

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 19, 2018

Findings Date: October 19, 2018

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: H-11526-18

Facility: FirstHealth Moore Regional Hospital

FID #: 943358

County: Moore

Applicant: FirstHealth of the Carolinas, Inc.

Project: Develop a new dedicated C-Section operating room

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

First Health of the Carolinas, Inc. (the applicant) proposes to develop a new dedicated Cesarean section (C-Section) operating room (OR), on the Women's and Children's inpatient unit at FirstHealth Moore Regional Hospital (FMRH). Upon completion of this project, Project ID# N-8843-12 (relocate one OR to Hoke County) and Project ID# H-11385-17 (develop one additional OR), FMRH will continue to have 15 shared surgical ORs, two dedicated inpatient surgical ORs and two dedicated endoscopy rooms. However, this project will increase the number of dedicated inpatient surgical ORs from two to three for a total of 18 ORs (15 shared and three dedicated), upon completion of this project and the two previously approved projects.

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 2018 State Medical Facilities Plan (SMFP). Further, the 2018 SMFP, on page 61, states:

“‘Dedicated C-Section Operating Rooms’ and associated cases are excluded from the calculation of need for additional operating rooms by the standard methodology; therefore, hospitals proposing to add a new operating room for use as a ‘Dedicated C-Section Operating Room’ shall apply for a certificate of need without regard to the need determinations in Chapter 6 of this Plan.”

Therefore, there are no need determinations applicable to this review.

Policies

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities is the only policy in the 2018 SMFP applicable to this review.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 33 of the 2018 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 \$2 million; therefore, Policy GEN-4 is applicable to this review. In Section B.4, page 12, the applicant states the proposed project will be in compliance with all applicable federal, state and local building codes, and

requirements for energy efficiency and consumption. The applicant also describes the energy and water conservation measures that will be used in development of the proposed project.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant does not propose the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2018 SMFP.
- The applicant adequately demonstrates that the application is consistent with all applicable policies in the SMFP.

- (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 develop a new dedicated C-Section OR on the Women's and Children's inpatient unit at FMRH. Upon completion of this project, Project ID# N-8843-12 (relocate one OR to Hoke County) and Project ID# H-11385-17 (develop one additional OR), FMRH will continue to have 17 ORs (15 shared and two dedicated) and two dedicated endoscopy rooms. However, this project will increase the number of dedicated inpatient surgical ORs to three for a total of 18 ORs, upon completion of this project and the two previously approved projects. According to recent progress reports submitted by the applicant, Project ID# N-8843-12 and Project ID# H-11385-17 are still under development.

Patient Origin

On page 57, the 2018 SMFP defines the service area for ORs as "*...the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.*" Thus, the service area for this

facility consists of Moore County. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 19, the applicant provides the historical patient origin, as shown in the following table.

FMRH C-Section OR Cases Historical Patient Origin		
County or ZIP Code Area	Last Full FY 10/1/2016 -9/30/2017	
	Number of Patients	% of Total
Moore	229	38.3%
Richmond	161	26.9%
Hoke	39	6.5%
Harnett	34	5.7%
Scotland	32	5.4%
Montgomery	29	4.8%
Lee	25	4.2%
Cumberland	19	3.2%
Robeson	8	1.3%
Chatham	7	1.2%
Randolph	7	1.2%
Anson	4	0.7%
Other	4	0.7%
Total	598	100%

In Section C, page 20, the applicant provides FMRH’s projected patient origin for the first, second and third full fiscal years (FY), FY2020, FY2021 and FY2022, as shown below in the table.

FMRH Dedicated C-Section OR Projected Patient Origin						
County or ZIP Code Area	FY2020		FY2021		FY2022	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Moore	236	38.3%	239	38.3%	241	38.3%
Richmond	166	26.9%	168	26.9%	169	26.9%
Hoke	40	6.5%	40	6.5%	41	6.5%
Harnett	35	5.7%	36	5.7%	36	5.7%
Scotland	33	5.4%	34	5.4%	34	5.4%
Montgomery	30	4.8%	30	4.8%	30	4.8%
Lee	26	4.2%	26	4.2%	26	4.2%
Cumberland	20	3.2%	20	3.2%	20	3.2%
Robeson	8	1.3%	8	1.3%	8	1.3%
Chatham	7	1.2%	7	1.2%	8	1.2%
Randolph	7	1.2%	7	1.2%	8	1.2%
Anson	4	0.7%	4	0.7%	4	0.7%
Other	4	0.7%	4	0.7%	4	0.7%
Total	617	100.0%	623	100.0%	629	100.0%

In supplemental information provided to the Agency on September 26, 2018, the applicant states the projected patient origin for FYs one through three is based on the historical patient origin of C-Sections performed in one of the shared ORs at the facility. The applicant also states that its methodology for projecting patient origin is based on multiplying the projected C-Section procedures stated on page 30 of the application by the historical county patient origin percentages calculated on page 19 of the application. The applicant's assumptions and methodology are reasonable and adequately supported.

