b> 01/01/16 - 12/31/16	<b>FFY 2017</b> 01/01/17 - 12/31/17	<b>FFY 2018</b> 01/01/18 - 12/31/18
Laboratory Procedures*	7,818,231	8,392,593	9,009,151

\* Includes both acute care and core reference laboratory procedures.

\*\* CMC's fiscal years corresponds to calendar years.

The applicant states in order to convert the laboratory procedure projections from FFYs to project years, the applicant added a quarter of one FFY laboratory procedure projection to three quarters of the following FFY laboratory procedure projection,  $[7,684,467 = (0.25 * \text{FFY 2015}) + (0.75 * \text{FFY 2016})]$ , as illustrated in the table below.

	<b>Project Year 1</b> 10/01/15 - 09/30/16	<b>Project Year 2</b> 10/01/16 - 09/30/17	<b>Project Year 3</b> 10/01/17 - 09/30/18
Laboratory Procedures	7,684,467	8,249,003	8,855,011

In Section III.1, pages 42-46, the applicant describes the assumptions and methodology used to project laboratory utilization at CMC. On page 42, 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 on the table above, between FFY 2009 and FFY 2012 (annualized), the compound annual growth rate (CAGR) was 7.35 percent.

On page 43, 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. Additionally, on page 44, the applicant states

*“...CMC’s proposed core reference lab will serve as a System resource providing highly specialized professional and technical support which will provide another source of growth as CHS’ metro facilities and regional hospitals shift lab testing to CMC’s proposed core reference lab.”*

Projected utilization is based on reasonable, credible, and supported assumptions.

In Section III.7, pages 61-62, the applicant addresses access to the medically underserved by stating “...CMC 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.” The applicant supplies supporting documentation in Exhibits 17-18, pages 267-288.

In summary, the applicant adequately identifies the population to be served and demonstrates the need the population proposed to be served has for the core reference laboratory 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

Even though the applicant is proposing to physically relocate the core reference laboratory operation to a leased facility 6.2 miles from CMC's main campus, the services offered by the applicant will not be reduced, eliminated, or relocated from the patient's perspective. Patients will continue to receive lab services in the same locations they currently receive these services. Therefore, this criterion is not applicable to this review.

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

C

In Section III.3, pages 50-52, the applicant describes the alternatives it considered prior to submission of this application, which include:

- 1) Maintain the Status Quo – the applicant concluded this option would not be in the best interest of its patients because this option would not address CMC's capacity constraints or improve core reference laboratory services at CMC.
- 2) Consolidate Acute Care and Core Reference Laboratory Operations at CMC - the applicant concluded this option would be ineffective in the long term and technically difficult in the short term. This option would involve staging renovations to accommodate both acute care and core laboratory operations, while maintaining day to day operations. Additionally, this option is not sustainable in the long-term because the laboratory department would quickly reach testing capacity, requiring further expansion or relocation of services.

- 3) Consolidate Acute Care Laboratory Operations at CMC, Develop an Off-Site Laboratory for Specialty Testing Only, and Outsource Physician Outreach Testing - the applicant concluded that sending routine reference testing to a third party laboratory would only have a modest impact on space requirements. Since routine reference testing requires the same equipment and space as specialty testing, the applicant determined this was not the most effective alternative.
- 4) Develop the Project as Proposed - the applicant states the proposed project, Phase I consolidation and relocation of the core reference laboratory operations to an off-site facility, is the most effective alternative. This option will create a centralized core reference laboratory operation, relieve capacity constraints at CMC, eliminate unnecessary waste, and provide more efficient service to CLN Charlotte-area hospitals, which results in a viable long-term solution.

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

The applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need for additional laboratory capacity at CMC now and in the near future. 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 that 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. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**

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

C

In Section VIII.2, page 95, the applicant projects the total capital cost of the project will be \$13,322,100, including \$7,497,600 for construction, \$1,466,250 for movable equipment purchase/lease, \$1,665,750 for interiors, \$2,333,800 for consultant fees, and \$358,700 for contingencies.

In Section IX, page 101, the applicant projects there will be no start-up or initial operating expenses. In Section VIII.3, page 96, the applicant states that 100 percent of the capital needs of the project will be financed with the accumulated reserves of Carolinas HealthCare System, a d/b/a for The Charlotte-Mecklenburg Hospital Authority.

