

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 29, 2017

Findings Date: November 29, 2017

Project Analyst: Tanya S. Rupp

Team Leader: Lisa Pittman

Project ID #: H-11385-17

Facility: FirstHealth Moore Regional Hospital

FID #: 943358

County: Moore

Applicant: FirstHealth of the Carolinas, Inc.

Project: Develop one additional shared OR pursuant to the need determination in the 2017 SMFP

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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.

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#### **Need Determination**

The 2017 State Medical Facilities Plan (2017 SMFP) includes a Need Determination for one additional operating room (OR) in the Moore County Operating Room Service Area. The applicant, FirstHealth of the Carolinas, Inc., proposes to develop one additional shared OR in existing space in the Women's and Children's Unit at FirstHealth Moore Regional Hospital (FHMRH) in Pinehurst. Following the addition of the OR, the hospital will have a total of 16 shared ORs and two dedicated open heart surgery ORs at the hospital. The application is consistent with the need determination for one OR in Moore County.

## **Policies**

Policy GEN-3: Basic Principles is the only policy in the 2017 SMFP applicable to this review.

Policy GEN-3, on page 33 of the 2017 SMFP, states:

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

The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section II.8, pages 21 - 23, Section V.7, pages 55 - 57 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section V.7, pages 58 - 59, Section VI, pages 61 - 69 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section V.7, page 60, Section VI.11, page 69 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant.

In summary, the application is consistent with the need determination in the 2017 SMFP and Policy GEN-3. Consequently, the application is conforming to this criterion.

- (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.

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The applicant proposes to utilize existing OR space in the Women’s and Children’s Unit of FirstHealth Moore Regional Hospital. In 2012, the applicant and FirstHealth of the Carolinas (the parent company) were awarded a certificate of need to develop an acute care hospital with one OR in Hoke County. As part of that project, FHMRH relocated one existing shared OR that had been utilized to perform C-sections and other gynecological procedures, and left the vacated OR space vacant. According to the applicant on page 32, the hospital wants to utilize the vacated OR space to increase services in the Women’s and Children’s Unit and perform gynecological and C-section procedures again in the existing OR space.

In Exhibit 3, the applicant provides letters from the Administrative Director of Women’s and Children’s services and the Director of Women’s Services at FHMRH, each of which expresses support for the proposal.

**Patient Origin**

In Section III.6, page 41, the applicant provides the projected patient origin for the first two operating years of the project (Fiscal Years 2019 and 2020), as shown in the following table:

**FHMRH Surgical Services Patient Origin  
Fiscal Years 2019 and 2020**

COUNTY	FY 2019	FY 2020
Moore	38.8%	38.8%
Richmond	12.9%	12.9%
Montgomery	7.7%	7.7%
Hoke	6.5%	6.5%
Lee	6.2%	6.2%
Other	28.0%	28.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Table may not sum due to rounding

On page 41, the applicant states the patient origin is expected to remain consistent with current surgical services patient origin. The applicant adequately identifies the population proposed to be served.

**Analysis of Need**

In Section III.1, pages 31 - 36, the applicant states the need for the OR at FHMRH is based on the hospital’s need to ensure that emergency C-sections can be performed with minimal delay, and the hospital’s response to surgeons who have requested additional early morning

surgery start times. The applicant identified several factors which support the demand for an additional OR and the commitment of FHMRH to meet that demand, which include:

- Physician/surgeon issues with OR time (page 32).
- Moore County current demographics and service area population growth trends (pages 33 - 34).
- Historical factors unique to FHMRH which influence demand for the OR (page 35).

Each of the factors is briefly described below:

*Physician/Surgeon Issues with OR Time*

On page 32, the applicant states that it submitted an application in 2010 (Project ID# N-8497-10) to develop a community hospital in Hoke County and, as a part of that application, FHMRH relocated one shared OR, previously utilized for C-sections<sup>1</sup>, to the new hospital. The space vacated by the OR was left unutilized, and new management at the Women's and Children's Unit believes the patients would be better served by again having a shared OR available in the Women's and Children's Unit, and that it is important to the provision of quality patient care. The space exists and would require little renovation for utilization.

In addition, the applicant states surgeons have been requesting early block time in the main OR at the Women's and Children's Unit; however, that is not possible in the main OR if the hospital must leave one OR available in the event a C-section becomes necessary. An additional OR would allow FHMRH to accommodate surgeon demand and have one shared OR always available for C-sections.

