

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 29, 2025

Findings Date: January 29, 2025

Project Analyst: Cynthia Bradford

Co-Signer: Micheala Mitchell

Project ID #: P-12569-24

Facility: UNC Health Wayne

FID #: 933535

County: Wayne

Applicant: Wayne Memorial Hospital, Inc.

Project: Develop no more than one unit of fixed cardiac catheterization equipment pursuant to the 2024 SMFP need determination for no more than 2 units of fixed cardiac catheterization equipment

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

Wayne Memorial Hospital, Inc. (hereinafter referred to as “the applicant”) proposes to develop no more than one unit of fixed cardiac catheterization equipment at UNC Health Wayne for a total of no more than two units of fixed cardiac catheterization equipment upon project completion.

Need Determination

Chapter 15 of the 2024 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional cardiac catheterization equipment in North Carolina by service area. Application of the need methodology in the 2024 SMFP, page 312, showed a need for one unit of fixed cardiac catheterization equipment in Wayne County. The applicant

does not propose to develop more units of fixed cardiac catheterization equipment than are determined to be needed in Wayne County. Therefore, the application is consistent with the need determination.

Policies

There is one policy in the 2024 SMFP which are applicable to this review. *Policy GEN-3: Basic Principles*, on page 29 of the 2024 SMFP, states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

In Section B, pages 27-30, the applicant explains why it believes its application is consistent with Policy GEN-3. The applicant states it is dedicated to ensuring quality care and patient safety, that it will not discriminate based on a number of characteristics and will provide resources for uninsured patients, and that its projected utilization is based on reasonable and adequately supported assumptions, including the need the population has for the services proposed.

Conclusion

The Agency reviewed the:

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

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

- The applicant does not propose to develop more fixed cardiac catheterization units than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-3* based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of fixed cardiac catheterization services in Wayne County.

- The applicant adequately documents how the project will promote equitable access to fixed cardiac catheterization services in Wayne County; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
- (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 develop no more than one unit of fixed cardiac catheterization equipment at UNC Health Wayne, pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment.

Patient Origin

On page 304, the 2024 SMFP defines the cardiac catheterization equipment service areas as “...the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.” Figure 5.1, on page 36, shows Wayne County as a single county service area. Therefore, the service area for the fixed cardiac catheterization equipment is Wayne County. Facilities may also serve residents of counties not included in their service area.

In Section C, pages 33-34, the following tables illustrate the applicant’s historical patient origin for their cardiac lab as well as for the entire facility.

Cardiac Cath Lab	UNC Health Wayne Historical Patient Origin	
	Last Full FY 07/01/2023 to 06/30/2024	
County or other geographic area such as ZIP code	Number of Patients	% of Total
Wayne	1,182	81.2%
Lenoir	114	7.8%
Duplin	50	3.4%
Johnston	25	1.7%
Other*	86	5.9%
Total	1,456	100.0%

*Other: Other counties in North Carolina as well as other states

Entire Facility	UNC Health Wayne Historical Patient Origin	
	Last Full FY 07/01/2023 to 06/30/2024	
County or other geographic areas such as ZIP code	Number of Patients	% of Total
Wayne	138,228	81.6%
Lenoir	9,761	5.8%
Johnston	5,470	3.2%
Duplin	4,726	2.8%
Sampson	2,463	1.5%
Other*	8,776	5.1%
Total	169,424	100.0%

*Other: Other counties in North Carolina as well as other states

In Section C, pages 34-36, the following tables illustrate the applicant’s projected patient origin for the cardiac lab as well as for the entire facility for the first three full fiscal years of operation, as summarized below.

