## **ATTACHMENT - REQUIRED STATE AGENCY FINDINGS**

#### **FINDINGS**

C = Conforming CA = Conditional NC = Nonconforming NA = Not Applicable

Decision Date:	October 22, 2019
Findings Date:	October 22, 2019
Project Analyst:	Tanya M. Saporito
Team Leader:	Gloria C. Hale
Project ID #:	O-11714-19
Facility:	New Hanover Regional Medical Center
FID #:	943372
County:	New Hanover
Applicant:	New Hanover Regional Medical Center
Project:	Add no more than 4 shared ORs pursuant to the 2019 SMFP need determination to the main campus of NHRMC for a total of 39 ORs
	the main campus of Mirking for a total of 59 OKs

## **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.

С

The applicant, New Hanover Regional Medical Center (NHRMC), proposes to add four operating rooms (ORs) to the main hospital for a total of 39 ORs upon project completion.

### Need Determination

Chapter 6 of the 2019 SMFP includes a methodology for determining the need for additional ORs in North Carolina by service area. Application of the need methodology in the 2019 SMFP identifies a need for six additional ORs in the New Hanover County OR service area. Therefore, the application is consistent with the need determination for six ORs in New Hanover County.

## **Policies**

There are two policies in the 2019 SMFP that are applicable to this review. Policy GEN-3: *Basic Principles*, and Policy GEN-4, *Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-3: Basic Principles, on page 31 of the 2019 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."

<u>Promote Safety and Quality</u> - The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 10 - 12; Section N, pages 72 - 73; Section O, pages 74 - 75 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.

<u>Promote Equitable Access</u> - The applicant describes how it believes the proposed project would promote equitable access in Section B, page 12; Section C, page 39; Section L, pages 68 - 70; Section N, page 73 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.

<u>Maximize Healthcare Value</u> - The applicant describes how it believes the proposed project would maximize health care value in Section B, pages 12 - 13, Section C, pages 38 - 39; Section K, pages 63 - 65, Section N, page 72; the applicant's pro forma financial statements in Section Q and supplemental information 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.

In Section B, pages 10 - 13, the applicant explains why it believes its application is consistent with Policy GEN-3. On page 13, the applicant states:

"[this project] will enhance patient safety, quality and access by addressing NHRMC's capacity constraints and maximize value by ensuring patients are served efficiently in the most cost-effective setting possible."

The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will maximize health care value and that the applicant's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2019 SMFP. Therefore, the application is consistent with policy GEN-3.

*Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 31 of the 2019 SMFP, states:

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

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

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

In Section B, page 14, the applicant explains why it believes its application is conforming to Policy GEN-4. The applicant states the project will be designed in compliance with applicable federal, state and local requirements for energy efficiency and consumption. Additionally, the applicant states the design will meet or exceed energy efficiency and water conservation standards in the North Carolina State Building Codes.

## **Conclusion**

The Agency reviewed the:

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

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

- The applicant does not propose to develop more ORs than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3.
- (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.

С

New Hanover Regional Medical Center is a non-profit hospital owned by New Hanover County. The applicant provides surgical services under its license at three locations: the main campus, the orthopedic hospital and Atlantic SurgiCenter. Pursuant to Project ID #O-11189-16, the applicant was approved to relocate all inpatient orthopedic services from the orthopedic hospital to the main campus of NHRMC. Pursuant to Project ID #O-11559-18, the applicant was approved as a co-applicant to develop a freestanding ambulatory surgical facility (ASF), Iron Gate Surgery Center, with three ORs that would also be relocated from the orthopedic hospital. In this application, the applicant proposes to add four additional ORs to the main hospital pursuant to the 2019 State Medical Facilities Plan (SMFP) need determination, for a total of 39 ORs upon project completion.

# Patient Origin

On page 55, the 2019 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." In Figure 6.1, page 60 of the 2019 SMFP, New Hanover County is shown as a single-county OR service area. Thus, the service area for this review consists of New Hanover County. Facilities may also serve residents of counties not included in the service area.

The following table illustrates current and projected patient origin, from Section C, pages 20 and 21:

COUNTY	Curi (10/1/17 –		THIRD FULL FY OF OPERATION FOLLOWING PROJECT COMPLETION (10/1/23 – 09/30/24)			
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL		
New Hanover	13,298	42.5%	10,141	42.5%		
Brunswick	6,113	19.5%	4,662	19.5%		
Pender	3,601	11.5%	2,746	11.5%		
Onslow	2,889	9.2%	2,203	9.2%		
Columbus	1,655	5.3%	1,262	5.3%		
Duplin	1,205	3.9%	919	3.9%		
Bladen	577	1.8%	440	1.8%		
All Other*	1,945	6.2%	1,483	6.2%		
Total	31,283	100.0%	23,855	100.0%		

\*On pages 20 and 21, the applicant lists the other North Carolina counties and states from which patients have historically been served and are projected to be served.

In Section C, page 21 the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

## Analysis of Need

In Section C, pages 22 - 35, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant summarizes its need for the additional ORs at the hospital as summarized below.