Analysis of Need

In Section C.1, page 14, the applicant states OR #3 is a shared OR that is always set up for C-Section procedures. The applicant further describes OR #3 as follows:

“... In order to be transferred to this shared OR a patient must first be moved past the recently approved OR on the Women's and Children's Unit, down a second corridor and around another corner to the elevators. The patient must wait for the elevator and once in the main OR, the patient has to travel down two more corridors and around two more corners. After delivery, the patient receives post-op care in both the shared OR and in the birthing room once transferred back to the Women's and Children's Unit. Moving the patient in this manner is inefficient and creates more anxiety for the patient who is already anxious about the procedure. It would be much more efficient and would promote better patient care to have a dedicated C-Section OR in the Women's and Children's Unit.”

In Section C.4, page 21, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services:

- *Meet the demand for C-Section services and maintain volume that is sufficient to operate the C-Section OR (See application page 21)*
- *Assure that C-Sections are performed with minimal delay (See application page 21)*
- *Make available an additional 250 mornings/days per year for surgeon block time by increasing the number of early morning surgery start times via a shared OR in the main OR (See application page 21)*

On pages 22-25, the applicant identified the need for the dedicated C-Section OR by reviewing the following factors:

1. Physician Issues (See page 22)

In a previously approved certificate of need (CON) application submitted in 2010, the applicant proposed to relocate a shared OR that was being utilized for C-Sections and other gynecological procedures at FMRH to a community hospital to be developed in Hoke County. This OR was not a dedicated C-Section OR.

The applicant states that since the time of the previously approved application, several factors changed including: (1) a new manager of the Women's and Children's Unit with different priorities than the previous manager; and (2)

surgeons' requests for early start block times in the main OR. This has been impeded by one shared OR always having to be set up for C-Section procedures.

2. Service Area Population Growth Trends in Moore County (See pages 23-24)

Based on data from the North Carolina State Office of Budget and Management (NCOSBM), the applicant projects a 6.0% growth in the female population between the ages of 18 and 54 from 2018 to 2023. The applicant states the population growth for ages 18 to 44, as shown below.

- 18-24 will grow by 11.4% and will represent 17.5% of Moore County's female population.
- 25-34 will grow by 5.6% and will represent 24.9% of Moore County's female population.
- 35-44 will grow by 8.4% and will represent 28.1% of Moore County's female population.

Overall demographics for female population of 18-54 in FMRH's overall service area (Harnett, Hoke, Lee, Montgomery, Moore, Richmond and Scotland counties) is expected to grow by 5.1% from 2018 to 2023. The applicant states the population growth for ages 18 to 44 as shown below.

- 18-24 will grow by 6.5% and will represent 19.3% of the 7-county female population.
- 25-34 will grow by 7.6% and will represent 26.7% of the 7-county female population.
- 35-44 will grow by 4.0% and will represent 27.3% of the 7-county female population.

The applicant concludes that growth in the 18-54 female population will result in continued demand for healthcare services including obstetrical and C-Section services in Moore County and its seven county service area.

3. Historical Factors Influencing Need from 2012 to 2017 (See page 25 and Exhibit C.4, Tab 4)

On page 25, the applicant states that it has the C-Section volume to "fully" justify a dedicated C-Section OR. The following table shows there was a 23.5% increase in deliveries at FMRH during FY2012 to FY2017; while C-Section deliveries increased from 38.8% of total deliveries in FY2012 to 45.3% of total deliveries in FY2016. The applicant also states that the percentage of C-Section deliveries declined to a small degree in 2017 to 43.4%.