UNC Health Wayne Projected Patient Origin						
Cardiac Cath Lab	FY 1		FY 2		FY 3	
	07/01/2026-06/30/2027		07/01/2027-06/30/2028		07/01/2028-06/30/2029	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Wayne	1,406	81.2%	1,491	81.2%	1,582	81.2%
Lenoir	135	7.8%	143	7.8%	152	7.8%
Duplin	59	3.4%	62	3.4%	66	3.4%
Johnston	29	1.7%	31	1.7%	33	1.7%
Other*	102	5.9%	109	5.9%	115	5.9%
Total	1,731	100.0%	1,836	100.0%	1,948	100.0%

Source: Section C, page 35

*Other: Other counties in North Carolina as well as other states

UNC Health Wayne Projected Patient Origin						
Entire Facility or Campus	FY 1		FY 2		FY 3	
	07/01/2026-06/30/2027		07/01/2027-06/30/2028		07/01/2028-06/30/2029	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Wayne	138,491	81.6%	138,571	81.6%	138,651	81.6%
Lenoir	9,844	5.8%	9,849	5.8%	9,855	5.8%
Johnston	5,431	3.2%	5,434	3.2%	5,437	3.2%
Duplin	4,752	2.8%	4,755	2.8%	4,758	2.8%
Sampson	2,546	1.5%	2,547	1.5%	2,549	1.5%
Other*	8,655	5.1%	8,661	5.1%	8,666	5.1%
Total	169,719	100.0%	169,817	100.0%	169,916	100.0%

Source: Section C, page 36

*Other: Other counties in North Carolina as well as other states

Currently, UNC Health Wayne operates one unit of fixed cardiac catheterization equipment at the facility in Wayne County. In Section Q, pages 107-109, the applicant provides the assumptions and methodology used to project its patient origin. The applicant projects patient origin based on FY 2024 patient origin for the entire licensed facility and an assumed growth rate of 5.4 percent per year based on the Wayne County projected population growth rate through 2029. The assumptions and methodology used to project patient origin are reasonable and adequately supported because they are based on the historical patient origin for the same services already being offered at the same location.

Analysis of Need

In Section C, pages 37-46, the applicant explains why it believes the population projected to utilize the proposed services needs the services, as summarized below.

- **Need for additional cardiac catheterization services at UNC Health Wayne;** The applicant states on pages 37-42, that as the sole provider of cardiac catheterization services in Wayne County, the entirety of the need for an additional unit of cardiac catheterization equipment was generated by UNC Health Wayne. UNC Health Wayne’s sole unit of cardiac catheterization equipment operated at over 110 percent of capacity in FY 2024. The applicant includes the historical cardiac catheterization utilization for UNC Health Wayne in the table below.

UNC Health Wayne Historical Cardiac Catheterization Utilization							
	FY19	FY20	FY21	FY22	FY23	FY24	FY19-FY24 CAGR*
Diagnostic Procedures	575	905	904	912	1,038	1,127	14.4%
Interventional Procedures	287	360	233	237	319	329	2.8%
Total Procedures	862	1,265	1,137	1,149	1,357	1,456	11.1%
Diagnostic Equivalent Procedures**	1,077	1,535	1,312	1,327	1,596	1,703	9.6%
Cardiac Catheterization Units	1	1	1	1	1	1	1
Total Existing Capacity^	1,500	1,500	1,500	1,500	1,500	1,500	1,500
Utilization^^	71.8%	102.3%	87.5%	88.5%	106.4%	113.5%	

Source: Section C, page 38

* Compound annual growth rate.

** Diagnostic Equivalent Procedures = Diagnostic + (Interventional x 1.75) + (<=14 Years Old x 2.0)

^ Total Existing Capacity = Number of Units x 1,500 Procedure Capacity

^^ Utilization = Diagnostic Equivalent Procedures ÷ Total Existing Capacity

The applicant states this incredibly high utilization rate for its sole unit of cardiac catheterization equipment indicates that UNC Health Wayne needs additional cardiac catheterization capacity in order to accommodate its patients, and that its current growth trend of cardiac catheterization volume is not sustainable – without additional capacity.

