ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

Decision Date:	July 19, 2019
Findings Date:	July 19, 2019
Project Analyst:	Julie M. Faenza
Team Leader:	Fatimah Wilson
Project ID #: Facility: FID #: County: Applicant: Project:	F-11706-19 Carolinas Gastroenterology Center - Kenilworth 190212 Mecklenburg Carolinas Physicians Network, Inc. Relocate the existing ambulatory surgical facility with two gastrointestinal endoscopy rooms and change the name to Carolinas Gastroenterology Center – Kenilworth

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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.

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Carolinas Physicians Network, Inc. (hereinafter referred to as CPN or "the applicant") proposes to relocate its existing ambulatory surgical facility (ASF) with two gastrointestinal endoscopy (GI endoscopy) rooms to a medical office building being developed at 1225 Harding Place, in Charlotte (MOB #2), and to change the name of the facility to Carolinas Gastroenterology Center – Kenilworth.

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 2019 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities (page 31 of the 2019 SMFP) is applicable to this review. **Policy GEN-4** states:

"Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need 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 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The proposed capital expenditure for this project is greater than \$2 million. In Section B, pages 16-18, the applicant provides a written statement describing its plan to work with a design team and facility management group to assure improved energy efficiency and water conservation. On page 16, the applicant states:

"Atrium Health is committed to energy efficiency and sustainability that balances the need for healthcare services and environmental sustainability in the communities it serves."

The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the application is consistent with Policy GEN-4.

- (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.

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The applicant proposes to relocate its existing ASF with two GI endoscopy rooms to MOB #2.

The existing ASF with two GI endoscopy rooms is named Carolinas Gastroenterology Center – Medical Center Plaza (CGC-MCP). After the relocation of the facility, it will be called Carolinas Gastroenterology Center – Kenilworth (CGC-K). When both the existing and proposed facilities are discussed and it is impractical or confusing to refer to the names of both facilities at the same time, these findings will refer to CGC-K for clarity.

In Section C, page 19, the applicant states that an unrelated third-party developer is building two medical office buildings (MOB #1 and MOB #2) and associated parking as part of a new medical campus in Charlotte called Atrium Health Kenilworth, which will serve as a site to consolidate physician practices that are part of CPN. Atrium Health Kenilworth will also have a diagnostic center. MOB #1 is located at 1237 Harding Place and MOB #2 is located at 1225 Harding Place. The Agency, in letters sent June 15, 2018 and November 7, 2018, determined that development of these medical office buildings, to the extent the development was not part of projects requiring a certificate of need, was exempt from review.

In Section A, page 8, the applicant provides an explanation of its corporate ownership structure. CPN's parent company (and sole owner of CPN) is Carolinas Health Network, Inc. The parent company of Carolinas Health Network, Inc. (and sole owner of Carolinas Health Network, Inc.) is The Charlotte-Mecklenburg Hospital Authority (CMHA). CMHA does business as Atrium Health. Thus, while the applicant for this project is CPN, the applicant and the facility are ultimately affiliated with and are part of CMHA and the Atrium Health system.

Patient Origin

The 2019 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as "...*the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.*" In Section G, page 46, the applicant defines the primary service area as Mecklenburg County. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

CGC-K Current and Projected Patient Origin					
Country	Current –	CY 2018	Projected FY	3 – CY 2023	
County	# of Cases	% of Total	# of Cases	% of Total	
Mecklenburg	3,576	78.0%	3,590	78.0%	
Gaston	297	6.5%	298	6.5%	
Cabarrus	126	2.7%	126	2.7%	
Union	124	2.7%	124	2.7%	
York (SC)	117	2.6%	118	2.6%	
Lincoln	60	1.3%	60	1.3%	
Other*	285	6.2%	286	6.2%	
Total	4,584	100.0%	4,602	100.0%	

The following table illustrates current and projected patient origin.

Source: Section C, pages 20-21

*Other includes Bladen, Buncombe, Burke, Caldwell, Catawba, Cleveland, Chester (SC), Davidson, Forsyth, Guilford, Harnett, Haywood, Iredell, Lancaster (SC), McDowell, Moore, New Hanover, Orange, Polk, Rowan, Rutherford, Stanly, Swain, Wake, and Watauga counties, as well as other states.