FMRH Historical C-Section Procedures						
	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017
Deliveries	1,116	1,128	1,211	1,333	1,366	1,379
Annual Change		12	83	122	33	13
% Annual Change		1.1%	7.4%	10.1%	2.5%	1.0%
C-Sections as % of Deliveries	38.8%	40.4%	40.9%	44.8%	45.3%	43.4%

[Source: License Renewal Applications (LRAs) and Need Methodology.]

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

- The applicant uses publicly available data to document the projected increase in population in its proposed service area;
- The applicant uses its own historical data to demonstrate increases in historical utilization

Projected Utilization

In Section C.7, pages 30-31, the applicant provides the assumptions and methodology used to project utilization, which below are summarized. The applicant used historical data of the projected deliveries and C-Section OR Cases from 2012 through the first three project years - 2020-2022, as illustrated below in the table.

FIRSTHEALTH MOORE REGIONAL HOSPITAL Historical and Projected Total Deliveries and C-Section Deliveries											
	Historical						Interim		Project Years 1-3		
Fiscal Year	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Deliveries	1,116	1,128	1,211	1,333	1,366	1,379	1,393	1,407	1,421	1,435	1,449
% Annual Change		1.1%	7.4%	10.1%	2.5%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
Dedicated C-Section ORs	0	0	0	0	0	0	0	0	1	1	1
C-Sections	433	456	495	597	619	598	604	611	617	623	629
C-Sections % of Deliveries	38.8%	40.4%	40.9%	44.8%	45.3%	43.4%	43.4%	43.4%	43.4%	43.4%	43.4%

Source: 2013-2018 LRAs; Need Methodology

C-Section Need Methodology – Over the last six years

- Deliveries have increased every year from 1,116 in FY 2012 to 1,379 in FY2017. The result is a 23.6% increase.
- C-Section cases have ranged between 433 and 619 from FY2012 to FY2016.
- C-Sections as a percentage of deliveries have ranged between 38.8% and 45.3% from FY2012 to FY2016.

Step 1

- From FY2018-FY2022, the applicant projects to have an annual increase of 1.0% in the number of deliveries at FMRH; based on the lowest annual delivery growth rate of 1.0% that was experienced in FY2017.

Step 2

- The percent of C-Section deliveries from FY2018-FY2022 is projected to be 43.4%; based on FY2017’s historical C-Section experience.

The applicant provides the following table in Section C.7, page 31 and states,

“The historical utilization at FMRH and the service area female population projections in Section C.4 support the volume projections.”

FMRH Historical and Projected Deliveries and C-Section Cases FY2011-FY2022				
Historical	FY2011	1,074	502	46.7%
	FY2012	1,116	433	38.8%
	FY2013	1,128	456	40.4%
	FY2014	1,211	495	40.9%
	FY2015	1,333	597	44.8%
	FY2016	1,366	619	45.3%
	FY2017	1,379	598	43.4%
Projected	FY2018	1,393	604	43.4%
	FY2019	1,407	611	43.4%
	FY2020	1,421	617	43.4%
	FY2021	1,435	623	43.4%
	FY2022	1,449	629	43.4%

The applicant refers the reader to Exhibit C.7, Tab 5 for utilization methodology supporting documentation.

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

- The applicant bases projected future utilization upon historical data for the service area population and the applicant’s experience in providing C-Section services; and
- The applicant adequately applies reasonable growth assumptions based on historical utilization.

Access

In Exhibit B.3, Tab 2, page 144, the applicant includes its *Non-Discrimination Policy* which states, *“FirstHealth of the Carolinas complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex...”*

In Section L.3, page 77, of the application, the applicant projects the following payor mix for C-Section OR surgical services during the second full fiscal year of operation following completion of the project, as shown below in the table.

FMRH C-Section OR Surgical Services Projected Payor Mix 10/1/2021 – 9/30/2022		
Payor Category	Entire Facility	Dedicated C-Section OR
Self-Pay	8.4%	0.5%
Medicare/Medicare Managed Care	62.9%	0.7%
Medicaid/Medicaid Managed Care	9.4%	48.2%
Commercial Insurance/Managed Care	15.4%	35.7%
Other (Champus/TRICARE)	3.9%	14.9%
Total	100.0%	100.0%

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information received

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.

C

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

- (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 develop a new dedicated C-Section OR for a total of 18 ORs upon completion of this project, Project ID# N-8843-12 (relocate one OR to Hoke County) and Project ID#H-11385-17 (develop one additional OR).

