ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

Decision Date: September 18, 2020 Findings Date: September 18, 2020

Project Analyst: Misty L. Piekaar-McWilliams

Team Leader: Fatimah Wilson

Project ID #: F-11903-20

Facility: Atrium Health Union West Medical Office Building (MOB) Diagnostic Center

FID #: 200460 County: Union

Applicant(s): Carolinas Physicians Network, Inc.

Project: Develop a new diagnostic center in a MOB to include cardiac ECHO

ultrasound, vascular ultrasound, Parks Flo Lab, Ob/Gyn ultrasound, colposcope, endocrinology ultrasound, pulmonary function test, and capsule

endoscopy system

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

Carolinas Physicians Network, Inc. (hereinafter referred to as CPN or "the applicant") proposes to develop a new diagnostic center, Atrium Health Union West MOB Diagnostic Center (AHU West MOB), in a new medical office building currently under development on the campus of Atrium Health Union West (AHU West) in Union County. The applicant proposes to acquire two (2) new cardiac echocardiography (Echo) ultrasound units, one (1) vascular ultrasound, one (1) Parks Flo Lab, one (1) Ob/Gyn ultrasound, one (1) colposcope, one (1) endocrinology ultrasound and one (1) capsule endoscopy system in addition to an existing pulmonary function test (PFT). The combined value of the medical diagnostic equipment costing \$10,000 or more exceeds the statutory threshold of \$500,000 and therefore

qualifies as a diagnostic center, which is a new institutional heath service, and which requires a certificate of need.

Need Determination

The applicant does not propose to acquire any medical equipment or offer any new institutional health services for which there is a need determination in the 2020 State Medical Facilities Plan (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.

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The applicant proposes to develop a new diagnostic center by acquiring two (2) new cardiac echocardiography (Echo) ultrasound units, one (1) vascular ultrasound, one (1) Parks Flo Lab, one (1) Ob/Gyn ultrasound, one (1) colposcope, one (1) endocrinology ultrasound and one (1) capsule endoscopy system in addition to an existing PFT located in a medical office building under development on the campus of AHU West in Union County.

In Section C, page 24, the applicant states it plans to develop the diagnostic center in a MOB currently under development on the AHU West campus. Several CPN physician clinics are, or will soon be, housed in the MOB. The medical diagnostic equipment that will comprise the proposed diagnostic clinic will encompass these physician clinics that are spread across multiple floors of the MOB. The Agency, in a letter dated March 7, 2019, determined that renovation of space in this medical office building, to the extent the renovation was not part of a project requiring a certificate of need, was not reviewable under the certificate of need statutes.

In Section A, page 6, 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 (Atrium). 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. Designation as a Diagnostic Center

In Section C, pages 24-27, the applicant states the proposed diagnostic center will feature physician offices and related medical diagnostic equipment on multiple floors of the medical office building. The applicant states the proposed diagnostic center will include the following

pieces of new and existing medical diagnostic equipment, each of which is worth \$10,000 or more:

Equipment	Number of Units	New or Existing	
MOB Level	1 - Cardiovascular	Clinic	
Cardiac Echo Ultrasound^	2	New	
Vascular Ultrasound	1	New	
Parks Flo Lab	1	New	
MOB Level 2 – Ob/Gyn Clinic			
Ob/Gyn Ultrasound	1	New	
Colposcope	1	New	
MOB Level	2 - Endocrinology	Clinic	
Endocrinology Ultrasound	1	New	
MOB Lev	el 2 – Pulmonary Cl	inic	
PFT	1	Existing/Relocated	
MOB Level 2 – Gas	troenterology/Hep	atology Clinic	
Capsule Endoscopy System	1	New	

Source: Section C, page 26

On page 24, the applicant states that the equipment identified as "existing" in the table above will be relocated from a nearby Union West Multi-Specialty Suite, an existing MOB, prior to the development of the proposed diagnostic center. The applicant states that the combined cost and/or value of the pieces of equipment listed above is more than \$500,000; therefore, a certificate of need is required to develop a diagnostic center. On Form F.1a, the applicant lists the cost of medical equipment as \$932,561.

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 2020 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 C, pages 28-33, and Section G, page 71, the applicant defines the service area as four (4) specific ZIP codes located within western Union County, as well as the remaining Union County ZIP codes, in addition to Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

AHU West MOB is not an existing facility; however, in Section C, pages 29-32, the applicant provides historical patient origin for PFT services only. The following table illustrates projected patient origin during the first three full fiscal years following project completion.

[^]One of the proposed new cardiac echo ultrasound units will include a treadmill.