In Section C, page 21, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 22-24, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services:

- <u>Facility Issues</u>: The applicant states the existing facility was not designed to accommodate growth and does not have adequate space for current standards of care. CGC-MCP's utilization is high, but due to limited space, it does not have enough preparation and recovery spaces to efficiently move patients through the facility. The applicant states the existing spaces have limited privacy and the nurse's station is not centrally located, making it a challenge to monitor patients. The applicant states that, because its facility is currently located on the main campus of Carolinas Medical Center (CMC), patients must navigate heavy traffic around and on the hospital campus and compete for limited parking. By relocating the facility, the applicant states it can develop more appropriately sized GI endoscopy rooms, increase the number of preparation and recovery areas, add increased privacy for patients, centrally locate the nurse's station, increase space in waiting areas, and eliminate the hassle of navigating a busy hospital campus while also increasing accessibility and availability of parking. The applicant further states the relocation allows CGC-K to be adjacent to physician offices on the campus of Atrium Health Kenilworth.
- <u>High Utilization</u>: The applicant states that, although the performance standards promulgated in 10A NCAC 14C .3903 do not apply to this proposed project, it is performing GI endoscopy procedures in numbers that exceed the performance standard. The applicant states its annual growth has been less than one half of one percent in recent

years due to the limited availability of space and projects continued high utilization following relocation.

• <u>Population Growth</u>: According to the North Carolina Office of State Budget and Management (NC OSBM), the Mecklenburg County population is projected to grow at a Compound Annual Growth Rate (CAGR) of 1.9 percent through 2023, and the population of Mecklenburg County residents age 65 and older will increase from 11.6 percent in 2019 to 13 percent in 2023. The applicant states the increase in the percent of the population age 65 and older is significant because older residents utilize healthcare services at a higher rate than younger residents.

The information is reasonable and adequately supported for the following reasons:

- The applicant provides reasonable and adequately supported information to support its assertion that relocating CGC-K will better serve patients.
- Reliable data sources are used to support assertions about population growth.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization for the first three full fiscal years following project completion, as shown in the table below.

CGC-K Historical, Interim, & Projected Utilization – CYs 2016 – 2023								
	Historical		Inte	erim		Projected		
	2016	2017	2018	2019	2020	FY 1 -2021	FY 2 - 2022	FY 3 - 2023
# of GI Endo Rooms	2	2	2	2	2	2	2	2
# of GI Endo Procedures	5,723	6,044	5,732	5,737	5,741	5,746	5,750	5,755
# of GI Endo Cases	4,546	4,707	4,584	4,588	4,591	4,595	4,598	4,602

In Section Q, pages 1-3, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The number of procedures performed at CGC-MCP grew at a CAGR of 0.08 percent between CY 2016 and CY 2018.
- Historical utilization includes procedures performed by physicians no longer affiliated with Atrium Health. When those procedures were removed from historical utilization, utilization declined at a CAGR of -38.2 percent between CY 2016 and CY 2018. Historical procedures performed by physicians continuing to be affiliated with Atrium Health grew at a CAGR of 35.3 percent between CY 2016 and CY 2018. The percent of GI endoscopy procedures performed by physicians continuing to be affiliated with Atrium Health has also continued to grow. The applicant projects utilization for interim years and the first three fiscal years to grow at a CAGR of 0.08 percent.

- The applicant uses CGC-MCP's CY 2018 ratio of procedures to cases (1.25), which it states is consistent with Mecklenburg County's FFY 2018 average ratio of procedures to cases.
- The first three full fiscal years of the project are CYs 2021, 2022, and 2023.

A summary of the applicant's assumptions and methodology for projecting utilization is shown in the table below.

CGC-K Projected Utilization – Summary of Assumptions/Methodology						
	Inte	Interim Projected			CAGR	
	2019	2020	FY 1 -2021	FY 2 - 2022	FY 3 - 2023	
# of GI Endo Rooms	2	2	2	2	2	
# of GI Endo Procedures	5,737	5,741	5,746	5,750	5,755	0.08%
Ratio of Procedures to Cases	1.25	1.25	1.25	1.25	1.25	
# of GI Endo Cases*	4,588	4,591	4,595	4,598	4,602	0.08%
Average # of Procedures per Room	2.869	2,871	2.873	2.875	2.878	

*In Section Q, page 2, the applicant states the number of cases is calculated as follows: Number of Cases = (Number of Procedures) / (Procedure to Case Ratio)

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant uses its own historical data to project utilization.
- The applicant accounts for changes in physician population and utilization by existing physicians in projecting utilization.

