

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2022

Findings Date: September 27, 2022

Project Analyst: Ena Lightbourne

Co-Signer: Micheala Mitchell

Project ID #: G-12210-22

Facility: Moses Cone Hospital

FID #: 943494

County: Guilford

Applicant(s): The Moses H. Cone Memorial Hospital

The Moses H. Cone Memorial Hospital Operating Corporation

Project: Add no more than one unit of interventional radiology equipment for a total of no more than three units of interventional radiology equipment upon project completion

REVIEW CRITERIA

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

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

C

Moses H. Cone Memorial Hospital and Moses H. Cone Memorial Hospital Operating Corporation, hereinafter collectively referred to as “the applicant” or “Cone Health”, propose to develop one interventional radiology (IR) lab at Moses Cone Hospital, by acquiring one unit of biplane angiography equipment, for a total of three IR labs at Moses Cone Hospital.

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 2022 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

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

Policy GEN-4, on page 30 of the 2022 SMFP, states:

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

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

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan 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 \$5 million. In Section B, page 24, the applicant describes a plan to ensure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

- (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.

The applicant proposes to develop one IR lab at Moses Cone Hospital, by acquiring one unit of biplane angiography equipment, for a total of three IR labs at Moses Cone Hospital.

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.” The 2022 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C, page 33, the applicant defines the primary service area (61.1% of total patients) for the proposed project as Guilford County. Facilities may also serve residents of counties not included in the service area.

The following tables illustrate historical and projected patient origin.

County	Moses Cone Hospital Interventional Radiology Historical Patient Origin	
	Last Full FY 10/1/2020-9/30/2021	
	Patients	% of Total
Guilford	2,122	61.1%
Rockingham	457	13.1%
Randolph	332	9.6%
Alamance	251	7.2%
East Forsyth*	88	2.7%
Other Counties and States**	224	6.3%
Total	3,474	100.0%

Source: Section C, page 31

*Consists of the following Zip Codes: 27009, 27284, and 27285

**Consists of 39 NC counties, nine states and the District of Columbia

Moses Cone Hospital Interventional Radiology Projected Patient Origin						
County	1 st Full FY		2 nd Full FY		3 rd Full FY	
	FY 2024		FY 2025		FY 2026	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Guilford	2,219	61.1%	2,252	61.1%	2,286	61.1%
Rockingham	478	13.1%	485	13.1%	492	13.1%
Randolph	347	9.6%	352	9.6%	358	9.6%
Alamance	262	7.2%	266	7.2%	270	7.2%
East Forsyth*	92	2.7%	93	2.7%	95	2.7%
Other Counties and States**	234	6.3%	238	6.3%	241	6.3%
Total	3,633	100.0%	3,687	100.0%	3,742	100.0%

Totals may not foot due to rounding.

Source: Section C, page 33

*Consists of the following Zip Codes: 27009, 27284, and 27285

**Consists of 39 NC counties, nine states and the District of Columbia

In Section C, page 32, the applicant provides the assumptions and methodology used to project its patient origin. On page 32, the applicant states:

“The percent distribution of patients by county is assumed to remain consistent with Moses Cone Hospital’s existing, well-established patient origin for interventional radiology as the service component and for the facility as a whole.”

The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant applies its projected utilization assumptions and methodology to project patient origin. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant identifies the historical growth of patients by county and applies a conservative growth rate based on projected population growth and future demand for IR services.
- The applicant assumes that the *“percent distribution of patient by county”* will be consistent for the first three years of the project.

Analysis of Need

In Section C, pages 35-43, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The projected population growth and historical utilization of IR services among the 45-65+ age cohort, the population most likely to be served. (pages 36-37)
- The rise in contributing factors such as obesity and diabetes that lead to the development of diseases that require IR services in the Moses Cone Hospital service area. (pages 37-40)

- The applicant cites data from the Advisory Board, “*a Health care analytics and consulting firm*” to determine the market demand for IR services and projects a 4.5% growth in the IR Moses Cone Hospital service area. (pages 41-42)
- The applicant demonstrates need based on the consistent growth in IR procedures performed at Moses Cone Hospital over the last four years and the use of its existing IR equipment which is currently operating at full capacity. (pages 42-43)

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

- The projected population growth of the age cohort most likely to utilize IR services.
- Historical and projected growth in IR procedures at Moses Cone Hospital.
- Moses Cone Hospital’s existing IR equipment is currently operating at full capacity.

