

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 16, 2017  
Findings Date: October 16, 2017

Project Analyst: Celia C. Inman  
Team Leader: Fatimah Wilson

Project ID #: G-11381-17  
Facility: Digestive Health Specialists, P.A.  
FID #: 170364  
County: Stokes  
Applicant: Digestive Health Specialists, P.A.  
Project: Develop an ASC with one licensed GI endoscopy room in an existing medical office building

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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

Digestive Health Specialists, P.A. (DHS), the applicant, proposes to develop an ambulatory surgery center (ASC) with one licensed GI endoscopy procedure room in an existing medical office building in King, Stokes County. In Section II.6, page 10, the applicant states that the DHS-King office currently provides a broad array of GI endoscopy, upper endoscopy, esophagoscopy and colonoscopy procedures and that no new service, equipment or types of procedures are planned or proposed for the proposed DHS-King ASC.

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 2017 State Medical Facilities Plan (SMFP). In addition, no policies in the 2017 SMFP are applicable to this review. Therefore, this criterion is not applicable in this review.

- (2) Repealed effective July 1, 1987.

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

C

DHS, the applicant, proposes to develop an ASC with one licensed GI endoscopy procedure room in leased space in the existing medical office building owned by DHS Properties, LLC, which opened in April 2017 at 434 Kirby Road, King, Stokes County. In Section I.13, page 4, the applicant states that the existing medical office building was “*designed and constructed with an endoscopy suite and facility space that meet the North Carolina construction standards to be licensed as an ambulatory surgical facility with one licensed GI endoscopy procedure room.*” In Section II.4, page 10, the applicant states that the present endoscopy suite with one GI endoscopy procedure room is adjacent to and physically separate from the DHS physician practice offices. The applicant further states:

*“Once the proposed project is approved, completed, and licensed, the ASC facility will continue to be physically separate from the Digestive Health Specialists office-based practice in accordance with the relevant Division of Facility Services construction / life safety standards.”*

Exhibit 7 contains the floor plan of the medical office building showing the firewalls and physical separation of the endoscopy suite.

**Patient Origin**

The 2017 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) states that “*Service Area*” means the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients. Therefore, the proposed service area for this review, as defined by the applicant on page 35, is Stokes County, from which the applicant states that 74% of its patients have originated since DHS-King began providing endoscopy services in April 2017. The applicant may also serve residents of counties not included in its proposed service area.

In Section III.6, page 35, the applicant provides the current and projected patient origin for GI endoscopy services provided at DHS-King. The following table shows DHS’ patient origin for the current year and the projected second operating year (OY).

<b>Digestive Health Specialists-King Patient Origin (Cases) by County</b>			
<b>County</b>	<b>Current (4/3/17 – 7/5/17)</b>	<b>Projected OY2 (CY 2020)</b>	
	<b>% of Patients</b>	<b># of Patients</b>	<b>% of Patients</b>
Stokes	73.89%	1,501	73.87%
Surry	13.32%	271	13.34%
Forsyth	8.62%	175	8.61%
Rockingham	0.78%	16	0.79%
Yadkin	0.52%	11	0.54%
Other NC Counties	0.78%	16	0.79%
Virginia	2.09%	42	2.07%
<b>Total</b>	<b>100.00%</b>	<b>2,032</b>	<b>100.00%</b>

Totals may not sum due to rounding

On page 35, the applicant states that projected patient origin is based on actual utilization April 3, 2017 through July 5, 2017. The applicant further states that it assumes future patient origin is likely to be similar because the physicians have existing relationships with patients and referring physicians in the service area. The applicant adequately identifies the population proposed to be served.

**Analysis of Need**

In Section III.1, pages 15-25, the applicant describes the factors which it states justify the need for the proposed project, including:

- The 2017 SMFP recognizes the need for an additional licensed GI endoscopy procedure room with scheduled opportunities to submit CON applications in all areas of the State. However, there are no need determinations that limit the number of licensed GI procedure rooms (page 16);
- Demographic data that shows growth in the senior population, which will increase demand for endoscopy services (pages 16-17);
- The need to enhance access to diagnostic endoscopy/colonoscopy screening procedures based on high incidence rates of cancer (pages 17-20);
- Highly utilized existing DHS licensed endoscopy procedure rooms (pages 20-23);
- Physician letters of support documenting increased utilization and a commitment to obtain licensure, certification and accreditation to expand access for patients (Exhibit 13); and
- Current and future GI endoscopy procedure volume projections (pages 26-31).

