Bernetta

Nov. 1, 2010 Review -
F-8602-10

Competitive Comments
Gaston Memorial Hospital
November 29, 2010

PROJECT I.D. NUMBER: F-8602-10 / Greater Gaston Center, LLC (GGC) / Develop a new ambulatory surgical facility with two gastrointestinal (GI) endoscopy rooms / Gaston County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

(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.

Statistical Need for Service

In Section III.1, page 32 of the application, GGC shows Gaston County age group population growth and identifies the NC Office of Budget and Management as the source of population projections. However, a review of the NC Office of Budget and Management website shows different population projections for Gaston County. The following tables show the population projections included in the application and the population projections at the NC Office of Budget and Management as of 8 September 2010; five weeks prior to the submission of the application:

GGC Application
Population Projections

	2010	2015
	Gaston	**Gaston**
0-17	49,495	51,543
18-44	75,539	77,085
45-64	56,354	59,118
65-85	24,584	28,880
85+	3,460	3,624
Totals	**209,432**	**220,250**

NC Office of Budget and Management
08Sept2010 Population Projections

	2010	2015
	Gaston	**Gaston**
0-17	49,489	51,494
18-44	75,501	76,974
45-64	56,333	59,055
65-85	24,577	28,851
85+	3,459	3,615
Totals	**209,359**	**219,989**

Continuing on page 32 of the application, GGC states that "the American Cancer Society recommends colonoscopy screenings for all persons over 50 years of age." However a review of the American Cancer Society website shows that the most recent medically reviewed colorectal cancer screening recommendation (2/22/2010, Please refer to the attached copy) calls for the use of any of the following tests:

- Flexible Sigmoidoscopy
- Colonoscopy
- Double-contrast barium enema
- CT colonoscopy
- Fecal occult blood test
- Fecal immunochemical test
- Stool DNA test

The only source that GGC footnotes to indentify a colonoscopy as the recommended screening test for colon cancer is an 8-year old, American Journal of Gastroenterology article (June 2002).

On page 33 of the application, GGC provides NC State Center for Health Statistic data that shows 110 new colon/rectal cancer cases are projected to be diagnosed on Gaston County residents in 2010. The inferred implication of GGC data is that colon cancer is on the rise in Gaston County because of an aging population and thus the need for additional GI endoscopy procedure rooms is supported.

However, a review of the NC State Center for Health Statistic data for the years 2001, 2005 and 2010 would show that the incidence of colon/rectal cancer in Gaston County is decreasing as the following table highlights:

	2001	2005	2010
Gaston County 55+ Population	43,716	46,393	53,969
NCSCHS Colon/Rectal Cancer Projected New Cases	100	105	110
55+ Incidence Rate per 1,000	2.29	2.26	2.04

On page 40 of the application, GGC infers that CaroMont Endoscopy Center currently has no timetable for when the center will be developed, this is not true. With the Final Agency Decision made on November 19, 2010 concerning CaroMont Health's Mount Holly MedPlex, the renovations needed to develop CaroMont's outpatient GI ASC will begin in March 2011, after the construction plans are approved by the DHSR Construction Section. As a result, the CaroMont GI endoscopy rooms should become operational by the end of 2011.

On page 41 of the application, GGC states that "many GI endoscopy patients have sought treatment outside of Gaston County due to the high cost of care at the area hospital and financial health plan incentives initiated by insurance companies. However, GGC provides no documentation to support the assertion that patients leave Gaston County because of either high cost of care or financial health plan incentives. None of the gastroenterologist members of the GGC or any referring physicians support these assertions. GGC attempts to support these anecdotal assumptions by showing the number of Gaston County residents who travelled to Mecklenburg County or Cleveland County ASCs for GI procedures. On page 42 of the application, GGC highlights that 1,347 Gaston County patients were treated at one of nine ASC. However, GGC fails to also highlight that 2,410 Gaston County patients travelled to adjacent county hospitals for a GI procedure. The number of Gaston County patients travelling out of Gaston County for a GI procedure negates GGC's assertion that patients are travelling out of the county for cost or financial incentives; rather this may merely indicate that Gaston County patients receive care where they work and may have either their primary care physician or gastroenterologist located in an adjacent county.

