

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 26, 2018

Findings Date: October 26, 2018

Project Analyst: Ena Lightbourne

Co-Signer: Fatimah Wilson

Project ID #: F-11560-18

Facility: Tryon Medical Partners

FID #: 180430

County: Mecklenburg

Applicant: Tryon Medical Partners, PLLC

Project: Develop a new ambulatory surgical facility with four gastrointestinal endoscopy (GI endoscopy) rooms

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.

C

The applicant, Tryon Medical Partners, PLLC (TMP) proposes to develop a new Ambulatory Surgical Facility (ASF) with four gastrointestinal endoscopy (GI endoscopy) 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 2018 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There is one policy in the 2018 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 B.4, page 15 and Section K.4 (c), Page 71, the applicant describes its plan to ensure energy efficiency and water conservation, stating that its HVAC, electrical, and lighting systems will meet State codes and industry standards. In addition, the applicant states it will use standard low flow water fixtures for water conservation. The applicant adequately demonstrates that the application includes a written statement describing the projects plan to assure improved energy efficiency and water conservation.

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 does not propose to develop any beds, services or acquire any equipment for which there is a need determination in the 2018 SMFP.
 - The applicant adequately demonstrates that the proposal 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.

C

TMP proposes to develop a new Ambulatory Surgical Facility (ASF) with four GI endoscopy rooms.

Patient Origin

The 2018 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6) does define the service area as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients. In Section C.3, page 20, the applicant defines the primary service area as Mecklenburg County. The applicant may also serve residents of counties not included in its proposed service area.

In Section C.3, page 20, the applicant provides a table illustrating the projected patient origin for GI endoscopy services at TMP, for the first three operating years, fiscal year (FY) 2019, FY2020 and FY2021, as follows:

**TMP
 Projected Patient Origin
 FY2019– FY2021**

County	1 st FULL FY2019 01/01/2019 to 12/31/2019		2 nd FULL FY2020 01/01/2020 to 12/31/2020		3 rd FULL FY2021 01/01/2021 to 12/31/2021	
	Mecklenburg	5,361	65.0%	6,435	65.0%	7,504
South Carolina	1,468	17.8%	1,762	17.8%	2,055	17.8%
Gaston	808	9.8%	970	9.8%	1,131	9.8%
Union	610	7.4%	733	7.4%	854	7.4%
Total	8,248 [8,247]	100.0%	9,900	100.0%	11,544	100.0%

Source: Section C.3, page 20

In Section C.3, page 20, the applicant provides the assumptions and methodology used to project patient origin. The applicant states it is based on historical patient origin of the gastroenterologists who will be providing the GI endoscopy services at TMP. Therefore, the projected patient origin is expected to be consistent with the gastroenterologist historical patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 21-25, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 21-25, the applicant states:

- SMFP reported GI endoscopy cases
 In Mecklenburg County, GI endoscopy procedures has increased 11.1% in the last five years. [page 22]
- Physician requirements and support
 At the time this application was submitted, five TMP gastroenterologists currently practicing at Mecklenburg Medical Group are credentialed and ready to perform GI endoscopy procedures at TMP, a new cost-effective and patient-friendly ambulatory surgical facility option in Mecklenburg County. This CON application proposes to provide the physicians with the diagnostic equipment they need to provide standard of care for service area resident upon leaving Mecklenburg Medical Group. [pages 22-23]
- County population growth trends
 From 2013-2018, the population of Mecklenburg County grew by 10.9 percent. Based on the North Carolina office of Statewide Budget and Management (NCOSBM) projections, Mecklenburg County’s population is projected to grow by an additional 10.0% between 2018 to 2023 and 20.1% between 2018 to 2028.

NCOSBM projects that the elderly population will be the fastest-growing population, increasing by 26.7 % between 2018 to 2023 and 55.5% between 2018 to 2028. [page 24]

- **ASF Industry Growth**

Key growth trends in the global GI sector are cited in the Becker’s ASC Review, identifying a probable 4.7 % compound annual growth rate in the GI sector through 2027. The Becker’s ASC Review also identifies a 3% annual increase in rectal cancer among people under 50. TMP is located in an area with a growing population, including 65+ older residents that is well positioned to leverage these trends. [page 25]

The information in the pages referenced above is reasonable and adequately supported for the following reasons:

- Increases in Mecklenburg County GI endoscopy procedures over the last five years
- Historical and projected population growth in Mecklenburg County
- Support of five gastroenterologists who credentialed and ready to perform GI endoscopy procedures at TMP.