County	FY 1 – C'	FY 1 – CY 2022		FY 2 – CY 2023		FY 3 – CY 2024	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	
ZIP Code 28079	713	16.9%	856	17.1%	1,371	16.9%	
ZIP Code 28110	793	18.8%	935	18.7%	1,528	18.8%	
ZIP Code 28104	661	15.7%	776	15.5%	1,283	15.8%	
ZIP Code 28173	895	21.2%	1,026	20.5%	1,734	21.3%	
Mecklenburg	594	14.1%	729	14.6%	1,143	14.0%	
Other Union	71	1.7%	106	2.1%	129	1.6%	
Other*	494	11.7%	583	11.6%	949	11.7%	
Total	4,220	100.0%	5,011	100.0%	8,137	100.0%	

Source: Section C, page 33

In Section C, page 34, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 35-42, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- With the new acute care hospital expected to be completed in 2022 (Project ID# F-11618-18), expected growth on the Atrium Health Union West Campus will result in demand. Concurrently, Atrium Health has filed a certificate of need application to develop a new outpatient infusion therapy clinic which is expected to lead to an increase demand for medical services in the health service area. Specifically, the applicant states on page 36, "Development of the Atrium Health Union West MOB, including the proposed diagnostic center and the concurrently proposed outpatient infusion therapy clinic, represents the next step in the development of comprehensive and convenient healthcare services to serve the residents of western Union County."
- By ensuring physician offices have the medical diagnostic equipment needed to diagnose
 patients, AHU West MOB allows patients to receive medical diagnostic services at the
 same location they see their providers much more quickly than if they had to be referred to
 an outside clinic with different scheduling.
- Providing the medical diagnostic equipment necessary for physicians at the physician
 offices avoids having to refer patients needing medical diagnostic services to a different
 location with potentially higher charges. Additionally, as a physician-based practice, AHU
 West MOB will provide patients with an opportunity to lower their out-of-pocket medical
 costs.

^{*}Other: On page 33 the applicant provides an extensive list of the other NC counties. This category also includes some other states.

• According to the North Carolina Office of State Budget and Management (NC OSBM), the Union County population is projected to grow at a Compound Annual Growth Rate (CAGR) of 2.4 percent between 2019 and 2024, and the percent of the population of Union County residents age 65 and older will increase from 13.0 percent in 2019 to 14.8 percent in 2024. 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 acquisition of additional medical diagnostic equipment for physicians utilizing AHU West MOB 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, as illustrated in the following table.

AHU West MOB Projected Utiliza	ation – FYs 1-3	(CYs 2022-2024	1)
Component	FY 1 (CY 2022)	FY 2 (CY 2023)	FY 3 (CY 2024)
Cardiac Echo Ultrasound – Units	2	2	2
Cardiac Echo Ultrasound – Procedures	1,096	1,233	2,191
Vascular Ultrasound – Units	1	1	1
Vascular Ultrasound – Procedures	609	711	1,299
Vascular Parks Flo Lab – Units	1	1	1
Vascular Parks Flo Lab – Procedures	174	204	372
Ob/Gyn Ultrasound – Units	1	1	1
Ob/Gyn Ultrasound – Procedures	1,620	1,823	3,038
Ob/Gyn Colposcope – Units	1	1	1
Ob/Gyn Colposcope – Procedures	108	122	203
Endocrinology Ultrasound – Units	1	1	1
Endocrinology Ultrasound – Procedures	108	122	135
Pulmonary PFT – Units	1	1	1
Pulmonary PFT – Procedures	486	778	875
Gastro./Hep. Capsule Endoscopy System – Units	1	1	1
Gastro./Hep. Capsule Endoscopy System – Procedures	19	22	24
Total Procedures	4,220	5,015	8,137

In Section C, pages 43-48, and in the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the annual maximum capacity per unit for each type of medical diagnostic equipment proposed in this application, as well as the assumptions and methodology used to project the annual maximum capacities. The annual maximum capacity for each type of medical diagnostic equipment proposed in this application is shown in the table below.

Annual Maximum C	Annual Maximum Capacity for Each Type of Medical Diagnostic Equipment Proposed							
Equipment Type	# Units	Patients/Hour	Hours/Day	Days/Year	Maximum Annual Capacity*			
Cardiac Echo Ultrasound^	2	1.00	7	250	3,500			
Vascular Ultrasound	1	1.00	7	250	1,750			
Parks Flo Lab	1	1.00	N/A^^	250	N/A^^			
Ob/Gyn Ultrasound	1	2.00	7	250	3,500			
Colposcope	1	2.00	N/A^^	250	N/A^^			
Endocrinology Ultrasound	1	2.00	N/A^^	250	N/A^^			
PFT	1	1.50	7	250	2,625			
Capsule Endoscopy System**	1	0.14	N/A^^	200	N/A^^			

Source: Section C, page 43; Form C Utilization – Assumptions and Methodology subsection of Section Q

In Section Q and clarifying information, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

The applicant further states that historical utilization is not provided specifically for AHU West MOB because the proposed facility is not an existing facility.

