ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: September 27, 2016
Findings Date: September 27, 2016

Project Analyst: Julie Halatek
Team Leader: Fatimah Wilson

Project ID #: O-11190-16
Facility: Endoscopy Center NHRMC Physicians Group
FID #: 160284
County: New Hanover
Applicants: New Hanover Regional Medical Center
Carolina Healthcare Associates, Inc.
Project: Relocate one GI endoscopy procedure room from New Hanover Regional Medical Center to Endoscopy Center NHRMC Physicians Group and relocate existing facility to a new location where it will be licensed for three GI endoscopy procedure rooms and the hospital will be licensed for only four GI endoscopy procedure rooms

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.

C

The applicants, New Hanover Regional Medical Center (NHRMC) and Carolina Healthcare Associates, Inc. (CHA) propose to relocate one existing gastrointestinal (GI) endoscopy procedure room from NHRMC to Endoscopy Center NHRMC Physicians Group (EC-NHRMC-PG) and simultaneously relocate EC-NHRMC-PG to a new location. Upon project completion, EC-NHRMC-PG will be licensed for three GI endoscopy procedure rooms and NHRMC will be licensed for four GI endoscopy procedure rooms.

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

There is one policy in the 2016 SMFP which is applicable to this review: Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-4 states:

> *"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*
>
> *In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*
>
> *Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

The proposed capital expenditure for this project is greater than $2 million and less than $5 million. In Section III.4, page 43, and Section XI.8, page 102, the applicants provide a written statement describing their plan to ensure energy efficiency and water conservation. The applicants adequately demonstrate that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

In summary, there are no need determinations in the 2016 SMFP that are applicable to this review. The application is conforming to Policy GEN-4. Therefore, the application is conforming to this criterion.

(2) Repealed effective July 1, 1987.

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

C

The applicants, New Hanover Regional Medical Center (NHRMC) and Carolina Healthcare Associates, Inc. (CHA) propose to relocate one existing gastrointestinal (GI) endoscopy procedure room from NHRMC to Endoscopy Center NHRMC Physicians Group (EC-NHRMC-PG) and simultaneously relocate EC-NHRMC-PG to a new location. Upon project completion, EC-NHRMC-PG will be licensed for three GI endoscopy procedure rooms and NHRMC will be licensed for four GI endoscopy procedure rooms.

In supplemental information received September 16, 2016, the applicants state that EC-NHRMC-PG is an operating division of CHA, which is the non-profit physician group practice of NHRMC. In an Executive Summary, on page 1 of the application, the applicants state that NHRMC is in the process of implementing a master facility plan with regard to services currently offered at NHRMC Orthopedic Hospital. The applicants state that the Orthopedic Hospital is a collection of individual buildings (along with expansions and renovations) that have been constructed or remodeled over the last 70 years. The applicants state that NHRMC determined that relocating the inpatient orthopedic services (acute care beds along with operating rooms) to the 17th Street campus of NHRMC was the most feasible option to provide the level of care it was expected to provide. As part of this master facility plan, five GI endoscopy procedure rooms currently located in the Surgical Pavilion will be relocated. Four of the rooms will stay with NHRMC in existing but renovated space adjacent to the Surgical Pavilion (not as part of this application) and one room will be relocated to EC-NHRMC-PG. EC-NHRMC-PG will then relocate to a facility that is currently occupied by a different CHA-affiliated practice, which will be moving to a different location in late 2017, vacating the space and allowing EC-NHRMC-PG to take over the existing space.

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 applicants using county lines, from which the applicant projects to serve patients. In Section III.5, page 44, the applicants define the primary service area as Brunswick, Columbus, New Hanover, Onslow, and Pender counties. Facilities may also serve residents of counties not included in their service area.

In Section III.7, page 47, the applicants provide current patient origin for GI endoscopy services for both NHRMC and EC-NHRMC-PG, as shown in the table below.

Current Patient Origin by County – FY 2015 NHRMC & EC-NHRMC-PG		
County	**NHRMC**	**EC-NHRMC-PG**
New Hanover	47.2%	53.5%
Brunswick	18.4%	21.1%
Pender	12.4%	10.4%
Onslow	7.2%	3.5%
Columbus	4.7%	4.0%
Other	10.1%	7.5%
Total	**100.0%**	**100.0%**

Totals may not foot due to rounding.

In Section III.6, page 46, the applicants provide projected patient origin for EC-NHRMC-PG for the first two operating years following project completion, as shown in the table below.

Projected Patient Origin by County – FYs 2020-2021 EC-NHRMC-PG				
County	**FY 2020**		**FY 2021**	
	Patients	**Percent**	**Patients**	**Percent**
New Hanover	1,893	51.9%	1,963	51.9%
Brunswick	744	20.4%	772	20.4%
Pender	398	10.9%	412	10.9%
Onslow	164	4.5%	170	4.5%
Columbus	150	4.1%	155	4.1%
Other	299	8.2%	310	8.2%
Total	**3,647**	**100.0%**	**3,782**	**100.0%**

Totals may not foot due to rounding.

On page 46, the applicants state future patient origin is based on the shifting of outpatient GI endoscopy cases from NHRMC to EC-NHRMC-PG. According to Google Maps, the proposed site of the relocated EC-NHRMC-PG facility is 0.7 miles from the existing site and one mile from the Surgical Pavilion at NHRMC. The projected patient origin is consistent with the range of percentages in the historical patient origin of the applicants. The applicants adequately identify the population proposed to be served.

