

ATTACHMENT – REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA – Conditional

NC – Nonconforming

NA = Not Applicable

Decision Date: August 28, 2015

Findings Date: August 28, 2015

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: J-11033-15

Facility: Johnston Health Endoscopy Services, LLC

FID #: 150206

County: Johnston

Applicant(s): Johnston Health Services Corporation and Johnston Health Endoscopy Services, LLC

Project: Develop a new licensed ambulatory surgery center with two GI endoscopy rooms in Clayton by relocating one GI endoscopy room from Johnston Health Clayton and developing a new GI endoscopy room

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

The applicants, Johnston Health Services Corporation (Johnston Health) and Johnston Health Endoscopy Services, LLC (JHES), propose to develop a new, separately licensed ambulatory surgery center (ASC) with two gastrointestinal (GI) endoscopy rooms in Clayton by relocating one GI endoscopy room from Johnston Health Clayton and developing a new GI endoscopy room. The name of the new facility will be Johnston Health Endoscopy Services, LLC (JHES). The applicants may be referred to collectively as either the applicants or Johnston Health.

In Section I.10, page 6, the applicants identify a lessor for the proposed project, Clayton-Summit Properties, LLC, however, the applicants state that the lessor is an unrelated party and

has no financial interest in JHES or Johnston Health. JHES and Johnston Health are responsible for all capital costs associated with the proposed project.

Johnston Health, the parent company for Johnston Health Smithfield and Johnston Health Clayton is currently licensed for three (3) GI endoscopy procedure rooms. Two are located at Johnston Health Smithfield and one is located at Johnston Health Clayton. The proposed project involves the relocation of the existing GI endoscopy room at the Clayton facility to JHES.

In 2003, Johnston Health began providing outpatient surgery services at a hospital-based outpatient facility, Summit Surgical Center in Clayton. The two dedicated ambulatory surgical operating rooms at Summit Surgical Center have since been relocated to Johnston Health Clayton by way of another project. In Section II.1, page 13, the applicant states that given its prior use as a two-room surgical ASC, the space is ideally suited for operation of a two-room GI endoscopy ASC.

Need Determination

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 2015 State Medical Facilities Plan (2015 SMFP).

Policies

In addition, there are no policies in the 2015 SMFP that are applicable to this review.

Conclusion

In summary, there are no need determinations or policies in the 2015 SMFP that are applicable to this review. Therefore, this criterion is not applicable.

- (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

The applicants propose to develop Johnston Health Endoscopy Services, LLC (JHES), a new, separately licensed ASC with two GI endoscopy rooms, by relocating one GI endoscopy room from Johnston Health Clayton and developing a new GI endoscopy room. The applicants propose to develop the ASC in an existing building in Clayton previously used as a two-room surgical ASC. Upon project completion, Johnston Health will be licensed for two GI

endoscopy rooms at Johnston Health Smithfield, and JHES will be licensed for two GI endoscopy rooms.

Population to be Served

The 2015 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C.3901(6) does define the service area as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.

JHES is not an existing facility; therefore it has no historical patient origin.

In Section III.6, page 91, the applicants provide the projected patient origin for the GI endoscopy rooms, as illustrated in the table below:

COUNTY	OY 1 # PTS.	% OF TOTAL	OY 2 # PTS.	% OF TOTAL
Johnston	1,171	72.8%	1,761	72.8%
Other*	438	22.2%	659	27.2%
Total	1,610	100.0%	2,420	100.0%

*The applicants define "other" as Cumberland, Duplin, Harnett, Lee, Lenoir, Nash, Perquimans, Pitt, Sampson, Wake, Wayne and Wilson counties, as well as other states. The percentage of patients from "other" areas ranges from 22.2% to 27.2%, as shown in the table.

On page 91, the applicants state the proposed facility's patient origin will be consistent with the historical patient origin for outpatient GI endoscopy procedures at Johnston Health Clayton for the following reasons:

- The proposed facility will be located less than three miles from Johnston Health Clayton;
- Johnston Health Clayton has historically served patients from across Johnston County; and
- Many patients receiving health care services at Johnston Health Smithfield originate from the Clayton area.

The applicants adequately identify the population proposed to be served.

Analysis of Need

In Section III.1, pages 60 – 74, the applicants state the following factors support the need to develop an ASC with two GI endoscopy rooms in Clayton:

- Need for expanded GI endoscopy capacity at Johnston Health (pp. 60 – 64);
- Need for expanded access to GI endoscopy services by Johnston County residents (pp. 64 – 71); and
- Need for expanded GI endoscopy access within a freestanding ambulatory surgery center setting (pp. 71 – 74).

Need for expanded GI endoscopy capacity at Johnston Health

The applicants describe the need to expand GI endoscopy capacity at Johnston Health based on the following factors: historical utilization, population growth, and access.

On page 61, the applicants state the number of GI endoscopy procedures performed in each of the three existing GI endoscopy rooms has increased by a compound annual growth rate (CAGR) of 21.9% overall, as shown in the table below:

YEAR	CLAYTON	SMITHFIELD	TOTAL	PER ROOM
FFY 2012	517	2,585	3,102	1,034
FFY 2013	708	2,772	3,480	1,160
FFY 2014	715	3,896	4,611	1,537
CAGR	17.6%	22.8%	21.9%	

*Source: Hospital License Renewal Applications

The performance standards in G.S. 131E-182(a) and the *Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities*, at 10 A NCAC 14C .3903(b) require an applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures to reasonably project to perform at least 1,500 procedures per room in the second year of operation. As shown in the table above, the applicants performed in excess of 1,500 GI endoscopy procedures per room in FFY 2014.

