ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

Decision Date:	July 24, 2020
Findings Date:	July 24, 2020
Project Analyst:	Gregory F. Yakaboski
Team Leader:	Fatimah Wilson
Project ID #:	F-11901-20
Facility:	Atrium Health Pineville Medical Plaza II Diagnostic Center
FID #:	200294
County:	Mecklenburg
Applicant:	Carolinas Physicians Network, Inc.
Project:	Develop a new diagnostic center with X-ray, ultrasound, EMG, and RMR

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 Pineville Medical Plaza II Diagnostic Center (AH Pineville MP II), in an existing medical office building on the campus of Atrium Health Pineville (AH Pineville) in Mecklenburg County. The applicant proposes to acquire one new maternal fetal medicine (MFM) ultrasound unit in addition to existing orthopedic and MFM ultrasound units, an orthopedic x-ray machine, neurology electromyography (EMG) unit, a dual-energy X-ray absorptiometry (DEXA) scanner and a resting metabolic rate (RMR) unit. 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 develop any beds or services for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP) nor acquire any medical equipment for which there is a need determination in the 2020 SMFP.

Policies

The applicant does not propose to offer a new institutional health service for which there are any applicable policies in the 2020 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.

С

The applicant proposes to develop a new diagnostic center by acquiring one new MFM ultrasound unit in addition to existing diagnostic equipment located in an existing medical office building on the campus of AH Pineville in Mecklenburg County.

In Section C, page 24, the applicant states it plans to develop the diagnostic center in an existing medical office building, Pineville Medical Plaza II. 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.

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/Relocated				
MOB Level 3- ORTHOPEDIC CLINIC						
Orthopedic Ultrasound	1	Existing				
Orthopedic X-Ray	2	Existing				
MOB Level 4-MA	TERNAL FETAL MED	DICAL CLINIC				
MFM Ultrasound	2	Existing				
MFM Ultrasound	1	New				
MOB Leve	4- NEUROLOGY CI	LINIC				
Neurology EMG	2	Existing				
MOB Level 4- W	EIGHT MANAGEM	ENT CLINIC				
Weight Management DEXA	1	Existing				
Scanner						
Weight Management RMR	1	Existing				

Source: Section C, page 26

On page 25, the applicant states that the equipment identified as "existing" in the table above is either currently located in the MOB or will be in the MOB prior to the development of the proposed diagnostic center.

On page 24, the applicant states that currently none of the physician clinics in the MOB have medical equipment valued at \$10,000 or more that when aggregated exceeds \$500,000. However, one of the physician's clinics, the MFM clinic, is proposing to acquire medical diagnostic equipment valued such that it will trigger the diagnostic center designation, therefore, the applicant is applying for all its non-hospital-based physician space in the MOB as a single diagnostic center. The applicant states that the combined cost and/or value of the pieces of equipment listed in the table 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 \$907,463.

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 27-32, and Section G, page 67, the applicant defines the service area as Mecklenburg, Union, Cleveland and Gaston 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 C, pages 28-29, the applicant provides historical patient origin for orthopedic ultrasound, orthopedic x-ray and neurology EMG as well as actual patient origin for AH Pineville MP II for the last full fiscal year (CY2019). While MFM ultrasound, weight management DEXA or weight management RMR services will be offered at AH Pineville MPII prior to the development of the proposed diagnostic center no historical patient origin is provided for those services as they have not historically been provided at AH Pineville MP II.

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

County	FY 1 - C	ŕ 2021	FY 2 – CY	(2022	FY 3 – CY 2023	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
York, SC	9,048	38.8%	11,323	38.0%	11,882	36.6%
Mecklenburg	7,125	30.6%	9,076	30.5%	9,849	30.3%
Lancaster, SC	2,555	11.0%	3,167	10.6%	3,261	10.0%
Union	1,072	4.6%	1,411	4.7%	1,646	5.1%
Cleveland	1,035	4.4%	1,536	5.2%	2,038	6.3%
Gaston	488	2.1%	667	2.2%	818	2.5%
Other*	1,986	8.5%	2,622	8.8%	2,991	9.2%
Total	23,309	100.0%	29,801	100.0%	32,486	100.0%

Source: Section C, page 32

*Other: On page 32 the applicant provides an extensive list of the other NC counties. This category also includes some other states.

