

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 25, 2024

Findings Date: June 25, 2024

Project Analyst: Yolanda W. Jackson

Co-Signer: Gloria C. Hale

Project ID #: F-12506-24

Facility: Atrium Health Imaging – Kenilworth Diagnostic Center

FID #: 220471

County: Mecklenburg

Applicant(s): Carolinas Physicians Network, Inc.

Project: Acquire no more than one photon-counting CT scanner for a total of no more than two CT scanners upon project completion

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. (hereinafter referred to as “applicant” or “CPN”) proposes to acquire no more than one photon-counting CT scanner for a total of no more than two CT scanners upon project completion.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2024 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2024 SMFP, on page 30, that is applicable to this review: Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-4 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 proposed capital expenditure for this project is greater than \$5 million. In Section B, pages 27-28, the applicant describes the project’s plan to assure improved energy efficiency and water conservation. The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 based on the following:

- The applicant adequately describes how the project will use the Standard Control Sequences of the Charlotte-Mecklenburg Hospital Authority (CMHA) to optimize energy efficiency in the Building Automation Systems (BAS) and Heating, Ventilation, and Air Conditioning (HVAC) systems.
- The applicant adequately describes how the project will select new plumbing fixtures to optimize water efficiency and life cycle benefits.
- The applicant adequately describes how the project will design new HVAC systems and select equipment that optimize water efficiency and life cycle benefits.

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.

- (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 proposes to acquire no more than one photon-counting CT scanner for use at Atrium Health Imaging - Kenilworth Diagnostic Center, an existing diagnostic center in Charlotte, Mecklenburg County, for a total of no more than two CT scanners upon project completion.

Patient Origin

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” The 2024 SMFP does not define the service area for CT scanners, nor are there any applicable rules adopted by the Department that define the service area for CT scanners. In Section G, page 72, the applicant defines the primary service area as Mecklenburg County. Providers may serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin for CT scans at Atrium Health Imaging – Kenilworth Diagnostic Center.

Atrium Health Imaging – Kenilworth Diagnostic Center CT Scans				
County	Historical CY 2023		Third Full Year of Operation following Project Completion CY 2028	
	# of Patients	% of Total	# of Patients	% of Total
Mecklenburg	2,601	44.2%	3,578	44.2%
York	992	16.8%	1,365	16.8%
Gaston	326	5.5%	448	5.5%
Union	285	4.8%	392	4.8%
Cabarrus	257	4.4%	354	4.4%
Lancaster	246	4.2%	338	4.2%
Iredell	141	2.4%	194	2.4%
Cleveland	120	2.0%	165	2.0%
Lincoln	118	2.0%	162	2.0%
Stanly	92	1.6%	127	1.6%
Catawba	76	1.3%	105	1.3%
Other^	636	10.8%	875	10.8%
Total	5,890	100.0%	8,103	100.0%

Source: Section C, pages 32 and 35

^Other includes Alamance, Alexander, Alleghany, Anson, Ashe, Avery, Beaufort, Bladen, Brunswick, Buncombe, Burke, Cabarrus, Caldwell, Carteret, Catawba, Cherokee, Clay, Columbus, Cumberland, Davidson, Davie, Durham, Forsyth, Franklin, Gaston, Greene, Guilford, Haywood, Henderson, Hoke, Jackson, Johnston, McDowell, Mitchell, Montgomery, New Hanover, Onslow, Orange, Person, Pitt, Polk, Randolph, Richmond, Robeson, Rockingham, Rowan, Rutherford, Scotland, Stanly, Stokes, Surry, Swain, Transylvania, Wake, Watauga, Wayne, Wilkes, Yadkin, and Yancey Counties in NC as well as other states.

