

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 18, 2021

Findings Date: June 18, 2021

Project Analyst: Misty L. Piekaar-McWilliams

Team Leader: Fatimah Wilson

Project ID #: G-12076-21

Facility: Alamance Regional Medical Center

FID #: 954565

County: Alamance

Applicant: The Moses H. Cone Memorial Hospital  
Alamance Regional Medical Center, Inc.

Project: Renovate and expand the heart and vascular center by acquiring one (1) additional CT scanner with cardiac capabilities and one (1) additional unit of angiography equipment for a total of no more than five (5) CT scanners and two (2) units of angiography equipment

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

The Moses H. Cone Memorial Hospital and Alamance Regional Medical Center, Inc. (hereinafter referred to as "ARMC" or "the applicant") proposes to renovate and expand the heart and vascular center at ARMC by acquiring one (1) additional CT (computed tomography) scanner with cardiac capabilities and one (1) additional unit of angiography equipment for a total of no more than five (5) CT scanners and two (2) units of angiography equipment. Per ARMC's 2021 license renewal application (LRA), ARMC has two (2) CT scanners located at its main campus, one (1) CT scanner located at MedCenter Mebane and one (1) CT scanner

located at Alamance Regional Outpatient Imaging. All four (4) existing CT scanners currently operate under the hospital's license.

### **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 2021 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

### **Policies**

There is one policy in the 2021 SMFP which is applicable to this review. *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 29 of the 2021 SMFP, states:

*“Any person proposing a capital expenditure greater than \$2 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 \$5.0 million. In Section B, page 25, the applicant describes the project’s plan to improve energy efficiency and conserve water. On page 25, the applicant states,

*“Cone Health is committed to assuring improved energy efficiency and water conservation in its construction projects...Examples that will be investigated as part of this endeavor include:*

- *Mechanical systems designed to optimize energy efficiency*
- *An energy efficient building envelope designed to minimize direct heat gain*

- *Water reclamation, reuse, and reduction strategies*
- *Low VOC materials to improve indoor air quality*
- *Spaces designated for the collection of recycled materials.”*

The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

### **Conclusion**

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 for the following reasons:
  - The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.
  - The applicant adequately documents their willingness to submit an Energy Efficiency and Sustainability Plan to the Agency’s Construction Section that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.

(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 renovate and expand the heart and vascular center at ARMC by acquiring one (1) additional CT scanner with cardiac capabilities and one (1) additional unit of angiography equipment for a total of no more than five (5) CT scanners and two (2) units of angiography equipment.

**Patient Origin**

N.C. Gen. Stat. §131E-176(24a) defines “service area” as: “... *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 2021 SMFP does not specifically define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. Thus, the service area for this review is as defined by the applicant.

In Section C, page 38, the applicant states its primary service area for its proposed services is Alamance, Guilford and Randolph counties. Facilities may also serve residents of counties not included in the service area.

In Section C, page 32, the applicant provides the following table which illustrates historical patient origin for angiography/vascular interventional radiology (VIR) services at ARMC.

VIR  County or ZIP Code	ARMC	
	Last Full Fiscal Year (FFY) 10/1/2019-9/30/2020	
	# of Cases	% of Total
27215	349	24.5%
27217*	341	23.9%
27253**	186	13.1%
27302	119	8.3%
27249	68	4.8%
27244	65	4.5%
27258	30	2.1%
27298	29	2.0%
27349	25	1.7%
27377	23	1.6%
Other Counties and States	191	13.4%
<b>Total</b>	<b>1,426</b>	<b>100.0%</b>

Source: Section C, page 32 of the application.

\*Includes PO Boxes 27202 and 27216

\*\*Includes PO Boxes 27359

In Section C, page 33, the applicant provides the following table which illustrates historical patient origin for CT services at ARMC.

CT Scanner	ARMC	
	Last Full Fiscal Year (FFY) 10/1/2019-9/30/2020	
	# of Cases	% of Total
County or ZIP Code		
27215*	6,154	26.4%
27217**	5,235	22.5%
27253***	3,517	15.1%
27302	1,616	6.9%
27244	1,188	5.1%
27249****	1,052	4.5%
27377	664	2.9%
27258	596	2.6%
27349	545	2.3%
27298	400	1.7%
Other Counties and States	2,327	10.0%
<b>Total</b>	<b>23,294</b>	<b>100.0%</b>

Source: Section C, page 33 of the application.

\*Includes PO Boxes 27201

\*\*Includes PO Boxes 27202 and 27216

\*\*\* Includes PO Boxes 27340 and 27359

\*\*\*\* Includes PO Boxes 27342

In Section C, pages 35, the applicant projects the following patient origin for angiography/VIR services for the first three (3) FFYs following project completion, as shown in the tables below:

VIR	ARMC					
	1 <sup>st</sup> FFY 10/1/2024-9/30/2025		2 <sup>nd</sup> FFY 10/1/2025-9/30/2026		3 <sup>rd</sup> FFY 10/1/2026-9/30/2027	
	# of Cases	% of Total	# of Cases	% of Total	# of Cases	% of Total
County or ZIP Code						
27215	456	24.5%	515	24.5%	580	24.5%
27217*	444	23.9%	504	23.9%	565	23.9%
27253**	243	13.1%	276	13.1%	309	13.1%
27302	155	8.3%	175	8.3%	197	8.3%
27249	88	4.8%	100	4.8%	112	4.8%
27244	84	4.5%	96	4.5%	107	4.5%
27258	39	2.1%	44	2.1%	50	2.1%
27298	38	2.0%	43	2.0%	48	2.0%
27349	32	1.7%	37	1.7%	41	1.7%
27377	30	1.6%	34	1.6%	38	1.6%
Other Counties and States	249	13.4%	283	13.4%	317	13.4%
<b>Total</b>	<b>1,858</b>	<b>100.0%</b>	<b>2,107</b>	<b>100.0%</b>	<b>2,364</b>	<b>100.0%</b>

Source: Section C, page 35 of the application.

\*Includes PO Boxes 27202 and 27216.