Access

In Section C, page 28, the applicant states:

"...Atrium Health's system-wide policies and procedures with regard to access to care apply to [CGC-K]. Please see Exhibit C.8 for Atrium Health's Non-Discrimination policies. As noted in Atrium Health's Non-Discrimination Policy Statement, '[n]o individual shall be subject to discrimination or denied the benefits of the services, programs, or activities of [Atrium Health] on the basis of race, color, religion, national origin, sex, age, disability or source of payment.' Atrium Health will continue to serve this population as dictated by the mission of Atrium Health, which is the foundation for every action taken. The mission is simple, but unique: To improve health, elevate hope, and advance healing – for all. This includes the medically underserved."

In Section L, page 65, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

CGC-K Payor Mix – FY 2 (CY 2022)		
Payor Source	Percent of Services	
Self-Pay	0.3%	
Medicare*	31.8%	
Medicaid*	1.2%	
Insurance*	66.6%	
Other**	0.1%	
Total	100.0%	

Note: The applicant states that it does not have charity care as a payor source, and that patients in every payor category receive charity care. *Including any managed care plans **"Other" includes Worker's Compensation and

TRICARE

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (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.

С

The applicant proposes to relocate its existing ASF with two GI endoscopy rooms to MOB #2.

In Section D, page 32, the applicant states it will relocate both its existing GI endoscopy rooms and will no longer offer GI endoscopy services at the current location.

In Section D, pages 32-36, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 32, the applicant states:

"The proposed project will not result in any reduction in access to these services; [CGC-K] will continue to serve the patients currently utilizing these services as the two existing GI endoscopy rooms will be relocated less than a half mile from their current location. As a result of the relocation, patients will have access to additional prep and recovery spaces with more privacy, providers will have expanded space in the two GI endoscopy rooms allowing for better delivery of care, and the overall structural design will foster better patient care and infection control."

In Section D, pages 35-36, the applicant states:

"..., the needs of the patients currently utilizing GI endoscopy services at [CGC-K] will continue to be met... CPN provides access to care for all patients regardless of race, color, religion, national origin, sex, age, disability, or source of payment. This will continue to be true following the proposed relocation...[CGC-K] will continue to serve the patients currently utilizing these services as the two existing GI endoscopy rooms will be relocated less than a half mile from their current location. As such, the proposed relocation will have no negative impact on geographic or financial accessibility to the existing services."

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

(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

The applicant proposes to relocate its existing ASF with two GI endoscopy rooms to MOB #2.

In Section E, page 37, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- <u>Maintain the Status Quo</u>: The applicant states that, due to the small size of the existing GI endoscopy rooms and insufficient space to accommodate continued volume growth, maintaining the status quote is not an effective alternative.
- <u>Develop CGC-K in a Different Location</u>: The applicant states other locations would not be as convenient or have the same access to parking, and other locations would not allow CGC-K to be located on the same site as the medical practice where physicians utilizing CGC-K will be located; therefore, this was not an effective alternative.

On page 37, the applicant states its proposal is the most effective alternative because it allows for development of a facility that meets modern standards of healthcare regarding size and space, it offers more easily accessible services to patients, and it allows for physicians utilizing the proposed facility to be located on the same site as CGC-K.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- **1.** Carolinas Physicians Network, Inc. shall materially comply with all representations made in the certificate of need application.
- 2. Carolinas Physicians Network, Inc. shall relocate its existing ambulatory surgical facility with two gastrointestinal endoscopy procedure rooms to MOB #2 at 1225 Harding Place in Charlotte.
- 3. Upon completion of the project, Carolinas Gastroenterology Center Kenilworth shall be licensed for no more than two gastrointestinal endoscopy procedure rooms.
- 4. Carolinas Physicians Network, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Sections F and Q of the application and that would otherwise require a certificate of need.
- 5. For the first three years of operation following completion of the project, Carolinas Physicians Network, Inc. shall not increase charges more than 5% of the charges projected in Sections F and Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.
- 6. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Carolinas Physicians Network, Inc. shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payor mix for the services authorized in this certificate of need.
 - **b.** Utilization of the services authorized in this certificate of need.
 - c. Revenues and operating costs for the services authorized in this certificate of need.
 - d. Average gross revenue per unit of service.
 - e. Average net revenue per unit of service.
 - f. Average operating cost per unit of service.
- 7. Carolinas Physicians Network, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency 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.

