

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: October 28, 2014

PROJECT ANALYST: Kim Randolph  
INTERM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: G-10309-14/ The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation d/b/a Annie Penn Hospital/ Add one gastrointestinal endoscopy room to existing facility for a total of three gastrointestinal endoscopy rooms/ Rockingham County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The Moses H. Cone Memorial Hospital and the Moses H. Cone Memorial Hospital Operating Corporation (collectively referred to as Cone Health) d/b/a Annie Penn Hospital is an existing, licensed, and accredited North Carolina acute care hospital located at 618 S. Main Street, Reidsville, in Rockingham County. Annie Penn Hospital propose to develop a third gastrointestinal (GI) endoscopy procedure room on the first floor of the existing hospital.

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2014 State Medical Facilities Plan (2014 SMFP).

The proposed addition of the GI endoscopy room requires new construction and renovation on the first floor of the hospital. The total projected cost for the proposed project is \$2,231,516. Since the total projected capital cost of the project is greater than two million

dollars, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, in 2014 SMFP, is applicable to this review.

Policy GEN-4 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.”*

In Section III.4, pages 65-67, the applicants describe the plans to assure improved energy conservation, water conservation, indoor air quality, and sustainable design. The applicants state the building is being designed to exceed the energy efficiency and water conservation standards of the 2012 North Carolina State Building Code. The application is consistent with Policy GEN-4. Therefore, the application is conforming to this criterion.

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

C

Annie Penn Hospital is an existing, licensed and accredited acute care hospital located in Reidsville, Rockingham County. Annie Penn Hospital provides GI endoscopy services in two

licensed GI endoscopy rooms and proposes to add one additional licensed GI endoscopy room to the hospital, for a total of three GI endoscopy rooms.

Population to be Served

In Sections III.6 and III.7, pages 67-68 and Exhibit 21, the applicants provide the current and projected patient origin for GI endoscopy services at Annie Penn Hospital, as illustrated in the following table.

County	Current FY 2014 (annualized)*	Projected	
		PY 1** FY 2016	PY 2** FY 2017
Rockingham	82.7%	82.7%	82.7%
Caswell	7.7%	7.7%	7.7%
Other***	9.6%	9.6%	9.6%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

\* Represents nine months of actual data, from October 1, 2013 to June 30, 2014.

\*\* Project Year (PY).

\*\*\* In Exhibit 21 and supplemental information provided in response to questions from the Project Analyst during the expedited review of this project, the applicants state ‘Other’ represents projected in-migration from the counties and states listed in Exhibit 21.

The applicants adequately identify the population proposed to be served.

Need for the Proposal

In Section III.1, page 48, the applicants state the following factors support the need to develop one additional GI endoscopy room at Annie Penn Hospital in Rockingham County:

- Utilization of existing GI endoscopy and operating room resources at Annie Penn Hospital (pp. 48-51);
- Current capacity and space constraints (pp. 51-52);
- Historical and projected growth of the service area population and of the population aged 55+ (pp. 53-54);
- Historical growth in GI endoscopy procedures in the service area and Annie Penn Hospital’s increasing market share (pp. 54-56); and
- Projected growth of GI endoscopy procedures in the service area (56-62).

Utilization Projections

The following table illustrates the applicants’ historical and projected utilization of the current and proposed GI endoscopy procedure rooms at Annie Penn Hospital, as reported by the applicants in Section IV, pages 72-73.

**Annie Penn Hospital GI Endoscopy Volume**

	Actual			Projected			
	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Total cases*	2,468	2,712	2,739	2,851	3,235	3,367	3,505
Total procedures*	3,286	3,661	3,687	3,838	4,342	4,520	4,705
# of GI rooms	2	2	2	2	3	3	3
Average # of procedures per room	1,643	1,831	1,844	1,919	1,447	1,507	1,568
Percent of capacity	1.10	1.22	1.23	0.96	0.96	1.00	1.05

\* Includes only cases and procedures performed in licensed GI endoscopy rooms. Sums may not total due to rounding.

As shown in the above table, in the second full operating year after project completion, Annie Penn Hospital projects to perform 4,520 GI endoscopy procedures in the three procedure rooms, which exceeds the minimal threshold of 1,500 procedures per room.

The applicants' assumptions and methodologies used to project utilization are provided on pages 73-78. On page 74, the applicants state they assumed the ratio of GI endoscopy cases to procedures will remain unchanged at 1:1.3. The applicants also state the methodology and assumptions account for the total number of GI endoscopy procedures at Annie Penn Hospital, including the more complex GI endoscopy procedures currently performed in an operating room, since the complex procedures will be performed in a GI endoscopy room upon completion of the project. The assumptions and methodologies are summarized below.

**Step 1: Review Historical Annie Penn Hospital GI Endoscopy Utilization**

On pages 73-74, the applicants state GI endoscopy procedures performed in both the licensed GI endoscopy rooms and the licensed operating rooms grew at a compound annual growth rate (CAGR) of 16.5% from FY 2011 through FY 2014 (annualized), as shown in the table below.

**Annie Penn Hospital Historical GI Endoscopy Volume**

	FY 2011	FY 2012	FY 2013	FY 2014*	% Change	CAGR
GI endo procedures in GI endo rooms	2,283	3,286	3,661	3,687	61.5%	17.3%
GI endo procedures in operating rooms	248	381	333	320	29.0%	8.9%
<b>Total</b>	<b>2,531</b>	<b>3,667</b>	<b>3,994</b>	<b>4,007</b>	<b>58.3%</b>	<b>16.5%</b>

\* Annualized.

On page 73 and in supplemental information provided by the applicants in response to questions from the Project Analyst during the expedited review of this project, the applicants explain that the flattened volume of GI endoscopy procedures in FY 2014 was due to capacity and space constraints and internal personnel policies.

**Step 2: Project Utilization for Annie Penn Hospital's GI Endoscopy Rooms**

On page 75, the applicants state

*“Using FY 2014 (annualized) volumes as a baseline, APH utilizes a projected annual growth rate based on one-fourth of its most recent three (3) year compound annual growth rate of 16.5% from FY 2011 – FY 2014 (annualized), or 4.1% to project future volumes (16.5% ÷ 4 = 4.1%).”*

The applicants state they assume all GI endoscopy cases currently performed in Annie Penn Hospital’s operating rooms will shift to the licensed GI endoscopy rooms upon completion of project.

