

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: Kim Meymandi

Team Leader: Fatimah Wilson

Project ID #: F-11905-20

Facility: Atrium Health Ballantyne Medical Office Building Diagnostic Center

FID #: 200461

County: Mecklenburg

Applicant(s): Carolina Physicians Network, Inc.

Project: Develop a new diagnostic center in an existing MOB to include Ob/Gyn ultrasound, urodynamics system, ECHO ultrasound, vascular ultrasound, nuclear medicine camera, X-ray and DEXA scanner

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 Ballantyne Medical Office Building Diagnostic Center (AH Ballantyne MOB Diagnostic Center), in an existing medical office building (MOB) on the campus of Atrium Health Ballantyne (AH Ballantyne) in Mecklenburg County. The applicant proposes to make operational one cardiac echocardiography (Echo) ultrasound and one nuclear medicine camera with treadmill (equipment already owned by CPN) in addition to existing ob/gyn ultrasounds, a urodynamics system, a cardiac echocardiography (echo) ultrasound with treadmill, vascular ultrasounds, a DEXA scanner, and an x-ray machine. 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 health 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.

C

The applicant proposes to develop a new diagnostic center by bringing back into operation a cardiac echocardiography (echo) ultrasound and a nuclear medicine camera with treadmill in addition to existing diagnostic equipment located in an existing medical office building on the campus of AH Ballantyne in Mecklenburg County.

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.1., pages 25-28, the applicant states that the medical diagnostic equipment that will comprise the proposed diagnostic center will be located in physician clinics and spread across two floors within the MOB and will serve to optimize CPN's and Atrium Health's ability to provide patient-centered care in the most cost-effective manner. The applicant further states that the proposed diagnostic center, which will include existing equipment and "new" equipment and associated upfitted leased space on two floors within the existing MOB, includes the following pieces of new and existing medical diagnostic equipment, each of which is worth \$10,000 or more:

AH Ballantyne MOB Diagnostic Center		
Type and Location of Medical Diagnostic Equipment		
Equipment	Number of Units	New or Existing
MOB Level 1-Ob/Gyn Clinic		
Ob/Gyn Ultrasound	2	Existing
Urodynamics System	1	Existing
MOB Level 2-Cardiovascular Clinic		
Cardio Echo Ultrasound	1	“New”
Cardio Echo Ultrasound with Treadmill	1	Existing
Nuclear Medicine Camera with Treadmill	1	“New”
Vascular Ultrasound	2	Existing
MOB Level 2-Internal Medicine Clinic		
DEXA Scanner	1	Existing
X-Ray	1	Existing

Source: Section C, page 26

On pages 26-27, the applicant states that they recently became aware that the total cost of all the medical diagnostic equipment which cost \$10,000 or more at its cardiovascular clinic in the MOB exceeded \$500,000, thus requiring diagnostic center designation. Upon realizing this, CPN took one cardiac echo ultrasound unit and the nuclear medicine camera with treadmill (labeled as “new”) out of service until a Certificate of Need for designation as a diagnostic center could be obtained. Currently, the cardiovascular clinic in the MOB is operating only one cardiac echo ultrasound with treadmill and two vascular ultrasound units, and the total value of the medical diagnostic equipment being used to provide health services in the clinic at the time of submission of the application is less than the \$500,000 diagnostic center threshold. Neither the Ob/Gyn clinic nor the internal medicine clinic located in the MOB has existing medical diagnostic equipment valued at \$10,000 or more that when aggregated exceeds \$500,000. 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 \$1,044,707.

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 28-34, and Section G, page 69, the applicant defines the service area as Mecklenburg and Union counties in North Carolina and Lancaster and York counties in South Carolina. Facilities may also serve residents of counties not included in their service area.

