## REQUIRED STATE AGENFY FINDINGS

**FINDINGS** 

C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date: July 26, 2024 Findings Date: July 26, 2024

Project Analyst: Tanya M. Saporito

Co-Signer: Lisa Pittman

Project ID #: G-12486-24

Facility: Cone Health MedCenter Asheboro

FID #: 240132 County: Randolph

Applicants: The Moses H. Cone Memorial Hospital

The Moses H. Cone Memorial Hospital Operating Corporation

Project: Develop a new diagnostic center with no more than one CT unit, one x-ray unit,

one ultrasound unit, one mammography unit, and one bone density unit

### **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.

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The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation, herein after collectively referred to as "the applicant," propose to develop a diagnostic center by acquiring no more than one CT scanner, one x-ray unit, one ultrasound unit, one mammography unit and one bone density (DEXA) unit in an existing medical office building in Randolph County. The diagnostic center will be an Independent Diagnostic Testing Facility (IDTF) located in Asheboro.

## **Need Determination**

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2024 State Medical Facilities Plan (SMFP).
- Acquire any medical equipment for which there is a need determination in the 2024 SMFP.
- Offer a new institutional health service for which there are any applicable policies in the 2024 SMFP.

Therefore Criterion (1) is not applicable to this review.

### **Policies**

One policy in Chapter 4 of the 2024 SMFP is applicable to this application: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

# **Policy GEN-4**

Policy GEN-4 on page 30 of the 2024 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 of 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 \$4 million. In Section B, page 25, the applicant describes the project's plan to improve energy efficiency and water conservation.

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 because the applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 based on the following:

- The applicant adequately documents that it has a plan in place to ensure water and energy conservation in the development of the proposed project.
- The applicant states it will develop and implement an Energy Efficiency and Sustainability Plan for the project as required by the CON Section following project approval.
- (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.

 $\mathbf{C}$ 

The applicant proposes to develop a diagnostic center by acquiring no more than one CT scanner, one x-ray unit, one ultrasound unit, one mammography unit and one bone density (DEXA) unit and upfit an existing medical office building in Randolph County.

## Designation as a Diagnostic Center

N.C. Gen. Stat. §131E-176(7a) as amended by Session Law 2023-7, effective March 27, 2023, which includes a cost threshold adjustment in effect at the time this application was received, states:

"Diagnostic center" means 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 three million dollars (\$3,000,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than three million dollars (\$3,000,000), 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. Beginning September

30, 2022, and on September 30 each year thereafter, the cost threshold amount in this subdivision shall be adjusted using the Medical Care Index component of the Consumer Price Index published by the U.S. Department of Labor for the 12-month period preceding the previous September 1."

The total cost of the proposed project is \$4,400,705, which exceeds the statutory threshold of \$2,971,200. Therefore, Cone Health MedCenter Asheboro qualifies as a diagnostic center, which is a new institutional health service, and which requires a Certificate of Need (CON).

## **Patient Origin**

N.C. Gen. Stat. §131E-176(24a) states, "Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility." The 2024 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C, page 32 the applicant defines the primary service area for the proposed diagnostic center as Randolph County. Facilities may also serve residents not included in their service area.

Since the applicant proposes to develop a new freestanding diagnostic center, there is no historical patient origin. In Exhibit C.2a and Exhibit C.2b the applicant provides FFY 2023 patient origin for diagnostic imaging services provided at Cone Health.

The following table illustrates projected patient origin for CT scanner services for Cone Health MedCenter Asheboro:

CONE HEALTH MEDCENTER ASHEBORO									
	PROJECTED PATIENT ORIGIN – CT SERVICES								
COUNTY	1 <sup>st</sup> Fu	JLL FY	2 <sup>ND</sup> Ft	JLL <b>FY</b>	3 <sup>RD</sup> Fu	JLL FY			
	10/01/2025-	-09/30/2026	10/01/2026	-09/30/2027	10/01/2027-	09/30/2028			
Randolph	2,982	85.8%	3,429	85.8%	4,213	85.8%			
Guilford	111	3.2%	128	3.2%	157	3.2%			
Montgomery	108	3.1%	124	3.1%	152	3.1%			
Davidson	104	3.0%	120	3.0%	147	3.0%			
Chatham	101	2.9%	116	2.9%	142	2.9%			
Other	70	2.0%	80	2.0%	98	2.0%			
Total	3,475	100.0%	3,996	100.0%	4,910	100.0%			

Source: Exhibit C.3b.

