

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 23, 2022

Findings Date: September 23, 2022

Project Analyst: Gregory F. Yakaboski

Co-Signer: Mike McKillip

Project ID #: F-12225-22

Facility: Atrium Health Women's Care-Maternal Fetal Medicine Diagnostic Center

FID #: 220470

County: Mecklenburg

Applicant: Carolinas Physicians Network, Inc.

Project: Develop a new diagnostic center

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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 to be known as Atrium Health Women's Care-Maternal Fetal Medicine Diagnostic Center (MFM-Dx Cntr), to include existing and new ultrasound equipment, on Kenilworth Avenue in Charlotte.

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2022 State Medical Facilities Plan (SMFP).

- Acquire any medical equipment for which there is a need determination in the 2022 SMFP.
- Offer a new institutional health service for which there are any applicable policies in the 2022 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- (2) Repealed effective July 1, 1987.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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, CPN, proposes to develop a new diagnostic center, to include existing and new ultrasound equipment.

The sole member of CPN is Carolinas Health Network, Inc (CHN). The sole member of CHN is The Charlotte-Mecklenburg Hospital Authority (CMHA). CMHA does business as Atrium Health.

Carolinas Medical Center (CMC) currently operates the Atrium Health CMC Women's Institute (Women's Institute) in the Morehead Medical Plaza on CMC's campus. The Women's Institute is comprised of both CPN's Maternal Fetal Medicine (MFM) clinic [MFM-Clinic] and a Reproductive Endocrinology and Infertility (REI) clinic [REI-Clinic]. Neither the MFM-Clinic nor the REI-Clinic are currently diagnostic centers as that term is defined by N.C. Gen. Stat. 131E-176(7a).

The applicant, CPN, proposes to develop the new diagnostic center, MFM-Dx Cntr, by relocating nine existing ultrasound units (seven from the MFM-Clinic and two from the REI-Clinic) from the Woman's Institute to a new location, and, in addition, add one new ultrasound unit for a total of ten ultrasound units at the new location. The MFM-Clinic will become part of the proposed MFM-Dx Cntr. The MFM-Clinic is relocating in its entirety to the proposed MFM-Dx Cntr. The REI-Clinic will remain on CMC's campus and acquire two new ultrasound units. The new location will be leased space at 905 Kenilworth Avenue in Charlotte.

The MFM-Clinic is currently hospital-based. The MFM-Clinic will become non-hospital based when it relocates to the MFM-Dx Cntr.

Designation as a Diagnostic Center

N.C. Gen. Stat. 131E-176(7a) states:

“Diagnostic center. – a freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds one million five hundred dollars (\$1,500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than exceeds one million five hundred dollars (\$1,500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater...”

In Section C, page 28, the applicant states that the total cost of the existing and proposed medical diagnostic equipment which costs \$10,000 or more, and the cost of the required upfit, will exceed the statutory threshold of \$1,500,000. Therefore, the proposed MFM-Dx Cntr qualifies as a diagnostic center, which is a new institutional health service, and which requires a Certificate of Need (CON).

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2022 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section G.1, page 67, the applicant defines the service area for the proposed diagnostic center as Mecklenburg County. Facilities may also serve residents not included in their service area.

The proposed diagnostic center has no historical patient origin. However, there is an existing clinic that provides MFM ultrasound services. MFM-Clinic is not an existing service as defined by the Certificate of Need (CON) law. The existing MFM-Clinic shares space with a Reproductive Endocrinology and Infertility (REI) clinic. There are currently seven ultrasound units located at the MFM-Clinic and two ultrasound units located at the REI clinic. These nine ultrasound units are proposed to be relocated to the proposed new diagnostic center. The proposed diagnostic center is proposed to have ten ultrasound units, these relocated nine ultrasound units and one new ultrasound unit. The following table shows both the historical patient origin of the MFM-Clinic and the projected patient origin of the MFM-Dx Cntr in CY2026, the third year of operation, as provided in the table on page 33 of the application.