Need for the Proposed Service

In Section III.1, pages 43-49 of the application, GGC provides the need methodology that results in the following procedure volume over the first three years of operation:

GGC Projected GI Volumes

	2012	2013	2014
GI Procedures	4,325	4,784	4,975

In Step 3 of the need methodology, page 45, GGC multiplies the projected Gaston County population by the statewide use rate for GI endoscopy performed in licensed rooms to calculate the expected number of GI procedures for Gaston County. However, GGC fails to show why the statewide use rate should be used as opposed to a Gaston County use rate. What similarities exist, if any, that support using a statewide use rate as opposed to a countywide use rate? GGC states that the average age is higher in Gaston County and also refers to an elevated incidence / risk of colon cancer; however, no supporting documentation shows that the average age of Gaston County is higher than the statewide average age and no data is provided to show an elevated incidence of colon cancer. Furthermore, if Gaston County does have an elevated incidence of colon cancer, there is no evidence provided that it is statistically significant or is within a normal standard deviation.

In Step 4 of the need methodology, page 46, GGC projects the following number of GI endoscopy procedures for the projected Gaston County population:

Gaston County
Projected GI Procedures

	2012	2013	2014
GI Procedures	13,778	14,023	14,270

In Step 5 of the need methodology, page 46, GGC assumes the following Gaston County market share for the first three years of operation:

Gaston County
Projected GI Procedure Market Share

	2012	2013	2014
GI Procedures	30.0%	32.5%	33.0%

These market share assumptions are partially supported by the number of GI endoscopy procedures that each member gastroenterologist projects to treat at the

GGC when it is operational. These projections are included on page 49 or the application and the letters in Exhibit 27. However, GGC and the gastroenterologists fail to identify where these GI procedure/patients will shift from.

GGC assumes 14,270 GI procedures from Gaston County patients in 2014 and using the procedure to patient ratio of 1.15, which was provided by GGC on page 47, CaroMont Health was able to calculate that 14,097 GI procedures (12,258 patients x 1.15 GI procedure per patient = 14,097 GI procedures) were performed on Gaston County patients in 2009. The current and projected GI procedure volumes are important because currently all 14,097 procedures are being treated at either an existing hospital or ASC. The following table shows where the current Gaston County patient GI procedures are performed in North Carolina:

2009 Gaston County GI Patients

	Patients	**Ratio**	**Procedures**	**Market Share**
Gaston Memorial Hospital	7,576	1.15	8,712	61.8%
Mecklenburg County Hospitals	1,826	1.15	2,100	14.9%
Mecklenburg County ASCs	1,771	1.15	2,037	14.4%
Cleveland County Hospitals	447	1.15	514	3.6%
Cleveland County ASCs	258	1.15	297	2.1%
Other NC Hospitals	192	1.15	221	1.6%
Lincoln County Hospitals	127	1.15	146	1.0%
Other NC ASCs	61	1.15	70	0.5%
Total	**12,258**	**1.15**	**14,097**	**100.0%**

Through its need methodology on pages 43-49 of the application, GGC essentially projects no volume increase in the number of GI procedures to be performed on Gaston County residents, as a result, even though GGC does not state so, it must assume that it will be shifting patients from existing GI endoscopy procedures rooms to GGC's proposed two GI endoscopy procedure rooms. Nowhere in either the application or the exhibits does GGC explain how it will alter or influence the referral patterns of physicians or the health care choices of Gaston County residents to seek GI endoscopy care outside of Gaston County. As a result the Agency must assume that the patients projected to be treated at the GGC will be patients shifted from Gaston Memorial Hospital, as 80% of the gastroenterologist members at GGC have privileges at Gaston Memorial Hospital.

Shifting GI endoscopy procedures from Gaston Memorial Hospital to GGC would result in underutilized services at Gaston Memorial Hospital. In fact, based on 2009 data in the 2010 Hospital License Renewal Application, the eight GI

endoscopy procedure rooms at Gaston Memorial Hospital were underutilized. The following table shows the number of GI procedures performed by Gaston Memorial Hospital as reported on its last three annual Hospital License Renewal Applications:

FY Year	Number of Procedures	Procedures/ Room	Percent Increase of Procedures
FY 2007	11,343	1,418	
FY 2008	11,654	1,457	2.7%
FY 2009	11,764	1,471	0.9%

Based on performance of 11,764 procedures in FY 2009, Gaston Memorial Hospital performed only 1,471 procedures per room (11,764 / 8 = 1,471) which is below the minimum utilization threshold of 1,500 GI endoscopy procedures per room. A decrease of 4,709 GI procedures at Gaston Memorial Hospital will result in a utilization rate of 882 procedure per room ((11,764 – 4,709) / 8 = 882), which is nearly half of the minimum threshold of 1,500 GI endoscopy procedures per room, not including the two CON approved GI endoscopy rooms that Gaston Memorial Hospital will be developing in 2011.