- Population growth in New Hanover County and other counties served the applicant states that the population growth in New Hanover County increased by 7.9% from 2014 2019. Based on that growth and information from Claritas, the applicant projects population to increase by 7.8% from 2019 2024. The applicant states the population growth of persons age 65 and older increased at an even higher rate than the younger population cohorts. The applicant states the entire population, including all age groups, is projected to increase by 6.8% between 2014 2024. NHRMC is the only tertiary hospital in the service area (pages 22 26).
- OR utilization at NHRMC the applicant states that the number of OR cases at NHRMC has increased overall by 11.6%, and 3.7% annually since FY 2015. NHRMC affiliated facilities have experienced similar growth in surgical services, despite a downturn in utilization following Hurricane Florence, which damaged significant parts of the hospital and service area (pages 26 27).
- Capacity constraints at NHRMC the applicant states the ORs at the hospital are operating above capacity, and between FY 2017 FY 2018, the ORs operated at over 120% of capacity. This kind of volume puts an incredible strain on surgeons, physicians, staff and patients. In Project ID #O-11189-16, the applicant was approved to relocate all inpatient orthopedic services and five ORs to the main campus of NHRMC. This project is still under development (Hurricane Florence delayed

development of many projects in the New Hanover County area), but is expected to further increase patient volume to an already congested campus (pages 27 - 30).

• Scheduling issues – the applicant states that the existing surgical capacity constraints cause scheduling delays for routine procedures and forces some procedures to be performed into the evening hours. The applicant states that between two and three cases per day are routinely delayed to the next day or later. Each of these scheduling issues creates additional strain on surgeons, staff and patients. On page 29, the applicant states:

"Holding a patient in an inpatient bed until the next day further exacerbates NHRMC's inpatient bed capacity challenges, negatively affects patient experience, and results in a higher cost of care. Patients express extreme frustration when they have [prepared for surgery all day] only to find out their procedure is delayed...."

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

- The applicant adequately demonstrates the need for additional ORs at NHRMC based on the 2019 SMFP OR need methodology.
- The applicant adequately documents that surgical volume at NHRMC increased by 3.7% per year since FY 2015, and increased overall by 11.6% during that same time.
- The applicant adequately demonstrates that the relocation of orthopedic services and five ORs from the NHRMC Orthopedic Hospital will create additional volume at an already crowded facility, thus necessitating the need for additional OR capacity.
- The applicant adequately demonstrates that the existing ORs operated at over 120% of capacity between FY 2017 and FY 2018, and that this volume negatively impacted surgeons, physicians, staff and patients.

# Projected Utilization

In supplemental information, Form C, the applicant provides historical and projected utilization for the ORs at the main campus and Iron Gate Surgery Center, as illustrated in the following tables (the three procedure rooms at NHRMC main campus will not be affected by this project):

	NHF	RMC Historica	l and Projecte	ed OR Utilizati	on		
	PRIOR FULL	INTERIM	INTERIM	INTERIM	1 <sup>st</sup> FULL FY	2 <sup>ND</sup> FULL FY	3 <sup>RD</sup> FULL FY
	FY	FULL FY	FULL FY	FULL FY	(10/2021 –	(10/2022 –	(10/2022 –
	(10/2017 –	(10/2018 –	(10/2019 –	(10/2020 –	09/2022)	09/2023)	09/2023)
	09/2018)	09/2019)	09/2020)	09/2021)			
Open Heart ORs	2	2	2	2	2	2	2
Dedicated C-Section ORs	3	3	3	3	3	3	3
Shared ORs <sup>1</sup>	29	29	29	26	30	30	30
Dedicated Ambulatory ORs <sup>2</sup>	4	4	4	4	4	4	4
Total ORs	38	38	38	35	39	39	39
Total OR Planning Inventory <sup>3</sup>	34	34	34	31	35	35	35
# Inpatient Surgical Cases	11,586	11,614	11,199	11,226	11,253	11,280	11,307
# Outpatient Surgical Cases	23,725	24,212	22,616	20,295	15,939	16,243	16,552
Inpatient Surgical Hours <sup>4</sup>	37,539	37,629	36,285	36,372	36,460	36,547	36,635
Outpatient Surgical Hours <sup>5</sup>	45,315	46,245	43,197	38,763	30,443	31,024	31,614
Total Surgical Hours	82,853	83,874	79,481	75,136	66,903	67,571	68,249
SMFP Group Assignment <sup>6</sup>	2	2	2	2	2	2	2
Standard Hours per OR per Year	1,950	1,950	1,950	1,950	1,950	1,950	1,950
Utilization <sup>7</sup>	125.0%	126.5%	119.9%	124.3%	98.0%	99.0%	100.0%

 In FY 2021 (10/2020 – 9/2021) three shared ORs will be relocated from NHRMC to Iron Gate Surgery Center, LLC, pursuant to Project ID#O-11559-18.

(2) The applicant states it maintains one shared OR for trauma cases, since it is a trauma provider.

(3) The OR Planning Inventory is the number of ORs available; excluding C-section ORs and Burn/trauma ORs (4).

(4) Inpatient Surgical Hours equals inpatient surgical cases times 3.24 (see pages 56 - 57 of the 2019 SMFP).

(5) Outpatient Surgical Hours equals outpatient surgical cases times 1.91 (see pages 56 - 57 of the 2019 SMFP).