In Section III.1, pages 61 – 62, the applicants state that Johnston County is the thirteenth fastest growing county in North Carolina based on numerical growth, and the twelfth fastest growing based on percentage growth. Furthermore, the 27520 and 27527 zip codes in Clayton are projected to grow at a CAGR of 1.6% and 2.3% respectively, between 2015 and 2020. The projected growth rate is based on Claritas data provided by the applicant in Exhibit 24.

On page 63, the applicants state the nearest freestanding GI endoscopy centers are located at least 20 miles to the northwest in Wake County. With outpatient GI endoscopy services provided in an ASC setting in Clayton and Smithfield, Johnston Health states it will more effectively serve Johnston County residents.

Expanded Access to GI Endoscopy Services

In Section III.1, pages 64 – 66, the applicants compare the incidence of colorectal cancer in Johnston County with Wake County and the state as a whole. In a footnote on page 65, the applicants state they chose to compare Johnston County to Wake County because “*it is the county in which the plurality of Johnston County residents receive GI endoscopy services if they do not receive care in Johnston County.*” The data shows the incidence of colorectal cancer in all three areas have declined since 2003. However, even with that decline, the incidence of colorectal cancer in Johnston County remains higher than that of North Carolina and Wake County.

On pages 66 – 68, the applicants compare the mortality rate for colorectal cancer in Johnston County, Wake County and North Carolina. As with the incidence rates, the mortality rates in all three areas have declined since 2003; however, the mortality rates in Johnston County remain higher than in Wake County or the state as a whole.

On pages 69 - 70, the applicants show that the number of GI endoscopy procedures performed in Johnston County in FFY 2013 was 2,148 procedures fewer than what was recommended based on the population statistics for the county. On page 70, the applicants state:

“Especially for non-emergent, screening procedures such as colonoscopy, patients will forego the procedure if access is not reasonably sufficient. Although access is driven by a number of factors, including access to gastroenterologists or other physicians credentialed to perform endoscopies, access to GI endoscopy facilities is also a factor....”

“Notably, Johnston County's rate of rooms per population is less than half that of both North Carolina and Wake County, while its volume per room is at least double.”

On page 71, the applicants state:

“Given clear national data that demonstrate the importance of screening and early-detection/treatment in reducing colorectal cancer incidence and mortality, combined with the low rates of GI endoscopy cases and higher colorectal cancer incidence and mortality rates in Johnston County, Johnston Health believes that expanded access to GI endoscopy services—including additional GI endoscopy rooms, gastroenterologists, and financial access—is needed to ensure a sufficient number of GI endoscopies can be performed to screen for and reduce both the incidence and mortality of colorectal cancer in Johnston County.”

As stated above, mortality rates from colorectal cancer are higher in Johnston County than in neighboring Wake County and the state as a whole. Furthermore, access to GI endoscopy services that could detect and treat such cancer is lower in Johnston County than in Wake County and the state as a whole.

Expanded GI Endoscopy Capacity Within an ASC Setting

In Section III.1, pages 71 – 74, the applicants describe the need in Johnston County for GI endoscopy procedures in an outpatient versus a hospital setting. The applicants state offering GI endoscopy procedures in an outpatient setting will provide:

- Improved Quality – the ASC will be dedicated to outpatient GI endoscopy procedures only, thus increasing quality of care and services;

- Improved Efficiency – the outpatient setting with two procedure rooms and recovery bays will allow for improved physician performance and maximum throughput;
- Lower Cost – since the procedures will not be performed in a hospital based setting, many of the overhead costs associated with hospitals will be eliminated. In addition, many deductibles and co-insurance payments are lower in an outpatient facility, thus further reducing the amount patients may have to pay; and
- Allow Hospital Physician Collaboration – Physicians with privileges at Johnston Health will own the JHES practice; as such, collaboration with the hospital will be part of the ongoing service offered to the patients.

Projected Utilization

In Section III, page 75 and Section IV, page 96, the applicants provide historical utilization for the three existing GI endoscopy rooms licensed by Johnston Health, as shown in the table below:

Historical Utilization, GI endoscopy rooms at Johnston Health

YEAR	CLAYTON	SMITHFIELD	TOTAL
FFY 2011	0*	2,603	2,603
FFY 2012	517	2,585	3,102
FFY 2013	708	2,772	3,480
FFY 2014	715	3,896	4,611
Compound Annual Growth Rate (CAGR)			21.0%

* FFY 2011 is the year the JH Clayton facility began offering GI endoscopy services.

