ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

DECISION DATE:	February 24, 2012
PROJECT ANALYST:	Gregory F. Yakaboski
ASSISTANT CHIEF:	Martha J. Frisone
PROJECT I.D. NUMBER:	F-8738-11 / The Charlotte-Mecklenburg Hospital Authority d/b/a/
	Carolinas Medical Center / Renovate space, relocate and consolidate
	six existing adult gastrointestinal (GI) endoscopy rooms and related
	adult endoscopy services within the Medical Center / Mecklenburg
	County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

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The Charlotte-Mecklenburg Hospital Authority d/b/a/ Carolinas Medical Center (CMC) proposes to relocate existing adult endoscopy services within the Medical Center. The proposed project includes renovating 17,800 square feet on the fourth floor of the Medical Center and adding 2,300 square feet to the existing mechanical penthouse located on the roof of the Medical Center to accommodate one additional air handler. There are no need determinations in the 2011 State Medical Facilities Plan (2011 SMFP) applicable to this review.

However, there is one policy in the 2011 SMFP which is applicable to this review. Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities 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 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."

The projected capital cost of the proposed project is \$7,251,000.

With regard to Policy GEN-4, in Section III.4, pages 65-67, the applicant states:

"CHS is committed to energy efficiency and sustainability that balances the need for health care 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.

Guiding Principles

- 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.

CHS employs a Facility Management Group with experienced, highly trained and qualified architects, engineers, project managers, tradesmen and technicians, who design, construct, operate and maintain CHS facilities.

Hospital equipment is maintained on a computerized preventive maintenance schedule and monitored using integrated building control systems. CHS's multi-disciplinary, team participates during planning and design to ensure that new systems and components incorporate demonstrated best practices as well as recommend new and improved practices. *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. 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. *LEED for Health Care is not yet available. Early drafts were based on GGHC.
- Provide natural lighting where possible to augment electrical lighting and reduce electricity usage compared to a traditional hospital.
- Design and locate windows to appropriately serve functions of lighting, ventilation and external views for patient rooms, family and staff areas.
- Control the solar heat gain into the facility through overhangs, natural buffers, sun controls and selection of glazing systems.
- Design for maximum efficiency and life cycle benefits within each mechanical system: heating, cooling, water, sewer and irrigation.
- Provide where feasible, heat recovery systems to extract heat normally wasted in exhaust air and transfer this energy to incoming ventilation air to reduce energy usage.
- Use energy guidelines of the United States Department of Housing and Urban Development, United States Department of Energy, and the American Society of Heating, Refrigeration, and Air Conditioning Engineers for the design of health care facilities.

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 described the project's plan to assure improved energy efficiency and water conservation. Thus, the application is conforming to Policy GEN-4 and 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.

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The applicant proposes to relocate existing adult endoscopy services within the Medical Center. The proposed project includes renovating 17,800 square feet on the fourth floor of the Medical Center and adding 2,300 square feet to the existing mechanical penthouse located on the roof of the Medical Center to accommodate one additional air handler. Upon project completion, the relocated adult GI endoscopy suite will include: 6 GI endoscopy rooms; 1 bronchoscopy room; 1 special procedures room; and 20 preparation/recovery bays.

Population to Be Served

In Section III.6, pages 69-71, the applicant provides historical and projected patient origin for GI endoscopy, manometry and bronchoscopy services provided at CMC, as illustrated in the following table:

County	Last Full Year: % of Total Patients	Year 1: % of Total Patients	Year 2: % of Total Patients
Mecklenburg	45.8%	45.8%	45.8%
Gaston	7.3%	7.3%	7.3%
Union	7.1%	7.1%	7.1%
Other	39.7%	39.7%	39.7%
Total	100.0%	100.0%	100.0%

In Section III.5, page 67, the applicant states "The geographic boundary of the proposed service area consists primarily of Mecklenburg, Gaston and Union counties. Based on the historical patient origin for GI endoscopy services at the medical center, and because the proposed project involves no changes to existing services, CMC expects the majority of the patients utilizing the services included in this application to continue to originate from these three counties."

Furthermore, on page 98, the applicant states,

"Projected patient origin is based on the historical patient origin for endoscopy services at CMC. Because the proposed project involves no changes to existing services, CMC expects its patient origin to remain the same."

The applicant adequately identifies the population proposed to be served.

Need for the Proposed Relocation within the Medical Center

In Section III.1, page 37, the applicant states

"The primary need for the proposed project is to optimize adult endoscopy services for the more efficient delivery of care.

•••

[T]he existing adult endoscopy suite is outdated and undersized to accommodate high acuity procedures and equipment. As a result, the existing suite is not currently designed as effectively and efficiently as it must be in order to allow CMC to continue to provide patients and families the high quality of endoscopy care that they expect from CMC. Thus, the unmet need that necessitates the proposed project is primarily qualitative, involving the ability of the endoscopy department to provide the best possible care in the most efficient manner. "

In Section III.1, pages 38-51, the applicant discusses the following:

- Growing Population: The applicant states that population growth is driving increased utilization of health care services in Mecklenburg County. The North Carolina Office of State Budget and Management ("NCOSBM") projects that the population of Mecklenburg County will increase 19.3% between 2010 and 2020. (See pages 38-39.)
- Aging Population: The applicant states that typically older residents utilize health care services at a higher rate than those who are younger. The NCOSBM projects Mecklenburg County's 65+ population will increase 58.1% over the next decade. (See pages 39-40.)
- Cancer Incidence: The applicant states that cancer risk increases with age. According to the North Carolina Central Cancer Registry, Mecklenburg County is projected to have the highest number of new cancer cases of all counties in North Carolina in 2011. (See pages 40-41.)