\*\*Includes PO Boxes 27359

In Section Q, the applicant provides the assumptions and methodology used to project its patient origin for VIR services. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant assumes the percent distribution of patients by ZIP code will remain consistent with the applicant’s historical patient origin distribution for angiography/VIR services.
- The applicant determined the number of patients who currently use similar services at other Cone Health facilities in Greensboro who it expects may shift to ARMC to be treated closer to home upon completion of the proposed project.
- The total service area population is projected to grow 1.2% annually over the next five years.
- The 65+ age cohort, which represents the majority of the patients currently utilizing the services to be expanded is projected to grow by 3.4% over the next five years.

In Section C, page 36, the applicant projects the following patient origin for CT services for the first three (3) FFYs following project completion, as shown in the tables below:

CT Scanner  County or ZIP Code	ARMC					
	1 <sup>st</sup> FFY 10/1/2024-9/30/2025		2 <sup>nd</sup> FFY 10/1/2025-9/30/2026		3 <sup>rd</sup> FFY 10/1/2026-9/30/2027	
	# of Cases	% of Total	# of Cases	% of Total	# of Cases	% of Total
27215*	6,468	26.4%	6,532	26.4%	6,597	26.4%
27217**	5,502	22.5%	5,557	22.5%	5,612	22.5%
27253***	3,936	15.1%	3,733	15.1%	3,771	15.1%
27302	1,698	6.9%	1,715	6.9%	1,733	6.9%
27244	1,249	5.1%	1,261	5.1%	1,274	5.1%
27249****	1,106	4.5%	1,117	4.5%	1,128	4.5%
27377	698	2.9%	705	2.9%	712	2.9%
27258	626	2.6%	633	2.6%	639	2.6%
27349	573	2.3%	579	2.3%	584	2.3%
27298	420	1.7%	425	1.7%	429	1.7%
Other Counties and States	2,446	10.0%	2,470	10.0%	2,495	10.0%
<b>Total</b>	<b>24,482</b>	<b>100.0%</b>	<b>24,727</b>	<b>100.0%</b>	<b>24,974</b>	<b>100.0%</b>

Source: Section C, page 36 of the application.

\*Includes PO Boxes 27201

\*\*Includes PO Boxes 27202 and 27216

\*\*\* Includes PO Boxes 27340 and 27359

\*\*\*\* Includes PO Boxes 27342

In Section Q, the applicant provides the assumptions and methodology used to project its patient origin for CT services. The applicant states that while CT volume decreased slightly between FY 2019-FY2020 due to the COVID-19 pandemic, the result was still a slight growth over the three-year period between FY2018-FY2020 (0.1%). The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant assumes the percent distribution of patients by ZIP code will remain consistent with the applicant's established patient origin distribution for CT services.
- The total service area population is projected to grow 1.2% annually over the next five years.
- The 65+ age cohort, which represents most of the patients currently utilizing the services to be expanded is projected to grow by 3.4% over the next five years.

### **Analysis of Need**

In Section C, pages 37-48, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- Population to be Served – The applicant states that most individuals using the proposed services are 65 and older. For this reason, the applicant projects the demand for services to increase due to projected population growth among this age group which will increase utilization as the residents in the service area age. (pages 38-39)
- Growth in Demand for Vascular Procedures – ARMC has experienced significant historical growth in demand for vascular services and expects the increase in demand to continue. The overall growth for vascular procedures is almost four (4) percent annually and the applicant provides supporting documentation in Exhibit C.4 which contains letters of support from physicians who currently use the lab and will continue to utilize the lab for procedures. (pages 40-42)
- Increasing Demand for Cardiac Procedures – The applicant states that there is an increase in demand for cardiac procedures. Specifically, it is expected for outpatient electrophysiology services to grow in demand as technology improves, and, thus, permitting patients to return home quicker. (pages 43-44)
- Capacity Constraints of Existing Equipment and Spaces, Resulting in Patient Travel Outside the Service Area – The applicant states that the current equipment is operating above 100% capacity. The applicant analyzed data from the North Carolina Healthcare Association, Hospital Industry Data Institute and licensed renewal agreements from North Carolina Division of Health Service Regulation and determined a percentage of residents residing in the service area are seeking services outside the service area. The applicant states residents residing in the service area are seeking services outside the service area due to a lack of capacity for existing services. (pages 44-48)

### **Projected Utilization**

#### **Computed Tomography**

In Section Q, pages 124-131, the applicant provides the assumptions and methodology used to project utilization for its CT services at ARMC, which are summarized below.

*For ARMC:*

Step 1: Determine the Projected Service Area Population Growth Rate (page 124).

The applicant projects a compound annual growth rate (CAGR) of 1.2% over the next five (5) years in the service area.

2020 Population	2025 population	# Change	% Change	CAGR
218,141	231,784	13,643	6.3%	1.2%

Source: Page 124 of the application.

The applicant then states that the majority of the patients currently utilizing CT services are over age 65. The applicant projects individuals 65 and older will grow at 3.4% per year over the next five (5) years.

Age Cohort	2020 Pop.	2025 Pop.	# Change	% Change	CAGR
65+	138,402	45,357	6,955	18.1%	3.4%

Source: Page 124 of the application.

Step 2: Determine Historical Growth in CT Procedures (page 124).

The applicant states there was a slight increase in utilization of CT services from 2018 to 2019; however, in 2020, due to the COVID-19 pandemic, utilization for CT services decreased from 2019 volumes. In 2019, ARMC provided 24,732 CT procedures whereas in 2020, ARMC provided 23,294 CT procedures resulting in a 0.1% CAGR between FY2018-FY2020.

Step 3: Determine Future Demand for Cardiac CT Procedures (page 125).

The applicant relied on data from Advisory Board, a healthcare intelligence firm that provides projections for inpatient discharges and outpatient procedures annually by service area. The applicant states that Cone Health alone already exceeds the total volumes that the Advisory Board would project for the entire market. The table below shows the growth in cardiac CT procedures for ARMC for the next five years.

Procedure Type	Current Estimate	5 Year Projection	# Change	% Change	CAGR
Cardiac CT	34	42	8	23.0%	4.2%

Source: Page 125 of the application

Step 4: Determine Future Demand for Overall CT Procedures (page 125).

The applicant states that the proposed additional CT scanner will not only be used for cardiac CT procedures, but also to decompress general purpose scans from the existing CT scanners at ARMC, thus the applicant also evaluated the overall market for CT scans based on data from Advisory Board, as shown in the table below.

