

## 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-12226-22

Facility: Atrium Health Imaging-Kenilworth Diagnostic Center

FID #: 220471

County: Mecklenburg

Applicants: Carolinas Physicians Network, Inc.

The Charlotte-Mecklenburg Hospital Authority

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.

### C

Carolinas Physicians Network, Inc. (CPN) and The Charlotte-Mecklenburg Hospital Authority (CMHA) hereinafter referred to as “CPN” or “the applicant”, proposes to develop a new diagnostic center to be known as Atrium Health Imaging- Kenilworth Diagnostic Center, (Kenilworth-Dx Cntr #2) at 1237 Harding Place in Charlotte.

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.

## **Need Determination**

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).

## **Policies**

There is one policy in the 2022 SMFP applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

**Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities**, on pages 30-31 of the 2022 SMFP, states:

*“Any person proposing a capital expenditure greater than \$4 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN 4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy-GEN 4. The plan shall not adversely affect patient or resident health, safety, or infection control.”*

The capital expenditure of the project is over \$4 million dollars. In Section B, pages 28-29, the applicant describes its plan to assure improved energy efficiency and water conservation.

## **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 based on the following:

- The applicant does not propose to develop any beds or services for which there is a need determination in the 2022 SMFP.
- The applicant adequately demonstrates that the proposal is consistent Policy GEN-4 based on the following:
  - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

- (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 MRI scanners, CT scanner, x-ray, ultrasound, nuclear medicine camera and echocardiogram.

In Section A, pages 23-24, and in Section C, pages 30-34, the applicant describes the proposed project as follows:

There is a medical office building (MOB #1) with four floors located at 1237 Harding Place in Charlotte. CPN currently operates a non-hospital licensed diagnostic center at this location known as Atrium Health Kenilworth Diagnostic Center #1 (Kenilworth-Dx Cntr #1). This existing diagnostic center encompasses both the 2<sup>nd</sup> and 4<sup>th</sup> floors of MOB#1 and is has existing diagnostic equipment on both the 2<sup>nd</sup> and the 4<sup>th</sup> floor of the MOB #1.

Kenilworth-Dx Cntr #1 (Project ID #F-11700-19) was issued a certificate on August 20, 2019. CPN, in Project ID# F-11760-19, was approved to add a fixed MRI scanner to Kenilworth-Dx Cntr #1. A certificate for Project ID #F-11760-19 was issued in February 28, 2020. Kenilworth-Dx Cntr #1 started offering services, including fixed MRI services on April 5, 2021. Kenilworth-Dx Cntr #1 provides cardiac MRI services.

The purpose of this application is to divide the existing Kenilworth-Dx Cntr #1 into two separate licensed diagnostic centers. One diagnostic center would be located exclusively on the 2<sup>nd</sup> floor and the other diagnostic center would be located exclusively on the 4<sup>th</sup> floor. This application is to create a new diagnostic center, solely encompassing the 2<sup>nd</sup> floor of MOB #1, including all the existing diagnostic equipment on the 2<sup>nd</sup> floor, to be known as Kenilworth-Dx Cntr #2.

Upon project completion, the existing diagnostic center, Kenilworth-Dx Cntr #1, will be solely located on the 4<sup>th</sup> floor of MOB #1.

The existing equipment on the 2<sup>nd</sup> floor of MOB #1 consists of: CT scanner (1), fixed MRI scanner (1), X-Ray (1), ultrasound (1), nuclear medicine camera (1), and echocardiogram units (9). This existing equipment would remain on the 2<sup>nd</sup> floor and be included as part of the new Kenilworth diagnostic center. In addition, as part of this application, an existing fixed MRI scanner currently located at Carolinas Medical Center (CMC) would be replaced and relocated to Kenilworth-Dx Cntr #2. This fixed MRI scanner will be the only new piece of equipment added to the existing equipment currently located on the 2<sup>nd</sup> floor of MOB #1 as part of the existing Kenilworth-Dx Cntr #1.

	Existing Equipment on 2 <sup>nd</sup> Floor of MOB #1*	New Equipment	Total Equipment Upon Project Completion in Kenilworth-Dx Cntr #2 on 2 <sup>nd</sup> Floor of MOB #1**
MRI	1	1	2
CT Scanner	1	0	1
X-ray	1	0	1
Ultrasound	1	0	1
Nuclear Medicine Camera	1	0	1
Echocardiogram	9	0	9

\*Currently part of existing diagnostic center- Kenilworth-Dx Cntr #1.

\*\* Equipment in new diagnostic center, Kenilworth-Dx Cntr #2, upon project completion.

