

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 15, 2018

Findings Date: October 15, 2018

Project Analyst: Julie M. Faenza

Chief: Martha J. Frisone

Project ID #: F-11525-18

Facility: Tryon Medical Partners – SouthPark

FID #: 180310

County: Mecklenburg

Applicant: Tryon Medical Partners, PLLC

Project: Develop a new diagnostic center

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.

NA

Tryon Medical Partners, PLLC (Tryon) proposes to develop a new diagnostic center, Tryon Medical Partners – SouthPark (TMP-S) in existing space located at 6060 Piedmont Row Drive South in Charlotte. The combined value of the medical diagnostic equipment costing \$10,000 or more exceeds the statutory threshold of \$500,000; therefore, the equipment qualifies as a diagnostic center, which is a new institutional health service, and which requires a certificate of need.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2018 State Medical Facilities Plan (SMFP)

- acquire any medical equipment for which there is a need determination in the 2018 SMFP
- offer a new institutional health service for which there are any policies in the 2018 SMFP

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a new diagnostic center in Mecklenburg County as part of developing a medical and surgical specialty practice. In Section A, pages 11-12, the applicant states that this practice will have some or all of 89 physicians leaving Mecklenburg Medical Group, which is owned by Atrium Health. Mecklenburg Medical Group was established in 1936 and was an independent practice until its acquisition by Carolinas HealthCare System in 1993. The applicant states that these physicians served patients from North and South Carolina at ten medical practices in the area which provided many different types of healthcare services. The applicant states that once the 89 physicians leave Mecklenburg Medical Group, they will no longer have access to the medical equipment they need in order to continue caring for their patients, and this diagnostic center is being established to provide the physicians with the needed equipment.

Designation as a Diagnostic Center

In Exhibit F.1, the applicant provides the purchase price of the proposed equipment, as shown in the table below.

TMP-S Proposed Equipment				
Equipment	Mfr/Model	#	Unit Cost	Total Cost
X-Ray	GE Proteus XRf	1	\$125,000	\$125,000
Densitometry	Hologic Horizon W	1	\$61,925	\$61,925
Echocardiogram	Phillips DS ie33 (refurb)	3	\$39,500	\$118,500
	Phillips DS ie33 Plus TEE (refurb)	1	\$84,000	\$84,000
	Quinton Q Stress	4	\$17,735	\$70,940
Vascular Lab	Phillips DS ie33 (refurb)	1	\$44,500	\$44,500
	Quinton Q Stress	1	\$17,735	\$17,735
Nuclear Lab	GE Discovery NM630	1	\$288,000	\$288,000
	Hot Lab	1	\$15,000	\$15,000
Pulmonary Function Testing Lab	VMAX Encore 22	1	\$53,005	\$53,005
	Whole Body Plethysmograph			
	Trackmaster TMX428CP Treadmill	1	\$7,254	\$7,254
Endo Ultrasound	GE Logiq E	2	\$35,000	\$70,000
			Total	\$955,859

Patient Origin

N.C.G.S. §131E-176(24a) states: “Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.” The 2018 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant.

In Section G, page 70, the applicant defines Mecklenburg County as the service area. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin during the third full operating year following project completion.

TMP-S Projected Patient Origin – OY 3 (CY 2021)								
County	%	# Patients ECG*	# Patients Nuclear Med	# Patients PFT**	# Patients Vascular Imaging	# Patients BDS***	# Patients Ultrasound	# Patients DR****
Mecklenburg	95%	2,962	735	1,220	1,039	3,178	1,511	11,339
Union	2%	62	15	26	22	67	32	239
Cabarrus	2%	62	15	26	22	67	32	239
Lancaster, SC	1%	31	8	13	11	33	16	119
Total	100%	3,120	774	1,284	1,094	3,345	1,590	11,936

*Echocardiography
 **Pulmonary Function Testing
 ***Bone Density Scanning
 ****Digital Radiography

In supplemental information, 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 37-39, and in supplemental information, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- The proposed diagnostic center requires the types of medical equipment proposed in order to provide patients with appropriate diagnostic services and determine treatment plans.
- The physicians who will be utilizing the medical equipment have been using similar equipment while employed by Atrium Health, but will no longer have access to that equipment, and need the proposed equipment to properly care for their patients.
- The population of Mecklenburg County is expected to grow significantly. Citing data from the North Carolina Office of State Budget and Management (NC OSBM), the applicant states the population of Mecklenburg County grew by 10.9 percent between 2013 and

2018; is projected to grow by 10 percent between 2018 and 2023; and is projected to grow 20.1 percent between 2018 and 2028.

- Despite a previous decline in non-invasive imaging procedures, the decline has leveled off; even if there is no growth in the utilization of imaging procedures, a population increase of 10 percent in the next five years and 20 percent in the next ten years will result in increased utilization.