Procedure Type	Current Estimate	5 Year Projection	# Change	% Change	CAGR
CT	43,559	46,755	3,196	7.3%	1.4%

Source: Page 125 of the application



**Step 5: Determine an Appropriate Growth Rate (page 125).**

The applicant applies a 1.0% growth rate which is less than the projected growth rate for the service area and less than the projected growth rate for individuals 65 and older. Persons 65 and older are many patients currently utilizing the proposed services.

**Historical and Projected CAGRs**

Overall Projected Service Area Growth Rate	1.2%
65+ Age Cohort Projected Service Area Growth Rate	3.4%
Historical CT Procedure Growth Rate	0.1%
Projected Cardiac CT Procedure Growth Rate	4.2%
Projected Overall CT Procedure Growth Rate	1.4%

Source: Page 125 of the application

**Step 6: Project ARMC CT Volumes (page 126).**

The applicant states that in fiscal year 2020, there were 23,294 CT scans performed at ARMC. These scans are projected forward from present to the third FY2020-FY2027 using a 1.0% growth rate.

	FY2020	FY2021	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027
CT Scans	23,294	23,527	23,762	24,000	24,240	24,482	24,727	24,974

Source: Page 126 of the application.

**Step 7: Calculate HECT Units (pages 126-127).**

The applicant then converts CT scans into HECT units for each type of CT scan using the conversion chart found on page 110 of the application. The applicant states that it assumes that the FY 2020 ratio of CT scans to HECT units will remain consistent throughout the project.

Using the projected ARMC CT volumes found in step 6 of this methodology, the applicant projects the following HECT units as illustrated in the table below:

	FY2020	FY2021	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027
CT Scans	23,294	23,527	23,762	24,000	24,240	24,482	24,727	24,974
HECT Units	36,465.75	36,831.50	37,196.25	37,571.25	37,946.75	38,327.00	38,707.75	39,097.25

Source: Page 127 of the application.

**Step 8: Calculate Projected Utilization (page 127).**

The applicant states that 10A NCAC 14C .2303 defines the capacity of a CT scanner as 5,100 HECT units. Using 5,100 HECT units as a baseline, the applicant projects utilization for the first three (3) FYs of operation.

	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>
Projected HECT Units	38,327.00	38,707.75	39,097.25
Perf. Standard (HECT Units)	5,100	5,100	5,100
# of CT Scanners	3	3	3
Total HECT Units	15,300	15,300	15,300
Utilization	250.5%	253.0%	255.5%

Source: Page 127 of the application.

*For ARMC Hospital License:*

The applicant states on page 128 of the application that it currently operates four (4) CT scanners on its hospital license. Per ARMC’s 2021 LRA, ARMC has two (2) CT scanners located at its main campus, one (1) CT scanner located at MedCenter Mebane and one (1) CT scanner located at Alamance Regional Outpatient Imaging.

Step 1: Determine the Projected Service Area Population Growth Rate (page 128).

The applicant projects a compound annual growth rate (CAGR) of 1.2% over the next five (5) years in the service area.

<b>2020 Population</b>	<b>2025 population</b>	<b># Change</b>	<b>% Change</b>	<b>CAGR</b>
218,141	231,784	13,643	6.3%	1.2%

Source: Page 128 of the application.

The applicant then states that the majority of the patients currently utilizing CT services are over age 65. The applicant projects individuals 65 and older will grow at 3.4% per year over the next five (5) years.

<b>Age Cohort</b>	<b>2020 Pop.</b>	<b>2025 Pop.</b>	<b># Change</b>	<b>% Change</b>	<b>CAGR</b>
65+	138,402	45,357	6,955	18.1%	3.4%

Source: Page 128 of the application.

Step 2: Determine Historical Growth in CT Procedures (page 128).

The applicant states that volumes for the existing CT scanners on the hospital’s license decreased slightly in CY 2020 due to the COVID-19 pandemic. However, based on LRA data for FY2018-FY2020, utilization for CT services increased, as shown in the table below from page 128 of the application.

<b>2018 Volumes</b>	<b>2019 Volumes</b>	<b>2020 Volumes</b>	<b># Change</b>	<b>% Change</b>	<b>CAGR</b>
27,556	29,243	29,421	1,865	6.8%	3.3%

Source: Page 128 of the application

Step 3: Determine Future Demand for Cardiac CT Procedures (page 129).

The applicant relied on data from Advisory Board, a healthcare intelligence firm that provides projections for inpatient discharges and outpatient procedures annually by service area. The applicant states that Cone Health alone already exceeds the total volumes that the Advisory

Board would project for the entire market. The table below shows the growth in cardiac CT procedures for ARMC for the next five years.

Procedure Type	Current Estimate	5 Year Projection	# Change	% Change	CAGR
Cardiac CT	34	42	8	23.0%	4.2%

Source: Page 129 of the application

Step 4: Determine Future Demand for Overall CT Procedures (page 129).

The applicant states that the proposed additional CT scanner will not only be used for cardiac CT procedures, but also to decompress general purpose scans from the existing CT scanners at ARMC, thus the applicant also evaluated the overall market for CT scans, as shown in the table below.

Procedure Type	Current Estimate	5 Year Projection	# Change	% Change	CAGR
CT	43,559	46,755	3,196	7.3%	1.4%

Source: Page 129 of the application

Step 5: Determine an Appropriate Growth Rate (page 129).

The applicant applies a 1.0% growth rate which is less than the projected growth rate for the service area and less than the projected growth rate for individuals 65 and older. Persons 65 and older are many patients currently utilizing the proposed services.

**Historical and Projected CAGRs**

Overall Projected Service Area Growth Rate	1.2%
65+ Age Cohort Projected Service Area Growth Rate	3.4%
Historical CT Procedure Growth Rate	0.1%
Projected Cardiac CT Procedure Growth Rate	4.2%
Projected Overall CT Procedure Growth Rate	1.4%

Source: Page 129 of the application

Step 6: Project ARMC CT Volumes (page 130).

The applicant states that in fiscal year 2020, there were 29,421 CT scans performed on all the CT scanners operating under the ARMC license. These scans are projected forward from present to the third fiscal year, FY 2020 to FY2027 using a 1.0% growth rate.

