ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

DECISION DATE: September 27, 2013

PROJECT ANALYST: Tanya S. Rupp TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: N-10147-13 / Southeastern Regional Medical Center, Inc. d/b/a/

Southeastern Ambulatory Surgery Center, LLC / Change in Scope for Project ID# N-8716-11 (relocate 4 ORs to a new ambulatory surgical facility) by relocating two GI endoscopy procedure rooms as well /

Robeson

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.

NA

Southeastern Regional Medical Center, Inc. (SRMC) operates an acute care hospital located in Lumberton, in Robeson County, which is licensed for 292 acute care beds and five gastrointestinal endoscopy (GI Endo) procedure rooms and offers emergency, hospice, nursing, imaging, and other services. Effective January 24, 2012, SRMC was issued a certificate of need (CON) for Project I.D. #N-8716-11 to relocate four existing shared operating rooms from Southeastern Regional Medical Center to develop a new, separately-licensed ambulatory surgical facility (ASC), Southeastern Ambulatory Surgery Center, LLC with four ambulatory surgical operating rooms, two minor procedure rooms, one YAG laser room, 23 pre/post – operative rooms, central sterile services, and other support space, for a total capital cost of \$13,761,923.

The applicants submit this current application, Project I.D. #N-10147-13, to request approval for a change in scope from the previously approved application. The applicants propose to eliminate one of the minor procedure rooms and the YAG laser room from the proposed ASC; to increase pre- and post-operative rooms from 23 to 26; to relocate two

gastrointestinal endoscopy (GI endo) procedure rooms from SRMC to Southeastern Ambulatory Surgery Center (SASC), and to de-license two of the remaining GI endoscopy rooms at SRMC. Furthermore, the applicants now project the capital cost to be \$13,523,527, which is a reduction of 1.8%, or \$238,396.

The applicants do not propose add any new health services or acquire any equipment for which there is a need determination in the 2013 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2013 SMFP that are applicable to this review. Furthermore, there are no policies in the 2013 SMFP that are applicable to this review. Consequently, this criterion is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

 \mathbf{C}

Effective January 24, 2012, SRMC was issued a CON for Project I.D. #N-8716-11 to relocate four existing shared operating rooms from Southeastern Regional Medical Center to develop a new, separately-licensed ambulatory surgical facility, Southeast Ambulatory Surgery Center, in a new building to be constructed at 4901 Dawn Drive in Lumberton. According to the applicants in Section II, page 16 of this application, the original ASC was to be constructed to provide the following services:

- Four ambulatory surgical operating rooms, relocated from SRMC
- One multi-purpose room to accommodate pain management and minor procedures
- One cystoscopy room
- One YAG laser room¹
- 23 pre and post-operative rooms
- Area for central sterile services
- Other surgical support space

This CON application is for a change in scope of the original application. In Section II.1, page 16, the applicants state:

"...ongoing planning for the ASC has resulted in the elimination of the cystoscopy room and the YAG laser room from the current plans as those procedures can more effectively be performed in locations other than dedicated rooms in the ASC. ... As an additional change in the scope of the previously approved project and the subject of

¹ YAG laser refers to Yttrium-aluminum-garnet laser, which is used in some eye surgeries and other minor outpatient procedures.

this application, SRMC proposes to relocate two GI endoscopy rooms from the medical center to the previously approved ASC. Given the addition of endoscopy services to the previously approved ASC, the number of pre/ post-operative rooms will increase to 26"

The applicants state that SASC will still be constructed on the same site that was approved in the original application; however, the design footprint will be reduced from 22,780 originally approved square feet to 15,845 square feet as proposed in this application. In addition, the previously approved capital cost of \$13,761,923 is now projected to be \$13,523,527, or a reduction of 1.8% (\$238,396). The applicants state on page 16 that the reduction in square feet will provide for more efficient operation of SASC.

