

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 27, 2020

Findings Date: January 27, 2020

Project Analyst: Tanya M. Saporito

Team Leader: Fatimah Wilson

Project ID #: O-11805-19

Facility: New Hanover Regional Medical Center

FID #: 943372

County: New Hanover

Applicant: New Hanover Regional Medical Center

Project: Acquire replacement cardiac catheterization equipment

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

New Hanover Regional Medical Center, referred to as NHRMC or “the applicant”, proposes to replace one unit of cardiac catheterization equipment. The applicant currently owns and operates five units of cardiac catheterization (cardiac cath) equipment, one of which (Cardiac Cath lab #5) has been used exclusively for interventional radiology. This application proposes to relocate Cardiac Cath lab #5 to space adjacent to Electrophysiology Services and replace that unit of cardiac cath equipment. Upon project completion, the existing equipment in Cardiac Cath lab #5 will be recategorized to be utilized exclusively for interventional radiology. The applicant states that the unit designated for interventional radiology will not perform cardiac cath procedures. NHRMC will continue to report an inventory of five units of cardiac cath equipment.

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 2019 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations that are applicable to this review.

Policies

There is one policy in the 2019 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

Policy GEN-4 on page 31 of the 2019 SMFP states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section 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 \$2 million but less than \$5 million. In Section B.11, page 22, the applicant explains why it believes its application is consistent with Policy GEN-4. The applicant states that NHRMC is committed to assuring improved energy efficiency and water conservation. The applicant lists several examples of strategies it will use for energy conservation. The applicant adequately demonstrates

that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- application, and
- 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 does not propose to develop any beds, services or equipment for which there is a need determination in the 2019 SMFP.
- The applicant adequately demonstrates that the proposal 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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to replace one unit of cardiac catheterization equipment.

NHRMC currently owns and operates five units of cardiac catheterization equipment at the main campus in Wilmington, one of which has been utilized exclusively for interventional radiology. The applicant proposes to replace and relocate that unit (Cardiac Cath lab #5) within the hospital. The existing equipment in Cardiac Cath lab #5 will be recategorized to be used exclusively for interventional radiology and will not be used to perform cardiac cath procedures. Upon project completion, NHRMC will continue to operate five units of cardiac cath equipment in the main hospital.

Patient Origin

In Chapter 9, page 173, the 2019 SMFP states, "*A cardiac catheterization (fixed or shared) equipment's service area is the cardiac catheterization equipment planning area in which the equipment is located. The cardiac catheterization equipment planning areas are the*

same as the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.” NHRMC is located in New Hanover County. In Figure 5.1, page 40 of the 2019 SMFP New Hanover County is listed as a single Acute Care Bed Service Area County; therefore, the service area is New Hanover County. Providers may serve residents of counties not included in their service area.

In Sections C.2, page 35, the applicant provides the historical FY 2018 patient origin for cardiac catheterization services at NHRMC, as summarized below.

**NHRMC Historical Cardiac Catheterization
 Patient Origin**

COUNTY	FY2018 (10/1/17 – 9/30/18)	
	# PATIENTS	% OF TOTAL
“Primary Service Area”		
New Hanover	1,571	32.8%
Brunswick	1,256	26.2%
Pender	540	11.3%
Onslow	484	10.1%
Columbus	437	9.1%
Subtotal	4,288	89.6%
“Secondary Service Area”		
Duplin	169	3.5%
Bladen	109	2.3%
Subtotal	278	5.8%
In-Migration*	219	4.6%
Total	4,786	100%

*On page 35 the applicant states in-migration includes 98 counties in North Carolina, South Carolina, and “Other counties”.

In Section C.3, page 36, the applicant provides the projected patient origin for NHRMC’s cardiac catheterization equipment in the first three full fiscal years following project completion, as summarized below.

NHRMC Projected Cardiac Catheterization Patient Origin

County	1 st Full FY 10/1/20 – 9/30/21		2 nd Full FY 10/1/21 – 9/30/22		3 rd Full FY 10/1/22 – 9/30/23	
	# Pts	% of Total	# Pts	% of Total	# Pts	% of Total
“Primary Service Area”						
New Hanover	1,906	32.8%	1,962	32.8%	2,021	32.8%
Brunswick	1,524	26.2%	1,569	26.2%	1,616	26.2%
Pender	655	11.3%	675	11.3%	695	11.3%
Onslow	587	10.1%	605	10.1%	623	10.1%
Columbus	530	9.1%	546	9.1%	562	9.1%
Subtotal	5,202	89.6%	5,357	89.6%	5,516	89.6%
“Secondary Service Area”						
Duplin	205	3.5%	211	3.5%	217	3.5%
Bladen	132	2.3%	136	2.3%	140	2.3%
Subtotal	337	5.8%	347	5.8%	358	5.8%
In-Migration	266	4.6%	274	4.6%	282	4.6%
Total	5,806	100%	5,979	100%	6,157	100%

*The applicant states in-migration includes 98 counties in North Carolina, South Carolina, and “Other counties”.

Totals may not sum due to rounding

In Section C.3(c), page 37, the applicant provides the assumptions and methodology used to project the number of patients by county of origin.

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 38 - 43, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 38, the applicant states:

“NHRMC proposes to acquire a GE Innova IGS-530 cardiac cath system to meet the internal need of the medical center for its cardiac cath service. The proposed system will:

- *Meet the expected demand for cardiac cath services and will achieve sufficient volumes to maintain its operation in New Hanover County.*
- *Increase patient access and throughput to cardiac cath services in the service area.*
- *Decrease staff fatigue due to extended, non-traditional hours of care.”*

On pages 39 - 43, the applicant states that the need the patients have for the proposed project results from the following main factors:

- Historical and projected service area population growth, especially for the 65+ age cohort that is most likely to use cardiac catheterization services (page 40).
- NHRMC physician group growth and increase in medical staff at NHRMC. The applicant states that in the past ten years, the medical staff at NHRMC increased from 470 to 648 staff members (page 40). On page 41 the applicant provides a table to illustrate the addition of 33 physicians and clinical staff members that have been added to NHRMC in 2018 and 2019.
- NHRMC began operating an Accountable Care Organization (ACO), Physician Quality Partners (PQP), in January 2014. The applicant explains that an ACO's purpose is to organize a group of health care providers to work collaboratively to accept "*collective accountability*" for the cost and quality of health care. The applicant describes the positive impact PQP has had at NHRMC (pages 41 - 42).
- High historical utilization of all services at NHRMC, including cardiac catheterization, as follows: (page 43)
 - Inpatient days of care increased by 29.3% from FY 2008 to FY 2018
 - Outpatient visits increased by 78.9% from FY 2008 to FY 2018
 - Emergency department visits increased by 30.6% from FY 2008 to FY 2018
 - Cardiac catheterization utilization increased by 31.2% from FY 2008 to FY 2018
- The applicant notes that NHRMC maintains a 74% market share of inpatient cardiac catheterization services, and a 58% market share of outpatient cardiac catheterization services in the service area. The applicant notes that there is some outmigration of cardiac catheterization services to other counties, and states NHRMC must expand and modernize its services (page 43).

The information provided by the applicant in the pages referenced above is reasonable and adequately supported for the following reasons:

- The total service area population (New Hanover, Brunswick, Columbus, Pender and Onslow counties) is projected to increase by 7.8% from 2019 – 2024.
- The total service area population age 65+ is projected to grow by 18.0% from 2019 -2024.
- The total population in New Hanover County alone is projected to increase by 8.6% from 2019 – 2024.
- The New Hanover County population age 65+ is projected to grow by 17.3% from 2019 -2024.
- The number of cardiac catheterization procedures performed at NHRMC grew from 4,310 procedures in FY 2014 to 5,653 procedures (annualized) in FY 2019.

Projected Utilization

In Section C, pages 47 – 48, the applicant provides a two-step methodology it uses to project utilization for NHRMC’s cardiac catheterization units through the first three full fiscal years following completion of the project, [FY 2021 - FY2023], which is summarized as follows:

Step 1: The applicant analyzed historical cardiac catheterization procedures performed at NHRMC from FY 2014 through FY 2018 and annualized the data for FY 2019. See the following table, from page 47:

	HISTORICAL					ANNUALIZED	5 YR. AVG. CHANGE	50% OF 5 YR. AVG. CHANGE
	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019		
Diagnostic Procedures	2,731	2,763	2,772	2,863	2,841	3,279		
Annual Change		1.2%	0.3%	3.3%	-0.8%	15.4%	3.9%	1.9%
Interventional Procedures	1,579	1,810	1,838	1,870	2,098	2,374		
Annual Change		14.6%	1.5%	1.7%	12.2%	13.2%	8.7%	4.3%
Total # Procedures	4,310	4,573	4,610	4,733	4,939	5,653		

Step 2: The applicant states growth in cardiac catheterization procedures is projected to continue at NHRMC, but calculates that growth based on 50% of the five year average annual change it calculated in Step 1. See the following table from page 48:

	½ FIVE YEAR AVG. CHANGE	INTERIM	OY 1	OY 2	OY 3
		FY 2020	FY 2021	FY 2022	FY 2023
Diagnostic Procedures		3,343	3,408	3,474	3,541
Factor = ½ of 5 Year Annual Change	1.9%				
Interventional Procedures		2,477	2,584	2,696	2,812
Factor = ½ of 5 Year Annual Change	4.3%				
Total # Procedures		5,819	5,992	6,170	6,354

Projected utilization is reasonable and adequately supported for the following reasons:

- Projected utilization is based on the applicant’s historical experience with the existing cardiac catheterization units at NHRMC.
- The applicant uses one-half of the five year average change rate it calculated based on the number of cardiac catheterization procedures performed at NHRMC from FY 2014 to FY 2018, which is conservative when compared to the growth rates of the total population and the 65+ population in the total service area and in New Hanover County and NHRMC actual historical volume increases.

Access

In Section C, page 49, the applicant states:

“NHRMC is a not-for-profit organization that does not discriminate against any class of patient based on ability to pay, race, ethnicity, sex, handicap, or age. NHRMC actively participates in both the Medicaid and Medicare programs. In FY 2018, Medicare patients accounted for 63.4 percent of cardiac cath cases; while Medicaid patients accounted for 4.3 percent of cardiac cath cases. In FY 2018, NHRMC provided nearly \$18.2 million in charity care and wrote-off over \$92.1 million in unpaid patient accounts.”

In Section L.3, page 89, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as summarized in the following table:

PROJECTED PAYOR MIX, FY 2023*

PAYOR CATEGORY	NHRMC SERVICES AS % OF TOTAL	CARDIAC CATHETERIZATION SERVICES AS % OF TOTAL
Self-Pay	9.8%	5.9%
Medicare	36.2%	63.4%
Medicaid	18.4%	4.3%
Insurance	28.0%	21.6%
TRICARE	2.8%	2.5%
Other (Specify)	4.8%	2.3%
Total	100.0%	100.0%

*The applicant indicates on page 89 that the table represents data for the third full FY following project completion, and states it is 10/1/20223 to 9/30/2024; however, in the remainder of the application, the applicant indicates the first three project years are FY 2021 through FY 2023.

Totals may not sum due to rounding

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application
- exhibits to the application, and
- Information which was publicly available during the review and used by the Agency

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

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

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

NA

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

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

CA

The applicant proposes to acquire one replacement unit of cardiac catheterization equipment.

In Section E, page 64, the applicant states it did not consider any alternatives to this proposal to replace one unit of cardiac catheterization equipment.

The applicant states:

“Currently, NHRMC utilizes one CON-approved, [sic] unit of cardiac catheterization equipment to treat interventional radiology cases in the medical center. This CON application proposes to replace that existing unit of cardiac catheterization equipment and perform only cardiac cath procedures in the future. The existing unit of cardiac cath equipment will be recategorized as interventional radiology equipment and no cardiac cath procedures will be performed on the equipment.”

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why did not consider any other alternative.

Conclusion

The Agency reviewed the:

- application, and
- 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. New Hanover Regional Medical Center shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, New Hanover Regional Medical Center shall materially comply with the last made representation.**
- 2. New Hanover Regional Medical Center shall acquire no more than one unit of cardiac catheterization equipment to replace one existing unit of cardiac catheterization equipment. The applicant shall recategorize the existing unit of cardiac catheterization equipment in Cardiac Cath Lab #5 to provide only interventional radiology procedures on that unit.**
- 3. New Hanover Regional Medical Center 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.**
- 4. 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, New Hanover Regional Medical Center 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.**

5. New Hanover Regional Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to acquire one replacement unit of cardiac catheterization equipment.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 108, the applicant projects the total capital cost of the project as shown in the table below:

ITEM	COST
Construction / Renovation Contract	\$2,300,000
Architect / Engineering Fees	\$ 130,000
Medical Equipment	\$1,926,920
Non-Medical Equipment	\$ 50,000
Furniture	\$ 10,0000
Consultant Fees	\$ 40,000
Contingency	\$ 40,000
Total	\$4,496,920

In Section F.3, page 68, the applicant projects \$21,998 in working capital, and no initial operating expenses.

In Section F, pages 65 and 68, the applicant provides the assumptions used to project the capital and working capital costs of the project. Exhibit F.1 contains supporting documentation.

Availability of Funds

In Section F, page 66, the applicant states that the capital cost will be funded as shown in the table below.

SOURCES OF CAPITAL COST FINANCING

TYPE	TOTAL
Loans	
Accumulated reserves or OE *	
Bonds	
Other – Cash or Cash Equivalents ¹	\$4,496,920
Total Financing	\$4,496,920

* OE = Owner’s Equity

(1) on pages 66 the applicant states “NHRMC will not use accumulated reserves [or loan financing] to fund the project.” In a table on the same page, the applicant notes that the capital cost will come from “accumulated reserves or OE”. The Project Analyst determined that the table contains a typographical error.

In Section F, page 69, the applicant states that the working capital will be funded as shown in the table below.

SOURCES OF WORKING CAPITAL FINANCING

TYPE	TOTAL
Loans	
Cash or Cash Equivalents, Accumulated reserves or OE *	\$21,998
Bonds	
Total Financing	\$21,998

* OE = Owner’s Equity

In Exhibit F.3, the applicant provides an October 10, 2019 letter from NHRMC’s Chief Financial Officer that confirms the availability of the funds and the commitment of the funds to the capital and working capital costs associated with this project. The applicant also provides NHRMC’s consolidated financial statements from FY 2018 in Exhibit F.2 that show \$113 million in cash and cash equivalents.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2, page 109, the applicant projects that revenues will exceed operating expenses for the cardiac catheterization services in the first three operating years of the project, as shown in the table below.

	1ST FULL FY FY 2021	2ND FULL FY FY 2022	3RD FULL FY FY 2023
Total Cardiac Catheterization Treatments*	5,992	6,170	6,354
Total Gross Revenues (Charges)	\$378,088,335	\$407,384,375	\$438,999,621
Total Net Revenue	\$75,239,579	\$75,977,186	\$76,824,934
Average Net Revenue per Treatment	\$12,705	\$12,313	\$12,090
Total Operating Expenses (Costs)	\$13,564,890	\$14,191,791	\$14,852,304
Average Operating Expense per ESTV Txt	\$2,264	\$2,300	\$2,337
Net Income	\$61,674,689	\$61,785,395	\$61,972,629

*The table on page 109 indicates the information is for “*interventional radiology*”; however, the applicant clarified that the table contained a typographical error and the information in the table in fact reflects cardiac catheterization information.
 Totals may not sum due to rounding

Conclusion

The Agency reviewed the:

- application,
- clarifying information requested by the Agency and
- 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.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to acquire one replacement unit of cardiac catheterization equipment.

In Chapter 9, page 173, the 2019 SMFP states, “A *cardiac catheterization (fixed or shared) equipment’s service area is the cardiac catheterization equipment planning area in which*

the equipment is located. The cardiac catheterization equipment planning areas are the same as the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.” NHRMC is located in New Hanover County. In Figure 5.1, page 40 of the 2019 SMFP New Hanover County is listed as a single Acute Care Bed Service Area County; therefore, the service area is New Hanover County. Providers may serve residents of counties not included in their service area.

Table 9X on page 182 of the 2019 SMFP shows a total of five units of cardiac cath equipment in New Hanover County, all of which are owned and operated by NHRMC.

The applicant proposes to replace one existing unit of cardiac catheterization equipment located at NHRMC and to recategorize the unit being replaced such that it will perform only interventional radiology procedures and no cardiac catheterization procedures. Therefore, the applicant does not propose to increase the inventory of cardiac catheterization equipment in the service area.

In Section G, page 73 and Exhibit G.3, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved cardiac catheterization equipment in the proposed service area. The applicant states:

“... only NHRMC and Southeastern Regional Medical Center (76 miles west of Wilmington in Laurinburg) perform cardiac cath procedures to any significant level as reported in the Hospital License Renewal Application.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant proposes to replace an existing unit of cardiac catheterization equipment with comparable equipment to serve its cardiac patients.
- The applicant proposes to recategorize the unit being replaced such that it continues to serve only interventional radiology patients as it has been at the hospital.
- The proposal would not result in an increase in the number of cardiac catheterization units utilized for cardiac catheterization procedures in the service area.
- The applicant adequately demonstrates that the proposed replacement unit of cardiac catheterization equipment is needed in addition to the existing or approved units.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- Information which was publicly available during the review and used by the Agency

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

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

C

In Section Q, Form H, page 115, the applicant provides the historical and projected staffing by full-time equivalent (FTE) position for NHRMC cardiac catheterization services, as summarized below.

Staffing – NHRMC Cardiac Catheterization Services

POSITION	CURRENT PRIOR FULL FY*	PROJECTED		
		1 ST FULL FY FY 2021	2 ND FULL FY FY 2022	3 RD FULL FY FY 2023
Manager	1.00	1.00	1.00	1.00
Technical Coordinator	0.03	0.03	0.03	0.03
Administrative Coordinator	0.03	0.03	0.03	0.03
Staff Nurse	10.90	14.75	14.75	14.75
Technologist	1.85	1.85	1.85	1.85
Cardiovascular Tech-C	8.86	11.06	11.06	11.06
Admin Associate I	1.00	1.00	1.00	1.00
Admin Associate II	1.61	1.61	1.61	1.61
Trauma Registrar I	0.05	0.05	0.05	0.05
TOTAL	25.33	31.38	31.38	31.38

*The applicant does not identify which FY the “current” FY refers to in this particular table; however, in each of the forms in Section Q (Form C, utilization; Pro Forma forms), the “current” FY is identified as FY 2018 (10/1/2017 – 9/30/2018). The Project Analyst assumes the same for Form H. The applicant projects two interim years, FY 2019 and FY 2020 respectively, in which the applicant projects the same staffing as in FY 2018. Those interim years are not reflected in the table since they are the same as prior FY 2018.

As can be seen in the table above, the applicant projects to add 3.85 FTE staff nurse positions and 2.2 FTE cardiovascular technician positions in the first three operating years of the project. In Section H, pages 75 - 76, the applicant provides its staffing-related assumptions. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.2, which is found in Section Q. In Section H, page 76, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application

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

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

C

In Section I, page 78, the applicant states that the following ancillary and support services are necessary to the project:

- Billing, Accounts Payable, Accounting
- Business Office/Admitting
- Facility Management
- Human Resources/Wage and Benefits
- Information Management
- Legal Services
- Materials Management
- Medical Record Services
- Planning and Marketing
- Precertification and Insurance
- Purchasing
- Quality Management
- Risk Management
- Scheduling /Staff education

On page 78, the applicant adequately explains that each ancillary and support service is already available at NHRMC and provides supporting documentation in Exhibit I-1.

In Section I, pages 79 - 80, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-3.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

NA

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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

services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section K, page 83, the applicant states that the project involves renovating 4,450 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 84, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit F.1.

On page 84, 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 and provides supporting documentation in Exhibit F.1.

On page 84, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 handicapped persons, 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.1(b), page 88, the applicant provides the following payor mix for NHRMC and cardiac catheterization services for FY 2018 (10/1/17 – 9/30/18):

NHRMC Historical Payor Mix, FY 2018

PAYOR CATEGORY	TOTAL HOSPITAL % OF TOTAL	CARDIAC CATHETERIZATION SERVICES AS % OF TOTAL
Self-Pay	9.8%	5.9%
Medicare*	36.2%	63.4%
Medicaid*	18.4%	4.3%
Insurance*	28.0%	21.6%
TRICARE	2.8%	2.5%
Other (Specify)	4.8%	2.3%
Total	100.0%	100.0%

*Includes any managed care plans

As shown in the table above, the applicant states that 4.3% of its cardiac catheterization services were reimbursed by Medicaid and 63.4% were reimbursed by Medicare in FY 2018.

In Section L.1, page 87, the applicant provides the following comparison.

Patients Served During Last Full Fiscal Year

	% OF TOTAL PATIENTS SERVED BY NHRMC	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	51.2%	52.3%
Male	48.8%	47.7%
Unknown	0.0%	0.0%
64 and Younger	44.5%	82.3%
65 and Older	55.5%	17.7%
American Indian	0.7%	0.6%
Asian	0.1%	1.6%
Black or African-American	20.0%	13.7%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	77.0%	77.4%
Other Race	1.3%	6.6%
Declined / Unavailable	0.8%	0.0%

The Agency reviewed the:

- application, and
- 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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 88, the applicant states it is not under an obligation to provide uncompensated care.

In Section L, page 88, the applicant states that during the last five years NHRMC has not had any civil rights access complaints filed against the facility.

The Agency reviewed the:

- application, and
- exhibits to the application

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

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

C

In Section L, page 89, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

NHRMC Projected Payor Mix, FY 2024

PAYOR CATEGORY	TOTAL HOSPITAL % OF TOTAL	CARDIAC CATHETERIZATION SERVICES AS % OF TOTAL
Self-Pay	9.8%	5.9%
Medicare*	36.2%	63.4%
Medicaid*	18.4%	4.3%
Insurance*	28.0%	21.6%
TRICARE	2.8%	2.5%
Other (Specify)	4.8%	2.3%
Total	100.0%	100.0%

*Includes any managed care plans

On page 89, the applicant provides the assumptions and methodology used to project payor mix following project completion. The projected payor mix is reasonable and adequately supported and is based on the historical payor mix for existing cardiac catheterization services at NHRMC.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application

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

- (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 90, the applicant adequately describes the range of means by which patients will have access to the proposed services, which is by physician referral.

The Agency reviewed the:

- application, and
- exhibits to the application

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

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

C

In Section M, page 92, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and lists the programs that currently utilize the training opportunities at NHRMC.

The Agency reviewed the:

- application, and
- exhibits to the application

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

C

The applicant proposes to acquire one replacement unit of cardiac catheterization equipment at the main hospital campus and relocate one unit of cardiac catheterization to be used exclusively for interventional radiology.

In Chapter 9, page 173, the 2019 SMFP states, “A *cardiac catheterization (fixed or shared) equipment’s service area is the cardiac catheterization equipment planning area in which the equipment is located. The cardiac catheterization equipment planning areas are the same as the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.*” NHRMC is located in New Hanover County. In Figure 5.1, page 40 of the 2019 SMFP New Hanover County is listed as a single Acute Care Bed Service Area County; therefore, the service area is New Hanover County. Providers may serve residents of counties not included in their service area.

Table 9X on page 182 of the 2019 SMFP shows a total of five units of cardiac cath equipment in New Hanover County, all of which are owned and operated by NHRMC.

The applicant proposes to replace one existing unit of cardiac catheterization equipment located at NHRMC and to recategorize the unit being replaced such that it will perform only interventional radiology procedures and no cardiac catheterization procedures. Therefore, the applicant does not propose to increase the inventory of cardiac catheterization equipment in the service area.

In Section N, pages 94 - 97, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed

services. On page 94, the applicant states the replacement cardiac catheterization unit is going to be located in the hospital, which is the only hospital in New Hanover County and the only hospital in the primary service area that offers cardiac catheterization services. Therefore, the proposed project is not expected to have a significant impact on competition in the service area. The applicant further states that the proposed project will have a positive impact on the cost effectiveness, quality, and access to cardiac catheterization services in the service area.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- Information which was publicly available during the review and used by the Agency

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

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

C

In Section Q, Form A Facilities, page 104, the applicant identifies NHRMC as the only hospital in New Hanover County.

In Section O, page 100, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred at NHRMC. 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, there have been no incidents related to quality of care at

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

NA

The Criteria and Standards for Section .1600 – Criteria and Standards for Cardiac Catheterization Equipment and Cardiac Angioplasty Equipment, which are promulgated in 10A NCAC 14C .1600 do not apply to replacement equipment; therefore, these Rules are not applicable to this review.