In addition, in Section II.6, page 10, the applicant states:

*“Having a licensed and accredited ambulatory surgery facility with one GI endoscopy room in King will enable patients to access services close to home and also enable DHS to obtain and maintain payor agreements with Medicare, Medicaid and additional commercial payors.”*

In summary, the applicant adequately demonstrates the need for one licensed GI endoscopy procedure room at DHS-King.

Projected Utilization

In Section III.1, page 31, the applicant provides the calendar year (CY) projected utilization at DHS-King as shown in the following table.

<b>Digestive Health Specialists-King Projected Utilization Operating Years 1-3</b>					
	<b>CY 2017 (Annualized)*</b>	<b>CY 2018 (Interim)</b>	<b>CY 2019 (OY1)</b>	<b>CY 2020 (OY2)</b>	<b>CY 2021 (OY3)</b>
# of Rooms	1	1	1	1	1
# of Cases/Patients	1,318	1,992	2,012	2,032	2,052
# of Procedures	1,503	2,251	2,273	2,296	2,319

\*Annualized based on actual April 3, 2017 through July 5, 2017, the length of time the DHS-King physicians have been performing endoscopy procedures

As shown in the table above, the applicant projects to be performing 2,296 GI endoscopy procedures in the one licensed GI endoscopy room during the second year following project completion. This exceeds the minimum of 1,500 GI endoscopy procedures per room per year as of the end of the second operating year as required by 10A NCAC 14C .3903(b).

In Section III.1, pages 26-31, the applicant provides the methodology and assumptions used to make the above projections, including:

- For its first 50 working days from April 3, 2017 to July 5, 2017, the DHS-King office, with one procedure room, averaged 7.66 cases per day and 8.74 procedures (1.13 procedures per case) per day. The applicant annualized the utilization through December for projected CY2017 utilization, based on 177 days of operation in 2017.
- Utilization for CY2018 was based on 7.66 cases per day, 260 days and a ratio of 1.13 procedures per case.
- A 1.0% annual growth rate was assumed for projecting cases in CY2019-2021.

The applicant states that the methodology and assumptions are reasonable based on the following:

- Actual patient utilization at DHS-King, year-to-date (page 26);

- 1.13 procedures per case is also the 2017 overall combined utilization for all of the DHS Endoscopy Centers, including DHS-King, year-to-date (page 33); and
- 1.0% growth rate is conservative based on:
  - the physician support letters from the two gastroenterologists who currently work at the facility predict 100 to 120 GI endoscopy procedures per month; there are eleven other DHS gastroenterologists that will have privileges (page 33);
  - demographics show the age cohort 60+ is growing 2% annually for the Stokes County service area and for the combined Stokes, Forsyth and Surry area, which represents 96% of DHS-King's proposed patient origin (pages 16 and 32); and
  - DHS-King's commitment to continued patient education and community outreach; as well as to obtaining licensure, certification for Medicare and Medicaid, and accreditation (page 27).

Projected utilization of proposed GI endoscopy procedures is based on reasonable and adequately supported assumptions regarding continued growth.

### Access

In Section II.6, page 10, the applicant states that the project will have a positive impact on access by providing outpatient endoscopy access for all patient payor categories in a highly efficient and cost effective ambulatory setting. The applicant further states:

*“Having a licensed and accredited ambulatory surgery facility with one GI endoscopy room in King will enable patients to access services close to home and also enable DHS to obtain and maintain payor agreements with Medicare, Medicaid and additional commercial payors.”*

In Section VI.2, page 46, the applicant states:

*“Digestive Health Specialists currently do and will continue to provide services to all of the above-listed categories of patients. As seen in Exhibit 14, (Governing Board and Medical Staff Bylaws Rules and Regulations), the applicant will not discriminate against anyone regardless of age, race, ethnicity, gender, disability, or ability to pay. Also, the applicant has already implemented charity care policies and referral arrangements to expand access to underserved persons as seen in Exhibit 15.”*

Exhibit 14, page 133, states that the Center shall strive to assist Medical Staff Members to meet certain health needs for patients without regard to race, color, religion, sex, age or national origin. Exhibit 15 contains a charity care policy.