Furthermore, GGC provided no basis for assuming that patients from Cleveland County would travel to its facility in Gaston County for GI endoscopy services given there are three licensed facilities with 9 GI endoscopy rooms in Cleveland County.

GGC did not adequately identify the population to be served and fails to adequately demonstrate the need of the population for two GI endoscopy rooms.

(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.

In Section III.9 of the application, GGC describes four alternatives. However, GGC's first reason for developing the two GI procedure rooms is that "the proposed project fulfills an unmet need in Gaston County." However, Gaston Memorial Hospital performed 11,764 GI endoscopy procedures in its eight GI endoscopy procedure rooms in FY2009, which is an average of 1,471 GI procedures per room and is below the minimum operating threshold of 1,500 procedures per room. Therefore, Gaston Memorial Hospital is not currently operating at capacity and no unmet need exists in Gaston County. See Criterion (3) for additional discussion.

Further, the application is not conforming to all other applicable statutory and regulatory review criteria. See discussion in Criteria (3), (4), (5), (6), (8), (18a) and "*Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in*

Licensed Health Service Facilities" in 10A NCAC 14C .3900. In summary, GGC fails to adequately demonstrate that its proposal is an effective alternative.

(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.

In the financial pro forma section of the application, GGC states the proposed average charge to patients for all procedures will be $710 per procedure in each of the first three years of the project. GGC projects in Form B, Income Statement, it will realize revenue in excess of expenses in each of the first three years of operation. However, the costs and revenues are not based on reasonable assumptions regarding the projected number of procedures to be performed. See Criterion (3) for discussion. Furthermore, the pro forma financial statements include errors in several expense calculations.

The following table highlights several of the errors:

Expense	Basis	Source	2012	2013	2014
Medical Supplies	$31 per procedure inflated 3% per year x # of procedures	Form B	$134,788	$167,536	$176,464
		GMH Calculation	$31 x 4,324 = **$134,044**	($31 x 1.03) x 4,784 = **$152,753**	($31 x 1.03 x 1.03) x 4,975 = **$163,617**
Other Purchased Services	Year 1 expense inflated 2% annually	Form B	$27,030	$30,797	$32,990
		GMH Calculation	**$27,030**	$27,030 x 1.02 = **$27,571**	$27,030 x 1.02 x 1.02 = **$28,122**
Legal Fees	Year 1 expense inflated 0% in Year 2 and 5% in Year 3	Form B	$5,000	$5,000	$5,250
		GMH Calculation	**$5,000**	$5,000 x 1.00 = **$5,000**	$5,000 x 1.00 x 1.05 = **$5,500**
Property Taxes and Licenses	Year 1 expense inflated 11% in Year 2 and 7% in Year 3	Form B	$35,000	$36,400	$37,856
		GMH Calculation	**$35,000**	$35,000 x 1.11 = **$38,850**	$35,000 x 1.11 x 1.07 = **$41,569**
Interest Expense for Project Capital Costs	Debt Amortization Schedule	Form B	$126,227	$147,155	$118,773
		Debt Amortization Schedule	**$171,810**	**$147,155**	**$118,773**

The error in Interest Expense for Project Capital Costs alone would result in the facility losing over $40,000 in the first year. This error results in at least a 12-month initial operating period where revenues do not cover expenses; thus GGC has not projected adequate working capital for the project.

Therefore, projected costs and revenues are unsupported and unreliable.

GGC has not demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues.

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

Based on 2009 data in the 2010 Hospital License Renewal Application, the eight GI endoscopy procedure rooms at Gaston Memorial Hospital were underutilized. The following table shows the number of GI procedures performed by Gaston Memorial Hospital as reported on its last three annual Hospital License Renewal Applications:

FY Year	Number of Procedures	Procedures/ Room	Percent Increase of Procedures
FY 2007	11,343	1,418	
FY 2008	11,654	1,457	2.7%
FY 2009	11,764	1,471	0.9%

Based on performance of 11,764 procedures in FY 2009, Gaston Memorial Hospital performed only 1,471 procedures per room (11,764 / 8 = 1,471) which is below the minimum utilization threshold of 1,500 GI endoscopy procedures per room. A decrease of 4,709 GI procedures at Gaston Memorial Hospital will result in a utilization rate of 882 procedure per room ((11,764 – 4,709) / 8 = 882), which is nearly half of the minimum threshold of 1,500 GI endoscopy procedures per room, not including the two CON approved GI endoscopy rooms that Gaston Memorial Hospital will be developing in 2011.