In Section C, page 32, 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 33-38, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- Growth in the AH Pineville campus as well as the service offerings at AH Pineville, now a tertiary care hospital, has resulted in demand which has increased faster than projected when AH Pineville was developed. Development of office buildings on the AH Pineville campus (as part of projects exempt from review as determined by the Agency) has helped deliver more efficient patient care.
- By ensuring physician offices have the medical diagnostic equipment needed to diagnose patients, AH Pineville MP II 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 Pineville MP II 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 1.77 percent between 2020 and 2030, and the percent of the population of Mecklenburg County residents age 65 and older will increase from 11.6 percent in 2019 to 13.8 percent in 2025. 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 AH Pineville MP II 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 Pineville MP II Projected Utilization – FYs 1-3 (CYs 2021-2023)						
Component	FY 1 (CY 2021)	FY 2 (CY 2022)	FY 3 (CY 2023)			
Orthopedic Ultrasound – Units	1	1	1			
Orthopedic Ultrasound- Procedure	836	836	836			
Orthopedic X-Ray – Units	2	2	2			
Orthopedic X-Ray- Procedures	15,600	19,500	19,500			
MFMU- Units	3	3	3			
MFMU-Procedures	5,000	7,500	10,000			
Neurology EMG- Units	2	2	2			
Neurology EMG- Procedures	781	781	781			
Weight Management DEXA-Units	1	1	1			
Weight Management DEXA-Procedures	261	261	261			
Weight Management RMR- Units	1	1	1			
Weight Management RMR-Procedures	830	923	1,107			
Total Procedures	23,308	29,801	32,485			

In Section C, pages 39-42, 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

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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	# Units	Patients/Hour	Hours/Day	Days/Year	Maximum Annual Capacity*	
Orthopedic Ultrasound	1	2.0	NA	250	NA	
Orthopedic X-ray	2	6.0	7	250	21,000	
MFM Ultrasound	3	2.0	7	250	10,500	
Neurology EMG	2	1.0	7	200**	2,800	
Weight Management DEXA Scanner	1	2.0	3.5***	250	1,750	
Weight Management RMR	1	4.0	3.5***	250	3,500	

Source: Section C, page 39; Form C Utilization – Assumptions and Methodology subsection of Section Q

NA: There is no dedicated staff and no assumed hours per day, therefore, there is no calculated maximum annual capacity. *Maximum Annual Capacity = (Units X Patients X Hours X Days)

**The applicant states procedures are performed four days per week due to physician availability.

*** The applicant states one cross-trained full-time employee is staffed for the DEXA Scanner and the RMR. The applicant assumes seven hours per day with the time evenly split between the two pieces of equipment.

In Section Q and supplemental 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 AH Pineville MP II 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.

The applicant is proposing to add only one new piece of diagnostic equipment, an MFM ultrasound, 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

MFM Ultrasound Utilization

	2019			
# of provider FTEs	0.80			
# of MFM Ultrasounds	2,099			
# of MFM Ultrasound per FTE	2,623			
Source: Form C page F				

CPN MFM Ultrasound Historical Utilization

Source: Form C, page 5.

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 clinics, including the Women's Institute NorthEast an existing CPN maternal fetal medicine (MFM) practice in the Charlotte-metropolitan area as well as input from existing MFM practice managers and physicians regarding anticipated provider practice patterns and efficiencies that are expected to be realized as the clinic matures the applicant projects an increase in the number of procedures per FTE to 3,500 in interim year CY2020 and to 5,000 per FTE in OY1-OY3 (CY2021-CY2023) as illustrated in the table below.

		Interim Year (CY2020)	OY1 (CY2021)	OY2 (CY2022)	OY3 (CY2023)
А	# of provider FTEs	0.80	1.00	1.50	2.00
В	# of MFM Ultrasounds per FTE	3,500	5,000	5,000	5,000
С	# of MFM Ultrasound*	2,800	5,000	7,500	10,000

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

By OY3 (CY2023), the applicant projects the three MFM ultrasounds will be operating at 95.2% of capacity as shown in the table below.

Equipment Type	Number of Units	Maximum Capacity	2023 Projected Utilization	2023 Percent of Capacity
MFM Ultrasound	3	10,500	10,000	95.2%

Source: Section Q, Form C page 6.

Existing Equipment

Orthopedic Ultrasound Utilization

CPN Orthopedic Ultrasound Historical Utilization					
	2019				
# of provider FTEs	0.71				
# of Orthopedic Ultrasounds	199				
# of Orthopedic Ultrasounds per	279				
FTE					

Source: Form C, page 2.