The following table illustrates projected patient origin for bone density (DEXA) services for Cone Health MedCenter Asheboro:

CONE HEALTH MEDCENTER ASHEBORO PROJECTED PATIENT ORIGIN — BONE DENSITY (DEXA)							
COUNTY	<b>1</b> <sup>sτ</sup> <b>F</b> ι	JLL FY	2 <sup>ND</sup> FU	JLL FY	3 <sup>RD</sup> FU	JLL FY	
	10/01/2025	10/01/2025-09/30/2026		10/01/2026-09/30/2027		-09/30/2028	
Randolph	213	85.8%	245	85.8%	317	85.8%	
Guilford	8	3.2%	9	3.2%	12	3.2%	
Montgomery	8	3.1%	9	3.1%	11	3.1%	
Davidson	7	3.0%	9	3.0%	11	3.0%	
Chatham	7	2.9%	8	2.9%	11	2.9%	
Other	5	2.0%	6	2.0%	7	2.0%	
Total	248	100.0%	286	100.0%	369	100.0%	

Source: Exhibit C.3b.

The following table illustrates projected patient origin for diagnostic radiography (X-ray) services for Cone Health MedCenter Asheboro:

CONE HEALTH MEDCENTER ASHEBORO PROJECTED PATIENT ORIGIN – X-RAY (DIAGNOSTIC RADIOGRAPHY)							
COUNTY	1 <sup>s⊤</sup> F∪	JLL FY	2 <sup>ND</sup> FU	JLL FY	3 <sup>RD</sup> Fu	JLL FY	
	10/01/2025-09/30/2026		10/01/2026-09/30/2027		10/01/2027-	09/30/2028	
Randolph	4,693	85.8%	5,398	85.8%	6,765	85.8%	
Guilford	175	3.2%	201	3.2%	252	3.2%	
Montgomery	170	3.1%	195	3.1%	244	3.1%	
Davidson	164	3.0%	189	3.0%	237	3.0%	
Chatham	159	2.9%	182	2.9%	229	2.9%	
Other	109	2.0%	126	2.0%	158	2.0%	
Total	5,470	100.0%	6,291	100.0%	7,885	100.0%	

Source: Exhibit C.3b.

The following table illustrates projected patient origin for mammography services for Cone Health MedCenter Asheboro:

CONE HEALTH MEDCENTER ASHEBORO							
		PROJECTED PATIE	NT ORIGIN - MA	MMOGRAPHY			
COUNTY	<b>1</b> <sup>sτ</sup> <b>F</b> ι	JLL FY	2 <sup>ND</sup> FU	JLL FY	3 <sup>RD</sup> FU	JLL FY	
	10/01/2025-09/30/2026 10/01/2026-09/30/2027 10/01/2027-09/30				09/30/2028		
Randolph	853	85.8%	980	85.8%	1,266	85.8%	
Guilford	32	3.2%	37	3.2%	47	3.2%	
Montgomery	31	3.1%	35	3.1%	46	3.1%	
Davidson	30	3.0%	34	3.0%	44	3.0%	
Chatham	29	2.9%	33	2.9%	43	2.9%	
Other	20	2.0%	23	2.0%	30	2.0%	
Total	994	100.0%	1,142	100.0%	1,476	100.0%	

Source: Exhibit C.3b.

The following table illustrates projected patient origin for ultrasound services for Cone Health MedCenter Asheboro:

CONE HEALTH MEDCENTER ASHEBORO PROJECTED PATIENT ORIGIN — ULTRASOUND								
COUNTY	1 <sup>sτ</sup> <b>F</b> ι	JLL FY	2 <sup>ND</sup> Ft	JLL FY	3 <sup>RD</sup> FU	JLL FY		
	10/01/2025-09/30/2026		10/01/2026	-09/30/2027	10/01/2027	-09/30/2028		
Randolph	1,451	85.8%	1,669	85.8%	2,004	85.8%		
Guilford	54	3.2%	62	3.2%	75	3.2%		
Montgomery	52	3.1%	60	3.1%	72	3.1%		
Davidson	51	3.0%	58	3.0%	70	3.0%		
Chatham	49	2.9%	56	2.9%	68	2.9%		
Other	34	2.0%	39	2.0%	47	2.0%		
Total	1,691	100.0%	1,945	100.0%	2,336	100.0%		

Source: Exhibit C.3b.