GGC fails to adequately demonstrate the need for the proposed GI endoscopy rooms in Gaston County. See Criterion (3) for discussion. Consequently, GGC fails to adequately demonstrate that its proposed project will not result in unnecessary duplication of existing or approved health service capabilities and facilities.

(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.

In Section V.2, GGC identifies Gaston Memorial Hospital as the facility with which the ambulatory surgical facility will have an agreement for patient transfer if additional medical support is needed. In Section V.2.(b), GGC references Exhibit 9 for correspondence to and from the hospital to document GGC's efforts to obtain a commitment to establish a patient transfer agreement. However, Exhibit 9 contains a letter from GGC to Gaston Memorial Hospital dated September 22, 2010 and an unsigned letter drafted by GGC to appear that Gaston Memorial Hospital's acceptance of the transfer agreement. When in fact, Gaston Memorial Hospital responded to GGC's September 22, 2010 letter on October 21, 2010 and clearly indicated that Gaston Memorial Hospital had "no intention of signing a written transfer agreement with the proposed facility." This letter is attached to these comments.

Consequently, GGC fails to adequately demonstrate that all necessary ancillary and support services will be available.

(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.

GGC fails to adequately demonstrate that its proposal will have a positive impact upon the cost effectiveness and quality of the proposed services. See Criteria (3), (4), (5), (6), and (8) for discussion.

(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.

SECTION .3900 - CRITERIA AND STANDARDS FOR GASTROINTESTINAL ENDOSCOPY PROCEDURE ROOMS IN LICENSED HEALTH SERVICE FACILITIES

10A NCAC 14C .3902 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information:

(1) the counties included in the applicant's proposed service area, as defined in 10A NCAC 14C .3906;

GGC identifies Gaston County as the origin of 95% of the facility's procedures, but fails to reasonably explain how it is not duplication existing services when it plans to shift approximately 50% of the GI procedures performed at Gaston Memorial Hospital to the proposed GGC.

(b) An applicant proposing to establish a new licensed ambulatory surgical facility for provision of GI endoscopy procedures shall submit the following information:

(1) a copy of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay;

GGC refers to Exhibit 17, the first page of the Governing Board, Medical Staff Bylaws, Rules and Regulations; however, the first page includes no description of prohibiting the exclusion of services. Furthermore, page 6 of the Medical Staff Bylaws includes the prohibition of exclusion from becoming a member of the medical staff, but not the prohibition of exclusion of services to patients.

(4) a written description of patient selection criteria including referral arrangements for high-risk patients;

GGC refers to Exhibit 16 for the patient selection criteria. Exhibit 16 includes three policies 3.1, 3.2, and 3.3 which highlight the indicators and contra indicators for the procedures proposed to be performed at GGC; however, none of the policies discusses the referral arrangements for high-risk patients.

10A NCAC 14C .3903 PERFORMANCE STANDARDS

(b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI endoscopy procedures only per GI endoscopy room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project.

GGC did not adequately demonstrate that the number of GI endoscopy procedures it projects to perform during year two is reasonable.

(e) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop an additional GI endoscopy room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in this Rule.

GGC fails to adequately describe all assumptions and the methodology used for each projection in this Rule. See Criterion 3 for the discussion of the lack of assumptions and methodology for the projected number of procedures to be performed.

10A NCAC 14C .3904 SUPPORT SERVICES

(a) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of an agreement between the applicant and a pathologist for provision of pathology services.

GGC refers to Exhibit 8 for the pathologist agreement; however, Exhibit 8 only includes a letter "expressing a willingness to provide pathology professional services."

(d) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide:

(2) documentation of an agreement to transfer and accept referrals of GI endoscopy patients from a hospital where physicians utilizing the facility have practice privileges; and

GGC did not contain a copy of a transfer agreement with a hospital or an agreement to transfer and accept referrals of GI endoscopy patients from a hospital.

(3) documentation of a transfer agreement with a hospital in case of an emergency.

Although GGC states that a transfer agreement with a hospital in case of an emergency is provided in Exhibit 9, there is no copy of a transfer agreement in Exhibit 9 or any other section of the application.

