

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 27, 2022

Findings Date: April 27, 2022

Project Analyst: Kim Meymandi

Co-Signer: Lisa Pittman

Project ID #: J-12188-22

Facility: North Chapel Hill Surgery Center

FID #: 180567

County: Orange

Applicant(s): North Chapel Hill Surgery Center, LLC

University of North Carolina Health Care System

Project: Cost overrun for Project ID #J-11645-18 (develop a freestanding ambulatory surgical facility)

### 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

North Chapel Hill Surgery Center, LLC and University of North Carolina Health Care System (herein after referred to collectively as “the applicant”) proposes a cost overrun (COR) for Project ID #J-11645-18, which approved the development of a freestanding ambulatory surgical facility (ASF) in Chapel Hill by developing no more than two operating rooms pursuant to the need determination in the 2018 SMFP and two procedure rooms. Subsequently, a Material Compliance was approved in December 2021 to not develop the two procedure rooms but still develop the two operating rooms pursuant to the need determination in the 2018 SMFP. This application proposes no material change in scope from the originally approved project and the December 2021 Material Compliance.

## **Need Determination**

The original project involved a need determination pursuant to the 2018 SMFP for two operating rooms in Orange County. That application was conforming to the need determination in the 2018 SMFP and approved for development. The current COR application 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 SMFP. Therefore, there are no need determinations applicable to this review.

## **Policies**

In the current COR application, the combined projected capital cost to develop the project is greater than \$4 million; thus, Policy GEN-4: *Energy Efficiency and Sustainability for Health Service Facilities* in the 2022 SMFP applies to this review.

Policy GEN-4: *Energy Efficiency and Sustainability for Health Service Facilities*, on pages 30-31 of the 2022 SMFP, states:

*“Any person proposing a capital expenditure greater than \$4 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 is 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 combined proposed capital expenditure for this project is greater than \$5 million. In Section B, page 27, the applicant describes the plans involved in achieving energy and water conservation goals and also provides a written statement:

*“As detailed above, the design of the proposed project will incorporate materials and equipment which enhance the containment of utilities and energy costs, as applicable to the proposed cost overrun project.”*

The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

### **Conclusion**

The Agency reviewed the:

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

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

- The applicant does not propose to develop any services for which there is a need determination in the 2022 State Medical Facilities Plan (SMFP).
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because the application includes 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 a COR for Project ID #J-11645-18 (develop a freestanding ambulatory surgical facility).

A certificate of need was issued on May 30, 2019 for Project ID #J-11645-18 and authorized a capital cost of \$4,305,924. The current application proposes a capital cost increase of \$2,232,699 over the previously approved capital cost for a total combined capital cost of \$6,538,623. The cost overrun application is necessary due to increased costs for labor and materials as well as additional construction and reconfiguration of space necessary to optimize space, efficiency, and comply with building codes and licensure rules. The application proposes no material change in scope from the originally approved project and the December 2021 Material Compliance.

### **Patient Origin**

On page 49, the 2022 SMFP defines the service area for operating rooms as, “...the single or multicounty grouping shown in Figure 6.1.” In Figure 6.1, page 55 of the 2022 SMFP, Orange County is shown as a single-county OR 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 Project ID #J-11645-18, the Agency determined the applicant had adequately identified the projected patient origin for the facility. The applicant proposes no changes in the current application which would affect that determination.

**Analysis of Need**

On Form F.1b in Section Q, the applicant provides a summary of the capital cost approved in Project ID #J-11645-18, the changes proposed in this application, and the new projected capital cost, as shown in the table below.

<b>North Chapel Hill Surgery Center – Previously Approved &amp; Proposed Capital Cost</b>			
	<b>Previously Approved (J-11645-18)</b>	<b>New Total Projected Capital Cost</b>	<b>Projected Changes to Capital Cost (J-12188-22)</b>
Site Preparation	\$335,000	\$0	(\$335,000)
Construction/Renovation Contract(s)	\$1,175,760	\$3,754,978	\$2,579,218
Landscaping	\$15,000	\$0	(\$15,000)
Architect/Engineering Fees	\$90,000	\$272,455	\$182,455
Medical Equipment	\$1,625,000	\$1,641,696	\$16,696
Non-Medical Equipment	\$416,526	\$433,779	\$17,253
Furniture	\$32,190	\$20,000	(\$12,190)
Consultant Fees	\$225,000	\$219,684	(\$5,316)
Other (Contingency, Escalation, Insurance, IT Costs)	\$391,448	\$196,031	(\$195,417)
<b>Total Capital Cost</b>	<b>\$4,305,924</b>	<b>\$6,538,623</b>	<b>\$2,232,699</b>