The following table illustrates projected patient origin for all diagnostic imaging services for Cone Health MedCenter Asheboro:

CONE HEALTH MEDCENTER ASHEBORO							
		PROJECTED PATI	ENT ORIGIN – ENT	TIRE FACILITY			
COUNTY	1 <sup>ST</sup> Fu	JLL FY	2 <sup>ND</sup> FU	JLL <b>FY</b>	3 <sup>RD</sup> Fu	JLL FY	
	10/01/2025-	0/01/2025-09/30/2026 10/01/2026-09/30/2027			10/01/2027-	09/30/2028	
Randolph	2,982	85.8%	3,429	85.8%	4,213	85.8%	
Guilford	111	3.2%	128	3.2%	157	3.2%	
Montgomery	108	3.1%	124	3.1%	152	3.1%	
Davidson	104	3.0%	120	3.0%	147	3.0%	
Chatham	101	2.9%	116	2.9%	142	2.9%	
Other	70	2.0%	80	2.0%	98	2.0%	
Total	11,878	100.0%	13,660	100.0%	16,976	100.0%	

Source: Exhibit C.3c.

In Section C, page 32 and in Exhibit C.2.a the applicant provides the assumptions and methodology used to project patient origin, which assumes the diagnostic imaging modalities will be located in a recently approved medical office building and on the same campus as the Cone Health Cancer Center Asheboro. Patient origin percentages by imaging modality are based Cone Health's existing diagnostic imaging patients. The applicant's assumptions are reasonable and adequately supported because they are based on the applicant's historical experience providing diagnostic services to patients in the service area.

## **Analysis of Need**

In Section C, pages 35-39, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

Need for Freestanding Independent Diagnostic Treatment Facility –The IDTF/diagnostic center will increase access in the service area to multiple diagnostic imaging modalities at a lower out-of-pocket cost than hospital-based imaging services (page 35).

<u>Projected population growth in Randolph County</u> – The applicant examined population data published by the North Carolina State Office of Budget and Management (OSBM) and determined that the total population of Randolph County is projected to increase by an average compound annual growth rate (CAGR) of 0.4% between 2023-2028. The greatest population growth, according to the data, will be in the age 65+ age groups, those groups more likely to need diagnostic imaging services. See the table that illustrates the projected population growth in the service area on page 36. The applicant also states that Toyota Motor Corporation has plans to develop a manufacturing facility by 2030, which will employ over 5,000 people at full production. The applicant states this influx will contribute to population growth in the area and the need for lower cost diagnostic imaging services (pages 35-36).

High rates of cardiovascular disease in Randolph County – The applicant consulted the 2022 Community Health Needs Assessment from the North Carolina Center for Health Statistics (NCHA) which shows that heart disease was the primary cause of death in Randolph County and in North Carolina. Additionally, data from NCHA and the applicant's historical data show that 97.1% of cardiac CT scans received by Randolph County residents at an outpatient site were performed outside of Randolph County. The applicant states Randolph County residents do not currently have access to freestanding diagnostic imaging services and will benefit from outpatient diagnostic imaging in Randolph County (pages 36-38).

<u>High rates of cancer in Randolph County</u> – The applicant states the same 2022 data from NCHA shows that cancer is second leading cause of death in Randolph County. An outpatient diagnostic imaging center in the county, particularly co-located with the Cancer Center that is under development will provide Randolph County residents with familiarity and continuity of care (pages 38-39).

<u>Projected growth in imaging in Randolph County</u> – The applicant consulted the Advisory Board Company, a health care intelligence and consulting organization, which projects the need for imaging services in Randolph County will increase between FY 2024-2029. The applicant provides a table on page 39 that illustrates the projected increase in imaging utilization by modality (page 39).

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

- The applicant provides reliable data to show projected population growth in the proposed service area, particularly the older age cohorts, which are more likely to utilize diagnostic imaging services.
- The applicant relies on published health data to show projected growth in diagnostic imaging through the first four project years.
- The applicant provides reliable information about the health status of Randolph County residents and the need for outpatient diagnostic imaging services.

### **Projected Utilization**

In Section Q, Form C.2a, page 96 and page 5 of the applicant's *Assumptions* in Section Q, the applicant provides projected utilization, as illustrated in the following table:

CONE HEALTH MEDCENTER ASHEBORO PROJECTED DIAGNOSTIC IMAGING MODALITY VOLUMES FFY 2026-FFY 2029								
MODALITY FFY 2026 FFY 2027 FFY 2028 FFY 2029								
СТ	3,475	3,996	4,910	6,033				
X-ray	5,470	6,291	7,885	9,883				
Mammography	994	1,142	1,476	1,907				
Ultrasound	1,691	1,945	2,336	2,806				
DEXA	248	286	369	477				
Total	11,878	13,660	16,976	21,106				

In Section Q, "Volume Methodology and Assumptions", the applicant provides the assumptions and methodology used to project utilization, as summarized below:

Step 1: Determine the existing and projected service area population growth rate – The applicant states the NC OSBM data indicates population in Randolph County from 2023-2028 will increase by a CAGR of 0.4%, though the older age cohorts will increase at a faster rate. The applicant states the older age groups are the groups more likely to need healthcare, including diagnostic imaging services, and states the growth projection is likely conservative, since there are plans for strong economic development projects in the county (page 1).