In Section E.1, page 46, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo – The applicant states that it could continue to perform both emergency and scheduled C-Section procedures in the main OR's shared OR but it will still be set up for C-Section procedures that could interfere with scheduling early morning OR procedures; plus, the shared OR located on the Women's and Children's Unit will not be utilized as efficiently because anesthesia services are better utilized when shared between two ORs. Therefore, maintaining the status quo by not seeking to develop a new dedicated C-Section OR is not the most effective alternative.

Perform C-Section Procedures in the Shared OR Located on the Women's and Children's Unit - The shared OR located on the Women's and Children's Unit will not be utilized as efficiently because anesthesia services are better utilized when shared between two ORs. Therefore, maintaining the status quo by not seeking to develop a new dedicated C-Section OR is not the most effective alternative.

On page 46, the applicant states that its proposal is the more cost efficient alternative because it would allow both emergency and scheduled C-Section procedures in the shared OR on Women's and Children's Unit and anesthesia services will be able to work more efficiently cost-wise and operationally by using the same resources to provide services in both ORs. This alternative is the best for both patients, physicians and staff.

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 criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. FirstHealth of the Carolinas, Inc. shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, FirstHealth of the Carolinas, Inc. shall materially comply with the last made representation.**
 - 2. FirstHealth of the Carolinas, Inc. shall develop one new dedicated C-Section operating room at FirstHealth Moore Regional Hospital.**
 - 3. Upon completion of the project and Project ID# N-8843-12 (relocate one OR to FirstHealth Moore Regional - Hoke Campus) and Project ID# H-11385-17 (develop one additional OR), FirstHealth Moore Regional Hospital shall be licensed for no more than one dedicated C-Section operating room, two dedicated inpatient surgical ORs, and 15 shared ORs for a total of 18 total operating rooms.**
 - 4. FirstHealth of the Carolinas, Inc. shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section F of the application, and that would otherwise require a certificate of need.**
 - 5. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, FirstHealth of the Carolinas, Inc. 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. FirstHealth of the Carolinas, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a dedicated C-Section OR at FMRH for a total of 18 ORs upon completion of this project, Project ID# N-8843-12 (relocate one OR to Hoke County) and Project ID# H-11385-17 (develop one additional OR).

Capital and Working Capital Costs

In Section Q, page 96, the applicant projects the total capital cost of the project as shown below in the table.

FMRH Dedicated C-Section Capital Costs	
1. Construction Costs	\$1,761,200
2. Construction Contingency Costs (10%)	\$176,120
3. Architectural/Engineering Fees	\$156,745
4. Medical Equipment	\$575,000
5. Non-Medical Equipment	\$75,000
6. Furniture	\$15,000
7. Consultant Fees	\$35,000
8. Other Contingency (5% of lines 1, 3, 4, 5, 6)	\$129,147
Total	\$2,923,212

In a request for supplemental information the agency received on September 26, 2018, applicant states,

“Please refer to Exhibit F.1, page 136 of the CON application for a copy of the certified architect construction estimate, construction contingency, and A/E fees. As no major medical equipment is being purchased for the C-Section OR project, FirstHealth did not seek vendor quotes for the miscellaneous medical equipment to be used in the C-Section OR, such as table, lights, stand, instruments, etc. The \$575,000 is based on recent equipment replacements in existing FirstHealth ORs.”

In Section F.3(a-c), page 50, the applicant proposes no start-up costs or initial operating expenses because FMRH already provides C-Section services.

Availability of Funds

In Section F.2(a), page 48, the applicant states that the capital cost of \$2.9 million will be funded via accumulated reserves. The applicant provides supporting documentation in Exhibit F.2, Tab 7, the applicant provides a letter from the Chief Financial Officer. The applicant also provides the consolidated financial statements from 2017 which state the availability of the funds to finance the proposed project.

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.4, page 100, the applicant projects

that revenues will exceed operating expenses in the first through third operating years of the project, as shown below in the table.

FMRH Revenues and Operating Expenses – C-Section Services			
	1st FY2020	2nd FY2021	3rd FY2022
Total C-Section Cases*	617	623	629
Total Gross Revenues (Charges)	\$11,780,011	\$12,251,402	\$12,740,475
Total Net Revenue	\$2,687,247	\$2,794,780	\$2,906,347
Average Net Revenue per Case	\$4,355	\$4,486	\$4,621
Total Operating Expenses (Costs)	\$995,008	\$1,021,235	\$1,048,293
Average Operating Expense per Case	\$1,613	\$1,639	\$1,667
Net Income	\$1,629,239	\$1,773,545	\$1,858,054

Source: Section Q, Form C, page 95.