Projected Utilization

In Section C.7 pages 30-33, the applicant provides its methodology for projecting utilization of GI endoscopy services at TMP, summarized as follows:

Step 1. The applicant utilizes the projected GI endoscopy procedures volumes of the five gastroenterologists to be performed during the first five years at TMP by using their historical physician performance.

The applicant identified from Table 6F: Endoscopy Room Inventory in the 2015 through Draft 2019 SMFPs, the number of GI endoscopy procedures performed in the licensed healthcare facilities located in Mecklenburg County in a table on page 31, summarized as follows:

**Mecklenburg County
Total GI Endoscopy Cases**

	2013	2014	2015	2016	2017
	A	B	C	D	E
Total GI Endoscopy Procedures	78,683	82,986	79,125	84,333	87,407

Step 2. The applicant calculates the Compound Annual Growth Rate (CAGR) for the number of GI endoscopy procedures performed in Mecklenburg County during the five year period from 2013 to 2017. The CAGR is 1.9%.

Step 3. The applicant calculates the projected annual growth in the number of GI endoscopy procedures in Mecklenburg County using the CAGR calculated in Step 2. The result was added to the previous year's total which resulted in the total projected GI Endoscopy procedures, summarized as follows:

**Projected Annual Growth and
 Total Projected GI Endoscopy Procedures**

		2017	2018	2019	2020	2021	2022
		E	F	G	H	I	J
Total GI Endoscopy Procedures	1	87,407					
5-Year (2013-2017) CAGR	2		1.9%	1.9%	1.9%	1.9%	1.9%
Projected Annual Growth	3		1,661	1,692	1,724	1,754	1,791
Total Projected GI Endoscopy Procedures	4		89,068	90,760	92,484	94,242	96,032

Step 4. The applicant calculates the projected number of GI endoscopy procedures to be performed for the first three years of operation at TMP utilizing the projected number of procedures performed by the five gastroenterologists who will perform these procedures during the first year at TMP. The applicant projects each physician will perform 1,650 procedures a year at a standard 10 hours of operation a day, summarized as follows:

Total Projected GI Endoscopy Procedures for TMP

Specialty	Year 1	Year 2	Year 3
Total GI Endoscopy Procedures	8,248	9,900	11,544
GI Endoscopy Procedures per GI Endoscopy Room per Day	8.25	9.9	11.5

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

- Projected amount of GI endoscopy procedures performed by the five gastroenterologists are reasonably based on the existing TMP Physician Performance.
- The Annual Growth in procedures performed in Mecklenburg County are calculating using the 5-Year (2013-2017) CAGR.
- Total amount of GI endocopy procedures performed Mecklenburg County was reasonably based on Table 6F: Endoscopy Room Inventory in the 2015 through Draft 2019 SMFPs.

Access

In Section C.8, page 34, the applicant states,

“TMP will not deny services to any patient due to economic status, race gender, age, handicap, or ability to pay. The services proposed in this application will be available to and accessible by any patient having a need for those services. As a certified provider under Title XVIII (Medicare), TMP will provide a full range of services to the elderly. Services to low income persons will be provided by TMP as certified provider under Title XIX (Medicaid). TMP will serve the medically indigent through charity care that equals \$98,000 in Year 3. The diagnostic center will be accessible by persons with disabilities and will meet applicable ADA standard.”

In Section L, page 78, 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.

**2nd Full FY Following completion of the Project
(1/1/2021-12/31/2021)**

Payor Source	Entire Facility
Self-Pay	0.7%
Medicare*	30.0%
Medicaid	5.1%
Insurance*	64.3%
Total	100.0%

*Including any managed care plans

The applicant states, in Section L, page 76, that there is no historical payor mix for TMP because TMP does not currently provide healthcare services in the service area. On page 78, the applicant states that GI endoscopy procedure payor mix is based on the existing payor mixes by the physicians expected to perform GI endoscopy procedures at TMP.

The projected payor mix is reasonable and adequately supported.

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 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.

NA

The applicant does not propose to reduce, eliminate or relocate GI endoscopy rooms or services; therefore, Criterion (3a) is not applicable to this review.

- (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, TMP proposes to develop a new Ambulatory Surgical Facility (ASF) with four GI rooms.