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

- Reliable data sources are used to support assertions about population growth.
- The applicant uses the data to make reasonable and adequately supported assumptions about future increases in utilization.

Projected Utilization

In supplemental information, the applicant provides projected utilization, as illustrated in the following table.

TMP-S Projected Utilization – OYs 1-3 (CYs 2019-2021)			
Component	OY 1 (CY 2019)	OY 2 (CY 2020)	OY 3 (CY 2021)
Digital X-Ray – Units	1	1	1
Digital X-Ray – Procedures	11,936	11,936	11,936
Dexa Scan – Units	1	1	1
Dexa Scan – Procedures	3,345	3,345	3,345
Echocardiogram – Units	4	4	4
Echocardiogram – Procedures	3,118	3,118	3,118
Vascular Lab – Units	1	1	1
Vascular Lab – Procedures	1,094	1,094	1,094
Nuclear Camera – Units	1	1	1
Nuclear Camera – Procedures	774	774	774
Pulmonary Fx Testing – Units	1	1	1
Pulmonary Fx Testing – Procedures	1,284	1,284	1,284
Endo Ultrasound – Units	2	2	2
Endo Ultrasound – Procedures	1,590	1,590	1,590
Total Procedures	23,141	23,141	23,141

In Section C, pages 46-49, and in supplemental information, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant states that all assumptions are based on the FY 2017 utilization of each physician, averaged by practice specialty. The applicant notes that the physicians were still employed with Mecklenburg Medical Group through August 31, 2018 and thus had access to the data provided for this application.

- Digital Radiography/Bone Density Scanning

In Section C, page 46, and in supplemental information, the applicant provides the following assumptions and methodology to project utilization for digital radiography imaging and bone density scanning for all three operating years, as shown in the table below.

TMP-B Projected Utilization – Digital Radiography/Bone Density Scanning – OYs 1-3 (CYs 2019-2021)							
	Cardiology	Internal Medicine	Internal Medicine ACP	Endocrinology	Endocrinology ACP	Pulmonology	Total
Clinic FTE	2	19	1	4	2	1	--
Patients/Half Day	11	10	9	8	8	11	--
Half Days/Week	9	9	9	9	9	9	--
Weeks/Year	46	46	46	46	46	46	--
Annual Patients	9,108	78,660	3,726	13,248	6,210	4,554	--
Digital Radiography Multiplier	15.0%	12.0%	12.0%	0.0%	0.0%	15.0%	--
Digital Radiography Volume	1,366	9,439	447	0	0	683	11,936
Bone Density Multiplier	0.0%	3.5%	0.0%	4.0%	1.0%	0.0%	--
Bone Density Volume	0	2,753	0	530	62	0	3,345

On page 46, and in supplemental information, the applicant provides the following assumptions:

- The Clinic FTE is how many physicians are available to see patients daily; the patients per half day is how many patients each physician can see in a half-day period; the clinic will be open nine half-days per week and 46 weeks per year; and the applicant calculated the annual number of patients each specialty will see based on those assumptions.
 - The Digital Radiography multipliers and the Bone Density multipliers are calculations to determine how many patients need either digital radiography or bone density scanning, and they are based on the physicians’ historical experience.
 - The applicant does not project any growth in the utilization during the first three operating years.
- Nuclear Medicine
 - The applicant projects there will be two cardiologists available on a daily basis to see patients; the cardiologists will see patients for nine half-days per week; and each cardiologist can see 11 patients per half-day period. The applicant states the clinic will be open 46 weeks per year.
 - The applicant states, based on the historical experience of the cardiologists, that approximately 8.5 percent of patients require a nuclear test after being seen.

- The applicant does not project any growth in the utilization during the first three operating years.
- Endo Ultrasound
 - The applicant projects there will be four endocrinologists available on a daily basis to see patients; the endocrinologists will see patients for nine half-days per week; and each endocrinologist can see eight patients per half-day period. The applicant states the clinic will be open 46 weeks per year.
 - The applicant states, based on the historical experience of the endocrinologists, that approximately 12 percent of patients require an endo ultrasound imaging procedure after being seen.
 - The applicant does not project any growth in the utilization during the first three operating years.
- Echocardiography
 - The applicant states that the two cardiologists performed a total of 3,118 echocardiography procedures during FY 2017.
 - The applicant does not project any growth in the utilization during the first three operating years.
- Vascular Imaging
 - The applicant states the two cardiologists performed a total of 1,094 vascular imaging procedures during FY 2017.
 - The applicant does not project any growth in the utilization during the first three operating years.
- Pulmonary Function Testing
 - The applicant states that physicians performed a total of 1,284 breathing capacity tests during FY 2017.
 - The applicant projects no growth in the historical volume during the first three operating years.