In Section III, page 76, the applicants provide the projected utilization for the three existing and one proposed GI endoscopy rooms, as shown in the table below:

**Projected Utilization, GI endoscopy rooms at JHES
and Johnston Health Smithfield**

YEAR	TOTAL # PROCEDURES	# PER ROOM (3 ROOMS)	# PER ROOM (4 ROOMS)
FFY 2015	5,173	1,724	1,293
FFY 2016	5,803	1,934	1,451
FFY 2017	6,511	2,170	1,628
FFY 2018	7,304	2,435	1,826
FFY 2019	8,355	2,785	2,089
Total CAGR	12.2%		

In Section IV, page 97, the applicants provide the projected utilization for JHES during the first three project years following completion, as shown in the table below:

JOHNSTON HEALTH ENDOSCOPY CENTER	FIRST FULL FEDERAL FISCAL YEAR (FFY 2017)	SECOND FULL FEDERAL FISCAL YEAR (FFY 2018)	THIRD FULL FEDERAL FISCAL YEAR (FFY 2019)
Number of procedures	2,204	3,313	3,716
Procedures per room	1,102	1,656	1,858

In Section III, page 77, the applicants take into account Project ID #J-10281-14, which was approved by the CON Section for the development of Clayton Endoscopy, a new ASC with two GI endoscopy procedure rooms, which is supported by two gastroenterologists who currently perform procedures at Johnston Health. Based on information in the application submitted for that project, the applicants subtracted the number of GI endoscopy procedures projected in Project ID #J-10281-14 to be performed by the two physicians at Clayton Endoscopy. The following table illustrates the shift and subsequent recalculation of volume at both locations:

Projected Utilization, GI endoscopy rooms at JHES and Johnston Health Smithfield following completion of J-10281-14

YEAR	TOTAL # PROCEDURES	# PER ROOM (3 ROOMS)	# PER ROOM (4 ROOMS)
FFY 2015	5,173	1,724	1,293
FFY 2016	5,803	1,934	1,451
FFY 2016 after shift of procedures	(5,803 – 618) 5,185	1,728	1,296
FFY 2017	5,817	1,939	1,454
FFY 2018	6,526	2,175	1,631
FFY 2019	7,321	2,440	1,830
CAGR	12.2%		

On page 79, the applicants state that although a 12.2% CAGR was used to project utilization (less the shift of cases to Clayton Endoscopy), the effective CAGR, including the subtraction of those cases is only 9.1%, which is an even more conservative projection.

On pages 80 – 86, the applicants provide additional information to support their utilization projections, including:

- Projected growth rate that is lower than historical growth rate;
- Physician support;
- Patient-friendly attributes of an ASC, including lower charge structure;
- Enhanced physician productivity in ASC setting;
- Expanded healthcare services at JH Clayton;
- The impact of being part of the UNC Health Care System.

The applicants adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. Thus, the applicants adequately demonstrate that they will perform at least 1,500 GI endoscopy procedures per room in the second project year as required by G.S. 131E-182(a) and 10A NCAC 14C .3903(b).

Access

In Section VI.2, page 105, the applicants state

“As is the practice of Johnston Health, the sole member of JHES, the new facility will provide care to all persons in need of its services, including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other underserved.”

In Section VI, page 115, the applicants project their GI endoscopy payor mix of Medicare and Medicaid cases will mirror the historical payor mix at Johnston Health Clayton, which is 65.2% during the second year of operation of the project.

Exhibit 11 contains a copy of Johnston Health’s financial policies. The applicants further describe their charity and financial payment policies on pages 105 and 110 - 111. The applicants project that Johnston Health will provide \$58,491 (4.0% of net revenue) in charity care and \$26,801 (1.9% of net revenue) in bad debt in the second year of operation.

The applicants adequately demonstrate the extent to which all residents of the area; 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 proposed services.

Conclusion

In summary, the applicants adequately identify the population to be served and adequately demonstrate the need the population proposed to be served has for the proposal and adequately demonstrate the extent to which all residents of the area, including 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.

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The applicants propose to relocate one existing GI endoscopy room from Johnston Health Clayton to another location in Clayton. According to MapQuest®, the distance from Johnston Health to the proposed location is approximately 12 miles, or 18 minutes driving time.

The needs of the population presently served will continue to be adequately met following the proposed relocation, since the proposed location is a few miles from the existing location. 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.

CA

In Section III.8, pages 93 – 94, the applicants describe the alternatives considered, which include the following:

1. Maintain the status quo – the applicants state on page 93 that this is not an effective alternative for meeting the needs of the patients it serves because it would not allow Johnston Health to provide less costly, more patient-focused GI endoscopy services to its patients.
2. Develop an additional endoscopy room at Johnston Health Clayton or Johnston Health Smithfield – the applicants state on page 93 that this alternative would fail to realize the benefits provided in a freestanding ASC, including patient convenience and lower costs to patients. This option also ignores the benefit of being able to provide outpatient GI endoscopy services to patients in a facility that already exists and thus would require minimal capital expenditure to renovate. To develop an additional room would require construction and its associated costs.
3. Proposed project to relocate one existing GI endoscopy room, develop one new GI endoscopy room, and develop an ASC in Clayton – the applicants state on page 94 that this proposal is the least costly and most effective alternative to address Johnston Health’s needs because it will accommodate Johnston County residents who currently seek GI endoscopy services in Wake County, and will provide the most cost-effective solution to meet current and future demand for GI endoscopy services.

The applicants adequately demonstrate that the proposed alternative is the most effective or least costly alternative.