The applicant also provides the projections for revenues and operating expenses for the entire hospital on Form F.3. In the projections for the entire hospital, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

FMRH Revenues and Operating Expenses – Entire Hospital			
	1st FY2020	2nd FY2021	3rd FY2022
Total Gross Revenues (Charges)	\$600,814,000	\$627,498,000	\$655,061,000
Total Net Revenue	\$566,181,000	\$591,327,000	\$617,301,000
Total Operating Expenses (Costs)	\$547,624,000	\$570,436,000	\$592,989,000
Net Income	\$53,190,000	\$57,063,000	\$62,072,000

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, pages 96-106 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
- Supplemental information requested by the Agency

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.

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

C

The applicant proposes to develop a new dedicated C-Section OR for a total of 18 ORs upon completion of this project, Project ID# N-8843-12 (relocate one OR to Hoke County) and Project ID#H-11385-17 (develop one additional OR).

On page 57, the 2018 SMFP defines the service area for operating rooms as *“the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1 [on page 62].”* Figure 6-1 shows Moore County as a single county OR service area. Thus, the service area for this facility consists of Moore County. Facilities may also serve residents of counties not included in their service area.

The operating room inventory of Moore County is shown in the table below.

Moore County Operating Room Inventory - 2018 SMFP					
Facility	Inpatient ORs	Ambulatory ORs	Shared ORs	CON Adjustments	Total
FMRH	2	0	15	-1*	17
The Eye Surgery Center of the Carolinas	0	3	0	0	3
Surgery Center of Pinehurst	0	6	0	0	6
Total*	2	9	15	0*	26

*Project ID# N-8843-12 (relocate one OR to Hoke) and Project ID# H-11385-17 (add one OR pursuant to need determination in the 2017 SMFP); therefore, the net adjustment is zero.

In Section G, pages 56-57, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved OR services in the Moore County service area. The applicant states:

“... The service area for the dedicated C-Section OR is Moore County and the only existing or approved facility providing C-Section services in the same service area is FMRH.

Therefore it is impossible for an unnecessary duplication of the service component (C-Section services) to occur in Moore County.”

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed dedicated C-Section OR is needed in addition to the existing or approved ORs and dedicated C-Section ORs in Moore County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 106, the applicant provides current and projected staffing for the proposed services. The applicant proposes to add 2.20 Full Time Equivalent staff (FTEs) as illustrated in the following table.

FMRH Dedicated C-Section OR - Proposed Staffing				
Position	Prior	Projected		
	FFY2019	1st FFY2020	2nd FFY2021	3rd FFY2022
Administrative Director	0.00	0.20	0.20	0.20
Registered Nurses	0.00	1.00	1.00	1.00
Technicians	0.00	1.00	1.00	1.00
TOTAL	0.00	2.20	2.20	2.20

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F, page 101, which is found in Section Q. In Section H, pages 59-60, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 61, the applicant identifies the current medical director. In Exhibit H.4, page 228, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section H, page 61, the applicant describes its physician recruitment plans, but states that there is no need currently to recruit physicians. In Exhibit H.4, Tab 11, 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

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

- (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 63 and Exhibit I.1, Tab 12, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Billing, Accounts Payable and General 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 and Infection Control
- Risk Management and Utilization Review
- Scheduling
- Staff Education

Also, on page 63, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1, Tab 12.

In Section I, page 64, the applicant describes its existing and proposed relationships with other local health care and social service providers and provided copies of transfer agreements in supplemental information requested by the Agency and received on September 26, 2018.

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

- Supplemental information requested by the Agency

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 67, the applicant states that the project involves renovating 4,403 square feet of existing space. Line drawings are provided in Exhibit K.2, Tab 13, pages 235-240.

In Section K.4, page 68 and in Section E.3, page 46, 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 C.1, Tab 3 and Exhibit F.1, Tab 6.

On page 68, 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 Section Q, Form F.4., and Table 12.

On page 69, 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(b), page 75, the applicant provides the historical payor mix during FY2017 for the proposed services, as shown below in the table.

