ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: January 29, 2013

PROJECT ANALYST: Tanya S. Rupp
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: F-10057-12 / The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center / Replace existing CT Scanner / 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 proposes to replace its existing 2003 Siemens Sensation 16-slice Computed Tomography (CT) scanner, located at Carolinas Medical Center (CMC) in Charlotte and install a Siemens Somatom Definition Flash replacement CT scanner in renovated space in the hospital. The applicant does not propose to increase the number of licensed beds in any category, add services, or acquire any equipment for which there is a need determination in the 2012 State Medical Facilities Plan (SMFP).

However, there is one policy in the 2012 SMFP applicable to the review of the application:

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES

"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178, 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 for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy-GEN 4. The plan shall not adversely affect patient or resident health, safety, or infection control."

In Section III.2, pages 53 – 54, and Section XI.7, pages 112 – 113, the applicant states:

"CHS 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.

<u>Guiding Principles</u>

1. *Implement environmental sustainability to improve and reduce our environmental impact*
2. *Integrate sustainable operational and facility best practices into existing and new facilities.*
3. *Encourage partners to engage in environmentally responsible practices.*
4. *Promote environmental sustainability in work, home and community.*
5. *Deliver improved performance to provide a long term return on investment that supports our mission and values.*

…

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.*
- *Design for maximum efficiency and life cycle benefits within each impacted mechanical system: heating, cooling, water and sewer.*

Moreover, the proposed replacement equipment will utilize plant chilled water rather than require the addition of a new chiller, which will promote efficiencies relative to cooling requirements. Currently, variable air volume systems, which utilize minimal reheat, are being used to cool the project area. Upon project completion, these systems will continue to provide only the necessary cooling required and will serve to reduce airflow/cooling demand when not required.

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

The applicant adequately describes its plan to assure improved energy efficiency and water conservation following project completion. Therefore, the application is conforming to Policy GEN-4, and is conforming to this criterion.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

Carolinas HealthCare System (CHS) was created in 1943 to construct and operate health care and hospital facilities in North Carolina. CHS operates several hospitals and health care facilities in North Carolina, including The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center (CMC). CMC, located in Charlotte, is currently licensed for 795 acute care beds and was just approved to add 19 acute care beds (Project ID#F-8761-11). CMC operates a Level I trauma center, is an academic medical center teaching hospital, operates the Levine Children's Hospital, the Sanger Heart and Vascular Institute, and offers many other services on several campuses. As part of its imaging program, CMC operates seven (7) fixed CT scanners at the medical center campus in Charlotte. Five of the fixed CT

scanners are stationary and two of the fixed CT scanners are portable and are used in the surgical suite and the intensive care unit. In February 2012, pursuant to Project ID#F-8793-11, the applicant was approved to relocate one of the fixed stationary CT scanners to its CMC-Morrocroft location in the Southpark area of Charlotte. In Section III, page 35, the applicant states:

> *"… three of the fixed stationary CT scanners are located within the main medical center and the remaining two are located in Morehead Medical Plaza (MMP), a hospital outpatient imaging center located on CMC's campus. CMC also operates two portable CT scanners (one is located in the medical center's intensive care unit and the other is in the operating room suite)."*

In this application, CMC proposes to replace its existing 2003 CT scanner with a Siemens Somatom Definition Flash CT scanner. The applicant proposes to renovate 1,046 square feet of existing space in the imaging suite to accommodate the replacement equipment.

Population to be Served

In Section III.4, page 58, the applicant provides the current patient origin for CT services provided at CMC. On page 57, the applicant provides current patient origin for acute care services at CMC. The historical patient origin for CT services is summarized in the table below, as reported by the applicant on page 58.

COUNTY	PERCENT OF PATIENTS
Mecklenburg	54.3%
York, South Carolina	6.2%
Union	5.9%
Gaston	5.2%
Cleveland	2.6%
Cabarrus	2.4%
Lancaster, South Carolina	2.4%
Lincoln	2.3%
Iredell	1.6%
Catawba	1.5%
Stanly	1.4%
Other*	14.2%
Total	100.0%

*On page 58, the applicant identifies the other counties in both North Carolina and South Carolina, as well as other states.

In Section III.5(a), page 59, the applicant projects that Mecklenburg will remain the primary service area for CT services. The applicant also identifies a secondary service area as *"Union, Gaston, Cleveland, Cabarrus, Lincoln, Iredell, Catawba, and Stanly counties in North Carolina and York and Lancaster counties in South Carolina."* On page 60, the applicant provides a map to illustrate the service areas as identified on page 59. In Section

III.5(c), page 61, the applicant projects patient origin for the first two years of operation following project completion, as shown in the table below.