*Service Area Population Growth Trends/Moore County Demographics*

On pages 33 - 34, the applicant states the population of Moore County increased by 6.3% from 2013 to 2017. Utilizing data provided by the North Carolina State Office of Budget and Management, the applicant states that population is projected to increase by an additional 5% from 2017 to 2021. The applicant provides specific cohort population growth projections on page 33.

In addition, on page 34, the applicant states the population of the other four counties that comprise the entire service area as defined by the applicant on page 39 increased by 2.4% from 2013 to 2017. Utilizing data provided by the North Carolina State Office of Budget and Management, the applicant states that same population is projected to increase by an additional 3.9% from 2017 to 2021.

Therefore, the population in the entire five-county service area is projected to increase during project development. Therefore, the applicant states surgical demand will also increase.

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<sup>1</sup> On page 32, the applicant states the OR was utilized for C-sections when needed; however, the OR was not a dedicated C-section OR.

*Historical Factors Influencing Demand for Surgical Services*

On page 35, the applicant provides the following table to illustrate historical demand for both OP and IP surgical services at FHMRH:

	FISCAL YEAR	IP CASES	OP CASES	TOTAL
<b>HISTORICAL</b>	2012	5,204	4,414	9,618
	2013	5,398	4,773	10,171
	2014	5,457	4,807	10,264
	2015	5,958	4,892	10,850
	2016	6,151	4,852	11,003
<b>ANNUALIZED</b>	2017	5,918	5,303	11,221

The data in the table shows that total surgical volume at FHMRH increased by 14.4% [(11,003 total cases in FY 2016 / 9,618 total cases in FY 2012) – 1 = 0.144]. When the annualized data from FY 2017 is considered, the growth rate rises to 16.6% [(11,221 / 9,618) - 1 = 0.166]. Surgical services at FHMRH have increased since 2013.

*Projected Utilization*

In Section IV.1, pages 46 – 47, the applicant provides data it used to project utilization of the ORs at the hospital. The applicant calculated future surgical utilization based on an analysis of historical utilization data and annualized 2017 surgical utilization data. The applicant projects the following utilization, as reported in a table on page 47:

FISCAL YEAR	INPATIENT CASES		OUTPATIENT CASES		TOTAL
	# CASES***	# CHANGE	# CASES	# CHANGE	
2012	5,204		4,414		9,618
2013	5,398	194	4,773	359	10,171
2014	5,457	59	4,807	34	10,264
2015	5,959	501	4,892	85	10,850
2016*	6,151	193	4,852	(40)	11,003
2017**	5,919	(233)	5,303	451	11,222
2018	6,315	396	5,317	14	11,632
2019	6,496	181	5,453	136	11,949
2020	6,677	181	5,589	136	12,266
2021	6,858	181	5,725	136	12,583

\*The applicant states this represents actual surgical cases

\*\*The applicant states this is annualized data

\*\*\*Excluding open-heart cases

The applicant states that overall surgical volume at FHMRH has continued to increase since 2012.

As shown above, the actual historical increase in surgical volume at FHMRH from 2012 to 2016 was 14.4% [(11,003 / 9,618) – 1 = 0.144; or 3.6% per year]. The projected growth is

consistent with historical utilization [(12,583 total cases in FY 2021 / 11,003 total cases in FY 2016) – 1 = 0.1436, or 2.9% per year].

Below is a table created by the analyst from data on page 47 that shows projected OR volume and the number of ORs needed at FHMRH:

<b>FHMRH PROJECTED SURGERY VOLUME AND OPERATING ROOM NEED</b>			
	<b>PY 1 FY 2019</b>	<b>PY 2 FY 2020</b>	<b>PY 3 FY 2021</b>
Projected Inpatient Surgery Cases	6,495	6,677	6,858
Projected Outpatient Surgery Cases	5,453	5,589	5,725
Total Surgical Hours Required*	27,664	28,411	29,162
Operating Rooms Needed (1,872 hours per OR)	14.8	15.2	15.5

\*Surgical hours required based on 1.5 hours per outpatient surgical case and 3.0 hours per inpatient surgical case.  
 Tables may not sum due to rounding