The applicant states the equipment proposed is intended to maximize the efficiency of the physicians using the equipment and efficiency of care to patients rather than to maximize utilization of the equipment.

New Equipment

Cardio Echo Ultrasound Utilization

The applicant assumes utilization per FTE (full-time equivalent) will increase in the future based on:

- increase in the number of providers that will practice in the clinic and be trained on this equipment.
- the applicant's historical experience in other comparable CPN clinics in which the applicant projects that the provider FTE can perform approximately 1,370 cardiac echo ultrasounds per year and utilization per provider FTE will ramp-up from 80% in operating year (OY) 1, to 90% in OY2 and 100% in OY3.

^{*}Maximum Annual Capacity = (# of Units X Procedures per Hour X Hours per Day X Days per Year)

^{**}The applicant states procedures are not performed on Fridays due to associated risk factors.

[^]The applicant states one of the proposed new cardiac echo ultrasound units will include a treadmill.

^{^^} The applicant states there is no dedicated staff for the Parks Flo Lab, colposcope, endocrinology ultrasound, and capsule endoscopy system equipment and no assumed hours of availability – thus, the applicant does not project maximum annual capacity.

		OY1	OY2	OY3
		(CY2022)	(CY2023)	(CY2024)
Α	# of provider FTEs	1.0	1.0	1.6
В	# of Cardiac Echo Ultrasounds per FTE	1,369.6	1,369.6	1,369.6
С	Ramp-up Percentage (%)	80%	90%	100%
D	# of Cardiac Echo Ultrasound*	1,096	1,233	2,191

Source: Section Q, Form C, page 4. *Row A x Row B x Row C = Row D.

By OY3 (CY2024), the applicant projects the two (2) Cardiac Echo ultrasound units will be operating at 62.6% of capacity as shown in the table below.

Equipment Type	Number of Units	Maximum	2024 Projected	2024 Percent
		Capacity	Utilization	of Capacity
Cardiac Echo Ultrasound	2	3,500	2,191	62.6%

Source: Section Q, Form C, page 4.

Vascular Ultrasound Utilization

The applicant assumes utilization per FTE will increase in the future based on:

- increase in the number of providers that will practice in the clinic and be trained on this equipment.
- the applicant's historical experience in other comparable CPN clinics in which the applicant projects that the provider FTE can perform approximately 1,015 vascular ultrasounds per year and utilization per provider FTE will ramp-up from 60% in OY1, to 70% in OY2 and 80% in OY3.

		OY1 (CY2022)	OY2 (CY2023)	OY3 (CY2024)
Α	# of provider FTEs	1.0	1.0	1.6
В	# of Vascular Ultrasounds per FTE	1,015	1,015	1,015
С	Ramp-up Percentage (%)	60%	70%	80%
D	# of Vascular Ultrasound*	609	711	1,299

Source: Section Q, Form C, page 5. *Row A x Row B x Row C = Row D.

By OY3 (CY2024), the applicant projects the vascular ultrasound will be operating at 74.2% of capacity as shown in the table below.

Equipment Type	Number of Units	Maximum Capacity	2024 Projected Utilization	2024 Percent of Capacity
Vascular Ultrasound	1	1,750	1,299	74.2%

Source: Section Q, Form C, page 5.

Vascular Parks Flo Lab Utilization

The applicant assumes utilization per FTE will increase in the future based on:

- increase in the number of providers that will practice in the clinic and be trained on this equipment.
- the applicant's historical experience in other comparable CPN clinics in which the applicant projects that approximately 29 out of every 100 vascular ultrasounds require a Parks Flo Lab procedure or a ratio of .29.

			OY2	OY3
		(CY2022)	(CY2023)	(CY2024)
Α	Projected # of Vascular Ultrasounds**	609	711	1,299
В	Ratio of Parks Flo Procedures to Vascular Ultrasounds	.29	.29	.29
С	# of Vascular Parks Flo Lab Procedures	174	204	372

NOTE: Sums may be rounded up or down in table

Source: Section Q, Form C, page 6.
**Source: Section Q, Form C, page 5.

By OY3 (CY2024), the applicant projects the vascular Parks Flo Lab will be performing 372 procedures as shown in the table below.

Equipment Type	Number of	Maximum	2024 Projected	2024 Percent of
	Units	Capacity	Utilization	Capacity
Vascular Parks Flo Lab	1	N/A*	372	N/A

Source: Section Q, Form C, page 7.