In Section II.1, pages 21-28, the applicant states

"The proposed project will not materially impact the previously approved surgical services projects (Project ID #s F-7781-07, F-8091-08, and F-8440-09), as discussed in the Overview section above. The scope of this proposed project involves space developed in conjunction with CMC's February 2011 Material Compliance Request and its previously approved Project ID # F-7781-07. This project does not propose to increase the total inventory of licensed operating rooms at CMC, which were the subject of the previously approved projects. Nor does it propose to increase the inventory of GI endoscopy rooms at CMC. Moreover, it is important to note that the proposed project does not impact GI endoscopy services dedicated to pediatric patients located within Levine Children's Hospital.

As discussed in Section III.1, changes in the volume and types of procedures performed at the medical center have resulted in a need to improve patient flow as

well as the need to increase support areas within the department. The proposed project will:

- Right-size the relocated GI endoscopy rooms to accommodate complex procedures and improve efficiency;
- Co-locate preparation and recovery areas closer to the endoscopy suite and increase capacity to support complex procedures;
- Increase physician/staff support capacity and locate these areas within the endoscopy suite;
- Increase endoscopy equipment and supply storage areas and locate these areas
 - within the endoscopy suite; and,
- *Improve and increase the size of the waiting area.*

CMC believes that the proposed project will allow the medical center to continue to provide high quality, state-of-the-art endoscopy services in an environment more responsive to the needs of patients and their families, as well as physicians and staff. The details of the proposed project are discussed below.

Relocation and Consolidation of Endoscopy Services

With this application, CMC proposes to relocate existing adult endoscopy services listed below from their current locations on the fourth floor of the main hospital to one central location on the fourth floor, Unit 4K. The existing space on 4K as developed is not finished for occupancy. As such, the proposed project involves upfit necessary to finish the space. Specifically, the proposed project involves the renovation/upfit of approximately 17,800 square feet of space to house and co-locate the following existing adult endoscopy services:

- GI endoscopy rooms;
- A bronchoscopy room;
- A special procedures room;
- *Preparation and recovery areas;*
- Staff support;
- *Storage; and,*
- Waiting area.

Please note that the proposed project also involves a 2,300 square foot addition to the mechanical penthouse on the roof of the existing medical center to accommodate one additional air handler to support the 17,800 square feet of renovated space proposed in this application. Please see the line drawings in Exhibit 5 ("Enlarged Penthouse Plan") for illustration.

Adult endoscopy services have been in their current location in the main hospital for more than a decade. Since that time no structural renovations have been made. As a result, the GI endoscopy suite is outdated, oddly configured, and undersized. Moreover, as detailed in the line drawing of level four of the medical center (see excerpt below) included in Exhibit 5 ("Existing Overall Plan"), existing adult endoscopy services are fragmented.

[see design schematic on page 23]

In particular and of note, one of the GI endoscopy rooms is isolated, located across the hall from the rest of the procedure room suite; the preparation area, which is located within the procedure room suite, is located across the hall from the recovery area; and there are no staff support or storage areas located within the existing suite, as these areas are currently located in another building which is accessible via a breezeway. As illustrated in the line drawings included in Exhibit 5 ("Enlarged Patient Unit Plan"), the new endoscopy suite will be designed to co-locate relocated adult endoscopy services located in the main hospital. Further, as discussed below, the proposed renovation will allow CMC to create GI endoscopy rooms that are properly sized to perform the high technology complex procedures that are the norm today. Moreover, the proposed renovation of these adult endoscopy services will give the department a consolidated, fresh look, bringing the appearance of CMC's relocated endoscopy services into the 21st century.

Procedure Rooms

GI Endoscopy Rooms

CMC is proposing to renovate existing space on level four of the medical center to house six relocated GI endoscopy rooms. As illustrated in the line drawings included in Exhibit 5 ("Existing Overall Plan"), the existing GI endoscopy rooms are outdated, oddly configured, and undersized. In particular, a number of the existing adult GI endoscopy rooms cannot support the technology needed to perform the types of higher acuity procedures performed in the endoscopy department that often rely on advanced technology. Specifically, four of the rooms CMC proposes to replace and right-size with this project measure approximately 194 square feet. These rooms are too small to adequately accommodate the technology and equipment necessary for complex endoscopy procedures.

As also evident on the line drawings included in Exhibit 5 ("Existing Overall Plan"), one of the GI endoscopy rooms is located across the hall, isolated from the rest of the procedure room suite and located outside of the entrance and exit to the procedure room suite. Patients undergoing procedures in this room must be transported across, a public corridor after being prepped in the procedure suite.

In addition, it should be noted that the existing suite does not have a lead lined room large enough with the equipment necessary to accommodate procedures requiring the use of fluoroscopy equipment. As such, procedures requiring the use of fluoroscopy equipment, such as ERCP are currently performed in another room located in the

radiology department.