In Section C, pages 42-43, the applicant explains why it believes the proposed increase in capital cost is necessary to develop the proposed project:

- **Increased Construction Contract Costs:** Following the issuance of the Certificate of Need for Project ID #J-11645-18, inflation and COVID-19 caused the cost of construction and materials to increase. The applicant determined that it was necessary to optimize the clinical space for the project and redesigned the upfit of the space. Construction costs also increased when the applicant identified areas in the existing space that required modifications to comply with building codes and licensure rules.
- **Increased Architect & Engineering Fees:** The applicant states that due to the lapse of time, modifications to the original design, and information required by the Town of Chapel Hill, the project line drawings had to be redrawn, thereby increasing these costs.
- **Medical Equipment/Non-Medical Equipment:** The applicant states both increased due to inflation and the resulting rising costs.

- Site Preparation and Landscaping: The applicant states costs decreased due to the applicant obtaining a new construction contract that includes site preparation and landscaping costs. These were separate line items in Project ID #J-11645-18.
- Consultant Fees: The applicant states costs decreased due to conservative estimates in the preparation and filing of Project ID #J-11645-18.
- Other Fees: The applicant states costs decreased due to a decrease in the need for future contingency fees resulting from the design phase being complete.

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

- The applicant adequately explains the reasons additional costs are necessary to develop the proposed project.
- The applicant explains why the changes to the design are necessary to develop the project in a manner compliant with building codes and licensure rules.
- The applicant provides line drawings of the proposed changes in Exhibit C.8-1 and a certified capital cost estimate in Exhibit F.5-1.

Projected Utilization

In Section C, page 44, the applicant states:

*“This cost overrun proposal in and of itself will not result in any change to projected utilization as it does not involve any change in licensed operating room services proposed in the previously approved application and subsequent material compliance approval. However, the need for this cost overrun has contributed to a delay in the start of operations for the ASF. As such, out of an abundance of caution, NCHSC has elected to provide updated utilization projections that are consistent with recent operating room projections for North Chapel Hill Surgery Center that were included in the previously approved Project ID # J-12092-21 to develop additional operating rooms at UNC Medical Center, adjusted herein for the delayed start date.”*

On Form C.3b in Section Q, the applicant projects utilization for the first three fiscal years of operation following project completion, as shown in the table below.

<b>Projected Utilization – NCHSC</b>				
	<b>Partial FY</b>	<b>1<sup>st</sup> FY</b>	<b>2<sup>nd</sup> FY</b>	<b>3<sup>rd</sup> FY</b>
	<b>(2/1/23-6/30/23)</b>	<b>7/1/23-6/30/24</b>	<b>7/1/24-6/30/25</b>	<b>7/1/25-6/30/26</b>
# of ORs	2	2	2	2
# of Surgical Cases	324	1,083	1,685	2,330
Outpatient Case Time (1)	70.1	70.1	70.1	70.1
Surgical Hours (2)	379	1,265	1,968	2,722
Group Assignment	6	6	6	6
Standard Hours/OR (3)	1,312	1,312	1,312	1,312
# of ORs Needed (4)	0.29	0.96	1.5	2.07

(1) The Final Case Time in minutes for new Group 5 facilities in the 2022 SMFP.

(2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.

(3) From Table 6B in the 2022 SMFP.

(4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

In Section Q, Form C – Assumptions and Methodology, the applicant provides the assumptions and methodology used to project utilization, as summarized below.

- The applicant uses the same assumptions used in Project ID# J-12092-21, the most recently approved UNC Health CON application for additional operating rooms in Orange County and provides the assumptions in Exhibit C.8-2.
- The applicant projects NCHSC’s utilization will grow 3.7 percent annually from SFY 2024 to 2026.
- The applicant projects that NCHSC will become operational on February 1, 2023 and assumes that the OR volume shifted to NCHSC will ramp up from 50 percent to 75 percent to 100 percent over the first three full fiscal years of operation.
- The applicant adjusts the SFY 2023 projected volume to reflect a start date of February 1, 2023 and 5 months of operation (SFY 2023 volume of 1,556 / 12 months X 5 months operation) and projects that 50 percent of the potential cases will be performed at NCHSC.
- In Section Q, page 2, the applicant provides the information for calculating the projections as shown in the following table.