Ob/Gyn Utilization

The applicant assumes utilization per FTE will increase in the future based on:

- increase in the number of providers that will practice in the clinic and be trained on this equipment.
- the applicant's historical experience in other comparable CPN clinics (Piedmont Ob/Gyn Ballantyne) in which the applicant projects that the provider FTE can perform approximately 1,012.5 Ob/Gyn ultrasounds per year and utilization per provider FTE will ramp-up from 80% in OY1, to 90% in OY2 and 100% in OY3.

		OY1 (CY2022)	OY2 (CY2023)	OY3 (CY2024)
Α	# of provider FTEs	2.0	2.0	3.0
В	# of Ob/Gyn Ultrasounds per FTE	1,012.5	1,012.5	1,012.5
С	Ramp-up Percentage (%)	80%	90%	100%
D	# of Ob/Gyn Ultrasounds*	1,620	1,823	3,038

Source: Section Q, Form C, page 7. *Row A x Row B x Row C = Row D.

^{*}Row A x Row B = Row C.

^{*}If the one (1) Parks Flo lab unit were staffed seven hours per day, maximum annual capacity would be 1,750 procedures.

By OY3 (CY2024), the applicant projects the Ob/Gyn ultrasound will be operating at 86.8% of capacity and performing 3,038 Ob/Gyn ultrasound procedures as shown in the table below.

Equipment Type	Number of Units	Maximum Capacity	2024 Projected Utilization	2024 Percent of Capacity
Ob/Gyn Ultrasound	1	3,500	3,038	86.8%

Source: Section Q, Form C, page 8.

Ob/Gyn Colposcope Utilization

The applicant assumes utilization per FTE will increase in the future based on:

- increase in the number of providers that will practice in the clinic and be trained on this equipment.
- the applicant's historical experience in other comparable CPN clinics (Piedmont Ob/Gyn Ballantyne) in which the applicant projects that the provider FTE will perform approximately 67.5 Ob/Gyn colposcopies per year and utilization per provider FTE will ramp-up from 80% in OY1, to 90% in OY2 and 100% in OY3.

		OY1 (CY2022)	OY2 (CY2023)	OY3 (CY2024)
Α	# of provider FTEs	2.0	2.0	3.0
В	# of Ob/Gyn Colposcopies per FTE	67.5	67.5	67.5
С	Ramp-up Percentage (%)	80%	90%	100%
D	# of Colposcopies*	108	122	203

Source: Section Q, Form C, page 9. *Row A x Row B x Row C = Row D.

By OY3 (CY2024), the applicant projects to perform 203 Ob/Gyn colposcopies as shown in the table below.

Equipment Type	Number of Units	Maximum Capacity	2024 Projected Utilization	2024 Percent of Capacity
Ob/Gyn Colposcopies	1	N/A*	203	N/A

Source: Section Q, Form C, page 9.

Endocrinology Ultrasound Utilization

The applicant assumes utilization per FTE will increase in the future based on:

- increase in the number of providers that will practice in the clinic and be trained on this equipment.
- the applicant's historical experience in other comparable CPN clinics in which the applicant projects that the provider FTE can perform approximately 135 endocrinology

^{*}Applicant states physicians perform colposcopies as needed and if the Ob/Gyn colposcope was fully staffed by dedicated physicians each day, maximum annual capacity would be 3,500 colposcopies.

		OY1 (CY2022)	OY2 (CY2023)	OY3 (CY2024)
Α	# of provider FTEs	1.0	1.0	1.0
В	# of Endocrinology Ultrasounds per FTE	135	135	135
С	Ramp-up Percentage (%)	80%	90%	100%
D	# of Endocrinology Ultrasounds*	108	122	135

ultrasounds per year and utilization per provider FTE will ramp-up from 80% in OY1, to 90% in OY2 and 100% in OY3.

Source: Section Q, Form C, page 10. *Row A x Row B x Row C = Row D.

By OY3 (CY2024), the applicant projects the endocrinology ultrasound will be performing 135 Endocrinology ultrasound procedures as shown in the table below.

Equipment Type	Number of Units	Maximum Capacity	2024 Projected Utilization	2024 Percent of Capacity
Endocrinology Ultrasound	1	N/A*	135	N/A

Source: Section Q, Form C, page 10.

Capsule Endoscopy Utilization

The applicant assumes utilization per FTE will increase in the future based on:

- increase in the number of providers that will practice in the clinic and be trained on this equipment.
- the applicant's historical experience in other comparable CPN clinics in which the applicant projects that the provider FTE can perform approximately 12 capsule endoscopies per year and utilization per provider FTE will ramp-up from 80% in OY1, to 90% in OY2 and 100% in OY3.