	FY2020	FY2021	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027
CT Scans	29,421	29,715	30,012	30,312	30,616	30,922	31,231	31,543

Source: Page 130 of the application.

Step 7: Calculate HECT Units (page 130).

The applicant then converts CT scans into HECT units for each type of CT scan using the conversion chart found on page 130 of the application. The applicant states that it assumes that the FY 2020 ratio of CT scans to HECT units will remain consistent throughout the project.

Using the projected CT volumes found in step 6 of this methodology, the applicant projects the following HECT units as illustrated in the table below:

	FY2020	FY2021	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027
CT Scans	29,421	29,715	30,012	30,312	30,616	30,922	31,231	31,543
HECT Units	46,788.00	47,256.00	47,728.00	48,207.25	48,688.75	49,176.75	49,665.75	50,164.25

Source: Page 130 of the application.

Step 8: Calculate Projected Utilization (page 131).

The applicant states that 10A NCAC 14C .2303 defines the capacity of a CT scanner as 5,100 HECT units. Using 5,100 HECT units as a baseline, the applicant projects utilization for the first three (3) fiscal years of operation.

	FY2025	FY2026	FY2027
Projected HECT Units	49,176.75	49,665.75	50,164.25
Perf. Standard (HECT Units)	5,100	5,100	5,100
# of CT Scanners	5	5	5
Total HECT Units	25,500	25,500	25,500
Utilization	192.9%	194.8%	196.7%

Source: Page 131 of the application.

Projected utilization for CT services is reasonable and adequately supported based on the following reasons:

- The applicant relies on data from established and reliable sources and cites to the sources of any data used.
- The applicant uses a projected growth rate of 1.0% which is a growth rate less than the overall projected growth rate for the service area and less than the projected growth rate for individuals 65 and older in the service area. Persons 65 and older are the majority of patients currently utilizing the services.
- The applicant bases projected utilization on the historical number of CT scans performed by ARMC.
- The applicant projects that the CT scanners owned, operated or affiliated with the applicant will perform 50,164.25 HECT units in the third year of operation (FY2027) or 10,032.85 HECT units per CT scanner ( $50,164.25/5 = 10,032.85$ ). This exceeds the minimum of 5,100 HECT units annually in the third year of operations as required by 10A NCAC 14C .2303.

Angiography/VIR Services

In Section Q, pages 132-137, the applicant provides the assumptions and methodology used to project utilization for angiography/VIR services, which are summarized below. The applicant

states on page 132 that it currently operates one (1) angiography/VIR unit and proposes to add one (1) additional angiography/VIR unit.

Step 1: Determine the Projected Service Area Population Growth Rate (page 132).

The applicant projects a compound annual growth rate (CAGR) of 1.2% over the next five (5) years in the service area.

2020 Population	2025 population	# Change	% Change	CAGR
218,141	231,784	13,643	6.3%	1.2%

Source: Page 132 of the application.

The applicant then states that the majority of the patients currently utilizing CT services are over age 65. The applicant projects individuals 65 and older will grow at 3.4% per year over the next five (5) years.

Age Cohort	2020 Pop.	2025 Pop.	# Change	% Change	CAGR
65+	138,402	45,357	6,955	18.1%	3.4%

Source: Page 132 of the application.

Step 2: Determine Historical Growth in Angiography/VIR Procedures (page 132).

The applicant states they analyzed the historical growth of VIR procedures, and despite CY 2020 being unusual due to the COVID-19 pandemic, volumes for existing angiography/VIR services increased from CY2019 to CY 2020, as shown in the table below.

2018 Volumes	2019 Volumes	2020 Volumes	# Change	% Change	CAGR
3,840	4,262	4,493	653	17.0%	8.2%

Source: Page 128 of the application

Step 3: Determine Future Demand for Angiography/VIR Procedures (page 133).

The applicant states they relied on data from the Advisory Board for projections of inpatient discharges based on MS-DRG, or diagnosis, but not by procedure. The applicant states that there is no logical grouping for these procedures given the variety in MS-DRGs that inpatients fall into. The Advisory Board also does not project outpatient procedures based on any specific procedure codes or groups. The table below shows the Advisory Board's outpatient projections for the types of procedures that are and will be performed at ARMC, as shown in the table below.

Procedure Type	Current Estimate	5 Year Projection	# Change	% Change	CAGR
Outpatient Total	1,882	2,271	389	20.7%	3.8%

Source: Page 133 of the application

Step 4: Determine Future Demand for Electrophysiology Procedures (page 133).

The applicant also relied on data from the Advisory Board for projections of electrophysiology procedures and states that unlike angiography/VIR procedures, electrophysiology patients can be easily categorized into inpatient MS-DRG groupings. The table below shows the Advisory Board’s inpatient and outpatient electrophysiology projections at ARMC, as shown in the table below.

Patient Type	Current Estimate	5 Year Projection	# Change	% Change	CAGR
Inpatient	134	126	-8	6.0%	-1.2%
Outpatient	260	373	113	43.7%	7.5%
<b>Total</b>	<b>394</b>	<b>499</b>	<b>105</b>	<b>26.6%</b>	<b>4.8%</b>

Source: Page 133 of the application

Step 5: Determine an Appropriate Growth Rate (pages 133-134).

The applicant applies a 3.4% growth rate which is equal to the projected growth rate for individuals 65 and older. This growth rate is less than the historical angiography/VIR procedure growth rate of 8.2%. Persons 65 and older are many patients currently utilizing the proposed services. The applicant states on page 134 that individuals 65 and older represent over half of the patients who utilize angiography services and represent the vast majority of patients who receive electrophysiology services.

**Historical and Projected CAGRs**

Overall Projected Service Area Growth Rate	1.2%
65+ Age Cohort Projected Service Area Growth Rate	3.4%
Historical Angiography/VIR Procedure Growth Rate	8.2%
Projected Angiography/VIR Procedure Growth Rate	3.8%
Projected Electrophysiology Procedure Growth Rate	4.8%

Source: Page 134 of the application

Step 6: Project ARMC Angiography/VIR Volumes (page 134).