In Section E, pages 46-47, 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:

- Maintain the Status Quo-The applicant states this is a poor alternative because the proposed GI endoscopy rooms and equipment is necessary to provided standard care. TMP physicians will provide patient care at a new medical practice beginning in late 2018, after leaving another medical group and their medical equipment. The proposed facility will be equipped with GI endoscopy rooms and equipment, allowing TMP to ability to provide standard care.
- Build a Freestanding ASF Building - The applicant states this alternative was rejected because it is the most expensive option. The cost to acquire land and construct a GI endoscopy specific ASF in Charlotte is much more expensive than what is proposed in the CON application.

- Up Fit Space within a Medical Office Building (MOB) for ASF – The applicant states upfitting a space within MOB for ASF is the most cost effective and efficient means to provide GI endoscopy procedures to resident in the service area. The applicant states TMP will provide a more economical choice for outpatient GI endoscopy service to the patients in the service areas. The ASF will allow TMP to focus on developing an efficient operating ASF through the facility’s policies and procedures, staffing, and space utilization.

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 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

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. Tryon Medical Partners, PLLC shall materially comply with all representations made in the certificate of need application.**
- 2. Tryon Medical Partners, PLLC shall develop a new ambulatory surgical facility with four gastrointestinal endoscopy procedure rooms.**
- 3. Upon completion of the project Tryon Medical Partners, PLLC shall be licensed for no more than four gastrointestinal endoscopy procedure rooms.**
- 4. Tryon Medical Partners, PLLC 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. Tryon Medical Partners, PLLC, shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**

6. **For the first three years of operation following completion of the project, Tryon Medical Partners, PLLC 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.**
 7. **The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**
 8. **Procedures performed in the procedure rooms shall not be reported for billing purposes as having been performed in a gastrointestinal endoscopy room and shall not be reported on the facility's license renewal application as procedures performed in a gastrointestinal endoscopy room.**
 10. **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, & 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.**
 11. **Tryon Medical Partners, PLLC 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.

C

The applicant, TMP proposes to develop a new Ambulatory Surgical Facility (ASF) with four GI rooms.

Capital and Working Capital Costs

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

Tryon Medical Partners, PLLC (TMP)

Construction Renovation	\$ 997,845
Construction Contingency	\$ 75,000
Architect and Engineering Fees	\$ 104,405
Medical Equipment	\$1,129,483
Non-Medical Equipment	\$ 60,000
Furniture	\$ 55,000
Consultant Fees	\$ 31,000
Other (Permits and Licenses)	\$ 99,920
Other (Contingency)	\$ 255,265
Total Capital Cost	\$2,807,918

*Includes tenant improvement costs for upfit of space.

**Includes sales taxes.

In Section Q, Forms F.1 – F.6 and Form H, the applicant provides the assumptions used to project the capital cost.

The applicant states that they are proposing to operate the GI endoscopy rooms prior to licensure as physician office-based GI endoscopy rooms. The applicant is not proposing any start-up expenses. In Section F, page 51, the applicant projects that initial operating expenses will be \$300,000 for a total working capital of \$300,000. In Exhibit F.1, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F.2, page 49, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	TMP	Total
Loans	\$ 2,807,918	\$ 2,807,918
Accumulated reserves or OE *		
Bonds		
Other		
Total Financing	\$ 2,807,918	\$ 2,807,918

* OE = Owner's Equity

In Section F.3, page 52, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loan	\$ 300,000
(b)	Cash or Cash Equivalents, Accumulated Reserves Owner's Equity	
(c)	Lines of credit	
(d)	Bonds	
(e)	Total *	\$ 300,000

Exhibit F-2 contains a letter dated August 2, 2018 from the First Vice president of Sun Trust Bank committing to financing through a commercial loan of \$2,807,918 for the total capital costs of the project and a line of credit in the amount of \$300,000 for the working capital.

Financial Feasibility

In Section Q, the applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.4 of the pro forma financial statements, the applicant projects that revenues will exceed expenses in the first three operating years of the project, as shown in the table below.

Tryon Medical Partners, PLLC

GI Endoscopy Services	Project Year 1 FY2020	Project Year 2 FY2021	Project Year 3 FY2022
Total Procedures	8,248	9,900	11,544
Total Gross Revenues (Charges)	\$ 10,557,440	\$ 12,798,720	\$ 15,073,324
Total Net Revenue	\$ 6,053,233	\$ 7,338,297	\$ 8,642,468
Average Net Revenue per Procedure	\$ 734	\$ 741	\$ 749
Total Operating Expenses (Costs)	\$ 4,645,749	\$ 5,151,527	\$ 5,686,323
Average Operating Expense per Procedure	\$ 563	\$ 520	\$ 493
Net Income	\$ 1,407,483 [1,407,484]	\$ 2,186,770	\$ 2,956,145

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See the applicant's assumptions regarding costs and charges following the pro forma financial statements in Section Q of the application. 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 and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working 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.

