

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2021

Findings Date: September 27, 2021

Project Analyst: Kim Meymandi

Co-signer: Lisa Pittman

Project ID #: J-12091-21

Facility: University of North Carolina Hospitals

FID #: 923517

County: Orange

Applicant(s): University of North Carolina Hospitals at Chapel Hill

Project: Acquire one biplane unit to develop a neurovascular hybrid operating room (OR) in an existing OR located in the surgical tower currently under development on the hospital main campus in Chapel Hill

REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

University of North Carolina Hospitals at Chapel Hill, hereinafter referred to as UNC Hospitals or “the applicant”, proposes to acquire one biplane unit to develop a neurovascular hybrid operating room (OR) in an existing OR located in the surgical tower currently under development on the hospital main campus in Chapel Hill.

Need Determinations

There are no need determinations in the 2021 State Medical Facilities Plan (SMFP) applicable to the proposed project.

Policies

There is one policy applicable to this review, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities 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 for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, page 26, the applicant describes the systems and features it will incorporate to address energy efficiency and sustainability and states, “...*the design of the proposed project will incorporate materials and equipment which enhance the containment of utilities and energy costs, as applicable to the renovation proposed.*”

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the application is consistent with Policy

GEN-4 by providing a written statement describing the project's plan to assure improved energy efficiency and water conservation.

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

C

The applicant proposes to acquire one biplane unit to develop a neurovascular hybrid OR in an existing OR on the hospital main campus in Chapel Hill.

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2021 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C.2, pages 32-33, the applicant defines the service area for the proposed project as the actual patient origin of 176 surgical cases performed in SFY2020 that would have been performed in the proposed neurovascular hybrid operating room if one had been available. Facilities may also serve residents of counties not included in the service area.

The following table illustrates historical and projected patient origin.

County	Last FFY 07/01/2019-6/30/2020		3 rd FFY 7/01/2026-6/30/2027	
	# of Patients	% of Total	# of Patients	% of Total
Cumberland	25	14.2%	28	14.2%
Orange	23	13.3%	26	13.3%
Wake	16	8.9%	17	8.9%
Chatham	12	7.1%	14	7.1%
Lee	12	7.1%	14	7.1%
Alamance	11	6.2%	12	6.2%
Harnett	8	4.4%	9	4.4%
Montgomery	5	2.7%	5	2.7%
Edgecombe	5	2.7%	5	2.7%
Randolph	5	2.7%	5	2.7%
Hoke	5	2.7%	5	2.7%
Moore	5	2.7%	5	2.7%
Robeson	3	1.8%	3	1.8%
Halifax	3	1.8%	3	1.8%
Durham	3	1.8%	3	1.8%
Johnston	3	1.8%	3	1.8%
Richmond	3	1.8%	3	1.8%
Guilford	3	1.8%	3	1.8%
Scotland	3	1.8%	3	1.8%
New Hanover	3	1.8%	3	1.8%
Wayne	3	1.8%	3	1.8%
Other*	17	9.8%	19	9.8%
Total	176	100.0%	195	100.0%

Source: Section C.3, pages 32 & 35

*Other includes all other North Carolina counties and other states

In Section C, page 34, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states:

“The projected patient origin for the proposed neuro vascular hybrid operating rooms is based on the actual patient origin of the 176 surgical cases performed in SFY 2020 that would be performed in the neurovascular hybrid operating room applied to projected neurovascular hybrid operating room cases. The proposed addition of a fixed biplane unit to an existing operating room to develop a neurovascular hybrid operating room is not expected to have any impact on patient origins for the patients requiring these procedures.”

The applicant’s assumptions are reasonable and adequately supported based on the following reasons:

- The applicant bases projections on historical surgical case data at UNC Hospitals appropriate for a neurovascular hybrid operating room.
- The projected patient origin is consistent with the historical patient origin.