		OY1 (CY2022)	OY2 (CY2023)	OY3 (CY2024)
Α	# of provider FTEs	2.0	2.0	2.0
В	# of Capsule Endoscopies per FTE	12	12	12
С	Ramp-up Percentage (%)	80%	90%	100%
D	# of Capsule Endoscopies*	19	22	24

Source: Section Q, Form C, page 12.

By OY3 (CY2024), the applicant projects to perform 24 capsule endoscopy procedures as shown in the table below.

Equipment Type	Number of Units	Maximum Capacity	2024 Projected Utilization	2024 Percent of Capacity	
Capsule Endoscopies	1	N/A*	24	N/A	

Source: Section Q, Form C, page 13.

^{*}Applicant states physicians perform endocrinology ultrasounds as needed and if the endocrinology ultrasound unit was fully staffed by dedicated physicians each day, maximum annual capacity would be 3,500 procedures.

^{*}Row A x Row B x Row C = Row D.

Note: Capsule endoscopies are not performed on Fridays due to potential complications associated with the procedure that could not be addressed the following day in the physician's office during working hours. This policy prevents a patient from having to visit the emergency room over the weekend.

*Applicant states physicians perform capsule endoscopies as needed and if the capsule endoscopy unit was fully staffed by dedicated physicians each day, maximum annual capacity would be 200 procedures.

Existing Equipment

Pulmonary Function Test (PFT)

The applicant assumes utilization per FTE will increase in the future based on:

- increase in the number of providers that will practice in the clinic and be trained on this equipment.
- the applicant's historical experience of the CPN pulmonary clinic that is proposed to relocate to AHU West MOB in which the applicant projects that the provider FTE can perform approximately 486 pulmonary PFTs per year and utilization per provider FTE will ramp-up from 80% in OY2, to 90% in OY3.
- Applicant states it will recruit an additional 1.0 provider FTE for the pulmonary clinic in OY2 (2023) as show in the table below.

		OY1	OY2	OY3
		(CY2022)	(CY2023)	(CY2024)
Α	# of provider FTEs	1.0	2.0	2.0
В	# of Pulmonary PFTs per FTE	486	486	486
С	Ramp-up Percentage (%)	N/A	80%	90%
D	# of Pulmonary PFTs*	486	778	875

Source: Section Q, Form C, page 11.
*Row A x Row B x Row C = Row D.

By OY3 (CY2024), the applicant projects the pulmonary PFT unit will be operating at 33.3% of capacity and performing 875 pulmonary PFT procedures as shown in the table below.

Equipment Type	Number of Units	Maximum Capacity	2024 Projected Utilization	2024 Percent of Capacity	
PFT	1	2,625	875	33.3%	

Source: Section Q, Form C, page 11.

All Equipment

Equipment Type	OY3 (CY2024) Projected Utilization	Maximum Annual Capacity*	OY3 (CY2024) Percent of Capacity
Cardiac Echo Ultrasound	2,191	3,500	62.6%
Vascular Ultrasound	1,299	1,750	74.2%
Parks Flo Lab	372	N/A	N/A
Ob/Gyn Ultrasound	3,038	3,500	86.8%
Colposcope	203	N/A	N/A
Endocrinology Ultrasound	135	N/A	N/A
PFT	875	2,625	33.3%
Capsule Endoscopy System	24	N/A	N/A

Projected utilization is reasonable and adequately supported based on the following reasons:

- Projected utilization is based in part on historical data and falls within the capacity limits established by the applicant.
- Projected utilization is based on the applicant's historical experience at comparable clinics.
- The applicant provides reasonable and adequately supported information to justify the need for equipment which is projected to be utilized at lower rates.

Access

In Section C, page 52, the applicant states:

"As previously noted, CMHA is the parent entity and sole member of CHN, which in turn is the sole member of CPN. Consistent with all CMHA facilities, CPN provides services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment. As such, CMHA d/b/a Atrium Health's system-wide policies and procedures with regard to access to care will apply to the proposed diagnostic center."

The applicant provides the estimated percentage during the third fiscal year of operation based on CY 2019 percentages, for each medically underserved group, as shown in the following table.