In Section VI.14, page 51, the applicant projects that 40% of the patients who will receive treatments in the second operating year (CY 2020) will have some or all of their services paid for by Medicare or Medicaid. The applicant further states that the projected payor mix is based

on the 2016 average payor mix for the existing licensed DHS Endoscopy Centers in North Carolina.

The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to the services proposed.

### **Conclusion**

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for a licensed GI endoscopy procedure room, and the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section III.8, pages 36-37, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintain the Status Quo - the applicant states that this is not an effective alternative based on the extremely high volume of the two GI endoscopy procedure rooms at the Digestive health facility in Winston-Salem. With the increased number of gastroenterologists, the overall procedure demand has resulted in a backlog in spite of the CON-approved facilities in Thomasville, Kernersville and Advance. Therefore, the applicant does not consider maintaining status quo as an effective alternative.
- Develop an ASC with two GI endoscopy procedure rooms – the applicant states that developing two GI procedure rooms in King is unrealistic based on the historical and projected utilization. Therefore, this alternative is not considered an effective alternative.
- Develop an ASC with one GI endoscopy procedure room, as proposed – the applicant states that this option would add capacity to match both patient demand for procedures and the growth of an existing DHS practice location.

The applicant further states that licensing the one GI endoscopy procedure room can be accomplished with no disruption of services and the proposed facility in King will be able to be licensed and accredited and will participate in the Medicare and Medicaid programs. Thus, the applicant determined this option was the most effective alternative.

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

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Digestive Health Specialists, P.A. shall materially comply with all representations made in the certificate of need application.**
- 2. Digestive Health Specialists, P.A. shall develop an ambulatory surgery center with no more than one licensed gastrointestinal endoscopy procedure room.**
- 3. Upon completion of the project, Digestive Health Specialists, P.A. shall be licensed for no more than one gastrointestinal endoscopy procedure room.**
- 4. Digestive Health Specialists, P.A. 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.**
- 5. The procedure room shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**
- 6. Procedures performed in the procedure room shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.**
- 7. Digestive Health Specialists, P.A. shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**
- 8. For the first three years of operation following completion of the project, Digestive Health Specialists, P.A. shall not increase charges more than 5% of the charges projected in Section X of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
- 9. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need,**

**Digestive Health Specialists, P.A. shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**

- a. Payor mix for the services authorized in this certificate of need.**
- b. Utilization of the services authorized in this certificate of need.**
- c. Revenues and operating costs for the services authorized in this certificate of need.**
- d. Average gross revenue per unit of service.**
- e. Average net revenue per unit of service.**
- f. Average operating cost per unit of service.**

**10. Digestive Health Specialists, P.A. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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The applicant proposes to develop an ASC with one licensed GI endoscopy procedure room in an existing medical office building.

**Capital and Working Capital Costs**

In Section VIII.2, page 61, the applicant states that the projected capital cost is \$60,000, composed of contingencies of \$10,000 for equipment and \$50,000 for the building. The applicant anticipates start-up and initial operating costs of \$2,500 each.

**Availability of Funds**

In Section VIII.8, page 63, the applicant states that the proposed project will be funded from available cash. Exhibit 24 contains a letter from the CEO of Digestive Health Specialists, P.A., dated August 4, 2017, which states Digestive Health Specialists' intent to fund the combined capital and working capital of \$65,000 from cash and cash equivalents, referencing \$336,023 in total Checking and Savings. Exhibit 9 contains the June 30, 2017 Balance Sheet for Digestive Health Specialists, P.A. which documents \$336,023 in total Checking and Savings. The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.



**Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In the pro forma financial statement (Form B), the applicant projects that operating expenses will exceed revenues in each of the first three operating years of the project, as summarized below.