COUNTY	YEAR 1: PROJECTED # SCANS	YEAR 1: % OF TOTAL SCANS	YEAR 1: PROJECTED # SCANS	YEAR 1: % OF TOTAL SCANS
Mecklenburg	33,462	54.3%	33,760	54.3%
York, South Carolina	3,846	6.2%	3,880	6.2%
Union	3,665	5.9%	3,698	5.9%
Gaston	3,212	5.2%	3,241	5.2%
Cleveland	1,621	2.6%	1,635	2.6%
Cabarrus	1,500	2.4%	1,513	2.4%
Lancaster, South Carolina	1,461	2.4%	1,474	2.4%
Lincoln	1,391	2.3%	1,404	2.3%
Iredell	969	1.6%	978	1.6%
Catawba	913	1.5%	921	1.5%
Stanly	870	1.4%	878	1.4%
Other	8,723	14.2%	8,800	14.2%
Total	**61,632**	**100.0%**	**62,182**	**100.0%**

On page 61, the applicant states it assumes that, for projected patient origin, one unweighted scan equals one patient. Also on page 61, the applicant defines *"other"* as it did for the current patient origin.

The applicant adequately identifies the population to be served.

Demonstration of Need

In Section II, page 22, the applicant states the existing CT scanner which is the subject of this application is a 2003 model and, as such, is technologically antiquated and thus insufficient to meet patient needs for CT services at CMC. The applicant states the diagnostic imaging quality and capability of the 2003 model is no longer consistent with current diagnostic imaging trends, and has reached the end of its useful life. Additionally, on page 23, the applicant states the imaging department at CMC consists of three suites, CT A, B, and C. The new CT scanner will be placed into the CT B suite, which will require renovation of the existing space to accommodate the new CT scanner.

In Section III.1, pages 34 – 51, the applicant describes the need CMC has for the replacement CT scanner, including a need at CMC to replace outdated equipment, a need for updated CT services and enhanced CT imaging capabilities, and a projected increase in the Mecklenburg County population that most commonly utilizes CT services. Each of the factors is analyzed below.

CMC need to replace outdated equipment

In Section III.1, pages 35 – 36, the applicant states:

> *"The equipment CMC proposes to replace, the Siemens Sensation 16-slice CT scanner, was purchased in 2003 and has been in continuous operation at CMC since that time. This 2003 model scanner is outdated and well past its five-year useful life as measured by the American Hospital Association's equipment lifetimes standards …. While the existing Siemens Sensation 16-slice CT model unit was state-of-the-art when it was installed in 2003, significant advancements in technology have occurred in the intervening time since its installation. As a result, the age of the existing equipment raises concerns relative to clinical application that drive the need to replace the existing equipment at this time.*
>
> *CMC proposes to replace its 2003 model Siemens Sensation CT scanner with a Siemens Somatom Definition Flash CT with Dual Source technology. …*
>
> *… the proposed replacement equipment will not only address the age concerns associated with the existing equipment, but will also enhance CMC's CT imaging capabilities which will in turn support the advanced, high acuity, academic environment at CMC."*

Need at CMC for updated and enhanced CT imaging services

In addition, in Section III.1, page 37, the applicant states:

> *"The need to enhance CT imaging capabilities at the medical center is driven not only by limitations associated with the age and inherent in the outdated design of the Siemens Sensation 16-slice model unit, but also the overall CT imaging capabilities at CMC. … CMC … maintains … five fixed stationary CT scanners on its campus ranging from one to 64 slice capability, all with unique applications and designs that fit CMC's diverse, complex patient needs."*

On page 37, the applicant states it has received CON approval to replace one of its existing 4-slice CT scanners as well. The applicant states the proposed replacement that is the subject of this application *"features unique applications and designs that not only differentiate it from the replacement that is currently underway, but which also address the need to enhance CMC's CT imaging capability…."*

In Section III.1, on pages 37 – 38, the applicant states it treats bariatric patients with increasing frequency, and the existing imaging equipment table weight limits are insufficient to accompany some of the bariatric patients who present to CMC. The applicant states:

> *"While transfer to another facility for CT imaging is feasible in some situations, the critical high acuity nature of many bariatric patients prohibits transfer. No available upgrade - short of the replacement CMC is proposing - can address the need for this capability at CMC.*
>
> …

The proposed Siemens Somatom Definition Flash CT scanner features a heavy duty patient table. The proposed CT scanner patient table can hold up to 650 pounds, which is 150 pounds more than any of the existing CT scanners at CMC. Increasing the patient table weight capacity aids in a more comfortable patient experience and will enable the medical center to accommodate larger, bariatric patients."