In Section C, pages 28-34, the applicant provides actual patient origin for the types of services to be offered for the last full fiscal year (CY 2019) as well as projected patient origin for the types of services proposed to be offered at AH Ballantyne MOB Diagnostic Center. On page

34, the applicant states it projected patient origin for all service components based on its CY 2019 patient origin for these services provided by physicians at the proposed AH Ballantyne MOB Diagnostic Center, and they expect patient origin for each of the proposed services to remain consistent with its CY 2019 experience through the third full fiscal year.

The following table illustrates projected patient origin during the first three full fiscal years following project completion.

AH Ballantyne MOB Diagnostic Center Projected Patient Origin FYs 1-3 (CYs 2022-2024)						
County	FY 1 – CY 2022		FY 2 – CY 2023		FY 3 – CY 2024	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Mecklenburg	6,920	48.0%	7,024	48.0%	7,130	48.0%
Lancaster	2,358	16.4%	2,392	16.4%	2,427	16.3%
York	2,336	16.2%	2,372	16.2%	2,409	16.2%
Union	1,734	12.0%	1,759	12.0%	1,784	12.0%
Other*	1,060	7.4%	1,077	7.4%	1,095	7.4%
Total	14,408	100.0%	14,624	100.0%	14,846	100.0%

Source: Section C, page 34

*Other includes Alleghany, Anson, Ashe, Avery, Brunswick, Burke, Cabarrus, Caldwell, Catawba, Clay, Cleveland, Craven, Cumberland, Forsyth, Gaston, Guilford, Haywood, Henderson, Iredell, Jackson, Lincoln, McDowell, Montgomery, Moore, Randolph, Richmond, Rowan, Rutherford, Stanly, Wake, and Watauga counties in North Carolina, as well as other states. In Section G, page 69, the applicant states that Gaston County patients represent 2.0 percent of total projected patients and it is the county with the highest percent of projected patients in the “Other” patient origin category.

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 35-40, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- The development of the proposed diagnostic center in the Ballantyne area of Charlotte will allow CPN to continue providing convenient, patient-centered care in a cost-effective manner to the residents of Ballantyne. The diagnostic center is part of a larger system initiative to bring healthcare closer to where patients live and work.
- By ensuring physician offices have the medical diagnostic equipment needed to diagnose patients, AH Ballantyne MOB Diagnostic Center 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, AH Ballantyne MOB Diagnostic Center will provide patients with an opportunity to lower their out-of-pocket medical costs.

- According to the North Carolina Office of State Budget and Management (NC OSBM), the Mecklenburg County population is projected to grow at a Compound Annual Growth Rate (CAGR) of 1.9 percent between 2019 and 2024, the percent of the population of Mecklenburg County residents age 65 and older will increase from 11.6 percent in 2019 to 13.4 percent in 2024, and 82 percent of the female population in Mecklenburg County will be over the age of 15. 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. Furthermore, the applicant states the number of female residents over the age of 15 supports the growing utilization of Ob/Gyn diagnostic services.

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 AH Ballantyne MOB Diagnostic Center 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.

AH Ballantyne MOB Diagnostic Center Projected Utilization – FYs 1-3 (CYs 2022-2023)			
Component	FY 1 (CY 2022)	FY 2 (CY 2023)	FY 3 (CY 2024)
Ob/Gyn Ultrasound – Units	2	2	2
Ob/Gyn Ultrasound - Procedure	4,075	4,161	4,249
Urodynamics System – Units	1	1	1
Urodynamics System - Procedures	28	28	29
Cardiac Echo Ultrasound- Units	2	2	2
Cardiac Echo Ultrasound -Procedures	3,561	3,561	3,561
Nuclear Medicine Camera- Units	1	1	1
Nuclear Medicine Camera - Procedures	1,006	1,025	1,045
Vascular Ultrasound-Units	2	2	2
Vascular Ultrasound-Procedures	2,795	2,849	2,904
DEXA Scanner- Units	1	1	1
DEXA Scanner-Procedures	1,146	1,168	1,191
X-Ray-Units	1	1	1
X-Ray-Procedures	1,797	1,832	1,867
Total Procedures	14,408	14,624	14,846