Exhibit 21, pages 299-300, contains a January 15, 2013 letter signed by the Chief Financial Officer for Carolinas HealthCare System, which states

*“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 22, pages 301-347, contains the audited financial statements for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System for the years ending December 31, 2011 and December 31, 2010. As of December 31, 2011, CHS had \$53,073,000 in cash and cash equivalents, \$1,922,872,000 in other assets (designated as funded depreciation) and \$2,911,029,000 in total net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In the Financial Section, pages 120-128, the applicant provides pro forma financial statements for the first three full fiscal years of the project. The applicant provides financials for the laboratory operation at CMC, which consists of both the acute care laboratory and the core reference laboratory operations. The applicant projects revenues will exceed operating expenses in each of the first three full fiscal years of the project, as illustrated in the table below.

<b>CMC Laboratory Department</b>	<b>FFY 1 01/01/16–12/31/16</b>	<b>FFY 2 01/01/17–12/31/17</b>	<b>FFY 3 01/01/18–12/31/18</b>
CMC Patient-Billable Procedures	6,041,866	6,485,728	6,962,199
Client-Billed Procedures	1,776,365	1,906,865	2,046,952
Total Billable Procedures	7,818,231	8,392,593	9,009,151

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	\$230,349,675	\$255,571,033	\$283,550,552
Total Expenses	\$137,104,755	\$150,892,523	\$166,102,531
Net Income	\$108,455,711	\$121,496,602	\$136,043,254

\* Source: Form C, page 122.

The applicant also projects a positive net income for the entire facility in each of the first three full fiscal years of the project, as illustrated in the table below.

<b>CMC Entire Facility</b>	<b>FFY 1 01/01/16–12/31/16</b>	<b>FFY 2 01/01/17–12/31/17</b>	<b>FFY 3 01/01/18–12/31/18</b>
Gross Patient Revenue	\$5,388,441,000	\$5,819,474,000	\$6,284,991,000
Deductions from Gross Patient Revenue	\$3,776,162,000	\$4,128,279,000	\$4,514,928,000
Net Patient Revenue	\$1,612,279,000	\$1,691,196,000	\$1,770,063,000
Total Expenses	\$1,415,705,000	\$1,475,177,000	\$1,536,068,000
Net Income	\$255,178,000	\$276,570,000	\$296,615,000

\* Source: Form B, page 121.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable. See pages 125-128 for the assumptions regarding costs and charges. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. 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

CMC is currently providing core reference laboratory services in three facilities: CMC; CMC-Mercy; and Carolinas Rehabilitation. In Section III.6, page 58, 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.”*

CMC proposes to relocate and consolidate its current core reference laboratory operations to an existing facility located 6.2 miles from the hospital campus, at 5040 Airport Center Parkway, Building H. Even though the applicant is proposing to physically relocate the core reference laboratory operation, the services offered by the applicant will be the same and are not being relocated from the patient’s perspective. The applicant adequately demonstrates the need for its proposal. See Criterion (3) for the discussion regarding the need to relocate and consolidate core reference laboratory operations, which is incorporated hereby as if set forth fully herein.

The applicant adequately demonstrates the proposed project will not result in the unnecessary duplication of existing or approved core reference laboratory 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.

C

In Section VII.1, pages 85-86, the applicant provides both the current staffing and proposed staffing for CMC’s laboratory operations, as illustrated in the table below.

<b>CMC Laboratory Operations*</b>	<b>Current Staffing FFY 2012</b>	<b>Proposed Staffing Year 2 FFY 2017</b>
<b>Position</b>	<b>Total # of Full Time Equivalent (FTE) Positions</b>	<b>Total # of Full Time Equivalent (FTE) Positions</b>
PRN	0.9	0.0
Aides and Attendants	73.1	106.0
Administration/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	0.0
<b>Total</b>	<b>326.8</b>	<b>401.9</b>

\* Includes staffing for all laboratory operations, regardless of physical location, but excludes histology operations (Project I.D. #F-8592-10).

On page 86, the applicant states that “...variations in FTEs from current to proposed staffing are the result of consolidation of fragmented services as well as the development of a core reference lab.”

In Section VII.3, page 87, the applicant states “No new positions will be established as a result of the proposed project.” The applicant states it does not expect to have difficulty recruiting the incremental FTEs to be added by the second full fiscal year of the project, since CHS is the fourth largest employer in North and South Carolina and has numerous educational programs from which to obtain staff.

In Section V.3, page 68, the applicant identifies the Chief of the Medical Staff at CMC and the Medical Director of the Laboratory Department. The applicant states that “The proposed project does not involve the provision of a new service; therefore, there will not

*be a change in leadership.*” Exhibit 16, pages 262-266, contains the curriculum vitae of the medical director.