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

- Projected utilization is based on historical data.
- The applicant does not project increases in utilization during the first three operating years.

Access

In Section C, page 50, 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 a certified provider under Title XIX (Medicaid). TMP will serve the medically indigent through charity care.... The diagnostic center will be accessible by persons with disabilities and will meet applicable ADA standards.”

In Section L, page 90, 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.

TMP-S Payor Mix – OY 2 (CY 2020)	
Payor Source	Percent of Services
Self-Pay*	1.0%
Medicare**	41.6%
Medicaid**	4.0%
Commercial Insurance**	53.4%
Total	100.0%

*The applicant states that charity care is included in this category.

**Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested 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 (payer 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 a service, eliminate a service, or relocate a facility or service. 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

Tryon proposes to develop a new diagnostic center, TMP-S, in Mecklenburg County as part of developing a medical and surgical specialty practice.

In Section E, pages 59-60, 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 not feasible because the physicians who will be using TMP-S need this equipment in order to provide care consistent with its community standards and to meet community needs. Therefore, this is not an effective alternative.
- **Build a Freestanding Diagnostic Center:** The applicant states that this option would be the most expensive but it would also result in the duplication of support and other services that the physician practice will already have. Therefore, this is not an effective alternative.

On page 60, the applicant states that its proposal is the most effective alternative because it results in lower costs to develop as well as lower patient charges, will result in fewer patient procedures and less wait time, and will result in better health outcomes for patients.

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 and any supplemental responses. In the event that representations conflict, Tryon Medical Partners, PLLC shall materially comply with the last made representation.**
 - 2. Tryon Medical Partners, PLLC shall develop a diagnostic imaging center as part of a physician and surgical specialty practice to be located in Charlotte.**
 - 3. Tryon Medical Partners, PLLC, as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section F of the application or that would otherwise require a certificate of need.**
 - 4. 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, Tryon Medical Partners, PLLC 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.**
 - 5. Tryon Medical Partners, PLLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance 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

Tryon proposes to develop a new diagnostic center, TMP-S, in Mecklenburg County as part of developing a medical and surgical specialty practice.

Capital and Working Capital Costs

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

Construction Costs	\$514,925
Medical Equipment Costs	\$955,859
Miscellaneous Costs/Contingency	\$325,003
Total	\$1,795,787

In Section F, page 64, the applicant projects that start-up costs will be \$52,118 and initial operating expenses will be \$40,000 for a total working capital of \$92,118. On page 64, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, page 62, the applicant states the capital costs of the project will be funded via a loan. In Section F, page 65, the applicant states the working capital costs of the project will be funded via a line of credit. Exhibits F.2 and F.3 contain identical versions a letter from a Vice President of SunTrust Bank, dated June 12, 2018, stating that SunTrust Bank will provide Tryon with funding up to \$1.8 million for its capital costs and up to \$100,000 for its working capital costs.

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.4, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

TMP-S Revenue and Expenses – OYs 1-3 (CYs 2019-2021)			
	OY 1 (CY 2019)	OY 2 (CY 2020)	OY 3 (CY 2021)
Total Imaging Procedures (IP)	23,141	23,141	23,141
Total Gross Revenues (Charges)	\$5,932,452	\$5,932,452	\$5,932,452
Total Net Revenue	\$3,207,953	\$3,207,953	\$3,207,953
Average Net Revenue per IP	\$139	\$139	\$139
Total Operating Expenses (Costs)	\$1,754,453	\$1,771,568	\$1,792,258
Average Operating Expense per IP	\$76	\$77	\$77
Net Income / (Loss)	\$1,453,499	\$1,436,385	\$1,415,694

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 and supplemental information 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
- Supplemental information requested 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 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

Tryon proposes to develop a new diagnostic center, TMP-S, in Mecklenburg County as part of developing a medical and surgical specialty practice.

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” The 2018 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant.

In Section G, page 70, the applicant defines Mecklenburg County as the service area. Facilities may also serve residents of counties not included in their service area.

In Section G, page 71, the applicant provides a list of outpatient diagnostic imaging service providers in Mecklenburg County and the number of imaging procedures those providers

performed, as shown in the table below. Utilization data is available only for hospital-owned imaging equipment.

Outpatient Diagnostic Imaging Centers/Utilization – Mecklenburg County – FY 2017*			
Facility	Ultrasound	Bone Density	Fixed X-Ray
CHS Pineville	9,014	0	31,100
CHS University	11,452	0	35,654
CMC	16,375	117	162,890
NHHMC	7,473	0	20,967
NHMMC	7,901	0	0
NHPMC	1,071	0	39,274

*Source: 2018 License Renewal Applications

In Section G, page 71, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic imaging center services in Mecklenburg County. The applicant states:

“The specialties that will be a part of the practice have medical diagnostic equipment that is required to aid the physician in diagnosing a patient’s illness or disease. These specialty patients will be referred by a primary care physician or self-referred for the expertise that the specialists possess; as a result, patients expect to receive appropriate care and diagnostic services so that after leaving the specialty practice (diagnostic center) they will have a diagnosis and a treatment plan.”