**Annie Penn Hospital Projected GI Endoscopy Volume**

	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>	<b>FY 2018</b>	<b>% Change from FY 15 to FY 18</b>
GI endo procedures in GI endo rooms	3,838	4,342	4,520	4,705	
GI endo procedures in operating rooms	333	0	0	0	
<b>Total</b>	<b>4,171</b>	<b>4,342</b>	<b>4,520</b>	<b>4,705</b>	<b>12.8%</b>
Annual growth rate	4.1%*	4.1%	4.1%	4.1%	

\* In supplemental information provided during the expedited review of this project, the applicants explain why they believes 4.1% is reasonable for FY 2015.

On page 76, the applicants state the 4.1% annual growth rate is reasonable because the number of GI endoscopy cases from FY 2011 – FY 2013 in Rockingham and Caswell counties, as reported in Table III-8, page 55, had a compounded annual growth rate of 11.4%, much higher than the applicants’ projected growth rate. The applicants also state that increasing use rates indicate that utilization of GI endoscopy services will increase at a higher rate than the population growth rate.

The applicants adequately demonstrate that it is reasonable to assume they will perform 4,520 GI endoscopy procedures in three GI endoscopy rooms in the second operating year, which is an average of 1,507 procedures per room [4,520 procedures / 3 rooms = 1,507 procedures per room]. Thus, the applicants reasonably demonstrate that they will perform at least 1,500 GI endoscopy procedures per room as required by G.S. 131E-182(a) and 10A NCAC 14C .3903(b).

Access to the Proposed Services

In Section VI.2, page 89, the applicants state

*“Cone Health does not discriminate against low-income person, racial and ethnic minorities, women, handicapped persons, the elderly, or other underserved persons, including the medically indigent, the uninsured and the underinsured. In general, the health services of Cone Health are available to any patient in need without restriction of any kind.”*

In Section VI, page 98, the applicants project their GI endoscopy payor mix of Medicare and Medicaid case will increase from 59.1% to 61.3% by the end of the second year after project completion.

Exhibit 23 contains a copy of Cone Health's Non-Discrimination in Providing Services and Patient Admission policies and its Uninsured Discount Policy. The applicants further describe their charity and financial payment policies on pages 89-93. The applicants project that Annie Penn Hospital will provide \$492,529 (13.10%) in charity care and \$241,972 (6.44%) in bad debt services to GI endoscopy patients in its first year of operation.

In summary, the applicants adequately identify the population to be served and demonstrate the need the population proposed to be served has for one additional GI endoscopy procedure room at Annie Penn Hospital. The applicants also adequately demonstrate the extent to which all residents of the service area, in particular, the underserved, will have access to the proposed services. Consequently, the application is conforming to this criterion.

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

NA

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

CA

In Section III.8, pages 68-70, the applicants describe the alternatives considered, which include the following:

- 1) Maintain the status quo – the applicants state on page 68 that this is not an effective alternative because it does not eliminate space constraints caused by the size of the current GI endoscopy rooms and does not provide a larger GI endoscopy room to accommodate cases that currently must be performed in an operating room. This alternative does not provide additional capacity to meet future demands.
- 2) Increase hours of operation – the applicants state on page 68, that this is not an effective alternative because it does not eliminate space constraints caused by the size of the current GI endoscopy rooms and does not provide a larger GI endoscopy room to accommodate cases that currently must be performed in an operating room. This

alternative does not provide additional capacity to meet future demands. Additionally, physicians may not be available to work increased hours.

- 3) Add one new room within the surgical suite – the applicants state on page 69 that this is not an effective alternative because the configuration of the surgical suite does not support the addition of an appropriately sized GI endoscopy room. Additionally, there is no expansion space to add the necessary pre- and post- procedure space. The applicants state an expansion of the building at the surgical suite location would be difficult, costly, and potentially impossible.
- 4) Add two new rooms in a freestanding location – the applicants state on page 69 that this is not an effective alternative because it does not make use of existing space and ancillary support services. Additionally, the applicants state it is likely this alternative would be more costly to develop than the selected alternative.
- 5) Proposed project to add one additional GI endoscopy room and reconfigure the GI endoscopy services within the facility – the applicants state on pages 69-70 that this proposal is the least costly and most effective alternative to address Annie Penn Hospital's needs because it will accommodate GI endoscopy cases currently performed in the operating room, better utilizes existing space, and provides the most cost-effective solution to meet current and future demand for services.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

The applicants adequately demonstrate that the proposed alternative is the most effective or least costly alternative to meet the need to improve GI endoscopy services at Annie Penn Hospital. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

1. **The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation d/b/a Annie Penn Hospital shall materially comply with all representations made in the certificate of need application and supplemental information received on September 24, 2014. In those instances where representations conflict, The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation d/b/a Annie Penn Hospital shall material comply with the last made representation.**
2. **The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation d/b/a Annie Penn Hospital shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**

3. **The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation d/b/a Annie Penn Hospital shall develop no more than one additional gastrointestinal endoscopy room and shall be licensed for a total of no more than three gastrointestinal endoscopy rooms at Annie Penn Hospital following project completion.**
  4. **The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation d/b/a Annie Penn Hospital shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.2, page 112, the applicants project the total capital cost for the project will be \$2,231,516. The capital costs include \$1,263,596 in construction costs and \$967,920 in miscellaneous costs which include equipment, furniture, consultant fees, and contingencies. In Section VIII.3, page 113, the applicants state the capital costs will be financed through Cone Health's accumulated reserves. In Section IX, page 117, the applicants state there will be no start up or initial operating expenses since Annie Penn Hospital is an existing facility.

Exhibit 26 contains a letter, dated July 10, 2014, from the Chief Financial Officer of Cone Health, confirming the availability of funding for the proposed project. The letter states, in part,

*"... Cone Health plans to use its unrestricted net assets to fund the addition of one (1) GI endoscopy room at Annie Penn Hospital. Total capital project costs are budgeted at \$2,231,516.*

...