Analysis of Need

In Section C, pages 37-39, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states that the need for the project is based on the following three factors:

Improved quality and patient outcomes (page 38)

The applicant proposes to use the biplane unit to primarily perform neurovascular surgical procedures, including aneurysm repair, carotid endarterectomies, and Transcarotid Artery Revascularization (TCAR) procedures but will also utilize it to perform ENT, orthopedic and advanced vascular surgical procedures. The applicant states that the biplane equipment provides more detailed imaging and less invasive incisions than the mobile C-arm machine currently utilized for neurovascular surgical procedures, resulting in improved oxygenation and blood flow to the brain thereby increasing safety and decreasing risks and recovery time.

Support teaching initiatives (page 38)

The applicant states that development of a neurovascular hybrid OR equipped with a biplane unit will support teaching initiatives and the recruitment of surgeons specializing in neurovascular procedures. The applicant states that with the use of the biplane, complex procedures can be performed more efficiently, and this will benefit both doctors and patients.

Eliminating the need to move patients during surgery (page 39)

The applicant states that UNC Hospitals currently has one biplane unit that is located in an Interventional Radiology procedure room. The applicant states that development of a biplane unit within a neurovascular hybrid OR will eliminate the need to move patients across the hospital campus during surgery, thereby reducing surgical case times and the risk of unnecessary surgical complications.

The information is reasonable and adequately supported based on the following reasons:

- Use of a biplane unit can provide multiple benefits to patients including increased image quality, smaller incisions, and a decrease of complications.
- UNC Hospital is a state-owned academic medical center and access to a neurovascular hybrid OR will support teaching initiatives and surgeon recruitment.
- Acquisition of a biplane unit and locating it in a neurovascular hybrid OR will provide improved access, efficiency and overall satisfaction for surgery patients.

Projected Utilization

In Section Q, Form C.2b, the applicant provides projected utilization, as illustrated in the following table.

	Partial FY 4/11/2024- 6/30/2024	1st Full FY 7/1/2024- 6/30/2025	2nd Full FY 7/1/2025- 6/30/2026	3rd Full FY 7/1/2026- 6/30/2027
Biplane Units	1	1	1	1
# of Procedures	41	189	192	195

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

Step 1: Identify the number of neurovascular surgical cases SFY 2019 and SFY 2020 that would benefit from the neurovascular hybrid OR

	SFY 2019	SFY 2020	Growth
Cases benefitting from Neurovascular Hybrid OR	121	176	55

Source: UNC Hospital internal data

Step 2: Calculate historical growth rate of inpatient OR cases

UNC Hospitals Historical Inpatient Operating Room Cases

	SFY 2017	SF 2018	SFY 2019	Pre-COVID CAGR 2017- 2019
UNC Medical Center Inpatient Cases	12,796	12,974	12,950	0.6%
UNC Hospitals Hillsborough Campus Inpatient Cases	1,150	1,228	1,412	10.8%
Total inpatient Cases	13,946	14,202	14,362	1.5%

- The applicant uses the total inpatient OR cases for the period SFY 2017 to 2019 to calculate a compounded annual growth rate (CAGR).
- In calculating the CAGR, the applicant did not use data from SFY 2020 or SFY 2021 due to the impact of the COVID-19 pandemic when all elective procedures and admissions were suspended.

Step 3: Project total future utilization of the biplane unit based on historical data

	SFY 2021	SFY 2022	SFY 2023	SFY 2024	SFY 2025	SFY 2026	SFY 2027	Pre-COVID CAGR 2017-2019
Potential Neurovascular Hybrid OR Cases	179	181	184	187	189	192	195	1.5%
Cases utilizing the biplane unit in the Hybrid OR				41*	189	192	195	1.5%

*utilization adjusted to reflect April 11, 2024 start date

- The applicant projects the potential number of neurovascular hybrid OR cases to grow by the pre-COVID surgical volume CAGR of 1.5%.
- The applicant projects the number of cases utilizing the biplane unit in the Hybrid OR to grow by the pre-COVID surgical volume CAGR of 1.5%.
- The applicant states that the OR cases projected to be performed using the biplane unit are not in addition to cases projected to be performed at UNC Medical Center in CON Project ID# J-012092-21 currently under review; rather, the cases projected to be performed using the proposed biplane unit will be a subset of cases projected to be performed at UNC Medical Center.
- The applicant states that the projected growth in utilization from SFY20 to SFY27 of 19 cases is conservative given the historical growth of 55 cases from SFY19 to SFY20.