County	Existing MFM-Clinic Historical (CY 2021)		Proposed Diagnostic Center [MFM-Dx Cntr] Third Full FY of Operation following Project Completion (CY 2026)	
	Patients	% of Total	Patients	% of Total
Mecklenburg	4,901	69.6%	7,342	69.6%
Gaston	425	6.0%	637	6.0%
Union	384	5.5%	575	5.5%
Lincoln	211	3.0%	316	3.0%
York, SC	204	2.9%	306	2.9%
Cleveland	170	2.4%	255	2.4%
Cabarrus	153	2.2%	229	2.2%
Catawba	104	1.5%	156	1.5%
Iredell	95	1.3%	142	1.3%
Lancaster, SC	70	1.0%	105	1.0%
Other*	323	4.6%	484	4.6%
Total	7,040	100.0%	10,546	100.0%

Source: Section C.2, page 31 and Section C.3, page 33.

Totals may not sum due to rounding

Other*: The counties covered by "Other" are listed in full on pages 31 and 33 respectively.

In Section C.3, page 33, the applicant describes the assumptions and methodology used to project its patient origin, stating:

“Projected patient origin for the service component is based on historical patient origin for MFM ultrasound procedures performed at the existing MFM clinic. CPN does not expect the proposed relocation of the existing ultrasound equipment to impact patient origin. ... The CY 2021 ratio of procedures to patients is assumed to remain constant through the project years and is applied to projected procedures to derive projected patients... .”

The applicant’s assumptions are reasonable and adequately supported because they are based on the MFM-Clinic’s historical (CY 2021) patient origin experience for the diagnostic modality (ultrasound) that will be relocated to the proposed diagnostic center.

Analysis of Need

In Section C.4, pages 35-37, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below:

- Need for additional ultrasound unit and relocation of existing equipment drove the need to develop a diagnostic center.
- Population growth in Mecklenburg County.

The information is reasonable and adequately supported based on the following:

- The applicant documents the proposed ultrasound equipment is essential for serving the patients who are high-risk MFM patients who undergo an ultrasound at each physician visit.
- The MFM-Clinic experienced a growth rate increase of 19.5% from CY2020 to CY2021 in ultrasound procedures.
- The proposed new space will provide more clinical space allowing the proposed diagnostic center to provide more physician coverage for MFM patients.
- The new diagnostic center will be operated as a freestanding (non-hospital based) facility which can provide lower cost care. Currently, the MFM-Clinic operates as a hospital-based practice.
- The projected growth of 1.8% of the service area population is based on credible information from the North Carolina Office of State Budget and Management (NCOSBM).
- Based on NCOSBM data, in 2022, the female population of child-bearing years (ages 15-44) will be 249,115 or over 40% of the Mecklenburg County female population.

Projected Utilization

In Section Q, Form C.2b Utilization, the applicant provides the projected utilization for the medical diagnostic equipment for the first three years of operation following completion of the project, as summarized in the following table.

	Partial FY (5/1/23 to 12/31/23)	1st FFY (CY2024)	2nd FFY (CY2025)	3rd FFY (CY2026)
# of Ultrasound Units	10	10	10	10
# of Procedures	9,666	16,254	18,011	18,828
# of Procedure/Per Unit	967	1,625	1,801	1,883

In Section Q, Form C Utilization- Assumptions and Methodology, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

The MFM-Dx Cntr provides services to woman of child-bearing years (ages 15-44).

Based on NCOSBM data the population cohort of females aged 15-44 is projected to grow 1.4% between 2021 and 2026.

The applicant, starting with the last full year for which historical data is available, 2021, grows MFM ultrasound procedures by 1.4% from CY2021 to CY2026 (the 3rd Project Year) as shown in the table below:

	CY2021	CY2022	CY2023	CY2024	CY2025	CY2026	CAGR
Ultrasound Procedures	12,569	12,747	12,928	13,112	13,298	13,486	1.4%

In addition, the MFM-Dx Cntr is projecting to add a physician. In CY2021 the average procedures per physician was 6,285 (12,569 ultrasound procedures/ 2 physicians = 6,285).

Starting in CY2023 the applicant projects adding a third (3rd) physician and “ramps up” the number of ultrasound procedures to be performed by the 3rd physician projecting 25%; 50%; 75% and 85% respectively for CY2023 through CY2026 as shown in the table below.