Population to be Served

In Section III.6, page 39 of the application, the applicants project the following patient population will be served by SASC:

County	PROJECTED Pts. Year 1	% OF TOTAL Pts. Year 1	PROJECTED PTS. YEAR 2	% OF TOTAL PTS. YEAR 2
Robeson	2,702	91.4%	2,745	91.4%
Bladen	156	5.3%	158	5.3%
Columbus	45	1.5%	46	1.5%
Cumberland	18	0.6%	18	0.6%
Scotland	4	0.1%	4	0.1%
Hoke	3	0.1%	3	0.1%
Other*	31	1.0%	31	1.0%
Total	2,958	100.0%	3,005	100.0%

^{*}The applicants state "Other" includes Ashe, Brunswick, Durham, Gates, Harnett, Johnston, Moore, New Hanover, Onslow, Richmond, and Sampson counties in North Carolina and other states.

On page 39, the applicants state the projected population to be served is based on SRMC historical data, adjusted to reflect those patients who will utilize the GI endoscopy services proposed in this application.

The applicants adequately identify the population proposed to be served by the addition of two outpatient GI endoscopy rooms to SASC.

Demonstration of Need

In Section III.1, pages 27 - 36 of the application, the applicants discuss the need for the change in scope of the previously approved project; specifically, the need the population to be served has for the GI endoscopy procedure rooms to be relocated from SRMC to SASC. On page 27, the applicants state:

"The unmet need for the proposed project is based on the following factors:

Need to provide GI endoscopy services at the previously approved ASC in

- order to provide high quality, lower cost, and improved access to these specialty procedures;
- Potential for physician collaboration in order to avoid duplication of services."

In addition, the applicants state that providing GI endoscopy services at SASC, rather than as an outpatient service at the hospital, will improve the quality of GI endoscopy services provided to patients, improve efficiency of operations, and lower the cost to the patient for the services. Each of these factors is discussed below.

Improve quality of GI endoscopy services

In Section III.1, pages 27 - 28, the applicants state:

"The ASC will be dedicated to outpatient endoscopy and surgical procedures. Patients will benefit from the improved quality of care that is inherent in such a facility where physicians, nurses, and staff are dedicated to these special procedures. Because each procedure performed in the two endoscopy rooms will be an endoscopy or related procedure, the rooms will always be equipped with the proper instruments, scopes, and tools for these special procedures. Nurses, technicians, and other staff at the facility will be efficient at assisting in, and caring for patients having, these procedures. Further, the ASC setting will decrease risk to the patient as it will remove outpatients from an inpatient facility, where higher acuity inpatients pose greater infection risks to the less acute outpatients."

<u>Improve efficiency of operations</u>

In Section III.1, pages 28 - 29, the applicants describe how the provision of GI endoscopy services at SASC will not only improve operational efficiency for the patients and provider, but will also provide more specialized services, thereby improving the experience and quality of care for the patient. On page 28, the applicants state:

"The outpatient facility setting with two endoscopy procedure rooms and preparation and recovery bays will allow physicians to perform a maximum number of procedures with improved patient throughput. Procedure schedules at the ASC will be more reliable because they are not subject to delays associated with emergencies or long, complicated inpatient procedures.

... Southeastern Ambulatory Surgery Center will have a more intimate setting designed specifically for outpatients and their needs. SRMC physicians believe that performing endoscopy procedures in an outpatient facility has a psychological benefit to patients. Patients arrive at an outpatient facility with the intention that they will be discharged at the end of the day. As such, they are mentally prepared to go home the same day. Conversely, being treated in an inpatient hospital setting can change a patient's psychological approach to his or her procedure and often results in patients being hesitant to be discharged."

In Section III.1, pages 28 - 30, the applicants discuss the benefit of providing GI endoscopy procedures at SASC within the context of lowering the cost to patients. On page 28, the applicants state:

"... Because the procedure is not performed in a facility that is hospital-based (i.e., billed under the hospital license), patients and payors do not incur charges associated with hospital-based care. As such, the relocation of GI endoscopy rooms to the ASC will enable the introduction of a separate charge schedule, which as a separately licensed freestanding facility will be lower than the existing hospital-based schedule. The change to the charge structure that will result from the proposed conversion of two existing endoscopy rooms from hospital-based to freestanding services will equate to significant cost savings to the healthcare system as a whole."