(6) This is the Group Planning Assignment, page 68 of the 2019 SMFP.

(7) Utilization is calculated by (Total surgical hours/Standard hours per OR per year)/# ORs in planning inventory.

	INTERIM FULL FY (10/2020 – 09/2021)	1 <sup>s⊤</sup> FULL FY (10/2021 – 09/2022)	2 <sup>№</sup> FULL FY (10/2022 – 09/2023)	3 <sup>№</sup> FULL FY (10/2022 – 09/2023)
# of ORs <sup>1</sup>	3	3	3	3
# Outpatient Cases	2,775	2,830	2,886	2,943
Total Surgical Hours <sup>2</sup>	3,552	3,622	3,694	3,767
SMFP Group Assignment	6	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312	1,312
Utilization <sup>3</sup>	90.2%	92.0%	93.8%	95.7%
Procedure Room	1	1	1	1
# Procedures	528	587	597	607*

#### Iron Gate Surgery Center Projected OR Utilization

(1) The ORs are all outpatient/dedicated ambulatory as this facility will be a free-standing ASF.

(2) Total surgical hours equals total cases times 1.28 (see pages 56 - 57 of the 2019 SMFP).

(3) Utilization is calculated by (Total surgical hours/Standard hours per OR per year)/# ORs.

\*the applicant put 607.17 in the table in the supplemental information and application; the project analyst rounded.

## Projected OR Utilization – NHRMC Hospital and Health System

In supplemental information, pages 1 - 6, the applicant projects utilization for the ORs on NHRMC's license and Iron Gate Surgery Center. It is worth noting that the applicant submitted a letter of support for Project ID #O-11720-19, filed in the same review cycle as this application, by Wilmington Eye Surgery Center. In its assumptions, the applicant assumes eye surgery volume will shift to Wilmington Eye Surgery Center assuming that facility receives CON approval and is licensed.

On page 1 of the supplemental information, the applicant states:

"...NHRMC accounted for the effects of Iron Gate Surgery Center and the relocated 5 ORs from the Orthopedic Hospital to NHRMC's main campus. Excluding the volume performed in 1 Trauma OR and 3 C-Section ORs on NHRMC's main campus, the projected utilization shows a need for 35 ORs at NHRMC, 2.9 ORs at Iron Gate Surgery Center, and 37.9 ORs systemwide by FY 2024. Consistent with this calculation, NHRMC proposes to operate 38 adjusted ORs following implementation of the proposed project."

	NHRMC	IRON GATE	TOTAL NHRMC					
		SURGERY	System					
		CENTER						
Inpatient Cases	11,307		11,307					
Assigned Annual Hours per OR (Inpatient)	3.24		3.24					
Inpatient Hours – NHRMC	36,636		36,636					
Outpatient Cases	16,552	2,943	19,495					
Assigned Annual Hours per OR (Outpatient)	1.91	1.28						
Outpatient Hours	31,615	3,767	35,382					
Total Case Time (IP hours + OP hours)	68,251	3,767	72,018					
Assigned Capacity <sup>1</sup>	1,950	1,312						
Total ORs Needed	35.0	2.9	37.9					

Total NHRMC System OR Need Calculation per 2019 SMFP

(1) See pages 56 – 57 of the 2019 SMFP.

The applicant provides its assumptions and methodology in a series of 8 steps, which are briefly summarized below:

Step 1: determine NHRMC and affiliates actual and projected OR inventory. The applicant considered the pending projects and OR relocations, as follows:

- 5 ORs to relocate from Orthopedic Hospital to NHRMC main campus as of 7/1/2020.
- 3 ORs to relocate from Orthopedic Hospital to Iron Gate Surgery Center, LLC. Iron Gate Surgery Center will become a freestanding ASF as of 10/1/2020.
- 4 ORs proposed to be added to NHRMC main campus (this project).
- 4 ORs at Atlantic SurgiCenter remain licensed as a department of NHRMC.

FACILITY / LOCATION	ACTUAL		INTERIM		PROPOSED				
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024		
Main Hospital <sup>1</sup>	22	22	27	27	31	31	31		
Orthopedic Hospital <sup>2</sup>	8	8	3						
Atlantic SurgiCenter <sup>3</sup>	4	4	4	4	4	4	4		
Total NHRMC Hospital	34	34	34	31	35	35	35		
Iron Gate Surgery Center <sup>4</sup>				3	3	3	3		
Total NHRMC Affiliates	34	34	34	34	38	38	38		

NHRMC and Affiliates' OR Adjusted Inventory

See the following table, from page 2 of the supplemental information:

(1) Excludes 3 C-section and 1 Trauma ORs

(2) Project ID #O-11189-16 approved relocation of 5 ORs from Orthopedic Hospital to NHRMC main campus as of 7/1/2020.

(3) Atlantic SurgiCenter is an ASF licensed as part of NHRMC.

(4) Project ID #O-11559-18 approved relocation of 3 ORs from Orthopedic Hospital to Iron Gate Surgery Center and separately license Iron Gate Surgery as freestanding ASF as of 10/1/2020.