*The funds for the proposed GI endoscopy project are included in the Cone Health capital budget."*

The applicants provide Cone Health's most recent audited financial statements. Exhibit 27 contains The Moses H. Cone Memorial Hospital and Affiliates' consolidated financial statements for years ending September 30, 2013 and 2012. Cone Health had \$11,895,000 in cash and cash equivalents, \$2,210,298,000 in total assets, 1,395,335,000 in unrestricted net assets, and \$1,411,467,000 in total net assets (total assets less total liabilities).

The applicants provide pro forma financial statements for the first three years of the project.

The applicants project Annie Penn Hospital’s GI endoscopy services revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below.

<b>Annie Penn Hospital GI Endoscopy Services</b>	<b>PY 1 FY 2016</b>	<b>PY 2 FY 2017</b>	<b>PY 3 FY 2018</b>
Projected # of Procedures	4,342	4,520	4,705
Projected Average Charge	\$2,774	\$2,790	\$2,807
Gross Patient Revenue	\$12,042,921	\$12,612,747	\$13,205,943
Deductions from Gross Patient Revenue	\$8,283,561	\$8,675,508	\$9,083,530
Net Patient Revenue	\$3,759,360	\$3,937,239	\$4,122,413
Total Expenses	\$2,297,632	\$2,313,036	\$2,321,012
Net Income	\$1,461,728	\$1,624,203	\$1,801,402

The applicants also project a positive net income for The Cone Health System in each of the first three operating years of the project. In Section II.7, page 35, the applicants provide the projected average facility charge per procedure for the 10 most common GI endoscopy procedures. In Section II.8, page 36, the applicants state the professional fees for the gastroenterologist, anesthesiologist and pathologist/pathology fees, if a biopsy is required, are billed separately by the physicians’ offices and are not included in the average charge.

The assumptions used by the applicants in preparation of the pro formas are reasonable, including projected utilization, costs and charges. See the Pro Formas tab of the application for the assumptions regarding costs and charges. The discussion regarding the projected utilization found in Criterion (3) is incorporated herein by reference. The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

Annie Penn Hospital operates two licensed GI endoscopy procedure rooms in Reidsville, Rockingham County. Annie Penn Hospital proposes to add one GI endoscopy procedure room to the hospital for a total of three GI endoscopy procedure rooms.

In Section III, pages 48-56, the applicants discuss utilization of the existing GI endoscopy rooms at Annie Penn Hospital. On page 48, the applicants state Annie Penn Hospital currently provides inpatient and outpatient GI endoscopy procedures in two licensed GI endoscopy rooms located within the Surgical Suite, on the first floor of the hospital. On page 49, the applicants state GI endoscopy volumes have increased an average of 17.3% over the last 4 years. On page 50, the applicants state that due to space and size limitations in the current GI endoscopy rooms at Annie Penn Hospital, complex GI endoscopy case are

performed in a licensed operating room. Based on performance standards promulgated in G.S. 131E-182(a) and 10A NCAC 14C .3903(b), using only procedures performed in GI endoscopy rooms, in FY 2014 (annualized) the facility operated at 123% of capacity [3687 / 3000 = 1.23]. On page 50, the applicants state Annie Penn Hospital can currently support 2.5 GI endoscopy rooms based on a planning capacity of 1,500 procedures per room and 3,687 procedures in FY 2014 (annualized) [3,683 / 1500 = 2.46]. The applicants state on page 51, that in FY 2014 (annualized), 4007 total GI endoscopy procedures were performed in the GI endoscopy rooms and ORs at Annie Penn Hospital, as shown in the table below.

	<b>FY 2011</b>	<b>FY 2012</b>	<b>FY 2013</b>	<b>FY 2014*</b>
GI endo procedures in GI endo rooms	2,283	3,286	3,661	3,687
GI endo procedures in operating rooms	248	381	333	320
<b>Total</b>	<b>2,531</b>	<b>3,667</b>	<b>3,994</b>	<b>4,007</b>
GI endoscopy rooms needed	1.7	2.4	2.7	2.7

\* Annualized.

On page 70, the applicants provide information regarding the number of GI endoscopy cases provided by the two hospital based providers in the applicants' proposed service area, which includes Rockingham and Caswell counties. The applicants state there are no freestanding ambulatory GI endoscopy services in Rockingham or Caswell counties. The following table lists the number of licensed GI endoscopy rooms and the number of GI cases per GI room, by provider, based on the 2014 hospital license renewal applications for each provider.

**FY 2013**  
**Hospital Based Facilities in the Applicants' Proposed Service Area**

<b>Facilities</b>	<b>County</b>	<b># of GI Rooms</b>	<b>Total # of GI Cases</b>	<b>Total # of GI Procedures</b>
Annie Penn Hospital	Rockingham	2	2,712	3,661
Morehead Memorial Hospital	Rockingham	2	1,449	0*
<b>Total</b>		<b>4</b>	<b>4,161</b>	<b>3,661</b>

\* Morehead Memorial Hospital did not report any procedures on its 2014 Hospital License Renewal Application.

The applicants state the need for the additional GI endoscopy procedure room is based primarily on existing and proposed patient volumes at Annie Penn Hospital along with the existing size and space limitations of the two existing GI endoscopy rooms located in the Surgical Suite. These are needs that Morehead Memorial Hospital cannot meet.

On pages 53-54, the applicants state that although Morehead Memorial Hospital's GI endoscopy rooms could be underutilized and the historical population growth for the applicants' service area declined by 1.2% from 2010 to 2014, the population growth in the service area is projected to increase 0.2% from 2014 to 2019. Additionally, the applicants state the population most likely to utilize GI endoscopy services, aged 55+, has increased 7.6% from 2010 to 2014 in the service area. This population aged 55+ is projected to increase by 9.5% from 2014 to 2019 in Rockingham and Caswell counties.

On page 55, the applicants state the total GI endoscopy cases for patients living in Rockingham and Caswell counties have increased from 4,735 cases to 5,875 cases, a total increase of 24.1% from FY 2011 - FY 2013. The applicants also state Annie Penn Hospital's market share increased during this time period from 28.3% to 41.5%, while Morehead Memorial Hospital's market share decreased during this time period from 23.5% to 16.5%, as shown in the table below.