In Section C, pages 41-45, 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 Capacity for Each Type of Medical Diagnostic Equipment Proposed					
Equipment Type	# of Units	Patients/Hour	Hours/Day	Days/Year	Maximum Annual Capacity*
Ob/Gyn Ultrasound	2	2	7	250	7,000
Urodynamics System	1	1	N/A^	250	N/A^
Cardiac Echo Ultrasound**	2	1	7	250	3,500
Nuclear Medicine Camera	1	0.75	7	250	1,313
Vascular Ultrasound	2	1	7	250	3,500
DEXA Scanner	1	2	3.5 [†]	250	1,750
X-Ray	1	5	3.5 [†]	250	4,375

Source: Section C, page 41; Form C Utilization – Assumptions and Methodology subsection of Section Q

*Maximum Annual Utilization= # of Units x Procedures per Hour x Hours per Day x Days per Year.

**The applicant states that one of the two cardiac echo ultrasound units includes a treadmill.

†The applicant states CPN staffs one cross-trained full-time employee to operate the DEXA scanner and the X-ray unit. CPN assumes that the one employee will split seven hours of operation per day evenly between the two equipment types.

^The applicant states there is no dedicated staff for the urodynamics system and no assumed hours per day of availability. As such, there is no calculated annual utilization for this equipment.

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

The applicant states that historical utilization is not provided specifically for AH Ballantyne MOB Diagnostic Center because the proposed facility is not an existing facility.

The applicant further states that, except for the urodynamics system, DEXA scanner, and x-ray unit, CPN expects to operate the medical diagnostic equipment for seven hours each day, Monday through Friday excluding holidays (or approximately 250 days per year). The urodynamics system does not have dedicated staff, therefore no calculated hours per day is available. The DEXA scanner and X-ray unit will be staffed by cross-trained staff and operated for three and a half hours per day. The applicant states the existing and proposed equipment for the diagnostic center 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.

The applicant is proposing to bring back into service two pieces of diagnostic equipment, a cardiac echo ultrasound and a nuclear medicine camera with treadmill (labeled as “new”), which triggers a diagnostic center designation when combined with the other existing equipment in the MFM clinic. Therefore, while none of the physician clinics in the MOB have medical equipment valued at \$10,000 or more that when aggregated exceeds \$500,000, the applicant is applying for all its non-hospital-based physician space in the MOB as a single diagnostic center.

New Equipment

Cardiac Echo Ultrasound Utilization

- The applicant analyzed internal historical data to project utilization for the two cardiac echo ultrasound units and believes that the 747.9 percent growth from 2018 to 2019 supports future growth for the service. The applicant states that the growth rate is attributed to a partial year of volume in 2018 and a ramp up period. Table 9 on page five of Form C shows that 3,561 cardiac echo ultrasound procedures were performed in 2019.
- The applicant states that, based on the projected population growth rate of Mecklenburg County as published by NC OSBM, it projects growth in cardiac echo ultrasound utilization at AH Ballantyne MOB Diagnostic Center at an annual growth rate of 1.9 percent for CY 2019 through CY 2024.
- The applicant projects cardiac echo ultrasound utilization demand will be 3,771 procedures in CY 2022; 3,844 procedures in CY 2023; and 3,918 procedures in CY 2024. This demand exceeds the assumed cardiac echo ultrasound maximum annual capacity of 3,500 procedures. The applicant states that due to taking one cardiac echo ultrasound unit out of service for seven months in 2020 and one month in 2021 their capacity to serve the total demand for services was reduced to 70.8 percent in CY 2020 and 95.8 percent in CY 2021. As such the applicant conservatively projects to perform 3,561 cardiac echo ultrasounds at AH Ballantyne MOB Diagnostic Center in CY 2022-2024.
- Based on the calculated maximum capacity of the cardiac echo ultrasound, the applicant projects the cardiac echo ultrasound will be utilized at 101.7% capacity in CY 2024.