Analysis of Need

In Section III.1, page 32, the applicants state that NHRMC is currently undertaking multiple projects as part of a master facility plan related to the services offered at the NHRMC Orthopedic Hospital. The applicants state:

> *"The NHRMC Orthopedic Hospital is a collection of individual buildings, building expansions, and building renovations that have been constructed/renovated over the last 70 years. Each of the buildings, expansions, and renovations occurred under the building codes and healthcare delivery models of the time. This collection of buildings currently warrants considerable renovations or complete demolition and reconstruction to be viable facilities for the level of healthcare delivery expected from*

NHRMC in the future. These issues and concerns were identified and assessed through a series of facility and healthcare service line reviews.

Through board, executive, service line, financial, and planning committee meetings where multiple alternatives were discussed. (sic) *NHRMC determined that relocating the inpatient orthopedic services, both acute care beds and operating rooms to the NHRMC 17th Street campus is the best alternative to achieve the level of care expected at NHRMC.*

…

The NHRMC GI Endoscopy Service will vacate these five [existing GI endoscopy] *rooms* [in the Surgical Pavilion] *and these rooms will be re-designated as operating rooms. The vacating of the GI rooms will occur through two projects:*

- *Project 1: The transfer of one (1) GI endoscopy room to the Endoscopy Center NHRMC Physician Group through this CON application submitted on June 15, 2016.*

- *Project 2: The renovation of existing space adjacent to the Surgical Pavilion within NHRMC to accommodate four (4) GI rooms and the associated pre-operative, post-operative, and support services, which will occur through a Letter of CON Exemption submitted prior to the end of this CON application's review period."*

In Section III.8, page 48, the applicants state that in order to best accomplish the master facility plan in relation to the NHRMC Orthopedic Hospital, the acute care beds and operating rooms proposed to be relocated as part of Project I.D. #O-11189-16 must relocate to the 17th Street campus, which requires the GI endoscopy procedure rooms to vacate their current location. The applicants also state that NHRMC has an operational goal to shift as many outpatient cases as possible to off-campus outpatient facilities.

In Section III.1, pages 33-39, the applicants state the following factors support the continued need for all GI endoscopy procedure rooms that are part of NHRMC to continue operation:

- New Hanover County Population Growth
- Primary Service Area Population Growth
- GI Relationship to Older Populations – Upper GI Diseases
- GI Relationship to Older Populations – Lower GI Diseases

<u>*New Hanover County Population Growth*</u>

In Section III.1, page 33, the applicants state that the population of New Hanover County grew by eight percent between 2011 and 2016, and that the North Carolina Office of State Budget and Management (NCOSBM) projects an additional 7.1 percent population increase between

2016 and 2021. The applicants further state that the population of residents ages 45-64 years, which represents 25 percent of New Hanover County's total population, grew by 4.8 percent between 2011 and 2016, and the same population is forecast by NCOSBM to grow another 3.2 percent between 2016 and 2011. Additionally, the applicants state that the elderly population (defined as 65+ years), representing 16.4 percent of New Hanover County's total population, grew by 23.4 percent between 2011 and 2016, and is forecast to grow an additional 18.9 percent between 2016 and 2021.

Primary Service Area Population Growth

In Section III.1, page 34, the applicants state that the population of the five counties that make up the primary service area (New Hanover, Brunswick, Columbus, Onslow, and Pender counties) grew by 7.8 percent between 2011 and 2016, and that the NCOSBM projects an additional 6.8 percent population increase between 2016 and 2021. The applicants further state that the population of residents ages 45-64 years, which represents 23.5 percent of the primary service area's total population, grew by 2.5 percent between 2011 and 2016, and the same population is forecast by NCOSBM to grow another 3.1 percent between 2016 and 2011. Additionally, the applicants state that the elderly population (defined as 65+ years), representing 16.7 percent of New Hanover County's total population, grew by 26.9 percent between 2011 and 2016, and is forecast to grow an additional 19.8 percent between 2016 and 2021.

GI Relationship to Older Populations – Upper GI Diseases

In Section III.1, pages 35-37, the applicants provide excerpts from articles and article summaries to demonstrate the link between patient age and prevalence of need for the types of procedures performed in a GI endoscopy procedure room to diagnose or treat upper GI diseases. The applicants state that the need for upper GI endoscopy services is much greater among the elderly and the prevalence increases as people age.

GI Relationship to Older Populations – Upper GI Diseases

In Section III.1, pages 38-39, the applicants provide excerpts from articles and article summaries to demonstrate the link between patient age and prevalence of need for the types of procedures performed in a GI endoscopy procedure room to diagnose or treat lower GI diseases. The applicants state that the prevalence of diverticular disease (which can be diagnosed and treated with GI endoscopy procedures) is 10 percent of people age 40+ years and 50 percent of people age 60+ years.

Projected Utilization

In Section IV, pages 51-60, the applicants provide historical utilization of the five existing GI endoscopy procedure rooms at NHRMC and the two existing GI endoscopy procedure rooms at EC-NHRMC-PG, projected utilization following the relocation of one GI endoscopy procedure room to EC-NHRMC-PG, and the assumptions and methodology used to project utilization, as discussed below.

Step 1. The applicants identified the historical FY 2014 and FY 2015 number of GI endoscopy cases and GI endoscopy procedures for inpatient and outpatient GI endoscopy procedure rooms at NHRMC and outpatient GI endoscopy procedure rooms at EC-NHRMC-PG. Additionally, the applicants identified the GI endoscopy case volume for the same three categories for the first six months of 2016 and annualized the numbers to estimate the total FY 2016 case volume, as shown below.