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, pages 27-28, the applicant states that the total cost of the existing and proposed medical diagnostic equipment which costs \$10,000 currently located on the 2<sup>nd</sup> floor of MOB#1 combined with the MRI scanner to be replaced and relocated to the 2<sup>nd</sup> floor of MOB#1 will exceed the statutory threshold of \$1,500,000. Therefore, Kenilworth-Dx Cntr #2

qualifies as a diagnostic center, which is a new institutional health service, and which requires a Certificate of Need (CON).

### **Patient Origin**

#### *Diagnostic Center Service Area*

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. 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.

#### *Fixed MRI scanner Service Area*

On page 341, the 2022 SMFP states:

*“A fixed MRI’s **service area** is the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1”.*

Figure 5.1 on page 38 of the 2022 SMFP shows Mecklenburg County as a single acute care bed service area. Therefore, for the purpose of this review, the fixed MRI service area is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

Kenilworth-Dx Cntr #2 is not an existing facility. However, except for a fixed MRI scanner which will be replaced and relocated from CMC to the proposed diagnostic center the applicant does have the historic patient origin for the equipment on the 2<sup>nd</sup> floor of Kenilworth-Dx Cntr #2, including fixed MRI services which is provided. Historical and projected patient origin for MRI service only is also provided. The location of the existing fixed MRI at CMC to be relocated to Kenilworth-Dx Cntr #2 and Kenilworth-Dx Cntr #2 are less than one-half mile apart. The following tables illustrate historical and projected patient origin.

County	Existing Kenilworth-Dx Cntr #1 (2 <sup>nd</sup> Floor Imaging Modalities) Historical (4/5/2021 to 12/31/2021)		Proposed Diagnostic Center Third Full FY of Operation following Project Completion (CY 2026)	
	Patients	% of Total	Patients	% of Total
Mecklenburg	3,445	45.9%	6,004	45.8%
York, SC	870	11.6%	1,526	11.6%
Gaston	491	6.5%	865	6.6%
Union	462	6.2%	781	6.0%
Lincoln	270	3.6%	410	3.1%
Cabarrus	267	3.6%	524	4.0%
Cleveland	254	3.4%	442	3.4%
Lancaster, SC	254	3.4%	405	3.1%
Iredell	208	2.8%	352	2.7%
Stanly	134	1.8%	294	2.2%
Catawba	117	1.6%	192	1.5%
Other*	738	9.8%	1,308	10.0%
Total	7,510	100.0%	13,105	100.0%

Source: Section C.2, page 37 and Section C.3, page 40.

Totals may not sum due to rounding.

\*Other: The counties covered by "Other" are listed in full on pages 37 and 40 respectively.

**MRI Service Only: Kenilworth-Dx Cntr #1-Historical**

County	Existing Kenilworth-Dx Cntr #1 Historical (4/5/2021 to 12/31/2021)	
	Patients	% of Total
Mecklenburg	844	45.7%
York, SC	217	11.8%
Gaston	124	6.7%
Union	104	5.6%
Cabarrus	88	4.8%
Cleveland	62	3.4%
Stanly	56	3.0%
Lancaster, SC	48	2.6%
Iredell	47	2.5%
Lincoln	43	2.3%
Rowan	25	1.4%
Catawba	24	1.3%
Other*	164	8.9%
Total	1,846	100.0%

Source: Section C.2, page 35.

Totals may not sum due to rounding.

\*Other: The counties covered by "Other" are listed in full on page 35.

**MRI Service Only: CMC-Historical**

County	CMC Historical (CY2021)	
	Patients	% of Total
Mecklenburg	8,422	59.8%
Gaston	922	6.5%
York, SC	881	6.3%
Union	690	4.9%
Cabarrus	396	2.8%
Cleveland	359	2.5%
Lancaster, SC	326	2.3%
Lincoln	288	2.0%
Iredell	170	1.2%
Catawba	157	1.1%
Other*	1,482	10.5%
Total	14,093	100.0%

Source: Section C.2, page 36.

Totals may not sum due to rounding.

\*Other: The counties covered by "Other" are listed in full on page 36.