In addition, CMC operates the Sanger Heart & Vascular Institute which offers cardiac and vascular CT imaging, among other services. The existing CT scanner lacks the capability to provide the quality of cardiac imaging that its patients need. On pages 38 – 39, the applicant states:

"…CMC's existing cardiac CT imaging capabilities are fairly basic given advances in technology and the age of CMC's existing equipment. Notably, existing technology at the medical center is limited in patients with high heart rates as the existing equipment does not have the ability to obtain high quality images between cardiac cycles. While time consuming efforts to lower patients' heart rates with pharmacological intervention can be used, it is often unsuccessful. When it comes to imaging cardiac patients, which involves capturing snapshots in between heartbeats, advances in available technology and ultimately image speed and resolution have effectively rendered older equipment obsolete. New developments in CT technology provide the ability to examine the structure of the heart with a level of detail that was not previously possible. In general, detector configurations have improved, the number of channels has increased, and rotation has increased - all of which results in better quality of cardiac images. Moreover, none of the existing equipment has the specialized application packages that come standard with the proposed replacement equipment….

As a cardiac Center of Excellence and the home to the Sanger Heart & Vascular Institute (SHVI), CMC believes that it is important for the medical center to offer the gold standard in cardiac CT imaging capability. The SHVI is the region's most comprehensive heart and vascular program, comprised of a network of heart specialists who have provided world-class heart care in North and South Carolina for more than half a century. … By offering total cardiac care, including preventive, diagnostic and full-range treatment of cardiovascular disease for pediatric and adult patients, SHVI is positioned to provide a level of care unmatched in the region. SHVI's innovations include the region's only heart transplant program, pediatric heart specialists, congenital surgery, clinical research, cardiac teaching program, and nationally-renowned specialists. The proposed replacement equipment will support and enhance CMC's strong cardiac program."

On page 40, the applicant states the proposed CT scanner will significantly increase imaging speed and improve resolution quality, which will benefit cardiac patients at CMC. The applicant also states the technology in the proposed Dual Source Flash CT scanner represents improvement in existing technology such that scan times could be reduced and thus radiation doses would likewise decrease. Furthermore, according to the applicant on page 40, the

increased scan times also allow CMC to image the heart with greater detail than is possible with existing equipment. On pages 40 – 41, the applicant states:

> *"The Dual Source Flash CT represents an innovation in CT technology - an innovation that does not exist with any CT scanner on CMC's campus. By utilizing two X-ray tubes that acquire images simultaneously, the scanner increases imaging speed, which has particular advantages relative to examinations of moving structures, such as the heart and thorax. As a result of the faster scanning speed, breath holds may not be required, there is no need to slow patients' hearts in order to obtain images, and the time needed to conduct emergency cardiac assessments can be reduced from one hour to ten minutes, greatly improving emergency department throughput. Notably, the proposed Somatom Definition Flash can scan the entire heart in only 250 milliseconds, which is less than half a heartbeat. The proposed scanner can also conduct emergency trauma scans of an entire body in less than five seconds.*
>
> *The proposed replacement system will also be configured with advanced cardiac imaging capability, enabling it to support advanced techniques for ventricular function imaging, dynamic imaging, tissue characterization, and coronary imaging. In particular, the Cardio BestPhase Plus will automatically detect the optimal phase for motionless coronary visualization. These features will address limitations of the existing equipment and will serve to support and augment CMC's strong cardiac program.*
>
> …
>
> *"…the replacement equipment operates at an extremely reduced radiation dose, requiring only a fraction of the radiation dose that systems previously required. The Somatom Definition Flash protects the most dose-sensitive body regions from direct X-ray exposure by switching the X-ray tube off for a certain range of projections. The result is reduced sensitive-area exposure up to 40 percent <u>without</u> loss of image quality. In addition, the Somatom Definition Flash eliminates pre-and post-spiral over-radiation. The Adaptive Dose Shield automatically moves shields into place to block unnecessary dose, saving up to an additional 25 percent dose in routine exams."* [emphasis in original]

Thus, the proposed replacement CT scanner will not only provide improved CT scan quality, but will also decrease patients' exposure to radiation.