As shown in the table above, in OY 3 (FY 2021), the applicant projects that 29,162 total surgical cases will be performed in the 16 ORs at FHMRH, which substantiates a need for 16 ORs consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b), as illustrated in the table below:

<b>OY</b>	<b>IP CASES</b>	<b>TOTAL HOURS (IP x 3 HRS. / CASE)</b>	<b>OP CASES</b>	<b>TOTAL HOURS (OP x 1.5 HRS. / CASE)</b>	<b>TOTAL IP AND OP CASES / 1,872 HRS. / OR / YEAR</b>	<b>NUMBER OF ORS NEEDED</b>
FY 2021	6,858	20,574	5,725	8,588	29,162	15.5

Projected utilization of the shared surgical operating rooms at FHMRH is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to develop one additional shared surgical operating room at the FHMRH Women’s and Children’s Unit.

**Access**

In Section VI.2, pages 61 - 62, the applicant states it will provide services to all persons regardless of race, sex, age, disability or national origin,. Exhibit 14 contains copies of FirstHealth’s non-discrimination policy. In Section VI.14, page 71, the applicant projects that 71.3% of the IP surgical cases, 48.2% of the OP surgical cases and 2.6% of the self pay/charity cases to be performed at FHMRH will be provided to Medicare, Medicaid or self pay/charity recipients. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

**Conclusion**

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the project, and demonstrates the extent to which all residents,

including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

NA

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

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

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In Section III.8, pages 43 - 44, the applicant describes the following alternatives:

- Maintain the Status Quo – The applicant states this was not an effective alternative because the space for the OR already exists following the relocation of one OR to the FirstHealth Moore-Hoke hospital, surgeons at FHMRH are requesting OR block time that cannot be accommodated by the existing ORs, and the current management believes a shared OR in the Women’s and Children’s Unit will increase quality of care for patients.
- Pursue a Joint Venture – The applicant states this was not an effective alternative because it would not address the internal needs of the FHMRH surgical services, including locating the OR inside FHMRH.
- Add one OR pursuant to the need determination in the 2017 SMFP to the Women’s and Children’s Unit.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all applicable statutory review criteria, and thus, the application is approvable. An application that cannot be approved is not an effective alternative.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **FirstHealth of the Carolinas, Inc. d/b/a FirstHealth Moore Regional Hospital shall materially comply with all representations made in the certificate of need application.**
  2. **FirstHealth of the Carolinas, Inc. d/b/a FirstHealth Moore Regional Hospital shall develop one additional shared operating room for a total of no more than 16 shared operating rooms and two dedicated open-heart surgery operating rooms.**
  3. **FirstHealth of the Carolinas, Inc. d/b/a FirstHealth Moore Regional Hospital shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section VIII of the application and that would otherwise require a certificate of need.**
  4. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, FirstHealth of the Carolinas, Inc. d/b/a FirstHealth Moore Regional Hospital shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
    - a. **Payor mix for the services authorized in this certificate of need.**
    - b. **Utilization of the services authorized in this certificate of need.**
    - c. **Revenues and operating costs for the services authorized in this certificate of need.**
    - d. **Average gross revenue per unit of service.**
    - e. **Average net revenue per unit of service.**
    - f. **Average operating cost per unit of service.**
  5. **FirstHealth of the Carolinas, Inc. d/b/a FirstHealth Moore Regional Hospital 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.

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In Section VIII.1, page 86, the applicant projects the total capital cost as follows:

**FHMRH Capital Cost**

DESCRIPTION	COST
Site Costs	N/A
Construction/Renovation Costs	\$40,000
Consultant Fees	\$37,500
<b>TOTAL</b>	<b>\$77,500</b>

In Section IX.1, page 90, the applicant states there are no start-up expenses or initial operating expenses associated with the project, since it involves developing an OR in existing OR space and the hospital is currently operational.

**Availability of Funds**

In Section VIII.3, page 87, the applicant states the entire capital cost will be funded with the accumulated reserves of FirstHealth of the Carolinas, Inc. In Exhibit 20, the applicant provides August 2, 2017 letter from the Chief Financial Officer of FirstHealth of the Carolinas, Inc. which documents its intent to fund the capital cost of the proposed project.