Step 2: Determine historical imaging volumes — The applicant identified the outpatient diagnostic imaging volumes currently performed at Cone Health sites outside of Randolph County for those patients originating from Randolph County. The imaging services were performed outside of Randolph County because Cone Health does not currently offer imaging services at a site within Randolph County. The applicant does not expect that 100% of those patients who reside in Randolph County and seek diagnostic imaging services at facilities outside of Randolph County will shift to the proposed diagnostic imaging facility; therefore, the applicant states these volumes represent a baseline. See the following table from page 2 of the Assumptions that illustrates FY 2023 outpatient volumes for patients originating from Randolph County:

IMAGING MODALITY	FY 2023 RANDOLPH COUNTY RESIDENT VOLUMES	
Diagnostic Radiology	2,775	
Computed Tomography	1,763	
Ultrasound	858	
Mammography	504	
Bone Density	126	
Total	6,026	

The applicant states these volumes do not include emergency department outpatient volumes.

Step 3: Project Randolph County outpatient imaging market — The applicant states there is currently no existing IDTF for imaging services in Randolph County, therefore, it projects that some volumes (excluding emergency department related imaging) will shift to a freestanding site when one is available. The applicant used the baseline volume for those Randolph County patients who already choose a Cone Health site for outpatient imaging services and determined that Cone Health currently serves approximately 5.6% of the diagnostic imaging market for the identified modalities.

The applicant projects to capture an additional portion of Randolph County imaging services at the proposed IDTF. The applicant provides the following assumptions:

- The applicant does not project that it will capture all of the available market for freestanding outpatient imaging services in the county or even a sizeable market share.
- The applicant projects to capture a "measurable increase" of the market, based on:
  - o The provision of a new service closer to where its patients live;
  - o The imaging center status as a lower-cost freestanding site;
  - Co-location of imaging services with the previously-approved Cone Health Cancer Center Asheboro and other physician practices;
  - o Additional technological capabilities, such as cardiac CT, which the applicant believes will capture additional market share.

The following table, from page 3 of the *Assumptions*, illustrates projected imaging volume growth in Randolph County from FY 2023-2028, using the CAGR calculated in *Step 1* and FY 2023 volumes as a baseline:

MODALITY	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028	5 YEAR
							CAGR
Diagnostic radiology	50,786	51,111	51,328	51,555	51,792	52,039	0.5%
СТ	16,033	16,130	16,162	16,194	16,227	16,260	0.3%
Ultrasound	27,256	27,503	27,571	28,005	28,267	28,535	0.9%
Mammography	10,031	10,015	9,967	9,921	9,877	9,836	-0.4%
Bone Density	2,991	2,967	2,943	2,918	2,984	2,870	-0.8%
Total	107,187	107,726	108,151	108,593	109,057	109,540	0.4%

<sup>\*</sup>Source: application Section Q, page 3 of *Assumptions*. Applicant states data is from Advisory Board, Outpatient Imaging Estimator

The applicant projects market share volumes for each modality through the third project year, adjusted based on historical volumes and the applicant's offering of new imaging services. The applicant projects to capture an overall market share of 19.3% across all imaging modalities by project year four, FFY 2028. See the table that illustrates the market share projections on page 4 of the *Assumptions*.

The applicant expects the proposed project to gradually increase its market capture over time but does not expect all modalities to increase at the same rate due to differences in likely shifts from other sites to MedCenter Asheboro, and the offering of cardiac CT angiography, since CT angiography is a differentiator in the market from standard CT scanners. By year five, Cone Health projects capturing approximately 20% of the Outpatient Imaging projected to occur in Randolph County. See the table on page 4 of the *Assumptions* that illustrates projected market share by modality through the first four project years.

Using the baseline volumes for Project Year One, the applicant applied the projected market share by modality to the projected market volumes to project utilization at the proposed IDTF.