10A NCAC 14C .3905 STAFFING AND STAFF TRAINING

(d) If the facility is not accredited by The Joint Commission on Accreditation of Healthcare Organizations, The Accreditation Association for Ambulatory Health Care, or The American Association for Accreditation of Ambulatory Surgical Facilities at the time the application is submitted, the applicant shall demonstrate that each of the following staff requirements will be met in the facility:

(1) a Medical director who is a board certified gastroenterologist, colorectal surgeon or general surgeon, is licensed to practice medicine in North Carolina and is directly involved in the routine direction and management of the facility;

GGC refers to Exhibit 34 for the Medical Director letter. The agreement in Exhibit 34 call for Co-Medical Directors and the pro forma financial statements to include expenses for two medical directors; however, only one medical director letter is included in Exhibit 34 from Dr. William Watkins, the medical director letter from Dr. Sam Drake is not included in the exhibit.

10A NCAC 14C .3906 FACILITY

(4) document that the applicant owns or otherwise has control of the site on which the proposed facility or GI endoscopy rooms will be located.

GGC refers to Exhibits 2 and 32 for "letters of availability," however; the rule requires documentation of ownership or control of the site. Neither proposed location has either a signed lease agreement or a signed agreement guaranteeing a lease if the CON is approved. As such GGC has fails to document either that it owns or controls the proposed sites.

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People at average risk

The American Cancer Society believes that preventing colorectal cancer (and not just finding it early) should be a major reason for getting tested. Finding and removing polyps keeps some people from getting colorectal cancer. Tests that have the best chance of finding both polyps and cancer are preferred if these tests are available to you and you are willing to have them.

Beginning at age 50, both men and women at *average risk* for developing colorectal cancer should use one of the screening tests below:

Tests that find polyps and cancer

- Flexible sigmoidoscopy every 5 years*
- Colonoscopy every 10 years
- Double-contrast barium enema every 5 years*
- CT colonography (virtual colonoscopy) every 5 years*

Tests that mainly find cancer

- Fecal occult blood test (FOBT) every year*,**
- Fecal immunochemical test (FIT) every year*,**
- Stool DNA test (sDNA), interval uncertain*

**Colonoscopy should be done if test results are positive.*
***For FOBT or FIT used as a screening test, the take-home multiple sample method should be used. An FOBT or FIT done during a digital rectal exam in the doctor's office is not adequate for screening.*

In a *digital rectal examination (DRE)*, a doctor examines your rectum with a lubricated, gloved finger. Although a DRE is often included as part of a routine physical exam, it is not recommended as a stand-alone test for colorectal cancer. This simple test, which is not usually painful, can detect masses in the anal canal or lower rectum. By itself, however, it is not a good test for detecting colorectal cancer due to its limited reach.

Doctors often find a small amount of stool in the rectum when doing a DRE. However, simply checking stool obtained in this fashion for bleeding with an FOBT or FIT is not an acceptable method of screening for colorectal cancer. Research has shown that this type of stool exam will miss more than 90% of colon abnormalities, including most cancers.

People at increased or high risk

If you are at an increased or high risk of colorectal cancer, you should begin colorectal cancer screening before age 50 and/or be screened more often. The following conditions place you at higher than average risk:

- A personal history of colorectal cancer or adenomatous polyps
- A personal history of inflammatory bowel disease (ulcerative colitis or Crohn's disease)
- A strong family history of colorectal cancer or polyps (see "Risk factors for colorectal cancer")
- A known family history of a hereditary colorectal cancer syndrome such as familial adenomatous polyposis (FAP) or hereditary non-polyposis colon cancer (HNPCC)

The table below suggests screening guidelines for those with *increased or high risk* of colorectal cancer based on specific risk factors. Some people may have more than one risk factor. Refer to the table below and discuss these recommendations with your

doctor. Based on your situation, your doctor can suggest the best screening option for you, as well as any changes in the schedule based on your individual risk.

American Cancer Society Guidelines on Screening and Surveillance for the Early Detection of Colorectal Adenomas and Cancer in People at Increased Risk or at High Risk			
Risk Category	**Age to Begin**	**Recommended Test(s)**	**Comment**
INCREASED RISK – Patients With a History of Polyps on Prior Colonoscopy			
People with small rectal hyperplastic polyps	Same as those at average risk	Colonoscopy, or other screening options at same intervals as for those at average risk	Those with hyperplastic polyposis syndrome are at increased risk for adenomatous polyps and cancer and should have more intensive follow-up.
People with 1 or 2 small (less than 1 cm) tubular adenomas with low-grade dysplasia	5 to 10 years after the polyps are removed	Colonoscopy	Time between tests should be based on other factors such as prior colonoscopy findings, family history, and patient and doctor preferences.
People with 3 to 10 adenomas, or a large (1 cm +) adenoma, or any adenomas	3 years after the polyps are removed	Colonoscopy	Adenomas must have been completely removed. If colonoscopy is normal or shows only 1 or 2 small