**Annie Penn Hospital GI Endoscopy Cases**

Facility	FY 2011		FY2012		FY 2013	
	# of Cases	% of Total	# of Cases	% of Total	# of Cases	% of Total
Annie Penn Hospital	1,341	28.3%	2,210	39.5%	2,439	41.5%
Morehead Memorial Hospital	1,113	23.5%	975	17.4%	967	16.5%
Others*	2,281	48.2%	2,421	43.1%	2,469	42.0%
<b>Total</b>	<b>4,735</b>	<b>100.0%</b>	<b>5,606</b>	<b>100.0%</b>	<b>5,875</b>	<b>100.0%</b>

\* Others includes seven facilities plus the 'Other' category listed in the application in Table III.8 page 55.

On page 70, the applicants state Morehead Memorial Hospital currently has one gastroenterologist on staff. In Section VII.8, page 108, the applicants state Annie Penn Hospital has three gastroenterologists who use and are expected to continue to use its GI endoscopy rooms.

Given Annie Penn Hospital's historical growth and increasing market share, the projected increase of 9.5% in the population age 55+ from 2014 to 2019, and Annie Penn Hospital's current ability to support 2.5 GI endoscopy rooms, it is reasonable to assume an additional GI endoscopy room will be needed, regardless of any underutilized capacity at Morehead Memorial Hospital. The applicants adequately demonstrate that developing one additional GI endoscopy room at Annie Penn Hospital would improve access to GI endoscopy services in Rockingham and Caswell counties.

In summary, the proposal will not result in the unnecessary duplication of existing or approved GI endoscopy rooms in the proposed service area. 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.

C

In Sections VII.1 and VII.2, pages 101-102, the applicants provide the current and proposed staffing for its GI endoscopy services for the second full fiscal year, as illustrated in the table below.

**Annie Penn Hospital's GI Endoscopy Services  
 # of Full-Time Equivalent Positions (FTEs)**

<b>Position</b>	<b>Current Staff</b>	<b>Projected Staff Additions</b>	<b>Total Projected Staff Year 2 FY 2017</b>
Registered Nurse (RN)	3.6	3.6	7.2
Assistant Director	0.5	0.0	0.5
Endo Technician	2.7	0.9	3.6
Specialty Coordinator	0.9	0.0	0.9
Nurse Technician	0.0	0.9	0.9
<b>Totals</b>	<b>7.7</b>	<b>5.4</b>	<b>13.1</b>

In Section VII.7, page 106, and supplemental information provided in response to questions from the Project Analyst during the expedited review of this project, the applicants provide the projected staffing at Annie Penn Hospital by functional area of operation, as illustrated in the table below.

**FTEs by Functional Area of Operation**

<b>Functional Area</b>	<b>Type</b>	<b># of FTE Positions</b>
Administration	Assistant Director	0.5
	Specialty Coordinator	0.9
Pre-operative	RN	1.8
Post-operative	RN	1.8
GI Endoscopy procedure room	RN	3.6
	Endoscopy Technicians	3.6
Equipment cleaning, safety & maintenance*	RN	0.0
	Endoscopy Technicians	0.0
Other	Nurse Technician	0.9
<b>Total FTEs</b>		<b>13.1</b>

\* Table VII.7, page 106, does not have a column labeled Equipment cleaning, safety & maintenance; however the applicants state in supplemental information provided in response to questions from the Project Analyst that the RNs and Endoscopy Technicians perform this function.

In Section VII.7, page 107, the applicants state Cone Health is among the largest employers in the Triad region with staff dedicated to recruitment and retention of employees. In Section VII.9, page 109, the applicants state that Dr. Sandi Fields currently serves as the Medical Director of Annie Penn Hospital's GI endoscopy program. Exhibit 22 contains a letter of support from Dr. Fields, dated July 15, 2014, indicating a willingness to continue to serve as the Medical Director for the Endoscopy Department at Annie Penn Hospital.

The applicants adequately document the availability of sufficient health manpower and management personnel to staff the proposed new GI endoscopy room at Annie Penn Hospital. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

Annie Penn Hospital is an existing hospital and provider of GI endoscopy services. The applicants state the necessary ancillary and support services are currently available at Annie Penn Hospital and identifies those services in Section II.2, pages 19-20. The applicants discuss coordination with the existing health care system in Sections V.2-V.6, pages 81-88. The applicants provide supporting documentation of coordination and support from hospital board members and administration and area physicians in Exhibits 1, 5, 8, 15, and 22. The applicants adequately demonstrate the availability of the necessary ancillary and support services and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person

proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section XI.5, page 124, the applicants propose to construct a 576 square foot addition and to renovate 5,513 square feet of the first floor of Annie Penn Hospital located at 618 S. Main Street, Reidsville, Rockingham County, for a total of 262,384 square feet after completion, as shown in the table below.

**Annie Penn Hospital's Current and Proposed Square Footage**

	<b>New Additional Square Feet</b>	<b>Renovated Square Feet</b>	<b>Total Square Feet</b>
Proposed Endoscopy Suite with two GI rooms	576	4,969	5,545
Surgical Suite with one GI room	0	544	544
<b>Total</b>	<b>576</b>	<b>5,513</b>	<b>6,089</b>

Exhibit 6 contains the line drawings for the proposed project and the supplemental information provided in response to questions from the Project Analyst during the expedited review of this project contains the line drawing for the original Surgical Suite at Annie Penn Hospital. Exhibit 31 contains a July 7, 2014 letter from McCulloch England Associates Architects certifying the construction costs of \$1,389,955 and an additional architectural/engineering fee of \$132,046. The letter indicates the construction cost estimate was provided by Vannoy Construction of Winston-Salem. This estimate is consistent with the projected capital costs in Section VIII, page 112.

In Section XI.6, page 125, the applicants estimate the following construction costs per square foot.

	<b>Square Feet</b>	<b>Construction Costs per Square Feet</b>	<b>Total Cost per Square Feet</b>
Proposed Endoscopy Suite with two GI rooms	5,545	\$207.52	\$366.48
Surgical Suite with one GI room	544	\$207.52	\$366.48
<b>Total</b>	<b>6,089</b>	<b>\$207.52</b>	<b>\$366.48</b>

In Section XI.8, pages 126-128, the applicants describe the energy efficient and sustainable design features of the proposed addition and renovations, established to exceed the energy efficiency and water conservation standards of the 2012 North Carolina State Building Code.