Nuclear Medicine Camera with Treadmill

- The applicant analyzed internal historical data to project utilization for the nuclear medicine camera with treadmill and believes that the 944.0 percent growth from 2018 to 2019 supports future growth for the service. The applicant states that the growth rate is attributed to a partial year of volume in 2018 and a ramp up period. Table 14 on page eight of Form C shows that 950 nuclear medicine camera procedures were performed in 2019.
- The applicant states that, based on the projected growth rate of Mecklenburg County as published by NC OSBM, it projects growth in nuclear medicine camera utilization at AH Ballantyne MOB Diagnostic Center at an annual growth rate of 1.9 percent for CY 2019 through CY 2024.
- The applicant projects to perform 1,045 nuclear medicine camera procedures at Ballantyne MOB Diagnostic Center in CY 2024. Based on the calculated maximum capacity of the nuclear medicine camera, the applicant projects the nuclear medicine camera will be utilized at 79.6 percent of capacity in CY 2024.

Existing Equipment

Ob/Gyn Ultrasound

- The applicant states internal data shows the growth rate of Ob/Gyn Ultrasound utilization from CY 2017 to CY 2019 has been flat. The applicant states it expects the future utilization rate of

ob/gyn ultrasounds to grow at the same rate as the population it serves (females ages 15 and over) in Mecklenburg County.

- The applicant states that, based on the projected growth rate of females ages 15 and over in Mecklenburg County, it projects growth in ob/gyn ultrasound utilization at AH Ballantyne MOB Diagnostic Center at an annual growth rate of 2.1% for CY 2020 through CY 2024.
- The applicant projects to perform 4,249 ob/gyn ultrasounds at AH Ballantyne MOB Diagnostic Center in CY 2024. Based on the calculated maximum capacity of the ob/gyn ultrasounds, the applicant projects the ob/gyn ultrasound machines will be utilized at 60.7 percent of capacity in CY 2024.

Urodynamics System

- The applicant states internal data shows urodynamics system utilization decreased at a CAGR of -1.9 percent between CY 2017 and CY 2019. However, the applicant notes in a request for clarifying information that there was positive growth from CY 2018 to CY 2019 when utilization of the urodynamics system increased by eight procedures (18 procedures in CY 2018 to 26 procedures in CY 2019) or a growth rate of 44 percent.
- The applicant states that, based on the projected growth rate of the population that the urodynamics system serves (females ages 15 and over) in Mecklenburg County, it projects growth in urodynamics system utilization at AH Ballantyne MOB Diagnostic Center at an annual rate of 2.1% for CY 2020 through CY 2024
- The applicant projects to perform 29 urodynamics system procedures at AH Ballantyne MOB Diagnostic Center in CY 2024. The applicant states the urodynamics system does not have dedicated staff and are utilized based on physician need; therefore, there is no maximum annual utilization calculated for the urodynamics system. While there is no maximum annual utilization calculated, the applicant states that if the urodynamics system was fully staffed by dedicated providers every day, the maximum annual capacity of the urodynamics system would be 1,750 procedures.

Vascular Ultrasound

- The applicant states internal data shows vascular ultrasound machine utilization grew at a CAGR of 92.4 percent between CY 2017 and CY 2019. The applicant notes that a portion of the growth rate is attributed to a ramp up period. Table 18 on page 10 of Form C shows that 2,639 vascular ultrasound procedures were performed in 2019.
- The applicant states that, based on the projected growth rate of the population of Mecklenburg county as published by NC OSBM, it projects growth in vascular ultrasound machine utilization at AH Ballantyne MOB Diagnostic Center at an annual growth rate of 1.9 percent for CY 2020 through CY 2024.
- The applicant projects to perform 2,904 vascular ultrasounds at AH Ballantyne MOB Diagnostic Center in CY 2024. Based on the calculated maximum annual capacity of the vascular ultrasound machine, the applicant projects the vascular ultrasound will be utilized at 83 percent of capacity in CY 2024.

