

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 19, 2018

Findings Date: September 19, 2018

Project Analyst: Celia C. Inman

Co-Signer: Fatimah Wilson

Project ID #: F-11523-18

Facility: Novant Health Huntersville Medical Center

FID #: 990440

County: Mecklenburg

Applicant: The Presbyterian Hospital

Project: Develop a second dedicated C-section OR

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.

NA

The applicant, The Presbyterian Hospital (“PH”) proposes to develop a second dedicated C-section operating room (OR) at Novant Health Huntersville Medical Center (“NHHMC”). NHHMC will be licensed for a total of eight ORs, including two dedicated C-section and six shared ORs upon completion of this project and Project ID #F-11110-15 (Relocate 48 acute care beds and one OR from Novant Health Presbyterian Medical Center to Novant Health Huntersville Medical Center for a total of 139 beds and 7 ORs).

Need Determination

Chapter 6 of the 2018 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional ORs by service area. Application of the standard need methodology in the 2018 SMFP identifies a need for six additional ORs in the Mecklenburg County operating room service area.

Per page 61 of the OR need methodology in the 2018 SMFP,

“Dedicated C-Section Operating Rooms” and associated cases are excluded from the calculation of need for additional operating rooms by the standard methodology; therefore, hospitals proposing to add a new operating room for use as a “Dedicated C-Section Operating Room” shall apply for a certificate of need without regard to the need determinations in Chapter 6 of this Plan. There are no other operating room exclusions for which this protocol is applicable.

A “Dedicated C-Section Operating Room” shall only be used to perform Cesarean Sections and other procedures performed on the patient in the same visit to the C-Section Operating Room, such that a patient receiving another procedure at the same time as the Cesarean Section would not need to be moved to a different operating room for the second procedure.”

The applicant is proposing to develop a second dedicated C-section OR at NHHMC; therefore, the need determination in the 2018 SMFP for six additional ORs in Mecklenburg County is not applicable to this review.

Policies

There are no policies in the 2018 SMFP which are applicable to this review.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that Criterion (1) is not applicable to this review for the following reasons:

- There are no need determinations in the 2018 SMFP applicable to this review.
- There are no policies in the 2018 SMFP applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC. In Section C.1, page 17, the applicant states:

“The labor and delivery at NHHMC originally was designed to expand to add a second C-Section room when needed. Therefore, the cost of the proposed project is only \$1,296,294. This includes expansion and upgrade of the space identified for the second C-Section room and necessary equipment. Upon completion of the project, NHHMC will have two dedicated C-Section operating rooms. The proposed project does not include any changes in general operating rooms, GI procedure rooms, or other procedure rooms at NHHMC.”

NHHMC will have two dedicated C-section ORs, six shared ORs, and three GI endoscopy procedure rooms, upon completion of this project and Project ID #F-11110-15 (Relocate 48 acute care beds and one OR from Novant Health Presbyterian Medical Center to Novant Health Huntersville Medical Center for a total of 139 beds and 7 ORs).

Patient Origin

On page 57, the 2018 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 62 of the 2018 SMFP, Mecklenburg County is shown as a single-county operating room service area. Thus, in this application, the service area is Mecklenburg County. Providers may serve residents of counties not included in their service area.

In Section C.2, pages 18-19, the applicant provides a ZIP code and county patient origin for the NHHMC C-section OR for the last full fiscal year (FY) October 1, 2016 – September 30, 2017. In Section C.3, pages 19-20, the applicant provides the projected patient origin (CY2021-CY2023), by ZIP code and county for the NHHMC C-section ORs. The following table summarizes the NHHMC C-section FY2017 historical patient origin by county and the projected patient origin by county for the second and third project years (PY).

**NHHMC Historical and Projected Patient Origin
 C-Section Operating Rooms**

County	Historical		Projected			
	FY2017		PY2 CY2022		PY3 CY2023	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Mecklenburg	278	65.3%	458	65.2%	505	65.3%
Lincoln	39	9.2%	64	9.1%	71	9.2%
Cabarrus	33	7.7%	51	7.3%	60	7.8%
Iredell	28	6.6%	16	2.3%	51	6.6%
Gaston	22	5.2%	36	5.1%	40	5.2%
All Other*	26	6.1%	43	6.1%	47	6.1%
TOTAL	426	100.0%	702	100.0%	773	100.0%

Source: the applicant sources Section Q, Table 9, which sources Trendstar

* All Other includes NC counties as reflected in the surgical patient origin in the NHHMC 2018 LRA: Alexander, Ashe, Buncombe, Caldwell, Carteret, Catawba, Cleveland, Davidson, Davie, Guilford, Richmond, Rowan, Stanly, Union, Wake, Wilkes, Yadkin counties; and other states.