The applicant then calculated the maximum capacity for each of the proposed imaging modalities, based on the following:

- 1. Calculate the minutes available per day by multiplying the number of proposed hours per day by 60 minutes;
- 2. Multiply the minutes available per day by the number of days per year to determine minutes per year;
- 3. Divide the minutes per year by average procedure time to determine maximum procedures available

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

- The applicant relied on its historical diagnostic imaging utilization and historical growth rates for projecting future utilization.
- The applicant relied on projected population growth rates, particularly of the older age cohorts, which are the groups more likely to utilize diagnostic imaging services.
- The applicant reasonably projected a shift of diagnostic imaging outpatients based on the number of Randolph County residents who have historically sought imaging services at a Cone Health facility outside of the county.
- The applicant's projections are based on patient preference for lower cost outpatient imaging services that can be performed in a freestanding facility.

# **Access to Medically Underserved Groups**

In Section C, page 45, the applicant states:

"Cone Health does not discriminate against low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, or other underserved persons, including the medically indigent, the uninsured and the underinsured. In general, the health services of Cone Health are available to any patient in need without restriction of any kind. Access to hospital services for disadvantaged groups is provided in an organized setting through Cone Health's hospital-based

outpatient clinics. Cone Health's well established community education and screening programs are available to the general public and ensure adequate access to Cone Health services for medically underserved persons. The proposed project will not alter the current level of accessibility to patients of Cone Health. Access to the proposed service components will be via physician referral for most scans, or self-referral for screening mammography."

On page 46, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

MEDICALLY UNDERSERVED GROUPS	% OF TOTAL PATIENTS
Low-income persons	14.6%
Racial and ethnic minorities	12.6%
Persons with disabilities*	
Women	65.0%
Persons 65 and older	55.8%
Medicare beneficiaries	55.0%
Medicaid recipients	10.6%

<sup>\*</sup>The applicant states it does track persons with disabilities.

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 states that it will provide access to all underserved groups, consistent with all Cone Health facilities.
- The applicant provides supporting documentation of its non-discrimination policies and financial aid programs to assist the underserved in Exhibit C.6.1.

## 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.

(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 proposes to develop a diagnostic center by acquiring no more than one CT scanner, one x-ray unit, one ultrasound unit, one mammography unit and one bone density (DEXA) unit and upfit an existing medical office building in Randolph County.

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.

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The applicant proposes to develop a diagnostic center by acquiring no more than one CT scanner, one x-ray unit, one ultrasound unit, one mammography unit and one bone density (DEXA) unit and upfit an existing medical office building in Randolph County.

In Section E, page 53, 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 that this alternative would fail to bring a
  new, lower cost freestanding alternative for imaging services in Randolph County.
  Additionally, this alternative would ignore the need for comprehensive healthcare
  services to be provided at the proposed facility. Thus, the applicant determined this is
  not the most effective alternative.
- <u>Develop the proposed project at a different site</u> The applicant considered locating the proposed IDTF at a different site in Randolph County, but determined that this alternative would require additional unnecessary expenses for land acquisition and construction. The applicant states this alternative would also unnecessarily duplicate services that are already provided at MedCenter Asheboro. Thus, the applicant determined this is not the most effective alternative.

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

- The applicant provides reasonable and adequately supported 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 all the reasons described above. Therefore, the application is approved subject to the following conditions:

- 1. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.
- 2. The certificate holder shall develop a diagnostic center by acquiring no more than one CT scanner, one x-ray unit, one ultrasound unit, one mammography unit and one bone density unit to be located Cone Health MedCenter Asheboro.

# 3. Progress Reports:

- a. Pursuant to G.S. 131E-189(a), the certificate holders 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: <a href="https://info.ncdhhs.gov/dhsr/coneed/progressreport.html">https://info.ncdhhs.gov/dhsr/coneed/progressreport.html</a>.
- 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 February 1, 2025.
- 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. 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.

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The applicant proposes to develop a diagnostic center by acquiring no more than one CT scanner, one x-ray unit, one ultrasound unit, one mammography unit and one bone density (DEXA) unit and upfit an existing medical office building in Randolph County.

## **Capital and Working Capital Costs**

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

CAPITAL COST	THE MOSES H. CONE
	MEMORIAL HOSPITAL
Construction / Renovation	\$1,238,000
Medical Equipment	\$2,897,237
Miscellaneous Costs	\$220,468
Total	\$4,400,705

In Section Q, Form F.1a, 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 provides equipment quotes for the proposed diagnostic equipment in Exhibits F.1.2.i F.1.2.v
- In Exhibit F.1.1, the applicant provides a construction cost estimate signed by the project architect which includes a cost breakdown that matches the construction cost listed on Form F.1a.