Historical GI Endoscopy Procedure/Case Volume – FYs 2014 – 2016						
Year	NHRMC Inpatient		NHRMC Outpatient		EC-NHRMC-PG Outpatient	
	Cases	Procedures	Cases	Procedures	Cases	Procedures
FY 2014	2,890	4,645	4,459	6,066	1,932	2,768
FY 2015	2,799	5,551	4,259	6,957	3,893	5,204
FY 2016 (annualized)	3,152	6,251	4,768	7,788	5,600	7,486

Step 2. The applicants calculated the average annual growth rate (AAGR) for the three categories of GI cases. They additionally calculated the AAGR for all outpatient GI cases in New Hanover County as a comparison, as shown in the tables below.

AAGR – GI Endoscopy Cases FYs 2014-2015 & Interim FY 2016				
	FY 2014	FY 2015	Interim FY 2016	AAGR
NHRMC – IP GI Cases	2,890	2,799	3,152	
AAGR		-3.1%	12.6%	4.8%
NHRMC – OP GI Cases	4,459	4,259	4,768	
AAGR		-4.5%	12.0%	3.8%
EC-NHRMC-EP – OP GI Cases	1,932	3,893	5,600	
AAGR		101.5%	43.8%	72.7%

AAGR – New Hanover County GI Endoscopy Cases FYs 2010-2014						
	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	AAGR
GI Cases	20,062	20,261	21,185	22,247	23,200	
AAGR		1.0%	4.6%	5.0%	4.3%	3.7%

Step 3. The applicants state that they chose to use the lower county-wide growth rate to allow for slower annual growth and to show financial feasibility with lower GI endoscopy volume projections. The applicants next calculated the GI endoscopy case volume for all three categories, using a 3.7 percent annual change rate (ACR) during the interim years prior to project completion, as shown in the table below.

Interim GI Endoscopy Case Volumes – FYs 2017 – 2019						
Year	NHRMC Inpatient		NHRMC Outpatient		EC-NHRMC-PG Outpatient	
	Cases	ACR	Cases	ACR	Cases	ACR
FY 2016	3,152		4,768		5,600	
FY 2017	3,269	3.7%	4,945	3.7%	5,808	3.7%
FY 2018	3,390	3.7%	5,129	3.7%	6,023	3.7%
FY 2019	3,516	3.7%	5,319	3.7%	6,247	3.7%

Step 4. The applicants calculated the NHRMC inpatient GI endoscopy case volume for the first three years following project completion (FY 2020 – 2022), using the same 3.7 percent ACR, as shown in the table below.

NHRMC – Inpatient GI Endoscopy Cases – Project Years 1-3				
	FY 2019 (interim)	**FY 2020**	**FY 2021**	**FY 2022**
IP GI Cases	3,516	3,647	3,782	3,923
ACR		3.7%	3.7%	3.7%

The applicants next calculated the NHRMC outpatient GI endoscopy case volume for the first three years following project completion (FY 2020 – 2022), again using the same 3.7 percent ACR, but additionally subtracted 2,273 outpatient GI endoscopy cases from the FY 2020 calculations that they project will shift to EC-NHRMC-PG. On page 57, the applicants state that these shifting cases do not include GI endoscopy cases which are better treated in a hospital setting due to co-morbidities or other reasons, and provide a list of types of cases that they state need to be performed at NHRMC. In supplemental information received September 16, 2016, the applicants state that GI physicians participated in a two day event during which they identified the outpatient cases that needed to remain at NHRMC (which are listed on page 57).

The applicants state in supplemental information that after the types of cases that should remain at NHRMC and those that could safely be done offsite were identified, they did a retrospective analysis of the cases for FY 2015 and annualized FY 2016. The applicants state that they chose to use the annualized FY 2016 number of cases that could be transferred, calculated their projections through the interim period, and then subtracted the 2,273 cases without any projected increases from the projected volume at the start of Operating Year One. The applicants then apply the 3.7 percent ACR to the remaining cases and project case volume forward through the end of the third year following project completion, as shown in the table below.

NHRMC – Outpatient GI Endoscopy Cases – Project Years 1-3				
	FY 2019 (interim)	**FY 2020**	**FY 2021**	**FY 2022**
OP GI Cases	5,319	3,243	3,364	3,489
ACR	3.7%		3.7%	3.7%
Total FY 2020 OP Cases	5,516			
Minus Cases Shifting to EC-NHRMC-PG	(2,273)			
PY 1 FY 2020 OP Cases	3,243			

The applicants finally calculated the EC-NHRMC-EP outpatient GI endoscopy case volume for the first three years following project completion (FY 2020 – 2022), again using the same 3.7 percent ACR, but added the 2,273 outpatient GI endoscopy cases that were subtracted from the OP GI cases performed at NHRMC, as discussed above, to the FY 2020 calculations. The applicants then apply the 3.7 percent ACR to the remaining cases and project case volume forward through the end of the third year following project completion, as shown in the table below.

EC-NHRMC-PG – Outpatient GI Endoscopy Cases – Project Years 1-3				
	FY 2019 (interim)	FY 2020	FY 2021	FY 2022
OP GI Cases	6,247	8,752	9,077	9,414
ACR	3.7%		3.7%	3.7%
Total FY 2020 OP Cases	6,479			
Add Cases Shifting From NHRMC	2,273			
PY 1 FY 2020 OP Cases	8,752			

Step 5. The applicants identified the historical case and procedure volume ratios for FY 2014-2015 for each category of GI endoscopy cases and procedures, as shown in the table below.