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. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

1. **Johnston Health Services Corporation and Johnston Health Endoscopy Services, LLC shall materially comply with all representations made in the certificate of need application.**
2. **Johnston Health Services Corporation and Johnston Health Endoscopy Services, LLC 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. **Johnston Health Services Corporation and Johnston Health Endoscopy Services, LLC shall relocate the existing gastrointestinal endoscopy room from Johnston Health Clayton to Johnston Health Endoscopy Services, LLC, and develop a new ambulatory surgical facility with no more than two gastrointestinal endoscopy rooms upon project completion.**
 4. **Johnston Health Services Corporation shall take the necessary steps to delicense the existing gastrointestinal room at Johnston Health Clayton upon project completion.**
 5. **Prior to issuance of the certificate of need, Johnston Health Endoscopy Services, LLC shall provide the agency with the documentation of an agreement to transfer and accept referrals of GI endoscopy patients from a hospital where physicians utilizing the facility have practice privileges.**
 6. **Johnston Health Services Corporation and Johnston Health Endoscopy Services, LLC 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 127, the applicants project the total capital cost for the project will be \$822,451. The capital cost includes \$224,753 in construction/renovation costs and \$597,698 in miscellaneous costs which include equipment, furniture, consultant fees, and contingencies. In Section VIII.3, page 127, the applicants state the capital costs will be financed through Johnston Health's accumulated reserves. In Section IX, page 131, the applicants project start up costs of \$98,239 and initial operating expenses of \$308,580, for a total working capital of \$406,819.

Exhibit 32 contains an April 15, 2015 letter from the Chief Financial Officer of Johnston Health, confirming the availability of funding for the proposed project. The letter states, in part:

"As the Chief Financial Officer for Johnston Health, the sole member of JHES, I am responsible for the financial operations of Johnston Health and its subsidiary entities. As such, I am very familiar with the organization's financial position. Total projected capital costs for the project are estimate[d] to be \$822,451. As the sole entity of both applicant entities, Johnston Health intends to use its reserve funds for the entire capital cost amount. In addition, JHES is expected to incur approximately \$406,819 in start-up and initial operating costs, which will also be funded by Johnston Health's reserves.

As documented in the audited financials that accompany the application, Johnston Health has sufficient reserves to fund the ASC project. Upon receipt of the certificate of need, Johnston Health will transfer funds to JHES to fund the proposed project, including start-up costs and initial operating costs.”

In Exhibit 33, the applicants provide Johnston Health’s most recent audited financial statements. As of December 31, 2013, Johnston Health had \$4,948,264 in cash and cash equivalents, and \$255,655,190 in total assets, and \$84,348,839 in total net assets (total assets less total liabilities).

The applicants provide pro forma financial statements for the first three years of the project, in which they project revenues will exceed expenses in the second and third years following project completion, as shown in the following table:

Johnston Health Endoscopy Services	PY 1 FFY 2016	PY 2 FFY 2017	PY 3 FFY 2018
Projected # of Procedures	2,204	3,313	3,716
Projected Average Charge	\$ 1,715	\$ 1,741	\$ 1,767
Gross Patient Revenue	\$3,779,643	\$5,767,209	\$6,567,134
Deductions from Gross Patient Revenue	\$2,817,726	\$4,299,458	\$4,895,802
Net Patient Revenue	\$ 961,917	\$1,467,751	\$1,671,332
Total Expenses	\$1,072,640	\$1,187,136	\$1,251,318
Net Income	(\$ 110,723)	\$ 280,615	\$ 420,013

In Section II.7, pages 39 - 41, the applicants provide the projected average facility charge per procedure for the 10 most common GI endoscopy procedures. In Section II.8, page 42, the applicants list the professional fees that will be billed separately by the physicians’ offices and will not be included in the average procedure charge.

The applicants adequately demonstrate that the projected revenues and operating costs are based on reasonable and adequately supported assumptions, including projected utilization. See the Pro Formas tab of the application, page 146, for the assumptions regarding costs and charges. The discussion regarding analysis of need and projected utilization found in Criterion (3) is incorporated herein by reference.

In summary, the applicants adequately demonstrate the availability of sufficient funds for the capital and working capital needs of the project and adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of operating costs and revenues. Therefore, the application is conforming to this criterion.

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

C

The applicants propose to develop Johnston Health Endoscopy Services, LLC (JHES), a new, separately licensed ASC with two GI endoscopy rooms, by relocating one GI endoscopy room from Johnston Health Clayton and developing a new GI endoscopy room. The applicants propose to develop the ASC in an existing building in Clayton previously used as a two-room surgical ASC. Upon project completion, Johnston Health will be licensed for two GI endoscopy rooms at Johnston Health Smithfield, and JHES will be licensed for two GI endoscopy rooms.

The 2015 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6) does define the service area as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.

In Section III, pages 66 - 71, the applicants show that the incidence of colorectal cancer in Johnston County is higher than in Wake County and North Carolina as a whole. Similarly, the applicants show that the mortality rate from colorectal cancer is higher in Johnston County than in Wake County and North Carolina. Despite this data, the applicants show on page 71 that Johnston County has fewer existing, licensed GI endoscopy procedure rooms per 100,000 population. See the following table that shows that Johnston County has 1 licensed GI endoscopy procedure room for every 59,102 people; whereas Wake County has 1 licensed GI endoscopy procedure room for every 23,392 people and North Carolina has 1 for every 21,923 [calculated by the analyst as follows: 2013 population / # GI endoscopy rooms].