**MRI Service: Kenilworth-Dx Cntr #2 - Projected**

County	1 <sup>st</sup> FFY (CY2024)		2 <sup>nd</sup> FFY (CY2025)		3 <sup>rd</sup> FFY (CY2026)	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Mecklenburg	1,929	45.7%	2,064	45.7%	2,210	45.7%
York, SC	496	11.8%	531	11.8%	568	11.8%
Gaston	283	6.7%	303	6.7%	325	6.7%
Union	238	5.6%	254	5.6%	272	5.6%
Cabarrus	201	4.8%	215	4.8%	230	4.8%
Cleveland	142	3.4%	152	3.4%	162	3.4%
Stanly	128	3.0%	137	3.0%	147	3.0%
Lancaster, SC	110	2.6%	117	2.6%	126	2.6%
Iredell	107	2.5%	115	2.5%	123	2.5%
Lincoln	98	2.3%	105	2.3%	113	2.3%
Rowan	57	1.4%	61	1.4%	65	1.4%
Catawba	55	1.3%	59	1.3%	63	1.3%
Other*	375	8.9%	401	8.9%	429	8.9%
Total	4,218	100.0%	4,515	100.0%	4,833	100.0%

Source: Section C.3, page 38.

Totals may not sum due to rounding.

\*Other: The counties covered by "Other" are listed in full on page 36.

In Section C.3, page 39, the applicant describes the assumptions and methodology used to project its patient origin, stating:

*“...each of the medical diagnostic services to e provided at Atrium Health Imaging-Kenilworth Diagnostic Center is currently provided as part of the existing diagnostic center, Atrium Health Kenilworth Diagnostic Center #1. Projected patient origin for the facility .... Is based on historical patient origin for procedures performed at Atrium Health Kenilworth Diagnostic Center #1 on the medical diagnostic equipment that is located on the second floor and will be included in Atrium Health Imaging-Kenilworth Diagnostic Center. The replacement and relocation of an existing fixed MRI scanner from CMC and the subsequent increase in MRI utilization at Kenilworth results in an insignificant change in projected patient origin for the entire facility.”*

The applicant’s assumptions are reasonable and adequately supported because they are based on the applicant’s historical patient origin experience for the diagnostic modalities that will be included in the proposed diagnostic center.

### **Analysis of Need**

In Section C.4, pages 41-44, 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 fixed MRI capacity with cardiac capabilities at the proposed diagnostic center.
- Allow CPN to reorganize its medical diagnostic equipment located at the Atrium Health Kenilworth campus in MOB#1 into two separate diagnostic centers.
- Population growing in Mecklenburg County, particularly growth in the age 65+ population cohort.

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

- The applicant documents that there is excess demand for fixed cardiac MRI services at the existing Kenilworth-Dx Cntr #1. In the first four months of 2022 the fixed MRI scanner performed more cardiac MRI scans than in the last nine months of operation in 2021.
- The applicant states that current patient backlog at Kenilworth-Dx Cntr #1 for cardiac MRI scans is three to four weeks out. This negatively impacts patient care.
- Additional cardiac MRI capacity at the diagnostic center allows decompression of the highly used MRI’s at CMC, thus freeing up much needed hospital- based MRI capacity.
- The existing Kenilworth-Dx Cntr #1 and the proposed Kenilworth-Dx Cntr #2 are, and will be, non-hospital based diagnostic centers which provide services at a lower out-of-pocket cost for most patients.
- The proposed diagnostic center also provides better patient access in terms of parking and separation from the congested healthcare campus.
- Currently, while one diagnostic center, the 2<sup>nd</sup> floor at MOB#1 functions as a comprehensive outpatient imaging center while the 4<sup>th</sup> floor at MOB#1 has equipment more specialized to the clinics in which they are located. Reorganizing the 2<sup>nd</sup> and 4<sup>th</sup>



floors of MOB#1 into two separate diagnostic centers permits more efficient functionality, operation and patient focus.

- The projected growth of the service area population is based on credible information from the North Carolina Office of State Budget and Management (NCOSBM). From 2022 to 2026, Mecklenburg County is projected to grow at 1.8% while the percent of the overall population of Mecklenburg County that is in the 65+ age cohort is projected to increase from 12.6% to 14.0% an increase of just over 28,000 people. Typically, older residents utilize healthcare services at a higher rate.
- The applicant provides letters of support to document the need for the proposed imaging services in Exhibit I.2.

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.