Population of Mecklenburg County

On pages 41 – 43, the applicant describes the population trends in Mecklenburg County with regard to the proposed replacement CT scanner. Citing information obtained from the North Carolina State Office of Budget and Management (NCOSBM), the applicant reports that the population of Mecklenburg County is projected to grow by 19.2% between 2010 and 2020. Furthermore, the applicant states NCOSBM reports that the age 65+ population group in

Mecklenburg County is projected to grow by 57.8% during that same time. On page 41, the applicant states:

> *"CMC's need to replace its existing outdated equipment is also supported by population growth and aging which drives increased utilization of healthcare services. Mecklenburg County and its surrounding communities are among the fastest growing regions in the country. According to data from the North Carolina Office of State Budget and Management (NC OSBM), … Mecklenburg County is the second fastest growing county in North Carolina based on numerical growth and the seventh fastest behind Hoke, Onslow, Harnett, Wake, Cumberland, and Brunswick counties based on percentage growth. Further, Mecklenburg County's high growth is projected to continue. In fact, the NC OSBM projects the population of Mecklenburg County to grow 19.2 percent between 2010 and 2020. …*
>
> *… By 2020, 11.8 percent of the total population in Mecklenburg County will be over the age of 65 (more than 129,000 people). Based on NC OSBM projections, Exhibit 18, of the counties in North Carolina, Mecklenburg County will have the second largest number of residents over the age of 65 in 2020. Further, within this decade, Mecklenburg County's 65+ population is projected to grow by 57.8 percent.* [emphasis in original]

On page 41, the applicant cites a study conducted by the Federal Interagency Forum on Aging Related Statistics to conclude that *"These data are significant because, typically, older residents utilize healthcare services at a higher rate than those who are younger."*

Therefore, the existing Siemens Sensation 16-slice CT scanner can no longer meet the needs of CMC's patients. Furthermore, according to the population statistics from the NC OSBM, the population groups most likely to need CT imaging services will increase in Mecklenburg County, such that the demand for CT imaging services will likewise increase.

Utilization

In Section III.1, pages 44 – 45, the applicant provides historical utilization of the existing CT scanners at CMC, as illustrated in the table below.

CT SCANS	CY 2009	CY 2010	CY 2011	CY 2012*
Head w/o contrast	14,525	14,479	16,335	16,962
Head w/ contrast	705	730	611	672
Head w/o and w/ contrast	820	874	1,331	1,174
Body w/ o contrast	17,173	16,736	13,935	14,120

Body w/ contrast	27,377	28,816	20,283	20,582
Body w/o and w/ contrast	7,848	8,544	6,453	6,680
Biopsy in addition to body scan w/ or w/o contrast	575	584	554	612
Abscess drainage in addition to body scan w/ or w/o contrast	277	367	338	284
Total CT scans	69,300	71,130	59,840	61,086

*Annualized based on 6 months of data.

On page 44, the applicant states:

> *"The apparent decline in CT utilization from 2010 to 2011 can be attributed to a major coding change that took place in January 2011 with two CPT codes (abdomen and pelvis). In January 2011, CMS bundled the two CPT codes (abdomen and pelvis) into one CPT code, decreasing coded volume within the codes for body procedures. Moreover, fluctuation by type from year to year can also be attributed to changes in coding (deactivation and activation). Finally, any differences … can be attributed to the difference in timeframe and a coding inaccuracy that resulted in the categorization of some of the body scans as head scans in CMC's 2012 HLRA data. The coding has since been resolved and the inaccuracy did not impact the overall total number of scans, just the designation by type."*

On page 45, the applicant provides a table that illustrates the conversion of historical scans to HECT units. See the following table:

HECT UNITS	CY 2009	CY 2010	CY 2011	CY 2012*
Head w/o contrast	14,525	14,479	16,335	16,962
Head w/ contrast	881	913	764	840
Head w/o and w/ contrast	1,435	1,530	2,329	2,055
Body w/ o contrast	25,760	25,104	20,903	21,180
Body w/ contrast	47,910	50,428	35,495	36,019
Body w/o and w/ contrast	21,582	23,496	17,746	18,370
Biopsy in addition to body scan w/ or w/o contrast	1,581	1,606	1,524	1,683
Abscess drainage in addition to body scan w/ or w/o contrast	1,108	1,468	1,352	1,136
Total HECT Units	114,782	119,023	96,447	98,244

*Annualized based on 6 months of data.