The renovation proposed in this application will allow CMC to create GI endoscopy rooms that are properly sized to perform the high technology complex procedures that are the norm today. As a part of this project, all of the relocated GI endoscopy rooms will be located adjacent to one another within the procedure room suite. Each of the relocated GI endoscopy rooms will be configured the same way, measuring approximately 240 square feet, so that each will be able to accommodate any procedure and the anesthesia team and equipment if needed (except for procedures requiring the use of fluoroscopy equipment, which will either be performed in the relocated. GI endoscopy room housing the proposed fluoroscopy equipment or the radiology department). Not only will the proposed renovation effectively right-size the GI endoscopy rooms, but it will also make it easier on staff to transport and maneuver patients in and out of the rooms.

As noted previously, ERCP procedures are currently performed in another room located in the radiology department. By acquiring Xray/fluoroscopy equipment to be located in one of the relocated right-sized GI endoscopy rooms, CMC will have the capability to provide these procedures within the new adult endoscopy suite as well.

Bronchoscopy and Special Procedures Rooms

The proposed project also involves the relocation of CMC's existing bronchoscopy and special procedures rooms. The bronchoscopy room is currently located within the procedure room suite and the special procedures room (for manometry procedures) is located adjacent to one of the GI endoscopy rooms, outside of the procedure room suite. These two procedure rooms will be relocated to the proposed new adult endoscopy suite. Moreover, the bronchoscopy room CMC proposes to relocate and replace is currently undersized, measuring only 156 square feet. As part of the relocation and replacement, CMC proposes to right-size the relocated bronchoscopy room to measure approximately 240 square feet.

In addition, the proposed project involves the acquisition of one new C-Arm. The proposed new C-Arm will be located in the relocated and right-sized bronchoscopy room. Currently, the adult and pediatric endoscopy suites share a C-Arm. Sharing this equipment not only poses scheduling difficulty, but also the frequent transportation of this heavy equipment raises concerns relating to potential staff injury or equipment damage. The acquisition of an additional unit for the new adult endoscopy suite will allow CMC to keep its existing unit at Levine Children's Hospital and have a unit dedicated to the new adult endoscopy suite.

Preparation and Recovery Areas

The current preparation and recovery areas are physically separated. The preparation area is located within the procedure room suite while the recovery area is located across the hall from the procedure room suite. Please see the line drawings

in Exhibit 5 for illustration ("Existing Overall Plan"). Given staffing requirements and the current location of the recovery and preparation areas, the medical center must staff two full time equivalents (FTEs) in each of these areas since they are located across the hall from one another and are not physically combined. Further, given the current location of the recovery area (across the hall from the procedure room suite), patients must be transported across a public corridor following their procedure to access the recovery area.

As illustrated in the line drawings included in Exhibit 5 ("Enlarged Patient Unit Plan"), the new endoscopy suite will be designed to co-locate the preparation and recovery areas which will improve flow and staffing efficiency. Moreover, given the types of procedures most commonly performed in the procedure rooms – complex - coupled with the fact that recovery time increases with the complexity of the procedure, the proposed project will include a total of 20 preparation and recovery bays, six more than currently exist.

Support and Storage Areas

There is no staff support or storage space located in the existing suite. As illustrated in the line drawings included in Exhibit 5 ("Existing Overall Plan"), staff must walk across a breezeway into another building to access storage areas and staff support areas including the staff lounge, administration, and conference room.

Staff support and storage areas will be located in the new endoscopy suite as illustrated in the line drawings included in Exhibit 5. Not only is there no support or storage space located within the existing suite, but also the space that is allotted for these areas (in a separate building) is inadequate. In fact, storage space, which is comprised of a single room, is so inadequate that the staff is currently utilizing its conference room for additional storage. The proposed project will address these inadequacies by increasing staff support and storage space. In particular, as discussed in Section III.1.(a), the increased use of technology has resulted in an increasing amount of equipment used during endoscopic procedures. Therefore, additional space is necessary to accommodate these requirements. As such, the proposed project will create additional endoscopy equipment and storage space as indicated in the line drawings included in Exhibit 5.

Waiting Area

In addition to the fragmented services discussed above, it is important to note that the existing waiting room area is grossly undersized to accommodate the suite's patients and family members. The existing waiting area measures approximately 400 square feet which, based on experience at CMC, is not sufficient to provide adequate and comfortable waiting areas for patients and their family members.

The new space will double the size of the waiting area from 400 to 800 square feet. In addition, it will be located adjacent to, but separate from, three consultation rooms.

CMC proposes to increase the number of chairs in the waiting area from 26 to 50 to allow the waiting area to accommodate more people. As illustrated on the line drawings included in Exhibit 5 ("Enlarged Patient Unit' Plan"), the chairs in the waiting area will be grouped together in a circular formation. CMC believes that this arrangement will increase the comfort of those waiting and will allow people to sit in smaller, more private groupings."

On pages 51-56, the applicant states the following regarding why existing adult GI endoscopy services need to be relocated within the Medical Center.

"the existing adult endoscopy suite is fragmented, outdated, and undersized.