*MRI Scanners*

Projected Utilization: MRI Scanners

	<b>1<sup>st</sup> Full FY CY2024</b>	<b>2<sup>nd</sup> Full FY CY2025</b>	<b>3<sup>rd</sup> Full FY CY2026</b>
# of MRI Scanner	2	2	2
# of Unweighted Scans	4,460	4,774	5,110
# of Weighted Scans	6,083	6,511	6,969
# of Weighted Scan per Scanner	3,041.5	3,255.5	3,484.5

*Other Diagnostic Equipment*

**Projected Utilization: Other Diagnostic Equipment**

	<b>1<sup>st</sup> Full FY CY2022</b>	<b>2<sup>nd</sup> Full FY CY2023</b>	<b>3<sup>rd</sup> Full FY CY2024</b>
<b>CT Scanner</b>			
# Units	1	1	1
# Scans	6,962	6,962	6,962
# of HECT Units	12,816	12,816	12,816
<b>Fixed X-Ray</b>			
# Units	1	1	1
# Procedures	1,443	1,470	1,496
<b>Nuclear Medicine</b>			
# Units	1	1	1
# Procedures	868	868	868
<b>Ultrasound</b>			
# Units	1	1	1
# Procedures	1,586	1,615	1,645
<b>Echocardiogram</b>			
# Units	1	1	1
# Procedures	8,749	8,908	9,071

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

*MRI Scanners*

**Historical and Projected Fixed MRI Scanners at MOB#1**

	<b>Year to Date CY2022*</b>	<b>Interim CY2023</b>	<b>1<sup>st</sup> FFY CY2024</b>	<b>2<sup>nd</sup> FFY CY2025</b>	<b>3<sup>rd</sup> FFY CY2026</b>	<b>CAGR</b>
Total weighted scans	5,310	5,683	6,083	6,511	6,969	7.0%
# of MRI scanners	1	1	2	2	2	
# of weighted scans per scanner	5,310	5,683	3,041.5	3,255.5	3,484.5	

\*Annualized based on the last six months of historical data (November 2021 – April 2022) from Kenilworth-Dx Cntr #1. The project analyst notes that the footnote for this table states that it was based on the first four months of data from January – April 2022, the most recent data available. However, annualized, the first four months of data totals 5,878 weighted scans. The 5,310 weighted scans is a more conservative baseline.

The project analyst notes that the table above reflects the historical and projected utilization for the fixed MRI scanner(s) at MOB#1; initially Kenilworth-Dx Cntr #1 and then Kenilworth-Dx Cntr #2.

Projected utilization is based on a projected growth rate of 7.0% for weighted cardiac scans is 25% (28/4 = 7) of the actual growth rate of 28.1% based on the combined growth rate for weighted cardiac MRI scans from CY2019-CY2021 performed at CMC and Kenilworth-Dx Cntr #1 as shown in the table below.

	<b>CY2019</b>	<b>CY2020</b>	<b>Partial CY2021*</b>	<b>Year to Date CY2022**</b>	<b>CAGR</b>
CMC	2,113	1,913	1,353	486	
Kenilworth-Dx Cntr #1	0	0	2,117*	1,959**	
Total Weighted Cardiac Scans	2,113	1,913	3,470	2,444	28.1%

\*Represents the actual data from April-December 2021, the nine months during which the MRI scanner at Kenilworth-Dx Cntr #1 was operational. The diagnostic center started offering services on April 5, 2021.

\*\*Annualized based on the first four months of data from CY2022.

### Other Diagnostic Equipment

	<b>Year to Date CY2022*</b>	<b>Interim CY2023</b>	<b>1<sup>st</sup> FFY CY2024</b>	<b>2<sup>nd</sup> FFY CY2025</b>	<b>3<sup>rd</sup> FFY CY2026</b>	<b>CAGR</b>
CT (Procedures)	6,962	6,962	6,962	6,962	6,962	0.0%
CT (HECT units)	12,816	12,816	12,816	12,816	12,816	0.0%
X-Ray	1,392	1,417	1,443	1,470	1,496	1.8%
Echocardiogram	8,438	8,592	8,749	8,908	9,071	1.8%
Nuclear Medicine Camera	868	868	868	868	868	0.0%
Ultrasound	1,530	1,558	1,586	1,615	1,645	1.8%

\*CY2022 was estimated by annualizing actual utilization experienced during the most recent six months of operation for which data is available.

- The CT scanner was held with no projected growth as it has reached maximum capacity.
- The nuclear medicine camera was projected to remain flat as cardiac CT and cardiac MRI become the standard cardiac diagnostic imaging tool.
- The X-Ray, Echocardiogram and Ultrasound units were projected to grow at the rate of projected population growth of Mecklenburg County

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

- Projected utilization is based on historical experience of Kenilworth-Dx Cntr #1 and CMC.