	CY2023	CY2024	CY2025	CY2026
Average Ultrasound Procedures per Physician	6,285	6,285	6,285	6,285
“Ramp Up” of 3 rd Physician	25%	50%	75%	85%
Incremental Procedures per by 3 rd Physician	1,571	3,142	4,713	5,342

The applicant then totals the projected growth of ultrasound procedures and the incremental procedures by a 3rd physician to determine total projected ultrasound procedures for the first three project years (CY2024 – CY2026) as shown in the table below:

	CY2023*	CY2024	CY2025	CY2026
Projected Ultrasound Procedures bases on 1.4% growth	8,619*	13,112	13,298	13,486
Incremental Procedures per by 3 rd Physician	1,571	3,142	4,713	5,342
Total projected ultrasound procedures	9,666	16,254	18,011	18,828

*Volumes adjusted to account for a projected May 1, 2023 start date for the proposed MFM-Dx Cntr.

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

- Projected utilization is based on historical experience of MFM-Clinic combined with the projected population growth (1.4%) of females of childbearing years in Mecklenburg County.
- In the MFM-Clinic the number of ultrasound procedures performed from CY2020 to CY2021 increased at a rate of 19.5%.
- Projected incremental procedures performed by a 3rd physician for the third project year (CY2026) are only projected at 85% of the average number of ultrasound procedures performed by physicians at the MFM-Clinic during CY2021.
- The MFM-Dx Cntr is to be located only a short distance from the existing MFM-Clinic and the MFM-Dx Cntr will be non-hospital based as opposed to the MFM-Clinic which is hospital-based meaning that the MFM-Dx Cntr will offer the same services at a lower cost to patients.
- Exhibit I.2 contains copies of letters of support for the proposed project.

Access to Medically Underserved Groups

In Section, C.6, page 44, the applicant states,

“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.”

On page 45, the applicant provides the estimated percentage for the following medically underserved groups at the proposed diagnostic center, as shown in the following table.

Medically Underserved Groups	Estimated Percentage of Total Services in Year 3
Low income persons*	na
Racial and ethnic minorities	32.9%
Women	100.0%
Persons with disabilities*	na
Persons 65 and over	0.1%
Medicare	0.6%
Medicaid	31.7%

Source: Table on page 45 of the application.

*Data is not maintained regarding the number of low income or disabled persons served.

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

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, are likely to have access to the proposed services.

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

C

The applicant, CPN, proposes to develop a new diagnostic center, to include existing and new ultrasound equipment.

In Section D, page 51, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 51, the applicant states:

“The MFM ultrasound service to be relocated to the proposed diagnostic center along with the MFM physician clinic will not continue to be offered at its existing location and the patients historically served by the equipment are expected to relocate to the proposed diagnostic center on Kenilworth Avenue, which is less than one-half mile from Morehead Medical Plaza.”

The information is reasonable and adequately supported based on the following:

- The MFM-Clinic is simply being relocated, in its entirety, approximately one-half mile down the street.
- The MFM-Clinic is currently hospital-based. It is being relocated to a proposed diagnostic center which will be non-hospital based which means that patients will have access to the same services at a lower cost.
- The new diagnostic center will allow, space wise, for increased physician coverage and, in addition will have more ultrasound units with the ability to increase the capacity of the ultrasound units while providing increased patient access in a more convenient location.
- The patients historically served by the current MFM-Clinic are expected to relocate to the proposed diagnostic center.

Access to Medically Underserved Groups

In Section D, page 52, the applicant states,

“The proposed project will not have any negative impact on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, or other underserved groups to obtain needed healthcare.”

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use MFM ultrasound services will be adequately met following completion of the project for the following reasons:

- The MFM ultrasound are specialized and given the close proximity of the existing MFM-Clinic to the new Kenilworth location combined with the fact that the MFM Clinic is moving to the MFM-Dx Cntr patients historically served by the MFM-Clinic are expected to relocate to the proposed diagnostic center.

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 needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
 - The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.
- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant, CPN, proposes to develop a new diagnostic center, to include existing and new ultrasound equipment.

In Section E, pages 55-56, 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 alternative would be less effective because maintaining the status quo would not account either the need to accommodate the increasing patient demand or the ability to provide lower-cost care in a freestanding setting operated by CPN. Therefore, the applicant determined that this alternative is less effective.
- Develop a different number of ultrasound units – The applicant states that the proposed ten ultrasound units, along with the room provided by the new location to accommodate additional physicians would adequately meet the projected patient needs. Therefore, the applicant determined that having more than ten ultrasound units at the proposed diagnostic center is not the most effective alternative.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Carolinas Physicians Network, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a new diagnostic center by relocating nine units of ultrasound equipment and acquiring one additional unit of ultrasound equipment, as designated in the application.**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on January 1, 2023.**
- 4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 5. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder 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.**

7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant, CPN, proposes to develop a new diagnostic center, to include existing and new ultrasound equipment.