Fragmented Services

As noted previously, major facility constraints involve the following issues:

- one of the GI endoscopy rooms is isolated, located across a public corridor from the rest of the procedure room suite;
- the preparation area, which is located within the procedure room suite, is located across the hall from the recovery area;
- *the recovery area is located across a public corridor from the procedure room suite; and,*
- there are no staff support or storage areas located within the existing suite, as these areas are currently located in another building which is accessible via a breezeway.

The proposed project will utilize existing space within the medical center to consolidate adult endoscopy services. The layout of the new suite illustrated in Exhibit 5 ("Enlarged Patient Unit Plan"), will improve throughput and increase efficiency.

All of the relocated adult GI endoscopy rooms will be right-sized and located adjacent to one another within the procedure room suite. As such, no patient will have to be transported across a public corridor following preparation to access a procedure room. Further, as discussed in detail below, each of the relocated GI endoscopy rooms will be able to accommodate any procedure and the anesthesia team and equipment if needed (except for procedures requiring the use of fluoroscopy equipment, which will either be performed in the relocated GI endoscopy room housing the proposed fluoroscopy equipment or the radiology department).

The proposed new suite will also physically co-locate recovery and preparation areas which will help improve flow and staffing efficiency. In the current layout, preparation and recovery are separated, making it difficult to utilize staff for both areas. In addition, given the location of these co-located areas, patients will no longer have to be transported across a public corridor to the recovery area. The proposed project will also increase the capacity of these areas and will include a total of 20 preparation and recovery bays, six more than currently exist. The need for this additional capacity is driven by the volume of complex procedures performed in the suite which require more recovery time than less complex procedures.

In addition, the proposed project will increase the size of physician/staff support and storage areas and locate them within the endoscopy suite. Staff will no longer waste time and walk the distance across a breezeway to access these areas. Currently, there is only one small storage room located across the breezeway. This room is grossly inadequate and staff is currently utilizing a portion of their conference room for additional storage. Given the type of procedures performed in the endoscopy suite and the increased use of technology, there is an increasing amount of equipment used during endoscopic procedures. Therefore, additional space is necessary to accommodate these requirements. As detailed in the line drawings, Exhibit 5, the proposed project includes significantly more equipment and supply storage space. In addition, as illustrated on the line drawings, there is space specifically allotted to "Scope Storage." This space is conveniently located adjacent to the "Scope Clean" space. This "Scope Storage" space will provide a location where instruments can be hung freely without coiling or risk of tangling/catching on doors or drawers.

Inefficient Design, Outdated and Undersized Rooms

Further, the existing adult GI endoscopy rooms are outdated, oddly configured, and undersized to support the technology needed to perform the higher acuity procedures commonly performed in these rooms. In particular, given their size and configuration, some of the GI endoscopy rooms can only accommodate certain types of procedures. In particular and of note:

- Only three of the GI endoscopy rooms can accommodate the anesthesia team and equipment.
- Only two of the GI endoscopy rooms have the space necessary to accommodate the equipment needed for RFA procedures in addition to the anesthesia team and equipment.
- Only one of the GI endoscopy rooms can accommodate the equipment needed for EUS procedures.
- Further, in one of the GI endoscopy rooms, staff must put down the bedside rails in order to transport and maneuver patients out of the door.

The size limitations of the GI endoscopy rooms not only limits the types of procedures that can be performed in the rooms as discussed above, but also poses problems relative to scheduling. In particular, size restrictions make scheduling certain specialty procedures at particular times difficult. In some instances procedures may have to be delayed or performed at different times from what the ordering physician would prefer. As part of the proposed project, each of the relocated GI endoscopy rooms will be configured the same way and right-sized, measuring approximately 240 square feet, so that each will be able to accommodate any procedure and the anesthesia team and equipment if needed (except for procedures requiring the use of fluoroscopy equipment, which will either be performed in the relocated GI endoscopy room housing the proposed fluoroscopy equipment or the radiology department). This will in turn allow for block scheduling. Efficient calendars are more easily planned using block scheduling of physicians performing similar or uniform procedures.

Finally, as noted previously, the existing patient waiting area is grossly undersized, measuring approximately 400 square feet. The proposed project will double the size of the waiting room area to properly accommodate the suite's patients and family members. CMC proposes to increase the number of chairs in the waiting area from 26 to 50 to allow the waiting area to accommodate more people. With as many as 50 potential patients through the suite on any given day, the size of the existing waiting room is clearly inadequate. As illustrated on the line drawings included in Exhibit 5 ("Enlarged Patient Unit Plan"), the chairs in the waiting area will be grouped together in a circular formation. CMC believes that this arrangement will increase the comfort of those waiting and will allow people to sit in smaller, more private groupings. Not only will the proposed project improve patient satisfaction and delivery of care, but also allow for more appropriately located, sized, and efficient space for the provision of endoscopy services.

The adult endoscopy suite must be capable of accommodating complex volume; all of the developments proposed in this application will upgrade the clinical capacity of the relocated adult endoscopy services, enabling CMC to better accommodate complex volume.

In addition, the proposed project involves the purchase of a C-Arm and an Xray/fluoroscopy machine. The C-Arm will be located in the relocated bronchoscopy room and used to perform bronchoscopy and EBUS procedures. Currently, the adult and pediatric endoscopy suites share a C-Arm. The current practice of transporting the heavy equipment-which is comprised of three separate pieces: a table, C-Arm, and screen-back and forth between the adult and pediatric endoscopy suites is inefficient and raises concerns relative to potential staff injury or equipment damage. The acquisition of an additional unit for the adult endoscopy suite will allow CMC to keep its existing unit at Levine Children's Hospital and have a unit dedicated to the adult endoscopy suite.