- The applicant documents that cardiac MRI scans can and are being performed on an outpatient basis at the non-hospital licensed diagnostic center, Kenilworth-Dx Cntr #1.
- CMC has historically shifted cardiac MRI scans to Kenilworth-Dx Cntr #1.
- The existing Kenilworth-Dx Cntr #1 and the proposed Kenilworth-Dx Cntr #2 are, and will be, non-hospital based diagnostic centers which provide services at a lower out-of-pocket cost for most patients as compared to the hospital-based service at CMC.
- The proposed diagnostic center also provides better patient access in terms of parking and separation from the congested healthcare campus.
- Exhibit I.2 contains copies of letters of support for the proposed project.
- Projected overall population increases and population increases in the 65+ age cohort in Mecklenburg County based on data from the NCOSBM support increases in the utilization of diagnostic imaging services.
- The project analyst notes that except for the MRI scanner being replaced and relocated approximately one-half mile from CMC to Kenilworth-Dx Cntr #2 at MOB#1 all of the other diagnostic imaging equipment, including an MRI scanner, was part of an approved and operational diagnostic center, Kenilworth-Dx Cntr #1, and was not being moved.

### **Access to Medically Underserved Groups**

In Section, C.6, page 51, 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 52, the applicant provides the estimated percentage for the following medically underserved groups at the proposed diagnostic center, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Estimated Percentage of Total Services in Year 3</b>
Low income persons*	na
Racial and ethnic minorities	20.0%
Women	48.4%
Persons with disabilities*	na
Persons 65 and over	41.9%
Medicare	43.5%
Medicaid	5.2%

Source: Table on page 52 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 MRI scanners, CT scanner, x-ray, ultrasound, nuclear medicine camera and echocardiogram.

The applicant, as part of the proposed project, plans on replacing and relocating an existing fixed MRI scanner from CMC to the proposed diagnostic center.

In Section D, page 58, 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 58, the applicant states:

*“The proposed project will not result in any reduction of existing, operational MRI capacity at CMC. Patients today are served by CMC’s four existing fixed MRI scanners and will continue to be served by the same four existing fixed MRI scanners following development of this project. ... CPN expects to meet the growing demand for cardiac MRI services at Atrium Health Imaging-Kenilworth Diagnostic Center rather than those patients being directed to CMC.”*

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

- CMC and Kenilworth-Dx Cntr #1 are ultimately controlled by the same entity.

- Kenilworth-Dx Cntr #1 started providing services, including fixed cardiac MRI services, on April 5, 2021. CMC started shifting cardiac MRI patients from CMC to Kenilworth-Dx Cntr #1 immediately upon the opening of the diagnostic center.
- CMC currently operates four fixed MRI scanners and was approved to acquire a fifth fixed MRI scanner pursuant to Project ID#F-12117-21. The fifth fixed MRI scanner was scheduled to offer services in CY2021. CPN also has one fixed MRI scanner at Kenilworth-Dx Cntr #1 for a total of six existing or approved fixed MRI scanners between CMC and CPN.
- CMC has filed a material compliance letter concurrently with this application to, in essence, use the approved “fifth fixed MRI scanner” to take the place of the fixed MRI scanner being relocated from CMC to the proposed diagnostic center such that upon project completion and approval of the material compliance letter CMC will have four fixed MRI scanners and Kenilworth-Dx Cntr #2 will have two fixed MRI scanners for a total of six fixed MRI scanners at CMC and CPN.

In Section Q, Form D, the applicant provides projected utilization, as illustrated in the following table.

	<b>Last FFY (CY2021)</b>	<b>Interim FFY (CY2022)</b>	<b>Interim FFY (CY2023)</b>	<b>1<sup>st</sup> FFY (CY2024)</b>
# of MRI Scanners	4	4	4	4
# of Unweighted Scans	15,132	15,354	15,645	16,016
#of Weighted Scans	20,310	20,608	20,999	21,497

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

CMC currently operates four fixed MRI scanners and was approved to acquire a fifth fixed MRI scanner pursuant to Project ID#F-12117-21. CPN also has one fixed MRI scanner at Kenilworth-Dx Cntr #1 for a total of six existing or approved fixed MRI scanners between CMC and CPN.

The projected number of weighted MRI scans at CMC in the table above reflect the projected volume of weighted MRI scans for CMC in Project #F-12117-21 (the “fifth” fixed MRI scanner).

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

- The projected number of weighted MRI scans at CMC in the table above reflect the projected volume of weighted MRI scans for CMC in the approved Project #F-12117-21 (the “fifth” fixed MRI scanner) based on four fixed MRI scanners at CMC as the proposed “fifth” fixed MRI scanner was not projected to be operational until CY2027.