<b>NCHSC Projected OR Cases</b>				
	SFY23	SFY24	SFY25	SFY26
Total OR Cases	648	2,166	2,246	2,330
Ramp Up	50%	50%	75%	100%
Cases	324	1,083	1,685	2,330

- The applicant states that based on discussions with surgeons, UNC Hospital administrators and internal data, the scope of services provided at NCHSC will not change from what was projected in Project ID# J-11645-18 and the proposed facility will be a Group 6 facility with a Facility Final Case Time of 70.1 minutes.

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

- The applicant adjusts the projected volumes based on a later start date and the most recently approved UNC Health CON application, Project ID# J-12092-21 where the Agency determined that the applicant had demonstrated projections for Orange County ORs were based on reasonable and adequately supported assumptions.
- The applicant uses the same ramp up assumptions utilized in Project ID# J-11645-18.
- The applicant relies on internal data and the experience of clinical staff and administrators to determine the scope of services at the proposed facility.

### **Access to Medically Underserved Groups**

The application for Project ID #J-11645-18, adequately demonstrated the extent to which all residents of the area, including underserved groups, were likely to have access to the proposed

services. The applicant proposes no changes in the current application which would affect that determination.

### **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.

- (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 in this application. 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 a COR for Project ID #J-11645-18 (develop a freestanding ambulatory surgical facility).

In Section E, page 51, 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 applicant states the only real alternative to the proposed project is to cease development of the previously approved Project ID #J-11645-18 and this alternative would prevent the development of a freestanding multi-specialty ASF in Chapel Hill which allows for a continuum of outpatient services that offers lower charges, convenient access, and separation from the more intensive services offered at UNC Hospitals. The applicant states that the cost overrun proposal is the most effective alternative because it allows for development of the freestanding ASF proposed in Project ID #J-11645-18.

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

- The applicant does not propose to change the scope of the previously approved Project ID #J-11645-18.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

### **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. Therefore, the application is approved subject to the following conditions:

- 1. North Chapel Hill Surgery Center, LLC and University of North Carolina Health Care System (hereinafter certificate holder) shall materially comply with the representations in this application, and the representations in Project I.D. #J-11645-18. Where representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. The certificate holder shall develop a new multi-specialty ambulatory surgical facility, North Chapel Hill Surgery Center, LLC by developing no more than two operating rooms.**
- 3. Upon completion of the project, North Chapel Hill Surgery Center, LLC shall be licensed for no more than two operating rooms.**
- 4. The approved combined capital expenditure for both Project ID #J-11645-18 and this project is \$6,538,623, an increase of \$2,232,699 over the previously approved capital expenditure of \$4,305,924 in Project ID #J-11645-18.**
- 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. The certificate holder shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care, or a comparable accreditation authority within two years following licensure of the facility.**

- 7. For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
  - 8. 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 fourth month. The first progress report shall be due on September 1, 2022 . The second progress report shall be due on January 1, 2023 and so forth.**
  - 10. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, the certificate holders 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.**
  - 11. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section 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 a COR for Project ID #J-11645-18 (develop a freestanding ambulatory surgical facility).

On Form F.1b in Section Q, the applicant provides a summary of the capital cost approved in Project ID #J-11645-18, the changes proposed in this application, and the new projected capital cost, as shown in the table below.