The applicant proposes to relocate its existing ASF with two GI endoscopy rooms to MOB #2.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the project, as shown in the table below.

Construction Costs	\$1,490,071
Medical Equipment Costs	\$380,070
Non-Medical Equipment/Furniture	\$59 <i>,</i> 870
Consultant/A&E Fees	\$141,856
Miscellaneous Costs/Contingency	\$286,316
Total	\$2,358,183

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 41, the applicant does not project any start-up or initial operating expenses.

Availability of Funds

In Section F, page 40, the applicant states the capital cost of the project will be funded via accumulated reserves of CMHA/Atrium Health. Exhibit F.2-1 contains a letter from the Executive Vice President and Chief Financial Officer of Atrium Health, who also serves as the Treasurer of CPN, dated May 15, 2019, stating CPN will fully commit the funding costs provided to it by CMHA to develop the proposed project.

Exhibit F.2-2 contains financial statements for CMHA/Atrium Health for the years ending December 31, 2017 and 2016. As of December 31, 2017, CMHA/Atrium Health had adequate cash and cash equivalents to fund the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicant projects that revenues will exceed operating expenses in the first three fiscal years of the project, as shown in the table below.

CGC-K Revenue and Expenses – FYs 1-3 (CYs 2021-2023)					
	FY 1 (CY 2021)	FY 2 (CY 2022)	FY 3 (CY 2023)		
Total Number of Procedures	5,746	5,750	5,755		
Total Gross Revenues (Charges)	\$8,632,988	\$8,898,966	\$9,173,140		
Total Net Revenue	\$4,184,149	\$4,313,061	\$4,445,944		
Average Net Revenue per Procedure	\$728	\$750	\$773		
Total Operating Expenses (Costs)	\$2,813,003	\$2,894,278	\$2,978,011		
Average Operating Expense per Procedure	\$490	\$503	\$517		
Net Income / (Loss)	\$1,371,146	\$1,418,783	\$1,467,933		

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application

for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital cost is based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

С

The applicant proposes to relocate its existing ASF with two GI endoscopy rooms to MOB #2.

The 2019 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as "...*the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.*" In Section G, page 46, the applicant defines the primary service area as Mecklenburg County. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

There are a total of 58 existing or approved GI endoscopy rooms across 19 facilities in Mecklenburg County, as shown in the table below.

Mecklenburg County GI Endoscopy Services – FFY 2018				
Existing Facilities	# of Rooms	FFY 2018 # of Cases	FFY 2018 # of Procedures	
Carolina Digestive Endoscopy Center	2	2,225	3,047	
Carolina Endoscopy Center – Huntersville	2	1,901	2,495	
Carolina Endoscopy Center – Pineville	2	2,659	3,750	
Carolina Endoscopy Center – University	2	2,020	2,694	
Carolinas Gastroenterology Center – Ballantyne	4	11,212	12,689	
CGC-MCP	2	5,280	5,804	
Atrium Health Pineville	2	3,936	5,488	
Atrium Health University City	1	1,702	2,462	
Carolinas Medical Center	12	12,621	18,686	
Charlotte Gastroenterology & Hepatology (AS0109)	4	6,227	7,440	
Charlotte Gastroenterology & Hepatology (AS0110)	2	5,745	6,729	
Endoscopy Center of Lake Norman	2	3,314	3,946	
Novant Health Ballantyne Outpatient Surgery*	1	234	234	
Novant Health Ballantyne Medical Center*	(1)	0	0	
Novant Health Huntersville Medical Center	3	1,958	1,988	
Novant Health Matthews Medical Center**	3	1,422	1,475	
Novant Health Mint Hill Medical Center**	1	0	0	
Novant Health Presbyterian Medical Center	9	3,399	3,485	
Tryon Medical Partners – Ballantyne***	4	0	0	
Total	58	65,855	82,412	

Sources: Section G, page 74; Table 6F: Endoscopy Room Inventory (pages 88-89 of the Proposed 2020 SMFP); Agency files *On April 30, 2019, the Agency issued a certificate of need for Novant Health Ballantyne Medical Center to develop a new hospital with one GI endoscopy room. The GI endoscopy room will be relocated from Novant Health Ballantyne Outpatient Surgery.