The applicant states that in FY 2020, there were 1,426 cases representing 4,493 procedures which required angiography/VIR equipment. These cases are projected forward from present to the third full fiscal year (2020 to 2027) using a 3.4% growth rate. The applicant states that cases are used here as later steps in the methodology require the calculation of room utilization based on time and cases, not procedures as a case can, and frequently does consist of multiple procedures, but each patient only has one case at a time.

	FY2020	FY2021	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027
Cases	1,426	1,474	1,524	1,576	1,629	1,684	1,741	1,800

Source: Page 134 of the application.

Step 7: Determine the Shift of Patients from Existing Cone Health Locations (pages 134-135).

The applicant states that it projects the additional equipment at ARMC will permit patients to be treated closer to home. The applicant states that they will use the same 3.4% growth rate

since the patients live in the identified service area and assumes that 25% of inpatients and 50% of outpatients will elect to receive care at ARMC instead of a Greensboro, with the exception of more specialized VIR services.

The following table illustrates the cases expected to shift from Moses Cone and Wesley Long in Greensboro.

<b>Current Location</b>	<b>Moses Cone Inpatient</b>	<b>Moses Cone Outpatient</b>	<b>Wesley Long Inpatient</b>	<b>Wesley Long Outpatient</b>
Total Cases from Service Area	286	330	63	195
% to be Served at ARMC	25%	25%	25%	50%
Cases to Shift to ARMC	71	82	16	97

Source: Page 135 of the application.

The applicant states that only 25% of both inpatient and outpatient cases are projected to shift from Moses Cone due to the specialized equipment only available there that will not be available at ARMC.

The following table illustrates the electrophysiology cases expected to shift from Moses Cone ARMC.

<b>Current Location</b>	<b>Moses Cone Inpatient</b>	<b>Moses Cone Outpatient</b>
Total Cases from Service Area	95	172
% to be Served at ARMC	25%	50%
Cases to Shift to ARMC	24	86

Source: Page 135 of the application.

The applicant states that by shifting patients from their Greensboro facilities to ARMC will provide for additional capacity in their Greensboro locations and decompress the interventional radiology labs which are highly utilized. The applicant also states that ARMC is currently performing its electrophysiology procedures in the operating room (OR) because of a lack of capacity in the existing angiography lab. Upon project completion, the applicant states that those procedures expected to shift to ARMC will be performed in the new interventional space, approximately 70 cases each year.

**Step 8: Project Volumes from Current Locations (pages 135-136).**

The applicant states they applied the 3.4 percent growth rate to the projected case volume of the three (3) locations identified in step 7 because the patients identified reside in the same service area, represent the same age cohort and will receive the same services. The applicant states that it does not expect patients or providers to immediately change locations and, consequently, projects 33% of volumes to shift in FY2025 (FY1), 67% of volumes to shift in FY2026 (FY2) and 100% of volumes to shift in FY2027 (FY3).

**Projected Cases to Shift**

Location	FY2020	FY2021	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027
Greensboro IR	267	276	285	295	305	315	326	337
Greensboro EP	110	113	117	121	125	130	134	139
ARMC EP	70	72	75	77	80	83	85	88
Subtotal Shifting Volumes	447	462	477	494	510	528	545	564

Source: Page 136 of the application.

**Total Projected Cases to Shift**

Location	FY2020	FY2021	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027
Greensboro IR	267	276	285	295	305	315	326	337
Greensboro EP	110	113	117	121	125	130	134	139
ARMC EP	70	72	75	77	80	83	85	88
Shift %	0%	0%	0%	0%	0%	33%	67%	100%
Subtotal Shifting Volumes	0	0	0	0	0	174	365	564

Source: Page 136 of the application.

Step 9: Combine the Volumes and Calculate Projected Utilization (pages 136-137).

The following table shows the initial volumes from step 6 and shifted volumes from step 8.

Location	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
<b>Existing Cases</b>	1,426	1,474	1,524	1,576	1,629	1,684	1,741	1,800
<b>Shifted Cases</b>	0	0	0	0	0	174	365	564
<b>Total Cases</b>	1,426	1,474	1,524	1,576	1,629	1,858	2,107	2,364

Source: Page 136 of the application.

The applicant states that the average case time for both a VIR case and an electrophysiology case is 1.5 hours and the lab is scheduled for use eight hours a day, 250 days a year, yielding an availability for each unit of equipment of 2,000 hours annually. The following table shows the total time used in each project year, the total time available and the utilization.

	FY2025	FY2026	FY2027
Total Cases	1,858	2,107	2,364
Avg Case Time (hrs.)	1.5	1.5	1.5
Total Case Time	2,788	3,160	3,546
Total Availability (hrs.)	4,000	4,000	4,000
Utilization	69.7%	79.0%	88.7%

Source: Page 137 of the application.

Projected utilization for angiography/VIR services is reasonable and adequately supported based on the following reasons:

- The applicant relies on data from established and reliable sources and cites to the sources of any data used.
- The applicant bases projected utilization on the historical angiography/VIR, and electrophysiology volumes performed at ARMC and affiliated Cone Health facilities in the same service area.



- The applicant uses a projected growth rate of 3.4% which is a growth rate less than the historical angiography/VIR procedure growth rate and equivalent to the projected growth rate for individuals 65 and older in the service area. Persons 65 and older are the majority of patients currently utilizing the services.
- The applicant bases projected utilization on the historical number of cases performed by ARMC and those cases expected to shift from there affiliated Greensboro facilities.

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

In Section C, page 53, the applicant states:

*“Cone Health is a private, not-for-profit organization established to serve the community by providing high quality, affordable, and comprehensive health care services to all patients, regardless of their economic status.”*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons*	
Racial and ethnic minorities	32.5%
Women	62.6%
Persons with disabilities*	
Persons 65 and older	38.2%
Medicare beneficiaries	53.3%
Medicaid recipients	12.2%

Source: Page 54 of the application.

\*The applicant states on page 54 it does not maintain data for the number of low-income individuals or individuals with disabilities it serves.

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 has implemented non-discrimination policies and provides supporting documentation in Exhibit C.6-1.
- The applicant is an active member of the community and involved in activities that support the community and provides supporting documentation in Exhibit C.6-2.