Step 2: Calculate NHRMC and NHRMC affiliates' projected inpatient (IP) case volume. the applicant utilized Truven data to project a 0.241% increase in inpatient utilization. The applicant also accounted for volume shifts consistent with the OR shifts as reflected in the table in Step 1. The Agency also granted an exemption in March 2019 to allow NHRMC to relocate two licensed ORs in which cystoscopy procedures were being perfomed to the surgical pavilion at the main hospital. As part of that exemption request, the applicant stated cystoscopy volume will shift from the ORs to the procedure rooms. See the following table that illustrates the projected IP case volume and shifts:

FACILITY / LOCATION	ACTUAL		INTERIM		PROPOSED			
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	
Main Hospital	9,213	9,235	9,411	11,226	11,253	11,280	11,307	
Orthopedic Hospital <sup>1</sup>	2,373	2,379	1,788					
Atlantic SurgiCenter								
Total NHRMC Hospital	11,586	11,614	11,199	11,226	11,253	11,280	11,307	
Iron Gate Surgery Center <sup>2</sup>								
Total NHRMC Affiliates	11,586	11,614	11,199	11,226	11,253	11,280	11,307	

NHRMC and Affiliates' IP Case Volume

(1) Project ID #L-11189-16 shifts five ORs from the Orthopedic Hospital to NHRMC main campus (7/1/2020).

(2) Project ID #O-11559-18 shifts three ORs from the Orthopedic hospital to Iron Gate Surgery Center; Iron Gate to become separately licensed freestanding ASF (10/1/2020).

Step 3: Calculate NHRMC and NHRMC affiliates' projected outpatient (OP) case volume. The applicant utilizes Truven data to project outpatient surgical growth at the main hospital and the NHRMC affiliates by a CAGR of 1.977%. The applicant also accounts for volume shifts consistent with the OR shifts reflected in the table in Step 1. NHRMC main hospital volume was calculated by applying the 1.977% CAGR to actual FY 2018 volumes and then accounting for volume shifts. See the following table from page 3 of the supplemental information:

#### New Hanover Regional Medical Center Project ID #O-11714-19 Page 10

FACILITY / LOCATION	ACTUAL		INTERIM		PROPOSED			
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	
Main Hospital	13,337	13,601	12,889	14,589	12,066	12,304	12,548	
Orthopedic Hospital <sup>1</sup>	4,280	4,365	3,338					
Atlantic SurgiCenter	6,108	6,246	6,388	5,706	3,873	3,938	4,005	
Total NHRMC Hospital	23,725	24,212	22,616	20,295	15,939	16,243	16,552	
Iron Gate Surgery Center <sup>2</sup>				2,775	2,830	2,886	2,943	
Total NHRMC Affiliates	23,725	24,212	22,616	23,070	18,769	19,129	19,495	

#### NHRMC and Affiliates' OP Case Volume

(1) Project ID #L-11189-16 shifts five ORs from the Orthopedic Hospital to NHRMC main campus (7/1/2020).

(2) Project ID #O-11559-18 shifts three ORs from the Orthopedic hospital to Iron Gate Surgery Center; Iron Gate to become separately licensed freestanding ASF (10/1/2020).

Steps 4 and 5: Determine assumed OR case times and calculate actual and projected surgical hours. The applicant applied the *Standard Average Final Case Times* from pages 56 - 57 of the 2019 SMFP to the cases determined in steps 2 and 3 to calculate total IP and OP surgical hours for NHRMC and affiliates. See the following table, from page 4 of the supplemental information:

#### NHRMC and Affiliates' Surgical Hours

FACILITY / LOCATION	Actual		INTERIM		PROPOSED			
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	
Total NHRMC Hospital <sup>1</sup>	82,853	83,874	79,481	75,136	66,903	67,572	68,251	
Iron Gate Surgery Center <sup>2</sup>				3,552	3,622	3,694	3,767	
Total NHRMC Affiliates	82,853	83,874	79,481	78,688	70,526	71,265	72,018	

(1) Calculated by multiplying total IP cases by 3.24 and total OP cases by 1.91 per pages 56 - 57, 2019 SMFP.

(2) Calculated by multiplying total cases by 1.28, per pages 56 - 57, 2019 SMFP.

Step 6: Calculate OR need using SMFP need methodology. The applicant calculated OR need using the information contained in Chapter 6 of the 2019 SMFP, applying OR Groups and *Standard Surgical Hours per Operating Room per Year*, as illustrated in the following table from page 5 of the supplemental information:

FACILITY / LOCATION	ACTUAL		INTERIM		PROPOSED			
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	
Total NHRMC Hospital (Group 2)	42.5	43.0	40.8	38.5	34.3	34.7	35.0	
Iron Gate Surgery Center (Group 6)				2.7	2.8	2.8	2.9	
Total NHRMC Affiliates Need	42.5	43.0	40.8	41.2	37.1	37.5	37.9	
Total NHRMC Affiliates Proposed	34.0	34.0	34.0	34.0	38.0	38.0	38.0	

#### NHRMC and Affiliates' OR Need

Note: Iron Gate Surgery Center will be a freestanding ASF, Group 6. NHRMC main hospital is a Group 2.