C

The applicant, TMP proposes to develop a new Ambulatory Surgical Facility (ASF) with four GI rooms.

The 2018 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6) does define the service area as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients. The applicant may also serve residents of counties not included in its proposed area.

There are 17 locations where patients can access GI endoscopy services in Mecklenburg County, which is the applicant's primary service area, as stated in Section C. In Section G, page 58, the applicant provides a table listing all of the GI endoscopy services locations in the service area, the number of licensed GI endoscopy procedure rooms, and the number of GI endoscopy procedures performed at each location based on the Draft 2019 SMFP, Table 6F: Endoscopy Room Inventory.

Facility	# of GI Endoscopy Rooms	Total GI Endoscopy Procedures
Carolina Digestive Endoscopy Center	1	4,615
Carolina Endoscopy Center-Huntsville	2	3,120
Carolina Endoscopy Center-Pineville	2	3,959
Carolina Endoscopy Center-University	2	3,799
Carolinas Gastroenterology-Ballantyne	2	16,879
Carolinas Gastroenterology-Medical Center Plaza	4	7,479
Carolinas Health System Pineville	2	4,622
Carolinas Health System University	2	2,459
Carolinas Medical Center	1	15,107
Charlotte Gastroenterology & Hepatology	12	7,215
Charlotte Gastroenterology & Hepatology	4	6,711
Endoscopy Center of Lake Norman	2	4,224
Novant Health Ballantyne Outpatient Surgery	2	174
Novant Health Huntsville Medical Center	1	2,015
Novant Health Matthews Medical Center	3	1,418
Novant Health-Presbyterian Medical Center	4	3,614
Presbyterian Hospital Mint Hill	9	0

Source: Draft 2019SMFP, table 6F: Endoscopy Room Inventory

In Section G, page 59, 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. The applicant states:

“.....the current Mecklenburg County GI endoscopy procedure volume is sufficient to fully utilize 58.3 GI endoscopy rooms, Mecklenburg County has 54 GI endoscopy rooms in its inventory. Mecklenburg County GI endoscopy projections result in a five-year increase of 8,625 GI endoscopy procedures, which is sufficient to fully utilize an additional 5.8 GI endoscopy rooms at 1,500 GI endoscopy procedures per room.”

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 applicant adequately demonstrates that the proposed GI endoscopy procedure rooms are needed in addition to the existing or approved GI endoscopy procedure rooms in the proposed service area.

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.

C

In Section Q, Form H, the applicant provides projected staffing in full-time equivalents (FTEs) for the proposed services as illustrated in the following table.

Position	# of FTEs		
	1st Year	2nd Year	3rd Year
Managers	3.0	3.0	3.0
Registered Nurses (RN)	12.0	12.0	12.0
Endoscopy Technician	7.0	7.0	7.0
Total	10.5	10.5	10.5

The assumptions and methodology used to project staffing are provided in Section Q, Form H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 of the pro forma financial statements, which is found in Section Q. In Section H, page 61, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Exhibit H.4, the applicant states that Dr. D. Scott Smith will serve as Medical Director of the TMP GI endoscopy center.

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.

C

In Section I, page 65, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Billing and Accounting
- Business Office
- Human Resources
- Information Management
- Legal Services
- Material Management
- Medical Record Services
- Precertification and Insurance
- Purchasing
- Quality Management and Infection Control
- Risk Management and Utilization Review
- Scheduling
- Staff Education

On page 65, the applicant states the ancillary and support services required to operate the ASF will be provided by TMP staff and provides supporting documentation in Exhibit I.1.

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.

C

In Section K, page 70, the applicant states that the project involves up fitting 11,530 square feet of a leased spaced within an existing medical office building in Charlotte. Line drawings are provided in Exhibit K.3.

On page 47, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 70, 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 and provides a table projecting a depreciation expense per GI endoscopy procedure in Year 3.

On page 71, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

In Section K, page 73, and Exhibit K.5, the applicant identifies the proposed site and provides information about the current owner and zoning for the site, and the availability of water, sewer and waste disposal and power at site.

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 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;

NA

Neither the applicant nor any related entities owns, operates or manages an existing health service facility located in the service area. Therefore, Criterion (13a) is not applicable to this review.

- (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;

NA

Neither the applicant nor any related entities owns, operates or manages an existing health service facility located in the service area. Therefore, Criterion (13b) is not applicable to this review.