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 and/or increased coverage from existing providers.

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		Interim Year (CY2020)	OY1 (CY2021)	OY2 (CY2022)	OY3 (CY2023)
А	# of provider FTEs	2.0	3.0	3.0	3.0
В	# of Orthopedic Ultrasounds per FTE	279	279	279	279
С	# of Orthopedic Ultrasounds*	558	836	836	836

Source: Section Q, Form C page 3.

*Row A x Row B = Row C.

Percent of Capacity by OY3 (CY2023)

Equipment Type	Number of Units	Maximum Capacity	2023 Projected Utilization	2023 Percent of Capacity*
Orthopedic Ultrasound	1	n/a	836	n/a

Source: Section Q, Form C page 3.

*NA: There is no dedicated staff and no assumed hours per day, therefore, there is no calculated maximum annual capacity.

Note: The applicant believes that to maintain efficient patient flow during orthopedic visits an orthopedic ultrasound is needed.

Orthopedic X-Ray Utilization

CPN Orthopedic X-ray Historical Utilization				
	2019			
# of provider FTEs	0.71			
# of Orthopedic X-rays	2,734			
# of Orthopedic X-rays per FTE	3,828			

Source: Form C, page 4.

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 existing orthopedic clinics in the southern Charlotte region, including the four existing locations of Carolina Orthopaedic Surgery Associates (COSA) in Pineville, Rock Hill, Lancaster and Fort Mill, as well as input from existing orthopedic clinic practice managers and physicians the applicant projects an increase in the number of procedures per FTE to 3,900 in interim year CY2020, to 5,200 in OY1 (CY2021), and to 6,500 per FTE in OY2 and OY3 (CY2022 and CY2023) as illustrated in the table below.

		Interim Year (CY2020)	OY1 (CY2021)	OY2 (CY2022)	OY3 (CY2023)
А	# of provider FTEs	2.0	3.0	3.0	3.0
В	# of Orthopedic X-rays per FTE	3,900	5,200	6,500	6,500
С	# of Orthopedic X-rays*	7,800	15,600	19,500	19,500

Source: Section Q, Form C page 4.

*Row A x Row B = Row C.

By OY3 (CY2023), the applicant projects the two orthopedic x-rays will be operating at 92.9% of capacity as shown in the table below.

Equipment Type	Number of Units	Maximum Capacity	2023 Projected Utilization	2023 Percent of Capacity
Orthopedic X-ray	2	21,000	19,500	92.9%

Source: Section Q, Form C page 4.

EMG Utilization

CPN EMG Historical Utilization 2019 2019		
	2019	
provider FTEs		

# of provider FTEs	0.30
# of EMG procedures	293
# of EMG procedures per FTE	977

Source: Form C, page 6.

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 ٠ equipment.

		Interim Year (CY2020)	OY1 (CY2021)	OY2 (CY2022)	OY3 (CY2023)
А	# of provider FTEs	0.40	0.80	0.80	0.80
В	# of EMG procedures per FTE	977	977	977	977
С	# of EMG procedures*	391	781	781	781

Source: Section Q, Form C page 7.

*Row A x Row B = Row C.

By OY3 (CY2023), the applicant projects the two EMG units will be operating at 27.9% of capacity as shown in the table below.

Equipment Type	Number of Units	Maximum Capacity	2023 Projected Utilization	2023 Percent of Capacity
Neurology EMG	2	2,800	781	27.9%

Source: Section Q, Form C page 7.

Note: The applicant states that the need for 2 EMG units is driven by the operational need to allow technicians and providers to rotate rooms, thus improving efficiency for both patients and providers.

DEXA Utilization

CPN DEXA Historical Utilization				
2019				
# of provider FTEs	1.0			
# of DEXA Scans	116			
# of DEXA Scans per FTE	116			

Source: Form C, page 8.

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.

		Interim Year (CY2020)	OY1 (CY2021)	OY2 (CY2022)	OY3 (CY2023)
А	# of provider FTEs	1.00	2.23	2.25	2.25
В	# of DEXA scans per FTE	116	116	116	116
С	# of DEXA scans*	116	261	261	261

Source: Section Q, Form C page 8.

*Row A x Row B = Row C.