Medically		Percentage of Total Patients							
Underserved Groups	Cardiac Echo Ultrasound	Vascular Ultrasound	Parks Flo Lab	Ob/Gyn Ultrasound	Colposcope	Endocrinology Ultrasound	PFT	Capsule Endoscopy System	
Low income persons	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
Racial & ethnic minorities	16.3%	14.0%	14.0%	32.3%	25.4%	21.7%	16.5%	25.0%	
Women	52.2%	60.9%	60.9%	100.0%	100.0%	79.8%	59.9%	45.8%	
Persons with Disabilities	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
The elderly	46.8%	41.3%	41.3%	2.1%	5.0%	47.1%	48.8%	51.4%	
Medicare beneficiaries	45.2%	44.4%	44.4%	2.3%	6.2%	46.7%	51.0%	52.8%	
Medicaid recipients	1.7%	3.5%	3.5%	10.7%	5.3%	1.1%	3.9%	4.2%	

Note: The applicant states CPN does not maintain data that includes the number of low income persons or handicapped (disabled) persons it serves.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Clarifying information requested by the Agency
- 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 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.

C

The applicant proposes to develop a new diagnostic center. While the applicant states in Section C.1, page 24, that the pulmonary function test and corresponding pulmonary clinic are being relocated to AHU West MOB in order to provide convenient proximity to Atrium Health Union West, the applicant also states in Section D.1, page 57, of the application that neither the pulmonary clinic nor the pulmonary function test are being relocated to another campus or facility. In response to a request for clarifying information from the Agency, the applicant states that their response in Section D.1 of the application is because the existing pulmonary clinic – which is a freestanding CPN physician practice - does not meet the definition of a 'Health Service Facility' as provided in N.C.G.S. 131E-176(9b) or the definition of a 'Campus' as provided in N.C.G.S. 131E-176(2c).

The applicant further clarified in their response to the agency that the location of the existing pulmonology clinic and pulmonary function test is located at 6050 West Highway 74 in Indian Trail, North Carolina and the proposed relocation of the existing pulmonary clinic and pulmonary function test to AHU West MOB would be approximately three (3) miles from its current location. Thus, the same patients who received services from the pulmonary clinic and pulmonary function test would still be able to receive those same services after the relocation.

Conclusion

The Agency reviewed 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 for the reasons stated above.

(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 develop a new diagnostic center by acquiring two (2) new cardiac echocardiography ultrasound units, one (1) vascular ultrasound, one (1) Parks Flo Lab, one (1) OB/Gyn ultrasound, one (1) colposcope, one (1) endocrinology ultrasound and one (1) capsule endoscopy system in addition to an existing PFT located in a medical office building under development on the campus of AHU West in Union County.

In Section E, pages 62-63, 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 this option would not allow enhanced and more convenient access to care by patients and would force patients to receive diagnostic services elsewhere; therefore, this is not an effective alternative.

<u>Develop the Diagnostic Center with a Different Number of Units of Equipment</u>: The applicant states developing the diagnostic center with fewer pieces of diagnostic imaging equipment would not meet the needs of physicians and patients, and states that developing the diagnostic center with more pieces of diagnostic imaging equipment is not warranted by patient demand at this time; therefore, this is not an effective alternative.

On page 62, the applicant states its proposal is the most effective alternative because it provides enhanced and more convenient access to patients, provides the necessary diagnostic imaging equipment for providers and patients, and does not add more diagnostic imaging equipment than patient demand requires.

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
- 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 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 and any clarifying responses. If representations conflict, Carolinas Physicians Network, Inc. shall materially comply with the last made representation.
- 2. Carolinas Physicians Network, Inc. shall develop a new diagnostic center by acquiring two (2) new cardiac echocardiography ultrasound units, one (1) new vascular ultrasound unit, one (1) new Parks Flo Lab, one (1) new Ob/Gyn ultrasound unit, one (1) new colposcope, one (1) new endocrinology ultrasound unit, and one (1) new capsule endoscopy system in addition to an existing Pulmonary Function Test.

- 3. AHU West MOB shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Sections F and Q 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, 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.
- 5. Carolinas Physicians Network, Inc. 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.

 \mathbf{C}

The applicant proposes to develop a new diagnostic center by acquiring two (2) new cardiac echocardiography ultrasound units, one (1) vascular ultrasound, one (1) Parks Flo Lab, one (1) OB/Gyn ultrasound, one (1) colposcope, one (1) endocrinology ultrasound and one (1) capsule endoscopy system in addition to an existing PFT located in a medical office building under development on the campus of AHU West in Union County

Capital and Working Capital Costs

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

Total	\$1,737,571
Miscellaneous Costs/Contingency	\$227,366
Consultant/A&E Fees	\$65,000
Non-Medical Equipment/Furniture	\$61,145
Medical Equipment Costs	\$932, 561
Construction Costs	\$451,499

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

In Section F, page 64, the applicant states the project does not involve any working capital costs.

Availability of Funds

In Section F, pages 64-65, 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, 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, 2019 and 2018. As of December 31, 2019, 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.2, the applicant projects that operating expenses will exceed revenues in the third fiscal year of the project, as shown in the table below.