Projected utilization is reasonable and adequately supported based on the following:

- The applicant relies on historical data from UNC Hospitals to project future utilization.
- The number of biplane unit appropriate cases at UNC Hospitals relies on historical cases from SFY19 and SFY20 and is projected through SFY27 based on the CAGR growth rate of IP OR cases prior to COVID.

Access to Medically Underserved Groups

In Section C.6, page 46 the applicant states, “No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status, or lack of medical insurance.” The applicant provides the estimated percentage for each medically underserved group during the third fiscal year, as shown in the following table.

Medically Underserved Groups	Percentage of Patients in 3rd Full Fiscal Year
Low income persons	Not available
Racial and ethnic minorities	39.4%
Women	41.7%
Persons with Disabilities	Not available
The elderly (persons 65 and older)	29.2%
Medicare beneficiaries	34.1%
Medicaid recipients	14.7%

Source: Table on page 46 of the application

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides an estimate for each medically underserved group it proposes to serve.
- The applicant provides written statements about offering access to all residents of the state, including underserved groups.

Conclusion

The Agency reviewed the:

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

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

- (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, ... persons [with disabilities], 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 acquire one biplane unit to develop a neurovascular hybrid OR in an existing OR on the hospital main campus in Chapel Hill.

In Section E, page 56, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the status quo* - The applicant states that maintaining the status quo is not an effective alternative because it would not be in the best interests of the hospital's patients, it would limit the hospital's teaching capabilities and prevent the hospital from providing the highest possible quality care.
- *Develop the hybrid OR on the Hillsborough campus* – The applicant states that developing the hybrid OR on the Hillsborough campus of UNC Hospitals would be more costly, would impact daily operations, hinder surgical capacity and fail to optimize the standard of care at UNC Hospital. The applicant states that UNC Hospital main campus is better equipped to perform complex surgical procedures and handle any major complications.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. University of North Carolina Hospitals at Chapel Hill (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall acquire a biplane unit to be located in a vascular hybrid operating room, developed in an existing operating room on the hospital main campus in Chapel Hill.**
- 3. Upon completion of the project, UNC Hospitals shall have a total of no more than 57 ORs (49 ORs on the main campus and 8 ORs on the Hillsborough campus) upon approval and completion of Project ID #J-12092-21 (add 3 ORs), and completion of Project ID #J-11644-18 (add 2 ORs), Project ID #J-11646-18 (add 2 ORs), and Project ID #J-11695-19 (add 1 OR).**
- 4. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**

- d. Progress reports shall be due on the first day of every sixth month. The first progress report shall be due on April 1, 2022. The second progress report shall be due on October 1, 2022 and so forth.**
 - 5. The certificate holder 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.**
 - 6. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder 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.**
 - 7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to acquire one biplane unit to develop a neurovascular hybrid OR in an existing OR on the hospital main campus in Chapel Hill.

Capital and Working Capital Costs

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

Site Costs	\$0
Construction Costs	\$830,900
Miscellaneous Costs	\$3,111,237
Total	\$3,942,137

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following reasons:

- Construction costs are based on the experience of the project architect and similar projects.
- Medical equipment costs and other costs include in miscellaneous costs are based on vendor estimates and the experience of the applicant with similar projects.

In Section F, pages 60-61, the applicant projects there will be no start-up, initial operating expenses and does not involve working capital.