The applicants adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative for the project as proposed and that the construction project will not unduly increase the costs and charges of providing health services. The

discussion regarding the costs and charges found in Criterion (5) is incorporated herein by reference. 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;

C

In Sections VI.12 and VI.13, pages 97-98, the applicants provide the GI endoscopy services payor mix, as a percentage of total GI endoscopy cases, during the last full fiscal year, FY 2013 (10/1/2012 - 09/30/2013), for the entire system (Cone Health) and for Annie Penn Hospital, as illustrated in the table below.

**FY 2013  
 GI Endoscopy Payor Mix**

<b>Payor</b>	<b>Entire System (Cone Health)</b>	<b>Annie Penn Hospital</b>
Self Pay / Indigent / Charity	7.4%	3.7%
Medicare / Medicare Managed Care	45.4%	53.3%
Medicaid	13.5%	5.8%
Managed Care / Commercial	29.9%	36.4%
Other (CHAMPUS/ Workers' Comp)	3.8%	0.8%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Exhibit 23 contains a copy of the Cone Health Non-Discrimination in Provision of Services policy and the Uninsured Discount Policy. Exhibit 24 contains a copy of the 2014 Cone Health Annual Report to our Communities which describes its community initiatives and financial support programs. Section VI.2, pages 89-90, contains additional discussion of charity care, financial payment policies and handicap access.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Rockingham County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population*</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population*</b>	<b>CY 2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center)*</b>
Rockingham County	19.9%	9.3%	19.0%
Statewide	16.5%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group would not typically utilize the 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 applicants demonstrate that medically underserved populations currently have adequate access to the GI endoscopy services offered at Annie Penn Hospital. 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;

In Section VI.11, page 97, the applicants state they have no obligation under applicable federal regulations to provide uncompensated care, community services, or access to care by minorities and handicapped persons. However, the applicants state Cone Health is dedicated to providing access to care for all those in its community. Exhibit 23 contains a copy of Cone Health Coverage Assistance and Financial Assistance and Hardship Settlement policies.

In Section VI.10, page 96, the applicants state there have been no civil rights access complaints filed against Annie Penn Hospital within the last five years. The application is conforming to this criterion.

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

C

In Section VI.14, page 98, the applicants provide the projected payor mix for Annie Penn Hospital's GI endoscopy cases during the second operating year (FY 2017), as illustrated in the table below.

**FY 2017 Projected Payor Mix  
Annie Penn Hospital**

<b>Payor</b>	<b>Percent of Total GI Endoscopy Cases</b>
Self Pay / Indigent / Charity	3.9%
Medicare / Medicare Managed Care	54.8%
Medicaid	6.5%
Managed Care / Commercial	34.2%
Other (CHAMPUS, Workers' Comp)	0.6%
<b>Total</b>	<b>100.0%</b>

In Section VI.4, page 90, the applicants state all patients will have access to Cone Health services regardless of their ability to pay. The applicants project Annie Penn Hospital will provide \$492,529 of charity care the first year of operation and \$515,834 in the second year. Exhibit 23 contains a copy of Cone Health Coverage Assistance and Financial Assistance, Hardship Settlement, and Patient Payment Plans policies. Section VI.2, pages 89-90, contains additional discussion of charity care, financial payment policies and handicap access.

In Section VI.3, page 90, the applicants state Cone Health facilities adhere to the Americans with Disabilities Act of 1990 and are physically designed to accommodate handicapped person in accordance with the North Carolina Accessibility Code.

The applicants demonstrate that medically underserved populations will continue to have adequate access to the proposed GI endoscopy services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.9, page 95, the applicants state that patients are referred to Annie Penn Hospital's GI endoscopy services by area physicians and other hospitals. The applicants state patients may self-refer to the emergency department and be referred for GI services. Cone Health will not turn patients away.

The applicants adequately demonstrate they offers a range of means by which a person will have access to GI endoscopy services at Annie Penn Hospital. 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.

C

See Section V.1, pages 79-80, for documentation that Cone Health currently accommodates the clinical needs of health professional training programs in the area and that they will continue to do so. The information provided is reasonable and supports a finding of conformity with this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
  
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicants propose to add one GI endoscopy procedure room to Annie Penn Hospital for a total of three GI endoscopy procedure rooms. The following table lists the current providers of GI endoscopy services in Rockingham and Caswell counties.

**Hospital Based Facilities in the Applicants' Projected Service Area**

<b>Facilities</b>	<b>County</b>	<b># of GI Rooms</b>	<b>Total # of GI Cases</b>	<b>Total # of GI Procedures</b>
Annie Penn Hospital	Rockingham	2	2,712	3,661
Morehead Memorial Hospital	Rockingham	2	1,449	0*
<b>Total</b>		<b>4</b>	<b>4,161</b>	<b>3,661</b>

\* Morehead Memorial Hospital did not report any procedures on its 2014 Hospital License Renewal Application.

In Section III.9, page 70, the applicants state the purpose of the proposed project is to allow Annie Penn Hospital to resolve the size and space limitations of the two existing GI endoscopy rooms to meet current and future patient demand at its existing facility.

In Section V.7, page 88, the applicants discuss the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicants state that by renovating and utilizing existing space to reconfigure GI endoscopy services at Annie Penn Hospital, they have chosen the most cost-effective option. See Sections II, III, V, VI and VII of the application where the applicants discuss the impact of the project on cost effectiveness, quality and access.

The information provided by the applicants in those sections is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to GI endoscopy services. This determination is based on the information in the application and the following analysis:

- The applicants adequately demonstrate the need to add one GI endoscopy room, for a total of three GI endoscopy rooms at Annie Penn Hospital and that it is a cost-effective alternative;
- The applicants adequately demonstrate that they will continue to provide quality services;
- The applicants adequately demonstrate that they will continue to provide adequate access to medically underserved populations; and

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.

C

Annie Penn Hospital is accredited by The Joint Commission on Accreditation of Healthcare Organizations and is certified for Medicare and Medicaid participation. According to the records

in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, no incidents have occurred at the facility 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.

### C

The proposal submitted by Annie Penn Hospital is conforming to all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities as promulgated in 10A NCAC 14C .3900, which are discussed below.