Projected Utilization

In Section Q, page 101, the applicant provides projected utilization, as illustrated in the following table.

Moses Cone Hospital Interventional Radiology Projected Utilization			
	1st Full FY (FY 2024)	2nd Full FY (FY 2025)	3rd Full FY (FY 2026)
# of Units	3	3	3
# of Procedures	3,633	3,687	3,742

In Section Q, pages 102-104, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Determine the Projected Service Area Growth Rate

The applicant cites data from ESRI, a supplier of geographical information system software, to demonstrate the projected population growth rate in the Moses Cone Hospital IR service area.

Moses Cone Hospital IR Service Area Current and Project Population					
County	2021 Population	2026 Population	# Change	% Change	CAGR*
Guilford	444,681	466,821	22,140	5.0%	1.0%
Alamance	87,723	92,412	4,689	5.3%	1.0%
Rockingham	83,865	84,139	274	0.3%	0.1%
Randolph	74,225	75,792	1,567	2.1%	0.4%
Forsyth	58,935	62,269	3,334	5.7%	1.1%
Total	749,429	781,433	32,004	4.3%	0.8%

Source: Section Q, page 102

*Compound Annual Growth Rate

Moses Cone Hospital Current and Projected Population Age 45+					
Age Cohort	2021 Population	2026 Population	# Change	% Change	CAGR
45-64	193,212	192,510	(702)	-0.4%	-0.1%
65+	132,094	152,886	20,792	15.7%	3.0%
Total	325,306	345,396	20,090	6.2%	1.2%

Source: Section Q, page 102

Step 2: Determine Historical Growth in IR Procedures

The applicant examines the facility’s historical growth rate of IR procedures during FY 2019-2021. The facility experienced an annual growth rate of 5.7% in IR procedures, as illustrated below.

Moses Cone Hospital Historical IR Procedures					
FY 2019	FY 2020	FY 2021	# Change (FY19- FY21)	% Change	CAGR
6,254	6,369	7,395	1,141	18.2%	5.7%

Source: Section Q, page 103

Step 3: Determine Future Demand for IR procedures

The applicant cites data from the Advisory Board to demonstrate the 5-Year (2020-2025) projected growth of IR procedures performed on patients classified as outpatient in a particular procedure group as defined by the Advisory Board.

Moses Cone Hospital Service Area Advisory Board IR Outpatient Projections					
Outpatient Procedure Group	Current Estimate	5-Year Projection	# Change	% Change	CAGR
Total	9,947	12,066	2,119	21.3%	3.9%

Source: Section Q, page 103

Step 4: Determine an Appropriate Growth Rate

The applicant reviews the historical and projected CAGR of IR procedures in the service area to determine the appropriate growth rate to use to projecting utilization.

Historical and Projected Compound Annual Growth Rates	
Overall Projected Service Area Growth Rate	0.8%
45+ Age Cohort Projected Service Area Growth Rate	1.2%
65+ Age Cohort Projected Service Area Growth Rate	3.0%
Historical Interventional Procedure Growth Rate	5.7%
Projected Interventional Procedure Growth Rate	3.9%

Source: Section Q, page 103

The applicant used a conservative CAGR of 1.5%, which is significantly lower than the projected growth rate of the 65+ age cohort, and the Advisory board’s projected growth rate.

Step 5: Project Moses Cone Hospital Interventional Volumes

The applicant projects the annual growth in cases using a CAGR of 1.5%, assuming the ratio of procedures per case will remain stable.