In Section C, page 34, the applicant provides the assumptions and methodology used to project its patient origin. The applicant projects patient origin based on its existing patient origin at Atrium Health Imaging – Kenilworth Diagnostic Center and the applicant does not anticipate the project to have an impact on patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 37-42, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The proposed photon-counting CT scanner will be used in diagnosing coronary artery disease. CT scans allow physicians to non-invasively gather detailed information on the heart’s structure and the cardiac CT provides information that cannot be obtained with cardiac catheterization or other cardiac imaging modalities. (page 38)
- Photon-counting CT scanners utilize new technology to collect higher resolution, more detailed images than traditional CT scanners. (pages 38-39)

- The proposed photon-counting CT scanner will be able to assess high-risk coronary artery disease patients that were previously unable to be served by existing traditional CT scanners in Mecklenburg County. Traditional CT scanners are excellent at evaluating the coronary arteries of most patients; however, they are less effective when assessing high-risk patients with heavily calcified coronary arteries or stents due to a “blooming” effect these factors can have on imaging. (page 39)
- Population growth in the region, aging, and the rate of cardiovascular disease will continue to contribute to growth in the demand for CT imaging in Mecklenburg County. (pages 40-41)

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

- Population growth, aging and the rate of cardiovascular disease in Mecklenburg County drive the need for the proposed photon-counting CT scanner.
- The applicant adequately demonstrates the proposed photon-counting CT scanner will provide detailed information on the heart’s structure and assist physicians in assessing high-risk coronary artery disease patients that were previously unable to be served by the existing traditional CT scanners in Mecklenburg County.

Projected Utilization

In Section Q, Form C.2a and Form C.2b, the applicant provides historical and projected utilization, as illustrated in the following tables.

Atrium Health Imaging - Kenilworth Diagnostic Center CT Scanner Historical and Interim Utilization		
	Last Full FY CY 2023	Interim Full FY CY 2024
# of Units	1	1
# of Scans	7,507	7,996
# of HECT Units	15,675	16,696

Atrium Health Imaging – Kenilworth Diagnostic Center CT Scanner Projected Utilization Upon Project Completion				
	Partial FY CY2025	1st Full FY CY2026	2nd Full FY CY2027	3rd Full FY CY2028
# of Units	2	2	2	2
# of Scans	8,517	9,071	9,662	10,291
# of HECT Units	17,783	18,941	20,175	21,488

In Section Q, Form C Utilization-*Assumption and Methodology*, pages 107-109, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The proposed project is projected to become operational on October 1, 2025. The first three full fiscal years of the project are CY2026, CY2027, and CY2028.
- The applicant states that Atrium Health Imaging – Kenilworth Diagnostic Center has experienced significant growth in CT utilization over the last three years as illustrated in the table below.

Atrium Health Imaging – Kenilworth Diagnostic Center Historical CT Utilization				
	CY2021[^]	CY2022	CY2023	CY2021- CY2023 CAGR*
CT Procedures	4,725	6,579	7,507	26.0%
CT (HECT units)	11,016	13,504	15,675	
Number of CT Units	1	1	1	

Source: Section Q, page 107

[^]CT scanner at Atrium Health Imaging-Kenilworth Diagnostic Center became operational on April 5, 2021. Thus, CY 2021 represents a partial year of data.

*Compound Annual Growth Rate

- The applicant stated that the total number of CT procedures performed at Atrium Health Imaging – Kenilworth Diagnostic Center grew at a CAGR of 26.0% from CY 2021 to CY 2023. Also, 91.2% of CT scans performed at Atrium Health Imaging-Kenilworth Diagnostic Center in CY 2023 were cardiac-related.
- The applicant states that while certain cardiac patient types will be given priority, the proposed photon-counting CT scanner will also be able to serve other patients that have historically been served by the existing traditional CT scanner at Atrium Health Imaging – Kenilworth Diagnostic Center.
- The applicant states that historical growth rates are a reasonable basis to project future CT utilization; however, conservatively the applicant believes that growth will be 25% of the historical growth rate or a CAGR of 6.5% in future years. The applicant calculated HECT units by applying the ratio of HECT units to CT scans (2.09 HECT units per CT Scan) to project the number of HECT units. The projected CT utilization is illustrated in the table below.

Atrium Health Imaging – Kenilworth Diagnostic Center Projected CT Utilization							
				PY1	PY2	PY3	CAGR
	CY23	CY24	CY25	CY26	CY27	CY28	
CT Procedures	7,507	7,996	8,517	9,071	9,662	10,291	6.5%
CT (HECT units)	15,675	16,696	17,783	18,941	20,175	21,488	
Number of CT Units	1	1	2	2	2	2	

Source: Section Q, page 108

Projected utilization is reasonable and adequately supported because the projected growth rate is conservative and based on the historical growth of CT procedures that Atrium Health Imaging-Kenilworth Diagnostic Center has experienced during the last three years.