The X-ray/fluoroscopy equipment will be located in one of the relocated GI endoscopy rooms. As noted previously, procedures requiring the use of fluoroscopy - equipment are currently performed in another room located in the radiology department. Patients are prepped in the endoscopy suite, transported through public corridors to the radiology department, and following their procedure transported back to the endoscopy suite for recovery through public corridors. The proposed project, which involves the acquisition of an X-ray/fluoroscopy unit, will enable CMC

to provide these procedures within the new adult endoscopy suite as well. This development will create a safer practice, with other endoscopy resources available and close by in the event of an emergency.

SUMMARY

The proposed project is needed to realign, renovate, and consolidate existing adult endoscopy services at CMC. The proposed project will upgrade the clinical capacity of the relocated adult endoscopy services and improve throughput and scheduling efficiency as a result of having a full complement of rooms capable of accommodating complex volume. Further, the proposed project will improve patient, physician, and staff satisfaction. The project as proposed is integral to CMC's mission and commitment - to providing the best care to its patients and fulfilling its responsibilities for research and teaching."

The applicant adequately demonstrates the need to relocate existing adult GI endoscopy services within the Medical Center.

Projected Utilization

In Section IV.1, pages 77-78, the applicant provides historical and projected utilization for adult endoscopy services, as illustrated in the tables below.

GI Endoscopy Rooms	Last Full FY 1/1/10 – 12/31/10 (Actual)	First Full FY 1/1/14- 12/31/14 (Projected)	Second Full FY 1/1/15-12/31/15 (Projected)	Third Full FY 1/1/16 – 12/31/16 (Projected)
# of Rooms*	9	9	9	9
# of Inpatient GI endoscopy procedures**	3,267	3,391	3,439	3,495
# of Outpatient GI endoscopy procedures**	10,170	10,555	10,705	10,880
Total	13,437	13,946	14,144	14,375

Average/room	1,493	1,549	1,571	1,597
		,		

*CMC states in a footnote on page 77 that "CMC's 2011 HLRA indicates a total of eight GI endoscopy rooms; however, as of the date of submission of this application, CMC is in the process of updating its licensure application to reflect the existence of a ninth room located in the radiology department that has been in operation continuously and used for the performance of GI endoscopy procedures for over 20 years."

**See Section III.1(b), pages 56-63. The applicant adequately explains the apparent discrepancies between historical utilization as reported in the CON application and CMC's hospital license renewal application.

Manometry- Special procedure room	Last Full FY- 1/1/10 – 12/31/10 (Actual)	First Full FY 1/1/14-12/31/14 (Projected)	Second Full FY 1/1/15-12/31/15 (Projected)	Third Full FY 1/1/16 – 12/31/16 (Projected)
# of rooms	1	1	1	1
# of Procedures	366	416	429	443

Bronchoscopy Room - (Bronchoscopy and EBUS)	Last Full FY- 1/1/10 – 12/31/10 (Actual)	First Full FY 1/1/14-12/31/14 (Projected)	Second Full FY 1/1/15- 12/31/15 (Projected)	Third Full FY 1/1/16 – 12/31/16 (Projected)
# of rooms	1	1	1	1
# of Procedures	1,255	1,992	2,235	2,509

In Section III.1(b), pages 56-63 the applicant provides the assumptions and methodology used to project utilization, as follows.

"<u>GI Endoscopy</u>

As previously discussed, as more traditional GI endoscopy procedures, such as EGD and colonoscopy, have shifted to outpatient facilities in recent years, CMC has experienced a decline in the number of traditional GI endoscopy procedures performed at the medical center. At the same time, it has experienced significant growth in more complex GI endoscopy procedures such as RFA, liver biopsy, EUS, and ERCP. Historical utilization of traditional and complex GI endoscopy procedures at CMC is provided in the table on the following page.

GI Endoscopy Procedure Type	FY 2008	FY 2009	FY 2010	CAGR*
Traditional	11,245	11,743	10,950	-1.3%
Complex	1,762	2,363	2,487	18.8%
Total**	13,007	14,106	13,437	1.6%

*Compound Annual Growth Rate

**Annual procedure totals shown in this table reflect CMC's fiscal year volume based on internal data. Because CMC's fiscal year aligns with the calendar year (January through December), the procedure totals in this table represent a different reporting period than volumes reported on annual hospital license renewal applications which require reporting for the federal fiscal year period (October through September).

CMC expects the general growth trends in traditional and complex procedures to continue. However, CMC conservatively projects that its traditional GI endoscopy procedure volume will continue to decline at its full CAGR of 1.3 percent, but only projects complex GI endoscopy procedures to grow at one-half of the actual historical CAGR. This results in the following projected GI endoscopy procedures through FY 2016, the third year of the proposed project.