By OY3 (CY2023), the applicant projects the DEXA unit will be operating at 14.9% of capacity as shown in the table below.

Equipment Type	Number of Units	Maximum Capacity	2023 Projected Utilization	2023 Percent of Capacity
DEXA Unit	1	1,750	261	14.9%

Source: Section Q, Form C page 8.

RMR Utilization

CPN RMR Historical Utilization				
	2019			
# of provider FTEs	1.0			
# of RMR Procedures	369			
# of RMR Procedures per FTE	369			
Source: Form C page 9				

Source: Form C, page 9.

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

		Interim Year (CY2020)	OY1 (CY2021)	OY2 (CY2022)	OY3 (CY2023)
А	# of provider FTEs	1.00	2.25	2.25	2.25
В	# of RMR Procedures per FTE	369	369	369	369
С	# of RMR Procedures *	369	830	923	1,107

Source: Section Q, Form C page 10.

*Row A x Row B = Row C.

By OY3 (CY2023), the applicant projects the RMR unit will be operating at 31.6% of capacity as shown in the table below.

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Equipment Type	Number of Units	Maximum Capacity	2023 Projected Utilization	2023 Percent of Capacity
RMR Unit	1	3,500	1,107	31.6%

Source: Section Q, Form C page 10.

<u>All Equipment</u>

Equipment Type	OY3 (CY2023) Projected Utilization	Maximum Annual Capacity*	OY3 (CY2023) Percent of Capacity
Orthopedic Ultrasound	836	NA	NA
Orthopedic X-ray	19,500	21,000	92.8%
MFM Ultrasound	10,000	10,500	95.2%
Neurology EMG	781	2,800	27.9%
Weight Management DEXA Scanner	261	1,750	14.9%
Weight Management RMR	1,107	3,500	31.6%

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 47, 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 L, page 85, 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 Pineville MPII Payor Mix – FY 3 (CY 2023)		
Payor Source	Percent of Services	
Self-Pay	4.1%	
Medicare*	21.9%	
Medicaid*	16.3%	
Insurance*	54.2%	
Other**	3.6%	
Total	100.0%	

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

*Including any managed care plans

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

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental 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.

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 acquiring one new MFM ultrasound unit in addition to existing diagnostic equipment located in an existing medical office building on the campus of AH Pineville in Mecklenburg County.

In Section E, page 57, 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 57, 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 supplemental 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 one new maternal fetal medicine ultrasound unit in addition to existing orthopedic and MFM ultrasound units, an orthopedic x-ray machine, neurology EMG, a DEXA scanner and an RMR in an existing medical office building, Pineville Medical Plaza II, on the campus of Atrium Health Pineville.
- **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.

The applicant proposes to develop a new diagnostic center by acquiring one new MFM ultrasound unit in addition to existing diagnostic equipment located in an existing medical office building on the campus of AH Pineville 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	\$495,600
Medical Equipment Costs	\$907,463
Non-Medical Equipment/Furniture	\$20,574
Consultant/A&E Fees	\$94,830
Miscellaneous Costs/Contingency	\$92 <i>,</i> 830
Total	\$1,611,297

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

In Section F, page 61, the applicant states the project does not involve any working capital costs.

Availability of Funds

In Section F, pages 59-60, 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, 2018 and 2017. As of December 31, 2018, 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.

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	FY 1 (CY 2021)	FY 2 (CY 2022)	FY 3 (CY 2023)
Total Procedures	23,308	29,801	32,485
Total Gross Revenues (Charges)	\$3,681,033	\$5,119,529	\$6,360,724
Total Net Revenue	\$1,392,190	\$1,918,325	\$2,352,851
Average Net Revenue per Procedure	\$60	\$64	\$72
Total Operating Expenses (Costs)	\$1,260,597	\$1,409,433	\$1,494,600
Average Operating Expense per Procedure	\$54	\$47	\$46
Net Income / (Loss)	\$131,592	\$508,891	\$858,251

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

С

The applicant proposes to develop a new diagnostic center by acquiring one new MFM ultrasound unit in addition to existing diagnostic equipment located in an existing medical office building on the campus of AH Pineville 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 27-32, and Section G, page 67, the applicant defines the service area as Mecklenburg, Union, Cleveland and Gaston counties in North Carolina and York and Lancaster and York counties in South Carolina. Facilities may also serve residents of counties not included in their service area.