- **Need for additional cardiac catheterization services in the service area;** On pages 42-46, the applicant states the proposed project is in response to a need determination for one unit of fixed cardiac catheterization equipment in the 2024 SMFP. The applicant states that Wayne County’s age 65 and older population is growing significantly faster than its

overall population, and that older residents utilize healthcare services more frequently than younger residents. The applicant states there is a higher prevalence of the need for cardiac catheterization services among ethnic populations across the country, particularly among the black population.¹ The applicant states that Wayne County has a relatively high percentage of black residents.² Additionally, aging and racial factors ultimately correspond with a high rate of cardiovascular disease in Wayne County. Among Wayne County residents, heart disease is the top cause of death for both the 65 and older age cohort, accounting for 25 percent of deaths (Exhibit C.4-2), and that the need to increase cardiac catheterization services in the area are driven by these factors.

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

- The 2024 SMFP identifies the need for one additional unit of fixed cardiac catheterization equipment in Wayne County.
- The applicant cites publicly available data to support its conclusions about population growth.
- The applicant provides documentation of growth of cardiac catheterization procedures at UNC Health Wayne.
- The total cardiac catheterization procedure volume at UNC Health Wayne has grown at a compound annual growth rate of 11.1%, with interventional procedures having an annual growth rate of 2.8%, with an overall utilization rate of 113.5% as of FY24.

Projected Utilization

In Section Q, Form C.2b, page 105, the applicant provides projected utilization for UNC Health Wayne, as illustrated in the following table.

UNC Health Wayne Cardiac Catheterization Projected Utilization					
	Partial FY26	FY27 PY1	FY28 PY2	FY29 PY3	CAGR
# Diagnostic Procedures	1,295	1,389	1,489	1,596	7.2%
# Interventional Procedures	338	343	348	352	1.4%
Total Procedures	1,633	1,731	1,836	1,948	6.0%
# of Diagnostic-Equivalent Procedures	1,887	1,989	2,097	2,212	5.4%

¹ “Racial and Ethnic Disparities in Heart Disease.” Centers for Disease Control and Prevention, April 2019, accessed August 28, 2024, at https://www.cdc.gov/nchs/hus/spotlight/HeartDiseaseSpotlight_2019_0404.pdf.

² NC OSBM

Following Forms C.2a and C.2b in Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant reviewed historical utilization and CAGRs for diagnostic, interventional, total, and weighted cardiac catheterization procedures for FYs 2019-2024. The applicant projected growth of both diagnostic and interventional procedures using CAGRs that are half of the historical growth of those respective procedures at UNC Health Wayne from FY 2019 through FY 2024. (page 107)
- The applicant began its projections with FY 2024 data and applied the projected growth rate to each type of procedure to project utilization at UNC Health Wayne the first three full operating years, as shown in the table below.

UNC Health Wayne Projected Fixed Cardiac Catheterization Utilization With Total Cardiac Catheterization Units							
	FY2024	FY2025	FY2026	FY2027 PY1	FY2028 PY2	FY2029 PY3	CAGR
Diagnostic Procedures	1,127	1,208	1,295	1,389	1,489	1,596	7.2%
Interventional Procedures	329	334	338	343	348	352	1.4%
Total Procedures	1,456	1,542	1,633	1,731	1,836	1,948	6.0%
Diagnostic-Equivalent Procedures	1,703	1,792	1,887	1,989	2,097	2,212	5.4%
Cardiac Catheterization Units	1	1	1	2	2	2	
Diagnostic Equivalent Procedures per Unit	1,703	1,792	1,887	994	1,048	1,106	

Source: Section Q, Form C Assumptions and Methodology, page 109

UNC Health Wayne

Pursuant to 10A NCAC 14C .1603(a)(5), an applicant proposing to acquire fixed cardiac catheterization equipment must demonstrate that the existing, approved, and proposed fixed cardiac catheterization units owned by the applicant or a related entity in a cardiac catheterization equipment service area will perform 900 or more diagnostic-equivalent cardiac catheterization procedures per unit during the third full fiscal year following project completion.

Immediately following Forms C.2a and C.2b in Section Q, the applicant provides the assumptions and methodology used to project utilization for the entire UNC Health Wayne facility in Wayne County, which are summarized below.