**Access to Medically Underserved Groups**

In Section D, page 59, the applicant states,

*“The proposed project is not expected to have any negative impact on the access to underserved groups who seek care, including MRI services, at CMC. As previously discussed, as a physician-based service, Atrium Health Imaging-Kenilworth Diagnostic Center can provide services at a lower out-of-pocket cost to most patients. ... The Atrium Health Kenilworth campus, which is less than on-half mile from CMC, also provides more convenient access away from congested healthcare campuses and supports important features like adequate parking. ... the replacement and relocation of an existing MRI scanner will offer significant benefits to patients that are not available elsewhere and will improve access for all, including the underserved.”*

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

- The fixed MRI scanner is being relocated to a freestanding non-hospital based diagnostic center less than one-half mile from CMC.
- Ultimately, CMC and the proposed diagnostic center, Kenilworth-Dx Cntr #2, are controlled by the same entity.
- Since Kenilworth-Dx Cntr #1 started offering services, including fixed MRI scanner services, on April 5, 2021, CMC has shifted cardiac MRI patients over to the diagnostic center.
- The diagnostic center provides more convenient access to cardiac MRI services at a lower cost to patients.
- The relocation of the fixed MRI scanner to the proposed diagnostic center will help decompress access to hospital-based MRI services at CMC.
- CMC currently has four MRI scanners. CMC was approved for a fifth MRI scanner (see Project ID# F-12117-21). CMC plans on using this approved fifth MRI scanner to take the place of the MRI scanner being relocated to the proposed diagnostic center. The applicant states *“relocation of the fixed MRI scanner from CMC to the proposed diagnostic center will not result in any reduction of existing, operational MRI capacity at CMC.”*

## **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 MRI scanners, CT scanner, x-ray, ultrasound, nuclear medicine camera and echocardiogram.

In Section E, page 63, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicant states this alternative would be less effective because maintaining the status quo would not permit the applicant to accommodate the increasing patient demand for outpatient cardiac MRI services in a cost-effective and resource-responsible manner in the shortest possible timeframe. Therefore, the applicant determined that this alternative is less effective.

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. and The Charlotte-Mecklenburg Hospital Authority (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 to include existing equipment [ one CT scanner, one MRI scanners, one X-Ray, one ultrasound,**



**one nuclear medicine camera, and nine echocardiogram units] and adding one additional MRI scanner by replacing and relocating an existing MRI scanner, 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.

The applicant, CPN, proposes to develop a new diagnostic center to include MRI scanners, CT scanner, x-ray, ultrasound, nuclear medicine camera and echocardiogram.

### **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	\$1,315,000
Architect/Engineering Fees	\$102,000
Medical Equipment	\$2,652,00
Misc (Furniture, Consultant Fees, IS, Security, Internal Allocation)	\$911,000
<b>Total</b>	<b>\$4,980,000</b>

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, architect and medical equipment costs are based on the letter from the architect in Exhibit F.1.
- IS, security, internal allocation costs, legal fees and consultant fees are based on the experience of CPN with similar projects.

In Section F, pages 67-68, the applicant states that there will be no working capital costs as

*“CPN currently operates each of the services included in this project in an existing diagnostic center in the same location. ... The proposed project does not involve any movement or disruption of the existing medical diagnostic equipment on the second floor nor will the proposed project result in any disruption in billing and revenue collection for the CPN services to be reconfigured and consolidated into the new Atrium Health Imaging-Kenilworth Diagnostic Center.”*

### **Availability of Funds**

In Section F, page 65, the applicant states that the capital cost 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	\$0
Accumulated reserves or OE *	\$4,980,000
Bonds	\$0
Other (Specify)	\$0
<b>Total Financing</b>	<b>\$4,980,000</b>

\* 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 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.2b, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as summarized in the table below.

**Kenilworth-Dx Cntr #2**

	1 <sup>st</sup> Full FY CY2024	2 <sup>nd</sup> Full FY CY2025	3 <sup>rd</sup> Full FY CY2026
Total Gross Revenues (Charges)	\$24,243,815	\$25,954,785	\$27,810,215
Total Net Revenue	\$7,512,972	\$8,071,076	\$8,677,916
Total Operating Expenses (Costs)	\$7,496,033	\$8,061,159	\$8,349,059
Net Income	\$16,939	\$9,916	\$328,857

\*Procedures from all services.

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

### C

The applicant, CPN, proposes to develop a new diagnostic center to include MRI scanners, CT scanner, x-ray, ultrasound, nuclear medicine camera and echocardiogram.

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. 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.

On page 341, the 2022 SMFP states:

*“A fixed MRI service area is the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1”.*

Figure 5.1 on page 38 of the 2022 SMFP shows Mecklenburg County as a single acute care bed service area. Therefore, for the purpose of this review, the fixed MRI service area is

Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Exhibit G.1 the applicant provides an excerpt of Table 17E-1, form the 2022 SMFP showing all existing and approved MRIs in Mecklenburg County and utilization.