Capital and Working Capital Costs

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

Construction/Renovation	\$306,600
Architect/Engineering Fees	\$135,460
Medical Equipment	\$1,196,948
Misc (Furniture, Consultant Fees, IS, Security, Internal Allocation)	\$136,380
Total	\$1,775,388

In Section Q, the applicant provides the assumptions used to project the capital cost. Exhibit F.1 contains supporting documentation. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Building renovation costs and architect/engineering fees are based on the letter from the architect in Exhibit F.1.
- Medical equipment costs are based on vendor estimates and CPN experience with similar projects.
- Internal allocation, consultant fees, security and furniture costs are based on CPN experience with other similar projects.

In Section F, pages 59-60, the applicant projects \$259,557 in start-up expenses and \$253,489 in initial operating expenses for total working capital expenses of \$495,046. On pages 59-60, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the information regarding projected start-up costs and initial operating expenses provided on pages 59-60 of the application.

Availability of Funds

In Section F, pages 57 and 60, the applicant states that the capital and working capital cost, respectively, will be funded by the cash reserves of CPN, as shown in the tables below.

Sources of Capital Financing

Type	Carolinas Physicians Network, Inc.
Loans	
Accumulated reserves or OE *	\$1,775,388
Bonds	
Other (Specify)	
Total Financing	\$1,775,388

* OE = Owner's Equity

Sources of Working Capital Financing

Type	Carolinas Physicians Network, Inc.
Loans	
Accumulated reserves or OE *	\$495,046
Bonds	
Other (Specify)	
Total Financing	\$495,046

* OE = Owner's Equity

In Exhibit F.2-1, the applicant provides a letter dated June 15, 2022, from the Executive Vice President and Chief Financial Officer for CMHA and Treasurer of CPN documenting that CMHA will provide the funds for the capital and working capital costs of the project and that CPN commits to utilizing the funds provided by CMHA for the proposed project.

Exhibit F.2-2 contains a copy of the audited financials of CMHA showing Cash and Cash Equivalents of \$799,598,000 as of December 31, 2021.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the documentation provided in Section F and Exhibits F.2-1 and F.2-2, as described above.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of this project. In Section Q, Form F.2, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as summarized in the table below.

	1st Full FY CY2024	2nd Full FY CY2025	3rd Full FY CY2026
Total Procedures	16,254	18,011	18,828
Total Gross Revenues (Charges)	\$7,516,195	\$8,578,601	\$9,236,815
Total Net Revenue	\$3,064,513	\$3,497,678	\$3,766,046
Average Net Revenue per Procedure	\$189	\$194	\$200
Total Operating Expenses (Costs)	\$2,386,176	\$2,488,695	\$2,574,144
Average Operating Expense per Procedure	\$147	\$138	\$137
Net Income	\$678,336	\$1,008,984	\$1,191,902

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

The applicant, CPN, proposes to develop a new diagnostic center, to include existing and new ultrasound equipment.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2022 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section G.1, page 67, the applicant defines the service area for the proposed diagnostic center as Mecklenburg County. Facilities may also serve residents not included in their service area.

In Section G.1, page 67, the applicant states,

“CPN is not aware of a public data source that provides an inventory of all existing and approved non-hospital facilities located in Mecklenburg County that provide the service proposed in this project.”

On page 67, the applicant lists the existing and approved hospitals in the service area which provide ultrasound services. In Exhibit G.1, the applicant provides the total annual utilization reported by the existing hospitals in Mecklenburg County for diagnostic services based on 2022 Hospital License Renewal Applications (HLRA). On page 68 the applicant lists the existing and approved diagnostic centers in Mecklenburg County that are owned or operated by CMHA or a related entity, including CPN, its physician partner.