<b>GI Endoscopy</b>	<b>OY1 CY2019</b>	<b>OY2 CY2020</b>	<b>OY3 CY2021</b>
Projected # of Procedures	2,273	2,296	2,319
Projected Average Charge	\$ 1,639	\$ 1,639	\$ 1,639
Gross Patient Revenue	\$ 3,725,447	\$3,763,144	\$3,800,841
Deductions from Gross Patient Revenue	\$ 1,997,967	\$2,018,184	\$2,038,401
Net Patient Revenue	\$ 1,727,480	\$1,744,960	\$1,762,440
Total Expenses	\$ 919,398	\$ 943,291	\$ 967,553
Net Income	\$ 808,082	\$ 801,669	\$ 794,887

The applicant’s projections of procedures and revenues are reasonable based on the number of cases projected for the first three operating years. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the capital and operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**Conclusion**

In summary, the applicant adequately demonstrates the availability of financing and that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges), and operating costs. 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 applicant proposes to develop an ASC with one licensed GI endoscopy procedure room in the existing DHS-King medical office building.

The 2017 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) defines the service area as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients. Therefore, the service area for this review, as defined by the applicant on page 35, is Stokes County. The applicant may also serve residents of counties not included in its proposed service area.

The 2017 SMFP lists Pioneer (LifeBrite) Community Hospital of Stokes as the only provider offering licensed GI endoscopy services in Stokes County. In Section V.3, page 44, the applicant states that the DHS physicians no longer have privileges at the hospital in Stokes County because of the physicians’ concern over the age of the GI endoscopy equipment and levels of supplies and resources at the hospital.

In Section III.9, page 37, the applicant provides a table showing the licensed endoscopy rooms as listed in the Proposed 2018 SMFP in Stokes, Forsyth and Surry counties which encompass 96% of DHS’s proposed patient origin, as summarized below.

<b>GI Endoscopy Service Providers in Stokes, Forsyth &amp; Surry Counties FY 2016 Data from Proposed 2018 SMFP</b>					
<b>Provider</b>	<b>County</b>	<b>Type of Facility</b>	<b>Endoscopy Rooms</b>	<b>Endoscopy Cases</b>	<b>Endoscopy Procedures</b>
LifeBrite Community Hospital of Stokes	Stokes	Hospital	1	325	370
Digestive Health Endoscopy Center Kernersville	Forsyth	ASC	2	3,096	3,359
Digestive Health Specialists, P.A.	Forsyth	ASC	2	5,846	6,387
Gastroenterology Associates of the Piedmont	Forsyth	ASC	4	10,116	12,380
Gastroenterology Associates of the Piedmont	Forsyth	ASC	4	5,097	6,364
North Carolina Baptist Hospital	Forsyth	Hospital	10	11,887	21,429
Novant Health Forsyth Medical Center	Forsyth	Hospital	4	4,205	5,028
Wake Forest Baptist Health Outpatient Endoscopy	Forsyth	ASC	2	1,994	2,263
Hugh Chatham Memorial Hospital	Surry	Hospital	4	1,738	
Northern Hospital of Surry County	Surry	Hospital	2	2,532	2,777
Gastroenterology Associates	Surry	ASC	1	242	242
<b>Total</b>			<b>36</b>	<b>40,078</b>	<b>60,599</b>

In Section III.9 (d), page 39, the applicant states that it does not expect the proposed DHS-King ASC project to result in a reduction of procedures currently performed in existing licensed facilities in Stokes, Forsyth or Surry Counties, stating:

*“Digestive Health Specialists does not [sic] control of the age and maintenance of endoscopy equipment, medical staff recruitment, staffing levels, patient charges, marketing programs, and insurance contracts at the existing facilities in these three counties. These factors are controlled by the existing non-DHS licensed providers that are summarized on page 37. Consequently the existing facilities with GI endoscopy procedure rooms are free to compete, recruit additional physicians, acquire new endoscopy equipment and enhance staffing levels and marketing programs.”*

As stated above, LifeBrite Community Hospital of Stokes is the only provider of licensed GI endoscopy procedure rooms in Stokes County. There are no licensed freestanding GI endoscopy centers in Stokes County.