FMRH Historical Payor Mix		
Payor Category	FMRH	C-Section Services as Percent of Total
Self-Pay*	8.4%	0.5%
Medicare**	62.9%	0.7%
Medicaid**	9.4%	48.2%
Insurance**	15.4%	35.7%
TRICARE	3.9%	14.9%
Total	100.0%	100.0%

*Self-pay includes indigent and charity patients. **Includes any managed care plans.

In Section L, pages 74, the applicant provides the following comparison.

	Percentage of Total Patients Served by FMRH during FY 2017	Percentage of the Population of the Service Area
Female	61.3%	52.2%
Male	38.7%	47.8%
Unknown	0.0%	0.0%
64 and Younger	66.8%	73.8%
65 and Older	33.2%	26.2%
American Indian	3.7%	1.0%
Asian	0.4%	1.5%
Black or African-American	28.5%	12.7%
Native Hawaiian or Pacific Islander	0.0%	0.0%
White or Caucasian	62.2%	82.7%
Other Race	4.6%	2.0%
Declined / Unavailable	0.6%	0.0%

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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.2(a-b), page 76, the applicant states that is not obligated to provide any such care.

In Section L(c), page 76, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3(a), page 77, 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 below in the table.

FMRH Projected Payor Mix FY 2022		
Payor Category	FMRH	C-Section Services as Percent of Total
Self-Pay*	8.4%	0.5%
Medicare**	62.9%	0.7%
Medicaid**	9.4%	48.2%
Insurance**	15.4%	35.7%
TRICARE	3.9%	14.9%
Total	100.0%	100.0%

*Self-pay includes indigent and charity patients. **Includes any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.5% of C-Section total services will be provided to self-pay

patients (which include charity care and indigent care patients), 0.7% to Medicare patients and 48.2% to Medicaid patients.

On pages 77-79, and the pro forma, pages 100-105, the applicant provides the assumptions and methodology used to project payor mix during the second fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based entirely on the historical payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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.5, page 79, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

The Agency reviewed 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 81, 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, Tab 15, pages 252-255.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to develop a new dedicated C-Section OR for a total of 18 ORs upon completion of this project, Project ID# N-8843-12 (relocate one OR to Hoke County) and Project ID#H-11385-17 (develop one additional OR).

The operating room inventory of Moore County is shown in the table below.

Moore County Operating Room Inventory - 2018 SMFP					
Facility	Inpatient ORs	Ambulatory ORs	Shared ORs	CON Adjustments	Total
FMRH	2	0	15	-1*	17
The Eye Surgery Center of the Carolinas	0	3	0	0	3
Surgery Center of Pinehurst	0	6	0	0	6
Total*	2	9	15	0*	26

*Project ID# N-8843-12 (relocate one OR to Hoke) and Project ID# H-11385-17 (add one OR pursuant to need determination in the 2017 SMFP); therefore, the net adjustment is zero.

In Section N, pages 82-85, 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 82, the applicant states:

“FirstHealth expects the C-Section OR project to have a positive impact on competition in the proposed service area.

... But in order to remain competitive and meet current and projected demand for its services, FirstHealth must take appropriate steps to expand its hospital. This CON application presents a reasonable and conservative approach to growth.”

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, N and Q of the application and any exhibits)
- Quality services will be provided (see Section N and O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 A, page 9, the applicant identifies the hospitals with ORs located in North Carolina owned and operated by the applicant. The applicant identifies a total of four (including FMRH) currently operating facilities of this type of located in North Carolina. In clarifying information received by the Agency on August 9, 2018, one of the applicant’s hospitals has not been in operation since November 2017.

In Section O, pages 90-91, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in none of these facilities. In Exhibit O.3, Tab 18, the FMRH CEO documents that all four hospitals have been in compliance with all Medicare Conditions of Participation. According to the files in the Acute and Home Care and Licensure Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no incidents related to quality of care occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care and

Licensure Section and considering the quality of care provided at all four facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

NA

The applicant proposes to develop a new dedicated C-Section OR. The Criteria and Standards for Surgical Services and Operating Rooms, which are promulgated in 10A NCAC 14C .2100, are not applicable to this review because the applicant does not propose to:

- Develop a new ambulatory surgical facility.
- Develop a new campus of an existing facility.
- Develop a new hospital.
- Convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program.
- Add a specialty to a specialty ambulatory surgical program.
- Increase the number of ORs which are not dedicated C-Section ORs in the facility or in the service area.
- Increase the number of dedicated C-Section ORs in a facility which already has at least one dedicated C-Section OR.