

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 21, 2022

Findings Date: June 21, 2022

Project Analyst: Kim Meymandi

Co-Signer: Lisa Pittman

Project ID #: J-12215-22

Facility: University of North Carolina Medical Center

FID #: 923517

County: Orange

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

Project: Acquire no more than one heart-lung bypass machine pursuant to Policy AC-6 of the 2022 SMFP

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 no more than one heart-lung bypass machine pursuant to Policy AC-6 of the 2022 SMFP.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2022 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There is one policy in the 2022 SMFP which is applicable to this review. *Policy AC-6: Heart-Lung Bypass Machines for Emergency Coverage*, on page 22 of the 2022 SMFP, states:

“To protect cardiac surgery patients, who may require emergency procedures while scheduled procedures are underway, a need is determined for one additional heart-lung bypass machine whenever a hospital is operating an open-heart surgery program with only one heart-lung bypass machine. The additional machine is to be used to assure appropriate coverage for emergencies and in no instance shall this machine be scheduled for use at the same time as the machine used to support scheduled open-heart surgery procedures. A certificate of need application for a machine acquired in accordance with this provision shall be exempt from compliance with the performance standards set forth in 10A NCAC 14C .1703.”

In Section B, page 26, the applicant explains why it believes its application is consistent with Policy AC-6. The applicant states,

“...UNC Hospitals’ open-heart surgery services include two programs, a pediatric open-heart surgery program with only one heart-lung bypass machine and an adult open-heart surgery program with three heart-lung bypass machines. The proposed project seeks to acquire one additional heart-lung bypass machine for emergency backup that is exclusively configured for and dedicated to the pediatric open-heart surgery program.

The proposed heart-lung bypass machine will not be used for scheduled cases but will be used to ensure appropriate coverage for pediatric emergencies requiring open-heart surgery utilizing a heart-lung bypass machine, and in no instance will it be scheduled for use at the same time as the existing heart-lung bypass machine dedicated to UNC Hospitals’ pediatric open-heart surgery program to support scheduled open-heart surgery procedures.”

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 the following reasons:

- The applicant adequately demonstrates that the proposal is consistent with Policy AC-6 for the following reasons:

- The applicant adequately documents that the acquisition of the proposed heart-lung bypass (HLB) equipment is necessary to accommodate and assure appropriate coverage for emergencies in the pediatric open-heart surgery program.
 - The applicant provides a written statement that the proposed HLB machine will not be used for scheduled cases and will in no instance be scheduled for use at the same time as the existing pediatric HLB machine.
- (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.

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UNC Hospitals proposes to acquire no more than one HLB machine pursuant to Policy AC-6 of the 2022 SMFP. The proposed equipment will be stored in the same space as the pediatric open-heart surgery program's existing HLB machine on the hospital's main campus in Chapel Hill and will be moved into an operating room only when needed for an emergency procedure if the pediatric open-heart surgery program's existing HLB machine malfunctions or is in use at the same time. In Section C.1, page 28, the applicant further explains the location of the proposed HLB machine as follows:

“UNC Hospitals is currently developing a replacement surgical tower on the Medical Center campus. The exempt surgical tower project involves the replacement and relocation of existing operating rooms from the main hospital building to the replacement surgical tower. In addition to the relocation of existing operating rooms, UNC Hospitals will relocate the three existing heart-lung bypass machines configured for adult patients to the new surgical tower, at which time pediatric and adult open-heart surgery cases will be performed in different locations and only the one heart-lung bypass machine configured for pediatric patients will remain at its current location, which, as detailed below, further necessitates the need for an emergency backup heart-lung bypass machine for the pediatric open-heart surgery program.”

Patient Origin

On pages 100-102, the 2022 SMFP discusses open heart surgery services in North Carolina. Open heart surgery services, as defined in Gen. Stat. §131E-176(18b) is *“The provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects.”*

Table 7B, page 101 of the 2022 SMFP, indicates there were 22 open-heart surgery programs in North Carolina in 2020, providing a statewide total of 9,011 procedures.

The 2022 SMFP does not discuss a need methodology or provide a definition of “service area” for open heart surgery services. However, N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” On page 50, the 2022 SMFP states, “*The SMFP contains two types of OR service areas: single and multicounty. Counties with at least one facility having a licensed OR that are not grouped with another county are single county service areas.*” In Figure 6.1, page 55 of the 2022 SMFP, Orange County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Orange County. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 32 and C.3, page 35, the applicant provides the historical and the projected patient origin for the first three full fiscal years (Full FY) of the proposed project, by county, as illustrated in the table below.