In Section C, page 19, the applicant states that the projected patient origin for NHHMC C-section ORs is assumed to be the same as the C-section patient origin in FFY2017, the last full federal fiscal year available for NHHMC at the time the application was submitted. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 21-28, the applicant explains why it believes the population projected to utilize the proposed acute care services needs the proposed services. On page 24, the applicant states that the need for the second C-section OR is justified by the following:

- population growth in the market (pages 21-24),
- significant growth in obstetrical services at NHHMC (pages 21-24),
- increasing number of total births in the service area and increasing NHHMC market share (pages 21-24),
- delays in C-sections at NHHMC in the last year, (pages 21-24),
- recruitment of OB/GYN staff at NHHMC (pages 21-24), and
- addition of the Nocturnist Program at NHHMC (pages 21-24),

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

- The applicant uses clearly cited and reasonable historical and demographical data to make the assumptions with regard to identifying the population to be served.
- The applicant uses clearly cited and reasonable demographical data to make the assumptions with regard to growth of the population to be served.
- The applicant adequately demonstrates the growth in total births in the service area and the increase in NHHMC’s market share.

- The applicant adequately demonstrates that NHHMC has had to delay several C-section deliveries which would not have had to have been delayed if there were a second C-section OR.
- The applicant adequately demonstrates that NH’s recruitment plan for NHHMC includes the addition of five OB/GYNs in 2018 and two to four more from 2019 to 2021, in addition to a Midwife.
- The applicant adequately demonstrates that the Nocturnist Program at NHHMC, added in 2018, partnering OB Hospitalists/Nocturnists with the OB physicians at NHHMC, enhances patient care with improved access to obstetrical care, which could in turn draw more patients.

Projected Utilization: C-Section Operating Rooms

In Section Q, page 84, the applicant provides projected utilization for the two NHHMC C-section ORs, as summarized in the following table:

SERVICE COMPONENT	INTERIM (CY 2018)	INTERIM (CY 2019)	INTERIM (JAN-MAR 2020)	INTERIM (APR-DEC 2020)	PY 1 (CY 2021)	PY 2 (CY 2022)	PY 3 (CY 2023)
# C-section ORs	1	1	1	2	2	2	2
# Cases	475	524	144	433	637	702	773
# Cases per C-section OR	475	524	144	217	318	351	387

Source: Application, page 84

In Section Q, Form C Utilization Assumptions and Methodology, pages 85-86, the applicant provides the assumptions and methodology used to project C-section operating room utilization, which is summarized below.

Methodology

- NHHMC FY2018 estimated births x NHHMC compound annual growth rate (CAGR) for births from 2014-2018 = projected total births at NHHMC.
- Projected total births at NHHMC x NHHMC historical percent of births that are C-sections = projected C-sections at NHHMC.

Assumptions

- The second C-section OR becomes operational in April 2020.
- Interim operating year is April 2020 through December 2020.
- PY1 is CY2021 (January 1, 2021 - December 31, 2021).
- Annualized FY2018 (October-May) total births is the baseline data for future projections of NHHMC births.
- The NHHMC 2014-2018 CAGR of 10.2% is used to project future births at NHHMC through FY2024.

- The NHHMC 2018 estimated C-section rate of total births (28.0%) is held constant to project future C-sections at NHHMC.

One might question using the annualized FY2018 volume as the baseline for future projections; however, the eight month annualized baseline volume is within ten births of the projected 2018 births based on the historical 3-year CAGR of 10.1% from 2014 through 2017; therefore, the annualized 2018 baseline is a reasonable assumption.

One might also question using the NHHMC 2018 estimated C-section rate of 28.0% for C-sections as a percent of total births based on the fact that the percentage of C-sections to total births has been on a reasonably steady decline (-1.9% four-year CAGR) from 30% in 2013 to 28% for the annualized 2018 percent. However, 28% is a relatively low percentage relative to the average 31% rate of C-section births to total births in Mecklenburg County, as reported on the 2018 LRAs of facilities with dedicated C-section ORs; therefore the Project Analyst does not find the use of a 28% rate for future C-sections at NHHMC to be unreasonable.