Furthermore, on page 29, the applicants provide a bar graph that depicts the lower Medicare coinsurance rates paid by patients in an ASC versus an outpatient hospital setting, for several types of outpatient procedures, including GI endoscopy procedures. The graph shows that in an ASC setting, a Medicare beneficiary could pay nearly twice as much coinsurance to a hospital than he or she would to an ASC for a basic colonoscopy.

In addition, in Section III.1, on pages 30 - 31, the applicants describe the benefits of providing GI endoscopy services in the Southeastern Ambulatory Surgery Center in terms of physician collaboration. On page 30, the applicants state:

"...As hospitals and physicians continue to face their own unique challenges in the ever-changing healthcare marketplace, collaboration can offer benefits for both parties. While historically, hospitals and physicians have worked with each other independently, over time such arrangements have come to be associated with rising healthcare costs, uncoordinated care, duplication of services, and inadequate patient access. ... A report released by PricewaterhouseCoopers found that two-thirds of physicians surveyed indicated that hospitals need physicians to reduce inpatient costs, signaling a need for better collaboration and care management. By partnering with a larger hospital system, joint ventures help physicians realize greater cost savings and greater control over operations.

... Through this relationship, cost savings and increased quality and access are passed on to the patient."

The applicants adequately demonstrate the need to relocate two existing GI endoscopy procedure rooms from SRMC to SASC.

Projected Utilization

In Section III.1(b), on pages 31 - 36 of the application, the applicants project utilization of the two GI endoscopy procedure rooms proposed in this application to be relocated to SASC, based upon the historical utilization of GI endoscopy procedure rooms at SRMC. On page 32, the applicants state:

"Since Federal Fiscal Year (FFY) 2009, outpatient GI endoscopy procedures at SRMC have grown 2.8 percent annually and inpatient cases have grown 4.4 percent annually. ... GI endoscopy procedures at SRMC overall have outpaced population growth in Robeson County."

Citing information from the hospital license renewal applications (LRAs) and the North Carolina State Office of Budget and Management, the applicants provide a table to compare historical population growth in Robeson County and GI endoscopy procedure utilization. See the following table, reproduced by the analyst:

SRMC	FFY 2009	FFY 2010	FFY 2011	FFY 2012	CAGR*
Inpatient GI Endoscopy Cases	701	922	749	799	4.4%
Outpatient GI Endoscopy Cases	3,033	2,833	3,019	3,294	2.8%
Total GI Endoscopy Cases	3,734	3,755	3,768	4,093	3.1%
Robeson County Population	133,162	134,422	134,216	134,433	0.3%

^{*}Compound Annual Growth Rate

On page 32 the applicants state that one case equals one patient.

In addition, effective December 17, 2009, a certificate of need was issued to Robeson Digestive Diseases, Inc., operated by Dr. Gregory Locklear, to develop an ambulatory surgical facility with two GI endoscopy procedure rooms in Lumberton. Dr. Locklear also performs GI endoscopy procedures at his office and at SRMC. In projecting future utilization of the number of GI endoscopy procedures to be performed at SASC, the applicants state on page 32:

"SRMC expects that most of its existing outpatient cases will shift to Southeastern Ambulatory Surgery Center, with the exception of cases historically performed by Dr. Gregory Locklear. ... SRMC has excluded the estimated 1,210 outpatient GI endoscopy cases performed by Dr. Locklear at SRMC in FFY 2012 from its future projections. ... SRMC assumes that outpatient cases, excluding Dr. Locklear's cases, and inpatient cases will grow at their historical annual growth rates, 2.8 and 4.4 percent respectively."

In addition, on page 33, the applicants state that the hospital projects to continue to serve in excess of 1,500 patients/cases per year in the other remaining GI endoscopy room following the relocation of the two GI endoscopy procedure rooms to SASC, and the de-licensing of two GI endoscopy procedure rooms at the hospital.

Furthermore, on page 33, the applicants state:

"Southeastern Ambulatory Surgery Center is expected to become operational on October 1, 2014 and, therefore, the first full fiscal year of the project is FFY 2015. When the facility opens, SRMC assumes that 75 percent of its existing outpatient GI endoscopy cases (excluding Dr. Locklear's) will shift to Southeastern Ambulatory Surgery Center based on internal discussions among administration and clinical leadership. SRMC conservatively assumes that 25 percent of its outpatient cases will remain at the medical center due to complications and patient or physician preference.