The applicant adequately demonstrates the need to develop the proposed ASC with one licensed GI endoscopy room, based on the number of patients they currently serve and propose to serve in the future. The applicant projects performing 2,296 GI endoscopy procedures during

the second full operating year following project completion. This exceeds the minimum of 1,500 GI endoscopy procedures per room per year as of the end of the second operating year as required by 10A NCAC 14C .3903(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the defined service area. Consequently, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.2, page 53, the applicant provides the proposed full-time equivalent (FTE) positions and proposed salaries for the proposed licensed GI endoscopy service for the second full operating year, CY2020, as illustrated in the table below:

<b>DHS-King Projected CY2020 Staffing</b>			
<b>Position</b>	<b>Projected FTE Positions</b>	<b>Projected Annual Salary</b>	<b>Total Projected Salary Expense CY 2020</b>
Administrator	0.20	\$ 159,135	\$ 31,827
Registered Nurse (RN)	2.25	\$ 59,410	\$ 133,673
Surgical Technician	2.00	\$ 33,949	\$ 67,898
Medical Records Technician	0.25	\$ 31,827	\$ 7,957
Non-health/technical personnel	1.25	\$ 55,167	\$ 68,959
<b>Total FTE Positions</b>	<b>5.95</b>		

In Section VII.3, page 53, the applicant states:

*“All of the positions are new for the facility. The proposed project will be financially and operationally separate from the existing physician practice.”*

The applicant discusses the availability of required personnel, stating that existing DHS personnel will be permitted to apply for the proposed positions and expectations are that some DHS existing staff will be hired for the proposed ASC. The applicant further states that it maintains an ongoing recruitment and retention program and will utilize recruitment resources as listed on page 53. In Section VII.8, page 57, the applicant states that a total of 13 gastroenterologists are expected to utilize the facility. In Section VII.9, page 58, the applicant identifies Marcum Gillis, MD, as the DHS medical director. Exhibit 13 contains physician letters of support.

The applicant adequately documents the availability of sufficient health manpower and management personnel to staff the proposed GI endoscopy procedure rooms at DHS-King. 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

In Sections II.1 and II.2, pages 8-9, the applicant discusses the necessary ancillary and support services it will provide for the proposed ASC. A table is provided on page 8 that lists all of the services needed and indicates the facility staff and contracted providers who will provide each of the services. Exhibits 4 and 5 contain documentation of agreements for pathology and pharmacy services, respectively. Exhibit 6 contains a patient transfer agreement between the applicant and Novant Health Forsyth Medical Center. In Section V.3, page 44, the applicant states:

*“The DHS physicians no longer have privileges at the hospital in Stokes County; the age of the GI endoscopy equipment and levels of supplies and resources at the hospital were a concern to the physicians. DHS gastroenterologists are committed to maintain privileges at Forsyth Medical Center in Winston-Salem.”*

In Section V.4, page 44, the applicant further states that DHS has long established relationships with the local healthcare community including primary care physicians, area hospitals, community agencies and the Wake Forest University School of Medicine PA program.

The applicant adequately demonstrates 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

The applicant proposes to develop an ASC with one licensed GI endoscopy procedure room in leased space in its existing medical office building. In Section I.13, page 4, the applicant states that the existing medical office building was designed and constructed with facility space that meets the North Carolina construction standards to be licensed as an ambulatory surgical facility with one licensed GI endoscopy procedure room. Exhibit 7 contains the floor plan of the medical office building showing the firewalls and physical separation of the endoscopy suite. The applicant states that it does not anticipate construction or renovation costs, but includes contingency capital for repairs, as documented in Exhibit 23. In Section XI.5, page 71, the applicant states:

*“The project capital cost includes the cost of an emergency generator and an allowance for any repairs or minor facility modifications that may relate to any new interpretations of the facility standards.”*

In Section XI.8, page 74, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design, and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. 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

The existing location in King is not a facility but a physician office practice that has been in operation for less than a full year. In supplemental information requested during the expedited review of this application, the applicant provided the payor mix for GI procedures being performed by the physician office practice, as shown below.

<b>DHS-King Current Payor Mix</b>	
<b>Payor</b>	<b>% of Procedures</b>
Self-Pay /Indigent	2.5%
Commercial Insurance	48.0%
Medicare / Medicare Managed Care	42.0%
Medicaid	5.0%
Managed Care	2.0%
Other *	0.5%
<b>Total</b>	<b>100.0%</b>

\*Champus, Commercial non-contracted, Financial Assistance

- (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

In Section VI.11, page 50, the applicant states that DHS has no federal obligations to provide uncompensated care but chooses to provide uncompensated care in its office practices and Endoscopy Centers as part of its professional services.