	JOHNSTON COUNTY	WAKE COUNTY	NORTH CAROLINA
# GI Endoscopy Rooms	3	44	461
2013 Population	177,308	964,616	9,861,952
Rooms/100,000	1.7	4.6	4.7
FFY 2013 Volume	6,228	43,162	493,306
FFY 2013 Volume/Room	2,076	981	1,070

In Project ID #J-10281-14, Wake Endoscopy Center, LLC (WEC) was approved to develop a freestanding ASC with two GI endoscopy procedure rooms in Clayton. In that application, WEC projected to serve the portion of Johnston County residents that it was already serving in its facility in Wake County. In this application, JHES anticipates a shift in its own patient origin to account for patients projected to be served by WEC. Despite that shift, JHES projects to perform 3,716 procedures in its two GI endoscopy procedure rooms in the third project year, which is 1,858 procedures per room. 10A NCAC 14C .3903(b) requires an applicant proposing to establish a new licensed ambulatory surgical facility to demonstrate that the facility will perform at least 1,500 GI endoscopy procedures per room in the second year of operation following completion of the project. The 1,858 procedures projected by the applicants exceeds the 1,500 procedures required by the performance standard.

In addition, in Section III.1, page 75, the applicants state GI endoscopy volumes have increased by a CAGR of 21.9% in Johnston County since FFY 2012. Based on performance standards

promulgated in G.S. 131E-182(a) and 10A NCAC 14C .3903(b), using procedures performed in the existing GI endoscopy rooms in Johnston County, Johnston Health endoscopy procedure rooms performed at 102% of capacity in FFY 2014 [4,611 total procedures / 4,500 total possible procedures = 1.0247].

In Section V, page 101, the applicants provide a list of six gastroenterologists with privileges at Johnston Health who will perform procedures at JHES.

Given the historical growth in GI endoscopy volume in Johnston County, the incidence of colorectal cancer in Johnston County and the mortality rate from colorectal cancer in Johnston County, both of which are higher than Wake County and North Carolina as a whole, it is reasonable to assume that the addition of one new GI endoscopy procedure room will be needed in Johnston County. Furthermore, the development of an ASC to perform GI endoscopy procedures will allow the applicants to offer GI endoscopy services more cost-effectively than in a hospital setting.

The applicants adequately demonstrate that developing the proposed ASC by relocating one GI endoscopy procedure room from Johnston Health Clayton and adding one new GI endoscopy procedure room would not result in an unnecessary duplication of existing or approved health service capabilities or facilities.

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 Section VII.2, page 117, the applicants project staffing in full time equivalents (FTE) positions during the second full fiscal year, as illustrated in the table below:

EMPLOYEE CATEGORY	# FTES
Professional Healthcare Administrators (Supervisor)	0.33
Registered Nurses	4.50
Endoscopy Technicians	2.00
CRNA	0.80
Secretary/Registrar	1.00
Total	8.63

In Section VII.9, page 123, the applicants state that Dr. Alma Jenkins has agreed to serve as the Medical Director of JHES. Exhibit 19 contains an April 15, 2015 letter from Dr. Jenkins indicating her willingness to serve as the Medical Director.

The applicants adequately document the availability of sufficient resources, including health manpower and management personnel, for the proposed ASC. 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

The applicants state the necessary ancillary and support services are currently available through Johnston Health and identifies those services in Section II.2, page 15. The applicants discuss coordination with the existing health care system in Sections V.2-V.6, pages 99 - 103. The applicants provide supporting documentation of coordination and support from hospital board members and administration and area physicians in Exhibits 5, 19, 27, and 35. The applicants adequately demonstrate they will provide or make arrangements for the necessary ancillary and support services and 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.

NA

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

C

In Sections VI.12 and VI.13, pages 114 - 115, the applicants provide the payor mix during FY 2014 for Johnston Health, as illustrated in the tables below.

Johnston Health Payor Mix, FY 2014

PAYOR	PROCEDURES AS % OF TOTAL
Self Pay/Indigent	5.1%
Commercial Insurance	10.8%
Medicare/Medicare Managed Care	60.1%
Medicaid	20.4%
Managed Care	3.6%
Total	100.0%

Johnston Health Clayton Outpatient Payor Mix, FY 2014

PAYOR	PROCEDURES AS % OF TOTAL
Self Pay/Indigent	1.0%
BCBS/Commercial Insurance	24.5%
Medicare/Medicare Managed Care	53.8%
Medicaid	11.4%
Managed Care	9.3%
Total	100.0%

Johnston Health Smithfield Outpatient Payor Mix, FY 2014

PAYOR	PROCEDURES AS % OF TOTAL
Self Pay/Indigent	5.9%
BCBS/Commercial Insurance	19.5%
Medicare/Medicare Managed Care	45.7%
Medicaid	20.1%
Managed Care	8.9%
Total	100.0%

Exhibit 11 contains a copy of the Johnston Health’s Admissions Policy, which contains policies pertaining to non-discrimination and provision of services to underserved populations. Section VI, pages 105 - 111, 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 Johnston County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Johnston County	17%	6.7%	20.0%
Statewide	17%	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 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 45.9% for those age 20 and younger and 30.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race

or gender does not include information on the number of elderly, minorities, handicapped persons or women utilizing health services.

The applicants demonstrated that medically underserved populations currently have adequate access to the applicant's existing services offered at Johnston Health. Therefore, the application is conforming to this criterion.

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 113, the applicants state:

“Aside from its non-profit status, Johnston Health has no obligation under federal regulations to provide uncompensated care or community service, nor will JHES. However, Johnston Health, the sole member of JHES, provides, without obligation, a considerable amount of bad debt and charity care.”

The applicants state on page 105 that Johnston Health and thus JHES will provides care to all persons, including low income, racial and ethnic minorities, women, handicapped persons, elderly and other underserved populations. In Section VI.8, pages 109 - 111, the applicants discuss JH's charity care policy. In Section VI.10, page 113, the applicants state that no civil rights complaints were filed against Johnston Health in the last five years. 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

C

In Section VI.14, page 115, the applicants project payor mix during the second year of operation following project completion, which is shown in the following table.