In Exhibit 21 the applicant provides copies of consolidated financial statements for years ending September 30, 2015 and 2016 for FirstHealth of the Carolinas, Inc. and Affiliates, which documents \$23,196,000 in cash and cash equivalents, \$1,089,492,000 in total assets and \$786,121,000 in net assets (total assets less total liabilities) as of December 31, 2016. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the 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 the pro forma financial statement (Form C) for surgical services, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

**Inpatient Surgical Procedures**

	1 <sup>ST</sup> FULL FISCAL YEAR	2 <sup>ND</sup> FULL FISCAL YEAR	3 <sup>RD</sup> FULL FISCAL YEAR
Total Surgical Procedures	6,495	6,676	6,857
Total Gross Revenues (Charges)	\$400,953,184	\$420,369,318	\$440,401,717
Total Net Revenue	\$118,240,292	\$123,966,071	\$129,873,586
Average Net Revenue per Procedure	\$18,204	\$18,568	\$18,940

**Outpatient Surgical Procedures**

	1 <sup>ST</sup> FULL FISCAL YEAR	2 <sup>ND</sup> FULL FISCAL YEAR	3 <sup>RD</sup> FULL FISCAL YEAR
Total Surgical Procedures	5,453	5,589	5,725
Total Gross Revenues (Charges)	\$86,153,390	\$90,068,132	\$94,105,002
Total Net Revenue	\$27,114,281	\$28,346,333	\$29,616,820
Average Net Revenue per Procedure	\$4,972	\$5,072	\$5,173

**Inpatient and Outpatient Surgical Procedures**

	1 <sup>ST</sup> FULL FISCAL YEAR	2 <sup>ND</sup> FULL FISCAL YEAR	3 <sup>RD</sup> FULL FISCAL YEAR
Total Surgical Procedures	11,840	12,265	12,582
Total Gross Revenues (Charges)	\$487,106,574	\$510,437,451	\$534,506,720
Total Net Revenue	\$137,073,761	\$143,634,967	\$150,403,792
Average Net Revenue per Procedure	\$11,577	\$11,711	\$11,954
Total Operating Expenses (Costs)	\$68,104,332	\$71,883,045	\$75,847,450
Average Operating Expense per Procedure	\$5,752	\$5,861	\$6,028
Net Income (total surgical services)	\$68,969,429	\$71,751,922	\$74,556,342

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section 13 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. 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.

**Conclusion**

In summary, the applicant adequately demonstrates the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

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On page 57, the 2017 SMFP states, “An operating room’s service area is 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.” Figure 6.1 on page 60 of the 2017 SMFP shows Moore County as a single-county OR service area. Thus, the service area is Moore County. Providers may serve residents of counties not included in their service area.

The following table identifies the existing and approved Ambulatory (AMB), inpatient (IP) and shared operating rooms located in the service area of Moore County, and the ambulatory and inpatient case volumes for each provider, as listed in Table 6A on page 67 of the 2017 SMFP.

**Moore County Operating Room Inventory, 2017 SMFP**

	<b>IP ORs</b>	<b>AMB ORs</b>	<b>SHARED ORs</b>	<b>EXCLUDED C-SECTION ORs</b>	<b>AMB SURGERY CASES</b>	<b>IP SURGERY CASES</b>
The Eye Surgery Center of the Carolinas	0	3	0	0	7,682	0
Surgery Center of Pinehurst	0	6	0	0	5,361	0
FirstHealth Moore Regional Hospital	2*	0	15	0	4,892	6,353
<b>Total Union County ORs</b>	<b>2</b>	<b>9</b>	<b>15</b>	<b>0</b>	<b>17,935</b>	<b>6,353</b>

\*Dedicated open-heart

As the table above indicates, there are a total of 15 shared operating rooms, two inpatient ORs, and nine ambulatory ORs in Moore County.

The applicant proposes to develop one additional shared OR in existing space in the Women’s and Children’s Unit at FirstHealth Moore Regional Hospital (FHMRH) in Pinehurst. Following the addition of the OR, the hospital will have a total of 16 shared ORs and two dedicated open-heart surgery ORs at the hospital.