with high-grade dysplasia or villous features			tubular adenomas with low-grade dysplasia, future colonoscopies can be done every 5 years.
People with more than 10 adenomas on a single exam	Within 3 years after the polyps are removed	Colonoscopy	Doctor should consider possibility of genetic syndrome (such as FAP or HNPCC).
People with sessile adenomas that are removed in pieces	2 to 6 months after adenoma removal	Colonoscopy	If entire adenoma has been removed, further testing should be based on doctor's judgment.
INCREASED RISK – Patients With Colorectal Cancer			
People diagnosed with colon or rectal cancer	At time of colorectal surgery, or can be 3 to 6 months later if person doesn't have cancer spread that can't be removed	Colonoscopy to view entire colon and remove all polyps	If the tumor presses on the colon/rectum and prevents colonoscopy, CT colonoscopy (with IV contrast) or DCBE may be done to look at the rest of the colon.
People who have had colon or rectal cancer removed by surgery	Within 1 year after cancer resection (or 1 year after colonoscopy to make sure	Colonoscopy	If normal, repeat exam in 3 years. If normal then, repeat exam every 5 years. Time between tests may be

	the rest of the colon/rectum was clear)		shorter if polyps are found or there is reason to suspect HNPCC. After low anterior resection for rectal cancer, exams of the rectum may be done every 3 to 6 months for the first 2 to 3 years to look for signs of recurrence.
INCREASED RISK – Patients With a Family History			
Colorectal cancer or adenomatous polyps in any first-degree relative before age 60, or in 2 or more first -degree relatives at any age (if not a hereditary syndrome).	Age 40, or 10 years before the youngest case in the immediate family, whichever is earlier	Colonoscopy	Every 5 years.
Colorectal cancer or adenomatous polyps in any first-degree relative aged 60 or older, or in at least 2 second-degree relatives at any age	Age 40	Same options as for those at average risk	Same intervals as for those at average risk.
HIGH RISK			

Familial adenomatous polyposis (FAP) diagnosed by genetic testing, or suspected FAP without genetic testing	Age 10 to 12	Yearly flexible sigmoidoscopy to look for signs of FAP; counseling to consider genetic testing if it hasn't been done	If genetic test is positive, removal of colon (colectomy) should be considered.
Hereditary non-polyposis colon cancer (HNPCC), or an increased risk of HNPCC based on family history without genetic testing	Age 20 to 25 years, or 10 years before the youngest case in the immediate family	Colonoscopy every 1 to 2 years; counseling to consider genetic testing if it hasn't been done	Genetic testing should be offered to first-degree relatives of people found to have HNPCC mutations by genetic tests. It should also be offered if 1 of the first 3 of the modified Bethesda criteria is met.1
Inflammatory bowel disease -Chronic ulcerative colitis -Crohn's disease	Cancer risk begins to be significant 8 years after the onset of pancolitis (involvement of entire large intestine), or 12 to 15 years after the onset of left-sided colitis	Colonoscopy every 1 to 2 years with biopsies for dysplasia	These people are best referred to a center with experience in the surveillance and management of inflammatory bowel disease.

1The Bethesda criteria can be found in the "Can colorectal cancer be prevented?" section of our larger Colorectal Cancer document.

Last Medical Review: 02/22/2010
Last Revised: 02/22/2010

CaroMont Health
Gaston Memorial Hospital

October 21, 2010

Via Facsimile: 704-866-9824
Nicole Semeraro
Greater Gaston Center, LLC
2451 Aberdeen Blvd., Ste A
Gastonia, NC 28054

Re: CON #ID No.: 006738-008602-F

Dear Ms. Semeraro:

I am writing to you on behalf of Gaston Memorial Hospital, a wholly owned subsidiary of CaroMont Health. We are in receipt of your letter dated September 21, 2010 requesting our support of the Greater Gaston Center's CON application and request to enter into a transfer agreement. Please be advised that we do not support your company's CON application and intend to vigorously oppose it. In addition, we have no intention of signing a written transfer agreement with the proposed facility.

Should you have any questions regarding this letter, please do not hesitate to contact me directly.

Very truly yours,

Jeffrey K. Hester

cc: Valinda Rutledge, CEO, CaroMont Health
Maria W. Long, VP General Counsel, CaroMont Health