UNC Medical Center: Open Heart Surgery Utilizing HLB

County	Historical (FY2021)		Third Full FY of Operation following Project Completion (FY2026)	
	Patients	% of Total	Patients	% of Total
Wake	46	11.9%	49	11.9%
Orange	36	9.1%	38	9.1%
Alamance	32	8.1%	34	8.1%
Cumberland	26	6.7%	28	6.7%
Nash	20	5.2%	21	5.2%
Chatham	19	4.9%	20	4.9%
Durham	16	4.2%	17	4.2%
Robeson	14	3.7%	15	3.7%
Moore	12	3.0%	12	3.0%
Lee	11	2.7%	11	2.7%
Guilford	10	2.5%	10	2.5%
Other*	149	38.0%	157	38.0%
Total	391	100.0%	413	100.0%

Source: Section C.2 and C.3, pages 32 and 35 of the application, respectively.

*Counties and other states included in the “Other” category are shown below the tables on pages 32 and 35 of the application.

In Section C.3(a), page 34, the applicant states that the projected patient origin is based on the historical patient origin for open-heart surgery utilizing a HLB machine at UNC Medical Center. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The projected patient origin is consistent with the historical patient origin.
- The applicant does not propose to develop any services or make any changes to its facility that could foreseeably impact the projected patient origin in more than minor ways.

Analysis of Need

In Section C.4, pages 37-41, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The need for emergency backup HLB machine dedicated to pediatric open-heart surgery (pages 37-40).
- The population growth in Orange County and throughout North Carolina particularly for the under 18 population (page 40).

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

- The applicant presents reasonable and credible information with regard to the necessary configurations for a HLB machine to serve pediatric patients.
- The applicant identifies the population to be served, the projected growth of the population within its identified service area, and the need the identified population has for the proposed services.
- The applicant provides reasonable information to support the need for the addition of a HLB machine to be used solely as backup for emergency coverage in the pediatric open-heart surgery program.

Projected Utilization

In Section Q, Form C, the applicant provides historical and projected utilization, as illustrated in the following table:

UNC Hospitals Heart-Lung Bypass Machines

	SFY 2021	SFY 2022	SFY 2023	SFY 2024 PY1	SFY 2025 PY2	SFY 2026 PY3
Number of Units	4	4	5	5	5	5
Actual and projected number of cases	391	395	400	404	408	413

Note: In Section Q, the applicant states that at no time will the proposed HLB machine be used for scheduled procedures.

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

- The applicant's fiscal year (FY) corresponds with the State Fiscal Year (SFY), which follows a July 1 through June 30 timeframe.
- The applicant projects the proposed project will be operational January 1, 2023, the beginning of the third quarter of SFY2023, therefore the first three full fiscal years are SFY2024, SFY2025, and SFY2026.
- UNC Hospitals is applying to acquire an additional HLB machine pursuant to Policy AC-6 of the 2022 SMFP. This policy does not require the applicant to meet a performance standard as the proposed HLB machine will be for emergency backup and exclusively configured for and dedicated to the pediatric open-heart surgery program.

- The applicant assumes a 1.1% annual growth rate for the projected number of open-heart procedures utilizing a HLB machine based on the compounded annual growth rate (CAGR) of North Carolina statewide population data from SFY2021 to SFY2026 obtained from Esri.
- The applicant assumes a 1.1% annual growth rate for the projected number of open-heart procedures with a HLB machine on standby based on the CAGR of North Carolina statewide population data from SFY2021 to SFY2026 obtained from Esri.
- The applicant does not propose to schedule any procedures on the proposed HLB machine, but rather will use the machine for emergency back up in the pediatric open-heart surgery program.
- The applicant’s projections are illustrated in the following table:

**UNC Hospitals Projected Total Open-Heart Procedures*
 SFY2021-SFY2026**

	SFY 2021	SFY 2022	SFY 2023	SFY 2024	SFY 2025	SFY 2018	CAGR 2021-2026
Open-Heart Procedures Utilizing a HLB Machine	391	395	400	404	408	413	1.1%
Open-Heart Procedures with a HLB Machine on Standby	161	163	165	166	168	170	1.1%
Total Open-Heart Surgery Procedures	552	558	564	570	577	583	1.1%

*adult and pediatric programs combined

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

- The applicant reasonably projects an increase in open-heart procedures utilizing a HLB machine and open-heart procedures with a HLB machine on standby based on the projected population growth rate for North Carolina statewide population from SFY2021 to SFY2026.
- The applicant provides reasonable and adequately supported information to justify the qualitative need for the proposed HLB machine pursuant to policy AC-6 in the 2022 SMFP.