Table 6C: Operating Room Need Determination on page 82 of the 2017 SMFP identifies a need for 1 operating room in Moore County, based on the need methodology as outlined in Step 5 on page 59 of the 2017 SMFP. The applicant proposes to add one shared OR in its Women’s and Children’s Unit of the hospital in Moore County, in space created when one shared OR was relocated to the FHMRH-Hoke Campus. The applicant is the only provider of inpatient and shared OR services in the county; of the other two facilities, one is a specialty ambulatory surgical facility and one is a multi-specialty ambulatory surgical facility.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved operating rooms in Moore County. Therefore, the application is conforming to this criterion.

- (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.

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In Section VII.2, page 74, the applicant projects to add two full time equivalent (FTE) registered nurses and two surgical technician positions to the existing staff for the ORs at the hospital, for a total of 112.5 FTEs. Since the hospital is operational, there is no need to add additional FTEs.

In Section VII.3, page 75, and Section VII.7, pages 77 - 80, the applicant describes FirstHealth's experience and process for recruiting and retaining staff. Exhibit 4 contains an August 2, 2017 letter signed by the director of Women's and Children's services and by the Director of Women's Services Line at FHMRH explaining the need for the OR and expressing support for the project. In Section VII.8, page 83, the applicant states the medical director is and will continue to be John F. Krahnert, Jr., M.D. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (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.

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In Sections II.1 and II.2, pages 12 – 18, and in Exhibit 5, the applicant identifies the necessary ancillary and support services, and describes how they will be provided. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, 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.

- (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. The applicant provides the projected payor mix in Section VI.14, page 71; and the applicant does not project a payor mix that includes HMOs. Therefore, this Criterion 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.

NA

The applicant does not propose to construct any new space, renovate existing space, or make more than minor renovations to existing space. The applicant is proposing to develop the OR in space that was previously designated as an OR prior to relocating the OR to the new FirstHealth Hoke Community Hospital in 2013. In this proposal, the applicant proposes to develop one OR pursuant to the need determination in the 2017 SMFP in the space vacated by the relocated OR.

- (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;

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In Section VI.13, page 70, the applicant reports the following payer mix for FHMRH's surgical services for FY 2016:

PAYOR CATEGORY	IP SURGICAL CASES AS PERCENT OF TOTAL	OP SURGICAL CASES AS PERCENT OF TOTAL
Self Pay/Charity	2.6%	3.1%
Medicare/Medicare Managed Care	62.7%	38.7%
Medicaid	8.6%	9.5%
Managed Care/Commercial Insurance	21.2%	42.1%
Other	4.9%	6.6%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Table may not sum due to rounding

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the service area, Moore County, and statewide.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Moore	24%	52%	23%	13%	9%	13%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

\*Excludes "White alone" who are "not Hispanic or Latino"

\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicant adequately demonstrates that it currently provides access to medically underserved populations. 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;

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Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 69, the applicants state,

*“In June 1995, FHMRH fulfilled its Hill-Burton quota to provide uncompensated care, community service, and access to minorities and handicapped persons under Hill-Burton. ... Nonetheless, based on its mission, FHMRH continues to provide uncompensated care ....”*

In Section VI.10, page 69, the applicants states that no civil rights access complaints have been filed against FirstHealth of the Carolinas, Inc. or FHMRH in last five years. 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 VI.14, page 71, the applicant projects the following payer mix for surgical services during the second operating year (FY 2020):

PAYER CATEGORY	IP SURGICAL CASES AS PERCENT OF TOTAL	OP SURGICAL CASES AS PERCENT OF TOTAL
Self Pay/Charity	2.6%	3.1%
Medicare/Medicare Managed Care	62.7%	38.7%
Medicaid	8.6%	9.5%
Managed Care/Commercial Insurance	21.2%	42.1%
Other	4.9%	6.6%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>

Table may not sum due to rounding

On page 71, the applicant states the projections are based on the historical experience of FHMRH. The applicant adequately demonstrates that the medically underserved population will have access to surgical services. Therefore, 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 VI.9, page 68, the applicant describes the range of means by which a person will have access to its surgical services. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to surgical services. Therefore, 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 V.1, page 48, the applicants state that FHMRH is committed to collaborative relationships with local and regional health professional training programs. Exhibit 10 contains a four page list of professional training programs with which the hospital has agreements. The information provided is reasonable and adequately supports a determination that 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 one additional shared OR in existing space in the Women's and Children's Unit at FirstHealth Moore Regional Hospital (FHMRH) in Pinehurst. Following the addition of the OR, the hospital will have a total of 16 shared ORs and two dedicated open-heart surgery ORs at the hospital.