Access to Medically Underserved Groups

In Section C, pages 49-50, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons*	
Racial and ethnic minorities	33.9%
Women	46.4%
Persons with Disabilities*	
Persons 65 and older	49.4%
Medicare beneficiaries	48.9%
Medicaid recipients	4.5%

Source: Section C, page 50

*CMHA and CPN do not maintain data of the number of low income and disabled persons served.

On page 49, the applicant states:

“Consistent with all CMHA facilities, CPN facilities provide services to all people in need of medical care. ... As noted in CMHA’s Non-Discrimination Policy Statement, ‘[n]o individual shall be subject to discrimination or denied the benefits of the services, programs, or activities of Atrium Health on the basis of race, color, religion, national origin, age, sex, sexual orientation, gender identity, gender expression, disability or source of payment.’ CMHA will continue to serve this population as dictated by the mission of CMHA, which is the foundation of every action taken. The mission is simple, but unique: To improve the health, elevate hope, and advance healing – for all. This includes the medically underserved.”

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 based on the following:

- The applicant provides estimated percentages of patients from underserved groups based on historical data from Atrium Health Imaging-Kenilworth Diagnostic Center in CY2023.
- The applicant provides written statements about offering access to all residents of the service area, including underserved groups and provides a summary of CMHA’s Non-Discrimination Policy in Exhibit C.6.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services and adequately supports its assumptions.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C

The applicant proposes to acquire no more than one photon-counting CT scanner for a total of no more than two CT scanners upon project completion.

In Section E, pages 60-61, 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 Status Quo** - The applicant states that the proposed photon-counting CT scanner will be able to assess high-risk coronary artery disease in patients who are currently not able to be served by the existing traditional CT scanners in Mecklenburg

County. The proposed scanner will also be the preferred imaging tool when assessing CABG (coronary artery bypass graft) patients with wires and structural heart patients because the scanner will be able to provide the most detailed images of the cardiac anatomy. The applicant states that the population growth and rate of cardiovascular disease in Mecklenburg County also supports additional CT imaging capacity. Therefore, maintaining the status quo is the less effective alternative.

- **Develop the Photon-Counting CT Scanner at Another Location** - The applicant states that the medical office building on the Atrium Kenilworth campus was designed to be a destination center for cardiac services and Atrium Health Imaging-Kenilworth Diagnostic Center is primarily dedicated to cardiac imaging. It is also home to several CPN physicians providing a wide variety of heart and vascular services. Therefore, developing the photon-counting CT scanner at another location was deemed a less effective alternative.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

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 acquire no more than one photon-counting CT scanner for a total of no more than two CT scanners at Atrium Health Imaging - Kenilworth Diagnostic Center upon project completion.**
- 3. The certificate holder shall 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.**
- 4. 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, 2025.
6. 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.
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 proposes to acquire no more than one photon-counting CT scanner for a total of no more than two CT scanners upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 110, the applicant projects the total capital cost of the project, as shown in the table below.

Atrium Health Imaging – Kenilworth Diagnostic Center Photon-Counting CT Scanner Projected Capital Cost	
Construction/Renovation Contract(s)	\$835,125
Architect/Engineering Fees	\$140,200
Medical Equipment	\$3,482,463
Non-Medical Equipment	\$4,365
Furniture	\$2,500
Consultant Fees	\$91,000
Other (IS, Security, Internal Allocation)	\$609,351
Total	\$5,165,004

In Section Q, page 111, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant projects construction costs and architect and engineering costs based on the experience of the project architect with similar projects.
- The costs of the medical equipment, non-medical equipment, and furniture are based on the vendor estimates and the experience of CPN with similar projects.
- All other costs are based on CPN's experience with similar projects.
- The applicant provides supporting documentation in Exhibit F.1.