The applicant provides calculation tables on pages 87-93 supporting its methodology and assumptions, as listed above. Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant bases projected utilization upon historical data for the service area population and the applicant's experience in providing OB and C-section services, and
- The applicant applies reasonable growth assumptions based on historical utilization.

Access

In Section C.8, page 31, the applicant states:

“Novant health does not exclude, deny benefits to, or otherwise discriminate against patients, students, or visitors on the basis of race; color; religion; national origin; culture; language; physical or mental disabilities; genetic information; age; sex, including pregnancy, childbirth or related medical conditions; marital status; sexual orientation; gender identity or expression; socioeconomic status; or source of payment in admission to, participation in, or receipt of the services and benefits of any of its programs and other activities, whether carried out by Novant Health directly or through a contractor or other entity with whom Novant Health arranges to carry out its programs or activities.”

In Section L.3, page 69, the applicant projects the following payor mix during the second full year of operation following completion of the project, as illustrated in the table below.

**Proposed Payor Mix
CY2022**

Payor Source	Entire Facility NHHMC	C-Section Operating Rooms
Self-Pay	6.1%	1.1%
Charity	1.1%	1.0%
Medicare *	34.8%	0.0%
Medicaid *	9.7%	16.8%
Insurance *	45.2%	79.2%
Other (Workers Comp, Tricare, other)	3.1%	1.9%
Total	100.0%	100.0%

* Including any managed care plans

Totals may not sum due to rounding

The applicant states on page 69 that the projected payor mix is based on the existing payor mix at NHHMC for C-section services. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, 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 following reasons:

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

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

NA

The applicant does not propose to reduce a service, eliminate a service 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.

CA

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC.

In Section E, pages 41-42, 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,
- convert an existing OR to a C-section OR, and
- develop the project as proposed.

On pages 41-42, the applicant states that its proposal is the most effective alternative because:

“Adding a second C-Section operating room is a more effective alternative than maintaining the status quo. Delaying C-Sections can be dangerous for both the mother and baby and can decrease patient satisfaction. Delays are occurring more frequently as obstetrical volumes at NHHMC have increased and scheduled patients are displaced for emergency C-Sections. Therefore, this alternative provides less effective, lower quality patient care than the development of a second C-Section OR.

Adding a second C-Section operating room is a more effective alternative than converting an existing NHHMC operating room to a C-Section OR. Conversion of a fully utilized NHHMC operating room would result in creating significant delays in surgical care for patients in need of surgical services. Therefore, this alternative provides less effective lower quality patient care than the development of a second C-Section OR.”

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

- the applicant adequately identifies the population to be served and demonstrates the need that population has for the proposed services,

- the applicant adequately demonstrates that the need and the projected utilization for the proposed project are based on reasonable and adequately supported assumptions, and
- the application is conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

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

- 1. The Presbyterian Hospital shall materially comply with all representations made in the certificate of need application.**
- 2. The Presbyterian Hospital shall develop one additional dedicated C-section OR for a total of two dedicated C-section ORs at Novant Health Huntersville Medical Center.**
- 3. Novant Health Huntersville Medical Center shall be licensed for no more than two dedicated C-section ORs, six shared ORs and three GI endoscopy procedure rooms upon completion of this project and Project ID #F-11110-15 (Relocate 48 acute care beds and one OR from Novant Health Presbyterian Medical Center to Novant Health Huntersville Medical Center for a total of 139 beds and 7 ORs).**
- 4. The Presbyterian Hospital shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.**
- 5. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, The Presbyterian 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.**
6. **The Presbyterian 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.

C

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC.

Capital and Working Capital Costs

In Section Q, Form F.1a Capital Cost, the applicant states the total capital cost is projected to be as follows:

NHHMC C-Section Project Capital Cost

Construction/Renovation Contract	\$ 764,779
Architect/Engineering Fees	\$ 75,735
Medical Equipment	\$ 284,790
Miscellaneous	\$ 170,990
TOTAL CAPITAL COST	\$ 1,296,294

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

In Section F.3, page 46, the applicant states that the total start-up expenses will be \$12,500 with no initial operating expenses. The applicant considers the start-up cost as an operational expense and does not capitalize the cost. Exhibit K.4 contains the construction cost estimate prepared by a North Carolina licensed architect, documenting construction and architect/engineering fees as shown in the table above.