DEXA Scanner and X-Ray

- The applicant states internal data shows DEXA scanner and x-ray utilization decreased at a CAGRs of -40.3 percent and -29.2 percent respectively between CY 2017 and CY 2019. The applicant attributes the decrease in utilization to physician turn over.
- The applicant states CPN is currently recruiting to replace several physicians and two additional providers are expected to begin practicing in the summer of 2020. The applicant projects that CPN will have a full complement of physicians by CY 2022 which will allow for 100 percent utilization of the DEXA scanner and x-ray unit.
- The applicant projects the rate of utilization for the DEXA scanner and x-ray unit will grow 1.9 percent, equivalent to the projected population growth in Mecklenburg County for CY 2023 and CY 2024.
- The applicant projects to perform 1,191 DEXA Scans and 1,867 x-rays in CY 2024. Based in the calculated maximum capacity of the DEXA scanner and x-ray unit, the applicant projects the DEXA scanner will be utilized at 68 percent of capacity and the x-ray unit will be utilized at 42.7 percent of capacity in CY 2024.

A summary of the applicant’s historical utilization, details of assumptions and methodology, and projected utilization for each type of equipment is shown in the table below.

AH Ballantyne MOB Diagnostic Center Utilization Assumptions, Methodology, and Projections – CY 2020 through CY 2024									
Component	CY 2017-2019 Growth %	CY 2020-2024 Growth %	CY 2020	CY 2021	FY 1 (CY 2022)	FY 2 (CY 2023)	FY 3 (CY 2024)	Max. Capacity	% of Max. Capacity
Cardiac Echo Ultrasounds (2 Units)*	--	1.9%	3,630	3,700	3,771	3,844	3,918	3,500	101.7%
Nuclear Medicine Camera (1 Unit)	--	1.9%	968	987	1,006	1,025	1,045	1,313	79.6%
Ob/Gyn Ultrasound (2 Units)	0.0%	2.1%	3,909	3,991	4,075	4,161	4,249	7,000	60.7%
Urodynamics System (1 Unit)	-1.9%	2.1%	27	27	28	28	29	NA	NA
Vascular Ultrasound (2 Units)	92.4%	1.9%	2,690	2,742	2,795	2,849	2,904	3,500	83.0%
DEXA Scanner (1 Unit)	-40.3%	1.9%	417	860	1,146	1,168	1,191	1,750	68.0%
X-Ray (1 Unit)	-29.2%	1.9%	918	1,348	1,797	1,832	1,867	4,375	42.7%
Total Tests			12,559	13,655	14,618	14,907	15,203	21,438	

Source: Form C Utilization – Assumptions and Methodology subsection of Section Q

*One of the two cardiac echo ultrasound units includes a treadmill

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

- Projected utilization is based in part on historical data.
- The applicant adequately explains why projecting growth is reasonable in the cases where historical data showed declines in utilization.
- The applicant uses conservative projected growth rates.
- 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 50, 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.”

In Section C, page 51 the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

AH Ballantyne MOB Diagnostic Center Projected Patient Population-FY 3 (CY 2024)							
Patient Population	Ob/Gyn Ultrasound	Urodynamics System	Cardiac Echo Ultrasound	Nuclear Medicine Camera	Vascular Ultrasound	DEXA Scanner	X-Ray
Low Income Persons							
Racial and Ethnic Minorities	34.2%	19.2%	18.0%	14.3%	17.2%	15.6%	18.2%
Women	100.0%	100.0%	52.3%	43.6%	60.8%	94.9%	59.8%
Handicapped Persons							
The Elderly	2.1%	23.1%	46.7%	66.9%	41.3%	71.9%	46.6%
Medicare Beneficiaries	2.3%	26.9%	45.2%	64.9%	44.4%	65.5%	45.8%
Medicaid Recipients	10.7%	19.2%	1.7%	1.1%	3.5%	0.5%	1.1%

Note: The applicant states that it does not maintain data that includes the number of low-income persons or handicapped 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 describes the extent to which all residents, including underserved groups, will have access to the proposed services 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

The applicant proposes to develop a new diagnostic center by bringing back into operation a cardiac echocardiography (echo) ultrasound and a nuclear medicine camera with treadmill in addition to existing diagnostic equipment located in an existing medical office building on the campus of AH Ballantyne in Mecklenburg County.