Step 7: Calculate OR capacity. The applicant calculated OR capacity in terms of total surgical hours by multiplying NHRMC OP and IP, and Iron Gate projected surgical hours calculated in

the applicant's methodology Step 5 by the standard hours per OR from the 2019 SMFP, as illustrated in the following table from page 5 of the supplemental information:

Annual and Annual of Capacity								
FACILITY / LOCATION	ACTUAL		INTERIM		PROPOSED			
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	
Total NHRMC Hospital (Group 2)	66,300	66,300	66,300	60,450	68,250	68,250	68,250	
Iron Gate Surgery Center (Group 6)				3,936	3,936	3,936	3,936	
Total NHRMC Affiliates	66,300	66,300	66,300	64,386	72,186	72,186	72,186	

NHRMC and Affiliates' OR Capacity

Note: Iron Gate Surgery Center Group 6 standard hours per OR = 1,312. NHRMC main hospital Group 2 standard hours per OR = 1,950.

Step 8: Calculate utilization as a percent of capacity. The applicant calculated historical utilization and projected future utilization by dividing surgical hours in methodology Step 5 by OR capacity in methodology Step 7, as illustrated in the following table from page 6 of the supplemental information:

Winnie and Annuales Othization as referent of capacity									
FACILITY / LOCATION	ACTUAL		INTERIM		PROPOSED				
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024		
Total NHRMC Hospital (Group 2)	125.0%	126.5%	119.9%	124.3%	98.0%	99.0%	100.0%		
Iron Gate Surgery Center (Group 6)				90.2%	92.0%	93.9%	95.7%		
Total NHRMC Affiliates	125.0%	126.5%	119.9%	122.2%	97.7%	98.7%	99.8%		

### NHRMC and Affiliates' Utilization as Percent of Capacity

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

- There is a need in the 2019 SMFP for six ORs in the New Hanover County OR Planning Area.
- The applicant relies on historical utilization to project future utilization.
- The applicant accounts for volume shifts consistent with OR relocations from NHRMC Orthopedic Hospital to both NHRMC main campus and Iron Gate Surgery Center.
- The applicant's historical utilization already meets the performance standard promulgated in 10A NCAC 14C .2103(a).

# Access

In Section C, page 38, the applicant states "*NHRMC is a not-for-profit organization that does not discriminate against any class of patient based on age, sex, religion, race, handicap, ethnicity, or ability to pay.*" In Section L, page 69, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

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	NHRMC MAIN	OPERATING
	CAMPUS AND NHRMC	Rooms
	<b>ORTHOPEDIC HOSPITAL</b>	
Self-Pay	9.8%	5.4%
Medicare*	41.3%	56.1%
Medicaid*	18.2%	11.7%
Insurance*	24.0%	21.0%
Other (specify)**	6.6%	5.9%
Total	100.0%	100.0%

The applicant states the information is from the 2019 License Renewal Application and internal data.

\*Includes managed care plans.

\*\*Includes Workers Comp and TRICARE for entire facility.

\*\*\*Includes NHRMC Main Campus and the Orthopedic Hospital.

The projected payor mix is reasonable and adequately supported.

### **Conclusion**

The Agency reviewed the:

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

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.

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### NA

The applicant does not propose to:

- Reduce a service
- Eliminate a service
- 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.

## CA

NHRMC proposes to add four ORs to the main hospital pursuant to the 2019 SMFP need determination for a total of 39 ORs upon project completion.

In Section E, pages 46 - 48, 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 this alternative would continue to cause capacity constraints at the hospital, where the latest utilization was 120% of available capacity. In addition, to maintain the status quo would result in surgeon and staff burn out, lengthy wait times for patients, and increased lengths of stay for inpatients needing surgical procedures.
- Add ORs to Atltantic SurgiCenter, which is an ambulatory surgical facility operated by the applicant the applicant determined that adding ORs to the ASF would alleviate capacity constraints at the main hospital by shifting lower acuity patients whose procedures could be performed in an outpatient setting; however, it would not address the continuing capacity issues at the main hospital. The applicant explains that it is the only tertiary care facility in the service area, and needs appropriate OR capacity to accept medically complex and higher acuity patients in the main hospital.

The applicant also addressed a combination of alternatives; specifically, adding four ORs to the main hospital and adding two ORs to Atlantic SurgiCenter, and states that is the most effective alternative to meet the need for ORs in New Hanover County. The applicant originally submitted a second application with this one, which proposed to add two ORs to Atlantic SurgiCenter. On July 15, 2019 that application was withdrawn, and this is the only application submitted by the applicant that is under review by the Agency. Withdrawal of that application effectively withdraws the last alternative and thus, the alternative considered most effective by the applicant is this application to add four ORs to the main hospital.

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 meets the need for additional ORs identified in the 2019 SMFP in New Hanover County.
- The application proposes a solution to OR capacity constraints at the hospital.
- The application proposes a solution to surgeon and staff burn out from extended hours because of capacity constraints at the hospital.
- The application proposes a solution to the lengthy waiting times for surgical patients at the hospital.