On page 57, the 2017 SMFP states, *"An operating room's service area is 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."* Figure 6.1 on page 60 of the 2017 SMFP shows Moore County as a single-county operating room service area. Thus, the service area is Moore County. Providers may serve residents of counties not included in their service area.

Table 6C: Operating Room Need Determination on page 82 of the 2017 SMFP identifies a need for 1 operating room in Moore County, based on the need methodology as outlined in Step 5 on page 59 of the 2017 SMFP. The applicant proposes to add one shared OR in its Women's and Children's Unit of the hospital in Moore County, in space created when one shared OR was relocated to the FHMRH-Hoke Campus. The applicant is the only provider of inpatient and shared OR services in the county; of the other two facilities, one is a specialty ambulatory surgical facility and one is a multi-specialty ambulatory surgical facility.

The applicant does not propose to develop more operating rooms than are determined to be needed in the service area.

The following table identifies the existing and approved Ambulatory (AMB), inpatient (IP) and shared operating rooms located in the service area of Moore County, and the ambulatory and inpatient case volumes for each provider, as listed in Table 6A on page 67 of the 2017 SMFP.

**Moore County Operating Room Inventory, 2017 SMFP**

	<b>IP ORs</b>	<b>AMB ORs</b>	<b>SHARED ORs</b>	<b>EXCLUDED C-SECTION ORs</b>	<b>AMB SURGERY CASES</b>	<b>IP SURGERY CASES</b>
The Eye Surgery Center of the Carolinas	0	3	0	0	7,682	0
Surgery Center of Pinehurst	0	6	0	0	5,361	0
FirstHealth Moore Regional Hospital	2*	0	15	0	4,892	6,353
<b>Total Union County ORs</b>	<b>2</b>	<b>9</b>	<b>15</b>	<b>0</b>	<b>17,935</b>	<b>6,353</b>

\*Dedicated open-heart

As the table above indicates, there are a total of 15 shared operating rooms, two inpatient ORs, and nine ambulatory ORs in Moore County.

The applicant proposes to develop one additional shared OR in existing space in the Women’s and Children’s Unit at FirstHealth Moore Regional Hospital (FHMRH) in Pinehurst. Following the addition of the OR, the hospital will have a total of 16 shared ORs and two dedicated open-heart surgery ORs at the hospital.

In Section VI, pages 61 - 72, the applicant discusses how the project will promote the cost-effectiveness, quality and access to the proposed services. See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access to the proposed services

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need, including projected utilization, and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (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

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no FirstHealth of the Carolinas facilities are currently out of compliance with a CMS Condition of Participation, nor have any other incidents occurred within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on any other facility owned and operated by FirstHealth of the Carolinas in North Carolina. After reviewing and considering information provided by the applicants and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at FirstHealth of the Carolinas 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.

C

The Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C.2100, are applicable to this review. The specific criteria are discussed below.

**SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS**

**.2103 PERFORMANCE STANDARDS**

- .2103 (a) In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks a year.*

-C- In Section II.10, page 27, the applicant states the facility will be available for scheduled surgical services five days per week, 52 weeks per year. Furthermore, the applicant states the emergency department will be available seven days per week, 52 weeks per year for emergency surgical services.

.2103 (b) *A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:*

*(1) demonstrate the need for the number of proposed operating rooms in the facility which is proposed to be developed or expanded in the third operating year of the project based on the following formula: {[ (Number of facility's projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of facility's projected outpatient cases times 1.5 hours) ] divided by 1872 hours} minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms or demonstrate conformance of the proposed project to Policy AC-3 in the State Medical Facilities Plan titled "Exemption From Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects;" and*

*(2) The number of rooms needed is determined as follows:*

*(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;*

*(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and*

*(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is*

*the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.*

- C- The Moore County operating room service area has 15 shared operating rooms, two inpatient operating rooms and nine ambulatory operating rooms. In Section IV.1, page 46, the applicant provides projections of surgical case volumes, surgical hours, and operating room need, which is summarized below:

<b>FHMRH PROJECTED SURGERY VOLUME AND OPERATING ROOM NEED</b>			
	<b>PY 1 FY 2019</b>	<b>PY 2 FY 2020</b>	<b>PY 3 FY 2021</b>
Projected Inpatient Surgery Cases	6,495	6,677	6,858
Projected Outpatient Surgery Cases	5,453	5,589	5,725
Total Surgical Hours Required*	27,664	28,411	29,162
Operating Rooms Needed (1,872 hours per OR)	14.8	15.2	15.5

\*Surgical hours required based on 1.5 hours per outpatient surgical case and 3.0 hours per inpatient surgical case.