Moses Cone Hospital Projected IR Cases							
	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Cases	3,474	3,526	3,579	3,633	3,687	3,742	3,799

Source: Section Q, page 104

Step 6: Calculate Utilization

Moses Cone Hospital Projected Utilization			
	FY 2024	FY 2025	FY 2026
Total Cases	3,633	3,687	3,742
Average Case Time (Hours)	1.5	1.5	1.5
Total Case Time (hours) (1)	5,449	5,531	5,614
Total Availability (hours) (2)	6,250	6,250	6,250
Utilization (3)	87%	88%	90%

Source: Section Q, page 104

(1) Total Cases x Average Case Time = Total Case Time

(2) Lab 1 250 days per year x 9 hours per day (2,250) + Lab 2 250 x 8 (2,000) + Lab 3 250 x 8 (2,000) = Total Availability (6250)

(3) Total Case Time / Total Availability = Utilization

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

- The projected utilization is based on the historical utilization of IR services at Moses Cone Hospital.
- The applicant’s utilization projections are supported by projected population growth in the service area.

- The applicant relied upon data from the Advisory Board and market analysis to determine the appropriate growth rate to project the volume of IR cases in the service area.
- The applicant projects utilization for the first three full fiscal year following project completion, based on a conservative annual growth rate of 1.5%.

Access to Medically Underserved Groups

In Section C, page 48, the applicant states:

“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.”

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

Medically Underserved Groups	Percentage of Total Patients
Low income persons*	n/a
Racial and ethnic minorities	48.7%
Women	60.1%
Persons with Disabilities*	n/a
Persons 65 and older	32.7%
Medicare beneficiaries	59.7%
Medicaid recipients	12.1%

Source: Section C, page 49

*On page 49, Moses Cone Hospital does not track this information.

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 because Moses Cone Hospital is an existing hospital facility in the service area currently providing services to medically underserved groups.

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 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 does not propose a reduction or elimination of a service, or the relocation of a facility or a service. Therefore, Criterion (3a) is not applicable to this review.

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

C

The applicant proposes to develop one IR lab at Moses Cone Hospital, by acquiring one unit of biplane angiography equipment, for a total of three IR labs at Moses Cone Hospital.

In Section E, pages 56-58, 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 was dismissed considering the high utilization of the existing IR labs. Not adding an additional IR lab can result in service interruptions and delays should the existing equipment require maintenance or repair.

Add an Additional Unit to the IR Lab at Wesley Long Hospital-The applicant states that this alternative would not accrue any cost-savings in comparison to the proposed project. Additionally, developing a unit at Wesley Long Hospital would not benefit Moses Cone Hospital, where expanded capacity is needed. Additionally, among the Cone Health system, the Moses Cone Hospital campus has the only comprehensive stroke center.

Purchase a Single Plane Unit of Vascular Angiography Equipment-The applicant states that although the equipment would be less costly, a single-plane unit would not be appropriate for stroke and other neurologic conditions. Moses Cone Hospital has only one bi-plane unit and scheduling neurological cases for that unit would be delayed if an emergency stroke patient is brought in during normal scheduled hours.

Extend the Hours the Units are Scheduled-The applicant states that this alternative would be more costly because it would require additional staff and supplies, and it would not address the high utilization of the existing IR labs.

On page 56, the applicant states that its proposal is the most effective alternative because it would address the growing utilization of the existing IR labs.

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

- The applicant's proposal will address the growing utilization of the existing IR labs and subsequently avoid interruptions and/or delays in services.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. The Moses H. Cone Memorial Hospital and Moses H. Cone Memorial Hospital Operating Corporation (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop one interventional radiology lab at Moses Cone Hospital, by acquiring one unit of biplane angiography equipment, for a total of three interventional radiology labs at Moses Cone Hospital.**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on February 1, 2023.**
- 4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**

5. **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.**
 6. **No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, The certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. **Payor mix for the services authorized in this certificate of need.**
 - b. **Utilization of the services authorized in this certificate of need.**
 - c. **Revenues and operating costs for the services authorized in this certificate of need.**
 - d. **Average gross revenue per unit of service.**
 - e. **Average net revenue per unit of service.**
 - f. **Average operating cost per unit of service.**
 7. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop one IR lab at Moses Cone Hospital, by acquiring one unit of biplane angiography equipment, for a total of three IR labs at Moses Cone Hospital.