In Section G, page 68, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved ultrasound diagnostic services in Mecklenburg County. The applicant states:

“The need for the proposed project is based on the growing patient demand for diagnostic services at the current MFM clinic located in the Moorhead Medical Plaza on CMC’s campus. CMHA and CPN have determined that there is a need to relocate and expand this clinic in order to accommodate the increasing patient demand as well as provide lower-cost care in a freestanding setting operated by CPN. 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 clinic’s MFM physicians. As mentioned previously, the clinic’s patients are high-risk MFM patients and, as such, receive an ultrasound procedure as part of their physician visit.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The applicant adequately demonstrates that the proposed diagnostic center is needed in addition to the existing or approved diagnostic centers in the service area to meet the identified need.

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 all the reasons described 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

The applicant, CPN, proposes to develop a new diagnostic center, to include existing and new ultrasound equipment.

In Section Q, Form H, the applicant provides the projected full-time equivalent (FTE) positions for the proposed diagnostic services at MFM-Dx Cntr, as shown in the table below.

Position	Projected FTE Positions 3rd Full FY - CY2026
Radiology Technologists	11.0
TOTAL	11.0

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 Sections H.2 and H.3, pages 70-71, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the information provided in Section H, pages 70-71, and in Section Q, Form H, as described above.

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

The applicant, CPN, proposes to develop a new diagnostic center, to include existing and new ultrasound equipment.

Ancillary and Support Services

In Section I.1, page 72, the applicant identifies the necessary ancillary and support services for the proposed services. On page 73, the applicant explains how each ancillary and support service is or will be made available. The applicant states,

“Please see Exhibit I.1 for a letter from Scott Rissmiller, MD, President of CPN, verifying the availability of the ancillary and support service for the proposed Atrium Health Women’s Care-MFH.”

The letter from the President of CPN states,

“The ancillary and support services needed to support the proposed project include, but are not limited to, administration, registration and billing, information technology, medical records, and housekeeping. Each of these services will be provided through the building lease or directly by CPN staff.”

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the information provided in Section I.1, and Exhibit I.1, as described above.

Coordination

In Section I.2, page 73, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant states,

“As part of CMHA, CPN has established relationships with area healthcare providers. CMHA’s and CPN’s relationship with other local healthcare and social service providers are well established and will continue following completion of the proposed project. By way of example, please note that the MFM clinic works closely with other primary Ob/Gyn and family medicine clinics in surrounding communities to manage the pregnancies of high-risk patients. ... In addition, MFM providers also work closely with local health departments in the market to co-manage pregnant patients in the community and coordinate deliveries at the appropriate facilities.”

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2 and Exhibit I.2, as described above.

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 all the reasons described above.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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

C

The applicant, CPN, proposes to develop a new diagnostic center, to include existing and new ultrasound equipment.

In Section K.1, page 76, the applicant states that the project involves renovation of 140 square feet of leased medical office space. Line drawings are provided in Exhibit C.1-1.

On pages 79-80, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibits C.1-1 and C.1-2. The site appears to be suitable for the proposed facility based on the applicant's representations and supporting documentation.

In Section K.3, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information and representations made by the applicant on page 77 of the application.

In Section K.3, 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 based on the information and representations made by the applicant on page 77 of the application.

On pages 77-78, 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 for all the reasons described above.

- (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 ... persons [with disabilities], 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

The proposed diagnostic center will be a new facility and does not have any past performance.

However, in Section L, page 82, the applicant provides the historical payor mix for the existing MFM-Clinic during the last full FY (CY2021) for the proposed services, as shown in the table below.

Payor Category	Percentage of Total Patients Served
Self-Pay	15.5%
Medicare*	0.6%
Medicaid*	31.7%
Insurance*	51.6%
Other (includes Worker Comp & TRICARE)	0.6%
Total	100.0%

Source: Table on page 82 of the application.

*Including any managed care plans.

In Section L, page 83, the applicant provides the following comparison.

Existing MFM-Clinic	Percentage of Total Patients Served during the Last Full FY	Percentage of the Population of the Service Area
Female	100.0%	51.9%
Male	0.0%	48.1%
Unknown	0.0%	0.0%
64 and Younger	99.9%	88.5%
65 and Older	0.1%	11.5%
American Indian	0.3%	0.8%
Asian	4.1%	6.3%
Black or African American	27.1%	33.0%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	36.3%	57.3%
Other Race	1.3%	2.5%
Declined / Unavailable	30.8%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the 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 persons with disabilities 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 84, the applicant states,

“CPN is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities. However, ... as part of CMHA, CPN provides and will continue to provide services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment.”