Tables may not sum due to rounding

On pages 46 - 47 of the application, the applicant projects the 16 ORs at FHMRH will perform 29,162 total surgical cases in the third year of operation which demonstrates a need for 16 ORs at the hospital [5,725 OP cases x 1.5 hours per case = 8,588 hours; 6,858 IP hours x 3 = 20,574. (8,588 + 20,574) / 1,872 = 15.57 or 16 operating rooms needed].

On page 47 and in Exhibit 9, the applicant provides assumptions and methodology by which it projects utilization in the ORs at the hospital. Projected utilization, which is based on reasonable and adequately supported assumptions, supports the need for 16 operating rooms. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- .2103 (c) *A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall:*

*(1) demonstrate the need for the number of proposed operating rooms in addition to the rooms in all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2) in the third operating year of the proposed project based on the following formula: {[ (Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of projected outpatient cases for all the applicant's or related entities' facilities times 1.5 hours) ] divided by 1872 hours} minus the total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care*

*units, and all dedicated open heart and C-Section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and*

(2) *The number of rooms needed is determined as follows:*

(A) *in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;*

(B) *in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and*

(C) *in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.*

The need determination identified in the 2017 SMFP will increase the number of ORs in the Moore County service area by one OR. The Union County operating room service currently area has greater than 10 operating rooms; therefore, .2103(c)(2)(A) above is applicable to this review.

-C- The Moore County operating room service area has 15 shared operating rooms, two inpatient operating rooms and nine ambulatory operating rooms. In Section IV.1, page 46, the applicant provides projections of surgical case volumes, surgical hours, and operating room need, which is summarized below:

<b>FHMRH PROJECTED SURGERY VOLUME AND OPERATING ROOM NEED</b>			
	<b>PY 1 FY 2019</b>	<b>PY 2 FY 2020</b>	<b>PY 3 FY 2021</b>
Projected Inpatient Surgery Cases	6,495	6,677	6,858
Projected Outpatient Surgery Cases	5,453	5,589	5,725
Total Surgical Hours Required*	27,664	28,411	29,162
Operating Rooms Needed (1,872 hours per OR)	14.8	15.2	15.5

\*Surgical hours required based on 1.5 hours per outpatient surgical case and 3.0 hours per inpatient surgical case.  
 Tables may not sum due to rounding

On pages 47 and in Exhibit 9, the applicant provided assumptions and methodology by which it projects utilization in the ORs at the hospital. Projected utilization, which is based on reasonable and adequately supported assumptions, supports the need for

three operating rooms. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

*.2103(d) An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved and proposed dedicated C-section rooms during the third year of operation following completion of the project.*

-NA- The applicant does not have an existing or approved dedicated C-section OR and is not proposing to develop a dedicated C-section OR.

*.2103(e) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:*

- (1) provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,872 hours per operating room per year, excluding dedicated open heart and C-Section operating rooms. The hours utilized per operating room shall be calculated as follows: [(Number of projected inpatient cases, excluding open heart and C-sections performed in dedicated rooms, times 3.0 hours) plus (Number of projected outpatient cases times 1.5 hours)] divided by the number of operating rooms, excluding dedicated open heart and C-Section operating rooms; and*
- (2) demonstrate the need in the third operating year of the project based on the following formula: [(Total number of projected outpatient cases for all ambulatory surgery programs in the service area times 1.5 hours) divided by 1872 hours] minus the total number of existing, approved and proposed outpatient or ambulatory surgical operating rooms and shared operating rooms in the service area. The need is demonstrated if the difference is a positive number greater than or equal to one, after the number is rounded to the next highest number for fractions of 0.50 or greater.*

-NA- The applicant is not proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

*.2103(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*

- C- In Section III.1, pages 31 - 35 and Exhibit 9, the applicant documents the assumptions and provides data supporting the methodology used for each projection in this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.