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In addition to the expected shift of volume from SRMC, Southeastern Ambulatory Surgery Center expects to serve some of the GI endoscopy patients that are currently leaving the county for care at other licensed freestanding GI endoscopy centers...."

On page 33, the applicants provide a table to illustrate the proposed shift in volume from SRMC to SASC, as described above. See the following table:

	FFY 2012	FFY 2013	FFY 2014	FFY 2015	FFY 2016	FFY 2017
Inpatient Cases	799	834	871	910	951	993
Outpatient Cases	2,084	2,142	2,202	2,264	2,327	2,392
% Outpatient Cases to Shift				75%	75%	75%
Outpatient Cases Shifted to CASC				1,698	1,745	1,794
Outpatient Cases Remain at SRMC				566	582	598
Total SRMC Cases				1,476	1,532	1,591

On pages 33 - 34, the applicants discuss the impact SASC with two GI endoscopy rooms will have on the trend of outmigration to surrounding counties for GI endoscopy services. The applicants researched the utilization in licensed, freestanding outpatient GI endoscopy centers in which Robeson County residents seek GI endoscopy services. Following is a table, reproduced from application page 34 that illustrates the outmigration:

FACILITY	FFY 2009	FFY 2010	FFY 2011	FFY 2012	CAGR
Fayetteville Gastroenterology Associates, PA	518	1,665	924	886	19.6%
Pinehurst Medical Clinic Endoscopy Center	507	475	492	460	-3.2%
Fayetteville Ambulatory Surgery Center	102	141	76	69	-12.2%
Cape Fear Center for Digestive Diseases	0*	NA*	309	265	NA
Subtotal	1,127	2,281	1,801	1,680	14.2%

^{*}The applicants state this facility was not operational in FFY 2009. Furthermore, the 2011 LRA does not provide the number of cases by county.

The applicants state on page 34 that it selected the "primary" outpatient facilities at which Robeson County patients sought GI endoscopy services in the years reflected in the table. The applicants state:

"Per the 2012 Ambulatory Surgical Facility License Renewal database (for 2011 data), maintained by the Medical Facilities Planning Section, 1,837 patients in total from Robeson County received GI endoscopy services at licensed freestanding GI

endoscopy centers outside of the county. The remaining 36 cases not accounted for in the FF1 2011 volumes in the table above were served by 14 other centers across the state...."

The analyst also looked at the LRAs and was able to verify the data presented in the table. Based on the number of GI endoscopy patients receiving services in Robeson County and the number of patients leaving to obtain GI endoscopy services at an outpatient facility in a neighboring county, the applicants state on page 34:

"Upon relocation of the two GI endoscopy rooms from SRMC to the ASC, Southeastern Ambulatory Surgery Center assumes that it will serve 75 percent of the 1,680 outpatient GI endoscopy cases currently provided by licensed freestanding GI endoscopy centers in other counties and conservatively projects that volume to remain constant"

Thus, the applicants project 1,260 out-of-county patients/procedures per year to shift from SRMC to SASC in the first three project years $(1,680 \times 0.75 = 1,260)$.

Combining the number of GI endoscopy cases expected to shift from SRMC and the number of out-of-county cases, the applicants project to perform the following GI endoscopy procedures at SASC:

	FFY 2015	FFY 2016	FFY 2017
OP cases shifted from SRMC	1,698	1,745	1,794
OP cases shifted from non-Robeson County providers	1,260	1,260	1,260
Total	2,598	3,005	3,054

Therefore, in the second and third project years, the applicants project to perform 3,005 procedures and 3,054 procedures, respectively.

As stated above, the applicants project the number of outpatients who will shift from out-of-county providers to SASC based on 75% of SRMC's FFY 2012 utilization. Furthermore, the applicants keep that number constant through FFY 2017, despite a 14.2% CAGR in procedures from FFY 2009 to FFY 2012. If the applicants had grown the number of cases projected to shift from out-of-county providers, then the total number of cases would likewise increase. Thus, projections that are based on a flat growth of out-of-county cases are reasonable.