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 diagnostic imaging center is needed in addition to the existing or approved diagnostic imaging centers.

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.

- (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 for the proposed services as illustrated in the following table.

TMP-S Projected Staffing			
Position	OY 1 (CY 2019)	OY 2 (CY 2020)	OY 3 (CY 2021)
Digital X-Ray Technologists	2.00	2.00	2.00
Dexa Scan Technologists	0.75	0.75	0.75
Echocardiogram Technologists	4.00	4.00	4.00
Vascular Technologists	1.00	1.00	1.00
Nuclear Technologists	1.00	1.00	1.00
Respiratory Therapists	1.00	1.00	1.00
Practice Manager	0.50	0.50	0.50
Clerical Check-In	1.00	1.10	1.10
Clerical Scheduler	0.50	0.60	0.60
Total	11.80	12.00	12.00

Source: Form H in Section Q of the application.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q and in supplemental information. In Section H, pages 73-74, 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.3, the applicant provides supporting documentation. In Section H, page 75, the applicant identifies the proposed medical director. In Exhibit H.4, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section H, page 75, the applicant describes its physician recruitment plans.

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 77, the applicant states that the following ancillary and support services are necessary for the proposed diagnostic imaging center:

- Billing and Accounting

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

On page 77, the applicant adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I.1.

In Section I, page 78, the applicant describes its efforts to develop relationships with other local health care and social service providers. The applicant states:

“The physicians of TMP have been proving [sic] health care services to residents of Mecklenburg County for decades, as such these physicians as a part of the Mecklenburg Medical Group have existing relationships with local health care providers including hospitals and ambulatory surgical facilities. Additionally, the physicians as a part of the Mecklenburg Medical Group have relationships with social service providers in as much as they had contact with those providers in relation to low income and indigent residents.

These relationships will continue in the future as the physicians are a part of TMP.”

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 81, the applicant states that the project involves upfitting 3,152 square feet of leased space. Line drawings are provided in Exhibit K.3.

In Section E, pages 59-60, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

In supplemental information, 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 that the new diagnostic

imaging center will be developed in an existing office building, which will keep construction costs to a minimum.

On page 82, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.4.

On pages 83-84, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer, and waste disposal and power at the site.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

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 own, operate, or manage 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 own, operate, or manage 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 90, 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.

TMP-S Payor Mix – OY 2 (CY 2020)	
Payor Source	Percent of Services
Self-Pay*	1.0%
Medicare**	41.6%
Medicaid**	4.0%
Commercial Insurance**	53.4%
Total	100.0%

*The applicant states that charity care is included in this category.

**Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.0 percent of total services will be provided to self-pay and charity care patients, 41.6 percent to Medicare patients, and 4.0 percent to Medicaid patients.

In supplemental information, 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 for the following reasons:

- Projected payor mix is based on the historical experience of the physicians proposing to utilize TMP-S.
- Projected payor mix is adjusted, based on that historical experience, to account for the projected utilization.

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.

C

In Section L, page 92, 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.

C

In Section M, page 94, 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.

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.

C

Tryon proposes to develop a new diagnostic center, TMP-S, in Mecklenburg County as part of developing a medical and surgical specialty practice.

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” The 2018 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant.

In Section G, page 70, the applicant defines Mecklenburg County as the service area. Facilities may also serve residents of counties not included in their service area.

In Section G, page 71, the applicant provides a list of outpatient diagnostic imaging service providers in Mecklenburg County and the number of imaging procedures those providers performed, as shown in the table below. Utilization data is available only for hospital-owned imaging equipment.

Outpatient Diagnostic Imaging Centers/Utilization – Mecklenburg County – FY 2017*			
Facility	Ultrasound	Bone Density	Fixed X-Ray
CHS Pineville	9,014	0	31,100
CHS University	11,452	0	35,654
CMC	16,375	117	162,890
NHHMC	7,473	0	20,967
NHMMC	7,901	0	0
NHPMC	1,071	0	39,274

*Source: 2018 License Renewal Applications

In Section N, pages 95-96, 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 95, the applicant states:

“TMP expects the diagnostic center project to have a positive impact on competition in the service area.

TMP will be competing not only with other providers of imaging 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

Neither the applicant nor any related entities own, operate, or manage an existing health service facility located 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.

NA

The applicant proposes to develop a new diagnostic center. There are no administrative rules that are applicable to proposals to develop a new diagnostic center.