- The applicant reviewed projected utilization for diagnostic, interventional, total, and weighted cardiac catheterization procedures for FY24-FY29. The applicant projected the following growth rates for types of cardiac catheterization procedures at each facility:

- From 2024 to 2029, UNC Health Wayne projected the growth of both diagnostic and interventional procedures using CAGRs that are half of the historical growth of those respective procedures at UNC Health Wayne from FY 2019 through FY 2024.
- The applicant then projected cardiac catheterization utilization for UNC Health Wayne through CY 2029, the third full fiscal year of the proposed project, based on the assumed 7.2 percent CAGR for diagnostic procedures, and 1.4 percent CAGR for interventional procedures.

As shown in the table above, the applicant projects that UNC Health Wayne will perform 2,212 diagnostic-equivalent cardiac catheterization procedures on two units of fixed cardiac catheterization equipment, or an average of 1,106 diagnostic-equivalent cardiac catheterization procedures per unit of fixed cardiac catheterization equipment during FY 2029. This meets the requirement promulgated in 10A NCAC 14C .1603(a)(5).

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

- The applicant projects utilization for the three project years (CY2027-CY2029), based on the assumed 7.2 percent CAGR for diagnostic procedures, and 1.4 percent CAGR for interventional procedures.
- The applicant’s projections of cardiac catheterization volumes are supported by the historical growth rate of cardiac catheterization volumes of the existing cardiac catheterization labs.

Access to Medically Underserved Groups

In Section C, pages 54, the applicant states

“UNC Health Wayne is managed by UNC Health. Given this, UNC Health Wayne follows certain administrative policies for UNC Health, including patient access and financial assistance policies. UNC Health Wayne has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status, or lack of medical insurance.”

On page 55, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups**	% of Total Patients
Racial and ethnic minorities	42.3%
Women	59.6%
Persons 65 and older	34.4%
Medicare beneficiaries	39.4%
Medicaid recipients	23.9%

On page 55, the applicant states it does not retain data on the number of disabled persons it serves and states that disabled persons will not be denied access to UNC Health Wayne.

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:

- UNC Health Wayne is part of an established health system in Wayne County that has established policies against discrimination.
- The applicant states it will not discriminate against patients on the basis of a number of categories and describes its policies for assisting uninsured and low-income patients with financial assistance.
- The applicant provides UNC Health's Non-Discrimination policies in Exhibit B.20-5, and its Patient Financial policies in Exhibit B.20-6.

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

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

C

The applicant proposes to develop no more than one unit of fixed cardiac catheterization equipment at UNC Health Wayne, pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment.

In Section E, page 66, the applicant describes the alternative 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:

Develop the Proposed Cardiac Catheterization Equipment at a Different Location – The applicant states that UNC Health Wayne currently offers cardiac catheterization services; it will be able to utilize mostly existing staff and personnel rather than incur unnecessary staffing costs to establish a new service at Atrium Health Harrisburg. Further, renovating existing vacant space is cost-effective, and operating multiple cardiac catheterization labs in one facility maximizes operational efficiencies, allowing for more rapid room cleanup, turnaround, and improved scheduling. UNC Health Wayne has a larger range of ancillary and support services available to cardiac patients, making the proposal outlined in this application an overall more effective alternative. For these reasons, the above alternative was rejected.

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 application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

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. Wayne Memorial Hospital, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop no more than one unit of fixed cardiac catheterization equipment at UNC Health Wayne pursuant to the need determination in the 2024 State Medical Facilities Plan for a total of no more than two units of fixed cardiac catheterization equipment upon project completion.**

3. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditure in Section Q of the application and that would otherwise require a certificate of need.**
 4. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**
 - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **The first progress report shall be due on July 1, 2025.**
 5. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop no more than one unit of fixed cardiac catheterization equipment at UNC Health Wayne, pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment.