# **Conclusion**

The Agency reviewed the:

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

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

- 1. New Hanover Regional Medical Center shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, New Hanover Regional Medical Center shall materially comply with the last made representation.
- 2. New Hanover Regional Medical Center shall develop no more than four additional operating rooms on the main campus for a total of no more than 39 operating rooms upon project completion.
- **3.** New Hanover Regional Medical Center shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
- 4. New Hanover Regional Medical Center shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
- 5. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, New Hanover Regional Medical Center shall submit, on the form

provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:

- a. Payor mix for the services authorized in this certificate of need.
- b. Utilization of the services authorized in this certificate of need.
- c. Revenues and operating costs for the services authorized in this certificate of need.
- d. Average gross revenue per unit of service.
- e. Average net revenue per unit of service.
- f. Average operating cost per unit of service.
- 6. New Hanover Regional Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

С

NHRMC proposes to add four ORs to the main hospital pursuant to the 2019 SMFP need determination for a total of 39 ORs upon project completion.

# **Capital and Working Capital Costs**

In Section Q, page 84, the applicant projects the total capital cost of the project as shown in the table below.

Site Costs	\$0
Construction Costs	\$5,358,300
Miscellaneous Costs	\$3,066,700
Total	\$8,425,000

In Section Q, pages 94 - 95, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 51 - 52, the applicant states that NHRMC is currently providing OR services at the hospital and thus there are no start-up costs or initial operating expenses associated with this project.

# Availability of Funds

In Section F, page 49, the applicant states that the capital cost will be funded as shown in the table below:

Түре	NEW HANOVER REGIONAL MEDICAL CENTER	TOTAL
Loans	\$0	\$0
Accumulated Reserved or OE*	\$8,425,000	\$8,425,000
Bonds	\$0	\$0
Other	\$0	\$0
Total	\$8,425,000	\$8,425,000

\*OE = owner's equity

In Exhibit F-2.1 the applicant provides a June 5, 2019 letter from the Executive Vice President and Chief Financial Officer for NHRMC documenting that the funds will be available for the capital cost of the project. Exhibit F-2.2 contains the most recent audited financial statements for NHRMC which indicate the hospital had \$113,479,000 in cash and cash equivalents as of September 30, 2018.

# **Financial Feasibility**

In supplemental information, the applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below:

	1 <sup>st</sup> Full Fiscal Year (FY 2022)	2 <sup>№</sup> FULL FISCAL YEAR (FY 2023)	3 <sup>RD</sup> FULL FISCAL YEAR (FY 2024)
Total Surgical Cases	12,066	12,304	12,548
Total Gross Revenue (charges)	\$773,271,527	\$818,680,334	\$866,811,765
Total Net Revenue	\$167,844,773	\$171,472,159	\$175,149,602
Average Net Revenue per Procedure	\$13,910	\$13,936	\$13,958
Total Operating Expenses (costs)	\$134,721,088	\$138,178,568	\$141,731,103
Average Operating Expense per Procedure	\$11,165	\$11,230	\$11,295
Net Income	\$33,123,685	\$33,293,591	\$33,418,499

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

# **Conclusion**

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the capital 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.

С

NHRMC proposes to add four ORs to the main hospital pursuant to the 2019 SMFP need determination for a total of 39 ORs upon project completion.

On page 55, the 2019 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." In Figure 6.1, page 60 of the 2019 SMFP, New Hanover County is shown as a single-county OR service area. Thus, the service area for this review consists of New Hanover County. Facilities may also serve residents of counties not included in the service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared operating rooms located in New Hanover County, and the inpatient and outpatient case volumes for each provider, from Tables 6A and 6B, pages 68 and 80 respectively, of the 2019 SMFP:

FACILITY	IP	OP	SHARED	EXCLUDED C-	CON	IP	ОР	GROUP
	ORs	ORs	ORs	Section/Trauma	ADJUSTMENT	SURGERY	SURGERY	
				<b>/BURN ORs</b>		CASES	CASES	
Wilmington ASC	0	0	0	0	1	0	0	-
Wilmington SurgCare	0	7	0	0	3	0	8,531	5
NHRMC	5	4	29	-3	0	11,924	25,301	2
<b>Total New Hanover County ORs</b>	5	11	29	-3	4			

As the table above indicates, there is one hospital and two existing or approved ambulatory surgical facilities (ASF) in New Hanover County with a total of five inpatient, 11 ambulatory and 29 shared operating rooms, including one C-Section OR.

In Section G, pages 55 - 56, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved surgical services in New Hanover County. The applicant states:

"...NHRMC's existing ORs operate well over capacity. NHRMC is the only acute care hospital in the primary service area and is the regional tertiary provider.

NHRMC is not proposing new services or to expand its current service area; rather, NHRMC is proposing additional OR capacity to better serve its existing service area. The proposed project is needed specifically to meet the needs of patients served by NHRMC.... The proposed project will not duplicate any other existing surgical service or provider."

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

- There is a need determination in the 2019 SMFP for six ORs and NHRMC proposes four ORs.
- The applicant adequately demonstrates that the proposed ORs are needed in addition to the existing or approved ORs in New Hanover County.

The Agency reviewed the:

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

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

С

NHRMC proposes to add four ORs to the main hospital pursuant to the 2019 SMFP need determination for a total of 39 ORs upon project completion.