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

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In Section VI.14, page 51, the applicant projects that 40% of the patients who will receive services at DHS-King in the second operating year (CY 2020) will have some

or all of their services paid for by Medicare or Medicaid, as summarized in the table below.

<b>DHS-King Projected Payor Mix – CY2020</b>	
<b>Payor</b>	<b>% of Procedures</b>
Self-Pay /Indigent	2%
Managed Care / Commercial Insurance	56%
Medicare / Medicare Managed Care	36%
Medicaid	4%
Other (Specify)*	2%
<b>Total</b>	<b>100%</b>

\*Other was not identified

On page 51, the applicant states that the above payor mix is based on the 2016 overall average of the existing licensed DHS Endoscopy Centers in North Carolina.

The applicant adequately demonstrates the extent to which medically underserved groups are likely to have access to the services offered at DHS-King. 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 V.2(d), page 43, the applicant states that the DHS physicians and the proposed ASC will accept patient referrals from hospitals and physicians in the community. In Section VI.9, page 49, the applicant describes the range of means by which a person will have access to the GI endoscopy services at DHS-King, including referrals from physicians. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to GI endoscopy 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.

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In Section V.1, page 42, the applicant states that DHS-King will provide access to the proposed ASC for health professional training programs. The applicant further states that DHS-Winston-Salem has an existing clinical training affiliation with Wake Forest University School of Medicine’s physician assistant program. Exhibit 12 contains a copy of a letter from the CEO of DHS to ECPI University Greensboro, stating DHS’ commitment to be utilized as a clinical training site. The information provided by the applicant is reasonable and credible and supports a finding of conformity to this criterion.

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

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The applicant proposes to develop an ASC with one licensed GI endoscopy procedure room in DHS-King's existing medical office building.

The 2017 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) defines the service area as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients. Therefore, the service area for this review, as defined by the applicant on page 35, is Stokes County. The applicant may also serve residents of counties not included in its proposed service area.

The 2017 SMFP lists Pioneer (LifeBrite) Community Hospital of Stokes as the only provider offering licensed GI endoscopy services in Stokes County. There are no licensed freestanding GI endoscopy centers in Stokes County.

In Section V.7, page 45, the applicant discusses how the proposed project will foster competition, stating:

*“Digestive Health Specialists Endoscopy Center-King combines the latest in medical technology with leading board-certified gastroenterologists to provide quality and affordable outpatient care in a highly personalized setting. The staff is comprised of a team of experienced and highly trained nurses and technicians. In addition, the proposed project will foster competition by providing expanded access to GI endoscopy services at an effective and convenient outpatient location in King, NC.”*

See also Sections II, III, V, VI, and VII of the application where the applicant discusses the impact of the project on cost effectiveness, quality, and access.

The information provided by the applicant 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 applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (3) and (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.

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In Section I.13, page 4, the applicant states that it currently owns, leases, or manages four licensed GI endoscopy centers in North Carolina. In Section II.12, page 14, the applicant states the DHS has no history of any facility license being revoked or Medicare/Medicaid provider agreements being terminated. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of the 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 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 the existing facility, the applicant provides 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.

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The application is conforming to all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities promulgated in 10A NCAC 14C .3900. The specific criteria are discussed below.

**.3903 PERFORMANCE STANDARDS**

(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 applicant does not propose to operate any surgical operating rooms. In Section XI, page 12, the applicant states that the utilization projection for the proposed GI endoscopy procedure room is based on five days per week and 52 weeks per year excluding then days for holidays.

(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 III, pages 26-34, the applicant provides the utilization methodology and assumptions and projects that DHS will perform 2,296 GI endoscopy procedures during CY2020, the second year of operation, in the one licensed GI endoscopy procedure room, which exceeds the 1,500 procedure per GI endoscopy room requirement in the second year of operation following completion of the project.

The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(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 13, the applicant states:

*“Digestive Health Specialists is committed to provide upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures. Each category of these procedures is reflected in the list of procedures that are*

*currently performed at DHS-King and will be performed at the proposed DHS King Endoscopy Center: ...”*

The table provided on page 13 includes those types of procedures.

- (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- The applicant does not own or operate any surgical operating rooms in the service area.
- (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- The applicant provides the assumptions and methodology used to project utilization in Section III, pages 26-34. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.