Capital and Working Capital Costs

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

UNC Health Wayne Capital Costs	
Construction/Renovation Contract (s)	\$1,609,820
Architect/Engineering Fees	\$125,000
Medical Equipment	\$1,543,416
Non-Medical Equipment	\$6,800
Furniture	\$2,700
Total Capital Costs	\$3,287,736

Immediately following Form F.1.a, in Section 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:

- Construction, Architect and Engineering costs are based on the experience of the project architect with similar projects.
- Medical equipment, non-medical equipment, and furniture costs are based on vendor estimates and the experience of UNC Health Wayne with similar projects.

In Exhibit F.2-1, the applicant provides a letter dated October 15, 2024, from the Chief Financial Officer, which states that the capital cost for this project are estimated to be \$3,287,736 with no additional start-up costs for this project. The applicant adequately demonstrates that projected working capital cost is based on reasonable and adequately supported assumptions because the applicant currently provides the services it proposes to add.

Availability of Funds

In Section F, page 67, the applicant states that the capital cost will be funded through accumulated reserves.

In Exhibit F.2-1, the applicant provides a letter dated October 15, 2024, from the Chief Financial Officer, committing to providing \$3,287,736 in capital costs for the proposed project.

Exhibit F.2-2 also contains the Wayne Health Corporation and Affiliates Combined Financial Statements which shows that for the fiscal year ending June 30, 2023, and 2022, the applicant has adequate cash equivalents and assets to fund 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, page 113, the applicant projects that revenues will not exceed operating expenses for the cardiac catheterization services at UNC Health Wayne during the first three full fiscal years following completion of the project, as shown in the table below.

UNC Health Wayne – Cardiac Catheterization Projected Revenues and Net Income upon Project Completion			
Cardiac Cath Only	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
	CY 2027	CY 2028	CY 2029
Total Procedures [^]	1,989	2,097	2,212
Total Gross Revenues (Charges)	\$51,902,598	\$56,371,952	\$61,265,444
Total Net Revenue	\$12,193,546	\$13,243,538	\$14,393,172
Average Net Revenue per Procedure	\$6,130	\$6,315	\$6,507
Total Operating Expenses (Costs)	\$11,067,243	\$11,835,037	\$12,670,104
Average Operating Expense per Procedure	\$5,564	\$5,644	\$5,728
Net Income	\$1,126,303	\$1,408,500	\$1,723,068

[^]Source: Section Q, Form C.2b

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’s projected payor mix is based on the applicant’s historical payor mix.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable

projections of revenues and operating expenses from its facility in Wayne County 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 no more than one unit of fixed cardiac catheterization equipment at UNC Health Wayne, pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment.

On page 304, the 2024 SMFP defines the cardiac catheterization equipment service areas as “...the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.” Figure 5.1, on page 36, shows Wayne County as a single county service area. Therefore, the service area for the fixed cardiac catheterization equipment is Wayne County. Facilities may also serve residents of counties not included in their service area.

According to Table 15A-3 in Chapter 15 of the 2024 SMFP, there is one facility, Wayne UNC Health Care, with a total of one unit of fixed cardiac catheterization equipment in Wayne County. Information about the facility and equipment is shown in the table below.

Fixed Cardiac Catheterization Equipment Inventory – Wayne County			
Facility	# Units	2022 Procedures	Machines Required (80% Utilization)
Wayne UNC Health Care	1	1,265	1

In Section G, page 77, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved cardiac catheterization services in Cabarrus County. The applicant states:

“...the need in the 2024 SMFP was generated by the highly utilized equipment at UNC Health Wayne County...”

...utilization of cardiac catheterization equipment at UNC Health Wayne has been high...

...and is enough to support additional cardiac catheterization resources. As such, the proposed project will not result in unnecessary duplication.”

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:

- There is a need determination in the 2024 SMFP for the proposed unit of fixed cardiac catheterization equipment in the service area.

- The applicant adequately demonstrates that the proposed cardiac catheterization equipment is needed in addition to the existing or approved cardiac catheterization equipment.

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 no more than one unit of fixed cardiac catheterization equipment at UNC Health Wayne, pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment.