In supplemental information, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

#### New Hanover Regional Medical Center Project ID #O-11714-19 Page 19

Position	CURRENT FTE	PROJECTED FTE POSITIONS				
	<b>POSITIONS*</b>	PY1 CY 2021	PY2 CY 2022	PY3 CY 2023		
Registered Nurse	120.00	121.50	121.50	121.50		
Surgical Technician	61.55	64.55	64.55	64.55		
Aides/Orderlies	25.80	25.80	25.80	25.80		
Anesthesiologists	2.39	3.89	3.89	3.89		
Radiology Technologist	7.37	7.37	7.37	7.37		
Central Sterile Supply	1.91	1.91	1.91	1.91		
Administrator (OR manager)	5.50	5.50	5.50	5.50		
Director of Nursing (Coordinator)	5.01	5.01	5.01	5.01		
Business Office	25.65	25.65	25.65	25.65		
Patient Liason/Technician	1.05	1.05	1.05	1.05		
Other	2.47	2.47	2.47	2.47		
TOTAL	258.70	264.70	264.70	264.70		

\*As of May 8, 2019, according to the applicant in supplemental information.

The assumptions and methodology used to project staffing are provided in supplemental information. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in supplemental information. In Section H, pages 57 - 58, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section I.3(b), page 61, the applicant identifies the Medical Director as William Hope, MD. In Exhibit I.3-2, the applicant provides a letter from Dr. Hope indicating a willingness to continue to serve as medical director for the proposed services. In Section H.2, pages 57 - 58, the applicant describes its physician recruitment plans. In Exhibit H.2, the applicant provides supporting documentation.

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

## **Conclusion**

The Agency reviewed the:

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

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

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

С

NHRMC proposes to add four ORs to the main hospital pursuant to the 2019 SMFP need determination for a total of 39 ORs upon project completion.

In Section I, page 59, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Imaging
- Laboratory
- Pharmacy
- Physical Therapy
- Respiratory Therapy
- Dietary Services
- Medical Records
- Materials Management
- Housekeeping
- Information Management
- Plant Management
- Utilization Review
- Risk Management
- Infection Control
- Quality Management
- Administrative Services
- Support Services

On page 59, the applicant adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I.1.

In Section I, page 60, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibits C.4(b) and I.2.

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

## **Conclusion**

The Agency reviewed the:

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

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

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

### NA

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

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

## NA

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

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

NHRMC proposes to add four ORs to the main hospital pursuant to the 2019 SMFP need determination for a total of 39 ORs upon project completion.

In Section K, page 63, the applicant states that the project involves constructing 3,650 square feet of new space and renovating 1,500 square feet of existing space. Line drawings are provided in Exhibit K-1.

On page 64, 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 K-3. In addition, on page 64 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.

On page 64, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K-3.

# **Conclusion**

The Agency reviewed the:

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

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
  - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

С

In Section L, page 68, the applicant provides the historical payor mix during FY 2018 for the NHRMC main campus and the NHRMC orthopedic hospital surgical cases, as summarized in the table below:

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PAYOR CATEGORY	SURGICAL SERVICES AS PERCENT OF TOTAL					
	NHRMC MAIN CAMPUS AND NHRMC Orthopedic Hospital	OPERATING ROOMS				
Self-Pay / Charity Care	9.8%	5.0%				
Medicare*	41.3%	51.9%				
Medicaid*	18.2%	10.0%				
Insurance*	24.0%	27.0%				
Other (specify)**	6.6%	6.2%				
Total	100.0%	100.0%				

\*Includes managed care plans

\*\*Other includes TRICARE and worker's comp.

Totals may not sum due to rounding.

In Section L, page 67, the applicant provides the following comparison.

	PERCENTAGE OF TOTAL PATIENTS SERVED BY NHRMC DURING THE LAST FULL FY 2018	Percentage of the Population of the Service Area: New Hanover County
Female	54.1%	50.1%
Male	45.9%	49.9%
Unknown	0.0%	0.0%
64 and Younger	54.6%	82.7%
65 and Older	45.4%	17.3%
American Indian	0.4%	0.9%
Asian	0.3%	1.3%
Black or African-American	14.6%	16.8%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	79.9%	73.6%
Other Race	4.6%	7.2%
Declined / Unavailable	0.2%	0.0%

### **Conclusion**

The Agency reviewed the:

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

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;

С

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 68, the applicant states that NHRMC has no obligation under applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons.

On page 68, the applicant states that there were no civil rights access complaints filed against NHRMC during the last five years.

The Agency reviewed the:

- Application,
- Exhibits to the application, and
- Remarks made at the public hearing.

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

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

### С

In Section L, page 69, the applicant projects the payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

	NHRMC MAIN CAMPUS	OPERATING ROOMS
	AND NHRMC	
	<b>ORTHOPEDIC HOSPITAL</b>	
Self-Pay / Charity Care	9.8%	5.4%
Medicare*	41.3%	56.1%
Medicaid*	18.2%	11.7%
Insurance*	24.0%	21.0%
Other (specify)**	6.6%	5.9%
Total	100.0%	100.0%

\*Includes managed care plans

\*\*Other includes TRICARE and worker's comp.

Totals may not sum due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects 9.8% of total surgical services will be provided to self-pay / charity care patients, 41.3% to Medicare patients and 18.2% to Medicaid patients.