Historical GI Endoscopy Procedure/Case Volume – FYs 2014 – 2015									
Year	NHRMC Inpatient			NHRMC Outpatient			EC-NHRMC-PG Outpatient		
	Cases	Procedures	Ratio*	Cases	Procedures	Ratio*	Cases	Procedures	Ratio*
FY 2014	2,890	4,645	1.8	4,459	6,066	1.4	1,932	2,768	1.4
FY 2015	2,799	5,551	2.0	4,259	6,957	1.6	3,893	5,204	1.3

*Ratio = number of procedures/number of cases = procedures per case

Step 6. The applicants multiplied the number of cases by the ratio of procedures to cases to obtain the projected GI endoscopy procedures for the first three years following project completion, as shown in the table below.

Projected GI Endoscopy Procedure/Case Volume* – FYs 2020 – 2022									
Year	NHRMC Inpatient			NHRMC Outpatient			EC-NHRMC-PG Outpatient		
	Cases	Ratio	Procedures	Cases	Ratio	Procedures	Cases	Ratio	Procedures
FY 2020	3,647	2.0	7,232	3,243	1.6	5,298	8,752	1.3	11,699
FY 2021	3,782	2.0	7,501	3,364	1.6	5,495	9,077	1.3	12,134
FY 2022	3,923	2.0	7,779	3,489	1.6	5,699	9,414	1.3	12,584

*The calculations performed by the applicants and represented in this table are not mathematically accurate; however, the mathematical difference is very slight, and additionally, since there is no performance standard, this minor inaccuracy does not change the determination in this criterion.

The applicants adequately demonstrate that NHRMC will perform 12,996 GI endoscopy procedures in four GI endoscopy procedure rooms during the second operating year following project completion (FY 2021), which is an average of 3,249 procedures per room [12,996 procedures / 4 rooms = 3,249 procedures per room]. Furthermore, the applicants adequately demonstrate that EC-NHRMC-PG will perform 12,134 procedures in three GI endoscopy procedure rooms during the second operating year following project completion (FY 2021), which is an average of 4,045 procedures per room [12,134 procedures / 3 rooms = 4,044.67 procedures per room].

There are no performance standards that apply to this review, because the applicants are not proposing to develop a new licensed GI endoscopy procedure room or a new ambulatory surgical facility. However, the performance standards that would be applicable to those types of applications provide a good guideline as to whether the projected utilization demonstrates a need for the proposed project. During the second operating year following project completion

(FY 2021), NHRMC projects to perform an average of 3,249 GI endoscopy procedures per room in its four rooms and EC-NHRMC-PG projects to perform an average of 4,045 GI endoscopy procedures per room in its three rooms. Projected utilization is based on reasonable and adequately supported assumptions. Therefore, the applicants reasonably demonstrate that the facilities will perform at least 1,500 GI endoscopy procedures per room in the second year of operation as outlined in G.S. 131E-182(a) and 10A NCAC 14C .3903(b) (a performance standard which does not carry legal weight with respect to these findings). Thus, the applicants adequately demonstrate the need the identified population has for the proposed services.

Access

In Sections VI.12 and VI.13, pages 76-77, the applicants provide the payor mix during FY 2015 for NHRMC and EC-NHRMC-PG for GI endoscopy services, as illustrated in the tables below.

EC-NHRMC-PG Historical Payor Mix FY 2015	
Payor Category	**Percent**
Self-Pay/Charity	0.4%
Medicare/Medicare Managed Care	57.0%
Medicaid	1.2%
Managed Care/Commercial Insurance	39.1%
Other Government	2.0%
Other	0.3%
Total	**100.0%**

NHRMC Historical Payor Mix – FY 2015 Inpatient & Outpatient GI Endo Services			
Payor Category	**Outpatient GI**	**Inpatient GI**	**Total GI**
Self-Pay/Charity	3.8%	6.6%	4.9%
Medicare/Medicare Managed Care	47.8%	64.9%	54.5%
Medicaid	11.3%	10.0%	10.8%
Managed Care/Commercial Insurance	32.6%	15.2%	25.7%
Other Government	4.0%	2.3%	3.3%
Other	0.6%	0.9%	0.8%
Total	**100.0%**	**100.0%**	**100.0%**

In Section VI.14, pages 78-79, the applicants project payor mix during the second year of operation following project completion, which is shown in the following tables.

EC-NHRMC-PG Projected Payor Mix FY 2021	
Payor Category	**Percent**
Self-Pay/Charity	1.3%
Medicare/Medicare Managed Care	54.6%
Medicaid	3.8%
Managed Care/Commercial Insurance	37.4%
Other Government	2.5%
Other	0.4%
Total	**100.0%**

NHRMC Projected Payor Mix – FY 2021 Inpatient & Outpatient GI Endo Services			
Payor Category	**Outpatient GI**	**Inpatient GI**	**Total GI**
Self-Pay/Charity	3.8%	6.6%	5.3%
Medicare/Medicare Managed Care	47.8%	64.9%	56.9%
Medicaid	11.3%	10.0%	10.6%
Managed Care/Commercial Insurance	32.6%	15.2%	23.4%
Other Government	4.0%	2.3%	3.1%
Other	0.6%	0.9%	0.8%
Total	**100.0%**	**100.0%**	**100.0%**

In Section VI.2, page 69, the applicants state that EC-NHRMC-PG provides services to Medicaid and other low-income patients, all racial groups, all ethnic minority groups, all religious minority groups, Medicare and other elderly groups, handicapped patients, and that it does not discriminate on the basis of gender. As shown above, the applicants project that anywhere from 58.4 percent to 74.9 percent, depending on the location of the GI endoscopy services, of all GI endoscopy procedures projected to be performed will be provided to recipients of Medicare/Medicaid. The applicants state they based the payor mix on the historical payor mixes while adjusting for the shifting of some outpatient cases from NHRMC to EC-NHRMC-PG. The projected payor mixes are consistent with the range of percentages in the historical payor mixes of the applicants. The applicants adequately demonstrate the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed.