### **Conclusion**

The Agency reviewed the:

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

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

- (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.

CA

The applicant proposes to renovate and expand the heart and vascular center at ARMC by acquiring one (1) additional CT scanner with cardiac capabilities and one (1) additional unit of angiography equipment for a total of no more than five (5) CT scanners and two (2) units of angiography equipment.

In Section E, pages 63-64, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicant states this was not an effective alternative because it would not alleviate any capacity constraints for the VIR suite or CT department. This alternative also would not modernize the VIR spaces in terms of lab size or adequate numbers of pre-recovery and post-recovery bays.
- Expand without the CT scanner – The applicant states this was not an effective alternative due to the CT scanners at ARMC currently operating at 300% capacity and any savings now would only be deferred until later because of capacity constraints. Additionally, the applicant states that if they expand without the CT scanners, the project would not take advantage of economies of scale while concurrently undertaking the construction project for the other portions of the Heart and Vascular Center.
- Locate the cardiac CT in another location – The applicant states this was not an effective alternative because this option would have resulted in higher total capital costs resulting from undertaking two (2) separate construction projects and also does not account for the fact that the proposed location in Burlington is more accessible to many of ARMC's patients.

On page 64, the applicant states since none of the alternatives were deemed superior to the proposed project, the applicant elected to pursue the proposed project.

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 credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all statutory and regulatory review criteria. Therefore, the application can be approved.

### **Conclusion**

The Agency reviewed the:

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

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

- 1. The Moses H. Cone Memorial Hospital and Alamance Regional Medical Center, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application and any clarifying responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. The certificate holder shall acquire no more than one (1) CT scanner and one (1) unit of angiography equipment.**
- 3. Upon completion of the project, the certificate holder shall have no more than five (5) CT scanners and two (2) units of angiography equipment.**
- 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. 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. **Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on October 1, 2021. The second progress report shall be due on February 1, 2022, and so forth.**
  6. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
    - a. **Payor mix for the services authorized in this certificate of need.**
    - b. **Utilization of the services authorized in this certificate of need.**
    - c. **Revenues and operating costs for the services authorized in this certificate of need.**
    - d. **Average gross revenue per unit of service.**
    - e. **Average net revenue per unit of service.**
    - f. **Average operating cost per unit of service.**
  7. **The certificate holder shall 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.**
  8. **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 renovate and expand the heart and vascular center at ARMC by acquiring one (1) additional CT scanner with cardiac capabilities and one (1) additional unit of angiography equipment for a total of no more than five (5) CT scanners and two (2) units of angiography equipment.

**Capital and Working Capital Costs**

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

**Proposed Capital Cost**

Site Preparation	\$738,000
Construction/Renovation Contract(s)	\$21,198,000
Architect/Engineering Fees	\$1,844,412
Medical Equipment	\$6,401,622
Non-Medical Equipment	\$328,104
Furniture	\$773,554
Other (Misc.-fees, survey, soil test)	\$220,000
<b>Total</b>	<b>\$31,503,642</b>

In Sections F and Q, 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 did not include purchase price, closing costs and landscaping costs in its capital costs calculations as it is an existing facility.
- The applicant projects capital costs on architect’s estimates and provides supporting documentation in Exhibit F.1.
- Financing is not included since capital costs will be funded through cash reserves.
- On page 67, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because this is an existing facility that is already operational.

**Availability of Funds**

In Section F, page 65, the applicant states that the capital cost will be funded as shown below in the table.

**Sources of Capital Cost Financing**

Type	CHPC
Loans	\$0
Accumulated reserves or OE *	\$31,503,642
Bonds	\$0
Other	\$0
<b>Total Financing</b>	<b>\$31,503,642</b>

\* OE = Owner’s Equity.

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

- The applicant provides a letter from the Chief Financial Officer of Cone Health indicating his willingness to fund the project through the applicant’s unrestricted net assets and provides supporting documentation in Exhibit F.2-1.
- Exhibit F.2-2 contains the Consolidated Financial Statements for the year ending September 30, 2020, showing the Moses H. Cone Memorial Hospital and its affiliates currently have \$328 million in cash and cash equivalents and \$3.2 billion in total assets.

**Financial Feasibility**

In Section Q, the applicant provides pro forma financial statements for the first three (3) full fiscal years of operation following completion of the project. In Section Q, the applicant projects that revenues will exceed operating expenses in each of the first three (3) full fiscal years of operation following project completion of the project, as shown in the table below.

**ARMC Revenues/Operating Expenses – Angiography/Interventional Radiology**

	<b>1<sup>ST</sup> FULL FISCAL YEAR 10/01/2024- 9/30/2025</b>	<b>2<sup>ND</sup> FULL FISCAL YEAR 10/01/2025- 9/30/2026</b>	<b>3<sup>RD</sup> FULL FISCAL YEAR 10/01/2026- 9/30/2027</b>
Total Cases	1,858	2,107	2,364
Total Gross Revenue	\$62,477,137	\$73,660,235	\$85,966,967
Total Net Revenue	\$17,266,364	\$19,913,859	\$22,735,878
Average Net Revenue per Procedure	\$9,293	\$9,451	\$9,618
Total Operating Expenses (Costs)	\$15,379,587	\$17,420,037	\$19,606,919
Average Operating Expense per Procedure	\$8,277	\$8,268	\$8,294
Net Income	\$1,886,778	\$2,493,823	\$3,128,959

Source: Form C, page 107, and Form F.2b, page 119.

Totals may not sum due to rounding

**ARMC Revenues/Operating Expenses – CT Scanner**

	<b>1<sup>ST</sup> FULL FISCAL YEAR 10/01/2024- 9/30/2025</b>	<b>2<sup>ND</sup> FULL FISCAL YEAR 10/01/2025- 9/30/2026</b>	<b>3<sup>RD</sup> FULL FISCAL YEAR 10/01/2026- 9/30/2027</b>
Total Procedures*	27,769	28,046	28,327
Total Gross Revenue	\$68,099,385	\$71,531,594	\$75,136,786
Total Net Revenue	\$19,936,219	\$20,498,138	\$21,076,821
Average Net Revenue per Procedure	\$718	\$731	\$744
Total Operating Expenses (Costs)	\$7,747,778	\$7,971,896	\$8,204,594
Average Operating Expense per Procedure	\$279	\$284	\$290
Net Income	\$12,188,441	\$12,526,242	\$12,872,227

Source: Form C, page 109, and Form F.2b, page 114.