In Section VI.14, page 62, the applicants demonstrate that the projected GI endoscopy payor mix at SASC will mirror the current, relevant outpatient GI endoscopy payor mix at SRMC, with 59.5% Medicare and Medicaid and 5% "Self-pay/Indigent/Workers Comp and Other Government Payors".

The applicants adequately demonstrate that it will perform 3,005 GI endoscopy procedures in the two GI endoscopy rooms in the second operating year, which is an average of 1,502.5

procedures per room [3,005 procedures/2 rooms = 1,505.2 procedures/room]. Thus, the applicants reasonably demonstrate it will perform at least 1,500 procedures per room as required by 10A NCAC 14C .3903(b).

In summary, the applicants adequately identify the population to be served, demonstrate the need for the proposed services, and commit to equal access for all patients, including underserved groups. 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.

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The applicants propose to relocate two of SRMC's five existing GI endoscopy rooms from the hospital's main campus to a previously approved ASC. According to MapQuest[®], the ASC will be located approximately 3.5 miles from SRMC; therefore, although the GI endoscopy rooms are being relocated, the relocation is in the same town and within 3.5 miles from the current location. Thus, there is little, if any, additional burden on patients who are accustomed to receiving GI endoscopy services at SRMC. In fact, the relocated GI endoscopy rooms will enable the applicants to serve patients who desire and are able to receive GI endoscopy services on an outpatient basis.

The applicants state in Section III, pages 32 – 35 of the application, that most of the patients who will be served at SASC represent a projected shift of existing patients from SRMC's main campus to the outpatient ASC, thereby providing these patients easier and more cost-effective access to services. In addition, on page 33, the applicants project that some patients who currently leave Robeson County for GI endoscopy services in outpatient facilities will also shift to SASC, since those services will now be offered on a lower-cost outpatient basis.

Furthermore, in Section III, pages 32-35, the applicants have shown that there will continue to be sufficient GI endoscopy capacity in Robeson County, even after SRMC relocates the two rooms to SASC and de-licenses two more rooms at SRMC. In Section III, page 33, the applicants also show that the relocation of two GI endoscopy rooms to SASC will not result in overutilization of the one remaining room at SRMC. The applicants adequately demonstrate that GI endoscopy patients who will continue to use GI endoscopy services at SRMC will not be adversely affected by the relocation of two GI endoscopy rooms to SASC, and the de-licensing of two additional GI endoscopy rooms at SRMC. Consequently, the application is conforming to this criterion.

(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.8, pages 40 - 42, the applicants describe several alternatives it considered prior to submitting this change of scope application, which include:

- 1) Maintain the Status Quo continue to develop the project as it was approved in Project ID # N-8716-11. The applicants state that alternative does not propose the most efficient use of resources for patients, and does not propose cost-effective services, particularly GI endoscopy services, for SRMC patients. Furthermore, the applicants state to maintain the status quo and develop the project as previously approved is inconsistent with SRMC's current Master Facility Plan, which involves relocating some outpatient services to a smaller outpatient campus.
- 2) Develop a new, separately licensed GI endoscopy center and leave the SASC project to be developed as previously approved. The applicants state that to develop a separate new ASC for the GI endoscopy rooms would not be a cost effective alternative. Adding the GI endoscopy procedure rooms to the previously approved SASC is a more efficient alternative, as it will share pre- and post-operative spaces.
- Relocate outpatient GI endoscopy services to SASC The applicants determined that this was the most effective alternative because SASC will be dedicated to outpatient surgical and endoscopy procedures with the patient in mind. The patient experience will be more efficient and less costly than performing outpatient surgical and GI endoscopy procedures in a hospital setting.

The applicants adequately demonstrate that the proposal to relocate two GI endoscopy rooms to SASC is its least costly or most effective alternative to meet the need for additional capacity at SRMC now and in the near future. The application is conforming to all applicable statutory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Southeastern Regional Medical Center d/b/a Southeastern Ambulatory Surgery Center shall materially comply with the representations made in this certificate of need application, Project ID# N-10147-13, and the certificate of need application Project ID# N-8716-11 as amended by this project. In those instances in which representations conflict, Southeastern Regional Medical Center d/b/a Southeastern Ambulatory Surgery Center shall materially comply with the last made representation.
- 2. Southeastern Regional Medical Center d/b/a Southeastern Ambulatory Surgery 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.