In summary, the applicants adequately identify the population to be served; adequately demonstrate the need the population to be served has for the proposed services based on reasonable and adequately supported utilization projections and assumptions; and adequately demonstrate the extent to which all residents of the area, including underserved groups, are likely to have access to the services. 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.

C

The applicants propose to relocate one existing GI endoscopy procedure room from NHRMC to EC-NHRMC-PG and simultaneously relocate EC-NHRMC-PG to a new location. Upon project completion, EC-NHRMC-PG will be licensed for three GI endoscopy procedure rooms and NHRMC will be licensed for four GI endoscopy procedure rooms.

In Section IV.1, pages 51-52, the applicants provide projected utilization for EC-NHRMC-PG following relocation of an existing GI endoscopy procedure room from NHRMC, as well as NHRMC, as shown in the table below.

Projected GI Endoscopy Procedure/Case Volume* – FYs 2020 – 2022									
Year	NHRMC Inpatient			NHRMC Outpatient			EC-NHRMC-PG Outpatient		
	Cases	Procedures	Rooms**	Cases	Procedures	Rooms**	Cases	Procedures	Rooms
FY 2020	3,647	7,232	4	3,243	5,298	4	8,752	11,699	3
FY 2021	3,782	7,501	4	3,364	5,495	4	9,077	12,134	3
FY 2022	3,923	7,779	4	3,489	5,699	4	9,414	12,584	3

*The calculations performed by the applicants and represented in this table are not mathematically accurate; however, the mathematical difference is very slight and does not affect the determination in this criterion.
**The four rooms are not individually designated as inpatient or outpatient.

As shown in the table above, the applicants project they will perform 13,478 procedures in the four GI endoscopy procedure rooms, or 3,370 procedures per room, during the third year following project completion, at NHRMC. Additionally, the applicants project to perform 12,584 procedures in the three GI endoscopy procedure rooms, or 4,195 procedures per room, during the third year following project completion. Therefore, based on the applicants' utilization projections, NHRMC and EC-NHRMC-PG would have adequate capacity to meet the need for GI endoscopy services for the population presently served following relocation of one GI endoscopy procedure room from NHRMC to EC-NHRMC-PG.

In Section VI.14, page 78, the applicants project the following payor mix for GI endoscopy services at EC-NHRMC-PG in the second year following project completion, as shown in the table below.

EC-NHRMC-PG Projected Payor Mix FY 2021	
Payor Category	Percent
Self-Pay/Charity	1.3%
Medicare/Medicare Managed Care	54.6%
Medicaid	3.8%
Managed Care/Commercial Insurance	37.4%
Other Government	2.5%
Other	0.4%
Total	**100.0%**

As shown in the table above, the applicants project that 58.4 percent of their GI endoscopy cases will be for patients who will have some or all of their care paid for by Medicare or Medicaid. The applicants adequately demonstrate that the relocation of one existing GI endoscopy procedure room from NHRMC to EC-NHRMC-PG will not have a negative effect 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.

In summary, the applicants adequately demonstrate that the needs of the population presently served at NHRMC, will be adequately met following the relocation of one of the existing GI endoscopy procedure rooms to EC-NHRMC-PG. Therefore, the application is conforming to this criterion.

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

CA

In Section III.2, page 40, and Section III.8, page 48, the applicants discuss the alternatives considered prior to submitting this application, which include:

- Maintain the Status Quo – the applicants state that this option is not feasible because of the need for the master facility plan renovation and relocation of elements of the NHRMC Orthopedic Hospital. The applicants also state that they have an operational goal to shift as many outpatient cases as reasonable to facilities that are not on the hospital campus.

- Pursue a Joint Venture – the applicants state this is not a viable option because the project is internal to NHRMC and EC-NHRMC-PG.

- Add a Third GI Endoscopy Procedure Room to the Existing Site of EC-NHRMC-PG – the applicants state this option is not feasible because the current location does not have the capacity to accommodate support space for staff as well as patients if a third GI endoscopy procedure room was added.

After considering the above alternatives, the applicants state that they believe relocating an existing licensed GI endoscopy procedure room from NHRMC to EC-NHRMC-PG and relocating the existing facility to a new location is the most effective alternative to meet the needs of the patient population in the area.