Availability of Funds

In Section F.2, page 43, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Novant Health, Inc.
Loans	
Accumulated reserves or OE *	\$1,296,294
Bonds	
Other (Specify)	
Total Financing **	\$1,296,294

* OE = Owner’s Equity

** Total financing should equal the total capital cost reported on Form F.1a Capital Cost

In Exhibit F.2, the applicant provides a June 15, 2018 letter from NH Senior Vice President, Geoffrey Gardner, which documents Novant Health, Inc.’s intent to fund the capital cost of the proposed project. The applicant provides a copy of Novant Health, Inc.’s consolidated financial statements for years ending December 31, 2017 and 2016, which documents \$408,698,000 in cash and cash equivalents, \$1,466,454,000 in total assets and \$3,929,878,000 in net assets (total assets less total liabilities) as of December 31, 2017. The applicant adequately demonstrates that sufficient funds will be available for the capital and working 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 Form F.3 Revenues and Expenses, page 102, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

NHHMC C-Section Operating Rooms

	PY1 CY2021	PY2 CY2022	PY3 CY20243
Total C-Section Only Cases	637	702	773
Total Gross Revenues (Charges)	\$14,609,054	\$16,421,769	\$18,427,372
Total Contractual Adjustments*	\$7,954,776	\$8,941,817	\$10,026,155
Total Net Revenue	\$6,654,278	\$7,479,952	\$8,401,217
Average Net Revenue per Case	\$10,446	\$10,655	\$10,868
Total Operating Expenses (Costs)	\$5,726,144	\$6,438,232	\$7,235,462
Average Operating Expense per Case	\$8,989.24	\$9,171.27	\$9,360.24
Net Income	\$928,133	\$1,041,719	\$1,165,755

Totals may not sum due to rounding

*Includes Charity Care and Bad Debt as follows:

	PY1 CY2021	PY2 CY2022	PY3 CY2023
Charity Care	\$300,654	\$337,960	\$362,982
Bad Debt	\$306,790	\$344,857	\$386,975

However, as discussed above in Criterion (3), the applicant projects the C-section births as a percentage of total births based on the annualized FFY2018 percent of 28.0%. The four-

year CAGR for C-sections, as a percentage of total births, is -1.9%, a declining percentage. Based on the declining CAGR of -1.9%, the number of C-section births is reduced to 599, 648, and 701 in CY2021 through CY2023, respectively. This 10% difference in annual utilization reduces gross and net patient revenue. However, even without reducing total operating costs, which includes variable costs which would be reduced, the project remains profitable; and therefore, financially feasible in each of the first full three years of operation.

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

Conclusion

The Agency reviewed the:

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

C

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC.

On page 57, the 2018 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 62 of the 2018 SMFP, Mecklenburg County is shown as a single-county operating room service area. Thus, in this application, the service area is Mecklenburg County. Providers may serve residents of counties not included in their service area.

The following table identifies the existing dedicated C-Section ORs in the OR service area of Mecklenburg County.

**Mecklenburg County C-Section Operating Room
 Inventory and Cases
 FY2017**

	Dedicated C-Section ORs	C-Section Births	Births per C-Section OR
Carolinas Healthcare System Pineville	2	639	320
Carolinas Medical Center	4	2,091	523
Carolinas HealthCare System University	1	416	416
Carolinas HealthCare System Total	7	3,146	449
NH Presbyterian Medical Center	3	1,695	565
NH Matthews Medical Center	2	667	334
NH Huntersville Medical Center	1	424	424
Novant Health System Total	6	2,786	464
Total Mecklenburg County C-Section ORs	13	5,932	456

Source: Inventory: 2018 SMFP, Surgical Cases by Specialty: LRAs

As the table above indicates, there are six licensed hospitals in Mecklenburg County with a total of 13 dedicated C-Section ORs, having performed 5,932 total surgical C-Section cases and averaging 456 cases per C-Section OR.

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC.

In Section G, pages 50-51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved operating room services in Mecklenburg County. On page 51, the applicant states:

“The purpose of the proposed project is to meet the growing demand for C-Sections at NHHMC in the most cost-effective way possible. Therefore, other existing providers are unable to meet the identified need of patients to be served by NHHMC.”

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

- The applicant adequately demonstrates the need for the proposed project.
- The applicant adequately demonstrates that the proposed dedicated C-section OR is needed in addition to the existing or approved dedicated C-section ORs.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC.

In Section Q, Form H - Staffing for NHHMC C-Section Operating Rooms, the applicant provides current and projected staffing by number of full time equivalent (FTE) positions for the service as illustrated in the following table.