	FY 1 (CY 2022)	FY 2 (CY 2023)	FY 3 (CY 2024)
Total Number of Procedures	4,220	5,015	8,137
Total Gross Revenues (Charges)	\$1,782,736	\$2,092,496	\$3,686,059
Total Net Revenue	\$714,679	\$840,169	\$1,462,914
Total Operating Expenses (Costs)	\$634,220	\$891,836	\$1,060,658
Average Operating Expense per Procedure	\$54	\$47	\$46
Net Income / (Loss)	\$80,460	(\$51,667)	\$402,256

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.

 \mathbf{C}

The applicant proposes to develop a new diagnostic center by acquiring two (2) new cardiac echocardiography ultrasound units, one (1) vascular ultrasound, one (1) Parks Flo Lab, one (1) OB/Gyn ultrasound, one (1) colposcope, one (1) endocrinology ultrasound and one (1) capsule endoscopy system in addition to an existing PFT located in a medical office building under development on the campus of AHU West in Union County.

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 2020 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 C, pages 28-33, and Section G, page 71, the applicant defines the service area as four (4) specific ZIP codes located within western Union County, as well as the remaining Union County ZIP codes, in addition to Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 71, the applicant lists all hospital facilities offering diagnostic imaging services in its defined service area, and states it is unaware of any publicly available data to show inventory and utilization of existing and approved non-hospital-based facilities and equipment providing services like those proposed in this application. In Exhibit G.2, the applicant provides copies of pages from 2020 Hospital License Renewal Applications (LRAs) for facilities in Mecklenburg and Union counties with equipment and services like those proposed in this application. On page 72, the applicant lists all the existing and approved diagnostic centers owned or operated by CPN or an affiliated entity.

In Section G, page 72, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic center services in Mecklenburg, and Union counties in North Carolina. The applicant states:

"The need for the proposed project is based on the need for CPN to provide convenient access to diagnostic services to support the physician clinics in the existing MOB. The proposed diagnostic center will serve to optimize CPN's and Atrium Health's ability to provide patient-centered care in a cost-effective manner. As such, no other provider can meet the identified need. Further, though other imaging and diagnostics services may be available in the service area, they are not reasonably available to the patients of the CPN physicians who will practice at Atrium Heath Union West MOB. Specifically, use of such equipment would require leaving the physician office building, registering as a patient at another facility, waiting hours, days, or weeks for an available appointment, then having to return to the CPN practice. Compared to the availability of the service within the same building, typically during the same visit, the use of other capacity in the service area is ineffective at providing sufficient access to patients."

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

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 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 current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Cardiovascular Clinic

Position	Projected FTE Staff		
	1 st Full Fiscal Year (CY2022)	2nd Full Fiscal Year (CY2023)	3rd Full Fiscal Year CY2024
Respiratory Therapists	.40	.80	1.00
Echocardiography Techs	1.00	1.50	2.00
Vascular Ultrasound Techs	.60	.80	1.00
TOTAL	2.00	3.10	4.00

Ob/Gyn Clinic

Position	Projected FTE Staff		
	1 st Full Fiscal Year (CY2022)	2nd Full Fiscal Year (CY2023)	3rd Full Fiscal Year CY2024
Radiology Technologists	1.00	1.00	1.00
TOTAL	1.00	1.00	1.00

Pulmonary Clinic

Position	Projected FTE Staff		
	1 st Full Fiscal Year (CY2022)	2nd Full Fiscal Year (CY2023)	3rd Full Fiscal Year CY2024
Respiratory Therapists	1.00	1.00	1.00
TOTAL	1.00	1.00	1.00

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.3, which is found in Section Q. In Section H.2 and H.3, pages 74-75, the applicant describes the methods used to recruit or fill new positions and its proposed training and continuing education programs and provides supporting documentation in Exhibit H.3. In Exhibit I.2, the applicant provides letters of support from local physicians.

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.

 \mathbf{C}

In Section I, page 76, the applicant states the following ancillary and support services are necessary for the proposed diagnostic center:

- Housekeeping
- Security
- Maintenance
- Registration
- Administration
- Other Ancillary and Support Services

On page 76, the applicant adequately explains how each ancillary and support service will be made available.

In Section I, pages 76-77, the applicant describes its existing 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.

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 renovating 1,197 square feet of space in an existing office building on the campus of AHU West. Line drawings are provided in Exhibit C.1.

In Section K, page 82, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

In Section K, page 82, 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 physician-based services have

lower out-of-pocket insurance costs, and consolidation of services allows for economies of scale.