Access to Medically Underserved Groups

In Section C.6, pages 47-48, the applicant states it will provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental condition, age, ability to pay, or any other factor.

The applicant provides the estimated percentage for each medically underserved group to be served during the third full fiscal year, as shown in the following table.

Medically Underserved Groups	3rd FY Percentage of Total Patients
Low income persons	Data unavailable
Racial and ethnic minorities	35.1%
Women	58.5%
Persons with Disabilities	Data unavailable
Persons 65 and older	29.0%
Medicare beneficiaries	33.7%
Medicaid recipients	13.5%

Source: Section C., page 48

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 has historically provided access to services to underserved groups.
- The applicant provides its projected payor mix, which includes underserved groups, and assumes it will remain constant for the first three years of operation.

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 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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services 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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose the reduction or elimination of a 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

UNC Hospitals proposes to acquire no more than one HLB machine pursuant to Policy AC-6 of the 2022 SMFP.

In Section E.2, pages 58-59, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the status quo* – The applicant states this alternative fails to address the needs of UNC Medical Center’s open-heart patients and would not ensure adequate emergency capacity for the pediatric open-heart program, particularly when the adult heart lung program moves to the surgical tower.
- *Reconfigure an existing HLB Machine* – The applicant states this is not a feasible alternative because it would result in the adult open-heart program having only two HLB machines; one for scheduled open-heart surgeries and one for emergency backup and would not be adequate to serve the needs of the adult open-heart program.
- *Acquire an additional HLB machine to be used for scheduled pediatric open-heart cases* – The applicant states that current pediatric open-heart surgery utilization volume does not support acquiring an additional HLB machine for the purpose of regularly-scheduled cases.

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

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 no more than one heart lung bypass machine pursuant to Policy AC-6 of the 2022 SMFP.**
 3. **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. **The first progress report shall be due on December 1, 2022.**
 4. **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.**
 5. **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.**
 6. **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

UNC Hospitals proposes to acquire no more than one HLB machine pursuant to Policy AC-6 of the 2022 SMFP.

Capital and Working Capital Costs

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

UNC Hospitals Capital Costs	
Medical Equipment Cost	\$275,708
Total	\$275,708

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:

- In Exhibit F.1, the applicant provides documentation to support the price for the HLB machine.
- In Section F, page 61 the applicant states that additional costs for equipment are based on the experience developing other similar services.
- In Section F, page 63, the applicant states that there will be no start-up or initial operating costs associated with this project.

Availability of Funds

In Section F.2, page 61, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing		
Type	UNC Hospitals	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$275,708	\$ 275,708
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$275,708	\$275,708

* OE = Owner's Equity

In Exhibit F.2-1, the applicant provides a letter dated April 15, 2022, from the Chief Financial Officer for UNC Hospitals, documenting the availability of funds to finance the proposed project. Exhibit F.2-2, contains the most recent financial statement for UNC Hospitals for the year ended June 30, 2021.

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

- Exhibit F.2-2 contains a copy of the audited financial statements for UNC Hospitals for the year ended June 30, 2021 which indicate that UNC Hospitals had \$107 million in cash and cash equivalents as of June 30, 2021 to fund the project.
- Exhibit F.2-1 contains a letter from the Chief Financial Officer for UNC Hospitals, documenting that UNC Hospitals intends to fund the total projected cost of the project through accumulated reserves.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years of the project, as shown in the table below.

UNC Hospitals Surgical Services Revenue and Expenses			
	FY 1 (FY2024)	FY 2 (FY2025)	FY 3 (FY2026)
Total Gross Revenues (Charges)	\$679,516,702	\$704,123,855	\$744,454,241
Total Net Revenue	\$269,416,489	\$279,172,795	\$295,163,088
Total Operating Expenses (Costs)	\$201,012,657	\$208,792,373	\$218,514,980
Net Income / (Loss)	\$68,403,832	\$70,380,422	\$76,648,108

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

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

UNC Hospitals proposes to acquire no more than one HLB machine pursuant to Policy AC-6 of the 2022 SMFP.