Position	Current	Projected		
	As of 5/29/2018	PY2 CY2021	PY3 CY2022	PY 3 CY2023
RNs	2.0	2.7	3.0	4.0
Technicians	1.0	1.3	1.5	2.0
Total	3.0	3.9	4.5	6.0

Source: Form H in Section Q of the application.

Totals may not sum due to rounding

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower / positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 52-55, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 56, the applicant identifies the current medical director. In Exhibit H-4b, the applicant provides a letter from the medical director indicating support for the project and providing her curriculum vitae. In Section H, pages 53-56, the applicant describes its physician recruitment plans. In Exhibit H, 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, 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.

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

C

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC.

In Section I, page 58, the applicant states that the following ancillary and support services are necessary for the proposed services:

- | | |
|------------------------------------|-----------------------------------|
| • Anesthesiology Services | • Information Technology |
| • Clinical Laboratory Services | • Legal Services |
| • Radiology Services | • Design Construction |
| • Housekeeping Services | • Facilities Planning, Accounting |
| • Plant Engineering Services | • Risk Management |
| • Business Office/Billing Services | • Interpreter Services |
| • Human Resources | • Marketing & Communications |
| • Corporate Education Training | • Public Safety |
| • Employee Occupational Health | |

On pages 58-59, the applicant adequately explains how each ancillary and support service is or will be made available.

In Section I, page 59, the applicant describes its existing and proposed relationships with other local health care and social service providers. Supporting documentation is provided in Exhibit I.

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, 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.

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

NA

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

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

NA

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

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

C

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC.

In Section K, page 62, the applicant states that the project involves renovating 1,000 square feet of existing space. Line drawings are provided in Exhibit K.2.

On pages 62-63, 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.4a.

On page 63, 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 63, the applicant identifies any applicable energy saving features that will be incorporated into the renovation plans and provides supporting documentation in Exhibit K.4c.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, 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.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and

ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC.

In Section L, page 67, the applicant provides the historical payor mix during CY2017, the last full year for the proposed services, as shown in the table below.

**Historical Payor Mix
 CY2017**

Payor Source	Entire Facility FHHMC	C-Section ORs
Self-Pay	6.1%	1.1%
Charity Care	1.1%	1.0%
Medicare *	34.8%	0.0%
Medicaid *	9.7%	16.8%
Insurance *	45.2%	79.2%
Workers Comp and Other Government	3.1%	1.9%
Total	100.0%	100.0%

Source: Page 67 of application

* Including any managed care plans

Totals may not sum due to rounding

In Section L, page 66, the applicant provides the following comparison.

	Percentage of Total Patients Served by NHHMC CY2017	Percentage of the Population of the Mecklenburg OR Service Area
Female	60.1%	51.2%
Male	39.9%	48.8%
Unknown	0.0%	0.0%
64 and Younger	70.9%	89.1%
65 and Older	29.1%	10.9%
American Indian	0.2%	1.0%
Asian	1.3%	5.5%
Black or African-American	21.7%	33.3%
Native Hawaiian or Pacific Islander	0.0%	Not Reported
White or Caucasian	68.6%	2.6%
Other Race	4.6%	57.6%
Declined / Unavailable	3.6%	0.0%

Source: Trendstar; NC Office State Budget & Management (NCOSBM); Section Q, Form C Assumptions Table 13

Data for Mecklenburg County, as provided on page 66 and in the table above, is not consistent with the data provided by the applicant in Table 13, representing the NCOSBM data. Based on Table 13, White or Caucasian should be 57.6% and Other Race should be 2.6%. Based on the comparison of the data, the applicant may have confused the rows in the table. Certainly, the 2.6% White or Caucasian for that identified service area was a red flag on the accuracy of the table.

Other than the typo reversal of percentages for White or Caucasian and Other Race, the applicant adequately identifies the extent to which underserved populations are likely to be served by the proposed project.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, 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;

C

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 67, the applicant states:

“Novant Health’s hospitals (NHFMC and NHPMC) fulfilled their Hill-Burton obligations long ago.

...

Since completing its Hill-Burton obligations, Novant Health’s acute care hospitals have continued their commitment to provide care to all persons, regardless of their ability to pay.”

In Section L, page 68, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any affiliated licensed hospitals located in North Carolina.

The Agency reviewed the:

- application,
- exhibits to the application, 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.

- (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

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC.