On page 69 and in supplemental information, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicant based the projected payor mix on historical inpatient and outpatient surgical cases at NHRMC and NHRMC orthopedic hospital.
- The applicant states that NHRMC provides surgical services to Medicare and Medicaid recipients, the uninsured and the underinsured, self-pay and commercial pay patients, without regard to race, color, religion, sex, age, national origin, handicap, or ability to pay.

The Agency reviewed the:

- Application,
- Exhibits to the application,
- Remarks made at the public hearing, and
- Responses to comments.

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.

## С

In Section L, page 70, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application, and
- Exhibits to the application.

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

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

С

In Section M, page 71, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes. The applicant states it currently has training agreements with over 110 health professional training programs, and that training opportunities will continue to be made available as needed.

The Agency reviewed the:

- Application, and
- Exhibits to the application.

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

С

NHRMC proposes to add four ORs to the main hospital pursuant to the 2019 SMFP need determination for a total of 39 ORs upon project completion.

On page 55, the 2019 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." In Figure 6.1, page 60 of the 2019 SMFP, New Hanover County is shown as a single-county OR service area. Thus, the service area for this review consists of New Hanover County. Facilities may also serve residents of counties not included in the service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared operating rooms located in New Hanover County, and the inpatient and outpatient case

FACILITY	IP ORs	OP ORs	SHARED ORS	Excluded C- Section/Trauma /Burn ORs	CON Adjustment	IP Surgery Cases	OP Surgery Cases	GROUP
Wilmington ASC	0	0	0	0	1	0	0	-
Wilmington SurgCare	0	7	0	0	3	0	8,531	5
NHRMC	5	4	29	-3	0	11,924	25,301	2
Total New Hanover County ORs	5	11	29	-3	4			

volumes for each provider, from Tables 6A and 6B, pages 68 and 80 respectively, of the 2019 SMFP:

As the table above indicates, there is one hospital and two existing or approved ambulatory surgical facilities (ASF) in New Hanover County with a total of five inpatient, 11 ambulatory and 29 shared operating rooms, including one C-Section OR.

In Section N, pages 72 - 73, 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. Beginning on page 72, the applicant states:

"This project will foster competition. NHRMC competes not only with other hospitals in the service area but also with much larger systems both inside and outside of North Carolina. NHRMC recognizes that patients have a choice of where to receive their care, and it strives to earn the loyalty of its patients every day.

•••

NHRMC has focused on providing high quality care while maintaining low costs since its opening, which demonstrates its commitment to maximizing healthcare value in delivering the surgical services it provides.

•••

...additional OR capacity will allow for more efficient scheduling of surgeries, reduce the likelihood of the surgical suite having to extend its hours and pay additional staff costs (including overtime), and reduce lengths of stay by decreasing wait times for inpatient surgical procedures.

•••

The proposed concurrent and complementary projects will improve quality by addressing NHRMC's significant surgical capacity constraints, reducing delays in scheduling non-emergency surgery and reducing patient lengths of stay."

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

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

## **Conclusion**

The Agency reviewed the:

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

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

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

## С

In Section A, page 9, the applicant lists the hospital, ASF and acute care facilities owned, managed and operated by New Hanover Regional Medical Center.

In Section O.3(c), page 75, the applicant states:

"NHRMC-affiliated facilities have not been found in noncompliance by CMS, the Division of Health Service Regulation, or NHRMC's accrediting body in the past 18 month look-back period for any incidents resulting in finding immediate jeopardy."

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care have not occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all of the facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

С

The application is conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms. The specific criteria are discussed below.

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

The following definitions apply to all rules in this Section:

- (1) "Approved operating rooms" means those operating rooms that were approved for a certificate of need by the Healthcare Planning and Certificate of Need Section (Agency) prior to the date on which the applicant's proposed project was submitted to the Agency, but that have not been licensed.
- (2) "Dedicated C-section operating room" means an operating room as defined in Chapter 6 in the 2018 State Medical Facilities Plan. For purposes of this Section, Chapter 6 in the 2018 State Medical Facilities Plan is hereby incorporated by reference including subsequent amendments and editions. This document is available at no cost at https://www.ncdhhs.gov/dhsr/ncsmfp/index.html.
- (3) "Existing operating rooms" means those operating rooms in ambulatory surgical facilities and hospitals that were reported in the Ambulatory Surgical Facility License Renewal Application Form or in the Hospital License Renewal Application Form submitted to the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation, and that were licensed prior to the beginning of the review period.
- (4) "Health System" shall have the same meaning as defined in Chapter 6 in the 2018 State Medical Facilities Plan.
- (5) "Operating room" means a room as defined in G.S. 131E-176(18c).
- (6) "Operating Room Need Methodology" means the Methodology for Projecting Operating Room Need in Chapter 6 in the 2018 State Medical Facilities Plan.
- (7) "Service area" means the Operating Room Service Area as defined in Chapter 6 in the 2018 State Medical Facilities Plan.

## .2103 PERFORMANCE STANDARDS

- .2103(a) An applicant proposing to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the 2019 State Medical Facilities Plan. The applicant is not required to use the population growth factor.
  - -C- The applicant projects sufficient surgical cases and hours to demonstrate the need for four additional ORs at NHRMC and in the applicant's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2019 SMFP, as shown in supplemental information. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- .2103(b) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.
  - -C- In supplemental information, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.