### **.3902 INFORMATION REQUIRED OF APPLICANT**

*.3902(a)(1) 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.;*

- C- In Section II.11, page 26, the applicants identify the proposed service area as Rockingham and Caswell counties. These two counties represent 90.4% of Annie Penn Hospital's historical GI endoscopy patient origin. In Section III.5, page 67, the applicants state that in FY 2014, from January through May, 90% of GI endoscopy

patients were from the proposed service area.

.3902(a)(2) *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: ... (2) with regard to services provided in the applicant's GI endoscopy rooms, identify:*

*(A) the number of existing and proposed GI endoscopy rooms in the licensed health service facility in which the proposed rooms will be located.*

-C- In Section II.11, page 26, the applicants state Annie Penn Hospital currently has two licensed GI endoscopy rooms and proposes one additional licensed GI endoscopy room.

*(B) the number of existing or approved GI endoscopy rooms in any other licensed health service facility in which the applicant or a related entity has a controlling interest that is located in the applicant's proposed service area.*

-C- In Section II.11, page 26, the applicants state that “Neither Cone Health nor a related entity owns or operates any other GI endoscopy rooms in the proposed service area.”

*(C) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, performed in the applicant's licensed or non-licensed GI endoscopy rooms in the last 12 months.*

-C- In Section II, page 28, the applicants indicate Annie Penn Hospital provided a total of 3,459 GI endoscopy procedures from April 2013 – March 2104, identified by CPT or ICD-9 CM procedure codes, in its two existing GI endoscopy rooms.

*(D) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project.*

-C- In Section II, page 30, the applicants provide the number of GI endoscopy procedures, identified by CPT or ICD-9-CM procedure codes, projected to be performed in Anne Penn Hospital's three licensed GI endoscopy rooms in each of the first three operating years of the project.

*(E) the number of procedures by type, other than GI endoscopy procedures, performed in the GI endoscopy rooms in the last 12 months.*

-C- In Section II, page 31, the applicants state that zero non-GI endoscopy procedures were performed in Annie Penn Hospital's two licensed GI endoscopy rooms in the last 12 months.

*(F) the number of procedures by type, other than GI endoscopy procedures, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project.*

- C- In Section II, page 31, the applicants state Annie Penn Hospital does not project to perform any non-GI endoscopy procedures in the three licensed GI endoscopy rooms in any of the first three operating years of the project.

*(G) the number of patients served in the licensed or non-licensed GI endoscopy rooms in the last 12 months.*

- C- In Section II, page 31, the applicants state that 2,697 patients were served at Annie Penn Hospital in its two licensed GI endoscopy rooms in the last 12 months, from April 2013 – March 2014. The applicants indicate they assumed the number of patients equals the number of cases.

*(H) the number of patients projected to be served in the GI endoscopy rooms in each of the first three operating years of the project.*

- C- In Section II, page 32, the applicants project to serve the following number of patients in Annie Penn Hospital’s three licensed GI endoscopy rooms in each of the first three operating years of the project.

	<b>PY 1 FY 2016</b>	<b>PY 2 FY 2017</b>	<b>PY 3 FY 2018</b>
GI Endoscopy Patients	3,235	3,367	3,505

.3902(a)(3) *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: ... (3) with regard to services provided in the applicant's operating rooms identify: (A) the number of existing operating rooms in the facility;*

- C- In Section II, page 32, the applicants state that Annie Penn Hospital has four shared surgical operating rooms. See Exhibit 11 for a copy of Annie Penn Hospital’s 2014 license.

*(B) the number of procedures by type performed in the operating rooms in the last 12 months; and*

- C- In Section II, page 33, the applicants list a total of 267 GI endoscopy procedures, by type, performed in Annie Penn Hospital’s 4 shared operating rooms in the last 12 months, from April 2013 – March 2014. In supplemental information provided by the applicants in response to questions from the Project Analyst during the expedited review of this project, the applicants list a total of 2,222 surgical procedures, by type,

performed in Annie Penn Hospital’s 4 shared operating rooms from April 2013 – March 2014.

*(C) the number of procedures by type projected to be performed in the operating rooms in each of the first three operating years of the project.*

-C- In Section II, page 33, the applicants state that after the addition of the third GI endoscopy procedure room at Annie Penn Hospital, no GI endoscopy procedures are projected to be performed in Annie Penn Hospital’s four shared operating rooms in each of the first three operating years of the project. In supplemental information provided by the applicants in response to questions from the Project Analyst during the expedited review of this project, the applicants project a total of 1944 surgical procedures, by type, to be performed in Annie Penn Hospital’s four licensed operating rooms in each of the first three operating years of the project, FY 2016 – FY 2018.

.3902(a)(4) *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: ... (4) the days and hours of operation of the facility in which the GI endoscopy rooms will be located.*

-C- In Section II, pages 33-34, the applicants state the GI endoscopy program is operated from 7:30 a.m. to 4:30 p.m. Monday through Friday with on-call services provided for evenings and weekends.

.3902(a)(5) *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: ... (5) if an applicant is an existing facility, the type and average facility charge for each of the 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months.*

-C- In Section II, page 34, the applicants provide the type and average facility charge for each of the 10 GI endoscopy procedures most commonly performed in the facility during the last 12 months for which detailed data is available, April 2013 – March 2014, as illustrated in the table below.

<b>Description</b>	<b>Average Charge</b>
Colonoscopy and biopsy	\$3,700
Upper GI endoscopy, biopsy	\$3,083
Lesion removal, colonoscopy	\$3,797
Diagnostic colonoscopy	\$2,194
Upper GI endoscopy, diagnosis	\$2,347
Dilate esophagus...	\$4,196
Colorectal cancer screening; colonoscopy not high risk (NC)	\$2,221

Upper GI endoscopy / guide wire	\$3,152
Esophagogastroduodenoscopy (EGD) w/ colosed biopsy	\$4,015
Esoph endoscopy, dilation...	\$3,665

.3902(a)(6) *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: ... (6) the type and projected average facility charge for the 10 GI endoscopy procedures which the applicant projects will be performed most often in the facility.*

-C- In Section II, page 35, the applicants provide the type and average facility charge for the 10 GI endoscopy procedures they project will be performed most often in the facility, as illustrated in the table below.