In Section F, pages 64-65, the applicant states that there will be no start-up costs or initial operating expenses because the proposed project does not involve a new service or facility.

Availability of Funds

In Section F, page 62, the applicant states that the capital cost will be funded by the Charlotte-Mecklenburg Hospital Authority (CMHA), the parent company of CHN, which in turn is the sole member of CPN, through accumulated reserves. Exhibit F.2-1 contains a letter dated April 15, 2024, from the Executive Vice President and Chief Financial Officer of CMHA stating their commitment to fund the project through CMHA's accumulated cash reserves. In Exhibit F.2-2, the applicant provides the most recent audited financial statements for CMHA, demonstrating sufficient cash and cash equivalents and assets limited as to use to fund the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the information provided in Section F and Exhibits F.2-1 and F.2-2 of the application.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, page 113, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

Atrium Health Imaging – Kenilworth Diagnostic Center CT Services	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
	FY2026	FY2027	FY2028
Total CT Procedures	9,071	9,662	10,291
Total Gross Revenues	\$15,007,599	\$16,464,399	\$18,062,613
Total Net Revenue	\$4,758,236	\$5,220,122	\$5,726,844
Average Net Revenue Per Procedure	\$525	\$540	\$556
Total Operating Costs	\$3,051,267	\$3,174,816	\$3,306,956
Average Operating Expense Per Procedure	\$336	\$329	\$321
Net Income	\$1,706,969	\$2,045,306	\$2,419,888

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 120-121. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant explains how it accounts for projected operating expenses and explains its revenue projections.
- 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 for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- 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 revenues and operating expenses for all the reasons described above.

- (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 proposes to acquire no more than one photon-counting CT scanner for a total of no more than two CT scanners upon project completion.

The 2024 SMFP does not define a service area for CT scanners. In Section G, page 72, the applicant defines its service area as Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 72, the applicant states that it is not aware of a public data source that provides a county-level inventory of all existing and approved facilities, including diagnostic centers, that provide CT services.

In Section G, page 72, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved CT services in Mecklenburg County. The applicant states:

“As discussed previously, the proposed photon-counting CT scanner will be the first of its kind in Mecklenburg County and will be able to assess high-risk coronary artery disease patients that were previously unable to be served by the existing traditional CT scanners in Mecklenburg County, including the existing CT scanner at Atrium Health Imaging – Kenilworth Diagnostic Center. Further, as discussed in C.4, overall CT imaging at Atrium Health Imaging – Kenilworth Diagnostic Center is growing rapidly, and 91.2 percent of CT scans performed at the diagnostic center in CY 2023 were cardiac related.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed photon-counting CT scanner is needed in addition to the existing or approved CT scanners.

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 proposes to acquire no more than one photon-counting CT scanner for a total of no more than two CT scanners upon project completion.

In Section Q, Form H, page 122, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Atrium Health Imaging – Kenilworth Diagnostic Center	Current Staff	Projected FTE Staff		
	as of 12/31/2023	1st Full FY	2nd Full FY	3rd Full FY
Nuclear Med Technologist	1.5	1.5	1.5	1.5
Exercise Physiologists	2.9	2.9	2.9	2.9
Manager Technologist	1.0	1.0	1.0	1.0
Sonographer Technologist	8.7	8.7	8.7	8.7
Xray Technologist	1.0	1.0	1.0	1.0
CT Technologist	3.6	7.2	7.2	7.2
MRI Technologist*	3.6	7.2	7.2	7.2
MRI Supervisor	1.0	1.0	1.0	1.0
Ultrasound Technologist	1.0	1.0	1.0	1.0
Registered Nurses	5.4	9.0	9.0	9.0
TOTAL	29.7	40.5	40.5	40.5

*MRI Technologists are increasing as a result of previously approved Project ID # F-12226-22

The assumptions and methodology used to project staffing are provided in Section Q, page 123. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 74-76, the applicant describes the methods used to recruit or fill new positions and its existing 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 following:

- CMHA has a human resources department and uses multiple strategies to attract and recruit talent.
- CMHA is the largest employer in Charlotte and second largest employer in North Carolina.
- All clinical staff are required to maintain certification by an appropriate, nationally recognized certification-accrediting body and attend in-service training.