The applicant adequately explains that the decrease in the total number of CT scans provided by CMS is attributable to changes in coding. From CY 2009 to 2010, the total number of HECT units increased by 3.7% [(119,023 / 114,782) – 1 = 0.0369]. From CY 2011 to CY 2012, the total number of HECT units increased by 1.9% [(98,244 / 96,447) – 1 = 0.0186]. The project analyst looked at the 2013 hospital license renewal application (LRA) for CMC, which shows the total number of HECT units performed during FFY 2012, as shown in the following table:

CT UTILIZATION AS REPORTED IN 2013 LRA	# CT SCANS	CONVERSION FACTOR	HECT UNITS
Head w/o contrast	17,061	1.00	17,061
Head w/ contrast	556	1.25	695
Head w/o and w/ contrast	1,439	1.75	2,518
Body w/ o contrast	14,300	1.50	21,450

Body w/ contrast	20,792	1.75	36,386
Body w/o and w/ contrast	6,582	2.75	18,101
Biopsy in addition to body scan w/ or w/o contrast	698	2.75	1,919
Abscess drainage in addition to body scan w/ or w/o contrast	727	4.00	2,908
Total CT scans	62,155		101,038

In Section III.1, pages 46 – 51, the applicant projects utilization for CT services at CMC for the first three project years, and provides the assumptions and methodology used to project utilization. On page 46, the applicant states that projected CT utilization was increased at the same rate the population of Mecklenburg County is projected to grow, which is 1.8%. The applicant used the actual utilization in CY 2011 as the base. Thus, the projected utilization in CY 2012 differs slightly from the annualized CY 2012 projected utilization. See the following table, from page 47 of the application:

CT SCANS	CY 2012	CY 2013	CY 2014	CY 2015	CY 2016
Head w/o contrast	16,624	16,918	17,217	17,522	17,832
Head w/ contrast	622	633	644	655	667
Head w/o and w/ contrast	1,355	1,378	1,403	1,428	1,453
Body w/ o contrast	14,181	14,432	14,688	14,947	15,212
Body w/ contrast	20,642	21,007	21,378	21,756	22,141
Body w/o and w/ contrast	6,567	6,683	6,801	6,922	7,044
Biopsy in addition to body scan w/ or w/o contrast	564	574	584	594	605
Abscess drainage in addition to body scan w/ or w/o contrast	344	350	356	363	369
Total CT scans	60,898	61,975	63,072	64,187	65,322

On page 46, the applicant states:

> *"To be conservative, CMC applied an annual growth rate of 1.8 percent to its total 2011 CT scans through CY 2016, the third calendar year of the proposed project. Note that this methodology results in a lower projection of CT procedures in 2012 than the annualized data provided above suggests is actually likely to be realized. CMC then distributed the total projected CT scans by type based on the actual mix experienced in 2011, the last full year of data available and reflecting the mix post-coding adjustments."*

On page 47, the applicant states it anticipates a shift of emergency department patients from CMC to two previously-approved CMC health pavilions (CMC Providence, Project ID #F-8740-11; and CMC Morrocroft, Project ID #F-8739-11). As a result, some CT scan volume will also shift to the approved health pavilions. The following table illustrates projected CT utilization after the shift, which is projected to begin in CY 2014.

CT SCANS	CY 2012	CY 2013	CY 2014	CY 2015	CY 2016
Head w/o contrast	16,624	16,918	16,869	17,122	17,378
Head w/ contrast	622	633	638	649	659
Head w/o and w/ contrast	1,355	1,378	1,403	1,427	1,453
Body w/ o contrast	14,181	14,432	14,204	14,392	14,582
Body w/ contrast	20,642	21,007	20,820	21,116	21,415

Body w/o and w/ contrast	6,567	6,683	6,644	6,741	6,839
Biopsy in addition to body scan w/ or w/o contrast	564	574	584	594	605
Abscess drainage in addition to body scan w/ or w/o contrast	344	350	356	363	369
Total CT scans	60,898	61,975	61,518	62,403	63,300

The applicant then converted the number of CT scans to HECT units, as illustrated in the following table, from page 49 of the application:

HECT UNITS	CY 2012	CY 2013	CY 2014	CY 2015	CY 2016
Head w/o contrast	16,624	16,918	16,869	17,122	17,378
Head w/ contrast	777	791	798	811	824
Head w/o and w/ contrast	2,370	2,412	2,454	2,498	2,542
Body w/ o contrast	21,272	21,648	21,306	21,588	21,873
Body w/ contrast	36,123	36,762	36,436	36,953	37,476
Body w/o and w/ contrast	18,060	18,379	18,271	18,538	18,808
Biopsy in addition to body scan w/ or w/o contrast	1,550	1,578	1,606	1,634	1,663
Abscess drainage in addition to body scan w/ or w/o contrast	1,376	1,400	1,425	1,450	1,476
Total HECT Units	98,153	99,889	99,165	100,594	102,041