Availability of Funds

In Section F, page 58, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	UNC Hospitals at Chapel Hill	Total
Loans	\$0	\$0
Cash and Cash Equivalents Accumulated reserves or Owner's Equity	\$3,942,136	\$3,942,136
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$3,942,136	\$3,942,136

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- Exhibit F.2-1 contains a letter from the Chief Accounting Officer of UNC Hospitals committing to fund the total projected capital cost of the project with accumulated reserves.
- Exhibit F.2-2 contains the most recent audited financial statements for UNC Hospitals, showing adequate funds to cover the projected capital costs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. On Form F.2 in Section Q, the applicant projects

revenues will exceed operating expenses in the first three full fiscal years following completion of the project, and provided the calculations shown in the table below.

UNC Medical Center’s Surgical Services Projected Revenue & Expenses			
FYs 1-3 (7/1/2024-6/30/2028)			
	FY 1 (7/1/24-6/30/25)	FY 2 (7/1/25-6/30/26)	FY 3 (7/1/26-6/30/27)
Total Surgical Cases Per Year*	26,936	27,648	28,383
Total Gross Revenue (Charges)	\$708,795,041	\$749,458,411	\$792,548,340
Total Net Revenue	\$280,696,695	\$296,800,185	\$313,864,639
Average Net Revenue per Surgical Case	\$10,421	\$10,735	\$11,058
Total Operating Expenses (Costs)	\$204,668,787	\$214,282,804	\$224,405,824
Average Operating Expense per Surgical Case	\$7,598	\$7,750	\$7,906
Net Income	\$76,027,909	\$82,517,381	\$89,458,815

*From clarifying information submitted to the Agency

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q and in clarifying information submitted to the Agency. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Total gross revenue is based on total projected surgical cases and an average charge based on FY 2020 average charge per case inflated annually at 3%.
- The applicant bases revenues and expenses on the broader surgical services at UNC Medical Center due to the proposed neurovascular hybrid OR and biplane unit not showing profitability as stand-alone service components.
- The applicant accounts for projected operating expenses, such as salaries, consistent with projections elsewhere in the application.
- Projected utilization is based on reasonable and adequately supported assumptions. See clarifying information submitted regarding projected utilization in Criterion (3) for Project ID# J-12092-21, which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 based on the following:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.

- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - 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 revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to acquire one biplane unit to develop a neurovascular hybrid OR in an existing OR on the hospital main campus in Chapel Hill.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2021 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section G.1, page 68, the applicant defines the service area for the proposed project as the same as for surgical services, which is as defined by the 2021 SMFP, Orange County. Facilities may also serve residents of counties not included in the service area.

In Section G, page 68, the applicant states it believes its proposal would not result in the unnecessary duplication of existing or approved neurovascular hybrid ORs with biplane units. The applicant states they currently operate two hybrid ORs and neither includes a fixed biplane unit and neither is a neurovascular hybrid operating room. Currently, there are no other fixed biplane units in Orange County and the applicant does not propose to increase the number of ORs. On page 69, the applicant states, “*...UNC Hospitals’ existing biplane unit is located within its interventional radiology department, making it difficult to utilize for other surgical interventions. The development of a second biplane unit within an operating room in the surgical tower currently under development will be used exclusively for surgical services and will obviate the need to move patients from room to room or across campus to access the existing biplane unit, thus improving efficiency and patient satisfaction while also enabling UNC hospitals to provide a broader scope of services to the community.*”

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

- Publicly available data does not track the number of neurovascular hybrid ORs and biplane units and the applicant adequately demonstrates that the proposed acquisition of a biplane unit to develop a neurovascular hybrid OR in an existing OR on the hospital main campus in Chapel Hill is needed in addition to any existing biplane units and neurovascular ORs in the service area.

- The applicant adequately demonstrates that the proposed biplane unit would be used in a neurovascular hybrid OR for surgical services when appropriate and would not result in any unnecessary duplication of services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 all the reasons described above.

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

C

The applicant proposes to acquire one biplane unit to develop a neurovascular hybrid OR in an existing OR on the hospital main campus in Chapel Hill.