GI Endoscopoy Procedure Type	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Traditional	10,805	10,663	10,522	10,383	10,246	10,111	-1.3%
Complex	2,721	2,977	3,257	3,563	3,898	4,264	9.4%
Total	13,526	13,639	13,778	13,946	14,144	14,375	1.1%

As shown in the table above, this methodology results in a projected CAGR for total GI endoscopy procedures of only 1.1 percent, which is less than the actual historical CAGR of 1.6 for total GI procedures. As such, CMC believes this methodology for projecting future GI endoscopy utilization is both conservative and reflective of the expected continued trends in traditional and complex procedure volume at the medical center.

Special Procedures (Manometry)

Historical utilization of manometry procedures at CMC, which are performed in the endoscopy department's special procedures room, is provided in the following table.

Special Procedures	FY 2008	FY 2009	FY 2010	CAGR
Manometry	209	276	366	32.3%

CMC expects the general growth trends in manometry procedures to continue. However, CMC recognizes that the high growth experienced in recent years has been largely attributable to the addition of several physicians who perform the majority of CMC's manometry procedures. Because this physician growth has now stabilized, CMC expects that the growth in its manometry volume will stabilize as well and as such, has very conservatively projected its manometry procedure volume to grow only at one-tenth of the actual historical CAGR. This results in the following projected manometry procedures through FY 2016, the third year of the proposed project.

Special Procedures	FY 2011	FY 2012	FY 2013	FY 2014	FY 2018	FY 2016	CAGR
Manometry	378	390	403	416	429	443	3.2

Manometry procedures require very specialized computers and equipment that is ideally kept in room, making it more efficient to perform these procedures in the special procedures room as opposed to one of the GI endoscopy rooms. As such, the need to maintain this room is driven by the need for an appropriate room in which to perform these procedures without unnecessarily occupying CMC's already highly utilized GI endoscopy or bronchoscopy rooms, which do not have additional capacity.

<u>Bronchoscopy</u>

Historical utilization of bronchoscopy procedures (including EBUS procedures) at CMC is provided in the following table.

Special Procedures	FY 2008	FY 2009	FY 2010	CAGR
Bronchoscopy	810	1,053	1,255	24.5%

CMC expects the general growth trends in bronchoscopy procedures to continue. However, CMC conservatively projects its bronchoscopy procedure volume to grow only at one-half of the actual historical CAGR. This results in the following projected bronchoscopy procedures through FY 2016, the third year of the proposed project.

Special Procedures	FY 2011	FY 2012	FY 2013	FY 2014	FY 2018	FY 2016	CAGR
Bronchoscopy	1,409	1,581	1,774	1,992	2,235	2,509	12.2%

Preparation and Recovery

As previously stated, the proposed project will increase the capacity of these areas and will include a total of 20 preparation and recovery bays, six more than currently exist. The need for this additional capacity is largely driven by the increasing volume of complex procedures performed in the suite which require more recovery time than traditional, less complex procedures. For example, while patients receiving a screening colonoscopy are usually young, healthy patients on few medications and with few comorbidities, patients at CMC are increasingly sicker. They are frequently on several medications, which must be reconciled requiring abundant documentation. They often have comorbidities such as cardiac issues, diabetes, and even ALS with paralysis just to name a few. These circumstances add at least 20 to 30 minutes of additional preparation time and can also add to the typical recovery time if there are any problems. Without sufficient capacity to accommodate the longer preparation and recovery times required for these more complex cases, the preparation and recovery area can fill to capacity causing unavoidable delays in procedures until the preparation and recovery area can decompress.

Further, the proposed preparation and recovery area will be right-sized according to current recommendations from The American Institute of Architects (AlA) Academy of Architecture for Health's Guidelines for Design and Construction of Hospital and Health Care Facilities from 2006. Specifically, the AlA recommends 1.5 preparation

spaces and one recovery space per procedure room, for a total of 2.5 combined. The adult endoscopy unit that is the subject of this application contains six GI endoscopy rooms, one special procedures room, and one bronchoscopy room, for a combined total of eight procedure rooms within the unit. Therefore, CMC's design to include 20 preparation and recovery spaces in the unit is consistent with the AlA's recommendations (20 preparation and recovery areas / 8 procedure rooms = 2.5 preparation and recovery spaces per procedure room). Additionally, as previously discussed, CMC performs GI endoscopy procedures in a ninth room that is currently located in the radiology department. As such, the 20 proposed preparation and recovered from procedures performed in a ninth room as well, thereby making CMC's design to include 20 preparation and recovery spaces conservative based on the AlA's guidelines (20 preparation and recovery spaces / 9 procedure rooms = 2.2 preparation and recovery spaces per procedure room)."

Projected utilization of the GI endoscopy rooms, special procedures room (manometry) and bronchoscopy room is based on reasonable, credible and supported assumptions regarding historical, interim and projected growth. Exhibit 24 contains letters from physicians expressing support for the proposed project. The applicant adequately demonstrated the need to relocate existing adult endoscopy services within the Medical Center.

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

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

NA

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

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In Section III.8, pages 72-73, the applicant describes the alternatives considered, including maintaining the status quo, relocating adult endoscopy services to another location within CMC and developing the project as proposed. Furthermore, the application is conforming to all other applicable statutory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a) and (20) for discussion. The applicant adequately demonstrated that the proposal is its least costly or most effective alternative. The application is conforming with 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 have no more than 9 GI endoscopy rooms at the Medical Center upon completion of the project.
- 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 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 or that would otherwise require a certificate of need.
- 5. 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.