- 3. The average facility fee charged by Southeastern Ambulatory Surgery Center shall be no more than \$2,212 in Project Year One, \$2,267 in Project Year Two, and \$2,324 in Project Year Three.
- 4. Southeastern Regional Medical Center shall be licensed for no more than one (1) GI endoscopy room upon project completion.
- 5. Upon licensure of the two GI endoscopy rooms at SASC, Southeastern Regional Medical Center shall take the necessary steps to de-license four existing GI Endoscopy procedure rooms at SRMC.
- 6. Southeastern Regional Medical Center d/b/a Southeastern Ambulatory Surgery Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to the 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 Project ID #N-8716-11, the applicants were previously approved for a capital cost of \$13,761,923. In this application, the applicants project a capital cost of \$13,523,527, which represents a 1.8% decrease. Therefore, since the capital cost proposed in this change of scope application is lower than the total capital cost amount that was previously approved, the applicants do not need to document the availability of funds for capital and operating needs of the project, or to demonstrate the immediate and long-term financial feasibility of the proposal. However, in Section VII.2, page 74, the applicants provide a table to illustrate the difference in capital cost between the two applications. See the following table:

	PREVIOUSLY	APPROVED (PROPOSED CAPITAL COST		
CATEGORY	SPOB*	SRMC	SASC COST	SRMC	SASC COST
	Cost	Cost		Cost	
Site Costs					
Purchase Price of Land	0	\$140,678	0	\$140,678	0
Closing Costs	0	\$21,000	0	\$21,000	0
Site Preparation Costs	\$630,000	0	0	\$613,371	0

Subtotal Site Costs	\$630,000	\$161,678	0	\$775,049	0
Construction					
Subtotal Construction	\$2,505,800	0	\$2,980,307	\$2,022,139	\$2,731,361
Miscellaneous Project Costs					
Equipment Purchase/Lease	0	0	\$5,096,623	0	\$5,868,455
Architect/Engineering Fees	0	0	\$452,000	0	\$191,008
Legal/Regulatory Fees	0	0	\$35,000	0	\$35,000
Market Analysis	0	0	\$26,000	0	\$26,000
Permits, Appraisals, etc.	0	0	\$35,000	0	\$35,000
Contingency Fees	0	0	\$1,450,515	0	\$1,450,515
Development Expenses/Fees	0	0	\$389,000	0	\$389,000
Subtotal	\$3,135,800	\$161,678	\$10,464,445	\$2,797,188	\$10,726,339
Total Project Capital Cost		\$13,761,923		\$13,5	23,527

In a footnote to the table provided by the applicants in Section VIII.2, on page 74 of the application, the applicants state:

"In the previously approved application, SRMC proposed to lease the site to Southeastern Physician Office Building, LLC through a ground lease, which would in turn lease the building to Southeastern Ambulatory Surgery Center, LLC. However, as proposed in this change in scope, SRMC will own and lease the building to Southeastern Ambulatory Surgery Center, LLC, thereby eliminating Southeastern Physician Office Building, LLC's involvement in the previously approved and proposed projects."

In Section IX.1, page 80, the applicants state the start-up expenses and working capital costs for the change of scope application are \$1,206,753. In the original application, the start-up expenses and working capital costs were projected to be \$1,060,853, which means that in this application the costs are projected to be \$145,900 higher than was originally approved. In Exhibit 18, the applicants provide a June 17, 2013 letter signed by the Chief Financial Officer of SRMC, which confirms the capital costs and the start-up costs and operating expenses reported in Section 8 of the application. Additionally, the letter documents that SRMC has sufficient reserves to fund both the capital cost of \$13,523,527, and the start-up costs and working capital expenses of \$1,206,753.

Below is a table that shows the facility's average charges for the first three project years, as reported by the applicant on page 97.