On pages 100-102, the 2022 SMFP discusses open heart surgery services in North Carolina. Open heart surgery services, as defined in Gen. Stat. §131E-176(18b) is “*The provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects.*”

The 2022 SMFP does not discuss a need methodology or provide a definition of “service area” for open heart surgery services. However, N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” On page 50, the 2022 SMFP states, “*The SMFP contains two types of OR service areas: single and multicounty. Counties with at least one facility having a licensed OR that are not grouped with another county are single county service areas.*” In Figure 6.1, page 55 of the 2022 SMFP, Orange County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Orange County. Facilities may also serve residents of counties not included in their service area.

Table 7B, page 101 of the 2022 SMFP, indicates there were 22 open-heart surgery programs in North Carolina in 2020, providing a statewide total of 9,011 procedures, as shown in the table below.

STATEWIDE OPEN-HEART SURGERY PROCEDURES				
FACILITY	CITY	COUNTY	# OF PROCURES PERFORMED IN FY2019	# OF PROCURES PERFORMED IN FY2020
Atrium Health Cabarrus	Concord	Cabarrus	194	239
Atrium Health Pineville	Pineville	Mecklenburg	234	158
Cape Fear Valley Medical Center	Fayetteville	Cumberland	195	162
CarolinaEast Medical Center	New Bern	Craven	331	219
Carolinas Medical Center	Charlotte	Mecklenburg	751	580
CaroMont Regional Medical Center	Gastonia	Gaston	240	275
Cone Health	Greensboro	Guilford	673	574
Duke Regional Hospital	Durham	Durham	151	107
Duke University Hospital	Durham	Durham	1,175	1,090
FirstHealth Moore Regional Hospital	Pinehurst	Moore	276	235
Frye Regional Medical Center	Hickory	Catawba	172	126
High Point Regional Health	High Point	Guilford	123	176
Mission Hospital	Asheville	Buncombe	1,198	1,051
New Hanover Regional Medical Center	Wilmington	New Hanover	466	395
North Carolina Baptist Hospital	Winston-Salem	Forsyth	942	789
Novant Health Forsyth Medical Center	Winston-Salem	Forsyth	506	380
Novant Health Presbyterian Medical Center	Charlotte	Mecklenburg	413	339
Rex Hospital	Raleigh	Wake	558	553
Southeastern Regional Medical Center	Lumberton	Robeson	78	81
University of North Carolina Hospitals	Chapel Hill	Orange	465	332
Vidant Medical Center	Greenville	Pitt	767	626
WakeMed	Raleigh	Wake	546	524
Total Procedures			10,454	9,011

UNC Hospitals proposes to acquire an additional HLB machine to be used as backup for emergency coverage only in the pediatric open-heart surgery program. The applicant does not propose any new or expanded services.

In Section G, page 71, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved open heart services with a heart-lung bypass machine in Orange County. The applicant states:

“The second heart lung bypass machine configured exclusively for pediatric patients will be used solely to assure appropriate coverage for emergencies and in no instance will it be scheduled for use at the same time as the one existing pediatric configured heart lung bypass machine, which is used to support scheduled pediatric open-heart surgery cases. As such, the proposed project will not result in any unnecessary duplication of pediatric open-heart surgery services utilizing a heart lung bypass machine.”

The applicant adequately demonstrates that the proposal will 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 an additional HLB machine configured exclusively for the pediatric open-heart surgery program to be used for emergency coverage.
- The applicant is the only provider of pediatric open-heart surgery services in Orange County.

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 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

UNC Hospitals proposes to acquire no more than one HLB machine pursuant to Policy AC-6 of the 2022 SMFP.

In Section Q Form H Staffing, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for UNC Hospitals’ HLB unit, as illustrated in the following table.

POSITION	Current FTE Staff	Projected FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 06/30/21	FY1 07/01/23 to 06/30/24	FY1 07/01/24 to 06/30/25	FY1 07/01/25 to 06/30/26
Chief Perfusionist	1.0	1.0	1.0	1.0
Chief Pediatric Perfusionist	1.0	1.0	1.0	1.0
Perfusionist Staff	4.1	4.1	4.1	4.1
Total	6.1	6.1	6.1	6.1

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, page 73, 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:

- The applicant does not project an increase in the FTE staffing positions and does not propose to offer any new services.
- The methods used to recruit or fill new positions and the existing training and continuing education programs are provided.