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.

- (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 proposes to acquire no more than one photon-counting CT scanner for a total of no more than two CT scanners upon project completion.

Ancillary and Support Services

In Section I, page 78, the applicant identifies the necessary ancillary and support services for the proposed services. On page 78, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because Atrium Health Imaging – Kenilworth Diagnostic Center currently provides these services to patients and will continue to provide the service after the proposed project is developed.

Coordination

In Section I, page 79, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- Atrium Health Imaging – Kenilworth Diagnostic Center is an established healthcare system in the service area with existing relationships with local health care and social service providers.
- Exhibit I.2 includes letters of support from physicians and other providers.

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

In Section K, page 82, the applicant states that the project involves the renovation of 713 square feet of existing space. Line drawings of the project are provided in Exhibit C.1-1.

On pages 82-83, 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 following:

- The design minimizes cost of the project by renovating existing space rather than constructing new space.
- There is a vacant space in proximity to the existing CT scanner at Atrium Health Imaging – Kenilworth Diagnostic Center where the proposed photon-counting CT scanner can be developed.
- The two CT scanners can share the existing CT control room with minimal upfit required.

In Section K, page 83, the applicant adequately explains why the proposal will not unduly increase the cost to the applicant of providing the proposed services or the cost and charges to the public for the proposed services. The applicant states:

“Through its conservative fiscal management, CMHA has set aside excess revenues from previous years to enable it to pay for projects such as the one proposed in this application, without necessitating an increase in costs or charges to pay for the project.

In Section B, pages 27-28, the applicant identifies any applicable energy saving features that will be incorporated into the construction plan.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... 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;

In Section L, page 86, the applicant provides the historical payor mix during FY2023 illustrated in the following table.

Payor Source	Percentage of Total Patients Served
Self-Pay	5.7%
Charity Care^	
Medicare*	48.9%
Medicaid*	4.5%
Insurance*	39.3%
Workers Compensation^^	
TRICARE^^	
Other (Other Payor)^^	1.7%
Total	100.0%

* Including any managed care plans.

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

^^Workers Compensation and TRICARE included in the Other payor category.

In Section L, page 87, the applicant provides the following comparison.

Atrium Health Imaging – Kenilworth Diagnostic Center	Last Full FY Before Submission of the Application	
	% of Total Patients	% of the Population of the Service Area*
Female	46.4%	51.6%
Male	53.5%	48.4%
Unknown	0.05%	0.0%
64 and Younger	54.1%	87.8%
65 and Older	49.4%	12.2%
American Indian	0.7%	0.9%
Asian	1.7%	6.7%
Black or African-American	29.3%	33.2%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	63.9%	56.4%
Other Race	2.1%	2.7%
Declined/Unavailable	2.2%	0.0%

* The percentages can be found online using the United States Census Bureau’s QuickFacts located online at: <http://www.census.gov/quickfacts/fact/table/US/PST045218>.

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 applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's

service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 88, the applicant states it has no such obligation.

In Section L, page 89, the applicant states there have been no patient civil rights access complaints have been filed against Atrium Health Imaging – Kenilworth Diagnostic Center in the 18 months immediately preceding the submission of its application.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 89, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Source	Percentage of Total Patient Served
Self-Pay	5.8%
Charity Care [^]	
Medicare*	48.5%
Medicaid*	4.3%
Insurance*	39.8%
Workers Compensation ^{^^}	
TRICARE ^{^^}	
Other (Other Payor) ^{^^}	1.6%
Total	100.0%

* Including any managed care plans.

[^]CPN internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care.

^{^^}Workers Compensation and TRICARE included in the Other payor category.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 5.8% of total services will be provided to self-pay patients, 48.5% to Medicare patients and 4.3% to Medicaid patients.

In Section L, page 89, the applicant provides the methodology and assumptions used to calculate these projections:

“Projected payor mix for Atrium Health Imaging – Kenilworth Diagnostic Center and the CT service component is based on CY 2023 payor mix for the entire facility and CT service component, respectively. With the expansion of Medicaid coverage in North Carolina, payor mix for the proposed services is expected to shift in the coming years. Based on what is known to date, it is expected that the increase in percentage of Medicaid patients will come primarily from those that are currently classified as Self-Pay. ... Until there is greater clarity to guide the specific shift between Self-Pay and Medicaid, CPN has assumed that the payor mix will be consistent with the historical payor mix assumptions above.”

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.

In Section L, page 91, the applicant adequately describes the range of means by which patients will have access to the proposed services. The applicant states:

“Patients utilizing the proposed photon-counting CT scanner at Atrium Health Imaging – Kenilworth Diagnostic Center will be either referred by their physician or referred by a member of the medical staff of a CMHA facility.”

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 92, 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 following:

- CMHA has established relationships with programs including Central Piedmont Community College, Queens University of Charlotte (including Presbyterian School of Nursing), University of North Carolina at Charlotte, and Gardner-Webb University.
- CMHA has a contractual agreement with the University of North Carolina at Chapel Hill to manage the South Piedmont Area Health Education Center (AHEC). This agreement also deems CMHA facilities as clinical rotation training sites for several advanced practice provider programs including Duke University, UNC at Chapel Hill, and Wake Forest School of Medicine.
- CMHA, along with Carolinas College of Health Sciences and Cabarrus College of Health Sciences, provide educational environments for physician extenders, nursing, radiology, and other allied health professionals annually. All of these health professionals use the facilities of CMHA to meet their clinical training requirements.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
 - (16) Repealed effective July 1, 1987.
 - (17) Repealed effective July 1, 1987.
 - (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to acquire no more than one photon-counting CT scanner for a total of no more than two CT scanners upon project completion.

The 2024 SMFP does not define a service area for CT scanners. In Section G, page 72, the applicant states that its primary service area is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section N, page 94, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states,

“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to CT imaging services. Further, as discussed in Section C.4, the proposed photon-counting scanner will be the first of its kind in Mecklenburg County and will bring clinical benefits to patients, particularly in cardiac CT imaging, such as the ability to assess high-risk coronary artery disease patients that were previously unable to be served by the existing traditional CT scanners in the county, including the existing CT scanner at Atrium Health Imaging – Kenilworth Diagnostic Center. Thus, the proposed project is expected to advance cardiac diagnosis and foster competition in the region.”

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 94-95, the applicant states that Atrium Health Imaging-Kenilworth Diagnostic Center as a physician-based

service, provides services at a lower out-of-pocket cost to most patients. Also, Atrium Health Imaging-Kenilworth Diagnostic Center, as a part of the CMHA system, benefits from significant cost-savings through the consolidation of multiple services and large economies of scale.

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

Regarding the impact of the proposal on quality, in Section N, page 95, the applicant states that Atrium Health Imaging- Kenilworth Diagnostic Center is accredited by the American College of Radiology (ACR) and Intersocietal Accreditation Commission (IAC). The applicant states that the proposed project will serve to enhance the quality of cardiac CT imaging services provided in Mecklenburg County and the proposed photon-counting CT scanner will be the first of its kind in Mecklenburg County and west of the Triangle, offering the latest advances in cardiac CT imaging.

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 95-96, the applicant states,

“Consistent with all CMHA facilities, CPN facilities provide services to all persons in need of medical care, regardless of race, color, religion, national origin, age, sex, sexual orientation, gender identity, gender expression, disability or source of payment, as demonstrated in CMHA’s Non-Discrimination Policies provided in Exhibit C.6. Atrium Health Imaging – Kenilworth Diagnostic Center will continue to serve this population as dictated by the mission of CMHA, which is the foundation for every action taken. The mission is simple, but unique: To improve the health, elevate hope, and advance healing – for all. This includes the medically underserved.”

See also Sections C and L 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:

- The proposal is cost effective because the applicant adequately demonstrated: 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.
- 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.
- 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
- Information publicly available during the review and used by the Agency
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described 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

In Form O, Section Q, page 124, the applicant identifies 11 diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O, page 99, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. 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 Criteria and Standards for Computed Tomography Equipment promulgated in 10A NCAC 14C .2300 were repealed effective January 1, 2022. Therefore, there are no rules applicable to this review.