However, the applicant states,

*“the existing Atrium Health Kenilworth Diagnostic Center #1 is the only facility that offers non-hospital based cardiac MRI services in Mecklenburg County; no other provider can meet the identified need.”*

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

*“The proposed project involves the replacement and relocation of an existing fixed MRI scanner from CMC to Atrium Health Imaging-Kenilworth Diagnostic Center. As such, the proposed project will not result in any addition to the Mecklenburg County inventory of MRI scanners. Further, the existing Atrium Health Kenilworth Diagnostic Center #1 is the only facility that offers non-hospital based cardiac MRI services in Mecklenburg County; no other provider can meet the identified need.”*

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.
- The replacement and relocation of an existing fixed MRI scanner from CMC approximately one-half mile away to the proposed diagnostic center in the same fixed MRI scanner service area would result in no net increase in the number of fixed MRI scanners in the Mecklenburg County fixed MRI scanner service area.

## **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 MRI scanners, CT scanner, x-ray, ultrasound, nuclear medicine camera and echocardiogram.

In Section Q, Form H, the applicant provides the projected full-time equivalent (FTE) positions for the proposed diagnostic services at Kenilworth-Dx Cntr #2 , as shown in the table below.

Position	Current FTE Staff*	Projected FTE Staff
	<i>(As of 12/31/2021)</i>	<b>3r Full Fiscal Year (CY 2026)</b>
Registered Nurses	2.0	4.5
MRI Technologist	2.9	7.4
MRI Supervisor	0.8	1.0
CT Technologist	2.8	3.7
Ultrasound Technologist	0.8	1.1
Xray Technologist	0.8	1.1
Sonographer Technologist	4.5	6.0
Nuclear Medicine Technologist	<b>1.5</b>	<b>2.0</b>
Exercise Physiologist	<b>2.3</b>	<b>3.0</b>
Manager Technologist	<b>0.8</b>	<b>1.0</b>
<b>TOTAL</b>	<b>19.1</b>	<b>30.8</b>

\*Note: While Kenilworth-Dx Cntr #2 will be a new facility it currently exists as part of the approved and operational diagnostic center known as Kenilworth-Dx Cntr #1.

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 77-78, 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 77-78, 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 MRI scanners, CT scanner, x-ray, ultrasound, nuclear medicine camera and echocardiogram.

### **Ancillary and Support Services**

In Section I.1, page 79, the applicant identifies the necessary ancillary and support services for the proposed services. On page 79 of the application and in Exhibit I.1, the applicant explains how each ancillary and support service is or will be made available. The applicant states,

*“Patients utilizing cardiac MRI services on the Atrium Health Kenilworth campus may require ... ancillary and support services... These services are currently provided in Atrium Health Kenilworth MOB #1 and will continue to be after the proposed project is developed.”*

The letter from the President of CPN in Exhibit I.1 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 80, 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.”*

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 MRI scanners, CT scanner, x-ray, ultrasound, nuclear medicine camera and echocardiogram

In Section K.2, page 83, the applicant states that the project involves renovation of 1000 square feet in a medical office building. Line drawings are provided in Exhibit C.1-2.

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 pages 83-84 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 84 of the application.

In Section B.21, on pages 28-29, 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 87, the applicant provides the historical payor mix for the existing Kenilworth-Dx Cntr #1 (2<sup>nd</sup> Floor Imaging Modalities) from 4/5/2021 to 12/31/2021 [the Kenilworth-Dx Cntr #1 began providing services on 4/5/2021]for the proposed services not including the second proposed MRI scanner, as shown in the table below.

Payor Category	Percentage of Total Patients Served
Self-Pay	3.7%
Medicare*	44.7%
Medicaid*	4.3%
Insurance*	45.5%
Other (includes Worker Comp & TRICARE)	1.8%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 87 of the application.

\*Including any managed care plans.

The MRI scanner proposed to be replaced and relocated to Kenilworth-Dx Cntr #2 is being relocated from CMC. In Section L, page 87, the applicant provides the historical payor mix for CMC for CY 2021, as shown in the table below.

Payor Category	Percentage of Total Patients Served
Self-Pay	10.9%
Medicare*	32.8%
Medicaid*	17.1%
Insurance*	37.6%
Other (includes Worker Comp & TRICARE)	1.6%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 87 of the application.

\*Including any managed care plans.

In Section L, pages 88-89, the applicant provides the following comparison.