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 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.

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Ancillary and Support Services

In Section I, pages 75-76, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is and will continue to 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:

- The stated ancillary and support services are currently available.
- The applicant provides evidence that the ancillary and support services will continue to be provided.

Coordination

In Section I, page 76, the applicant describes its existing 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 based on the following:

- The applicant provides information regarding relationships with the existing health care system in Exhibit I.1.
- The applicant provides a letter from the facility president in Exhibit I.1 committing to the continuation of the established relationships.

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.

- (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.

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (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

In Section L, pages 83 and 87, the applicant provides the projected payor mix for UNC Hospitals and open-heart surgery cases using a HLB machine for the FY2026 and states that due to uncertainty around healthcare reform these projections are consistent with the payor mix from FY2021, as shown in the table below.

Payment Source	Percent of Total for Entire Facility	Percent of Total Open-Heart Surgery using HLB
Self-Pay	9.3%	6.4%
Medicare	33.7%	36.3%
Medicaid	13.5%	24.2%
Insurance	39.4%	25.2%
Other*	4.1%	7.9%
Total**	100.0%	100.0%

*The applicant states the "Other" category includes TRICARE, Workers Compensation, Department of Corrections and other payors.

**Totals may not foot due to rounding.

In Section L.1, page 84, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility during the Last Full FY2019	Percentage of the Population of the Service Area
Female	58.5%	52.3%
Male	41.5%	47.7%
Unknown	0.0%	0.0%
64 and Younger	71.0%	85.4%
65 and Older	29.0%	14.6%
American Indian	0.8%	0.6%
Asian	2.1%	8.1%
Black or African-American	22.6%	11.8%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	60.6%	69.5%
Other Race	9.5%	9.9%
Declined / Unavailable	4.3%	0.0%

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 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 85, the applicant states,

“UNC Hospitals has long since satisfied its “free care” obligation under the Hill-Burton Act. Charity care provided by UNC Hospitals for State Fiscal Year 2021 is estimated to be \$253.4 million. UNC Hospitals provides care to all

persons based only on their need for care and without regard to minority status or handicap/disability.”

In Section L, page 86, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility identified in Section A, Question 4.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3, pages 86 and 87, the applicant projects the following payor mix for UNC Hospitals and open-heart surgery utilizing a HLB machine during the third year of operation (FY2024) following completion of the project, as shown in the following table.

Payment Source	Percent of Total for Entire Facility	Percent of Total Open-Heart Surgery using HLB
Self-Pay	9.3%	6.4%
Medicare	33.7%	36.3%
Medicaid	13.5%	24.2%
Insurance	39.4%	25.2%
Other*	4.1%	7.9%
Total**	100.0%	100.0%

*The applicant states the "Other" category includes TRICARE, Workers Compensation, Department of Corrections and other payors.

**Totals may not foot due to rounding.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 6.4 percent of total open-heart surgery utilizing a HLB machine will be provided to self-pay patients, 36.3 percent to Medicare patients, and 24.2 percent to Medicaid patients.

In Section Q, 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 because it is based on the applicant's historical experience.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 88, 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

UNC Hospitals proposes to acquire no more than one HLB machine pursuant to Policy AC-6 of the 2022 SMFP.

In Section M, pages 90-91, 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 will have access to the facility for training purposes based on the following:

- The applicant currently provides applicable health professional training programs in the community at large with access to the facility

- The applicant sponsors numerous fellowship training programs, providing access to its clinical departments and various divisions.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

UNC Hospitals proposes to acquire no more than one HLB machine pursuant to Policy AC-6 of the 2022 SMFP.

On pages 100-102, the 2022 SMFP discusses open heart surgery services in North Carolina. Open heart surgery services, as defined in Gen. Stat. §131E-176(18b) is *“The provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects.”*

The 2022 SMFP does not discuss a need methodology or provide a definition of “service area” for open heart surgery services. However, N.C.G.S. §131E-176(24a) states: *“Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.”* On page 50, the 2022 SMFP states, *“The SMFP contains two types of OR service areas: single and multicounty. Counties with at least one facility having a licensed OR that are not grouped with another county are single county service areas.”* In Figure 6.1, page 55 of the 2022 SMFP, Orange County is shown as a single-county operating room service area. Thus, the

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

Table 7B, page 101 of the 2022 SMFP, indicates there were 22 open-heart surgery programs in North Carolina in 2020, providing a statewide total of 9,011 procedures, as shown in the table below.