Description	OY1 FY 2016	OY2 FY 2017	OY3 FY 2018
Colonoscopy and biopsy	\$3,774	\$3,812	\$3,850
Upper GI endoscopy, biopsy	\$3,145	\$3,177	\$3,208
Lesion removal, colonoscopy	\$3,873	\$3,912	\$3,951
Diagnostic colonoscopy	\$2,238	\$2,261	\$2,283
Upper GI endoscopy, diagnosis	\$2,394	\$2,418	\$2,442
Dilate esophagus...	\$4,281	\$4,323	\$4,367
Colorectal cancer screening; colonoscopy not high risk (NC)	\$2,265	\$2,288	\$2,311
Upper GI endoscopy / guide wire	\$3,216	\$3,248	\$3,280
Esophagogastroduodenoscopy (EGD) w/ colosed biopsy	\$4,095	\$4,136	\$4,178
Esoph endoscopy, dilation...	\$3,738	\$3,776	\$3,813

.3902(a)(7) *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: ... (7) a list of all services and items included in each charge, and a description of the bases on which these costs are included in the charge.*

-C- In Section II, page 35, the applicants state

*“The charge is based on the acuity of the GI procedure and the duration/length of time of the procedure. The total charge includes items such as: nursing and technical personnel time; use of facility/endoscopy rooms; linens; medications; billable medical supplies; equipment use; administrative services; record keeping; housekeeping; and other miscellaneous fees.”*

.3902(a)(8) *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: ...*

*(8) identification of all services and items (e.g., medications, anesthesia) that will not be included in the facility's charges.*

-C- In Section II, page 36, the applicants describe the services that will not be included in the facility's charges. These services include: professional fees for the gastroenterologist performing the procedure; the anesthesiologist; and pathologist/pathology fees if a biopsy is required; lab tests prior to the procedure; emergency transportation; and room and board charges for inpatients.

*.3902(a)(9) 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: ... (9) if an applicant is an existing facility, the average reimbursement received per procedure for each of the 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months.*

-C- In Section II, page 37, the applicants provide the average reimbursement received per procedure for each of the 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months for which detailed data was available, April 2013 – March 2014, as illustrated below.

<b>Description</b>	<b>Average Reimbursement</b>
Colonoscopy and biopsy	\$1,358
Upper GI endoscopy, biopsy	\$850
Lesion removal, colonoscopy	\$1,169
Diagnostic colonoscopy	\$1,071
Upper GI endoscopy, diagnosis	\$838
Dilate esophagus...	\$1,201
Colorectal cancer screening; colonoscopy not high risk (NC)	\$644
Upper GI endoscopy / guide wire	\$586
Esophagogastroduodenoscopy (EGD) w/ colosed biopsy	\$1,090
Esoph endoscopy, dilation...	\$1,252

*.3902(a)(10) 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: ... (10) the average reimbursement projected to be received for each of the 10 GI endoscopy procedures which the applicant projects will be performed most frequently in the facility.*

- C- In Section II, page 38, the applicants provide the average reimbursement projected to be received for the 10 GI endoscopy procedures which the applicants project will be performed most frequently in the facility for the first three project years.

<b>Description</b>	<b>OY 1 FY 2016</b>	<b>OY 2 FY 2017</b>	<b>OY 3 FY 2018</b>
Colonoscopy and biopsy	\$1,374	\$1,382	\$1,390
Upper GI endoscopy, biopsy	\$860	\$865	\$870
Lesion removal, colonoscopy	\$1,183	\$1,190	\$1,197
Diagnostic colonoscopy	\$1,084	\$1,091	\$1,097
Upper GI endoscopy, diagnosis	\$848	\$854	\$859
Dilate esophagus...	\$1,216	\$1,223	\$1,231
Colorectal cancer screening; colonoscopy not high risk (NC)	\$652	\$656	\$660
Upper GI endoscopy / guide wire	\$593	\$597	\$600
Esophagogastroduodenoscopy (EGD) w/ colosed biopsy	\$1,103	\$1,110	\$1,117
Esoph endoscopy, dilation...	\$1,267	\$1,274	\$1,282

*.3902(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;*

*(2) a written commitment to participate in and comply with conditions of participation in the Medicare and Medicaid programs within three months after licensure of the facility;*

*(3) a description of strategies to be used and activities to be undertaken by the applicant to assure the proposed services will be accessible by indigent patients without regard to their ability to pay;*

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

*(5) the number of GI endoscopy procedures performed by the applicant in any other existing licensed health service facility in each of the last 12 months, by facility;*

*(6) if the applicant proposes reducing the number of GI endoscopy procedures it performs in existing licensed facilities, the specific rationale for its change in practice pattern.*

-NA- Annie Penn Hospital is an existing provider of GI endoscopy services and does not propose to establish a new licensed ambulatory surgical facility.

**.3903 PERFORMANCE STANDARDS**

.3903(a) *In providing projections for operating rooms, as required in this Rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding 10 days for holidays.*

-C- In Section II, page 39, the applicants state Annie Penn Hospital’s GI Endoscopy Department operates at least 250 days per year and is available 365 days per year for emergency cases.

.3903(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.*

-C- In Section II, page 40, Annie Penn Hospital projects to perform 4,520 GI endoscopy procedures during PY 2, FY 2017, for three GI endoscopy rooms, which is an average of 1,507 procedures per room (4,520 procedures / 3 GI endoscopy procedure rooms = 1,507 procedures per room) as shown in the following table.

	<b>PY 1 FY 2016</b>	<b>PY 2 FY 2017</b>	<b>PY 3 FY 2018</b>
Projected GI endoscopy procedures	4,342	4,520	4,705
Number of GI endoscopy procedure rooms	3	3	3
Number of GI endoscopy procedures per room	1,447	1,507	1,568

In Section IV, pages 73-78 of the application, the applicants provide the assumptions and methodology used to project utilization. The discussion regarding the projected utilization found in Criterion (3) is incorporated herein by reference.

.3903(c) *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 demonstrate that at least the following types of GI endoscopy procedures will be provided in the proposed facility or GI*

*endoscopy room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.*

-C- In Section II, page 40, the applicants state they currently provide and will continue to provide upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures at Annie Penn Hospital.