In Section E, page 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 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.

Develop the Diagnostic Center with a Different Complement of Diagnostic Imaging Equipment: 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 60, 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, the certificate holder shall material comply with the last made representation.**
- 2. Carolinas Physicians Network, Inc. shall develop a new diagnostic center by bringing back into operation a cardiac echocardiography (echo) ultrasound and a nuclear medicine camera with treadmill in addition to existing ob/gyn ultrasounds, a urodynamics system, vascular ultrasounds, a DEXA scanner, and an x-ray machine located in an existing medical office building, Atrium Health Ballantyne Medical Office Building.**
- 3. Carolinas Physicians Network, Inc., as part of this project, shall not acquire 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.

C

The applicant proposes to develop a new diagnostic center by bringing back into operation a cardiac echocardiography (echo) ultrasound and a nuclear medicine camera with treadmill in addition to existing diagnostic equipment located in an existing medical office building on the campus of AH Ballantyne in Mecklenburg 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.

Construction Costs	\$130,000
Medical Equipment Costs	\$1,044,707
Non-Medical Equipment/Furniture	\$55,005
Consultant/A&E Fees	\$102,234
Miscellaneous Costs/Contingency	\$112,630
Total	\$1,444,576

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

In Section F, page 65, the applicant states the project does not involve any working capital costs.

Availability of Funds

In Section F, pages 62-63, 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 first three fiscal years of the project, as shown in the table below.

AH Ballantyne MOB Diagnostic Center Revenue and Expenses – FYs 1-3 (CYs 2022-2024)			
	FY 1 (CY 2022)	FY 2 (CY 2023)	FY 3 (CY 2024)
Total Tests/Procedures	14,408	14,624	14,846
Total Gross Revenues (Charges)	\$7,272,487	\$7,574,151	\$7,889,073
Total Net Revenue	\$2,495,450	\$2,602,467	\$2,714,325
Average Net Revenue per Test	\$173	\$178	\$183
Total Operating Expenses (Costs)	\$1,488,063	\$1,531,773	\$1,577,003
Average Operating Expense per Test	\$103	\$105	\$106
Net Income / (Loss)	\$1,007,387	\$1,070,6994	\$1,137,322

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.

C

The applicant proposes to develop a new diagnostic center by bringing back into operation a cardiac echocardiography (echo) ultrasound and a nuclear medicine camera with treadmill in

addition to existing diagnostic equipment located in an existing medical office building on the campus of AH Ballantyne in Mecklenburg 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 28-34, and Section G, page 69, the applicant defines the service area as Mecklenburg and Union counties in North Carolina and York and Lancaster counties in South Carolina. Facilities may also serve residents of counties not included in their service area.

In Section G, page 69, 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 License Renewal Applications (LRAs) and the 2018 South Carolina Joint Annual Reports, the most recent data available for South Carolina, for facilities in Mecklenburg, Union, Lancaster, and York counties with equipment and services like those proposed in this application. On page 70, the applicant lists all the existing and approved diagnostic centers owned or operated by CPN or an affiliated entity.

In Section G, page 70, 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 and Lancaster and York counties in South 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. No other provider can meet the identified need. Further, though other imaging and diagnostic services may be available in the service area, they are not reasonably available to the patients of the CPN physicians located at the 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.