STATEWIDE OPEN-HEART SURGERY PROCEDURES				
FACILITY	CITY	COUNTY	# OF PROCURES PERFORMED IN FY2019	# OF PROCURES PERFORMED IN FY2020
Atrium Health Cabarrus	Concord	Cabarrus	194	239
Atrium Health Pineville	Pineville	Mecklenburg	234	158
Cape Fear Valley Medical Center	Fayetteville	Cumberland	195	162
CarolinaEast Medical Center	New Bern	Craven	331	219
Carolinas Medical Center	Charlotte	Mecklenburg	751	580
CaroMont Regional Medical Center	Gastonia	Gaston	240	275
Cone Health	Greensboro	Guilford	673	574
Duke Regional Hospital	Durham	Durham	151	107
Duke University Hospital	Durham	Durham	1,175	1,090
FirstHealth Moore Regional Hospital	Pinehurst	Moore	276	235
Frye Regional Medical Center	Hickory	Catawba	172	126
High Point Regional Health	High Point	Guilford	123	176
Mission Hospital	Asheville	Buncombe	1,198	1,051
New Hanover Regional Medical Center	Wilmington	New Hanover	466	395
North Carolina Baptist Hospital	Winston-Salem	Forsyth	942	789
Novant Health Forsyth Medical Center	Winston-Salem	Forsyth	506	380
Novant Health Presbyterian Medical Center	Charlotte	Mecklenburg	413	339
Rex Hospital	Raleigh	Wake	558	553
Southeastern Regional Medical Center	Lumberton	Robeson	78	81
University of North Carolina Hospitals	Chapel Hill	Orange	465	332
Vidant Medical Center	Greenville	Pitt	767	626
WakeMed	Raleigh	Wake	546	524
Total Procedures			10,454	9,011

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 93, the applicant states:

“In particular, the proposed project will enhance competition by bolstering the pediatric open-heart surgery services available at UNC Hospitals. Ensuring that there are sufficient appropriately configured heart lung bypass machines in both the pediatric and adult open heart surgery programs to provide safe, high quality care for all patients in need of open heart surgery services will improve UNC hospitals ability to compete with other providers and will thus be in compliance with the spirit and legislative intent of the Certificate of Need Law.”

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

“By acquiring and configuring the proposed emergency heart-lung bypass machine exclusively for pediatric cases, UNC Hospitals is able to provide safer, more effective, and more efficient care than the less favorable alternative of reconfiguring an existing heart-lung bypass machine from adult parameters to pediatric parameters in the event of an emergency.

...

The flexibility and cost savings associated with the ability to perform an emergency surgery is a considerably more effective use of physical and financial resources than transferring the patient to a different hospital with open-heart surgery service availability or undergoing time intensive machine reconfigurations that delay care and may increase the risks posed to the patient.”

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

Regarding the impact of the proposal on quality, in Section N, page 94, the applicant states:

“The proposed project will assure appropriate coverage in the event of an emergent need for pediatric open-heart surgery utilizing a heart-lung bypass machine while the existing pediatric configured heart-lung bypass machine is in use or otherwise unavailable.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 97, 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 as demonstrated in Section C.6.

....

UNC Hospitals expects that patients with limited financial resources will continue to access its services upon completion of the project.”

See also Sections C and L 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 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 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 based on 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

In Section Q Form O, the applicant identifies the open-heart surgery programs located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies three facilities owned, operated, or managed by UNC or a related entity and located in North Carolina.

In Section O, page 99, the applicant states that, during the 18 months immediately preceding the submittal of the application, no UNC Hospital related facility has been found to have had an incident related to quality of care that resulted in a finding of "*Immediate Jeopardy*". After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all UNC Hospital facilities, the applicant provides 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 no more than one HLB machine pursuant to Policy AC-6 of the 2022 SMFP.

The Criteria and Standards for promulgated in 10A NCAC 14C .1703 are not applicable to this review because the HLB machine to be acquired pursuant to Policy AC-6 of the 2022 SMFP is to be used and configured exclusively for pediatric patients for emergency backup only and will at no time be scheduled for use at the same time as the existing HLB machine configured for pediatric open-heart surgery procedures.