Capital and Working Capital Costs

In Section Q, page 105, the applicant projects the total capital cost of the project, as shown in the table below.

Moses Cone Hospital Projected Capital Cost	
Construction/Renovation Contract(s)	\$1,914,123
Architect/Engineering Fees	\$317,800
Medical Equipment	\$2,064,475
Non-Medical Equipment	\$292,915
Furniture	\$40,000
Other (IT, Equipment, Testing, Contingency)	\$655,695
Total	\$5,285,008

In Section Q, page 106, 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 that are based the architect and construction management team’s experience with similar projects.

In Section F, page 61, the applicant states that there will be no start-up or initial operating costs associated with this project because the hospital and radiology department are already operating.

Availability of Funds

In Section F, page 59, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing		
Type	Moses Cone Hospital	Total
Loans	\$5,285,008	\$5,285,008
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$ 5,285,008	\$5,285,008

* OE = Owner’s Equity

Exhibit F.2.1 contains a letter dated April 18, 2022, from the Chief Financial Officer for Cone Health, authorizing the use of accumulated reserves for the capital needs of the project. The applicant provides the 2021 Consolidated Balance Sheets for Moses H. Cone Memorial Hospital and Affiliates, which states over \$200 million in cash and cash equivalents and over \$3 billion in assets available to fund the capital cost of the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that

revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

Moses Cone Hospital Interventional Radiology	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
	FY 2024	FY 2025	FY 2026
Total Cases	3,633	3,687	3,742
Total Gross Revenues (Charges)	\$59,004,233	\$62, 284,868	\$65,747,907
Total Net Revenue	\$24,917,392	\$25,291,153	\$25,670,520
Average Net Revenue per Case	\$6,859	\$6,860	\$6,860
Total Operating Expenses (Costs)	\$16,542,652	\$16,941,751	\$17,352,993
Average Operating Expense per Cases	\$4,553	\$4,595	\$4,637
Net Income	\$8,374,740	\$8,349,401	\$8,317,527

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:

- Average gross patient revenue per visit is projected based on the average gross patient revenue for patients utilizing services during the last full fiscal year.
- Deductions are projected using the FY 2021 actual deductions and reflects the assumptions related to changes in reimbursement.
- Operating costs such as salaries are based on the FY 2021 actual expenses and reflects a salary inflation of 4% annually.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions 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.

C

The applicant proposes to develop one IR lab at Moses Cone Hospital, by acquiring one unit of biplane angiography equipment, for a total of three IR labs at Moses Cone Hospital.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2022 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C, page 33, the applicant defines the primary service area (61.1% of total patients) for the proposed project as Guilford County. Facilities may also serve residents of counties not included in the service area.

In Section G, page 68, the applicant identifies the existing approved health service facilities located in the proposed service area that provide “*similar service components.*”

Name	County	Type
Wesley Long Hospital	Guilford	Acute Care Hospital
Atrium Health Wake Forest Baptist High Point Medical Center	Guilford	Acute Care Hospital
Greensboro Imaging	Guilford	Diagnostic Center
Alamance Regional Medical Center	Alamance	Acute Care Hospital
Randolph Hospital	Randolph	Acute Care Hospital

In Section G, pages 68-69, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved IR services in Guilford County. The applicant states:

“...the proposed project will alleviate capacity constraints of the already established and well-utilized service at Moses Cone Hospital. The existing interventional radiology equipment already operates at over 100% capacity and the proposed project will simply allow additional capacity for Cone Health to serve patients who already choose to come to Moses Cone Hospital for care.”

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’s proposal will provide additional capacity to existing IR equipment that is highly utilized by the patients who choose Moses Cone Hospital for services.