In Section G, page 66, 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, Cleveland, Gaston Lancaster, and York counties with equipment and services like those proposed in this application. On page 67, the applicant lists all the existing and approved diagnostic centers owned or operated by CPN or an affiliated entity.

In Section G, page 67, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic center services in Mecklenburg, Union, Cleveland and Gaston 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 and to increase collaboration among the clinics in the existing MOB. 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 Atrium Health Pineville Medical Plaza II."

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.

С

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.

Position	Projected FTE Staff			
	1st Full Fiscal Year2nd Full Fiscal Year3rd Full Fiscal Year(CY2021)(CY2022)CY2023			
Radiology Technologists	6.8	6.8	6.8	
TOTAL	6.8	6.8	6.8	

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 69-70, 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.

С

In Section I, page 71, 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 71, the applicant adequately explains how each ancillary and support service will be made available.

In Section I, pages 71-72, 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. Therefore, Criterion (9) is not applicable to this review.

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO.

In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

С

In Section K, page 76, the applicant states that the project involves renovating 215 square feet of space in an existing medical office building on the campus of AH Pineville. Line drawings are provided in Exhibit C.1.

In Section K, page 77, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

In Section K, page 77, 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 77-79, 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;

С

In Section L, page 84, the applicant provides the historical payor mix for CY 2019 for the physician services that were located at AH Pineville MPII during that time (orthopedic ultrasound, orthopedic x-ray and neurology EMG), as shown in the table below.

Historical Payor Mix at AH Pineville MPII for Existing Services – CY 2019			
Entire Facility			
Payor Source % of Services			
Self-Pay Self-Pay	4.1%		
Medicare*	21.9%		
Medicaid*	16.3%		
Insurance*	54.2%		
Other**	3.6%		
Total	100.0%		

Source: Atrium Health 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 83, the applicant provides the following comparison.

Atrium Health Pineville Medical Plaza II Diagnostic Center Project ID #F-11901-20 Page 22

	% of Patients	Percent of Population by County					Percent of Population by Co			
AH Pineville MPII CY 2019	Served during CY 2019	Mecklenburg	Union	Lancaster	York	Gaston	Cleveland			
Female	60.0%	51.9%	50.8%	51.5%	51.8%	51.8%	51.9%			
Male	40.0%	48.1%	49.2%	48.5%	48.2%	48.2%	48.1%			
Unknown	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%			
64 and Younger	61.5%	88.8%	87.3%	79.0%	85.7%	83.9%	81.4%			
65 and Older	38.5%	11.2%	12.7%	21.0%	14.3%	16.1%	18.6%			
American Indian	0.4%	0.8%	0.6%	0.3%	0.9%	0.6%	0.4%			
Asian	1.1%	6.4%	3.4%	1.5%	2.5%	1.6%	1.0%			
Black or African- American	17.7%	32.9%	12.3%	21.6%	19.4%	17.6%	20.9%			
Native Hawaiian or Pacific Islander	0.0	0.1%	0.1%	0.0%	0.1%	0.1%	0.0%			
White or Caucasian	79.8%	57.5%	81.6%	74.9%	75.0%	78.0%	75.9%			
Other Race	0.2%	2.4%	2.0%	1.6%	2.2%	2.1%	1.8%			
Declined / Unavailable	0.8%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%			

Sources: Atrium Health 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;

С

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 84, the applicant states that it has no such obligations. In Section L, page 85, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

С

In Section L, page 85, 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 Pineville MPII Payor Mix – FY 3 (CY 2023)		
Payor Source	Percent of Services	
Self-Pay	4.1%	
Medicare*	21.9%	
Medicaid*	16.3%	
Insurance*	54.2%	
Other**	3.6%	
Total	100.0%	
Note: The applicant states that it does not have charity		

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 4.1 percent of total services will be provided to self-pay patients, 21.9 percent to Medicare patients, and 16.3 percent to Medicaid patients.

In Section L, page 86, 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.

С

In Section L.5, page 87, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

С

In Section M, page 88, 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.

С

The applicant proposes to develop a new diagnostic center by acquiring one new MFM ultrasound unit in addition to existing diagnostic equipment located in an existing medical office building on the campus of AH Pineville 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 27-32, and Section G, page 67, the applicant defines the service area as Mecklenburg, Union, Cleveland and Gaston counties in North Carolina and York 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 90, 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 90, 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 90, 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 92, 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.

С

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 95, 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.