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 applicants adequately demonstrate 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. **New Hanover Regional Medical Center and Carolina Healthcare Associates, Inc. shall materially comply with all representations made in the certificate of need application and in the supplemental information received September 16, 2016. In those instances where representations conflict, New Hanover Regional Medical Center and Carolina Healthcare Associates, Inc. shall materially comply with the last made representation.**

2. **New Hanover Regional Medical Center and Carolina Healthcare Associates, Inc. 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. **New Hanover Regional Medical Center and Carolina Healthcare Associates, Inc. shall relocate no more than one additional gastrointestinal endoscopy procedure room from New Hanover Regional Medical Center and shall be licensed for a total of no more than three gastrointestinal endoscopy procedure rooms at Endoscopy Center NHRMC Physician Group following project completion.**

4. **New Hanover Regional Medical Center and Carolina Healthcare Associates, Inc. shall take the necessary steps to delicense one gastrointestinal endoscopy procedure room at New Hanover Regional Medical Center, for a total of no more than four gastrointestinal endoscopy procedure room upon project completion.**

5. **New Hanover Regional Medical Center and Carolina Healthcare Associates, Inc. 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

The applicants propose to relocate one existing GI endoscopy procedure room from NHRMC to EC-NHRMC-PG and simultaneously relocate EC-NHRMC-PG to a new location. Upon project completion, EC-NHRMC-PG will be licensed for three GI endoscopy procedure rooms and NHRMC will be licensed for four GI endoscopy procedure rooms.

Capital and Working Capital Costs

In Section VIII.2, page 88, the applicants project the total capital cost for the project will be $3,500,000, which includes costs for labor and construction, moveable equipment, administrative/legal/consulting fees, information technology, and a contingency. In Section IX, page 92, the applicants state there will be no start-up costs or working capital costs associated with the project, since there are no new services proposed with this project.

Availability of Funds

In Section VIII.3, page 89, the applicants state that $3,000,000 of the capital cost will be financed by CHA; $252,028 of the capital cost will be financed by NHRMC, and $247,972 will be financed via equipment lease. Exhibit 19 contains a letter from the CFO of NHRMC, stating that NHRMC will transfer $252,028 to CHA for the purpose of funding the proposed project from its cash and cash equivalents. Exhibit 19 also contains a letter from the CEO and Chair of CHA stating that it will use $3,000,000 from its cash and cash equivalents for the proposed project; it will use the $252,028 transferred by NHRMC for the proposed project; and it will enter into a lease agreement for $247,972 for the associated medical equipment for the project (a copy of the quote for this lease is included in Exhibit 19).

In supplemental information received September 16, 2016, the applicants state that NHRMC is the sole member of CHA. Exhibit 20 contains a copy of NHRMC's audited financial statements for fiscal years 2014 and 2015, which show $139,119,000 in cash and cash equivalents and $775,086,000 in net assets (total assets less total liabilities) as of September 30, 2015. The applicants state in supplemental information that CHA is identified as an "obligated unit" in the NHRMC audited financial statements but that because they are affiliated NHRMC can cover any financial issues associated with CHA operations.

Financial Feasibility

In Section XIII, the applicants provide pro forma financial statements for the first three years of the project. The applicants project that EC-NHRMC-PG GI endoscopy services revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the following table:

EC-NHRMC-PG Projected Revenue/Expenses – Project Years 1-3			
	Project Year 1 FY 2020	**Project Year 2 FY 2021**	**Project Year 3 FY 2022**
Projected # of GI Endoscopy Cases	8,752	9,077	9,414
Projected Average Charge	$1,929	$2,016	$2,107
Gross Patient Revenue	$16,883,414	$18,298,131	$19,831,393
Deductions from Gross Patient Revenue	$13,031,007	$14,122,919	$15,306,325
Net Patient Revenue	$3,852,407	$4,175,213	$4,525,068
Total Expenses	$2,096,775	$2,153,977	$2,214,060
Net Income	$1,755,632	$2,021,236	$2,311,008

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

In summary, the applicants adequately demonstrate the availability of sufficient funds for the capital needs of the project and adequately demonstrate that the financial feasibility of the

proposal is based upon reasonable projections of operating costs and charges. Therefore, the application is conforming to this criterion.

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

C

The applicants propose to relocate one existing GI endoscopy procedure room from NHRMC to EC-NHRMC-PG and simultaneously relocate EC-NHRMC-PG to a new location. Upon project completion, EC-NHRMC-PG will be licensed for three GI endoscopy procedure rooms and NHRMC will be licensed for four GI endoscopy procedure rooms.

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 applicants using county lines, from which the applicant projects to serve patients. In Section III.5, page 44, the applicants define the primary service area as Brunswick, Columbus, New Hanover, Onslow, and Pender counties. Facilities may also serve residents of counties not included in their service area.

There are 11 locations where patients can access GI endoscopy services in Brunswick, Columbus, New Hanover, Onslow, and Pender counties, which comprise the applicants' primary service area, as stated in Section III.6, page 46.

In Section III.9, page 49, the applicants provide a table that lists existing GI endoscopy facilities in the applicants' defined service area and the number of GI procedures performed in each during FY 2015. The applicants state that the data source is the draft 2017 SMFP. The Project Analyst added additional data for each facility from the draft 2017 SMFP and calculated utilization.