	OY 1 (FY 2015)	OY 2 (FY 2016)	OY 3 (FY 2017)
Projected Average Charge	\$2,212	\$2,267	\$2,324
Projected Average Reimbursement	\$739	\$757	\$756

The applicants state on page 100, in the Financials section of the application, that the projected average charges are based on "the experience of SRMC, reduced by 35 percent to

account for the lower reimbursement associated with GI endoscopy cases completed in an ASC setting...."

In the projected revenue and expense statement in the *Financials* section of the application, the applicants project that revenues will exceed operating costs in each of the first three operating years.

The following table illustrates the projected revenue and expenses for GI endoscopy services at SASC for each of the first three project years, as reported by the applicants in the financials section of the application.

	FY 2015	FY 2016	FY 2017
	(10/1/14 - 9/30/15)	(10/1/15 - 9/30/16)	(10/1/16 - 9/30/17)
Net Revenue	\$1,667,903	\$1,737,024	\$1,809,344
Expenses	\$1,038,720	\$1,042,798	\$1,050,326
Profit	\$ 629,183	\$ 694,226	\$ 759,018

The assumptions used by the applicants in preparation of the pro formas for projected utilization, costs and charges are based on the applicant's experience providing GI endoscopy services at SRMC. See the Financials Tab of the application for the pro formas and assumptions. The applicants adequately demonstrate that the financial feasibility of the proposal is based on reasonable, credible and supported projections of costs and charges. Therefore, the application is conforming to this criterion.

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

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The original application, Project ID #N-8716-11, was conforming to this criterion. In this application, the applicants propose to relocate two existing GI endoscopy rooms from SRMC to SASC. The proposed relocation of existing GI endoscopy rooms is within the same county. The applicant is not proposing to increase the number of GI endoscopy rooms, nor relocate the rooms out of Robeson County. Thus, the inventory of GI endoscopy rooms in Robeson County will not change, and the population presently served will continue to be served following the relocation. Therefore, 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.2, pages 64 - 65, the applicants state:

"The proposed project involves the transfer of existing endoscopy rooms from SRMC to Southeastern Ambulatory Surgery Center, a wholly owned subsidiary of SRMC. As

such, the service to be provided at the ASC is an existing service at SRMC, with existing staff In fact, it is likely that the projected FTEs are existing employees of SRMC who will cease employment with the medical center and become directly employed by Southeastern Ambulatory Surgery Center upon development of the project."

In Section VII.2, page 64, the applicant provides a table, reproduced below, to illustrate projected staffing for the GI endoscopy services at SASC.

EMPLOYEE CATEGORY	PROJECTED FTES
Administrator	0.2
Registered Nurses	4.0
Nursing Aids	3.0
Scheduler/Non-health Administration	0.4
Medical Record Technician	1.0
Total	8.6

In addition, in Section II, on page 17, the applicant lists seven physicians who have committed to performing GI endoscopy services at SASC. On page 17, the applicant states that all physicians to be associated with SASC will be credentialed, active staff members at SRMC. Furthermore, the applicant states on page 17 that Dr. Harvey Allen, board certified in internal medicine and gastroenterology, will serve as the medical director for endoscopy services at SASC. In exhibit 13, the applicant provides a copy of Dr. Allen's curriculum vitae, and in Exhibit 23, the applicant provides letters of support for the project from area physicians, including Dr. Allen. The applicants adequately document the availability of sufficient health manpower and management personnel to provide the proposed GI endoscopy services at SASC. 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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The original application, Project ID #N-8716-11, was conforming to this criterion and the applicants propose no changes in this current application to affect that determination. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

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The original application, Project ID #N-8716-11, was conforming to this criterion, wherein the applicants proposed to construct 22,780 square feet, to include four ambulatory surgical operating rooms, one minor procedure room, one cystoscopy room, one YAG laser room, 23 pre/post operative rooms, and other support and administrative space. In the current application, the applicants propose construction on the same site that was approved in the original application; however, the applicants propose a decrease in the number of square feet to be constructed and a change in space configuration within the ASC. See the following table, which illustrates the square feet proposed for the ASC:

DEPARTMENT	PROPOSED SF	CONSTRUCTION COST PER SF	TOTAL CONSTRUCTION
			Cost
Administration	950	300.00	\$285,000
Operative Areas*	6,932	300.00	\$2,079,600
Pre-Operative	2,367	300.00	\$710,100
Post-Operative	2,316	300.00	\$694,800
Common Area	3,280	300.00	\$984,000
Total	15,845	300.00	\$4,753,500

In Exhibit 21, the applicant provides a copy of a construction cost estimate signed by a licensed architect that confirms construction costs as noted in Section VIII and in the table above.