.3903(d) *If an applicant, which proposes 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, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria: (1) if the applicant or a related entity performs GI endoscopy procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI endoscopy cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or (2) demonstrate that GI endoscopy procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future.*

-NA- In Section II, page 41, the applicants state Annie Penn Hospital currently performs GI endoscopy procedures in an operating room “... due to size limitations of the existing endoscopy rooms to accommodate anesthesia equipment for complex endoscopy cases. However, following completion of the proposed project, which includes expansion of an existing endoscopy room located within the Surgical Suite, all GI endoscopy procedures will be performed in the GI rooms and no GI endoscopy procedures will be performed in the ORs.”

.3903(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.*

-C- In Section IV, pages 73-78, the applicants describe the assumptions and the methodology they used to project GI endoscopy procedures. The discussion regarding the projected utilization found in Criterion (3) is incorporated herein by reference.

#### **.3904 SUPPORT SERVICES**

.3904(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.*

- C- Exhibit 15 contains a copy of the agreement between Cone Health and Greensboro Pathology to provide pathology services to Annie Penn Hospital.
  
- .3904(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 provide a copy of the guidelines it shall follow in the administration of conscious sedation or any type of anesthetic to be used, including procedures for tracking and responding to adverse reactions and unexpected outcomes.*
  
- C- Exhibit 16 contains a copy of the Cone Health's GI endoscopy policies and procedures regarding sedation and anesthesiology.
  
- .3904(c) *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 the policies and procedures it shall utilize for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure room between cases.*
  
- C- Exhibit 17 contains a copy of Cone Health's policies and procedures for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure rooms between cases.
  
- .3904(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:*
  - (1) *evidence that physicians utilizing the proposed facility will have practice privileges at an existing hospital in the county in which the proposed facility will be located or in a contiguous county.*
  
- C- In Section II, page 42, the applicants state that all physicians using the GI endoscopy procedure rooms at Annie Penn Hospital are currently and will continue to be credentialed at the hospital and will be part of the Cone Health active medical staff.
  - (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.*
  
- C- The proposed new licensed GI endoscopy room will be located within Annie Penn Hospital, which is an acute care hospital.
  - (3) *documentation of a transfer agreement with a hospital in case of an emergency.*

- C- The proposed new licensed GI endoscopy room will be located within Annie Penn Hospital, which is an acute care hospital. In case of an emergency, patients will be transferred to the appropriate area within the hospital.

**.3905 STAFFING AND STAFF TRAINING**

*.3905(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 identify the number of staff to be utilized in the following areas: (1) administration; (2) pre-operative; (3) post-operative; (4) procedure rooms; (5) equipment cleaning, safety, and maintenance; and (6) other.*

- C- In Section VII.7, page 106, the applicants project staffing at Annie Penn Hospital, by area of operation, a shown in the following table.

<b>Area of Operation</b>	<b>Employee Category</b>	<b># of FTE Positions</b>
Administration	Assistant Director	0.5
	Specialty Coordinator	0.9
Pre-operative	RN	1.8
Post-operative	RN	1.8
GI endoscopy procedure room	RN	3.6
	Endoscopy Technicians	3.6
Equipment cleaning, safety & maintenance*	RN	0.0
	Endoscopy Technicians	0.0
Other	Nurse Technician	0.9
<b>Total FTEs</b>		<b>13.1</b>

\* The table in Section VII.7, page 106, does not have a column labeled Equipment, cleaning, safety and maintenance; however the applicants provide supplemental information in response to questions from the Project Analyst that the RNs and Endoscopy Technicians perform this function.

*.3905(b) The 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 identify the number of physicians by specialty and board certification status that currently utilize the facility and that are projected to utilize the facility.*

- C- In Section II, page 44, the applicants state Annie Penn Hospital has an active medical staff of nearly 60 physicians. Dr. Sandi Fields, Dr. Najeeb Rehman and Dr. Robert Rourk are the three board-certified gastroenterologists that currently utilize the GI endoscopy rooms and are projected to utilize the GI endoscopy rooms following completion of the project.

*.3905(c) The 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 criteria to be used by the facility in extending privileges to medical personnel that will provide services in the facility.*

- C- Exhibit 18 contains a copy of the Cone Health Medical and Dental Staff Bylaws and Rules and Regulations. Sections 4 and 5 list the categories of staff and the criteria used to extend privileges to Medical Staff at Annie Penn Hospital.

*.3905(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;*

*(2) all physicians performing GI endoscopy procedures in the facility shall be board eligible or board certified gastroenterologists by American Board of Internal Medicine, colorectal surgeons by American Board of Colon and Rectal Surgery or general surgeons by American Board of Surgery;*

*(3) all physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the proposed service area;*

*(4) at least one registered nurse shall be employed per procedure room;*

*(5) additional staff or patient care technicians shall be employed to provide assistance in procedure rooms, as needed; and,*

*(6) a least one health care professional who is present during the period the procedure is performed and during postoperative recovery shall be ACLS*

*certified; and, at least one other health care professional who is present in the facility shall be BCLS certified.*

-NA- In Section II.7, page 22, the applicants state Annie Penn Hospital is accredited by The Joint Commission. See Exhibit 10 for a copy of the accreditation certificate.

**.3906 FACILITY**

*.3906(a) An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's office or within a general acute care hospital shall demonstrate reporting and accounting mechanisms exist that confirm the licensed ambulatory surgery facility is a separately identifiable entity physically and administratively, and is financially independent and distinct from other operations of the facility in which it is located.*

*(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 commit to obtain accreditation and to submit documentation of accreditation of the facility by The Accreditation Association for Ambulatory Health Care, The Joint Commission on Accreditation of Healthcare Organizations, or The American Association for Accreditation of Ambulatory Surgical Facilities within one year of completion of the proposed project.*

*(c) If the facility is not accredited at the time the application is submitted, 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:*

*(1) document that the physical environment of the facility conforms to the requirements of federal, state, and local regulatory bodies.*

*(2) provide a floor plan of the proposed facility identifying the following areas: (A) receiving/registering area; (B) waiting area; (C) pre-operative area; (D) procedure room by type; and (E) recovery area.*

*(3) demonstrate that the procedure room suite is separate and physically segregated from the general office area; and,*

*(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.*

-NA- Annie Penn Hospital is an existing general acute care hospital and the proposed GI endoscopy room will be licensed as part of the hospital.