GI Endoscopy Facilities – Brunswick, Columbus, New Hanover, Onslow, & Pender counties FY 2015 Data and Utilization

Facility	Type	County	# GI Endoscopy Rooms	# Procedures	Procedures per Room	% Utilization*
Dosher Memorial Hospital	Hospital	Brunswick	2	688	334	22.9%
Novant Health Brunswick MC	Hospital	Brunswick	2	3,539	1,770	118.0%
Columbus Regional HCS	Hospital	Columbus	3	1,994	665	44.3%
EC-NHRMC-PG	Freestanding	New Hanover	2	5,204	2,602	173.4%
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Wilmington Gastroenterology	Freestanding	New Hanover	4	13,217	3,304	220.3%
Wilmington Health	Freestanding	New Hanover	3	4,674	1,558	103.9%
Wilmington SurgCare	Freestanding	New Hanover	3	277	92	6.1%
East Carolina Gastroenterology EC	Freestanding	Onslow	1	2,139	2,139	142.6%
Onslow Memorial Hospital	Hospital	Onslow	3	2,785	928	61.9%
Pender Memorial Hospital	Hospital	Pender	1	278	278	18.5%
Total GI Endoscopy Room Utilization			**29**	**47,303**	**1,631**	**108.7%**

*Utilization based on 10A NCAC 14C .3902, which requires (in reviews where it is applicable) 1,500 procedures per day per room.

The inventory of GI endoscopy procedure rooms in the applicants' defined service area is not changing as a result of this proposal. The table shows that NHRMC and EC-NHRMC-PG have some of the highest utilization in the service area, and NHRMC is the highest utilized hospital in the service area for GI endoscopy services. Furthermore, the applicants' proposal to move as many outpatient cases off of the hospital campus as possible allows them to provide outpatient GI endoscopy services more cost-effectively than if the services were performed at NHRMC to those patients needing the services.

The applicants adequately demonstrate that relocating one GI endoscopy procedure room to EC-NHRMC-PG and simultaneously relocating the existing facility would not result in an unnecessary duplication of existing or approved health service capabilities or facilities.

Therefore, the application is conforming to this criterion.

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

C

In Section VII.1, page 80, the applicants state there are currently 11.0 full time equivalent (FTE) positions at EC-NHRMC-PG. In Section VII.2, page 81, the applicants state that they project to add FTE positions to bring the total number of FTE positions to 12.5 upon project completion. In Section VII.3, page 82, the applicants discuss their recruitment and hiring practices and state they have not had any past difficulties in recruiting new staff.

In Section VII.9, page 85, the applicants state that Dr. Jack Ramage, Jr., is the current medical director of GI endoscopy services at EC-NHRMC-PG. Exhibit 13 contains a letter from Dr. Ramage, agreeing to continue to serve in that capacity following the relocate of the GI endoscopy procedure room and the relocation of the facility.

The applicants adequately document 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

The applicants list all of the necessary ancillary and support services that are currently available at EC-NHRMC-PG and identify those services in Section II.2, page 20. Exhibit 5 contains a letter from the Practice Director of EC-NHRMC-PG describing the ancillary services provided. The applicants discuss coordination with the existing health care system in Sections V.2 - V.6, pages 62-65. The applicants provide supporting documentation of coordination and support from hospital and area physicians in Exhibits 12, 13, and 23. The applicants adequately

demonstrate the facility 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.

C

The applicants propose to relocate an existing licensed GI endoscopy procedure room to EC-NHRMC-PG and then relocate EC-NHRMC-PG to a newly vacated facility. Exhibit 22 contains a letter from an architect that estimates construction costs that are consistent with the project capital cost projections provided by the applicants in Section VIII.2, page 88, of the application. In Section III.4, page 43, and Section XI.8, page 102, the applicants describe 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 applicants adequately demonstrate 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

In Sections VI.12 and VI.13, pages 76-77, the applicants provide the payor mix during FY 2015 for NHRMC and EC-NHRMC-PG for GI endoscopy services, as illustrated in the tables below.

EC-NHRMC-PG Historical Payor Mix FY 2015	
Payor Category	**Percent**
Self-Pay/Charity	0.4%
Medicare/Medicare Managed Care	57.0%
Medicaid	1.2%
Managed Care/Commercial Insurance	39.1%
Other Government	2.0%
Other	0.3%
Total	**100.0%**

NHRMC Historical Payor Mix – FY 2015 Inpatient & Outpatient GI Endo Services			
Payor Category	**Outpatient GI**	**Inpatient GI**	**Total GI**
Self-Pay/Charity	3.8%	6.6%	4.9%
Medicare/Medicare Managed Care	47.8%	64.9%	54.5%
Medicaid	11.3%	10.0%	10.8%
Managed Care/Commercial Insurance	32.6%	15.2%	25.7%
Other Government	4.0%	2.3%	3.3%
Other	0.6%	0.9%	0.8%
Total	**100.0%**	**100.0%**	**100.0%**

Exhibit 14 contains a copy of EC-NHRMC-PG's and NHRMC's Financial and Access Policies, which contains policies pertaining to non-discrimination and provision of services to underserved populations. In Section VI.8, pages 69-74, the applicants

provide additional discussion of charity care, financial payment policies, and handicap access.

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 applicants' service area.

Percent of Population						
County	**% 65+**	**% Female**	**% Racial & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
Brunswick	27%	51%	19%	16%	12%	19%
Columbus	18%	51%	40%	24%	15%	21%
New Hanover	16%	52%	23%	18%	9%	19%
Onslow	8%	45%	33%	14%	11%	16%
Pender	17%	50%	26%	15%	13%	20%
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 applicants' current payor mix would be of little value. The population data by age, race, or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicants demonstrate that they currently provide adequate access to medically underserved populations. 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 75, the applicants state that they have no obligation under any federal statutes to provide uncompensated care, community service, or access. Exhibit 15 contains information about NHRMC's community benefits report. In Section VI.2, page 70, the applicants state they will continue to be accessible to all persons, including the medically indigent and other underserved populations. In Section VI.10, page 75, the applicants state that no civil rights complaints were filed against CHA, NHRMC, or

EC-NHRMC-PG 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, pages 78-79, the applicants project payor mix during the second year of operation following project completion, which is shown in the following tables.