On pages 49 – 50, the applicant converts the CY CT utilization to Federal Fiscal Year (FFY) projections, since the project is scheduled to begin in October 2013. For example, the applicant added the volume in the last quarter of CY 2013 to the volume in the first three quarters of CY 2014 to project volume in the first project year, which is FFY 2014. See the following tables:

CT SCANS	FFY 2014	FFY 2015	FFY 2016
Head w/o contrast	16,881	17,058	17,314
Head w/ contrast	637	646	657
Head w/o and w/ contrast	1,397	1,421	1,446
Body w/ o contrast	14,261	14,345	14,534
Body w/ contrast	20,867	21,042	21,340
Body w/o and w/ contrast	6,654	6,717	6,815
Biopsy in addition to body scan w/ or w/o contrast	581	592	602
Abscess drainage in addition to body scan w/ or w/o contrast	355	361	367
Total CT scans	61,632	62,182	63,076

HECT UNITS	FFY 2014	FFY 2015	FFY 2016
Head w/o contrast	16,881	17,058	17,314
Head w/ contrast	796	808	821
Head w/o and w/ contrast	2,444	2,487	2,531

Body w/ o contrast	21,391	21,517	21,802
Body w/ contrast	36,517	36,824	37,346
Body w/o and w/ contrast	18,298	18,472	18,741
Biopsy in addition to body scan w/ or w/o contrast	1,599	1,627	1,656
Abscess drainage in addition to body scan w/ or w/o contrast	1,419	1,444	1,469
Total HECT Units	99,346	100,236	101,679

As shown in the table above, in the third project year, the five CT scanners are projected to perform an average of 20,335.8 HECT units per scanner [101,679 / 5 = 20,335.8]. Thus, the applicant projects to provide in excess of the performance standard in 10A NCAC 14C .2303, which requires an applicant to demonstrate that each fixed or mobile CT scanner will perform at least 5,100 HECT units in the third year of operation following project completion [101,679 HECT units in year three / 5 CT scanners = 20,335.8 HECT units per CT Scanner] if applying for an additional CT scanner. The applicant adequately demonstrates that projected utilization is based on reasonable, credible and supported assumptions. The applicant adequately demonstrates the need to replace the existing CT scanner.

In summary, the applicant adequately identifies the population it proposes to serve and adequately demonstrates the need the population has for the proposed CT replacement. Consequently, 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

The applicant proposes to replace an existing fixed CT scanner with a new CT scanner that will provide better quality scans, particularly cardiac and vascular scans; lower doses of radiation to the patient, and will better accommodate CMC's bariatric patients. The replacement CT scanner will be placed in the imaging suite in renovated existing space. The applicant states in Section III.3, pages 55 - 56, that it considered several alternatives before proposing this project, which include maintaining the status quo and replacing the existing CT scanner for less than $2,000,000. The applicant states the proposed alternative is the most effective alternative to meet CMC's need to provide improved CT imaging to its patients; particularly with regard to the cardiac and bariatric patients it serves at the hospital and the Sanger Heart and Vascular Institute.

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

The applicant adequately demonstrates that the proposed project is the least costly or most effective alternative to meet the need for a replacement CT scanner at CMC. Therefore, the application is conforming to this criterion and is 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 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, pages 97 - 98, the applicant projects the total capital cost for the project will be $2,639,000, for fixed and moveable equipment acquisition and consultant fees. In Section IX, page 103, the applicant states that there are no start-up or initial operating expenses, as this is not a new facility or service.

In Section VIII.8, page 98, the applicant states that the project will be financed with the accumulated reserves of The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System. Exhibit 28 contains an October 15, 2012 letter signed by the Executive VP and CFO for Carolinas HealthCare System, which states:

> *"As the Chief Financial Officer for The Charlotte-Mecklenburg Hospital Authority d/b/a 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. The total capital expenditure for this project is estimated to be $2,639,000. There are no start-up costs related to this project.*

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 29 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. The balance sheet shows total assets in the amount of $5,315,925,000, including cash and cash equivalents in the amount of $53,073,000 as of December 31, 2011. The financial statements also show Carolinas HealthCare System had current net assets (total current assets less total current liabilities) in the amount of $210,799,000. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