Totals may not sum due to rounding

\*Includes procedures for all CT scanners operated by applicant.

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 adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the applicant’s historical experience.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

### C

The applicant proposes to renovate and expand the heart and vascular center at ARMC by acquiring one (1) additional CT scanner with cardiac capabilities and one (1) additional unit of angiography equipment for a total of no more than five (5) CT scanners and two (2) units of angiography equipment.

N.C. Gen. Stat. §131E-176(24a) defines “service area” as: “... *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 2021 SMFP does not specifically define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. Thus, the service area for this review is as defined by the applicant.

In Section C, page 38, the applicant states its primary service area for its proposed services is Alamance, Guilford and Randolph counties. Facilities may also serve residents of counties not included in the service area.

The applicant states on page 74 that there is no comprehensive listing of CT or VIR providers available. However, the applicant reviewed data from the American College of Radiology (ACR). ACR lists two (2) additional facilities, Alliance Medical Associates, PLLC and UNC Hospitals Burlington Imaging and Breast Center, as providing CT services in the service area. The applicant is not aware of any providers of VIR services in the service area.

In Section G, page 74, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved CT or VIR services in the service area. On page 74, the applicant states:

*“The need for the proposed project is based on the historical volumes and projected growth at Alamance Regional Medical Center. The existing services offered are highly utilized, and current equipment is operating above 100% capacity. As demonstrated in Sections C and Q of this application, the need for this project is not based on assumptions of patients choosing Alamance Regional Medical Center over competing facilities, but rather based on population growth and redistribution of existing Cone Health patients who would prefer care closer to home. Additionally, Alamance Regional Medical Center is believed to be the only provider of vascular interventional radiology in the service area and, therefore, cannot duplicate the service provided by any other provider in the service area.”*

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 states it is not aware of any other providers offering VIR services in the area.
- The applicant demonstrates there is a need for increasing the existing services and states the current equipment is operating above 100% capacity.

**Conclusion**

The Agency reviewed the:

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

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

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

**ARMC Current and Proposed Staffing-CT Scanner**

Position	Current Staff	Projected FTE Staff		
	As of 9/30/2020	1st FFY	2nd FFY	3rd FFY
Imaging Technician	9.5	10.0	10.1	10.2
Imaging Clinical Specialist	0.8	0.8	0.8	0.8
<b>TOTAL</b>	10.0	11.0	11.0	11.0

Totals may not sum due to rounding



**ARMC Current and Proposed Staffing-Angiography/Interventional Radiology**

Position	Current Staff	Projected FTE Staff		
	As of 9/30/2020*	1st FFY	2nd FFY	3rd FFY
Angiography/IR Lab Specialist	5.0	6.6	7.4	8.4
Registered Nurse	0.1	0.1	0.1	0.1
Radiation Technician	1.0	1.3	1.5	1.6
<b>TOTAL</b>	6.0	8.0	9.0	10.0

Totals may not sum due to rounding

\*The project analyst assumes the applicant captured current staffing employee numbers for angiography/interventional radiology services for the same date as CT services.

The applicant bases its assumptions and methodology to project staffing on its historical experience.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 75-77, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs and provides supporting documentation in Exhibits H.2 and H.3.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the applicant’s experience in recruiting qualified staff and the applicant’s ongoing training and development curriculum.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

**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 as an existing health system, the applicant already provides all of the services deemed to be necessary ancillary and support services and provides supporting documentation in Exhibit I.1. The applicant adequately

demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant provides a letter dated April 15, 2021, from the president of ARMC indicating the necessary ancillary and support services are currently being offered at the facility and assures these services will continue to be offered at ARMC.

### **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 because the applicant provides examples of existing projects including but not limited to CareLink and Greensboro Area Health Education Center which demonstrate its existing relationships with other local health care and social service providers in the area.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

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

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

NA

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

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

C

The applicant proposes to renovate and expand the heart and vascular center at ARMC by acquiring one (1) additional CT scanner with cardiac capabilities and one (1) additional unit of angiography equipment for a total of no more than five (5) CT scanners and two (2) units of angiography equipment.

In Section K, page 82, the applicant states that the project involves construction of new space consisting of 14,400 square feet and renovating 48,930 square feet of existing space at ARMC. Line drawings are provided in Exhibit K.4-1.

In Section K, page 83, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states because the proposed project involves renovation of existing space, the capital costs will be minimized compared to options that would have required new construction on multiple sites.
- The applicant is committed to using lean principles in the design and construction of facilities in order to gain construction and operating efficiencies.

In Section K, page 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 proposed project is financially feasible and will not affect negatively the applicant's financial stability as illustrated in the applicant's Section Q pro-forma calculations.
- In Section L, pages 88-90, the applicant states it is dedicated to providing care for all in its communities regardless of the ability to pay and does provide charity or reduced cost care to its patients.

In Section K, pages 83-84, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

### C

In Section L, page 86 and clarifying information, the applicant provides the historical payor mix during the last full fiscal year (10/1/2019-9/30/2020) for the entire hospital and for angiography/VIR and CT services, as shown in the table below.

Payor Category	Entire Facility % of Total Patients Served	VIR % of Total Patients Served	CT % of Total Patients Served
Self-Pay	9.0%	3.8%	12.1%
Medicare*	44.0%	72.0%	50.5%
Medicaid*	14.2%	7.8%	10.0%
Insurance*	30.0%	15.4%	22.8%
Worker's Compensation	0.5%	0.1%	0.5%
TRICARE	0.5%	0.2%	0.5%
Other	1.7%	0.7%	3.6%
Total	100.0%	100.0%	100.0%

Source: Page 86.

\*Including any managed care plans. Totals may not sun due to rounding.