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

**Proposed Payor Mix
CY2022**

Payor Source	Entire Facility FHHMC	C-Section ORs
Self-Pay	6.1%	1.1%
Charity Care	1.1%	1.0%
Medicare *	34.8%	0.0%
Medicaid *	9.7%	16.8%
Insurance *	45.2%	79.2%
Workers Comp and Other Government	3.1%	1.9%
Total	100.0%	100.0%

Source: Page 69 of application

* Including any managed care plans

Totals may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.1% of C-section services will be provided to self-pay and charity care patients and 16.8% to Medicaid patients.

On page 69, 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:

- projected payor mix is based on the existing payor mix at NHHMC for C-section services, and
- the applicant will continue Novant Health's commitment to underserved populations and be accessible to those who seek care there.

The Agency reviewed the:

- application,
- exhibits to the application, 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.

- (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

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC.

In Section L, page 71, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application,
- exhibits to the application, 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.

- (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

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC.

In Section M, page 72, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- (15) Repealed effective July 1, 1987.

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

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

C

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC.

On page 57, the 2018 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 62 of the 2018 SMFP, Mecklenburg County is shown as a single-county operating room service area. Thus, in this application, the service area is Mecklenburg County. Providers may serve residents of counties not included in their service area.

The following table identifies the existing dedicated C-Section ORs in the Mecklenburg County OR service area.

**Mecklenburg County C-Section Operating Room
 Inventory and Cases
 FY2017**

	Dedicated C-Section ORs	C-Section Births	Births per C-Section OR
Carolinas Healthcare System Pineville	2	639	320
Carolinas Medical Center	4	2,091	523
Carolinas HealthCare System University	1	416	416
Carolinas HealthCare System Total	7	3,146	449
NH Presbyterian Medical Center	3	1,695	565
NH Matthews Medical Center	2	667	334
NH Huntersville Medical Center	1	424	424
Novant Health System Total	6	2,786	464
Total Mecklenburg County C-Section ORs	13	5,932	456

Source: Inventory: 2018 SMFP, Surgical Cases by Specialty: LRAs

As the table above indicates, there are six licensed hospitals in Mecklenburg County with a total of 13 C-Section ORs, having performed 5,932 total surgical C-Section cases and averaging 456 cases per C-Section OR in FY2017.

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC.

In Section N, pages 74-75, 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. The applicant states:

“The proposed expansion of C-section services at NHHMC will enhance beneficial competition and choice for the populations served by NHHMC obstetrical services. The expanded labor and delivery suite and recruitment of additional OB/GYN specialists and subspecialists will allow OB/GYNs and their patients expanded options to identify the best venue for their obstetrical care.

...

The additional C-Section ORs will allow NHHMC to manage the flow of C-Section patients better to avoid delays that extend inpatient stays and to avoid overtime costs for obstetrical staff. ... Better management of the flow of OB patients will also make costs more predictable. This will facilitate Novant Health’s ability to negotiate flat rate and bundled prices with health plans for high volume services such as obstetrics.

...

Competition can be a useful tool in expanding local geographic access to services, promoting cost effectiveness by putting downward pressure on costs of care, and encouraging the consistency in the delivery of quality care.

...

Novant Health and NHHMC have existing strategies with specific activities designed to assure services will be accessible by indigent patients without regard to ability to pay.”

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
- Information which was publicly available during the review and used by the Agency.

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

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

C

The applicant proposes to develop a second dedicated C-section OR in existing space in the labor and delivery unit on the second floor at NHHMC.

In Section O.3, page 78, the applicant identifies the acute care hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 13 hospitals with surgical services located in North Carolina.

In Section O, page 78, the applicant states that, during the 18 months immediately preceding the submittal of the application, neither DHSR nor CMS has determined that the Novant Health related facilities operated out of compliance with Medicare Conditions of participation. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no incidents related to quality of care occurred in any of the 13 Novant Health related 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 13 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) 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 demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.

-NA- The applicant does not propose 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.

.2103(b) A proposal 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 third operating year of the proposed project based on the Operating Room Need

Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.

- NA- The applicant proposes to add one additional dedicated C-section OR.
- .2103(c) *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.*
- C- The applicant demonstrates that an average of at least 365 C-sections were performed per dedicated C-section OR at NHHMC. In Section Q, page 84, the applicant shows NHHMC performed 475 C-sections in its one dedicated C-section OR in CY2017 and projects to perform 387 C-sections per OR in the third year of operation following project completion.
- .2103(d) *An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty area 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 1,312.5 hours per operating room per year; and*
 - (2) *demonstrate the need in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.*
- NA- The applicant does not propose to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty area to a specialty ambulatory surgical program.
- .2103(e) *The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*
- C- In Section Q, Form C and Tables 1-12, 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.