- The applicant adequately demonstrates that the proposed IR lab is needed in addition to the existing IR labs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop one IR lab at Moses Cone Hospital, by acquiring one unit of biplane angiography equipment, for a total of three IR labs at Moses Cone Hospital.

In Section Q, page 111, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 09/30/2021	2nd Full Fiscal Year (FY 2025)
Interventional Radiology Technician	9.3	9.9
Clinical Imaging Specialist	1.1	1.1
TOTAL	10.4	11.0

The assumptions and methodology used to project staffing are provided in Section Q, page 112. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 70-71, 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:

- Moses Cone Hospital has well-established methods to recruit and retain staff.

- All of Moses Cone Hospital's personnel are educated, trained, and licensed, including clinical staff. Moses Cone Hospital has an established education department providing ongoing training and 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.

C

The applicant proposes to develop one IR lab at Moses Cone Hospital, by acquiring one unit of biplane angiography equipment, for a total of three IR labs at Moses Cone Hospital.

Ancillary and Support Services

In Section I, page 73, the applicant identifies the necessary ancillary and support services for the proposed services. On page 73, the applicant explains how each ancillary and support service is or will be made available 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 is an existing provider in the service area with established ancillary and support services in place.
- In Exhibit I.1, the applicant provides a letter from the president of Moses Cone Hospital, stating the availability of ancillary and support services.

Coordination

In Section I, page 74, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on Moses Cone Hospital's role as a regional referral center. Additionally, Moses Cone Hospital has developed several projects that promote relationships with local health care providers. These projects include:

CareLink-A four vehicle critical care transport program operated by Moses Cone Hospital serving hospitals and physicians offices in and around the service area.

Greensboro Area Health Education Center (AHEC)-Cone Health is the sponsoring organization which provides continuing education services for a diverse group of health care professionals through the six-county 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 develop one IR lab at Moses Cone Hospital, by acquiring one unit of biplane angiography equipment, for a total of three IR labs at Moses Cone Hospital.

In Section K, page 77, the applicant states that the project involves renovating 2,353 square feet of existing space. Line drawings are provided in Exhibit K.1.

On pages 77-78, 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 project involves renovating an existing space as opposed to constructing new space, which can incur higher costs.
- The applicant is committed to incorporate cost-effectiveness in the development of the project.

On page 78, 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 applicant's demonstration of financial feasibility based on the assumptions and methodology used in preparation of financial statements provided in section Q.

On pages 78-79, 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 81, the applicant provides the historical payor mix during FY 2021 for the proposed services, as shown in the table below.

Moses Cone Hospital Historical Payor Mix FY 2021	
Payor Source	Entire Facility as Percent of Total
Self-Pay	5.9%
Charity Care [^]	n/a
Medicare*	59.7%
Medicaid*	12.1%
Insurance*	20.2%
Workers Compensation	0.2%
TRICARE	0.2%
Other	1.8%
Total	100.0%

Source: Section L, page 81

*Including any managed care plans.

[^]Applicant does not consider Charity Care as a separate payor source.

In Section L, page 82, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	60.1%	52.4%
Male	39.9%	47.6%
Unknown	0.04%	0.0%
64 and Younger	67.3%	83.4%
65 and Older	32.7%	16.6%
American Indian	0.4%	0.9%
Asian	1.5%	3.3%
Black or African-American	40.8%	27.0%
Native Hawaiian or Pacific Islander	0.05%	0.2%
White or Caucasian	49.9%	66.3%
Other Race	5.9%	2.3%
Declined / Unavailable	1.5%	0.0%

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

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 83, the applicant states:

“Cone Health has no obligation under applicable federal regulations to provide uncompensated care, community service or access by minorities or

handicapped persons. However, Cone Health is dedicated to providing care for all in its communities regardless of the ability to pay...

In Section L, page 84, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints were filed against the facility or any similar facilities owned by the applicant or a related entity and 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, page 84, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the tables below.