**During most of FFY 2018, Novant Health Matthews Medical Center had four GI endoscopy rooms and Novant Health Mint Hill Medical Center had no GI endoscopy rooms; as of September 20, 2018, one GI endoscopy room was relocated from Novant Health Matthews Medical Center to Novant Health Mint Hill Medical Center.

***On November 27, 2018, the Agency issued a certificate of need for Tryon Medical Partners – Ballantyne to develop a new ASF with four GI endoscopy rooms.

In Section G, pages 46-48, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Mecklenburg County. On page 48, the applicant states:

"The proposed project will not result in any unnecessary duplication of the existing or approved facilities that provide the same services and are located in the service area because the two existing GI endoscopy rooms proposed to relocate to Atrium Health Kenilworth are existing and well utilized...There will be no change to the number of GI endoscopy rooms [in Mecklenburg County] as a result of the proposed project."

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the proposal would not result in a change in the number of existing or approved GI endoscopy rooms in Mecklenburg County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(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.

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In Section Q, Form H, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

CGC-K Current & Projected Staffing Last FY (CY 2018), All FYs (CYs 2021, 2022, 2023)		
Position	FTEs	
Registered Nurse	8.39	
Aides and Attendants	1.90	
Administrative/Management	0.15	
Supervisory	0.36	
Technicians	2.14	
Clerical and Secretarial	2.18	
Total 15.1		

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 49-50, the applicant describes the methods to be used to recruit or fill new positions and its training and continuing education programs. The applicant provides supporting documentation in Exhibit H.3. In Section H, page 50, the applicant identifies the current medical director. In Exhibit H.4, the applicant provides a letter from the medical director expressing support for the proposed project and indicating a willingness to continue to serve as medical director. In Section H, page 50, the applicant states it does not need physician recruitment plans for the proposed project.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

• Application

• Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(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.

С

In Section I, page 52, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Laboratory Testing
- Diagnostic Procedures
- Housekeeping
- Security
- Maintenance
- Registration and Administration
- Other Ancillary and Support Services

On page 52, the applicant adequately explains how each ancillary and support service is or will be made available.

In Section I, page 52, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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.

С

In Section K, page 55, the applicant states that the project involves upfitting 7,212 square feet of leased space in a medical office building being developed by an unrelated third-party developer. Line drawings are provided in Exhibit C.1-4.

In Section K, page 56, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

In Section K, page 56, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges

to the public for the proposed services. The applicant states development of a freestanding ASF for GI endoscopy services results in lower costs to patients and that, as part of Atrium Health, the facility benefits from cost savings due to large economies of scale.

In Section K, pages 57-58, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the healthrelated 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;

С

In Section L, page 64, the applicant provides the historical payor mix for CY 2018 at CGC-MCP, as shown in the table below.

CGC-MCP Historical Payor Mix – CY 2018		
Payor Source	Percent of Services	
Self-Pay	0.3%	
Medicare*	31.8%	
Medicaid*	1.2%	
Insurance*	66.6%	
Other**	0.1%	
Total	100.0%	

Note: The applicant states that it does not have charity care as a payor source, and that patients in every payor category receive charity care.

*Including any managed care plans

**"Other" includes Worker's Compensation and TRICARE

	% of Total Patients Served at	% of the Population of
	CGC-MCP during CY 2018	Mecklenburg County
Female	58.1%	51.2%
Male	41.9%	48.8%
Unknown	0.0%	0.0%
64 and Younger	77.5%	88.7%
65 and Older	22.5%	11.3%
American Indian	0.3%	0.4%
Asian	1.6%	6.1%
Black or African-American	27.8%	32.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	60.4%	51.6%
Other Race	4.5%	9.8%
Declined / Unavailable	5.5%	0.0%

In Section L, pages 62-63, the applicant provides the following comparison.

Sources: CPN Internal Data, NC OSBM

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents 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. 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;

С

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 64, the applicant states that the facility is under no obligation under any applicable federal regulations.