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

Position	Current FTE Staff	Projected FTE Staff		
	FY2020	1 st Full Fiscal Year FY2026	2nd Full Fiscal Year FY2027	3rd Full Fiscal Year FY2028
Registered Nurse	222.20	257.20	257.20	257.20
Surgical Technician	140.95	159.28	159.28	159.28
Aides/Orderlies	37.63	45.29	45.29	45.29
Clerical Staff	5.41	6.08	6.08	6.08
Radiology Technologists	0.20	0.20	0.20	0.20
Respiratory Therapists	0.56	0.56	0.56	0.56
Administrator	26.04	26.37	26.37	26.37
Business Office	26.84	26.84	26.84	26.84
Perfusionist	5.13	5.13	5.13	5.13
Phlebotomist	1.89	1.89	1.89	1.89
Total	466.86	528.86	528.86	528.86

The assumptions and methodology used to project staffing are provided in Section H, page 71, and Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.3b. In Section H.2 and

H.3, pages 71-72, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following reasons:

- UNC Hospitals has historically been able to meet staffing needs of the facility utilizing a variety of means to both recruit and maintain staff.
- The proposed project does not involve the addition of any new positions and current staff do not require any additional training for the operation of the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire one biplane unit to develop a neurovascular hybrid OR in an existing OR on the hospital main campus in Chapel Hill.

Ancillary and Support Services

In Section I.1, page 73, the applicant identifies the necessary ancillary and support services for the proposed services. On page 73, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- UNC Hospitals is an existing facility that currently already provides all the identified ancillary and support services.
- UNC Hospitals is an established facility that has historically been able to meet the need for ancillary and support services.
- The applicant provides a letter from the President of UNC Hospitals documenting that the provision of ancillary and support services within the facility will continue.

Coordination

In Section I.2, page 74, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because UNC Hospitals is an existing hospital with extensive working relationships with area healthcare and social service providers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

The applicant is not an HMO. 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 acquire one biplane unit to develop a neurovascular hybrid OR in an existing OR on the hospital main campus in Chapel Hill.

In Section K, page 77, the applicant states that the project does not involve the construction of new space; rather, it involves renovating 1,554 square feet of space by adding four steel support beams to an existing OR located on Level 2 of the CON exempt surgical tower currently under development. Line drawings are provided in Exhibit C.1-2.

On pages 77-78, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The renovation is a minor upfit to the CON-exempt surgical tower currently under development.
- The majority of the design and construction costs for the proposed project are accounted for in the construction of the CON-exempt surgical tower and existing OR.

On page 78, 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 based on the following:

- The proposed biplane unit will improve the efficiency of procedures performed, reducing the need for additional interventions.
- The project involves a minor upfit to a space already being developed.
- The applicant states that the proposed project will be funded through accumulated reserves and therefore will not require an increase in charges.

On pages 78 and 79, the applicant identifies how any applicable energy saving features will be incorporated into the construction plans.

- (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 ... persons [with disabilities], 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 acquire one biplane unit to develop a neurovascular hybrid OR in an existing OR on the hospital main campus in Chapel Hill.

In Section L, page 82, the applicant provides the historical payor mix during the last full FY (7/1/2019 to 6/30/2020) for all services at UNC Hospitals, as shown in the table below.

UNC Hospitals: All Services

Payor Category	Percent of Total Patients Served
Self-Pay	8.8%
Charity Care [^]	--
Medicare*	34.1%
Medicaid*	14.7%
Insurance*	37.7%
Workers Compensation**	--
TRICARE**	--
Other	4.7%
Total	100.0%

*Including any managed care plans

[^]Information not available

^{^^}Information included in Other

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

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	41.7%	52.3%
Male	58.3%	47.7%
Unknown	0.0%	0.0%
64 and Younger	70.8%	85.40%
65 and Older	29.2%	14.6%
American Indian	0.8%	0.6%
Asian	2.1%	8.1%
Black or African American	22.5%	11.8%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	60.6%	76.9%
Other Race	9.8%	2.5%
Declined / Unavailable	4.1%	0.0%

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

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 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 persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 84, the applicant states it has no such obligation.