Moses Cone Hospital Projected Payor Mix 3rd Full FY, FY 2026	
Payor Source	Entire Facility as Percent of Total
Self-Pay	5.9%
Charity Care [^]	n/a
Medicare*	59.7%
Medicaid*	12.1%
Insurance*	20.2%
Workers Compensation	0.2%
TRICARE	0.2%
Other	1.8%
Total	100.0%

Source: Section L, page 84

*Including any managed care plans.

[^]Applicant does not consider Charity Care as a separate payor source.

Moses Cone Hospital Interventional Radiology Projected Payor Mix 3rd Full FY, FY 2026	
Payor Source	Entire Facility as Percent of Total
Self-Pay	8.8%
Charity Care [^]	n/a
Medicare*	34.8%
Medicaid*	22.1%
Insurance*	31.5%
Workers Compensation	0.4%
TRICARE	0.5%
Other	1.9%
Total	100.0%

Source: Section L, page 84;

*Including any managed care.

[^]Applicant does not consider Charity Care as a separate payor source.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 8.8% of total services will be provided to self-pay patients, 34.8% to Medicare patients and 22.1% to Medicaid patients.

On page 85, 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 based on the assumption that projected payor mix will be consistent with the facility's historical payor mix.

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 86, 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 develop one IR lab at Moses Cone Hospital, by acquiring one unit of biplane angiography equipment, for a total of three IR labs at Moses Cone Hospital.

In Section M, pages 87-88, 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 have access to the facility for training purposes based on the following:

- In partnership with the University of North Carolina at Chapel Hill, Moses Cone Hospital sponsors accredited residency and fellowship programs in a variety of medical fields, provides residency and serves as a clinical rotation site for pediatric residents.
- The health professional training programs at over 20 education institutions currently utilize Moses Cone Hospital's training opportunities.

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 one IR lab at Moses Cone Hospital, by acquiring one unit of biplane angiography equipment, for a total of three IR labs at Moses Cone Hospital.

N.C. Gen. Stat. §131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.” The 2022 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C, page 33, the applicant defines the primary service area (61.1% of total patients) for the proposed project as Guilford County. Facilities may also serve residents of counties not included in the service area.

In Section G, page 68, the applicant identifies the existing approved health service facilities located in the proposed service area that provide “similar service components.”

Name	County	Type
Wesley Long Hospital	Guilford	Acute Care Hospital
Atrium Health Wake Forest Baptist High Point Medical Center	Guilford	Acute Care Hospital
Greensboro Imaging	Guilford	Diagnostic Center
Alamance Regional Medical Center	Alamance	Acute Care Hospital
Randolph Hospital	Randolph	Acute Care Hospital

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

“The proposed project will expand an existing, well-utilized service at Moses Cone Hospital (MCH). As such, the proposed project is not expected to have a significant impact on competition in the proposed service area.

...

With a demonstrated history of providing cost-effective, high quality, and accessible care, Cone Health provides the best option for fostering competition for interventional radiology services.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 91, the applicant states:

“Increased capacity for this complex care service will allow for quicker times for treatment, which reduces the need for costlier interventions and treatments from strokes and other cerebrovascular accidents.”

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

Regarding the impact of the proposal on quality, in Section N, page 91, the applicant states:

“As Moses Cone Hospital is a Comprehensive Stroke Center accredited by the Joint Commission, the proposed project will further enhance the quality of the stroke and neurological services provided at MCH.”

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

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

“The proposed project will increase access to high quality services at Moses Cone Hospital. As part of its community-based mission, Cone Health makes these services available to all patients, regardless of their ability to pay.”

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately 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

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

- (19) Repealed effective July 1, 1987.

- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, page 113, the applicant identifies the acute care hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of four (including Moses Cone Hospital) of this type of facility located in North Carolina.

In Section O, page 95, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy had not occurred in any of these facilities. 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, incidents related to quality of care had not occurred in any of these facilities. 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 four facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to develop one interventional radiology lab at Moses Cone Hospital, by acquiring one unit of biplane angiography equipment. There are no administrative rules that are applicable to this proposal.