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

CT SERVICES	**PROJECT YEAR 1 (CY 2014)**	**PROJECT YEAR 2 (CY 2015)**	**PROJECT YEAR 3 (CY 2016)**
Number of Scans	61,518	62,403	63,300
Gross Patient Revenue	$198,675,432	$207,580,934	$216,881,289
Deductions from Gross Patient Revenue	$132,365,399	$138,298,595	$144,494,857
Net Patient Revenue	$ 66,310,033	$ 69,282,339	$ 72,386,431
Total Expenses	$ 19,204,270	$ 20,043,493	$ 20,920,497
Net Income	$ 47,105,763	$ 49,248,846	$ 51,465,934

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See pages 123 - 125 of the application following the *"financials"* tab for the assumptions regarding costs and charges. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges, and therefore, the application is conforming to this criterion

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

C

The applicant proposes to replace its existing, outdated 2003 Siemens Sensation 16-slice CT scanner with a new Siemens Somatom Definition Flash CT scanner and to renovate existing space to accommodate the replacement equipment. The proposal will not result in a change in the inventory of CT scanners located in Mecklenburg County. The applicant adequately demonstrates the need to replace the outdated equipment. Therefore, the applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing or

approved CT scanners located 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 89 - 90, the applicant provides the current and projected staffing for the entire CT department at CMC. The applicant also states that no new positions will result from this project.

	CURRENT STAFFING CY 2012		PROPOSED STAFFING CY 2015	
POSITION	TOTAL # OF CURRENT FTE POSITIONS	AVERAGE ANNUAL SALARY PER FTE POSITION	TOTAL # OF PROPOSED FTE POSITIONS	AVERAGE ANNUAL SALARY PER FTE POSITION
Radiology				
Technologists	24	$62,161	24	$69,923
Clerical	2.5	$33,321	2.5	$37,482
Supervisor	1.0	$69,956	1.0	$78,691
Total	**27.5**		**27.5**	

In Section V.3(c), page 72, the applicant states there will be no change in leadership positions in the CT imaging department following replacement of the CT scanner. Therefore, Dr. Jack Lucas currently serves as Chief of Medical Staff at CMC and will continue in that capacity following project completion. In Exhibit 23, the applicant provides an October 15, 2012 letter signed by Dr. Lucas in which he affirms his commitment to continue to serve as Chief of Medical Staff following completion of the project. In Exhibit 33, the applicant provides 18 letters from area physicians, each indicating his or her support for the proposed replacement CT scanner. The applicant demonstrates 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.

C

In Section II.2, page 26, the applicant states that since CMC is an existing hospital and an academic medical center teaching hospital, all necessary ancillary and support services are currently in place, and will continue to be available subsequent to the CT replacement. In Exhibit 6, the applicant provides an October 15, 2012 letter from the Acting Divisional

President and COO of CHS Central Division, which documents that these services will continue to be provided following replacement of the CT scanner. Furthermore, in Section V.2, page 71, the applicant states existing transfer agreements between CMC and area healthcare providers will continue following project completion. In Exhibit 22, the applicant provides an extensive list of area healthcare providers with which it currently has transfer agreements. The applicant provides a copy of a transfer agreement in Exhibit 22. The applicant provides letters of support for the proposal from area physicians in Exhibit 33. The applicant adequately demonstrates the availability of necessary ancillary and support services, and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers: (i) would be available under a contract of at least 5 years duration; (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO; (iii) would cost no more than if the services were provided by the HMO; and (iv)would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

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

NA

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as

medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

C

In Section VI.12, page 86, the applicant provides the current payor mix for all services provided at CMC during CY 2011, as shown in the table below:

Entire Facility CY 2011

CURRENT PATIENT DAYS/PROCEDURES AS A PERCENT OF TOTAL UTILIZATION	PERCENT
Self Pay/Indigent/Charity/Other*	7.8%
Medicare/Medicare Managed Care	32.0%
Medicaid	30.5%
Managed Care/ Commercial	30.0%
Total	**100.0%**

*On page 86, the applicant states *"Other"* includes *"workers comp and other government payors."*

On page 87, the applicant provides the current payor mix for CT services provided at CMC during CY 2011, as shown in the table below:

CMC CT Services CY 2011

CURRENT PATIENT DAYS/PROCEDURES AS A PERCENT OF TOTAL UTILIZATION	PERCENT
Self Pay/Indigent/Charity/Other*	21.4%
Medicare/Medicare Managed Care	31.3%
Medicaid	15.4%
Managed Care/ Commercial	31.8%
Total	**100.0%**

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

COUNTY	TOTAL # MEDICAID ELIGIBLES AS % OF TOTAL POPULATION JUNE 2010	TOTAL # MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION JUNE 2010	% UNINSURED CY 2008 - 09 (ESTIMATE BY CECIL G. SHEPS CENTER)

Mecklenburg	15.0%	5.1%	20.1%
Statewide	17.0%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the CT services offered by CMC.