In Section L, page 85, the applicant states that during the last 18 months no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 86, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	Percent of Total Patients Served
Self-Pay	9.2%
Charity Care [^]	--
Medicare*	26.2%
Medicaid*	20.6%
Insurance*	30.7%
Workers Compensation ^{^^}	--
TRICARE ^{^^}	--
Other	13.3%
Total	100.00%

*Including any managed care plans

[^]Information not available

^{^^}Information included in Other

As shown in the table above, during third full fiscal year of operation, the applicant projects that 9.2% of total services will be provided to self-pay patients, 26.2% to Medicare patients and 14.85% to Medicaid patients.

On page 85, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following reasons:

- UNC Hospitals relied on historical data from its FY2020 payor mix for surgical services.
- UNC Hospitals held the historical payor mix constant through the third project year (7/1/2027 to 6/30/2028).

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.5, page 87, 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

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 acquire one biplane unit to develop a neurovascular hybrid OR in an existing OR on the hospital main campus in Chapel Hill.

In Section M, pages 89-90, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following reasons:

- UNC Hospitals is an academic medical center with a long history of supporting health professional training programs in the community.
- UNC Hospitals serves as a clinical teaching site for a broad range of healthcare disciplines and has numerous health professional schools on campus. A complete list of accredited residencies and fellowships is provided on page 89 of the application.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire one biplane unit to develop a neurovascular hybrid OR in an existing OR on the hospital main campus in Chapel Hill.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2021 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section G.1, page 68, the applicant defines the service area for the proposed project as the same for surgical services, which is as defined by the 2021 SMFP, Orange County. Facilities may also serve residents of counties not included in the service area.

In Section G, page 68, the applicant states they currently operate two hybrid ORs and neither includes a fixed biplane unit and neither is a neurovascular hybrid operating room. Currently, there are no other fixed biplane units in Orange County and the applicant does not propose to increase the number of ORs.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 92, the applicant states:

"...the proposed project will enhance competition by enhancing and expanding the types of surgical services available at UNC Hospitals, which will improve its ability to compete with other providers."

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 92-93, the applicant states:

"UNC Hospitals' proposal aims to maximize value by utilizing space currently under construction that can accommodate the neurovascular hybrid operating room instead of undergoing new or additional construction."

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, pages 93-95, the applicant states:

"UNC Hospitals is known for providing high quality services and expects the proposed project to enhance and expand its surgical offerings while bolstering its high-quality reputation. The proposed project will add a needed neurovascular hybrid operating room to UNC Medical Center to support surgical cases that are best provided with this equipment."

UNC Hospitals has a demonstrated reputation for providing high quality healthcare services to its patients and is committed to continuing to provide excellent, high quality healthcare. UNC Health, including UNC Hospitals, has earned various rankings and awards that demonstrate its ability to provide ongoing quality care."

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 95, the applicant states:

"As North Carolina's only state owned, comprehensive, full service hospital system, UNC hospitals has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status or lack of medical insurance as demonstrated in Section C.6."

See also Sections L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 based on all the reasons described above.

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

C

In Section Q, Form O, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 19 of this type of facility located in North Carolina.

In Section O.4, page 98, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these facilities. However, both facilities timely submitted plans of correction which were accepted with follow-up reviews being conducted at each facility for documentation. 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 occurred in two of these facilities, Johnston Health and UNC Health Southeastern. As of the date of this decision, both facilities had made the appropriate corrections and were back in compliance.

After reviewing and considering information provided by the applicant, the Acute and Home Care Licensure and Certification Section, DHSR, considering the quality of care provided at all 19 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.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to acquire one biplane unit to develop a neurovascular hybrid OR in an existing OR on the hospital main campus in Chapel Hill. There are no administrative rules that are applicable to this proposal.