Johnston Health Endoscopy Services, LLC FFY 2018

PAYOR	PROCEDURES AS % OF TOTAL
Self Pay/Indigent	1.0%
BCBS/Commercial Insurance	24.5%
Medicare/Medicare Managed Care	53.8%
Medicaid	11.4%
Managed Care	9.3%
Total	100.0%

As shown above, the applicants project that 65.2% of all GI endoscopy procedures to be performed at JHES will be provided to recipients of Medicare/Medicaid. In Section IV.14, page 115, the applicants state:

“...projected payor mix for the proposed services is based on historical payor mix experienced by Johnston Health Clayton for outpatient GI endoscopy procedures. Because the proposed facility is located in Clayton, less than three miles from Johnston Health Clayton, Johnston Health believes that the historical payor mix for GI endoscopy services at Johnston Health Clayton is an accurate representation of expected payor mix at JHES.”

The applicants demonstrate that medically underserved populations will continue to have adequate access to the GI endoscopy services offered at JHES. 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 111, the applicants describe the range of means by which a person will have access to JHES’s endoscopy services. The applicants adequately demonstrate that the facility will offer a range of means by which patients will have access to the proposed services. 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 98 – 99 and referenced exhibits for documentation that Johnston 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 develop Johnston Health Endoscopy Services, LLC (JHES), a new, separately licensed ASC with two GI endoscopy rooms, by relocating one GI endoscopy room from Johnston Health Clayton and developing a new GI endoscopy room. The applicants propose to develop the ASC in an existing building in Clayton previously used as a two-room surgical ASC. Upon project completion, Johnston Health will be licensed for two GI endoscopy rooms at Johnston Health Smithfield, and JHES will be licensed for two GI endoscopy rooms.

The 2015 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6) does define the service area as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.

There are currently three licensed GI endoscopy procedure rooms in Johnston County, all of which are licensed as part of Johnston Health. This application proposes to relocate one existing GI endoscopy room and develop one new GI endoscopy room, so that there will be a total of four licensed GI endoscopy procedure rooms following completion of this project. The applicants demonstrate that the existing GI endoscopy procedure rooms in Johnston County are operating at over 100% capacity, and even with the recently approved Clayton Endoscopy Center, utilization is projected to be in excess of 100% by the second project year.

In Section V.7, page 104, the applicants describe the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access to GI endoscopy services. The applicants state that the offering of GI endoscopy services in a purely outpatient setting will provide efficiencies and conveniences in both finances and operations to both physicians and patients that are not available in a hospital or an in-patient setting.

See also Sections II, III, V, VI and VII in which 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, credible 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 develop a freestanding, separately licensed ASC by relocating one existing GI endoscopy room and adding one new GI

endoscopy room, for a total of two GI endoscopy rooms at Johnston Health Endoscopy Services, LLC and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criterion (3) and (4), respectively, are incorporated herein by reference.

- The applicants adequately demonstrate that they will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicants adequately demonstrate that they will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

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

In Section I, page 10, the applicants state that Johnston Health currently owns, lease or manages two acute care hospitals in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of this application through the date of the decision, no facilities were found to be out of compliance with one or more Medicare conditions of participation. At this time, all of the facilities are in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at both facilities, the applicants provided sufficient evidence that quality care has been provided in the past. 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 Johnston Health 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 21, the applicants identify the primary service area as Johnston County, *representing* approximately 73% of projected procedures. In Section III.6, page 91, the applicants identify the other counties included in 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 21, the applicants state JHES is not an existing facility and thus has no existing licensed GI endoscopy rooms. However, Johnston Health, which is the sole member of JHES, operates three GI endoscopy rooms, two in Smithfield and one in Clayton. In this application, the applicants propose to add one additional GI endoscopy procedure room, such that JHES will operate two licensed GI endoscopy procedure rooms and Johnston Health Smithfield will operate two licensed GI endoscopy rooms.

(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 22, the applicants state that Johnston Health Smithfield currently operates two GI endoscopy procedure rooms and Johnston Health Clayton operates one GI endoscopy procedure room.

(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.11, pages 22 - 23, the applicants state JHES is not an existing facility; however, Johnston Health performed a total of 4,281 GI endoscopy procedures in the 12 months preceding submittal of the application, 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.11, pages 25 - 28, the applicants provide the number of GI endoscopy procedures, identified by CPT or ICD-9-CM procedure codes, projected to be performed in Johnston Health's two licensed GI endoscopy rooms and JHES's two 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.11, page 28, the applicants state that JHES is not yet licensed and thus performed no GI endoscopy procedures in the last 12 months. The applicants state that no procedures other than GI endoscopy procedures were performed in either Johnston Health Clayton or Johnston Health Smithfield 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.

- NA- In Section II.11, page 29, the applicants state Johnston Health and JHES do not project to perform any non-GI endoscopy procedures in the four 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.11, page 29, the applicants state that 2,973 patients were served at Johnston Health in its three licensed GI endoscopy rooms in the last 12 months. The applicants state the procedure to patient ratio is 1.44 to 1.

(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.11, pages 29 - 30, the applicants project to serve the following number of patients in JHES's two licensed GI endoscopy rooms in each of the first three operating years of the project. The applicants state the procedure to patient ratio for outpatient procedures, which are the procedures that will be performed in the proposed ASC, is 1.37 to 1.