In Section F.3, page 56, the applicant states there will be no start-up costs or operating costs associated with the project, since the ASF will be developed in a previously-approved medical office building.

### **Availability of Funds**

In Section F, page 54, the applicant states the capital cost will be funded through the accumulated reserves of The Moses H. Cone Memorial Hospital.

In Exhibit F.2-1 the applicant provides a February 15, 2024 letter signed by the Chief Financial Officer of Cone Health that confirms the availability of sufficient funding for the capital needs of the project, and commits those funds to project development. Exhibit F.2.2 contains the FY 2023 Cone Health audited financial statements that confirm sufficient cash and cash equivalents to fund the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides documentation of Cone Health's commitment to use cash reserves to develop the proposed project.
- The applicant documents the availability of sufficient financial resources to fund the proposed project capital cost.

# Financial Feasibility

In Section Q and in supplemental information provided at the Agency's request, the applicant provides pro forma financial statements for each of the proposed diagnostic modalities for the first three full fiscal years of operation following project completion. In Section Q Form F.2b, the applicant projects that revenues will exceed operating expenses in the fourth full fiscal year (FY), October 1, 2028 to September 30, 2029 following project completion for the entire facility, as shown in the following table:

CONE HEALTH MEDCENTER ASHEBORO PROJECTED PROCEDURES AND REVENUE UPON PROJECT COMPLETION							
ALL SERVICES PY 1 PY 2 PY 3 PY 4 (10/1/25-9/30/26) (10/1/26-9/30/27) (10/1/27-9/30/28) (10/1/28-9/30/29)							
Total # of Procedures*	14,068	16,179	20,071	24,909			
Gross Revenue	\$4,667,379	\$5,582,022	\$7,155,245	\$9,174,400			
Net Revenue	\$1,708,775	\$2,043,667	\$2,623,086	\$3,368,066			
Avg Net Revenue per Imaging Proc.	\$121	\$126	\$131	\$135			
Operating Costs	\$2,056,195	\$2,290,706	\$2,685,085	\$3,187,372			
Avg Operating Cost per Imaging Proc.	\$146	\$142	\$1354	\$128			
Net Income	\$(347,420)	\$(247,039)	\$(61,999)	\$180,694			

<sup>\*</sup>Total of all procedures from all proposed diagnostic imaging equipment. From Form C.2a, page 96.

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:

- The applicant bases its projections of revenues and expenses, including medical supplies, gross patient revenue and expenses on Cone Health MedCenter Kernersville's FY 2023 experience, adjusted for inflation.
- Projected utilization is based on reasonable and adequately supported assumptions. The
  discussion regarding projected utilization found in Criterion (3) is incorporated herein
  by reference.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information provided at the Agency's request

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

- The applicant adequately demonstrates that the capital cost is based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working 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.

 $\mathbf{C}$ 

The applicant proposes to develop a diagnostic center by acquiring no more than one CT scanner, one x-ray unit, one ultrasound unit, one mammography unit and one bone density (DEXA) unit and upfit an existing medical office building in Randolph County.

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 2024 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 proposes to locate the IDTF in a previously approved medical office building in Randolph County. Thus, the service area is Randolph County. Facilities may also serve residents not included in the defined service area.

In Section G, page 62, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic imaging services in Randolph County. The applicant states:

"Cone Health is not currently aware of any sites located in Randolph County that provide all the same services in the proposed project, other than the HOPD site located at Randolph Health. The proposed project will be billed at freestanding rates and therefore, offers an alternative to patients seeking a lower cost option without leaving the county for imaging services. Additionally, the proposed project will serve the expected growth in the market, particularly for patients being seen in the Medical Office Building in which the project will be located. Therefore, the

proposed project will enhance clinical services in the county, not unnecessarily duplicate existing health services."

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 proposes to add diagnostic imaging equipment to a medical office building.
- The applicant adequately demonstrates the need for the proposed diagnostic imaging center.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

 $\mathbf{C}$ 

The applicant proposes to develop a diagnostic center by acquiring no more than one CT scanner, one x-ray unit, one ultrasound unit, one mammography unit and one bone density (DEXA) unit and upfit an existing medical office building in Randolph County.