In Section Q, Form H, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as shown in the table below.

UNC Health Wayne Cardiac Catheterization Lab Projected FTE Staffing				
	Current	1st Fiscal Year FY 2027	2nd Fiscal Year FY 2028	3rd Fiscal Year FY 2029
Registered Nurses	5.0	7.0	7.0	7.0
Cardiovascular Specialists	5.0	7.0	7.0	7.0
TOTAL	10.0	14.0	14.0	14.0

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 79-80, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant is an existing provider of fixed cardiac catheterization services which already employs staff necessary to offer fixed cardiac catheterization services.
- The applicant is part of a large and established healthcare system in Wayne County.

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 no more than one unit of fixed cardiac catheterization equipment at UNC Health Wayne, pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment.

Ancillary and Support Services

In Section I, page 81, the applicant identifies the necessary ancillary and support services for the proposed services. On page 81, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because UNC Health Wayne currently provides the ancillary and support services that will be necessary for the additional unit of fixed cardiac catheterization equipment.

Coordination

In Section I, page 82, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant is an existing provider with established relationships with healthcare and social services providers in the service area.
- In Exhibit I.2, the applicant provides letters of support from UNC Health physicians supporting the addition of an additional unit of fixed cardiac catheterization equipment.

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 no more than one unit of fixed cardiac catheterization equipment at UNC Health Wayne, pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment.

In Section K, page 85, the applicant states that the project involves renovating 1,130 square feet of new space. Line drawings are provided in Exhibit C.1-1. The renovated square footage proposed in this application will accommodate the fixed cardiac cath lab.

On pages 85-86, 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's proposal involves renovating the existing space to minimize the cost of the project rather than constructing new space.
- The proposed cardiac catheterization equipment will be developed in space adjacent to UNC Health Wayne's existing suite of angiography services, thereby using the existing space at UNC Health Wayne efficiently.

On page 86, 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 applicant is able to service the capital costs of the project without increasing charges to the public.

On page 86 the applicant identifies 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 89, the applicant provides the historical payor mix during FY 2023 for UNC Health Wayne, as shown in the table below.

UNC Health Wayne	
Payor Category	% of Total
Self-Pay	6.7%
Charity Care	
Medicare*	39.4%
Medicaid*	20.5%
Insurance*	23.9%
Workers Compensation	
TRICARE	
Other Gov't/Institutional	9.5%
Total	100.0%

*Including any managed care plans

In Section L, page 90, the applicant provides the following comparison.

UNC Health Wayne	% of Total Patients Served During Last Full FY	% of the Population of the service area*
Female	59.6%	50.4%
Male	40.3%	49.6%
Unknown	0.1%	0.0%
64 and Younger	65.6%	82.4%
65 and Older	32.4%	17.6%
American Indian	0.3%	0.9%
Asian	0.7%	1.4%
Black or African-American	35.3%	32.2%
Native Hawaiian or Pacific Islander	0.1%	0.2%
White or Caucasian	57.1%	62.3%
Other Race	5.9%	3.1%
Declined / Unavailable	0.6%	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>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 91, the applicant states it has no such obligation.

In Section L, page 92, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, pages 92-93, 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 table below.

UNC Health Wayne Projected Payor Mix – FY3 (2029)		
Payor Category	% of Total – Entire Facility	% of Total – Cardiac Catheterization^{^^^}
Self-Pay	3.4%	1.0%
Charity Care [^]		
Medicare*	39.4%	66.8%
Medicaid*	23.9%	6.9%
Insurance*	23.9%	16.8%
Workers Compensation ^{^^}		
TRICARE ^{^^}		
Other	9.5%	8.5%
Total	100.0%	100.0%

*Including any managed care plans.

[^] UNC Health Wayne internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care. Please see Form F.2 for charity care projections.

^{^^} Workers Compensation, TRICARE, and other payors are included in the “Other” payor category.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.4% of total services and 1.0% of cardiac catheterization services will be provided to self-pay patients, 39.4% of total services and 66.8% of cardiac catheterization services to Medicare patients, and 23.9% of total services and 6.9% of cardiac catheterization services to Medicaid patients.

On pages 93-94, 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 historical payor mix for UNC Health Wayne.

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 94, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 no more than one unit of fixed cardiac catheterization equipment at UNC Health Wayne, pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment.

In Section M, page 95, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant states,

“UNC Health Wayne has contracts in place with numerous colleges for nursing, phlebotomy, radiology technician, and paramedical training, including the colleges noted above. Job shadowing opportunities are also available to students to further their professional development. UNC Health Wayne’s numerous programs will remain in place in the future, including for cardiac catheterization services.”

The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant has existing clinical education agreements with area health education programs in the service area and across the State of North Carolina.
- The applicant states all educational programs that have clinical agreements with multiple healthcare systems and will have the same access upon completion of the proposed project.

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 no more than one unit of fixed cardiac catheterization equipment at UNC Health Wayne, pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment.

On page 304, the 2024 SMFP defines the cardiac catheterization equipment service areas as “...the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.” Figure 5.1, on page 36, shows Wayne County as a single county service area. Therefore, the service area for the fixed cardiac catheterization equipment is Wayne County. Facilities may also serve residents of counties not included in their service area.

According to Table 15A-3 in Chapter 15 of the 2024 SMFP, there is one facility, Wayne UNC Health Care, with a total of one unit of fixed cardiac catheterization equipment in Wayne County. Information about the facility and equipment is shown in the table below.

Fixed Cardiac Catheterization Equipment Inventory – Wayne County			
Facility	# Units	2022 Procedures	Machines Required (80% Utilization)
Wayne UNC Health Care	1	1,265	1

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 97, the applicant states:

“UNC Health Wayne regularly cares for patients from multiple counties in eastern North Carolina. As such, UNC Health Wayne believes the proposed project will foster

competition in the proposed service area. The proposed project will enhance competition by bolstering the cardiac catheterization services available at UNC Health Wayne, which will improve its ability to compete with other providers across the region and will promote cost-effectiveness, quality, and access to services in the proposed service area.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 97, the applicant refers to Section B.20.c which states:

“UNC Health Wayne is the only provider of cardiac catheterization services in Wayne County, patients in need must be transferred to a neighboring county facility if capacity is unavailable. The cost and sometimes cumbersome process of transferring a patient due to a lack of capacity increases the overall cost for a particular cardiac catheterization service, while also increasing the length of time before patients can access vital service. Increasing cardiac catheterization capacity at UNC Health Wayne will allow for its providers to care for patients closer to home and will reduce the likelihood that a patient must be transferred to a different facility for care.”

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 97, the applicant refers to Section B.20.a which states:

“UNC Health Wayne’s commitment to providing quality care will be guided by the policies already in use at other UNC Health facilities. For example, UNC Health Wayne’s Performance Improvement Plan, Utilization Review Plan and Process, and Risk Management and Patient Safety Plans.”

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, pages 97-98, the applicant refers to Section B.20.a, which states:

“The proposed project will promote access to healthcare services in the service area, particularly for the medically underserved. UNC Health Wayne prohibits the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability, or the patient’s 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 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 all the reasons described above.

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

C

The applicant proposes to develop no more than one unit of fixed cardiac catheterization equipment at UNC Health Wayne, pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment.

On Form O in Section Q, page 120, the applicant identifies the hospitals with fixed cardiac catheterization equipment located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of twelve hospitals with fixed cardiac catheterization equipment located in North Carolina.

In Section O, page 100, the applicant states that none of the facilities in Form O were determined by the Division of Health Service Regulation to have had any situation resulting in a finding of immediate jeopardy during the 18 month look-back period. After reviewing and considering the information provided by the applicant and the Acute Care and Home Care License and Certification Section and considering the quality of care provided at all twelve facilities, the applicant has 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.

C

The Criteria and Standards for Cardiac Catheterization Equipment and Cardiac Angioplasty Equipment promulgated in 10A NCAC 14C .1600 are applicable to this review. The application is conforming to all applicable criteria. The specific criteria are discussed below.

10A NCAC 14C .1603 PERFORMANCE STANDARDS

(a) *An applicant proposing to acquire fixed cardiac catheterization equipment pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

(1) *identify the existing fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in the proposed fixed cardiac catheterization equipment service area;*

-C- In Section Q, Form C.2a, page 104, the applicant identifies one (1) existing unit of fixed cardiac catheterization equipment at UNC Health Wayne. The 2024 SMFP lists the existing 2022 cardiac catheterization inventory for UNC Health Wayne in the table below.

Fixed Cardiac Catheterization Equipment Inventory – Wayne County			
Facility	# Units	2022 Procedures	Machines Required (80% Utilization)
UNC Health Wayne	1	1,265	1

(2) *identify the approved fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in the proposed fixed cardiac catheterization equipment service area;*

-C- In Section C, page 57, the applicant states there are no approved fixed cardiac catheterization equipment owned or operated by the applicant or a related entity in the proposed fixed cardiac catheterization equipment service area (Wayne County).

(3) *provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed cardiac*

catheterization equipment during each of the first three full fiscal years of operation following completion of the project;

-C- In Section Q, Form C.2b, page 105, the applicant provides projected utilization of the existing, approved, and proposed fixed cardiac catheterization equipment owned or operated by the applicant or a related entity located in Wayne County during each of the first three full fiscal years of operation following completion of the project.

(4) *provide the assumptions and methodology used to project the utilization required by Subparagraph (3) of this Paragraph; and*

-C- Immediately following Form C.2b in Section Q, the applicant provides the assumptions and methodology used to project utilization of the existing, approved, and proposed fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in Wayne County during each of the first three full fiscal years of operation following completion of the project.

(5) *project that the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed cardiac catheterization equipment shall perform 900 or more diagnostic-equivalent cardiac catheterization procedures per unit of cardiac catheterization equipment during the third full fiscal year of operation following completion of the project.*

-C- In Section Q, Form C.2b, page 105, the applicant projects that the existing, approved, and proposed fixed cardiac catheterization equipment owned or operated by the applicant or a related entity located in Wayne County will perform 900 or more diagnostic-equivalent procedures per unit of cardiac catheterization equipment during the third full fiscal year of operation following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(b) *An applicant proposing to acquire shared fixed cardiac catheterization equipment pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

(1) *provide projected utilization of the proposed shared fixed cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;*

(2) *provide the assumptions and methodology used to project the utilization required by Subparagraph (1) of this Paragraph; and*

(3) *project that the proposed shared fixed cardiac catheterization equipment shall perform 225 or more diagnostic-equivalent cardiac catheterization and angiography procedures during the third full fiscal year of operation following completion of the project.*

-NA- The applicant does not propose to acquire shared fixed cardiac catheterization equipment.

- (c) *An applicant proposing to acquire mobile cardiac catheterization equipment pursuant to a need determination in the State Medical Facilities Plan in effect as of the first day of the review period shall:*
- (1) *identify the existing mobile cardiac catheterization equipment owned or operated by the applicant or a related entity that provides cardiac catheterization services at host sites located in the proposed mobile cardiac catheterization equipment service area;*
 - (2) *identify the approved mobile cardiac catheterization equipment owned or operated by the applicant or a related entity that will provide cardiac catheterization services at host sites located in the proposed mobile cardiac catheterization equipment service area;*
 - (3) *provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;*
 - (4) *provide the assumptions and methodology used to project the utilization required by Subparagraph (3) of this Paragraph; and*
 - (5) *project that the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile cardiac catheterization equipment shall perform 225 or more diagnostic-equivalent cardiac catheterization procedures per unit of cardiac catheterization equipment during the third full fiscal year of operation following completion of the project.*
- NA- The applicant does not propose to acquire mobile cardiac catheterization equipment.