PROJECT YEAR	PROCEDURES	PATIENTS
PY 1	2,204	1,610
PY 2	3,313	2,420
PY 3	3,716	2,714

On page 30, the applicants project to serve the following number of patients in Johnston Health Smithfield in the first three years of operation of JHES. The procedure to patient ratio is 1.44 to 1.

PROJECT YEAR	PROCEDURES	PATIENTS
PY 1	3,614	2,510
PY 2	3,214	2,232
PY 3	3,604	2,503

.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.11, page 30 - 32, the applicants state that Johnston Health currently has five shared surgical operating rooms and one C-Section room at Johnston Health Smithfield, and two dedicated outpatient operating rooms at Johnston Health Clayton. In addition, in May 2015, one additional shared operating room became operational pursuant to Project ID #J-8360-09. The applicants state on page 31 that the two dedicated outpatient operating rooms that were at Johnston Health Clayton will be converted to shared operating rooms.

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

-C- In Section II.11, pages 32 - 33, the applicants list a total of 2,219 surgical procedures, by type, performed in Johnston Health's shared operating rooms (both Johnston Health Smithfield and Johnston Health Clayton) in the last 12 months.

(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.11, pages 33 - 36, the applicants provide the number of procedures by type projected to be performed in Johnston Health's operating rooms in each of the first three years of the project. These numbers include the procedures to be performed at Johnston Health Smithfield, Johnston Health Clayton, and the newly formed JHES.

.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.11, page 36, the applicants state the GI endoscopy program will be operated from 6:30 a.m. to 5:00 p.m., with patient appointments scheduled from 7:00 a.m. to 4:30 p.m. Monday through Friday.

.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- JHES is not an existing facility; however, in Section II.11, pages 37 - 39, the applicants provide the type and average facility charge for each of the 10 GI endoscopy procedures most commonly performed in Johnston Health Smithfield and Johnston Health Clayton during the last 12 months for which data is available.

.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.11, pages 39 - 41, the applicants provide the type and average facility charge for the 10 GI endoscopy procedures they project will be performed most often at JHES, Johnston Health Smithfield, and Johnston Health Clayton.

.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.11, pages 41 - 42, the applicants state

“JHES is proposing to develop a Medicare-certified GI endoscopy ASC. Medicare reimburses a flat facility fee which requires the inclusion of the following services and items, which JHES also expects to be part of the flat facility fee for all other payors:

- *Nursing services, services furnished by technical personnel, and other related services;*

- *Patient use of ASC facilities;*
- *Drugs and biologicals for which separate payment is not made under the outpatient prospective payment system, e.g. dressings, supplies, appliances, and equipment;*
- *Administrative, recordkeeping, and housekeeping items and services;*
- *Blood, blood plasma, and platelets, with the exception of those to which the blood deductible applies; and*
- *Materials for anesthesia.”*

.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.11, page 42, the applicants describe the services that will not be included in the facility’s charges. These services include: physicians’ services, durable medical equipment, ambulance services, independent laboratory services, and other services excluded from payment by CMS.

.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- JHES is not an existing facility. However, in Section II.11, pages 43 - 45, the applicants provide the average reimbursement received per procedure for each of the 10 GI endoscopy procedures most commonly performed in Johnston Health Smithfield and Johnston Health Clayton in the preceding 12 months for which data was available.

.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.11, pages 45 - 47, 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 each facility for the first three project years.

.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;

-C- In Exhibit 11, the applicants provide a copy of Johnston Health's admission and financial policies. The applicants state that JHES is a wholly owned subsidiary of Johnston Health and as such, will adhere to those same policies.

(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;

-C- In Exhibit 12, the applicants provide a copy of an April 15, 2015 letter from Dr. Alma Jenkins, proposed Medical Director of JHES, in which she commits 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;

-C- In Exhibit 11, the applicants provide a copy of Johnston Health's admission and financial policies, which describe the strategies to be used and activities to be undertaken to assure accessibility of services. The applicants state that JHES is a wholly owned subsidiary of Johnston Health and as such, will adhere to those same policies.

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

-C- In Exhibit 13, the applicants provide a copy of Johnston Health's patient selection criteria, including referral for high-risk patients. The applicants state that JHES is a wholly owned subsidiary of Johnston Health and as such, will adhere to those same policies.

(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;

-NA- In Section II.11, page 49, the applicants state that Johnston Health did not perform any GI endoscopy procedures in any other licensed health service facility in the last 12 months.

(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.

- C- The applicants state that the relocation of one existing GI endoscopy room to JHES will result in a shift of outpatient procedures from Johnston Health Smithfield to the proposed ASC. In Section III.1, the applicants describe the rationale for the change in practice patterns.

.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.

- NA- The proposed project does not involve licensed operating rooms; however, in Section II.11, page 49, the applicants state JHES’s and Johnston Health’s GI endoscopy rooms will operate five days per week and 52 weeks per year.