In Section Q, Form H, page 108 the applicant provides projected full-time equivalent (FTE) positions for the proposed diagnostic center, as illustrated in the following table:

MedCenter Asheboro Total Staffing					
FTE POSITION	1 <sup>ST</sup> FULL FY FFY 2026	2 <sup>ND</sup> FULL FY FFY 2027	3 <sup>RD</sup> FULL FY FFY 2028	4 <sup>™</sup> FULL FY FFY 2029	
Administrative	1.0	1.0	1.0	1.0	
Clinical Support Staff	0.1	0.2	0.2	0.2	
Other Clinical (Radiology)	9.7	11.2	13.7	16.7	
Total	10.9	12.3	14.8	17.9	

The assumptions and methodology used to project staffing are provided in Sections H and Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3(b). In Section H, pages 64-66, 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:

- The applicant is an established healthcare employer and has strong relationships with area nursing schools and allied health profession programs at the local community colleges.
- Those relationships will continue following project development.

### 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.

 $\mathbf{C}$ 

The applicant proposes to develop a diagnostic center by acquiring no more than one CT scanner, one x-ray unit, one ultrasound unit, one mammography unit and one bone density (DEXA) unit and upfit an existing medical office building in Randolph County.

#### **Ancillary and Support Services**

In a table in Section I, page 67, the applicant identifies the necessary ancillary and support services for the proposed diagnostic imaging services and explains how each ancillary and support service is and will continue to be available. The applicant provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because the applicant has established relationships with local health care and social service providers throughout the service area, and these relationships will extend to Cone Health MedCenter Asheboro.

## **Coordination**

In Section I, page 68, the applicant describes its existing and proposed relationships with other local health care and diagnostic service providers. The applicant adequately demonstrates that

the proposed services will be coordinated with the existing health care system because the applicant currently coordinates its services with the existing health care system and will continue to do so following the development of the proposed diagnostic imaging center.

### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

 $\mathbf{C}$ 

The applicant proposes to develop a diagnostic center by acquiring no more than one CT scanner, one x-ray unit, one ultrasound unit, one mammography unit and one bone density (DEXA) unit and upfit an existing medical office building in Randolph County.

In Section K, page 71 the applicant states the project involves renovating 2,566 square feet of existing space in a previously approved medical office building. Line drawings are provided in Exhibit K.1.

In Section K, pages 71-72 the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal, explaining that renovating existing space rather than constructing new space is less costly and more effective than acquiring land and building a new facility.

In Section K, page 72 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.

In Section K, page 72 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 healthrelated 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;

#### NA

In Section L, page 76, the applicant states the proposed diagnostic center is not an existing facility; therefore, it has no historical payor mix to report. However, the applicant provides payor mix for existing Randolph County residents who received outpatient imaging services at Cone Health sites outside of Randolph County, as shown in the following table, from page 75:

PAYOR SOURCE	% OF TOTAL PTS. SERVED
Self-Pay	5.3%
Charity Care	
Medicare*	44.3%
Medicaid*	6.8%
Insurance*	42.5%
Workers Compensation	0.2%
TRICARE	0.3%
Other^	0.6%
Total	100.0%

<sup>\*</sup>Including managed care plans

On page 76 the applicant states Cone Health internal data does not track charity care as a payor source for its patients.

In Section L, page 76, the applicant provides the following comparison:

<sup>^</sup>On page 76 the applicant states that "other" includes "Disability, Other Programs, Other Liability"

All Cone Health Imaging Facilities	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	65.0%	50.4%
Male	35.0%	49.6%
Unknown	0.0%	0.0%
64 and Younger	57.8%	81.4%
65 and Older	42.2%	18.6%
American Indian	0.3%	1.2%
Asian	0.4%	1.7%
Black or African-American	6.1%	7.1%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	87.6%	76.5%
Other Race	3.3%	2.1%
Declined / Unavailable	2.3%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 77, the applicant states it has no such obligation.

In Section L, page 78, the applicant states that no patient civil rights equal access complaints have been filed against Cone Health in the 18 months immediately preceding the application deadline.

#### 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

 $\mathbf{C}$ 

In Section L, pages 79-80 the applicant projects payor mix for all diagnostic imaging services and for the entire facility during the third full fiscal year (FFY 2028) of operation following completion of the project. The following table illustrates the projected payor mix for the entire facility:

Cone Health MedCenter Asheboro Entire Facility Projected Payor Mix FFY 2028				
PAYOR CATEGORY	% OF TOTAL			
Self-Pay	4.0%			
Medicare*	55.0%			
Medicaid*	10.6%			
Insurance*	30.0%			
Workers Compensation	0.2%			
TRICARE	0.2%			
Total	100.0%			

Source: Application, page 79

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 4.0% of total services provided by Cone Health MedCenter Asheboro will be provided to self-pay patients, and 55.0% and 10.6% of total services will be provided to Medicare and Medicaid patients, respectively. On page 81, the applicant states it does not track charity care as a payor source, but states it historically represents approximately 1% of gross revenue.