In Section XI.8, on page 89, the applicants state that applicable energy savings features will be incorporated into the plans. In Exhibit 10, the applicant provides a document from the same architectural firm that verified construction costs, which provides a detailed accounting of the energy-saving features that will be incorporated into the design of SASC. The applicants adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative for the project they propose, and that the construction costs will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges, which are hereby incorporated as if fully set forth herein. Therefore, the application is conforming to this criterion. The applicants do not propose any additional changes in this current application to affect the previous determination of conformity in Project ID #N-8716-11. Therefore, the application is conforming to this criterion.

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

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The original application, Project ID #N-8716-11, was conforming to this criterion and the applicants propose no changes in this current application to affect that determination. Therefore, the application is conforming to this criterion.

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

 \mathbf{C}

The original application, Project ID #N-8716-11, was conforming to this criterion and the applicants propose no changes in this current application to affect that determination. Therefore, 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

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The following table illustrates the projected payor mix for GI endoscopy services during the second operating year, as reported by the applicant in the financial section of the application, on page 97.

SECOND FULL PROJECT FISCAL YEAR PROJECTED PROCEDURES AS % OF TOTAL			
Self Pay / Indigent / Charity	5.0%		
Medicare	42.8%		
Medicaid	16.7%		
Commercial	13.4%		
Blue Cross / Blue Shield	22.0%		
Total	100.0%		

The original application, Project ID #N-8716-11, was conforming to this criterion and the applicants propose no changes in this current application to affect that determination. Therefore, the application is conforming to this criterion.

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

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The original application, Project ID #N-8716-11, was conforming to this criterion and the applicants propose no changes in this current application to affect that determination. Therefore, the application is conforming to this criterion.

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

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The original application, Project ID #N-8716-11, was conforming to this criterion and the applicants propose no changes in this current application to affect that determination. Therefore, the application is conforming to this criterion.

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

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

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Effective January 24, 2012, SRMC was issued a certificate of need to relocate four existing operating rooms from the hospital to establish a separately licensed ambulatory surgical facility (Southeast Ambulatory Surgery Center).

In this application, the applicants propose to relocate two existing GI endoscopy rooms from the hospital to SASC, and to de-license two GI endo rooms at SRMC. In addition, the applicants propose not to develop the YAG laser room or the cystoscopy room as proposed in the original application. Based on the historical utilization of GI endoscopy services in Robeson County and at SRMC, the applicants project to serve in excess of 1,500 GI endoscopy cases (which the applicants equate with patients) in the second and third project years, as required by 10A NCAC 14C .3903(b).

In Section III.8, on page 42 of the application, the applicants discuss the benefits of offering GI endoscopy services in an outpatient ASC, such as lower cost to the patient and faster throughput. In addition, in Section V.7, on pages 50 - 51, the applicants discuss the positive effect this project will have on competition in the area, since it will offer outpatient GI endoscopy services as a cost-effective alternative to patients who need those services. See also Sections II, III, V, VI and VII of the original application, Project I.D. #N-8716-11. The original application was conforming to this criterion and the applicants propose no changes in this current application to affect that determination.

The information provided by the applicants is reasonable and credible and adequately demonstrates that the expected effects of the proposal include a positive impact on cost-effectiveness, quality and access to services in Robeson County. This determination is based on the information in the application and the following analysis:

- The applicants adequately demonstrate the need to relocate two existing GI endoscopy procedure rooms from SRMC to the ASC previously approved in Project ID #N-8716-11, and that it is a cost-effective alternative;
- The applicants have and will continue to provide quality services; and
- The applicants have and will continue to provide adequate access to medically underserved populations.

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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SRMC is accredited by the Joint Commission and certified by CMS for Medicare and Medicaid participation. According to the records in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents have occurred at SRMC within the eighteen months immediately preceding the date of this decision for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA