

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 27, 2016

Findings Date: July 27, 2016

Project Analyst: Bernetta Thorne-Williams

Team Leader: Lisa Pittman

Project ID #: J-11166-16

Facility: Duke University Hospital

FID #: 943138

County: Durham

Applicant(s): Duke University Health System d/b/a Duke University Hospital

Project: Add one GI endoscopy procedure room for a total of 11 GI endoscopy procedure rooms upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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 applicant, Duke University Health System (DUHS) d/b/a Duke University Hospital (DUH) proposes to develop one new gastrointestinal (GI) endoscopy procedure room by renovating existing space in its pediatric suite. DUH currently has 10 licensed GI endoscopy procedures rooms and proposes the addition of one GI procedure room for a total of 11 licensed GI endoscopy procedure rooms upon project completion.

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 2016 State Medical Facilities Plan (2016 SMFP).

Policies

In addition, there are no policies in the 2016 SMFP that are applicable to this review.

Conclusion

In summary, there are no need determinations or policies in the 2016 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- (2) Repealed effective July 1, 1987.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 applicant states on page 14 that DUH has two procedure rooms located in its pediatric suite, one of the two procedure rooms is currently licensed as a GI endoscopy procedure room. In this application, the applicant proposes to renovate the second existing procedure room to accommodate GI endoscopy procedures for a total of 11 GI endoscopy procedure rooms at DUH upon project completion.

Population to be Served

The 2016 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. Facilities may also serve residents of counties not included in their defined service area.

In Section III.5, page 17, the applicant defines its primary service area as Durham, Alamance, Granville, Orange, Person, Vance and Wake counties. Additionally, as an academic medical center, DUH has provided and projects to continue to provide treatment for patients throughout North Carolina and other states.

In Sections III.6 and III.7, pages 18-22, the applicant provides both current and projected patient origin for pediatric GI endoscopy services at DUH, as illustrated in the following table:

County	Historical Patient Origin, FY 2016*	Projected Patient Origin, FY 2018		Projected Patient Origin, FY 2018	
	% of Total	# of Patients	% of Total	# of Patients	% of Total
Alamance	2.70%	53	2.70%	53	2.70%
Cumberland	5.75%	112	5.75%	113	5.73%
Durham	13.74%	269	13.74%	271	13.74%
Guilford	3.84%	75	3.84%	76	3.84%
Johnston	2.24%	44	2.24%	44	2.22%
Orange	2.02%	39	2.02%	40	2.02%
Wake	20.82%	407	20.82%	411	20.82%
Other NC counties	37.94%	743	37.93%	751	37.94%
Other States	10.95%	214	10.95%	216	10.95%
Total	100.00%	1,956 [1,948]	100.00%	1,975 [1,971]	100.00%

*2016 volume annualized

**Only those counties that represent at least 2% of the pediatric GI endoscopy procedures at DUH are listed above.

Those counties that represent less than 2% volume are grouped into the other counties category.

***Totals may not foot due to rounding

On page 20, the applicant states it does not have any reason to anticipate a change in its patient origin. The applicant adequately identifies the population proposed to be served.

Analysis of Need

In Section II, page 8, the applicant states that as an academic medical center, Level I Trauma Center and quaternary referral center, DUH has all the necessary ancillary and support services required to support the addition of one GI endoscopy procedure room. On page 9, the applicant states that the development of the second GI endoscopy room in the pediatric suite would allow for greater access to existing services, and increase flexibility and scheduling of pediatric procedures.

In Section III.1, page 14, the applicant provides a list of GI endoscopic and non-GI procedures currently performed in the two existing pediatric procedure rooms. The proposed additional GI endoscopy procedure room would be used primarily to accommodate pediatric procedures. The applicant further states on page 14 that the GI endoscopy procedure rooms designated for adult procedures are highly utilized and cannot routinely accommodate pediatric procedures.

In Section III.1, pages 15-16, the applicant states the following two factors support the need to add one additional GI endoscopy procedure room:

- Increased utilization
- Population growth

Increased Utilization

On page 15, the applicant reports that DUH operates nine GI endoscopy rooms dedicated to adult procedures and one GI endoscopy pediatric procedure room. The applicant reports that the 10 endoscopy procedure rooms at DUH exceeded 1,800 procedures, per room in fiscal year (FY) 2015 ($18,255/10=1,825$). The applicant states FY 2015 utilization reflects a 3.5% increase in volume over FY 2014 utilization and a more than 40% increase in volume since FY 2013.

	FY 2013	FY 2014	FY 2015
# of GI Endo Rooms	10	10	10
Total GI procedures	12,926	17,633	18,255
Average number of procedures per machine	1,293	1,763	1,826
Percent of increase in procedures 2014-2015		3.5%	
Percent of increase in procedures 2013-2015			41.2%

Hence, the applicant states that there is no capacity in its adult GI procedure rooms to regularly accommodate pediatric endoscopy cases. Furthermore, the applicant states on page 11, that even with no change in current utilization, DUH would have an average volume of 1,660 procedures with 11 procedure rooms.

DUH is the only provider of pediatric endoscopy services in Durham County (see page 23).

Population Growth

In Section III.1, page 16, the applicant identifies its primary service area as Durham, Alamance, Granville, Orange, Person, Vance and Wake counties. The applicant provides a table on page 16 which illustrates the projected growth in each of those counties over a five year period from 2014 to 2019, as shown below.

COUNTY	TOTAL ESTIMATED POPULATION 2014	TOTAL ESTIMATED POPULATION 2019	5 YEAR AVERAGE GROWTH
Primary Service Area Population	1,793,242	1,924,064	7.3%
Alamance	163,053	169,181	3.8%
Durham	283,385	303,876	7.2%
Granville	51,900	53,689	3.4%
Orange	147,596	157,878	7.0%
Person	45,098	45,838	1.6%
Vance	46,042	46,504	1.0%
Wake	1,056,168	1,147,098	8.6%

DUH states that as an academic medical center, it will continue to provide treatment for patients throughout North Carolina and other states.

Projected Utilization

In Section II, page 11, the applicant provides historical and projected utilization for DUH's total licensed GI endoscopy rooms, as illustrated below:

YEAR	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
# OF GI ENDO ROOMS	10	10	10	10	11	11	11
Total GI Procedures	17,633	18,255	18,394	18,833	19,022	19,212	19,404
Total # of procedures	1,763	1,826	1,839	1,883	1,729	1,747	1,764

In Section IV.1, page 24, the applicant provides historical and projected utilization for the two pediatric GI endoscopy rooms, as illustrated below:

	FY 2014	FY 2015	INTERIM FY 2016	INTERIM FY 2017	OY 1 FY 2018	OY 2 FY 2019	OY 3 FY 2020
# of GI Endo Rooms	1	1	1	1	2	2	2
# of other procedure rooms	1	1	1	1			
# of inpatient GI procedures	398	432	308	312	315	318	321
# of outpatient GI procedures	1,058	954	1,053	1,103	1,114	1,125	1,136
# of inpatient non GI procedures	303	251	276	283	286	289	292
# of outpatient non GI procedures	979	921	977	1,017	1,027	1,037	1,048
Total # of procedures	2,738	2,558	2,614	2,715	2,742	2,770	2,797

DUH states on page 24 that its fiscal year runs from July 1 to June 30.

The applicant provides the following assumptions on pages 24-25:

- The applicant experienced a small decrease in pediatric procedures between FY 2014 and FY 2015. The applicant attributed this decrease to the departure of two physicians for which DUH is currently recruiting.
- DUH projects a return to historic utilization growth rates once those two positions are filled.
- FY 2016 volume is based on annualizing its 8-month year-to-date total.
- FY 2017 projections are based on internal budget forecasts using FY 2016 data.
- From FY 2018 – FY 2020, DUH projects total procedure growth at a rate of 1% annually.
- Use of a 1% growth rate is consistent with the population growth rate in the primary service area.
- The applicant provides data for inpatient GI/non GI procedures and outpatient GI procedures/non GI procedures separately.

In Section XII, page 59, the applicant projects operation of the second pediatric GI endoscopy procedure room by July 1, 2017.

As an academic medical center, DUH is not required to document or project utilization for any other facility pursuant to G.S. 131E-183(b), which states:

“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.”

The applicant adequately demonstrates that it is reasonable to assume it will perform 19,212 GI endoscopy procedures in 11 GI endoscopy procedure rooms in the second operating year, FY 2019 which is an average of 1,747 procedures per room [19,212 / 11 = 1,746.5]. Thus, the applicant reasonably demonstrates that it will perform at least 1,500 GI endoscopy procedures per room as required by G.S. 131E-182(a) and 10A NCAC 14C .3903(b).

Projected utilization is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to for one additional GI procedure room for a total of 11 licensed GI endoscopy procedure rooms upon project completion.

Access

In Section VI.2, pages 30, the applicant states:

“The services of Duke University Hospital are open to all area and non-area residents for inpatient, outpatient, and other healthcare services on a walk-in, emergency, appointment, or referral basis. There is no discrimination on the basis of race, ethnicity, age, gender, or disability.”

In Section VI.13, page 35, the applicant states that Medicare comprised 0.9% and Medicaid comprised 56% of its historical payor mix for inpatient pediatric GI endoscopy services in FY 2016 (annualized). The applicant further states on page 35, that outpatient pediatric GI endoscopy services were comprised of 0.4% Medicare recipients and 36.0% Medicaid recipients during the same timeframe.

In Section VI.14, page 36, the applicant projects that Medicare will comprise 1.7% and Medicaid will comprise 41.9% of its combined projected inpatient and outpatient pediatric GI endoscopy procedures in FY 2019

The applicant describes its charity and financial payment policies on pages 30-33. The applicant projects, in Section VI.8, page 33 that DUH will provide \$146,345,921 (6.3% of net revenue) in charity care to patients in the project’s second year of operation.

In summary, the applicant adequately identifies the population to be served and demonstrates the need the population proposed to be served has for one additional GI endoscopy procedure room at DUH for a total of 11 GI endoscopy procedure rooms following project completion. The applicant also adequately demonstrates the extent to which all residents of the service area,

in particular, the underserved, will have access to the proposed services. Consequently, the application is conforming to this criterion.

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

NA

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

CA

In Section III.8, page 23, the applicant discusses the alternatives considered, which include:

- Maintain the Status Quo - the applicant states that this option ignores the need for an additional GI endoscopy procedure room at DUH in its pediatric suite. Furthermore, the applicant states the adult GI endoscopy procedures rooms have a high utilization rate which prohibits the regular use of those procedure rooms for pediatric procedures (see page 15 of the application).
- The project as proposed – the applicant states the best option is to upfit an existing procedure room located within the pediatric suite which will allow greater access to existing pediatric endoscopy services. The applicant concludes this is its most effective alternative to meet the growing need for GI endoscopy services.

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

In summary, the applicant adequately demonstrates that this 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. **Duke University Health System d/b/a Duke University Hospital shall materially comply with all representations made in the certificate of need application.**
2. **Duke University Health System d/b/a Duke University Hospital shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**

3. **Duke University Health System d/b/a Duke University Hospital shall add no more than one gastrointestinal endoscopy procedure room for a total of no more than eleven gastrointestinal endoscopy procedure rooms at Duke University Hospital following project completion.**
 4. **Duke University Health System d/b/a Duke University Hospital shall prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay.**
 5. **Duke University Health System d/b/a Duke University Hospital 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.

C

DUH proposes to develop one new GI endoscopy procedure room by renovating existing space in its pediatric suite. DUH currently has 10 licensed GI endoscopy procedure rooms and proposes the addition of one GI procedure room for a total of 11 licensed GI endoscopy procedure rooms upon project completion.

Capital and Working Capital Costs

In Section VIII.1, page 45, the applicant projects the total capital cost for the project will be \$750,000 which includes \$505,000 in renovation costs, \$80,000 in fixed equipment and furniture costs, \$85,000 in architect fees and \$80,000 for utilities/permits/inspections and contingency costs. In Section IX, page 50, the applicant states there will be no start-up costs or working capital costs associated with the project.

Availability of Funds

In Section VIII.3, page 46, the applicant states the capital costs will be financed through the accumulated reserves of DUHS. In Exhibit 12, the applicant provides a letter dated April 8, 2016 from the Senior Vice President, Chief Financial Officer and Treasurer of DUHS, which states:

“As the Chief Financial Officer ... I am very familiar with the organization's financial position. DUHS will fund the capital cost and project start-up costs from existing accumulated cash reserves, and this will certify that DUHS has as much as \$750,000 in accumulated reserves to devote to this project.”

In Exhibit 7 the applicant provides the consolidated audited financial statements for Duke University Health System, Ins., and affiliates for fiscal years 2014 and 2015, which show \$434,336,000 in cash and cash equivalents and \$3,182,882,000 in net assets (total assets less total liabilities) as of June 30, 2015.

Financial Feasibility

In Section X, page 63, the applicant provides pro forma financial statements for the first three years of the project. The applicant projects that DUH GI endoscopy services operating expenses will exceed revenues in each of the first two operating years of the project, as illustrated in the following table:

DUH GI ENDOSCOPY PROCEDURES	OPERATING YEAR 1 FY 2018	OPERATING YEAR 2 FY 2019
Projected # of Inpatient Procedures	601	607
Projected # of Outpatient Procedures	2,141	2,163
Projected Average Charge per Procedure - Inpatient	\$182,344	\$ 182,344
Projected Average Charge per Procedure - Outpatient	\$6,919	\$6,919
Gross Patient Revenue - Inpatient	\$109,579,469	\$110,675,264
Gross Patient Revenue - Outpatient	\$14,815,495	\$14,963,650
Deductions from Gross Patient Revenue - Inpatient	\$76,805,626	\$77,386,303
Deductions from Gross Patient Revenue - Outpatient	\$10,657,007	\$10,719,850
Net Patient Revenue - Inpatient	\$32,773,843	\$33,288,961
Net Patient Revenue - Outpatient	\$4,158,488	\$4,243,800
Total Expenses - Inpatient	\$43,029,944	\$44,408,288
Total Expenses - Outpatient	\$4,456,927	\$4,587,754
Net Income - Inpatient	(\$10,256,101)	(\$11,119,327)
Net Income - Outpatient	(\$298,438)	(\$343,954)

Source: Form C

However, revenues will exceed operating expenses for the entire DUHS during each project year (see Form B).

In Section X, page 62, the applicant states net revenue is based on historical trends, future population growth, the implementation of approved capital projects, inflation, and proposed future reimbursement regulations for GI endoscopy services provided at DUH.

The applicant adequately demonstrates that the projected revenues and operating costs are based on reasonable and adequately supported assumptions, including projected utilization. See Section X of the application, page 62, for the assumptions regarding revenues and expenses. The discussion regarding analysis of need and projected utilization found in Criterion (3) is incorporated herein by reference.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project and adequately demonstrates 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

DUH proposes to develop one new GI endoscopy procedure room by renovating existing space in its pediatric suite. DUH currently has 10 licensed GI endoscopy procedure rooms and proposes the addition of one GI procedure room for a total of 11 licensed GI endoscopy procedure rooms upon project completion.

The 2016 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, for which the applicant projects to serve patients. In Section III.5, page 17, the applicant defines its primary service area as Durham, Alamance, Granville, Orange, Person, Vance and Wake counties. Additionally, as an academic medical center, DUH has provided treatment for patients throughout North Carolina and other states. DUH is also the only provider of pediatric GI endoscopy services in Durham County (see page 23).

According to the 2016 SMFP there are three providers of GI endoscopy services in Durham County. Table 6F of the 2016 SMFP lists those following providers and their FFY 2014 utilization.

Durham County GI Endoscopy Inventory – FFY 2014

FACILITY	COUNTY	# GI ENDOSCOPY ROOMS	# PROCEDURES	PROCEDURES PER ROOM	% UTILIZATION*
Duke Regional Hospital	Durham	4	5,154	1,289	86%
Duke University Hospital	Durham	10	17,634	1,763	118%
Triangle Endoscopy Center	Durham	4	5,858	1,465	98%
Durham County Total		18	28,646	1,116	106%

*Utilization based on 10A NCAC 14C .3903, which requires 1,500 procedures per day per room

**Utilization rounded up to nearest whole number

The table above illustrates that in FFY 2014 utilization at both DUHS hospitals was greater than 85%. Furthermore, Triangle Endoscopy Center operated above 95% utilization. Utilization for Durham County was 106%.