In Section L, page 64, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

С

In Section L, page 65, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

CGC-K Payor Mix – FY 2 (CY 2022)		
Payor Source	Percent of Services	
Self-Pay	0.3%	
Medicare*	31.8%	
Medicaid*	1.2%	
Insurance*	66.6%	
Other**	0.1%	
Total	100.0%	

Note: The applicant states that it does not have charity care as a payor source, and that patients in every payor category receive charity care. *Including any managed care plans **"Other" includes Worker's Compensation and TRICARE

As shown in the table above, during the second full fiscal year of operation, the applicant projects 0.3 percent of total services will be provided to self-pay patients, 31.8 percent to Medicare patients, and 1.2 percent to Medicaid patients.

In Section L, page 65, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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.

С

In Section L, page 66, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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.

С

In Section M, pages 68-69, the applicant describes the extent to which health professional training programs in the area have will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.

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

С

The applicant proposes to relocate its existing ASF with two GI endoscopy rooms to MOB #2.

The 2019 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as "...*the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.*" In Section G, page 46, the applicant defines the primary service area as Mecklenburg County. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

There are a total of 58 existing or approved GI endoscopy rooms across 19 facilities in Mecklenburg County, as shown in the table below.

Mecklenburg County GI Endoscopy Services – FFY 2018			
Existing Facilities	# of Rooms	FFY 2018 # of Cases	FFY 2018 # of Procedures
Carolina Digestive Endoscopy Center	2	2,225	3,047
Carolina Endoscopy Center – Huntersville	2	1,901	2,495
Carolina Endoscopy Center – Pineville	2	2,659	3,750
Carolina Endoscopy Center – University	2	2,020	2,694
Carolinas Gastroenterology Center – Ballantyne	4	11,212	12,689
CGC-MCP	2	5,280	5,804
Atrium Health Pineville	2	3,936	5,488
Atrium Health University City	1	1,702	2,462
Carolinas Medical Center	12	12,621	18,686
Charlotte Gastroenterology & Hepatology (AS0109)	4	6,227	7,440
Charlotte Gastroenterology & Hepatology (AS0110)	2	5,745	6,729
Endoscopy Center of Lake Norman	2	3,314	3,946
Novant Health Ballantyne Outpatient Surgery*	1	234	234
Novant Health Ballantyne Medical Center*	(1)	0	0
Novant Health Huntersville Medical Center	3	1,958	1,988
Novant Health Matthews Medical Center**	3	1,422	1,475
Novant Health Mint Hill Medical Center**	1	0	0
Novant Health Presbyterian Medical Center	9	3,399	3,485
Tryon Medical Partners – Ballantyne***	4	0	0
Total	58	65,855	82,412

Sources: Section G, page 74; Table 6F: Endoscopy Room Inventory (pages 88-89 of the Proposed 2020 SMFP); Agency files *On April 30, 2019, the Agency issued a certificate of need for Novant Health Ballantyne Medical Center to develop a new hospital with one GI endoscopy room. The GI endoscopy room will be relocated from Novant Health Ballantyne Outpatient Surgery.

**During most of FFY 2018, Novant Health Matthews Medical Center had four GI endoscopy rooms and Novant Health Mint Hill Medical Center had no GI endoscopy rooms; as of September 20, 2018, one GI endoscopy room was relocated from Novant Health Matthews Medical Center to Novant Health Mint Hill Medical Center.

***On November 27, 2018, the Agency issued a certificate of need for Tryon Medical Partners – Ballantyne to develop a new ASF with four GI endoscopy rooms.

In Section N, pages 70-71, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 70, the applicant states:

"The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to GI endoscopy services."

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).

• Access will be provided to underserved groups (see Sections C, D, and L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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.

С

In Exhibit O.3, the applicant provides a list of all healthcare facilities with GI endoscopy rooms and ASFs located in North Carolina which are owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 26 hospitals and ASFs that potentially offer GI endoscopy services located in North Carolina.

In Section O, page 75, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care which occurred any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in two of these facilities. 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 all 26 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.

NA

The applicant proposes to relocate its existing ASF with two GI endoscopy rooms to a new location. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3900, are not applicable to this review because the applicant does not propose to establish a new licensed ASF for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility.