

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 15, 2019

Findings Date: January 15, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: O-11748-19

Facility: New Hanover Regional Medical Center

FID #: 943372

County: New Hanover

Applicant: New Hanover Regional Medical Center

Project: Acquire a bi-plane system for interventional radiology

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 (NHRMC) or “the applicant” proposes to acquire a Siemens Artis Q bi-plane system for interventional radiology (IR), including interventional neuroradiology, to develop a dedicated IR room at NHRMC through the renovation of existing space.

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, no need determinations 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, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety, or infection control.”

The proposed capital expenditure for this project is greater than \$5 million. In Section B.11, page 22, the applicant describes a plan to ensure energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the applicant’s plans to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

- (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 acquire a bi-plane system for interventional radiology at NHRMC.

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.” The 2019 SMFP does not define a service area for a bi-plane system, nor are there any applicable rules adopted by the Department that define the service area for a bi-plane system. In Section C.3, page 38, the applicant defines the service area for the proposed interventional radiology services as consisting of New Hanover, Brunswick, Columbus, Onslow, Pender, Duplin, Bladen, Robeson and Sampson counties in North Carolina and Horry County in South Carolina. Facilities may also serve residents of counties not included in the service area.

The following table illustrates current and projected patient origin of IR cases at NHRMC.

County	Current (10/01/2017 to 9/30/2018)		Third Full FY of Operation following Project Completion (10/01/2023 to 9/30/2024)	
	Patients	% of Total	Patients	% of Total
New Hanover	969	42.8%	1,302	42.8%
Brunswick	469	20.7%	630	20.7%
Pender	267	11.8%	359	11.8%
Onslow	179	7.9%	240	7.9%
Columbus	116	5.1%	155	5.1%
Duplin	84	3.7%	113	3.7%
Bladen	54	2.4%	73	2.4%
Robeson	34	1.5%	46	1.5%
Horry	9	0.4%	12	0.4%
Sampson	9	0.4%	12	0.4%
In-Migration*	75	3.4%	103	3.4%
Total	2,265	100.0%	3,042	100.0%

Source: Section C, Tables on pages 37-38.

*In-Migration includes 48 North Carolina and South Carolina Counties.

In Section C, page 39, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 40-45, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 40, the applicant states that it identified the internal medical center need for an additional IR system within NHRMC's Radiology Department in Wilmington based on the reasons summarized below:

“NHRMC proposes to acquire a Siemens Artis Q to meet internal demand of the medical center for its IR service. The proposed IR system will:

- *Meet the expected demand for IR services and will achieve sufficient volumes to maintain its operation in New Hanover County.*
- *Increase patient access and throughput to IR services in the service area.”*

NHRMC, in determining need for the proposed service, reviewed:

- *Population Growth in the Service Area* (pages 41-42).
- *Support for its Comprehensive Stroke Center* (page 45).
- *Growth of NHRMC's Physician Group* (pages 43-43).
- *Support for Physician Quality Partners, an Accountable Care Organization operated by NHRMC* (page 44)
- *Growth in NHRMC Utilization* (page 45).

The information is reasonable and adequately supported for the following reasons:

- The population projections by the NCOSBM indicates that NHRMC's primary service area (New Hanover, Brunswick, Columbus, Onslow and Pender counties) is expected to grow by 7.8% from 2019 to 2024, with the population cohort Age 65+ projected to increase by 18.0% from 2019 to 2024.
- NHRMC is scheduled to add additional physicians to its physician network which will increase the number of referrals to NHRMC services. NHRMC's medical staff has grown in the last decade from 470 to 648.
- NHRMC is the only hospital in southeastern North Carolina to offer 24/7 neuro-interventional coverage to treat patients suffering cerebrovascular emergencies, including stroke and aneurysms. As such, development of an additional IR Room

will expand NHRMC’s capability to provide time sensitive care and ensure adequate access and redundancy to support the comprehensive stroke center.

- Historical IR cases at NHRMC experienced a 66.3% growth from FY2016 to FY2018 increasing from 1,362 cases to 2,265 cases.
- NHRMC started operating an Accountable Care Organization (ACO) in January 2014. Since implementation of the ACO, NHRMC’s overall market share in its service area has grown from 18.1% to 20.9%.

Projected Utilization

In Section Q, the applicant provides historical and projected utilization, as illustrated in the following tables.

Historical IR Cases: NHRMC

	Historical					Annualized
	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019
IR Cases	1,534	1,537	1,362	1,720	2,265	2,461

Source: Section Q, page 102.

Projected IR Cases: NHRMC

	FY2020	FY2021	FY2022	FY2023	FY2024
IR Cases	2,567	2,679	2,794	2,915	3,042

Source: Section Q, page 102.

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

Step #1) Determine Annual Percentage Change Rate

Historical IR Cases: NHRMC

	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019*
IR Cases	1,534	1,537	1,362	1,720	2,265	2,461
# of IR Systems	2	2	2	2	2	2
Capacity of an IR System	1,500	1,500	1,500	1,500	1,500	1,500
Annual Percentage Change in # of IR Cases**	n/a	0.2%	-11.4%	26.3%	31.7%	8.7%
Utilization	51.1%	51.2%	45.4%	57.3%	75.5%	82.0%

Source: Section Q, page 102.

*Annualized.

**The applicant calculated annual percentage of change by subtracting current year’s volume from previous year’s volume and dividing the result by the previous year’s volume.

The applicant projected IR cases to continue to increase but at slightly below 50.0% of the FY2019 annual change rate or 4.3% [$8.7\% / 2 = 4.35\%$].

Step #2) Project Increase in IR Cases Based on Annual Change Rate

To project utilization for the first three operating years (OYs), the applicant applied the annual average change rate of 4.3% from Step 1 above starting with the annualized IR cases from FY2019 as shown in the table below:

	FY2019*	FY2020	FY2021	FY2022	FY2023	FY2024
IR Cases X Annual Change Rate of 4.3%	2,461	2,567	2,679	2,794	2,915	3,042
Annual Percentage Increase in # of IR Cases		4.3%	4.3%	4.3%	4.3%	4.3%
# of IR Systems	2	2	2	3	3	3
Capacity of an IR System	1,500	1,500	1,500	1,500	1,500	1,500
Utilization	82.0%	85.6%	89.3%	62.1%	64.8%	67.6%

Source: Section Q, page 102.

*Annualized.

The historical compound annual growth rate (CAGR) for IR cases at NHRMC for the five-year period of FY2014 to FY2019 is 9.92%.

The CAGR for projected utilization of IR cases at NHRMC for the five-year period of FY2019 to FY2024 is 4.33%

By the OY3(FY2024), utilization of the three IR systems is projected to be 67.6%.

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

- The applicant’s utilization projections are supported by an increase in historical IR cases at NHRMC over a five-year period.
- The applicant projects utilization for the five-year period of FY2019 to FY2024 (OY3). Based on a conservative annual change rate which is only 50.0% of the annual change rate from FY2018 to FY2019.
- The 5-year historical CAGR for IR cases, FY2014 to FY2019 annualized, at NHRMC is 9.92%. The applicant uses a more conservative growth rate of 4.3% to project utilization for FY2019 through FY2024.
- The three IR systems are projected to be well utilized by OY3(FY2024).

Access

In Section C, page 51, 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.” In Section L, page 85, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Category	Entire Facility: Percent of Total	Interventional Radiology Services: Percent of Total
Self-Pay	9.8%	5.1%
Medicare*	36.2%	49.3%
Medicaid*	18.4%	8.9%
Insurance*	28.0%	34.5%
TRICARE	2.8%	1.8%
Other (specify)	4.8%	0.4%
Total	100.0%	100.0%

Source: Table on page 85 of the application.

*Including any managed care plans.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information publicly available during the review and used by the Agency

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

- The applicant adequately 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 a reduction or elimination of a service, or the relocation of a facility or a service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to acquire a bi-plane system for interventional radiology at NHRMC.

In Section E, page 60, the applicant states that there are no alternatives to consider that will accommodate the existing and future interventional radiology need at NHRMC.

On page 60, the applicant states that its proposal is the most effective alternative because it is the only alternative that will accommodate both the existing and projected need for interventional radiology at NHRMC.

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 it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Remarks made at the public hearing
- 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.**
- 2. New Hanover Regional Medical Center shall acquire no more than one bi-plane system for interventional radiology for a total of no more than two bi-plane systems for interventional radiology.**
- 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. **New Hanover Regional Medical Center shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
 5. **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.**
 6. **New Hanover Regional Medical Center 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 acquire a bi-plane system for interventional radiology at NHRMC.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 103, the applicant projects the total capital cost of the project as shown in the table below.

Site Costs	\$0
Construction Costs	\$4,059,000
Miscellaneous Costs	\$3,121,000
Total	\$7,180,000

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 64, the applicant projects that start-up costs will be \$23,212 and initial operating expenses will be \$0 for a total working capital of \$23,212. On page 64, the applicant

provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, page 62, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing		
Type	NHRMC	Total
Loans	\$0	\$0
Cash or Cash Equivalents, Accumulated reserves or OE *	\$ 7,180,000	\$7,180,000
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$7,180,00	\$7,180,00

* OE = Owner's Equity

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

Sources of Financing for Working Capital- NHRMC		Amount
(a)	Loans	\$0
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$23,212
(c)	Lines of credit	\$0
(d)	Bonds	\$0
(e)	Total *	\$23,212

In Exhibit F-2.1 the applicant provides a letter dated August 10, 2019 from NHRMC's Chief Financial Officer documenting that the funds will be available for the capital cost and working capital cost of the project. Exhibit F-2.2 contains the most recent audited financial statements for NHRMC which indicate on page 12 that the hospital had \$113,479,000 in cash and cash equivalents as of September 30, 2018.

Financial Feasibility

In Section Q, the applicant provided pro forma financial statements for NHRMC's interventional radiology services for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
Total IR Cases	2,794	2,915	3,042
Total Gross Revenues (Charges)	\$198,705,625	\$217,676,536	\$238,518,224
Total Net Revenue	\$34,878,838	\$35,923,202	\$37,001,380
Average Net Revenue per IR Case	\$12,483	\$12,324	\$12,164
Total Operating Expenses (Costs)	\$6,563,485	\$6,946,223	\$7,355,718
Average Operating Expense per IR Case	\$2,349	\$2,383	\$2418
Net Income	\$28,315,354	\$28,976,980	\$29,645,662

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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 a bi-plane system for interventional radiology at NHRMC.

N.C. Gen. Stat. §131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.” The 2019 SMFP does not define a service area for a bi-plane system, nor are there any applicable rules adopted by the Department that define the service area for a bi-plane system. In Section C.4, page 42, the applicant defines the service for the proposed interventional radiology services as consisting of New Hanover, Brunswick,

Columbus, Onslow, Pender, Duplin, Bladen, Robeson, and Sampson counties in North Carolina and Horry County in South Carolina. Facilities may also serve residents of counties not included in the service area.

In Section G, page 68, the applicant, based on the 2019 Hospital License Renewal Applications, identifies all existing facilities in the proposed service area that provide the same service components proposed in this application as illustrated in the following table:

Facility	Units	Total Procedures
New Hanover Regional Medical Center	3	2,806
J. Arthur Doshier Memorial Hospital	0	0
Novant Health Brunswick Medical Center	0	0
Pender Memorial Hospital	0	0
Onslow Memorial Hospital	0	0
Columbus Regional HealthCare System	0	0
Vidant Duplin Hospital	0	0
Cape Fear Valley-Bladen County Hospital	0	0
Southeastern Regional Medical Center	1	1,816
Sampson Regional Medical Center	0	0

Source: Table on page 68 of the application.

The data provided on the Hospital License Renewal Applications is too broadly defined for comparative purposes as applicant states on page 68,

“The 2019 Hospital License Renewal Application, Table 10h.-Other Imaging Equipment identifies Special Procedures/Angiography Equipment. This broad description does not allow NHRMC to know for certain if the report volumes are IR procedures, angiography procedures, or other non-IR and non-angiography procedures. None-the-less, NHRMC is providing the reported data.”

In Section G, page 69, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved IR services in the service area. The applicant states:

“Only NHRMC and Southeastern Regional Medical Center (76 miles west of Wilmington in Laurinburg) perform Special Procedures/Angiography procedures 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 adequately demonstrates that the proposed bi-plane system for interventional radiology is needed in addition to the existing or approved interventional radiology systems.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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

The applicant proposes to acquire a bi-plane system for interventional radiology at NHRMC.

In Section Q, Form H, page 110, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	(10/1/17 to 9/30/18)	2nd Full Fiscal Year (10/1/22 to 9/30/23)
Lead Interventional Rad Tech	1.09	1.09
Rad Tech	6.68	9.90
Imaging Scheduler	1.01	1.01
TOTAL	8.78	12.00

The assumptions and methodology used to project staffing are provided in Sections H and Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Sections H.2 and H.3, pages 71 and 72, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 76, the applicant identifies the current medical director. In Exhibit I.3, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H.3, I.3 and M.1, the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Remarks made at the public hearing

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

The applicant proposes to acquire a bi-plane system for interventional radiology at NHRMC.

In Section I, page 74, the applicant states that the following ancillary and support services are necessary for the proposed services:

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

On page 74, the applicant adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I.1.

In Section I, page 75, the applicant describes its efforts to develop 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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 79, the applicant states that the project involves renovating 7,800 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 80, in Section K and in Section E.2, page 60, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 80, 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 Exhibits F.1 and F.1a.

In Section K.3(c), page 80, 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
- Remarks made at the public hearing

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, page 84, the applicant provides the historical payor mix during the last full fiscal year (10/1/2017 to 9/30/2018) for the hospital and for interventional radiology services, as shown in the table below.

Payor Category	Entire Facility: Percent of Total	Interventional Radiology Services: Percent of Total
Self-Pay	9.8%	5.1%
Medicare*	36.2%	49.3%
Medicaid*	18.4%	8.9%
Insurance*	28.0%	34.5%
TRICARE	2.8%	1.8%
Other (specify)	4.8%	0.4%
Total	100.0%	100.0%

Source: Table on page 84 of the application.

*Including any managed care plans.

In Section L, page 83, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	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%

Source: Table on page 83 of the application.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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 84, the applicant states,

“NHRMC is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons.”

In Section L, page 84, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility nor any related hospital located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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 85, the applicant projects the following payor mix for the proposed services during the third full fiscal year (10/1/2023 to 9/30/2024) of operation following completion of the project, as shown in the table below.

Payor Category	Entire Facility: Percent of Total	Interventional Radiology Services: Percent of Total
Self-Pay	9.8%	5.1%
Medicare*	36.2%	49.3%
Medicaid*	18.4%	8.9%
Insurance*	28.0%	34.5%
TRICARE	2.8%	1.8%
Other (specify)	4.8%	0.4%
Total	100.0%	100.0%

Source: Table on page 85 of the application.

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 5.1% of interventional radiology services will be provided to self-pay patients, 49.3% to Medicare patients and 8.9% to Medicaid patients.

On page 85, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix of patients currently utilizing the services at NHRMC.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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 88, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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 a bi-plane system for interventional radiology at NHRMC.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2019 SMFP does not define a service area for a bi-plane system, nor are there any applicable rules adopted by the Department that define the service area for a bi-plane system. In Section C.4, page 42, the applicant defines the service for the proposed interventional radiology services as consisting of New Hanover, Brunswick, Columbus, Onslow, Pender, Duplin, Bladen, Robeson and Sampson counties in North Carolina and Horry County in South Carolina. Facilities may also serve residents of counties not included in the service area.

In Section G, page 68, the applicant, based on the 2019 Hospital License Renewal Applications, identifies all existing facilities in the proposed service area that provide the same service components proposed in this application as illustrated in the following table:

Facility	Units	Total Procedures
New Hanover Regional Medical Center	3	2,806
J. Arthur Doshier Memorial Hospital	0	0
Novant Health Brunswick Medical Center	0	0
Pender Memorial Hospital	0	0
Onslow Memorial Hospital	0	0
Columbus Regional HealthCare System	0	0
Vidant Duplin Hospital	0	0
Cape Fear Valley-Bladen County Hospital	0	0
Southeastern Regional Medical Center	1	1,816
Sampson Regional Medical Center	0	0

Source: Table on page 68 of the application.

The data provided on the Hospital License Renewal Applications is too broadly defined for comparative purposes as applicant states on page 68,

“The 2019 Hospital License Renewal Application, Table 10h.-Other Imaging Equipment identifies Special Procedures/Angiography Equipment. This broad description does not allow NHRMC to know for certain if the report volumes are IR procedures, angiography procedures, or other non-IR and non-angiography procedures. None-the-less, NHRMC is providing the reported data.”

In Section N, pages 90-92, 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 90, the applicant states that it *“expects ... the proposed IR system to have a positive or at least a neutral effect on competition in the service area... The IR system will be located in NHRMC, which is the only hospital in New Hanover County and the only hospital in the primary service area that offers Special Procedures/Angiography procedures.”*

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
- Remarks made at the public hearing
- 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 O.3, page 96, the applicant states:

“NHRMC was not found by the Division of Health Service Regulation or CMS to have had any incidents resulting in a finding of immediate jeopardy during the 18-month look-back period.”

Furthermore, in Exhibit O.3, the applicant includes a letter from the President and Chief Executive Officer of NHRMC, dated August 10, 2019, which states:

“Please accept this letter as documentation that in accordance with Section O.3 that the following facilities provide quality care during the 18 months immediately preceding submission of the application (18-month look-back period) by operating in compliance with all Medicare Conditions of Participation:

- *New Hanover Regional Medical Center*
- *NHRMC Orthopedic Hospital*
- *Betty H. Cameron Women’s and Children’s Hospital*
- *NHRMC Behavioral Health Hospital*
- *NHRMC Rehabilitation Hospital”*

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care resulting in a finding of immediate jeopardy have not occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all of the 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 applicant proposes to acquire a bi-plane system for interventional radiology. There are no administrative rules that are applicable to this proposal.