- (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 L, page 78, 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:

**2nd Full FY Following completion of the Project
(1/1/2021-12/31/2021)**

Payor Category	GI Endo services as Percent of Total
Self-Pay/Indigent/Charity	0.7%
Medicare*	30.0%
Medicaid	5.1%
Insurance*	64.3%
Total	100.0%

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.7% of total services will be provided to self-pay, indigent, charity care patients, 30% to Medicare patients and 5.1% to Medicaid patients.

On page 78, 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 current outpatient payor mix for GI endoscopy services at TMP.

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.

C

In Section L, page 79, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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.

C

In Section M, page 81, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.2.

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.

C

The applicant, TMP proposes to develop a new Ambulatory Surgical Facility (ASF) with four GI rooms.

The 2018 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6) does define the service area as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients. The applicant may also serve residents of counties not included in its proposed area.

There are 17 locations where patients can access GI endoscopy services in Mecklenburg County, which is the applicant's primary service area, as stated in Section C. In Section G, page 58, the applicant provides a table listing all of the GI endoscopy services locations in the service area, the number of licensed GI endoscopy procedure rooms, and the number of GI endoscopy procedures performed at each location based on the Draft 2019 SMFP, Table 6F: Endoscopy Room Inventory.

Facility	# of GI Endoscopy Rooms	Total GI Endoscopy Procedures
Carolina Digestive Endoscopy Center	1	4,615
Carolina Endoscopy Center-Huntsville	2	3,120
Carolina Endoscopy Center-Pineville	2	3,959
Carolina Endoscopy Center-University	2	3,799
Carolinas Gastroenterology-Ballantyne	2	16,879
Carolinas Gastroenterology-Medical Center Plaza	4	7,479
Carolinas Health System Pineville	2	4,622
Carolinas Health System University	2	2,459
Carolinas Medical Center	1	15,107
Charlotte Gastroenterology & Hepatology	12	7,215
Charlotte Gastroenterology & Hepatology	4	6,711
Endoscopy Center of Lake Norman	2	4,224
Novant Health Ballantyne Outpatient Surgery	2	174
Novant Health Huntsville Medical Center	1	2,015
Novant Health Matthews Medical Center	3	1,418
Novant Health-Presbyterian Medical Center	4	3,614
Presbyterian Hospital Mint Hill	9	0

Source: Draft 2019SMFP, table 6F: Endoscopy Room Inventory

In Section N, page 83, 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 83, the applicant states:

TMP expects the ASF project to have a positive impact on competition in the service area. TMP will be competing not only with other providers of outpatient GI endoscopy services, but also with local hospitals in the service area. TMP hopes to promote the idea that patients have a choice of where to receive their care and it will strive to earn the loyalty of its patients every day. As a non-hospital based provider, procedure charges will be dramatically lower than the charges that were charged as an Atrium Health-owned medical practice.

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 Section L of the application and any exhibits)

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.

- (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.

NA

In supplemental information, the applicant states that neither it nor any related entities own or manage any other licensed health care facilities in North Carolina.

Therefore, Criterion (20) is not applicable to this review.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

.3903 PERFORMANCE STANDARDS

- (a) *In providing projections for operating rooms, as required in this Rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding 10 days for holidays.*
- NA- The applicant does not propose to develop operating rooms. Therefore, this Rule is not applicable to this review.
- (b) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI endoscopy procedures only per GI endoscopy room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project.*
- C- In Section C, page 37, the applicant states it will perform 9,900 GI endoscopy procedures at 2,475 per room in FY2021, the second operating year of the proposed project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (b) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall demonstrate that at least the following types of GI endoscopy procedures will be provided in the proposed facility or GI endoscopy room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.*
- C- In Section C, page 23, the applicant states that upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures will be provided at TMP, consistent with outpatient GI endoscopy procedures currently performed by the five gastroenterologists at Atrium Health-owned Medical Group who will be performing at TMP.
- (d) *If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria:*
- (1) *if the applicant or a related entity performs GI endoscopy procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI endoscopy cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or*

(2) *demonstrate that GI endoscopy procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future.*

-NA- Neither the applicant nor any related entities own any operating rooms in Mecklenburg County. Therefore, this Rule is not applicable to this review.

(e) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop an additional GI endoscopy room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in this Rule.*

-C- In Section C, pages 29-33, the applicant provides the assumptions and methodology used to project GI endoscopy procedures at the proposed facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.