AH Ballantyne MOB Diagnostic Center Projected Staffing			
Position	FTEs		
	FY 1 (CY 2022)	FY 2 (CY 2023)	FY 3 (CY 2024)
Radiology Technologists	4.0		
Respiratory Therapists	1.0		
Echocardiography Tech	2.0		
Vascular Ultra Tech	2.0		
Total	9.0		

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.3, which is found in Section Q. In Section H, pages 72-73, the applicant describes the methods to be 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.

C

In Section I, page 74, 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 74, the applicant adequately explains how each ancillary and support service will be made available.

In Section I, pages 74-75, 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.

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.

- (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 79, the applicant states that the project does not involve the construction, renovation or upfit of space. Instead the project involves bringing the proposed “new” equipment, which consists of the cardio echo ultrasound and the nuclear medicine camera with treadmill back into operation.

In Section K, page 80, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

In Section K, page 80, 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.

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 85, the applicant provides the historical payor mix for CY 2019 for the physician services that were located at AH Ballantyne MOB Diagnostic Center during that time (ob/gyn ultrasound, urodynamics system, cardiac echo ultrasound, nuclear medicine camera, vascular ultrasound, DEXA scanner, and chest X-ray), as shown in the table below.

Historical Payor Mix at AH Ballantyne MOB Diagnostic Center for Existing Services – CY 2019	
Entire Facility	
Payor Source	% of Services
Self-Pay	2.6%
Medicare*	33.9%
Medicaid*	4.8%
Insurance*	58.1%
Other**	0.6%
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.

*Including any managed care plans

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

In Section L, page 84, the applicant provides the following comparison.

AH Ballantyne MOB Diagnostic Center	% of Patients Served during CY 2018	Percent of Population by County			
		Mecklenburg	Union	Lancaster	York
Female	69.7%	51.9%	50.8%	51.5%	51.8%
Male	30.3%	48.1%	49.2%	48.5%	48.2%
Unknown	0.0%	0.0%	0.0%	0.0%	0.0%
64 and Younger	65.5%	88.8%	87.3%	79.0%	85.7%
65 and Older	34.5%	11.2%	12.7%	21.0%	14.3%
American Indian	0.4%	0.8%	0.6%	0.3%	0.9%
Asian	5.7%	6.4%	3.4%	1.5%	2.5%
Black or African-American	13.8%	32.9%	12.3%	21.6%	19.4%
Native Hawaiian or Pacific Islander	0.0%	0.1%	0.1%	0.0%	0.1%
White or Caucasian	77.8%	57.5%	81.6%	74.9%	75.0%
Other Race	0.4%	2.4%	2.0%	1.6%	2.2%
Declined / Unavailable	1.9%	0.0%	0.0%	0.0%	0.0%

Sources: CPN Internal Data, 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, page 86, the applicant states that it has no such obligations.

In Section L, page 86, 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

C

In Section L, page 87, 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.

AH Ballantyne MOB Diagnostic Center Payor Mix – FY 3 (CY 2024)	
Payor Source	Percent of Services
Self-Pay	2.6%
Medicare*	33.9%
Medicaid*	4.8%
Insurance*	58.1%
Other**	0.8%
Total	100.0%

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

*Including any managed care plans

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

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.6 percent of total services will be provided to self-pay patients, 33.9 percent to Medicare patients, and 4.8 percent to Medicaid patients.

In Section L, pages 87-88, 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.

C

In Section L, page 88, 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 90, 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.

C

The applicant proposes to develop a new diagnostic center by bringing back into operation a cardiac echocardiography (echo) ultrasound and a nuclear medicine camera with treadmill in addition to existing diagnostic equipment located in an existing medical office building on the campus of AH Ballantyne in Mecklenburg 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 28-34, and Section G, page 69, the applicant defines the service area as Mecklenburg and Union counties in North Carolina and Lancaster and York counties in South Carolina. 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 92, 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 92, 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 92, 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, pages 94, 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.

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 ten diagnostic centers located in North Carolina.

In Section O, page 98, the applicant states:

“Each of the facilities identified...has continually maintained all relevant 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 ten 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.

NA

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