On page 78, the applicant provides the assumptions used to project payor mix during the third full fiscal year of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical payor mix for its outpatient diagnostic services for Randolph County patients who seek diagnostic imaging services outside of Randolph County. Additionally, the applicant states on page 78 that the proposed facility will be developed in a medical office building located on the same campus as the Cone Health Cancer Center, for which a certificate of need was issued on June 26, 2023. Therefore, the applicant

anticipates the payor mix for the proposed diagnostic center will be similar to that of the cancer center.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

 $\mathbf{C}$ 

In Section L, page 81, the applicant describes the means by which a person will have access to the proposed diagnostic services at Cone Health MedCenter Asheboro.

## **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.

 $\mathbf{C}$ 

The applicant proposes to develop a diagnostic center by acquiring no more than one CT scanner, one x-ray unit, one ultrasound unit, one mammography unit and one bone density (DEXA) unit and upfit an existing medical office building in Randolph County.

In Section M, pages 82-83 the applicant describes the extent to which health professional training programs in the area currently have access to Cone Health facilities for training purposes. The applicant states that established agreements with health education programs will include the proposed diagnostic center. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the 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 proposes to develop a diagnostic center by acquiring no more than one CT scanner, one x-ray unit, one ultrasound unit, one mammography unit and one bone density (DEXA) unit and upfit an existing medical office building in Randolph County.

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 2024 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 proposes to locate the IDTF in a previously approved medical office building in Randolph County. Thus, the service area is Randolph County. Facilities may also serve residents not included in the defined service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 85 the applicant states:

"The proposed project will offer another choice for the residents of Randolph County to receive imaging services in their community. It will be billed at freestanding rates, not Hospital Outpatient Department rates, and will provide a low-cost alternative compared to HOPD services. There is currently not an

Independent Diagnostic Testing Facility in Randolph County, particularly one that offers a comprehensive menu of services, including CT, X-ray, Mammography, Ultrasound, and bone density in one location outside of a hospital setting. ... Cone Health proposes to offer Cardiac Computed Tomography Angiography as part of the CT service component. This enhanced capability will allow providers to visualize possible blockages in the blood vessels of the heart without a more invasive diagnostic heart catheterization with comparable accuracy and at a lower cost to the patient, providing another choice for patients."

Regarding the expected effects of the proposal on cost effectiveness, in Section N, page 85 the applicant states:

"The proposed project illustrates Cone Health's commitment to providing costeffective care in an efficient manner. ... the proposed project will provide additional imaging capacity in Randolph County and allow patients to have more choice in where they receive their imaging services. Because the proposed project will be billed to the patient at freestanding rates versus Hospital Outpatient Department (HOPD) rates, patients using the service will likely have lower copays and coinsurance totals than they would receiving the service in an HOPD location."

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

Regarding the expected effects of the proposal on quality in the service area, in Section N, page 86 the applicant states:

"Cone Health has a long history of providing the proposed services and will apply that experience to the proposed project. Cone Health has been awarded multiple honors including high scores in patient safety and patient care."

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

Regarding the expected effects of the proposal on access by medically underserved groups in the service area, in Section N, page 86 the applicant states:

"Cone Health is committed to being a leader in providing cost-effective, highquality health care services to citizens in its service area in both inpatient and outpatient settings. As part of this commitment, it makes these services available to all community residents, without regard to ability to pay."

See also Sections B, 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:

- 1) 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.
- 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.

#### 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.

- (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 proposes to develop a diagnostic center by acquiring no more than one CT scanner, one x-ray unit, one ultrasound unit, one mammography unit and one bone density (DEXA) unit and upfit an existing medical office building in Randolph County.

In Section Q, Form O, the applicant identifies all diagnostic centers and hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 11 hospitals and diagnostic centers located in North Carolina. Diagnostic centers are not subject to DHSR license requirements.

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 of 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 proposes to develop a diagnostic center by acquiring no more than one CT scanner, one x-ray unit, one ultrasound unit, one mammography unit and one bone density (DEXA) unit and upfit an existing medical office building in Randolph County.

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

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

The applicant proposes no additional equipment for which performance standards apply. Therefore, no performance standards apply to this review.