EC-NHRMC-PG Projected Payor Mix FY 2021	
Payor Category	**Percent**
Self-Pay/Charity	1.3%
Medicare/Medicare Managed Care	54.6%
Medicaid	3.8%
Managed Care/Commercial Insurance	37.4%
Other Government	2.5%
Other	0.4%
Total	**100.0%**

NHRMC Projected Payor Mix – FY 2021 Inpatient & Outpatient GI Endo Services			
Payor Category	**Outpatient GI**	**Inpatient GI**	**Total GI**
Self-Pay/Charity	3.8%	6.6%	5.3%
Medicare/Medicare Managed Care	47.8%	64.9%	56.9%
Medicaid	11.3%	10.0%	10.6%
Managed Care/Commercial Insurance	32.6%	15.2%	23.4%
Other Government	4.0%	2.3%	3.1%
Other	0.6%	0.9%	0.8%
Total	**100.0%**	**100.0%**	**100.0%**

As shown above, the applicants project that anywhere from 58.4 percent to 74.9 percent, depending on the location of the GI endoscopy services, of all GI endoscopy procedures projected to be performed will be provided to recipients of Medicare/Medicaid. The applicants state they based the projected payor mix on the historical payor mixes while adjusting for the shifting of some outpatient cases from NHRMC to EC-NHRMC-PG. The discussion regarding outpatient cases shifting as part of projected utilization found in Criterion (3) is incorporated herein by reference.

The applicants demonstrate that medically underserved populations will continue to have adequate access to the GI endoscopy services offered at NHRMC and EC-NHRMC-PG. 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 74, the applicants describe the range of means by which a person will have access to EC-NHRMC-PG's endoscopy services. The applicants adequately demonstrate that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

See Section V.1, page 61, and Exhibit 11 for documentation that NHRMC and EC-NHRMC-PG accommodate the clinical needs of health professional training programs in the area and will continue to do so. The information provided is reasonable and supports a finding of conformity with this criterion.

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

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

C

The applicants propose to relocate one existing GI endoscopy procedure room from NHRMC to EC-NHRMC-PG and simultaneously relocate EC-NHRMC-PG to a new location. Upon project completion, EC-NHRMC-PG will be licensed for three GI endoscopy procedure rooms and NHRMC will be licensed for four GI endoscopy procedure rooms.

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 applicants using county lines, from which the applicant projects to serve patients. In Section III.5, page 44, the applicants define the primary service area as Brunswick, Columbus, New

Hanover, Onslow, and Pender counties. Facilities may also serve residents of counties not included in their service area.

There are 11 locations where patients can access GI endoscopy services in Brunswick, Columbus, New Hanover, Onslow, and Pender counties, which comprise the applicants' primary service area, as stated in Section III.6, page 46.

In Section III.9, page 49, the applicants provide a table that lists existing GI endoscopy facilities in the applicants' defined service area and the number of GI procedures performed in each during FY 2015. The applicants state that the data source is the draft 2017 SMFP. The Project Analyst added additional data for each facility from the draft 2017 SMFP and calculated utilization.

GI Endoscopy Facilities – Brunswick, Columbus, New Hanover, Onslow, & Pender counties FY 2015 Data and Utilization

Facility	Type	County	# GI Endoscopy Rooms	# Procedures	Procedures per Room	% Utilization*
Dosher Memorial Hospital	Hospital	Brunswick	2	688	334	22.9%
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EC-NHRMC-PG	Freestanding	New Hanover	2	5,204	2,602	173.4%
NHRMC	Hospital	New Hanover	5	12,508	2,502	166.8%
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Wilmington Health	Freestanding	New Hanover	3	4,674	1,558	103.9%
Wilmington SurgCare	Freestanding	New Hanover	3	277	92	6.1%
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Onslow Memorial Hospital	Hospital	Onslow	3	2,785	928	61.9%
Pender Memorial Hospital	Hospital	Pender	1	278	278	18.5%
Total GI Endoscopy Room Utilization			**29**	**47,303**	**1,631**	**108.7%**

*Utilization based on 10A NCAC 14C .3902, which requires (in reviews where it is applicable) 1,500 procedures per day per room.

The total complement of GI endoscopy procedure rooms in the county will not change following completion of this project. The applicants adequately demonstrate that utilization of the four GI endoscopy procedure rooms at NHRMC and the three GI endoscopy procedure rooms at EC-NHRMC-PG is projected to be in excess of 100 percent by the second project year.

In Section V.7, pages 66-68, the applicants discuss 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 applicants discuss the impact of the project on cost-effectiveness, quality, and access.

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

- The applicants adequately demonstrate the need for the 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 applicants adequately demonstrate that they will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.

- The applicants adequately demonstrate that they will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a), 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.

C

In Section I.13, pages 11-12, the applicants provide a list of other healthcare facilities they currently own, lease, or manage 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, there were two instances where NHRMC or an affiliated facility was out of compliance with Medicare conditions of participation within the last 18 months. The problems have since been corrected and at this time, all of the facilities are in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at both facilities, the applicants provide 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.

NA

The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities as promulgated in 10A NCAC 14C .3900 are not applicable to this review, because the applicants are not proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy procedure room in a licensed health service facility. The applicants propose to relocate an existing licensed GI endoscopy procedure room from NHRMC to EC-NHRMC-PG and then relocate the facility.