The applicant adequately demonstrates the availability of adequate health manpower and management personnel for the provision of the laboratory 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

In Section II.2, page 29, the applicant states that CMC is an existing full-service acute care hospital with all the necessary ancillary and support services currently available. The applicant states the current ancillary and support services will support the proposed consolidation and relocation of laboratory operations. The applicant provides supporting documentation in Exhibit 6, page 185.

The applicant discusses coordination with the existing health care system in Sections V.1 – V.6, pages 65-70. The applicant provides supporting documentation in Exhibits 14 – 15, pages 244-261 and includes letters of support from area physicians in Exhibit 25, pages 352-365. The information provided in these sections and exhibits is reasonable and credible and supports a finding of conformity with 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

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 82.

<b>Payor Category</b>	<b>CMC Entire Facility Patient Days/ Procedures as Percent of Total Utilization</b>	<b>CMC Laboratory* Patient Days/ Procedures as Percent of Total Utilization</b>
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 Insurance	30.0%	25.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

\* Includes both acute care and core reference laboratory operations.

\*\* Includes other government payors and worker's compensation.

In Section VI.4, page 75, the applicant states

*“CHS is committed to providing financial assistance to every person in need of medically necessary treatment even if that person is uninsured, ineligible for other government programs, or unable to pay based on their individual financial situation.”*

The applicant provides supporting documentation in Exhibit 18, pages 278-288.

In Section VI.2, page 74, 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 provides supporting documentation in Exhibit 17, pages 267-277.

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.

	<b>Total # of Medicaid Eligibles as % of Total Population *</b>	<b>Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center) *</b>
Mecklenburg	15%	5.1%	20.1%

Statewide	17%	6.7%	19.7%
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\*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 48.6% for those age 20 and younger and 31.6% 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 laboratory 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

In Section VI.11, page 81, the applicant states

*“CMC has had no obligation 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, page 81, the applicant states that no civil rights access complaints have been filed against any CHS affiliated entity in the last five years.

The application is conforming to this criterion.

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

C

The following table illustrates the projected payor mix for the entire facility and for laboratory operations during the second fiscal year (FFY 2017) following completion of the proposed project, as reported by the applicant in Sections VI.14 – VI.15, pages 83-84.

<b>Payor Category</b>	<b>CMC Entire Facility Patient Days/ Procedures as Percent of Total Utilization</b>	<b>CMC Laboratory* Patient Days/ Procedures as Percent of Total Utilization</b>
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 Insurance	30.0%	25.0%
Total	100.0%	100.0%

\* Includes both acute care and core reference laboratory operations.

\*\* Includes other government payors and worker's compensation.

In Section VI.15, page 84, the applicant assumes the payor mix will be consistent with the historical payor mix reported in FFY 2011. The applicant acknowledges it expects future shift in the payor mix due to implementation of the Affordable Care Act (ACA) but indicates reasonable assumptions are not possible yet, due to the current uncertainty surrounding how the program will be implemented in North Carolina.

In Section VI.2, page 74, the applicant describes the policy for providing access to the proposed facility as follows:

*“[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.”*

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming with 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, pages 80-81, the applicant documents the range of means by which patients have access to the services provided at CMC. The information provided is reasonable and credible and supports a finding of conformity with 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, pages 65-67, and Exhibit 14, pages 244-254, CMC documents that it accommodates the clinical needs of health professional training programs in the area and that it will continue to do so. 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.

C

The applicant proposes to consolidate and relocate its core reference laboratory operations to a leased facility located 6.2 miles from CMC. The core reference laboratory operations currently have clinical service components located in three facilities: CMC; CMC-Mercy; and Carolinas Rehabilitation. The applicant is not proposing to add any additional beds, equipment, or new services in Mecklenburg County.

The applicant currently provides core reference laboratory services in Mecklenburg County and the surrounding area along with other national, regional, and local core reference laboratory service providers. In Section III.6, page 58, 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 70-73, 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 71, 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 73, 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 core reference laboratory services in Mecklenburg County. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to consolidate and relocate its core reference laboratory operations and that it is a cost-effective alternative (see Section III of the application);

- The applicant will continue to provide quality services (see Sections II and VII of the application); and
- The applicant will continue to provide adequate access to medically underserved populations (see Sections III and VI of the application).

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

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, during a March 4, 2011 survey, a physical environment condition was cited related to life safety concerns. 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 and there are no quality of care deficiencies outstanding 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.

NA