The applicant adequately demonstrates that developing the proposed pediatric GI endoscopy room in an existing procedure room will 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 38, the applicant projects staffing in full time equivalents (FTE) positions for the service component proposed during the second full fiscal year, as illustrated in the table below:

OY 2 2019	
EMPLOYEE CATEGORY	# FTES
Nursing Manager	1.0
RN	3.0
Certified Medical Assistants (CMA)	3.0
Total	7.0

The applicant currently operates with 6.0 FTEs in its pediatric GI endoscopy suite. The applicant proposes the addition of one additional CMA FTE position. The applicant states on page 38, *“Projected staff increases reflected projected volume increases in existing services.”*

In Section VII.9, page 42, the applicant states that Dr. Thomas Owens is the Chief Medical Officer of DUH.

The applicant adequately documents the availability of sufficient resources, including health manpower and management personnel, for the project as proposed. 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

As an academic medical center, Level I Trauma Center and quaternary referral center, DUH states all of the necessary ancillary and support services are currently available and identifies those services in Section II.2, page 8. The applicant discusses coordination with the existing health care systems in Exhibit 9. The applicant adequately demonstrates it will continue to provide or make arrangements for the necessary ancillary and support services and the proposed services will be coordinated with the existing health care 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, page 35, the applicant provides the payor mix during FY 2015 for the entire hospital and the pediatric GI endoscopy services at DUH, as illustrated in the tables below.

**Entire Hospital Payor Mix
FY 2015**

PAYOR	PROCEDURES AS % OF TOTAL
Self Pay/Indigent	5.5%
Medicare / Medicare Managed Care	38.4%
Medicaid	19.1%
Commercial Insurance	1.1%
Managed Care	29.4%
Other	6.4%
Total	100.0%

*Other includes Duke Select, Champus Tricare, Durham VA, Tricare Standard, other Non-NC Medicaid, or other governmental agencies and programs

**Pediatric GI Endoscopy Payor Mix
Projected FY 2016 Annualized**

PAYOR	PROCEDURES AS % OF TOTAL	
	INPATIENT	OUTPATIENT
Self Pay/Indigent	0.0%	2.7%
Commercial Insurance	1.3%	1.9%
Medicare / Medicare Managed Care	0.9%	0.4%
Medicaid	56.0%	36.0%
Managed Care	32.4%	48.1%
Other*	9.3%	10.9%
Total	100.0%	100.0%

*Other includes Duke Select, Champus Tricare, Durham VA, Tricare Standard, other Non-NC Medicaid, or other governmental agencies and programs

Exhibit 5 contains a copy of DUH's Admissions Policy, which contains policies pertaining to non-discrimination and provision of services to underserved populations. In Section VI.8, pages 32-33, the applicant provides additional discussion of DUH's charity care policy.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Durham	11%	52%	58%	17%	7%	18%
Alamance	16%	52%	34%	18%	10%	20%
Granville	15%	49%	42%	16%	15%	17%
Orange	11%	52%	30%	14%	6%	15%
Person	18%	51%	34%	19%	13%	17%
Wake	10%	51%	39%	12%	5%	14%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

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, women or handicapped persons utilizing health services.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services offered at DUH. 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 34, the applicant states:

"Duke University Health System hospitals have now satisfied the requirements of applicable Federal regulations to provide, on an annual basis, a certain amount of uncompensated care in return for Hill Burton funds previously received. They have no special obligation under applicable Federal regulations to provided uncompensated care, community service, or access by minorities and handicapped persons other than those obligations which apply to private, not-for-profit, acute care hospitals which participate in the Medicare, Medicaid, and Title V programs."

The applicant states it will continue to provide care to all persons, including low income, racial and ethnic minorities, women, handicapped persons, elderly and other underserved populations. In Section VI.10, page 34, the applicant states that no civil rights complaints were filed against DUH 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 36, the applicant projects payor mix during the second year of operation following project completion for the proposed service component, as shown in the following table.