<b>North Chapel Hill Surgery Center – Previously Approved &amp; Proposed Capital Cost</b>			
	<b>Previously Approved (J-11645-18)</b>	<b>New Total Projected Capital Cost</b>	<b>Projected Changes to Capital Cost (J-12188-22)</b>
Site Preparation	\$335,000	\$0	(\$335,000)
Construction/Renovation Contract(s)	\$1,175,760	\$3,754,978	\$2,579,218
Landscaping	\$15,000	\$0	(\$15,000)
Architect/Engineering Fees	\$90,000	\$272,455	\$182,455
Medical Equipment	\$1,625,000	\$1,641,696	\$16,696
Non-Medical Equipment	\$416,526	\$433,779	\$17,253
Furniture	\$32,190	\$20,000	(\$12,190)
Consultant Fees	\$225,000	\$219,684	(\$5,316)
Other (Contingency, Escalation, Insurance, IT Costs)	\$391,448	\$196,031	(\$195,417)
<b>Total Capital Cost</b>	<b>\$4,305,924</b>	<b>\$6,538,623</b>	<b>\$2,232,699</b>

In Section C, pages 42-43, and immediately following Form F.1b 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:

- The applicant explains in detail the items in each category projecting an increase from the originally approved capital expenditure.
- The applicant provides floor plans showing updated designs in Exhibit C.8-1.
- The applicant provides a certified cost estimate signed by an architect in Exhibit F.5-1.

In Project ID #J-11645-18, the applicant stated start-up costs will be \$260,189 and initial operating expenses will be \$341,044 for a total working capital of \$601,233. The Agency determined Project ID #J-11645-18 was conforming to this criterion. In Section F, page 54, the applicant projects total start-up costs and initial operating expenses of \$230,597 and \$876,776, respectively, for a total of \$1,107,333 in working capital, \$506,500 above the previously approved working capital of \$601,233. On page 54, the applicant explains the additional incremental increase in working capital is due to updated utilization projections.

### **Availability of Funds**

In Project ID # J-11645-18, the Agency determined that the applicant adequately demonstrated it had sufficient funds available for the capital and working capital needs of the project in the amount of \$4,305,924 and \$601,233, respectively. The current application proposes a capital cost increase of \$2,232,699 over the previously approved capital cost and a working capital increase of \$506,500 over the previously approved working capital cost.

Exhibit F.5-2 contains a letter dated February 15, 2022 from the Chief Financial Officer for UNC Hospitals documenting that UNC Hospitals is willing to commit accumulated reserves to fund 50 percent of the total capital and working capital costs of the COR project. Exhibit F.5-3 contains a letter dated February 15, 2022 from the Chief Financial Officer for Rex Hospital, Inc. stating that Rex Hospital, Inc. is willing to commit accumulated reserves to fund 50 percent of the total capital and working capital costs of the COR project.

Exhibit F.5-4 contains the Consolidated Financial Statements for UNC Hospitals. for the year ending June 30, 2021. As of June 30, 2021, UNC Hospitals had adequate cash and assets to fund the original CON-approved costs and the proposed increase in the projected capital and working capital cost.

Exhibit F.5-5 contains the Consolidated Financial Statements for Rex Healthcare, Inc. for the year ending June 30, 2021. As of June 30, 2021, Rex Healthcare, Inc. had adequate cash and assets to fund the original CON-approved costs and the proposed increase in the projected capital and working capital cost.

The applicant adequately demonstrates the availability of sufficient funds for the original CON-approved costs and the proposed increase in the projected capital and working capital cost based on the following:

- The applicant provides a letter from appropriate company officers confirming the availability of the funding proposed for the capital and working capital needs of the project and a commitment to use that funding accordingly.
- The applicant provides adequate documentation of the availability of accumulated reserves it proposes to use to fund the capital needs of the project.

### **Financial Feasibility**

In Project ID #J-11645-18, the applicant projected revenues would exceed operating expenses during the second and third full fiscal years of operation following project completion. The Agency determined Project ID #J-11645-18 had demonstrated the financial feasibility of the proposal was based on reasonable projections of costs and charges.

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses beginning in the third full fiscal year following completion of the project, as shown in the table below.

<b>Revenues and Operating Expenses – NCHSC</b>			
	<b>1<sup>st</sup> Full FY SFY 2024</b>	<b>2<sup>nd</sup> Full FY SFY 2025</b>	<b>3<sup>rd</sup> Full FY SFY 2026</b>
Total OR Cases	1,083	1,685	2,330
Total Gross Revenues (Charges)	\$9,059,793	\$14,514,365	\$20,678,554
Total Net Revenue	\$3,148,653	\$5,044,343	\$7,186,655
Total Net Revenue per Case	\$2,907	\$2,994	\$3,084
Total Operating Expenses (Costs)	\$3,827,991	\$5,176,048	\$6,713,107
Total Operating Expenses per Case	\$3,535	\$3,072	\$2,881
<b>Net Income/(Losses)</b>	<b>(\$679,337)</b>	<b>(\$131,704)</b>	<b>\$473,547</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Forms F.2b and F.3b in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant clearly identifies the sources of data used to project revenues and expenses.
- The applicant makes adjustments to revenues based on an annual inflation rate of 3.0 percent.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) 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 for the following reasons:

- The applicant adequately demonstrates that the capital and working 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 and working 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 a COR for Project ID #J-11645-18 (develop a freestanding ambulatory surgical facility).