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

	Percentage of Total Patients Served by ARMC during the Last Full FY	Percentage of the Population of the Service Area
Female	62.6%	51.9%
Male	37.4%	48.1%
Unknown	0.1%	0.0%
64 and Younger	61.8%	82.4%
65 and Older	38.2%	17.6%
American Indian	0.2%	0.7%
Asian	0.5%	1.7%
Black or African American	25.0%	20.4%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	67.5%	67.9%
Other Race	5.5%	9.3%
Declined / Unavailable	1.3%	0.0%

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Clarifying responses requested 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,

*“Cone Health is dedicated to providing care for all in its communities regardless of the ability to pay, as demonstrated in Exhibit C.6-1, which contains copies of Cone Health’s patient accounting policies .”*

In Section L, page 89, the applicant states that during the last 18 months no patient civil rights access complaints have been filed against the facility or any related entities located in North Carolina.

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, pages 89-90, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project for VIR services and CT services, as illustrated in the following table.

<b>ARMC – Fiscal Year 3 (10/1/2026-9/30/2027)</b>			
<b>Payor Category</b>	<b>Entire Facility</b>	<b>VIR</b>	<b>CT Scanner</b>
Self-Pay	9.0%	3.8%	12.1%
Medicare*	44.0%	72.0%	50.5%
Medicaid*	14.2%	7.8%	10.0%
Insurance*	30.0%	15.4%	22.8%
Workers Compensation	0.5%	0.1%	0.5%
TRICARE	0.5%	0.2%	0.5%
Other	1.7%	0.7%	3.6%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Pages 89-90 of the application.

\*Including any managed care plans.  
Totals may not sum due to rounding.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 9.0 percent of total services, 3.8 percent of its VIR services and 12.1 percent of its CT services will be provided to self-pay patients, 44.0 percent of total services, 72 percent of VIR services and 50.5 percent of CT services will be provided to Medicare patients, and 14.2 percent of total services, 7.8 percent of VIR services and 10.0 percent of CT services will be provided to Medicaid patients.

On page 90, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical payor mix.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

### C

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

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to renovate and expand the heart and vascular center at ARMC by acquiring one (1) additional CT scanner with cardiac capabilities and one (1) additional unit of angiography equipment for a total of no more than five (5) CT scanners and two (2) units of angiography equipment.

In Section M, pages 93-94, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant states it has long standing relationships with numerous academic institutions in the area and lists those academic institutions on pages 93-94 of the application.
- The applicant states the proposed facility will serve as a clinical training site for students.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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



C

The applicant proposes to renovate and expand the heart and vascular center at ARMC by acquiring one (1) additional CT scanner with cardiac capabilities and one (1) additional unit of angiography equipment for a total of no more than five (5) CT scanners and two (2) units of angiography equipment.

N.C. Gen. Stat. §131E-176(24a) defines “service area” as: “... *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 2021 SMFP does not specifically define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. Thus, the service area for this review is as defined by the applicant.

In Section C, page 38, the applicant states its primary service area for its proposed services is Alamance, Guilford and Randolph counties. Facilities may also serve residents of counties not included in the service area.

The applicant states on page 74 that there is no comprehensive listing of CT or VIR providers available. However, the applicant reviewed data from the American College of Radiology (ACR). ACR accredits over 38,000 facilities although it is not mandatory for imaging facilities to seek accreditation from ACR. ACR lists two (2) additional facilities, Alliance Medical Associates, PLLC and UNC Hospitals Burlington Imaging and Breast Center, as providing CT services in the service area. The applicant is not aware of any providers of VIR services in the service area.

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

*“By utilizing and reconfiguring existing space to the extent possible for the proposed project, Cone Health has chosen the most cost-effective option, thereby improving the value to the patient and fostering competition.”*

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

*“The proposed project includes additional screening services via a CT scanner with cardiac capabilities. This service can identify blockages of coronary arteries and discover cardiac disease before it develops to the point of needing costly intervention. This service will save costs for both patients and payors as well as improve the health of Cone Health’s patients.”*

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

Regarding the impact of the proposal on quality, in Section N, page 97, the applicant states:

*“The proposed project will expand upon Cone Health and Alamance Regional Medical Center’s existing quality care. Cone Health and Alamance Regional Medical Center*

*have been recognized by multiple organizations for quality care as detailed in Section O of this application. The proposed project will allow Alamance Regional Medical Center to continue to deliver quality care to patients needing cardiovascular care.”*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 97, the applicant states:

*“As part of its community-based mission, Cone Health makes these services available to all patients regardless of their ability to pay.”*

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:

- 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 and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

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

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

In Section Q, Form O, the applicant identifies the facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of seven (7) facilities located in North Carolina.

In Section O, page 102, the applicant states that, during the 18 months immediately preceding the submittal of the application, one (1) incident related to quality of care occurred in one (1) of these facilities. The applicant states that the reason for the immediate jeopardy has been rectified and the facility is back in compliance. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, all seven (7) facilities are back in compliance. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all facilities associated with the applicant, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application submitted by the applicant is conforming or conditionally conforming to all applicable Criteria and Standards for CT equipment as promulgated in 10A NCAC 14C .2300. The specific criteria are discussed below.

**10A NCAC 14C .2303      PERFORMANCE STANDARDS**

*An applicant proposing to acquire a CT scanner shall demonstrate each of the following:*

- (1) *each fixed or mobile CT scanner to be acquired shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment;*
- C- In Section Q, page 131, the applicant projects that the CT scanners owned by the applicant will perform 50,164.25 HECT units in the third year of operation (FY2027) or 10,032.85 HECT units per CT scanner ( $50,164.25/5 = 10,032.85$ ). This exceeds the minimum of 5,100 HECT units annually in the third year of operations as required by 10A NCAC 14C .2303. The discussion regarding

projected utilization found in Criterion (3) is incorporated herein by reference.

- (2) *each existing fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall have performed at least 5,100 HECT units in the 12-month period prior to submittal of the application; and*
- C- In Section Q, page 130, the applicant states in FY2020 the entire facility provided 29,421 CT scans. The applicant further states in FY2020 the four (4) CT scanners at ARMC (entire facility) performed 46,788.00 HECT units for an average total of 11,697 HECT units per CT scanner ( $46,788.00/4=11,697$ ).
- (3) *each existing and approved fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment.*
- C- In Section Q, pages 124-131, the applicant projects that all CT scanners operated or approved at all sites for the applicant will exceed 5,100 HECT units per CT scanner by the third year of operations for the proposed project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.