**Pediatric GI Endoscopy Payor Mix
Projected FY 2019**

PAYOR	PROCEDURES AS % OF TOTAL	PROCEDURES AS % OF TOTAL
	INPATIENT	OUTPATIENT
Self Pay/Indigent	0.6%	1.6%
Commercial Insurance	1.5%	2.0%
Medicare / Medicare Managed Care	0.6%	2.0%
Medicaid	57.8%	37.4%
Managed Care	29.8%	45.8%
Other*	9.7%	11.2%
Total	100.0%	100.0%

*Other includes Duke Select, Champus Tricare, Durham VA, Tricare Standard, other Non-NC Medicaid, or other governmental agencies and programs

As shown above, the applicant projects that 58.4% of its inpatients and 39.4% of all outpatient pediatric GI endoscopy procedures projected to be performed will be provided to recipients of Medicare/Medicaid. In Section IV.14, page 36, the applicant states it assumes 16% of self pay patients each year will move either into Medicaid (12%) or the Managed Care Exchange (4%).

The applicant demonstrates that medically underserved populations will continue to have adequate access to the pediatric GI endoscopy services offered at DUH. 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 33, the applicant describes the range of means by which a person will have access to DUH's endoscopy services. The applicant adequately demonstrates 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.

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As an academic medical center, DUH accommodates the clinical needs of health professional training programs in the area. See Section V.1, page 26 and referenced exhibits for documentation that DUH accommodates the clinical needs of health professional training programs in the area and that it 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.

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DUH proposes to develop one new GI endoscopy room by renovating existing space in its pediatric suite. DUH currently has 10 licensed GI endoscopy procedure rooms and proposes the addition of one GI endoscopy room for a total of 11 licensed GI endoscopy rooms upon project completion.

The 2016 SMFP does not define the service area for GI endoscopy 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.

According to the 2016 SMFP there are three providers of GI endoscopy services in Durham County. Table 6F of the 2016 SMFP list the following providers of GI endoscopy services.

Durham County GI Endoscopy Inventory

FACILITY	COUNTY	# GI ENDOSCOPY ROOMS	# PROCEDURES	PROCEDURES PER ROOM	% UTILIZATION*
Duke Regional Hospital	Durham	4	5,154	1,289	86%
Duke University Hospital	Durham	10	17,634	1,763	118%
Triangle Endoscopy Center	Durham	4	5,858	1,465	98%

*Utilization based on 10A NCAC 14C .3902, which requires 1,500 procedures per day per room

**Utilization rounded up to nearest whole number

The total complement of GI endoscopy rooms in Durham County will increase by one licensed GI endoscopy room following completion of this project. The applicant adequately demonstrates that utilization of the two pediatric GI endoscopy procedure rooms at DUH is projected to be 92.3% by the second project year.

As an academic medical center, DUH is not required to document or project utilization for any of its others facilities pursuant to G.S. 131E-183(b), which states:

“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.”

See Section V.7, page 29, where the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services.

See also Sections II, III, V, VI and VII in which 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 its proposal and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.

- The applicant adequately demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (3), and (13) are 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, pages 5-6, the applicant provides a list of other health care facilities it currently owns, leases or manages 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 applicant 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.

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The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities as promulgated in 10A NCAC 14C .3900, are applicable to this review, as discussed below.

10A NCAC 14C .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 ten days for holidays.

- C- In Section II, page 10, the applicant states that DUH proposes to operate its pediatric endoscopy room at least 250 days per year, which is five days per week, 52 weeks per year, excluding ten 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 II, page 11, the applicant provides a table which illustrates the applicant projects to perform 19,212 GI endoscopy procedures by FY 2019, which is operating year 2 for the proposed project. Additionally, on page 11, the applicant states as an academic medical center, DUH is not required to project utilization of any other facility in the service area, including those facilities that are related entities. However, DUH projects on page 11 that the 15 procedure rooms operated by DUHS (four procedure rooms at Duke Regional Hospital and the eleven at DUH) would perform a total of 24,558 procedures in 2020 for an average of 1,637 ($24,558/15= 1,637.2$) procedures per room.
- (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 12, the applicant states DUH currently performs pediatric upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures in its existing pediatric GI endoscopy room. The applicant further states that DUH will continue to perform these procedures in the proposed pediatric GI endoscopy room.
- (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
- NA- As an academic medical center, DUH is not required to document or project utilization for any of its other facilities pursuant to G.S. 131E-183(b), which states:

“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.”