In Section K, pages 82-83, 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 health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 89, the applicant provides the historical payor mix for CY 2019 for the existing PFT services that will be relocated to AHU West MOB, as shown in the table below.

Historical Payor Mix for Existing PFT Services – CY 2019		
Payor Source	Percentage	
Self-Pay	3.3%	
Medicare*	51.0%	
Medicaid*	3.9%	
Insurance*	40.7%	
Other**	1.0%	
Total	100.0%	

Source: CPN internal data

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.

Note: Totals may not sum due to rounding.

Note: Section L, page 89, says last fiscal year before submission of application is January 1, 2024, to December 31, 2024, which is a typographical error. The correct dates are January 1, 2019, to December 31, 2019.

In Section L, page 88, the applicant provides the following comparison.

AHU WEST MOB	% of Patients Served	Percent of Population by County	
AND WEST WICE	during CY 2019	Union	Mecklenburg
Female	N/A	50.8%	51.9%
Male	N/A	49.2%	48.1%
Unknown	N/A	N/A	N/A
64 and Younger	N/A	87.3%	88.8%
65 and Older	N/A	12.7%	11.2%
American Indian	N/A	0.6%	0.8%
Asian	N/A	3.4%	6.4%
Black or African-American	N/A	12.3%	32.9%
Native Hawaiian or Pacific	N/A	0.1%	0.1%
Islander		0.1%	0.1%
White or Caucasian	N/A	81.6%	57.5%
Other Race	N/A	2.0%	2.4%
Declined / Unavailable	N/A	N/A	N/A

Sources: US Census Bureau QuickFacts

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;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 89, the applicant states that it has no such obligations.

^{*}Including any managed care plans

^{**&}quot;Other" includes Worker's Compensation and TRICARE

In Section L, page 89, 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

 \mathbf{C}

In Section L, page 90, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

AHU West MOB Payor Mix – FY 3 (CY 2024)	
Payor Source	Percent of Services
Self-Pay	2.7%
Medicare*	29.6%
Medicaid*	5.4%
Insurance*	61.7%
Other**	.7%
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.

Note: Totals may not sum due to rounding.

*Including any managed care plans

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

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.7 percent of total services will be provided to self-pay patients, 29.6 percent to Medicare patients, and 5.4 percent to Medicaid patients.

In Section L, pages 90-91, the applicant provides the assumptions and methodology used to project payor mix during the third 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 CPN's historical experience in providing the proposed services.
- The applicant provides reasonable and adequately supported information to explain why there are no changes to the projected payor mix in future years.

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.

 \mathbf{C}

In Section L.5, 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 93, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes.

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.

 \mathbf{C}

The applicant proposes to develop a new diagnostic center by acquiring two (2) new cardiac echocardiography ultrasound units, one (1) vascular ultrasound, one (1) Parks Flo Lab, one (1) OB/Gyn ultrasound, one (1) colposcope, one (1) endocrinology ultrasound and one (1) capsule endoscopy system in addition to an existing PFT located in a medical office building under development on the campus of AHU West in Union County.

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 2020 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 C, pages 28-33, and Section G, page 71, the applicant defines the service area as four (4) specific ZIP codes located within western Union County, as well as the remaining Union County ZIP codes, in addition to Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 95, the applicant states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 95, the applicant states:

"The proposed project will enable CPN and Atrium Health to continue to provide their patients with the best care possible, while also being responsive in a healthcare environment that emphasizes cost containment and efficient utilization of existing resources."

Regarding the impact of the proposal on quality, in Section N, page 95, the applicant states:

"CPN believes that the proposed project will promote safety and quality in the delivery of healthcare services. CPN and Atrium Health are known for providing high quality services and expect the proposed project to bolster this reputation."

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 97, the applicant states:

"The proposed project will improve access to diagnostic services in the service area. CPN and Atrium Health have long-promoted economic access to their services as they have historically provided services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay...

Further, as a physician-based service, the proposed diagnostic center will provide services at a low out-of-pocket cost to most patients. Since physician-based services are categorized in a lower tier, patients benefit from low out-of-pocket expenses. As such, the proposed project will increase access to CPN's services, including to medically underserved groups."

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, K, N, and Q of the application and any exhibits)
- Quality (see Sections C, N, and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L, and N of the application and any exhibits)

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 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.

 \mathbf{C}

On Form A in Section Q, the applicant identifies all other diagnostic centers in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 11 diagnostic centers located in North Carolina.

In Section O, page 100, the applicant states:

"Each of the facilities identified...has continually maintained all relevant and applicable licensure, certification, and accreditation for the 18 months preceding the submission of this application."

After reviewing and considering information provided by the applicant regarding the quality of care provided at all 11 diagnostic centers, 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.

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