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 demonstrates that CMC currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.2, page 79, the applicant states CMC provides services to all people, "*regardless of race, sex, creed, age, national origin, handicap, or ability to pay.*" In Exhibit 24, the applicant provides a copy of CHS's non-discrimination policy, which confirms the above statement. Also on page 79, the applicant states CMC provided more than $268 Million, which is 8.1% of gross revenue, in uncompensated care (charity care and bad debt) in CY 2011. In Section VI.10, page 85, the applicant states no civil

rights equal access complaints or violations were filed against *"any affiliated entity of CHS"* in the last five years. The application is conforming to this criterion.

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

C

In Section VI.14 and VI.15, pages 87 - 88, the applicant projects the following payor mix for all of CMC's services and for CT services during Project Year Two (CY 2015):

Entire Facility CY 2015

ENTIRE FACILITY PATIENT DAYS/PROCEDURES AS A PERCENT OF TOTAL UTILIZATION (CY 2015)	PERCENT
Self Pay/Indigent/Charity/Other*	7.8%
Medicare/Medicare Managed Care	32.0%
Medicaid	30.5%
Managed Care/ Commercial	30.0%
Total	**100.0%**

*On page 87, the applicant states *"Other"* includes *"workers comp and other government payors."*

CT Services CY 2015

PATIENT DAYS/PROCEDURES AS A PERCENT OF TOTAL UTILIZATION	PERCENT
Self Pay/Indigent/Charity/Other	21.4%
Medicare/Medicare Managed Care	31.3%
Medicaid	15.4%
Managed Care/ Commercial	31.8%
Total	**100.0%**

As shown in the tables above and the tables in Criterion (13a), the applicant assumes no change in payor mix following the CT replacement.

In Section VI.4, page 80, the applicants state *"…all persons will continue to have access to CMC's services regardless of their ability to pay."* In Exhibit 24 the applicants provide a copy of Carolinas HealthCare System's Non-Discrimination Policy, which indicates that care will be provided to all persons, including those underinsured and uninsured, as stated above. The applicant demonstrates that CMC will continue to provide adequate access to medically underserved groups. Therefore, the application is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9, page 84, the applicant states persons will have access to services at CMC through physician referrals and emergency admission. The application is conforming to this criterion.

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

C

In Section V.1, pages 69 - 70, the applicant states the hospital currently has training agreements in place with many area health professional training programs, including but not limited to:

- Central Piedmont Community College
- Queens University of Charlotte
- University of North Carolina at Chapel Hill
- Presbyterian School of Nursing
- Mercy School of Nursing

On page 70, the applicant states the established relationships CMC has with area schools and other training programs will not change following the CT replacement. In Exhibit 21, the applicant provides a copy of a typical training agreement used by CMC. The applicant adequately demonstrates that the hospital will continue to accommodate the clinical needs of area health professional training programs. Therefore, the application is conforming to this criterion.

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

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

C

CMC currently operates seven fixed CT scanners at its campus in Charlotte. In this application, CMC proposes to replace its existing 2003 Siemens CT scanner with a new Siemens Somatom

CT scanner, in order to better serve its cardiac, bariatric, and general patients. The need to replace the 2003 CT scanner is a need internal to and thus specific to CMC.

In Section III.6, page 63, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states:

> *"As discussed in Section III.1, the need for the proposed project is an internal, facility-driven need at CMC. Moreover, Section III.1(b) clearly demonstrates CMC's need to maintain its capacity of CT scanners. In addition, CMC serves a unique role as an academic medical center and is the only facility that can accommodate the highly specialized or highly acute patients in the region. Thus, no other providers are able to serve this segment of CMC's patient population."*

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 replace its 2003 Siemens CT scanner and that it is a cost-effective alternative;
- The applicant adequately demonstrates it will continue to provide quality services; and
- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations.

The application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

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

C

CMC is certified by the Centers for Medicare and Medicaid for participation in the Medicare and Medicaid programs, and licensed by the NC Division of Health Service Regulation as an acute care hospital. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding the date of this decision for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

NA