	Percentage of Total Patients Served during the Last Full FY	Percentage of Total Patients Served during the Last Full FY	Percentage of the Population of the Service Area
	Kenilworth-Dx Cntr #1	CMC	Service Area
Female	48.4%	58.8%	51.9%
Male	51.6%	41.1%	48.1%
Unknown	0.0%	0.1%	0.0%
64 and Younger	58.1%	73.2%	88.5%
65 and Older	41.9%	26.8%	11.5%
American Indian	0.3%	0.6%	0.8%
Asian	1.3%	2.5%	6.3%
Black or African American	17.6%	27.9%	33.0%
Native Hawaiian or Pacific Islander	0.1%	0.1%	0.1%
White or Caucasian	61.5%	51.0%	57.3%
Other Race	0.7%	1.3%	2.5%
Declined / Unavailable	18.5%	16.6%	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, pages 89-90, 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 90, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against CPN, CMHA, 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 91, the applicant projects the payor mix for the both the entire proposed diagnostic center and just the MRI service component during the third full fiscal year (CY2026) of operation following completion of the project, as shown in the tables below.

**Kenilworth-Dx Cntr #2: Entire Facility**

<b>Payor Category</b>	<b>Percentage of Total Patients Served</b>
Self-Pay	3.8%
Medicare*	44.3%
Medicaid*	4.5%
Insurance*	45.5%
Other (includes Workers Comp and TRICARE)	1.9%
<b>Total</b>	<b>100.0%</b>

\*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.

**Kenilworth-Dx Cntr #2: MRI Services Only**

<b>Payor Category</b>	<b>Percentage of Total Patients Served</b>
Self-Pay	4.4%
Medicare*	41.3%
Medicaid*	5.8%
Insurance*	46.0%
Other (includes Workers Comp and TRICARE)	2.5%
<b>Total</b>	<b>100.0%</b>

\*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 4.4% of total MRI services will be provided to self-pay patients, 41.3% to Medicare patients and 5.8% to Medicaid patients.

On page 90, 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 the historical experience of Kenilworth-Dx Cntr #1 [2<sup>nd</sup> floor modalities] from the last 4/5/2021 to 12/31/2021 providing the proposed services at the same location as part of the existing Kenilworth-Dx Cntr #1[2<sup>nd</sup> floor modalities only].

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 93, the applicant adequately describes the range of means by which patients will have access to the proposed additional MRI 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 MRI scanners, CT scanner, x-ray, ultrasound, nuclear medicine camera and echocardiogram.

In Section M.1, page 94, 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 94, 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 MRI scanners, CT scanner, x-ray, ultrasound, nuclear medicine camera and echocardiogram.

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. 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.

On page 341, the 2022 SMFP states:

*“A fixed MRIs **service area** is the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1”.*

Figure 5.1 on page 38 of the 2022 SMFP shows Mecklenburg County as a single acute care bed service area. Therefore, for the purpose of this review, the fixed MRI service area is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Exhibit G.1 the applicant provides an excerpt of Table 17E-1, form the 2022 SMFP showing all existing and approved MRIs in Mecklenburg County and utilization.

However, the applicant states,

*“the existing Atrium Health Kenilworth Diagnostic Center #1 is the only facility that offers non-hospital based cardiac MRI services in Mecklenburg County; no other provider can meet the identified need.”*

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 96, the applicant states:

*“The proposed project will enhance competition in the service area by promoting cost effectiveness, quality and access to cardiac MRI diagnostic services.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 96, the applicant states:

*“As a physician-based service, the proposed diagnostic center will provide services, including MRI 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, Atrium Health Imaging-Kenilworth 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 96-97, 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 97, the applicant states:

*“The proposed project will improve access to cardiac MRI 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 and the applicant’s record of providing quality care in the past.



- 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 MRI scanners, CT scanner, x-ray, ultrasound, nuclear medicine camera and echocardiogram.

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 101, 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 MRI scanners, CT scanner, x-ray, ultrasound, nuclear medicine camera and echocardiogram.

The Criteria and Standards for Diagnostic Centers were repealed, effective March 16, 2017.

The applicant proposes to replace an existing fixed MRI scanner currently located at CMC and relocate it to the proposed new diagnostic center. The Criteria and Standards for Magnetic Resonance Imaging Scanners, which are promulgated in 10A NCAC 14C .2700, are not applicable to this review because they do not apply to proposals to replace existing MRI scanners.

The proposed new diagnostic includes an existing CT scanner. The Criteria and Standards for Computed Tomography Equipment (CT scanners) were repealed, effective January 1, 2022.

Therefore, there are no performance standards applicable to this review.