.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 Sections III.1, page 81, and IV.1, pages 96 - 97, the applicants project to perform at least 1,500 GI endoscopy procedures per GI endoscopy room in each licensed facility in the second year of operation following project completion. See the following table, from page 81:

YEAR	SMITHFIELD		CLAYTON (HOSPITAL)		JHES	TOTAL
	IP	OP	IP	OP	OP ONLY	
FFY 2015	1,254	2,940	0	980	0	5,173
FFY 2016	1,256	2,750	0	1,179	0	5,185
FFY 2017	1,410	2,204	0	0	2,204	5,817
FFY 2018	1,581	1,632	0	0	3,313	6,526
FFY 2019	1,774	1,830	0	0	3,716	7,321

In Section III, pages 74 - 85, the applicants provide the assumptions and methodology used to project utilization. The discussion regarding analysis of need and 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.11, page 50, the applicants state they will continue to provide upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures at the proposed ASC.

.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.

- C- In Section II.11, page 51, the applicants state Johnston Health does not currently perform GI endoscopy procedures in its operating rooms. The applicant projects the following cases per day in the shared operating rooms at Johnston Health Clayton and Johnston Health Smithfield:

FACILITY	YEAR 2 CASES	# SHARED ORS	YEAR 2 CASES PER DAY
Johnston Health Clayton	2,676	3	3.87
Johnston Health Smithfield	4,279	5	3.43

.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 III1(b), pages 74 - 85, the applicants describe the assumptions and the methodology they used to project GI endoscopy procedures. The discussion regarding analysis of need and 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 14 contains a copy of an April 15, 2015 letter from the CEO of Johnston Health that confirms Johnston Health's willingness to provide pathology services to JHES.
- .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 15 contains a copy of Johnston Health's GI endoscopy policies and procedures regarding sedation and anesthesiology. On page 52, the applicants state that as wholly owned subsidiary of Johnston Health, JHES will adhere to those same policies and procedures.
- .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 16 contains a copy of Johnston Health's policies and procedures for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure rooms between cases. On page 52, the applicants state that as wholly owned subsidiary of Johnston Health, JHES will adhere to those same policies and procedures.
- .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.11, page 53, the applicants state that all physicians using the GI endoscopy procedure rooms at JHES will have practice privileges at Johnston Health. In Exhibit 17 the applicants provide a copy of a letter from Dr. Alma Jenkins, the proposed Medical Director for JHES, detailing the practice privilege requirement for the medical staff at JHES.

(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.

-CA- In Section II.1, page 53, the applicants state the physicians who will perform procedures at JHES are members of the medical staff at Johnston Health; therefore, no transfer agreements are necessary. However, this rule requires documentation of an agreement between the proposed ASC and a hospital. The application is conforming to this Rule, subject to Condition 5 in Criterion (4).

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

-C- In Section II.1, page 53, the applicants state the physicians who will perform procedures at JHES are members of the medical staff at Johnston Health; therefore, no transfer agreements are necessary.

.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 Table VII.7, page 120, the applicants project staffing at **JHES**, by area of operation, as shown in the following table:

EMPLOYEE CATEGORY	ADMINISTRATION FTES	PRE-OP FTES	POST-OP FTES	# FTES PER ROOM	TOTAL FTES
Professional Health Care Administrators	0.33				0.33
Registered Nurses		1.25	1.25	2.00	4.50
Endoscopy Technologists				2.00	2.00
CRNA				0.80	0.80
“Non-health professionals” / technical	1.00				1.00
Totals	1.33	1.25	1.25	4.80	8.63

.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.11, page 54, the applicants provide a table that shows seven physicians who will utilize JHES, all of whom currently perform GI endoscopy procedures at

Johnston Health. All of the physicians are either board-certified or board-eligible in gastroenterology, internal medicine or surgery.

.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 17 contains a copy of Johnston Health's policies regarding extending privileges to medical personnel. As a wholly owned subsidiary of Johnston Health, JHES will abide by those same policies and procedures.

.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;

-C- Exhibit 19 contains a copy of the curriculum vitae for Dr. Alma Jenkins, the proposed Medical Director for JHES. Dr. Jenkins is licensed to practice medicine in North Carolina and is board-certified in gastroenterology and internal medicine. The applicants state on page 55 that Dr. Jenkins will be 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;

-C- In Section II.11, page 56, the applicants state all of the physicians who will utilize JHES are either board-certified or board-eligible in gastroenterology, internal medicine or 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;

-C- In Section II.11, page 56, the applicants state each of the physicians who will utilize JHES is a member in good standing at Johnston Health.

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

- C- In Section VII.7, page 120, the applicants state there will be two registered nurses per GI endoscopy procedure room.

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

- C- In Section VII.7, page 120, the applicants show all staff by area of operation, including endoscopy technologists, who will provide assistance in procedure rooms.

(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.

- C- In Section II.11, page 57, the applicants state at least one ACLS certified healthcare professional and at least one other BCLS certified health professional will be present at JHES at all times. In Exhibit 20, the applicants provide an April 15, 2015 letter signed by Dr. Jenkins confirming that those personnel will be present at JHES.

.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.

- NA- The applicants are not 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.

(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- In Exhibit 12, the applicants provide a letter from Dr. Alma Jenkins that confirms JHES's intention to obtain accreditation by the Joint Commission within one year of completion of the 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.

- C- In Exhibit 21 the applicants provide a letter from David J. Brown, certified architect that confirms the facility will conform to all 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.

- C- In Exhibit 4 the applicants provide a floor plan that identifies the areas indicated in this rule.

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

- C- In Exhibit 4 the applicants provide a floor plan that indicates the procedure rooms are physically segregated from the general office area.

(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.

- C- In Exhibit 1 the applicants provide a copy of a lease agreement and a letter from the CEO of Johnston Health, assigning a portion of the lease to JHES.