In Section L, page 84, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against CPN or any related entity of CMHA.

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 85, the applicant projects the payor mix for the proposed diagnostic center during the third full fiscal year (CY2026) of operation following completion of the project, as shown in the table below.

Payor Category	Percentage of Total Patients Served
Self-Pay	15.5%
Medicare*	0.6%
Medicaid*	31.7%
Insurance*	51.6%
Other (includes Workers Comp and TRICARE)	0.6%
Total	100.0%

*Including any managed care plans

Note: CMHA internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 15.5% of total ultrasound services will be provided to self-pay patients, 0.6% to Medicare patients and 31.7% to Medicaid patients.

On page 84, the applicant provides the assumptions and methodology used to project payor mix during the first three years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's proposed patient payor mix is based on CPN's historical experience providing the proposed services at its existing MFM-Clinic.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (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 87, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant, CPN, proposes to develop a new diagnostic center, to include existing and new ultrasound equipment.

In Section M.1, page 88, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the information provided in Section M, page 88, and Exhibit M.1, as described above.

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 all the reasons described above.

- (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, CPN, proposes to develop a new diagnostic center, to include existing and new ultrasound equipment.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives*

services from a health service facility.” The 2022 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section G.1, page 67, the applicant defines the service area for the proposed diagnostic center as Mecklenburg County. Facilities may also serve residents not included in their service area.

In Section G.1, page 67, the applicant states, *“CPN is not aware of a public data source that provides an inventory of all existing and approved non-hospital facilities located in Mecklenburg County that provide the service proposed in this project.”* On page 67, the applicant lists the existing and approved hospitals in the service area which provide ultrasound services. In Exhibit G.1, the applicant provides the total annual utilization reported by the existing hospitals in Mecklenburg County for diagnostic services based on 2022 Hospital License Renewal Applications (HLRA). On page 68 the applicant lists the existing and approved diagnostic centers in Mecklenburg County that are owned or operated by CMHA or a related entity, including CPN, its physician partner.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 90, the applicant states:

“The proposed project will 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:

“As a physician-based service, the proposed diagnostic center will provide services at a lower out-of-pocket cost to most patients. Insurance companies categorize hospital-based services in a higher tier than they do physician-based services, meaning the patient’s out-of-pocket expenses are lower when receiving physician-based care. Further, the proposed diagnostic center, as part of a larger CMHA system, benefits from significant cost savings measures through the consolidation of multiple services and large economies of scale.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, pages 90-91, the applicant states,

“CMHA, including, CPN is dedicated to providing the highest quality care and is continually recognized locally and nationally for its commitment to delivering efficient, quality care. ... CPN always strives to provide quality care; as such, Atrium Health Medical Group has in place a Quality Assessment and Performance Improvement Plan, Exhibit O.1-1, as well as a Quality Oversight Committee (QOC) Plan, Exhibit O.1-2, which are utilized by CPN.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 91, the applicant states:

“The proposed project will improve access to MFM diagnostic services in Mecklenburg County, including those who are medically underserved. CMHA ... historically has provided services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay as demonstrated in CMHA’s Non-Discrimination Policies, provided in Exhibit C.6.”

See also Section L and C of the application and any exhibits.

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, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrates: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

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 based on 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.

C

The applicant, CPN, proposes to develop a new diagnostic center, to include existing and new ultrasound equipment.

On Form O in Section Q, the applicant identifies all other diagnostic centers, including hospitals, in North Carolina owned, operated, or managed by the applicant or a related entity.

The applicant identifies a total of 21 diagnostic centers and 23 hospitals located in North Carolina.

In Section O, page 95, the applicant states:

“Each of the facilities identified in Form O 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 diagnostic centers identified in Form O, 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.

G.S. 131E-183 (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, CPN, proposes to develop a new diagnostic center to include existing and new ultrasound equipment.

The Criteria and Standards for Diagnostic Centers were repealed, effective March 16, 2017. The project does not involve any other regulated medical diagnostic equipment for which there are applicable Criteria and Standards. Therefore, there are no performance standards applicable to this review.