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In Section VIII.1, page 109, the applicant states the total capital cost of the project will be \$7,251,000. In Section IX, page 113, the applicant states that there will be no start-up or initial operating expenses. In Section VIII.3, page 109, the applicant states that the total capital cost of the project will be financed with a bond issued in 2011. Exhibit 31 contains a letter from the Executive Vice President and Chief Financial Officer of Carolinas HealthCare System, dated September 15, 2011, which states:

"As a requirement of the Certificate of Need application process, I have been asked to document the availability of funds for the proposed endoscopy services renovation and relocation at Carolinas Medical Center. As the Chief Financial Officer for Carolinas HealthCare System, I am responsible for the financial operations of Carolinas Medical Center. As such, I am very familiar with the organization's financial position. The total capital expenditure for the project is estimated to be \$7,251,000 and will be funded through proceeds from bonds issued in 2011.

For verification of the availability of these funds and our ability to finance this project internally, please refer to the cover page from the official statements from bond issue 2011A, which has been included with this letter. This expenditure of funds will not impact any other capital projects currently underway or planned for during the coming years."

Exhibit 31 also contained a cover page of a bond issue for \$149,995,000 for The Charlotte-Mecklenburg Hospital Authority (North Carolina) Doing Business as Carolinas HealthCare System with a delivery date of on or about May 19, 2011.

Exhibit 32 contains the audited financial statements for The Charlotte-Mecklenburg Hospital Authority (d/b/a Carolinas HealthCare System) which shows, on page 12 of the exhibit, \$128,597,000 in Cash and Cash Equivalents, Total Current Assets of \$843,761,000, and Total Net Assets of \$3,369,254,000 of December 31, 2010. CMC adequately demonstrates the availability of sufficient funds for the capital needs of the proposed project.

In the projected revenue and expense statements for Carolinas Medical Center's Endoscopy Services (GI Endoscopy, Special Procedures, and Bronchoscopy) (Form C), the applicant projects revenues will exceed operating expenses in the first three project years following completion of the proposed project, as illustrated in the table below

	First Full FY	Second Full FY	Third Full FY
	(1/1/14 - 12/31/14)	(1/1/15 - 12/31/15)	(1/1/16 - 12/31/16)
Gross Patient Revenue	\$34,967,113	\$36,944,613	\$39,146,113
Deductions from Gross Patient	\$23,785,165	\$25,135,893	\$26,640,042
Revenue			
Net Patient Revenue	\$11,181,948	\$11,808,720	\$12,506,071
Total Expenses (Direct and Indirect)	\$8,639,799	\$8,955,630	\$9,292,622
Net Income	\$2,542,149	\$2,853,091	\$3,213,449

The assumptions used by the applicant in preparation of the pro forma financial statements provided in the application are reasonable, including projected utilization. See Criterion (3) for discussion of projected utilization. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Consequently, 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.

The applicant proposes to renovate existing space on the fourth floor of the Medical Center to relocate existing adult GI endoscopy services within the Medical Center. The applicant does not propose to increase the number of GI endoscopy rooms in the service area. The applicant adequately demonstrates the need for its proposal. See Criterion (3) for additional discussion. Therefore, the applicant adequately demonstrates that the proposed project would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. 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.

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In Section VII, pages 98-99, the applicant states that the current staffing is 48.05 full-time equivalent (FTE) positions and projects no change in the second full operating year of the proposed project. On page 99 the applicant states that "*the proposed project does not involve any new positions or incremental FTEs.*" In Section VII.7, pages 103-104, the applicant describes its experience and procedures for recruiting and retaining personnel. In Section VII.9, page 137, the applicant identifies Dr. Tom Pacicco as the Medical Officer for GI endoscopy services. The applicant adequately demonstrates the availability of sufficient health manpower and administrative 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.

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In Section II.2, page 29, the applicant describes the necessary ancillary and support services for the proposed services. Exhibit 6 contains a letter from CMC's Chief Operating Officer which states "This letter is provided as documentation of the current availability of all necessary ancillary and support services required for the operation the adult endoscopy suite as proposed in Carolinas Medical Center's (CMC's) certificate of need application submitted on September 15, 2011. As an existing full-service acute care hospital, CMC already has all necessary ancillary and support services. In Section V.2, page 81, the applicant states "Please see Exhibit 22 for a copy of the standard transfer agreement used by CHS facilities and list of facilities that have transfer agreements with CMC. These agreements will not change following completion of the proposed project." In Section V.3, pages 82-83 and Section V.4, pages 83-84, the applicant describes efforts to develop relationships with local physicians and physicians support in physicians support for the proposed project. The applicant adequately demonstrates that the proposed project.

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

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

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

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In Section VI.12, page 94, the applicant provides the payer mix during FY2010 for all services provided at CMC, as illustrated in the table below.

CMC- Entire Facility Last Full Fiscal Year- FY2010

Payer Category	Patient Days as % of Total Utilization
Medicare	32.9%
Medicaid	32.3%
Managed Care/ Commercial	29.1%
Self Pay/Other*	5.7%
Total	100.0%

*Other includes workers compensation and other government payors. Note: Numbers may not foot due to computer rounding.