On page 49, the 2022 SMFP defines the service area for operating rooms as, “...*the single or multicounty grouping shown in Figure 6.1.*” In Figure 6.1, page 55 of the 2022 SMFP, Orange County is shown as a single-county OR 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 G, page 56, the applicant states it does not propose to add any service components or services in this application that were not previously approved in Project ID #J-11645-18.

Project ID #J-11645-18 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

**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 a COR for Project ID #J-11645-18 (develop a freestanding ambulatory surgical facility).

The application for Project ID #J-11645-18 adequately demonstrated the availability of resources, including health manpower and management personnel to provide the proposed services and no changes are proposed in this application which would affect that determination.

**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.

- (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 a COR for Project ID #J-11645-18 (develop a freestanding ambulatory surgical facility).

The application for Project ID #J-11645-18 adequately demonstrated the availability of the ancillary and support services necessary to the provision of the proposed services and adequately demonstrated the proposed services would be coordinated with the existing healthcare system and no changes are proposed in this application which would affect that determination.

### **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.

- (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

- (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 a COR for Project ID #J-11645-18 (develop a freestanding ambulatory surgical facility).

In Section K, page 67, the applicant states that there have been no changes to the size of the facility from that approved in Project ID #J-11645-18. The applicant states it made changes in design and construction plans to meet applicable codes and regulations. The applicant provides line drawings in Exhibit C.8-1.

On page 67, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the need to construct a facility that will meet applicable building codes and regulations.

On page 68, 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 applicant states the project will represent a low-cost alternative for the provision of outpatient services.

- The applicant states that because the facility will be part of the larger UNC Health system, it will benefit from cost savings measures due to economies of scale.

In Section B, page 27, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Project ID #J-11645-18 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

### **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.

- (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 a COR for Project ID #J-11645-18 (develop a freestanding ambulatory surgical facility).

Project ID #J-11645-18 was conforming to this criterion and the applicant proposes no changes in the current application which would affect that determination.

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.

- (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;

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Project ID #J-11645-18 was found conforming to this criterion and the applicant proposes no changes in the current application which would affect that determination.

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.

- (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

Project ID #J-11645-18 was found conforming to this criterion and the applicant proposes no changes in the current application which would affect that determination.

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.

- (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

Project ID #J-11645-18 was found conforming to this criterion and the applicant proposes no changes in the current application which would affect that determination.

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.

- (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 a COR for Project ID #J-11645-18 (develop a freestanding ambulatory surgical facility).

Project ID #J-11645-18 adequately demonstrated that the proposed health services will accommodate the clinical needs of health professional training programs in the area. The applicant proposes no changes in the current application which would affect that determination.

**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.

- (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 a COR for Project ID #J-11645-18 (develop a freestanding ambulatory surgical facility).

The application for Project ID #J-11645-18 adequately demonstrated the expected effects of the proposed services on competition and how any enhanced competition would have a positive impact on cost-effectiveness, quality, and access to the services proposed. The applicant proposes no changes in this application which would affect that determination.

### **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 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 Facilities, the applicant identifies the related hospital facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 23 facilities located in North Carolina.

In Section O, pages 78-79, the applicant states that, during the 18 months immediately preceding submission of the application, incidents related to quality of care at occurred at three UNC Health Care System facilities. In Section O.4, the applicant states that all of the facilities are back in compliance with all Medicare Conditions of Participation. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, all of the facilities are back in compliance with Medicare Conditions of Participation. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 19 hospitals and ASFs, 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 Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100, as published at the time, were applicable to Project I.D. #J-11645-18, and that project was conforming with all applicable administrative rules. In this application for a COR, the applicant does not propose to increase the number of ORs in the service area, therefore, the criteria and standards for surgical services and operating rooms do not apply.