In Section VI.13, pages 94-95, the applicant provides the payer mix during FY2010 for GI endoscopy, manometry, and bronchoscopy/EBUS services provided at CMC, as illustrated in the table below.

CMC- GI Endoscopy Procedures Last Full Fiscal Year- FY2010

Payer Category	Procedures as % of Total Utilization
Medicare	36.6%
Medicaid	11.1%
Managed Care/ Commercial	41.2%
Self Pay/Other*	11.1%
Total	100.0%

*Other includes workers compensation and other government payors. Note: Numbers may not foot due to computer rounding.

CMC- Manometry Procedures		
Last Full Fiscal Year- FY2010		

Payer Category	Procedures as % of Total Utilization
Medicare	27.6%
Medicaid	8.5%
Managed Care/ Commercial	57.4%
Self Pay/Other*	6.6%
Total	100.0%

*Other includes workers compensation and other government payors. Note: Numbers may not foot due to computer rounding.

Last Full Fiscal T cal- F 12010	
Payer Category	Procedures as % of Total Utilization
Medicare	36.0 %
Medicaid	21.7%
Managed Care/ Commercial	36.7%
Self Pay/Other*	5.7%
Total	100.0%

CMC- Bronchoscopy/EBUS procedures Last Full Fiscal Year- FY2010

*Other includes workers compensation and other government payors. Note: Numbers may not foot due to computer rounding.

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 as of CY2008-2009. The data in the table was obtained February 17, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

County	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Mecklenburg	15%	5.1%	20.1%
Statewide	17%	6.7%	19.7%

*Source: DMA Website: http://www.ncdhhs.gov/dma/pub/index.htm

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 adult GI endoscopy services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of 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 applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to CMC's existing services. 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;

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In Section VI.10(a), page 93, the applicant states that no civil rights access complaints have been filed against any affiliated entity of CHS in the last five years. According to the Acute and Home Care Licensure and Certification Section, DHSR, the facility is currently in compliance with EMTALA regulations. 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

С

In Section VI.14, pages 95-96, the applicant provides the payer mix during the second year following completion of the proposed project for GI endoscopy, manometry, and bronchoscopy/EBUS services provided at CMC, as illustrated in the tables below.

Payer Category	Procedures as % of Total Utilization
Medicare	36.6%
Medicaid	11.1%
Managed Care/ Commercial	41.2%
Self Pay/Other*	11.1%
Total	100.0%

CMC- GI Endoscopy Procedures FY2015

*Other includes workers compensation and other government payors. Note: Numbers may not foot due to computer rounding.

CMC- Manometry Procedures	5
FY2015	

Payer Category	Procedures as % of Total Utilization
Medicare	27.6%
Medicaid	8.5%
Managed Care/ Commercial	57.4%
Self Pay/Other*	6.6%
Total	100.0%

*Other includes workers compensation and other government payors. Note: Numbers may not foot due to computer rounding.

CMC- Bronchoscopy/EBUS procedures FY2015

Payer Category	Procedures as % of Total Utilization
Medicare	36.0 %
Medicaid	21.7%
Managed Care/ Commercial	36.7%
Self Pay/Other*	5.7%
Total	100.0%

*Other includes workers compensation and other government payors. Note: Numbers may not foot due to computer rounding.

In Section VI.14, page 94, the applicant states,

"CMC does not expect the proposed project to result in any changes to its existing payor mix. As such, projected payor mix for GI endoscopy procedures, manometry procedures, and bronchoscopy/EBUS procedures is based on CM's actual FY 2010 payor mix for each service."

In Section VI.2, page 87, 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.*" See also Exhibit 27 which contains a copy of CMC's Non-Discrimination Policy.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services and 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.

See Section VI.9, pages 92-93, for documentation of a range of means by which persons will have access to the proposed services. The information provided in the application 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.

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In Section V.1, pages 79-81, the applicant states that CMC has extensive relationships with area clinical training programs. On page 79, the applicant states "As a part of its broad commitment to medical education, CMC has established relationships with many programs including Central Piedmont Community College (CPCC), Queens University of Charlotte, University of North Carolina at Charlotte (UNCC), Gardner-Webb University, Presbyterian School of Nursing and Mercy School of Nursing." Exhibit 21 contains a list of current educational affiliations. The information provided is reasonable and credible and supports a finding of conformity 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.

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See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that relocation of adult GI endoscopy rooms services within the Medical Center would have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The applicant adequately demonstrates the need to relocate its existing adult GI endoscopy services within the Medical Center and the proposal is a cost-effective alternative to meet the demonstrated need [see Criteria (1), (3), (4) and (5) for additional discussion];
- The applicant has and will continue to provide quality services [see Criteria (7), (8) and (20) for additional discussion]; and

• The applicant has and will continue to provide adequate access to medically underserved populations [see Criterion (13) for additional discussion].

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

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According to the files in the Acute and Home Care Licensure and Certification Section on February 2, 2011, CMC was surveyed as a result of a complaint. That survey resulted in an Immediate Jeopardy (IJ) and condition-level deficiencies. Based on a full survey on March 4, 2011 and a follow-up survey on May 5, 2011, the IJ had been abated and the quality of care deficiencies had been corrected. Therefore, the application is conforming with 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